

**EVALUATION OF THE APPLICATION SUBMITTED BY KADLEC REGIONAL
MEDICAL CENTER PROPOSING;
1) A RECONCILIATION OF UN-LICENSED BASSINETTES AT THE HOSPITAL,
2) ESTABLISH A NICU LEVEL III NEONATE PROGRAM, AND
3) EXPANSION OF NICU LEVEL III BASSINETTES**

APPLICANT DESCRIPTION

Kadlec Medical Center (Kadlec) is a non-profit, acute care hospital located at 888 Swift Boulevard in the city of Richland, within Benton County. Kadlec is currently a provider of Medicare and Medicaid services to the residents of Benton and Franklin counties and the surrounding areas. The hospital is licensed for 188 acute care beds. The hospital also operates a 15-bed intermediate care (ICN) level II nursery. The hospital holds a three-year accreditation from the Joint Commission. [CN historical files; Joint Commission website]

This application proposes to establish an expanded neonatal program consisting of 12 ICN level II bassinets and a 15 bassinet level III neonatal intensive care unit (NICU). The program will be housed in space that is planned as part of a built-out of current facilities. The project will consist of: 1) recognizing the 21 ICN level II bassinets, currently in operation, but not licensed as part of the hospital’s bed capacity, 2) expand the total bassinet count of the unit to 27, and 3) establish a CN approved 15-bed NICU level III program. As proposed, Kadlec intends to operate 12 of the current bassinets as ICN level II beds and use the remaining 15 beds (6 new + 9 re-classified ICN level II) for NICU level III services. If approved, the licensed capacity of Kadlec will total 215 beds (188 medical/surgical, 12 ICN level II, and 15 NICU level III). [Amended Application, p4 & 24]

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

Current status	Bassinets	Proposed status	Bassinets
Unlicensed ICN level II	15	Licensed ICN level II	12
Unapproved Unlicensed overflow	6	Licensed NICU level III	15
Totals	21		27

A NICU level III obstetric service is offered in an area designed, organized, equipped, and staffed to provide services to the few women and infants requiring full intensive care services for the most serious type of maternal-fetal and neonatal illnesses and abnormalities. Such a service provides the coordination of care, communication, transfer, and transportation for NICU level III patients in a given region. NICU level III services include the provision of leadership in preparatory and continuing education in prenatal and perinatal care and may be involved in clinical and basic research. Hereinafter, the proposed program will be referred to as "NICU level III" services. [Washington Administrative Code 246-310-020]

Currently, Kadlec has the space to accommodate 15 bassinets that it uses for the necessary ICN level II services. When at capacity, an overflow unit made up of 6 additional bassinets has been established in another area of the hospital. Kadlec acknowledges that it currently

treats neonates that are classified as NICU level III as necessary during the treatment of traditional ICN level II births. When a facility is determined to be performing a service that requires prior CN review and approval and that authorization has not been obtained, the remedy may be to require the facility to close the service until a CN has been applied for and approved. Although, the department does not condone Kadlec's actions of providing NICU level III services without prior CN approval, Kadlec is following the direction given by the department in its February 2008 Determination of Reviewability¹.

If approved, Kadlec anticipates this project would be implemented in two steps. Initially, Kadlec would update their licensed capacity and provide ICN level II and NICU level III neonatal services in the 21 bassinets currently available at the hospital. This step would allow Kadlec to immediately begin offering the approved NICU level III services. In addition, Kadlec would begin the remodel the Orchard Pavilion to accommodate the complete compliment of bassinets. At project completion in 2013, Kadlec would be operating 12 ICN level II and 15 NICU level III bassinets. [Amended Application, p5 & 18]

The capital expenditure associated with the project is \$10,809,797. Of that amount, 46% is related to construction costs, 25% is related to moveable equipment, and the remaining is related to expenses detailed below in Table 2. [Amended Application, p33]

Table 2
Project's Estimated Capital Costs

Breakdown Of Costs	Total	% Of Total
Leasehold Improvements	\$ 5,023,893	46%
Fixed & Moveable Equipment	\$ 2,673,954	25%
Architect / Consulting Fees	\$ 1,006,633	9%
Financing Expenses	\$ 1,346,632	12%
Taxes & Review Fees	\$ 758,685	7%
Total	\$ 10,809,797	100.00%

On February 19, 2008 issued Determination of Reviewability (DOR08-17) concluded Kadlec was not CN approved to be providing NICU level III care. The department therefore views the proposed project as follows.

- Establishment of a new tertiary health service – NICU level III
- The bed addition proposes includes:
 - a. 12 ICN level II
 - b. 15 NICU level III

¹ Determination of Reviewability (DOR) 08-17

APPLICABILITY OF CERTIFICATE OF NEED LAW

This project is subject to Certificate of Need review as the establishment of a new tertiary health 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)(i)(C) and as a bed addition under RCW 70-38-105(4)(e) and WAC 246-310-020(1)(c).

APPLICATION CHRONOLOGY

September 12, 2008	Letter of Intent Submitted
March 12, 2009	Application Submitted
March 13, 2009 through July 26, 2009	Department's Pre-Review Activities & Extension <ul style="list-style-type: none">• 1st screening activities and responses
July 27, 2009	Amended Application, Submitted
July 28, 2009 through August 26, 2009	Department's Pre-Review Activities <ul style="list-style-type: none">• 1st screening activities and responses
August 27, 2009	Beginning of Review
October 13, 2009	Public Hearing Conducted / End of Public Comment
October 23, 2009	Rebuttal Documents Submitted to Department
December 14, 2009	Department's Anticipated Decision Date
June 18, 2010	Department's Actual Decision Date

AFFECTED PERSONS

During the review of this application, one entity sought and received affected person status under WAC 246-310-010.

- Kennewick General Hospital—an acute care hospital located in the city of Kennewick, within Benton County.

SOURCE INFORMATION REVIEWED

- Kadlec Regional Medical Center's Certificate of Need Application received March 12, 2009
- Kadlec Regional Medical Center's Certificate of Need Amended Application, received July 27, 2009
- Kadlec Regional Medical Center's supplemental information dated August 20, 2009
- Public comments submitted throughout the review of the project and at public hearing
- Comprehensive Hospital Abstract Reporting System (CHARS) data obtained from the Department of Health's Office of Hospital and Patient Data Systems
- Financial feasibility and cost containment evaluation prepared by the Department of Health's Hospital and Patient Data Systems (November 18, 2009)
- Historical charity care data obtained from the Department of Health's Hospital and Patient Data Systems (2005, 2006, and 2007 summaries)

- Population data obtained from Office of Financial Management (OFM) dated November 2007
- Licensing and/or survey data provided by the Department of Health's Investigations and Inspections Office
- Washington State Perinatal Levels of Care Criteria adopted by the Perinatal Advisory Committee--February 2005
- February 19, 2008 Determination of Reviewability 08-17
- Certificate of Need Historical files

CRITERIA EVALUATION

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

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

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

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

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

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

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

To obtain Certificate of Need approval, Kadlec Regional Medical Center 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).² Where applicable, the applicant must demonstrate compliance with the above criteria by meeting the 2005 Perinatal Level of Care Guidelines established by the Washington State Perinatal Advisory Committee.

CONCLUSION

For the reasons stated in this evaluation, the application submitted on behalf of Kadlec Regional Medical Center proposing a level III neonatal unit at the hospital to add 27 beds (12 ICN level II and a 15 NICU level III) is consistent with applicable criteria of the Certificate of Need Program, and a Certificate of Need should be issued.

This approval does not include NICU level IIIC.

Approved Capital Expenditure equals \$10,809,797.

Terms

1. Kadlec will provide a copy of the Perinatal Written policy and procedure for neonatal transport required as part of the Washington State Perinatal Levels of Care guidelines.
2. Kadlec will provide a copy of the guidelines for continued care during transport required as part of the Washington State Perinatal Levels of Care guidelines.
3. Kadlec will provide confirmation of the collaboration for coordinating outreach education between hospitals required as part of the Washington State Perinatal Levels of Care guidelines.

² 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).

A. Need (WAC 246-310-210)

Based on the source information reviewed, 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.

ICN level II

Kadlec acknowledges that it is currently operating 21 (15 + 6 overflow) ICN level II bassinets in addition to their 188 licensed acute care beds. This application proposes to increase their licensed capacity to include the ICN level II bassinets that are currently in use at the hospital. [Amended Application, p10]

Kadlec received approval in 1980 to provide ICN level II services and has been actively providing this care, though with a fewer number of bassinets than originally proposed³. Over time, the hospital stopped counting these beds as part of their licensed bed complement. Instead, they counted them in addition to the total approved bed capacity of the hospital. This portion of the proposed project is to add to the total number of bassinets at the hospital. Specifically, correcting the hospital's licensed capacity of 188 beds to equal 200 licensed beds (188 + 12 ICN level II bassinets). The review will consist of the applicant's reported planning area and the current utilization of the Kadlec ICN level II program. Patient origin data for 2007 provided in the application shows an Average Daily Census (ADC) of 4.3 ICN level II bassinets. [Amended Application, Table 11]

NICU level III

WAC 246-310-020 states (in summary) that a NICU level III service is to be in an area designed, organized, equipped, and staffed to provide services to the few women and infants requiring full intensive care services for the most serious type of maternal-fetal and neonatal illnesses and abnormalities. Such a service provides the coordination of care, communication, transfer, and transportation for NICU level III patients in a given region. NICU level III services include the provision of leadership in preparatory and continuing education in prenatal and perinatal care and may be involved in clinical and basic research.

NICU 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 NICU level III services, no such methodology exists. Given that the department has not developed an established methodology for NICU level III services, an evaluation of the need criterion begins with an evaluation of the methodology provided by the applicant.

³ The 1980 decision allowed for the expansion of 15 ICN level II bassinets to a total of 27. Current records indicate the hospital never fully executed the previous CN.

In addition to the establishment of a tertiary health service, NICU level III care also results in a bed addition to Kadlec Regional Medical Center. Patient origin data for 2007 provided in the application shows an ADC of 7.5 NICU level III bassinettes. [Amended Application, Table 11]

Comprehensive Hospital Abstract Reporting System (CHARS) data is used to assist in demonstrating need for a NICU 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 #15.⁴

DRG	Definition	Level of Care
385 / 789	Neonates, Died Or Transferred To Another Acute Care Facility	Levels 3
386 / 790	Extreme Immaturity Or Respiratory Distress Syndrome, Neonate	Levels 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	Level 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 NICU level III patients are included in DRGs 789 and 790, with a few NICU level III patients in DRG 791.

To support its establishment of NICU level III services and justify the 12 ICN level II bassinettes, Kadlec applied a 4-step forecast methodology using the hospital’s primary service area of Benton and Franklin County. Below is a discussion of Kadlec’s numeric methodology and the assumptions/data used by Kadlec in each step. Throughout the methodology and calculations, Kadlec used six years of historical data (2002-2007) from DRGs 789 and 790 for NICU level III calculations; and DRGs 791, 792, and 793 for ICN level II calculations. The DRG 794 classification was tabulated separately and are included in the totals as indicated. [Amended Application, p25]

⁴ 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.

Kadlec Medical Center’s Need Methodology

Step 1 – Average annual growth rates were calculated for level II and level III patient days for Benton-Franklin counties in the period 2002-2007.

In this step, the applicant totaled patient days within Kadlec’s neonatal program for the DRG’s associated with ICN level II and NICU level III from 2002 through 2007 (excluding DRG 794). The values are based upon CHARS reporting data for the corresponding years and an average annual growth rate is calculated over a seven year period. The values are summarized in Table 3. [August 20, 2009 Supplemental Information, p1]

**Table 3
Total Kadlec Neonatal Program Patient Days**

	2002	2003	2004	2005	2006	2007	Avg. Annual Growth
ICN level II ⁵	1,047	1,319	1,593	1,877	1,732	1,692	9.6%
NICU level III	1,840	2,165	2,549	2,423	2,535	2,757	8.1%
Combined Totals	2,887	3,484	4,142	4,300	4,267	4,449	8.6%

Step 2 – Projections, by year, were developed from 2007 actuals using growth rates calculated as described above.

In this step, Kadlec considered a slightly different patient day count for their neonatal program, which included a subset of patients residing inside and outside the defined planning area, and are summarized below in Table 4. The applicant also included patient days classified under DRG 794. Kadlec further added to the totals by including ‘other DRG’s’ in which is the applicant defines as being “too sick for Kadlec’s pediatric department”. These include infants that: [Amended Application, p23 & Table 11]

- are born full term but need constant monitoring for clinical reasons;
- are transferred from other area hospitals who require a higher level of care than that available at the local provider;
- multiple birth infants needing constant monitoring;
- infants born via c-section or vaginally which require stabilization in the first few hours of life;
- babies who have outgrown the high acuity DRG’s but still require constant monitoring; and
- infants who are no longer critically ill, but still require long-term catheter placement for IV therapy.

⁵ Excludes DRG 794

**Table 4
Patient Days Totals Applied by the Applicant for 2007**

	Total Patient Days
ICN level II	1,477
NICU level III	2,752
DRG 794	95
Other DRG's	44
Total	4,368

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

In this step, Kadlec calculated the ADC for the program at its current capacity of 15 bassinets. It continues to include the additional patient days from the surrounding communities to the Benton/Franklin planning area and the DRG classifications outlined in step 2. The results are detailed in Table 5. [Amended Application, Table 11]

**Table 5
Patient Days and Occupancy at Kadlec in 2007**

	Total Patient Days	ADC	Occupancy @ 15 beds	Occupancy @ 21 beds
ICN level II	1,477	4.0	27.0%	19.1%
NICU level III	2,752	7.5	50.3%	36.2%
DRG 794	95	0.3	1.7%	0.01%
Other DRG's	44	0.1	0.8%	0.01%
Total	4,368	12.0	79.8%	57.1%

As demonstrated above, the ICN level II program at Kadlec operated at an ADC of 4.3 (including DRG 794) and the NICU level III care provided reached an ADC of 7.5. The total occupancy rate of the 15 bassinets is approaching 80%. When the 6-bed over-flow unit⁶ is considered, the capacity falls to approximately 57%. The applicant refers to the sunsetted State Health Plan when they claim, “The State Health Plan (“SHP”) does not specifically reference occupancy for neonatal intensive care units. More generally, the SHP references occupancy standards for hospitals and specific services on page C-37, Volume II, where it states ‘Average annual occupancy rates for hospitals and specific services should not be less than ...55% for obstetric services statewide’”. The applicant contends that the rate calculated for 2007 exceeds this standard by a notable margin. [Amended Application, p22, FN5]

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

⁶ The applicant acknowledges that it operates 6 over-flow bassinets when the 15 bed neonate unit is at capacity. As a result the patient days cited include those patient days of newborns located in the over-flow area and total capacity would equal 21 when total current capacity is addressed.

Sacred Heart should apply to the Spokane NICU program. According to the conclusions of that report, the optimal occupancy rate for Sacred Heart is 65% of the current total occupancy. Kadlec applied this conclusion to compute an Adjusted Average Daily Census (AADC) for the neonatal program at Kadlec Medical Center from the data outlined in Table 5. The resulting values are represented in Table 6. [Amended Application, p22, FN5 & Table 11]

Table 6
Applicant Computed Patient Days and Proposed AADC in 2007

	Total Patient Days	ADC	AADC	Adj. Occupancy @ 15 beds
ICN level II	1,477	4.0	6.2	41.5%
NICU level III	2,752	7.6	11.6	77.3%
Overlap – DRG 794	95	0.3	0.4	2.7%
Other DRG’s	44	0.1	0.2	1.2%
Total	4,368	12.0	18.4	122.7%

Based upon these modified calculations, Kadlec produced a 10 year forecast of need for additional neonate demand. The applicant applied the high-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 Kadlec projected that need would exceed the current operational capacity of 21 by 2014, when a standard ADC is calculated. The current capacity was exceeded in 2008 when Kadlec applied it’s AADC adjustment. The results, through 2016, are summarized below in Table 7. [Amended Application, p26 & Table 12]

Table 7
Kadlec Projections for level II/III Neonate Care

	2008	2009	2010	2011	2012	2013	2014	2015	2016
ICN level II	2,717	2,965	3,236	3,531	3,853	4,204	4,588	5,006	5,463
NICU level III	2,714	2,820	2,931	3,045	3,164	3,288	3,417	3,550	3,689
Total	5,431	5,785	6,167	6,576	7,017	7,492	8,005	8,557	9,152
Total ADC	14.9	15.9	16.9	18.0	19.2	20.5	21.9	23.4	25.1
Total AADC	22.9	24.4	26.0	27.7	29.6	31.6	33.7	36.1	38.6

To further demonstrate need for additional NICU level III capacity in the planning area, Kadlec provided the following comments related to the neonate services at Kadlec. “If this request is not granted, total patient days of neonates treated in Kadlec’s neonatal unit will continue to exceed capacity, requiring, at some point, the unit to close to new admits – this is projected to occur as soon as 2010”. Kadlec continues, “Furthermore, Kadlec is the leading provider of tertiary services in the Benton-Franklin Planning Area, and historically, it has provided this level of care; closing to new admits would harm quality and continuity of care”. [Amended Application, p27]

Public Comment

During review of this application, the department received letters of support and testimony from many in the community. There were no letters or comments in opposition to this project. Comment submitted from various regional hospitals attest to the need for additional capacity at Kadlec to help prevent the need to transfer premature newborns to more distant hospitals in Spokane, Tacoma, or Seattle. Testimony from representatives of Children’s Hospital in Seattle addressed a growing relationship between Neonatologists within the two hospitals which is working to provide additional expertise for addressing the health needs of the neonates in the unit. Additional testimony was received from residents who have directly benefitted from the care provided to level II and level III newborns and the Richland City Council submitted a resolution that was passed in support of the expansion plans.

Department’s Need Methodology

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

Kadlec Service Area

Kadlec defines its primary service area to be Benton and Franklin counties. Located in Benton County, Kadlec is expected to serve that county. Franklin County is immediately north and east of Benton County and is considered part of the hospital’s prescribed service area. Because of Kadlec’s close location to the Oregon border, it is appropriate to consider patients residing across the border in Oregon. Table 8 identifies the primary counties in Kadlec’s defined service area and the corresponding number of patient days classified as ICN level II or NICU level III neonatal care being provided at Kadlec. [2007 CHARS]

**Table 8
Reported Kadlec Level II/III Patient Days - 2007**

County	ICN level II Days⁷	NICU level III Days	Total Patient Days
Adams	18	40	58
Benton	1,106	1,158	2,264
Franklin	678	1,009	1,687
Grant	22	4	26
Walla Walla	52	112	164
Yakima	116	142	258
Subtotal	1,992	2,465	4,457
Oregon	296	292	588
Total	2,288	2,757	5,045

⁷ Includes reported days for DRG 794

Kadlec’s rationale for the expansion of the neonatal unit has focused upon the population and growth rate of the Benton and Franklin planning area residents who comprise the majority of their patient days. Kadlec reviewed its 2002 through 2007 historical discharge data for MDC #15 and applied the results to the methodology outlined earlier in this analysis. Relying upon the hospitals prescribed planning area, and including DRGs that require space within the neonate unit, the applicant forecasted a need for additional bassinets. In total, the department’s review of the reported patient days in 2007 show that Benton/Franklin County is the appropriate planning area with approximately 78% of the programs ICN level II and NICU level III total patient days residing in these two counties.

Population Projections

Kadlec projected the female aged 15-44 population based upon the high series projections produced by OFM for Benton and Franklin counties. The department relies upon the intermediate/medium series in projecting population for this age group. In a set of revised forecasts from November 2007, OFM included efforts to fully capture a rapid growth period in Benton and Franklin counties beginning in 2002. In addition to the new medium series in 2007, OFM re-produced high and low population projections. The low series is intended to reflect what might happen if the area experienced an economic downturn and the high series is based on the assumption that the counties might sustain the fast growth throughout the forecast horizon.

Historical trends (1960-2000) indicate that both Benton and Franklin counties have a tendency to fluctuate dramatically, making long-term projections with either the High or the Low series less applicable. The adjustments made to the medium series projections by OFM in 2007 appear to be sufficient to approximate the likely population projections for the region. There is no indication that the 2007 OFM forecasts are inaccurate or subject to the same circumstances which were considered in the production of the update. Table 9 identifies the difference in the population projections used by the applicant and the totals that would result from the use of the intermediate series. [OFM 2007 County GMA Forecast Report]

**Table 9
Benton Franklin Planning Area Population Projections – Female age 15-44**

	2008	2010	2015	2020
Kadlec High Totals	46,750	49,367	56,566	64,815
DOH Intermediate Totals	47,106	48,295	51,448	54,570
Difference	356	(1,072)	(5,118)	(10,245)

As demonstrated, the projections show comparable results in the immediate forecast through 2010. The primary discrepancy occurs in the extrapolation to 2015 and 2020, which would directly affect the need forecast that Kadlec presented through 2018. When combined with the reported county birth rates per 1000 females in this age group for 2007, the departments forecast would be proportionately smaller in each of the population totals for the years extending up to and beyond 2015.

Current Available Capacity

Kadlec is currently treating NICU level III patients within its current approved ICN level II beds. The hospital’s neonate capacity, as the applicant acknowledges, also includes the use of 6 additional over-flow bassinets as the 15 bed unit reaches capacity. Table 10 shows the historical ADC of the bassinets at Kadlec based upon data reported to the department for the defined expanded planning area. [CHARS Historical reports]

Table 10
Kadlec Regional Medical Center’s Historical ADC for Extended Planning Area

	2002	2003	2004	2005	2006	2007
ICN level II ADC	4.02	5.02	5.84	6.99	6.54	6.27
NICU level III ADC	5.04	5.93	6.98	6.64	6.40	7.55
Combined ADC	9.06	10.95	12.82	13.63	12.93	13.82
% Occupancy of 15 Approved Bassinets	60.4%	73.0%	85.5%	90.8%	86.2%	92.1%

As shown in Table 10, the 15 approved ICN level II bassinets would be sufficient based upon the historical number of ICN level II patient days. However, over this same time period, Kadlec has had an ADC of between 5 and 7.5 NICU level III neonates. With this level of NICU level III care being provided, the 15 approved bassinets may not be sufficient. The six additional bassinets⁸ Kadlec has been using would reduce the average occupancy to 65.8%, based on 2007 data.

As stated by the applicant, and supported by department records, Kadlec is the only approved provider of ICN level II services in the planning area. Kennewick General Hospital (KGH) also has an application under review for a 10-bed ICN level II unit⁹. In that application, KGH also has been providing a level of care beyond its CN authorized level. Table 11 details the authorized and unauthorized capacity in the planning area.

Table 11
Reported Neonate Capacity in Benton/Franklin County

	Kadlec	KGH
Approved Unlicensed ICN level II	15	0
Unapproved Unlicensed ICN level II	6	10
Totals	21	10

Kadlec also based its need methodology on capacity standards cited in the SHP under the discussion of the acute care bed methodology. What was not discussed in the application was a section of the SHP which directly addresses the occupancy rates for existing tertiary neonatal

⁸ A 2005 application from Kadlec regarding an acute care expansion identifies only 8 ICN level II bassinets.

⁹ Kadlec’s amended application was received 7/27/2009 with the Beginning of Review occurring on 8/27/2009. Kennewick’s application was received 7/31/2009 and began review 10/5/2009

services¹⁰. Under this detail, an occupancy rate of 75% is applied to level II/III programs in the year prior to application and in the third year following approval.

Within its numeric forecast, Kadlec provided projections, using historical patient days and market share, for the potential capacity for Kadlec through 2018. The ADC in year 2008 equals 14.9, split evenly for ICN level II and NICU level III service, and projects the combined ADC to increase to 25.1 in year 2016, the third year after completion of the project. [Amended Application, Table 12]

NICU level III adjusted occupancy of 65%

The applicant’s use of an Adjusted Average Daily Census (AADC) is not referenced in any materials as a basis for establishing need for neonatal services. Further, the independent report referenced was conducted for an unrelated facility in Spokane, Washington with specific conditions and assumptions that may not be consistent with the operations at Kadlec’s Richland hospital. Though a hospital may implement any internal measures in the optimal capacity for a particular program, the department is not inclined to apply a reduced ADC by any factor not prescribed in state guidelines. [Amended Application, p26 & Table 12]

Further, the application of the AADC in the projection of neonates artificially inflates the numbers of neonates actually receiving care within the hospital. This increases the projected daily census, but do not actually represent an actual increase the number of neonates in bassinettes.

Table 12
Affects of AADC upon Actual Program ADC

	2008	2009	2010	2011	2012	2013	2014	2015	2016
ICN level II ADC	2,717	2,965	3,236	3,531	3,853	4,204	4,588	5,006	5,463
Actual ADC	7.44	8.12	8.87	9.67	10.56	11.52	12.57	13.72	14.97
65% AADC	11.45	12.50	13.64	14.88	16.24	17.72	19.34	21.10	23.03
NICU level III	2,714	2,820	2,931	3,045	3,164	3,288	3,417	3,550	3,689
Actual ADC	7.44	7.73	8.03	8.34	8.67	9.01	9.36	9.73	10.11
65% AADC	11.44	11.89	12.35	12.83	13.34	13.86	14.40	14.96	15.55
Total Actual ADC	14.9	15.9	16.9	18	19.2	20.5	21.9	23.4	25.1
65% AADC	22.9	24.4	26	27.7	29.6	31.6	33.7	36.1	38.6
Total AADC Inflation	8	9	9	10	10	11	12	13	14

* Slight differences in totals due to rounding factors

¹⁰ Volume II State Health Plan, Page B-5, (8)

As shown in Table 12, the AADC values (previously detailed in Table 7) do not represent any actual increase in the number of neonates receiving treatment. Rather, they simply represent a mathematically derived increase that do not represent any actual admits and artificially increase the projected need.

The results, in relation to a more current reference for care standards, such as the Perinatal Levels of Care guidelines, require ICN level II and NICU level III nurseries to have an average daily census (ADC) of at least 10, rather than focusing on a programs occupancy rate. Using the applicant’s projections, Kadlec exceeded this standard in 2008. [Amended Application, p24; Washington State Perinatal Levels of Care guidelines, p4]

Department Conclusion

Upon review of the information above, the department has recalculated the projected patient days and ADC values presented by the applicant with specific modifications. The applicant’s patient day projections, which are based upon historical trends and market share, were adjusted down according to difference in the high series population figures from those reported in the intermediate series. The results, detailed in Table 13 show that Kadlec maintains the Levels of Care ADC guidelines for ICN level II/ NICU level III services.

Table 13
Recalculated Neonatal Benton/Franklin Patient Day Projections –
Using OFM Medium Population Series

	2008	2009	2010	2011	2012	2013	2014	2015	2016
ICN level II	2,738	2,943	3,166	3,400	3,655	3,930	4,229	4,553	4,887
level II ADC	7.50	8.06	8.67	9.32	10.01	10.77	11.59	12.47	13.39
NICU level III	2,735	2,799	2,867	2,932	3,001	3,074	3,150	3,229	3,300
level III ADC	7.49	7.67	7.86	8.03	8.22	8.42	8.63	8.85	9.04
Total ADC	14.99	15.73	16.53	17.35	18.23	19.19	20.22	21.32	22.43

The original method submitted by the applicant, and the revised forecast produced by the department, both identify a growing need for NICU level III service in the community. Each show differing, but comparable, census calculations that approach or exceed levels that could compromise the availability of the tertiary care for the residents of the planning area. As a result, the department can conclude there is a need for NICU level III capacity in the planning area.

Further, NICU level III bassinets are equipped to appropriately care for ICN level II neonates. This is not the case in reverse. Based on the department’s need methodology results, Kadlec’s proposed bed addition of 27 (12 ICN level II and 15 NICU level III) has been demonstrated.

Based on the above information, the department concludes that request for 12 ICN level II and 15 NICU level III beds 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.

Kadlec 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, Kadlec 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, Kadlec provided a copy of its current Admission Policy. The policy outlines the process/criteria that Kadlec uses to admit patients for treatment or care at the hospital. The policy also states that any patient requiring care is accepted for treatment at Kadlec without regard to race, religion, sex, age, or ability to pay. This policy is consistent with Certificate of Need requirements. [Amended Application, Appendix 12]

To determine whether low income residents would have access to the proposed services, the department uses the facility's Medicaid eligibility or contracting with Medicaid as the measure to make that determination. Kadlec 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 Kadlec identifies the facility's financial resources as including Medicaid revenues. [Amended Application, p14; August 20, 2009 Supplemental Information, Exhibit 15]

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.

Kadlec also provided a copy of its current Financial Assistance Program that would continue to be used if this project is approved. This program has been reviewed and approved by the department's Hospital and Patient Data Systems¹¹. The program outlines the process a patient would use to access charity care. Further, the Kadlec included a 'charity care' line item as a deduction from revenue within the pro forma financial documents for the hospital. [August 20, 2009 Supplemental Information, Exhibit 15]

¹¹ www.doh.wa.gov/ehsphl/hospdata/charitycare/charitypolicies

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 Benton County, Kadlec is one of 21 hospitals in the Central Region. According to 2005-2007¹² charity care data obtained from HPDS, Kadlec has historically provided more than the average charity care provided in the region. Kadlec's most recent three years (2005-2007) percentages of charity care for gross and adjusted revenues are 2.78% and 5.93%, respectively. The 2005-2007 average for the Central Region is 1.91% for gross revenue and 4.45% for adjusted revenue. [HPDS 2005-2007 charity care summaries]

Kadlec's pro forma revenue and expense statements indicate that the hospital will provide charity care at approximately 2.93% of gross revenue and 6.41% of adjusted revenue. RCW 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 Kadlec is above the regional averages and Kadlec 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. [August 20, 2009 Supplemental Information, Exhibit 15]

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

Based on the source information reviewed, 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, Kadlec provided Pro Forma Financial Statements for the hospital with and without the proposed project. These reports provided the figures necessary to isolate the projections for the proposed expansion. A summary of the financial projections for the neonatal project alone is shown in Table 14 below. [Amended Application, Appendix 15]

¹² Year 2008 charity care data is not available as of the writing of this evaluation.

Table 14
Neonate II/III Cost Center Projected Statement of Operations Summary
Years 2013 through 2016

	Projected Year 1 (2013)	Projected Year 2 (2014)	Projected Year 3 (2015)	Projected Year 4 (2016)
Total Operating Revenue	\$ 2,424,847	\$ 3,354,960	\$ 4,353,449	\$ 4,973,417
Total Operating Expenses	\$ 3,265,022	\$ 3,897,850	\$ 4,579,146	\$ 5,310,718
Net Profit or (Loss)	(\$ 840,175)	(\$ 542,890)	(\$ 225,697)	(\$ 337,301)

Kadlec projects that it will begin providing NICU level III services at full capacity in year 2013. The ‘total operating revenue’ line item in Table 14 is the result of gross revenue minus any deductions for contractual allowances, bad debt, and charity care directly related to the neonate II/III cost center. The ‘total operating expenses’ line item includes staff salaries/wages and all hospital cost allocations related to the neonate II/III cost center. As shown, the neonate program will lose money through the year 2016, though extended projections produced by the applicant do indicate a potential profit. Considering the degree of specialty care and the commiserate increase in expenses for each admit into a ICN level II or NICU level III bassinette, a hospital showing a cost center loss would not be unexpected. [Amended Application, Appendix 15]

When the forecasts for the hospital as a whole are reviewed, the results are notably better and the amount of the cost center losses forecasted above are not sufficient to alter the hospitals overall financial health. A summary of the financial projections for the hospital, including the proposed neonatal project, is shown in Table 15 below.

Table 15
Hospital w/ Project Projected Statement of Operations Summary
Years 2013 through 2016

	Projected Year 1 (2013)	Projected Year 2 (2014)	Projected Year 3 (2015)	Projected Year 4 (2016)
Total Operating Revenue	\$ 276,590,784	\$ 283,749,814	\$ 290,660,826	\$ 295,558,232
Total Operating Expenses	\$ 258,242,882	\$ 263,354,967	\$ 266,207,302	\$ 268,347,165
Net Profit or (Loss)	\$ 21,680,605	\$ 23,727,550	\$ 27,786,227	\$ 30,543,770

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.

The reported capital expenditure for the project is \$10,809,797. HPDS provides a summary of the balance sheets from the application in Table 16.

Table 16
Kadlec Regional Medical Center Balance Sheet for Current Year 2008

Assets		Liabilities	
Current	\$ 47,875,001	Current	\$ 31,386,947
Board	\$ 10,898,484	Long Term Debt	\$ 98,119,455
Property/Plant/Equip	\$ 133,004,820	Total Liabilities	\$ 129,506,402
Other	\$ 47,567,074	Equity	\$ 109,838,974
Total Assets	\$ 239,345,379	Total Liabilities and Equity	\$ 239,345,376

The capital expenditure is projected to be \$10,809,797 or 4.52% of total assets. As summarized by HPDS, “[Kadlec] indicates it will use a bond and capital allowance to finance this project. The hospital has been spending down its Board Designated assets over the past few years. In 2004 it was \$43.6 million and in 2008 it is \$10.8 million. Their property plant and equipment increased during the same time from \$77.2 million to \$133.0 million. Long term debt in 2004 was \$33.7 million and at the end of 2008 was \$98.1 million. With these factors available for consideration, HPDS concluded, “This project will not adversely impact reserves, or total assets, total liability or the general health of the hospital in a significant way”. The complete breakout of the project costs are displayed below in Table 17. [HPDS Analysis, p2]

Table 17
Kadlec Balance Sheet Asset Ratios

Level II/III expansion	Project Costs
Capital Expenditure	\$ 10,809,797
Percent of Total Assets	4.52%
Percent of Board Designated Assets	99.19%
Percent of Long-term Debt	11.02%
Percent of Equity	9.84%

As mentioned above, HPDS compared the financial health of Kadlec Regional Medical Center to the statewide 2008 financial ratio guidelines for hospital operations. HPDS also included the financial ratios for the proposed project for years 2013-2015, or three years after project completion. Table 18 summarizes the comparison provided by HPDS. [HPDS analysis, p3]

Table 18
Current and Projected HPDS Debt Ratios for Kadlec Regional Medical Center
and NICU Expansion Project

Category	Trend ¹³	State 2007	Kadlec 2008	Application Project Only		
				Projected 2013	Projected 2014	Projected 2015
Long Term Debt to Equity	B	0.527	0.893	0.420	0.362	0.309
Current Assets/Current Liabilities	A	1.877	1.525	1.791	1.803	1.794
Assets Funded by Liabilities	B	0.436	0.541	0.356	0.326	0.297
Operating Exp/Operating Rev	B	0.949	0.950	1.346	1.162	1.052
Debt Service Coverage	A	4.701	1.927	4.865	5.317	5.335
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					

As HPDS reports, “When a hospital is in a building phase and for a few years after, the ratios will be poorer, other thing(s) being equal, than a hospital that has not been through a building phase. The operating expense/operating revenue ratio is above 1.0 which means the hospital is expecting to lose money on the NICU for those years. The pro-forma data which reports out to 2018 show a profit in that year. Current Assets/Current Liabilities, while lower than the state average is ok based on other ratios. Assets funded by Liability and Debt Service coverage are improving at an adequate rate”. [HPDS analysis, p3]

Based on the information above, the department 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.

Kadlec identified a capital expenditure for this project of \$10,809,797. The costs are broken down in Table 19 below.

¹³ A is better if above the ratio, and B is better if below the ratio.

**Table 19
Kadlec Regional Medical Center's Capital Cost Breakdown**

Breakdown Of Costs	Total	% Of Total
Leasehold Improvements	\$ 5,023,893	46%
Fixed & Moveable Equipment	\$ 2,673,954	25%
Architect / Consulting Fees	\$ 1,006,633	9%
Financing Expenses	\$ 1,346,632	12%
Taxes & Review Fees	\$ 758,685	7%
Total	\$ 10,809,797	100.00%

To further assist the department in its evaluation of this sub-criterion, HPDS reviewed the financial data reported by each hospital. The analysis states, "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. Kadlec Medical Center 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 analysis, p3]

HPDS also notes those newborn days in Intensive Care are usually a small percent of the total. HPDS reviewed the hospital inpatient database (CHARS) for comparison data. Revenue Code 0172 is Level II Nursery care and 0173 is Level III Nursery 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 2008 in CHARS was slightly more than the projections in the applicant's combined level II and III pro-forma. However the Level III CHARS data was much more than the combined level II and III pro-forma as can be expected given the higher acuity of level III care. [HPDS analysis, p3]

**Table 20
Projected Statement of Operations Summary**

	Projected Year 1 (2013)	Projected Year 2 (2014)	Projected Year 3 (2015)
Patient Days	\$ 7,492	\$ 8,005	\$ 8,557
Total Net Revenue	\$ 2,424,847	\$ 3,354,960	\$ 4,353,449
Total Expense	\$ 3,265,022	\$ 3,897,850	\$ 4,579,146
Net Profit or (Loss)	\$ (840,175)	\$ (542,890)	\$ (225,697)
Operating Rev. per Pat Day	\$ 324	\$ 419	\$ 509
Operating Exp. per Pat Day	\$ 436	\$ 487	\$ 535
Net Profit per Pat Day	\$ (112)	\$ (68)	\$ (26)

HPDS determined that the project costs to the patient and community appears to be comparable to current providers. [HPDS analysis, p4]

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.

(3) The project can be appropriately financed.

WAC 246-310 does not contain specific source of financing criteria as identified in WAC 246-310-200(2)(a)(i). There are also no known recognized standards as identified in WAC 246-310-200(2)(a)(ii) and (b) that directs how a project of this type and size should be financed. Therefore, using its experience and expertise the department compared the proposed project's source of financing to those previously considered by the department.

To finance this project, Kadlec intends to pursue tax exempt bonds to cover \$9,430,000 of the total expenditure. The \$1,379,797 balance will be funded through available capital. As shown previously in Table 13, the hospital's long-term debt and equity percentages appear to be a reasonable option. Kadlec also considered the project costs in relation to its effect on the hospital's cash reserves and concluded, "given [the project's] size, it was most prudent to debt-finance it because cash reserves would not be sufficient, given cash flow requirements and other capital projects, to completely fund it internally". [Amended Application, p36]

After reviewing Kadlec's balance sheet and intended funding source, staff from HPDS also determined that the financing methods used are appropriate for this type of project. Based on the information above, the department concludes that the project can be appropriately financed and this sub-criterion is met. [HPDS analysis, p4]

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 term 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, Kadlec's proposed NICU level III services will be offered in conjunction with its existing ICN level II services. Current staffing levels of the unit are not expected to change until 2011. At that time, Kadlec will begin adding FTEs in areas within and in support of the expansion to a 27-bassinette program. The total FTE counts cited below indicates any impact on staff would be a direct result of increased patient volumes, and staff would be adjusted as appropriate to meet the care delivery needs. [Amended Application, Exhibit 18]

Table 21
Kadlec Regional Medical Center's Projected FTEs
with 12 ICN level II & 15 NICU level III Compliment

FTE class	2011	2012	2013	2014	2015	2016
Direct Staff (RN/LPN)	4.31	4.58	4.87	5.18	5.88	6.27
Management	0.56	0.60	0.63	0.67	0.77	0.82
Admin	0.66	0.70	0.74	0.79	0.90	0.96
Clerical	2.10	2.23	2.38	2.53	2.87	3.05
Staffing Totals	7.63	8.11	8.62	9.17	10.42	11.10

Kadlec states that it expects no difficulty in recruiting FTEs for a variety of reasons. In addition to a low nursing turnover rate and what is described as a “well-developed recruiting and retention program”, Kadlec does not anticipate experiencing any difficulties in attracting the necessary qualified staff to fill the anticipated positions. [Amended Application, p40]

In addition to the staff identified in Table 21 above, Dr. Anthony Hadeed and Dr. Miriam Zaragoza, physicians certified in maternal-fetal medicine, as the key medical staff for the neonatal unit. Supplementing the identified staff is an active working relationship with Seattle Children’s Hospital which provides Kadlec with on-call neonatal coverage and consultation services. As Kadlec explains, “Seattle Children’s also provides medical oversight/consultation services to the medical director”. In addition, Seattle Children’s also supports “on-going education for staff, grand rounds, coverage, consultation, and real time echo cardiology (readings) for Kadlec’s NICU service”. [Amended Application, p42]

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.

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 ICN level II and NICU level III services. Within the guidelines, NICU level III services are separated into A, B, and C -- with A being the least intensive of NICU level III services 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. Kadlec is already providing level I, ICN level II level care. Kadlec began offering NICU level III neonatal services (both A and B) prior to receiving CN approval.

Kadlec intends to continue providing ICN level II and NICU level III services during the planned expansion, and then increase its capacity upon completion of the expansion in 2013. Kadlec provided a comparison chart as verification and documentation that its proposed NICU level III services currently meet or exceed the advisory committee's recommended guidelines.

The department will compare this project using NICU level IIIB guidelines. The applicant is not requesting, and will not be evaluated, on standards for NICU level IIIC services which require separate approval. IF the department approves this project, that approval would not include level IIIC care. [Amended Application, Exhibit 21]

The chart outlined on the following pages shows the comparison.

Kadlec Regional Medical Center and Perinatal Levels of Care Criteria Comparison

GUIDELINE	Kadlec	Pass/Fail
General Function		Pass
<p><u>All NICU 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>Kadlec’s NICU is staffed to accept and care for complicated pregnancies of all gestational ages. We provide mechanical ventilation and perform procedures for central venous catheters.</p> <p>Kadlec submits data to the Vermont-Oxford database</p> <p>Kadlec’s NICU, through its relationship with Seattle Children’s, provides immediate consultation from pediatric surgical subspecialists</p>	
Neonatal Patients: Services and Capabilities		Pass
<p><u>All NICU level IIIA patients and services plus:</u></p> <p><u>NICU level IIIB-</u> Infants of all gestational ages 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 ICN level II/NICU level III patients</p>	<p>Kadlec can provide care to the neonates of all gestational ages.</p> <p>Kadlec’s NICU provides advanced respiratory support and advanced imaging</p> <p>Kadlec reports that 2007 CHARS data demonstrates a current ADC of 12.0</p>	

GUIDELINE	Kadlec	Pass/Fail
	(when combining ICN level II and NICU level III data); expansion to NICU level III services is expected to increase the programs overall ADC.	

GUIDELINE	Kadlec	Pass/Fail
Obstetrical Patients: Services and Capabilities		Pass
<p><u>NICU level IIIA patients and services plus:</u> <u>NICU level IIIB</u></p> <p>Pregnancies at all gestational ages Capabilities include diagnosis and treatment of all perinatal problems</p>	<p>Kadlec treats pregnancies of all gestational ages and has the capability to diagnose and treat all Perinatal problems.</p>	
Patient Transport		Pass
<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 NICU level IIIA and NICU 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>Kadlec has its own maternal and neonatal transport team.</p> <p>Kadlec's transport team transports patients to and from Kadlec from communities in Southeast Washington and Northeast Oregon</p>	

GUIDELINE	Kadlec	Pass/Fail
<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 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 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>Policy to be requested as a term by the department if approved</p> <p>Guidelines to be requested as a term by the department if approved</p> <p>Verification to be requested as a term by the department if approved</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>Kadlec's obstetrical department has a chairperson (not a medical director)</p> <p>Kadlec's NICU has a medical director (Anthony Hadeed, MD) who is board certified in neonatology</p>	

GUIDELINE	Kadlec	Pass/Fail
Medical Providers		Pass
<p><u>ICN level IIA 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>Kadlec has the capacity to provide immediate availability of an obstetrician who is capable of managing complicated labor and delivery patients.</p> <p>Kadlec’s NICU has immediate availability of neonatologists, pediatric hospitalists or neonatal nurse practitioner to manage all severely ill neonates</p>	
<p><u>NICU 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>Kadlec has obstetrical anesthesiologist or nurse anesthetist who is immediately available.</p> <p>Pediatric imaging is also readily available. Seattle Children’s reads any echocardiography scan</p>	
Nurse:Patient Ratio		
<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>Kadlec adheres to these staffing ratios</p>	

GUIDELINE	Kadlec	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	Kadlec	Pass/Fail
<i>Nursing Management</i>		Pass
<u>ICN level IIB through NICU level IIIC</u> Same as Level I plus: Advanced degree is desirable	Kadlec's Manager of NICU is Kelly Harper, RNC, BSN	
<i>Support Providers: Pharmacy, Nutrition/Lactation and OT/PT</i>		Pass
<u>NICU level IIIB</u> <u>Pharmacy services</u> - same as ICN level IIB <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	<u>Pharmacy services</u> Kadlec has a registered pharmacist with experience in neonatal/Perinatal pharmacology in-house 24/7 <u>Nutrition/Lactation</u> Kadlec's NICU has a dietician experienced in perinatal nutrition. All patients are provided with nutritional counseling prior to discharge.	

GUIDELINE	Kadlec	Pass/Fail
<u>OT/PT</u> Provide for inpatient consultation and outpatient follow-up- services	<u>OT/PT</u> Kadlec staff and referral as needed	
<i>Support Providers: Social Services/Case Management, Respiratory Therapy, Nurse Educator/Clinical Specialist</i>		Pass
<u>Social Services/case management</u> ICN 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 <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. <u>Respiratory Therapy</u> ICN level IIB plus: Ratio of one Respiratory Care Practitioner to six or fewer ventilated neonates with additional staff for procedures [1:6]	<u>Social Services/case management</u> Kadlec’s NICU has a full time licensed MSW experienced with the problems of high-risk mothers and babies available 24/7 <u>Nurse Educator/Clinical Nurse Specialist</u> Kadlec’s has a nurse educator to coordinate staff education and development <u>Respiratory Therapy</u> Kadlec’s NICU has a respiratory care practitioner available for the unit for all infants requiring any oxygen needs whether it is CPAP or any other ventilatory support	

GUIDELINE	Kadlec	Pass/Fail
<i>X-Ray Ultrasound</i>		Pass
ICN level IIB services plus: Advanced level ultrasound available to Labor & Delivery and Nursery on-site and on a daily basis	Kadlec has advanced level ultrasound available within both the birthing center and the NICU	
<i>Laboratory and Blood Bank Services</i>		Pass
<u>Laboratory</u> Comprehensive services available 24 hrs/day <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	Kadlec’s in-house laboratory provides comprehensive services 24/7. NICU RN’s do all phlebotomy and IV placements in all neonates Kadlec has blood bank services available for both urgent and non urgent needs.	

If approved, the department will place a term on the certificate for Kadlec to supply the policies and guidelines established to meet the expectations outlined in the Patient Transport portion of these guidelines.

In addition to the comparison chart provided on the previous pages, Kadlec also included the following documents:

Kadlec Medical Center Discharge Planning Policy

[Amended Application, Exhibit 19]

This discharge policy outlines a list of policies and procedures designed to ensure that all appropriate steps are covered before the patient is discharged. The plan details a seven step process to establish a discharge plan. Kadlec also offers the following classes and services:

- Lactation classes
 - Infant CPR,
 - Neonatal hearing screens,
 - Retinal exams,
 - Bereavement support services,
 - Post partum depression services,
 - Infant massage, and
 - NICU and early intervention feeding for medically fragile children

Kadlec Medical Center Utilization Review Policy

[Amended Application, Exhibit 20]

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.

Based on the information provided by Kadlec 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, Kadlec's NICU 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.*

Kadlec will continue to provide Medicare and Medicaid services to the residents of Benton County and surrounding communities. The hospital contracts with the Joint Commission to survey and accredit the quality of service provided. The Joint Commission lists Kadlec in full

compliance with all applicable standards following the most recent on-site survey in August 2008.¹⁴

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 three years, IIO completed one licensing survey at the hospital.¹⁵ 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 Kadlec's NICU level III staff is already in place for the existing ICN level II service. Kadlec provided names and professional license number for all credentialed staff. Quality of care for Kadlec'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 Kadlec's family birth center and special care nursery reveals no recorded sanctions. [Compliance history provided by Medical Quality Assurance Commission]

On February 19, 2008, DOR08-07 was issued to Kadlec concerning their operation of a level III NICU. That DOR concluded that Kadlec had began offering NICU level III care without receiving prior CN approval. This application is to correct this failure. Since this is the first infraction of failing to comply with the CN law and rules, the department will not make a negative finding for this sub-criterion. However, future projects could be jeopardized if additional CN infractions are documented.

Based on Kadlec'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 NICU 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.

In response to this sub-criterion, Kadlec restates that it is the only recognized ICN level II provider in the planning area. As such, they are also the only facility that has the potential to treat the NICU level III newborns that cross-over from the ICN level II births. Specifically, Kadlec states, "This project is requesting CN-recognition of services Kadlec already provides.

¹⁴ <http://www.qualitycheck.org>

¹⁵ Survey completed February 2007.

Without the program (neonatal services) there would be a very significant gap in the residents' continuity of care. Thus, the program promotes continuity and lack of fragmentation". [Amended Application, p42]

The above response provided by Kadlec addresses continuity of care for Kadlec, 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 NICU 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 Kadlec'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. In addition to the oversight and consultation support addressed previously, the relationship provides Kadlec with on-going education for staff, grand rounds, coverage and real-time echo cardiology readings for infants admitted to the unit at Kadlec. [Amended Application, p42]

The department concludes that there is reasonable assurance that approval of this project would allow residents access to approved quality NICU level III service. Further, Kadlec's relationships within the existing health care system would continue and is 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 addressed in sub-section (3) above and is considered met.

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

Based on the source information reviewed, 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, Kadlec has met the review criteria under WAC 246-310-210, WAC 246-310-220, and WAC 246-310-230. Kadlec 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 as part of the WAC 246-310-230 evaluation. Therefore, the department moves to step two below.

Step Two

Before submitting this application, Kadlec considered one primary alternative to the application that was submitted. Below is a summary of Kadlec's reasoning and rationale for the current application

Maintain current operations and affirm status with department

Kadlec considered not submitting an application and work to convince the program to affirm the operations of the neonatal unit as it is currently operating. This was the applicant's preferred method, but complications with such a process did not assure the desired outcome for the hospital. As such, Kadlec concluded, "Given our desire to be in full conformance with Program requirements, and further given our need to expand within the next few years, we opted to submit a CN at this time". [Amended Application, p44]

Submit an application seeking approval for a NICU level III expansion

Upon review of unit census, Kadlec considered current planning area volumes and likely growth in the need for advanced neonatal care from the region. Once an expansion was determined to be a likely consequence, Kadlec states that after it assumed "a reasonable (but possibly conservative) growth rate, and a target midnight occupancy of 65%, we identified a need for at least 8 additional beds". In applying an hospital imposed standard of care, the

applicant surmised, “Kadlec’s current level of referrals/transfers of neonates born at other hospitals, coupled with expected general growth in demand, led us to conclude that a lower targeted occupancy (i.e.: 65%) was needed to assure timely access to NICU services”.

The department agrees with Kadlec that option one was not feasible. The department in February, 2008, completed a Determination of Reviewability for Kadlec regarding this issue. By letter, the department concluded Kadlec had expanded its ICN level II to include NICU level III services without prior Certificate of Need review and approval. At that time, the department informed Kadlec that a Certificate of Need review was necessary for it to provide NICU level III care.

Taking into account the community support, and the results of the department’s version of the numeric need methodology, the department concludes that the project described is the best available alternative for the community. This sub-criterion is met.

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 NICU level III service within Benton County. 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 Benton and Franklin counties. 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 requires construction of NICU level III space at Kadlec. 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 requires construction of NICU level III space at Kadlec. 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 NICU level III services to the residents in Benton and Franklin counties by reducing the number of transfers allowing for minimal interruptions of treatment and staffing continuity. The department is satisfied the project is appropriate and needed. This sub-criterion is met.