

**STATE OF WASHINGTON
DEPARTMENT OF HEALTH
ADJUDICATIVE SERVICE UNIT**

In Re:)	
)	Docket No. 06-12-C-2002CN
SOUTHWEST WASHINGTON)	Master Case No. M2008-117728
MEDICAL CENTER, CERTIFICATE OF)	
NEED APPLICATION FOR LEVEL III)	FINDINGS OF FACT,
NEONATAL INTENSIVE CARE UNIT,)	CONCLUSIONS OF LAW
)	AND FINAL ORDER
SOUTHWEST WASHINGTON)	
MEDICAL CENTER,)	
)	
Petitioner.)	
_____)	

APPEARANCES:

Petitioner, Southwest Washington Medical Center, Inc., by
Stamper Rubens PS, per
Randall L. Stamper and Edward H. Turner, Attorneys at Law

Intervenor, Legacy Health Systems and Legacy Salmon Creek Hospital, by
Davis Wright Tremaine, LLP, per
Brad Fisher, Attorney at Law

Department of Health Certificate of Need Program, by
Office of the Attorney General, per
Geoffrey W. Hymans, Assistant Attorney General

PRESIDING OFFICER: John F. Kuntz, Health Law Judge

The Presiding Officer, on authority delegated to him by the Secretary of Health, convened a hearing in Tumwater, Washington on October 15 - 17, 2007. Petitioner Southwest Washington Medical Center (Southwest) appealed the Certificate of Need Program (the Program) decision denying the Southwest application to establish a

FINDINGS OF FACT,
CONCLUSIONS OF LAW
AND FINAL ORDER

Level III Neonatal Intensive Care Unit in Clark County, Vancouver, Washington.

Application Denied.

ISSUE

Did the Petitioner's application meet the certificate of need criteria necessary to establish a neonatal intensive care nursery required under chapters 70.38RCW and/or 246-310 WAC?

SUMMARY OF THE PROCEEDING

The Program presented the testimony of Program Analyst Karen Nidermayer. Southwest presented the testimony of Renata Atkins; Linda Diane Waller, M.D.; Karla Rowe; and Robert McGuirk. Legacy Health Systems (Legacy) and its affiliate Legacy Salmon Creek Hospital (Legacy Salmon Creek) presented the testimony of Jody Carona; Jonathan Avery; and Carla Harris.

The following exhibits were offered for admission at hearing:

- Exhibit 1: Southwest certificate of need application record (AR) (AR pages 1-1393)¹.
- Exhibit 2: Analysis of the Certificate of Need Application Submitted by Evergreen Hospital Medical Center Proposing to Establish a Neonatal Intensive Care Nursery and Level III Obstetric Services at the Hospital.
- Exhibit 3: Reconsideration Evaluation of the Certificate of Need Application Submitted by Overlake Hospital Medical Center Proposing to Establish a Neonatal Intensive Care Nursery and Level III Obstetric Services at the Hospital.

¹ Exhibit 1 (the Southwest application) was admitted at the prehearing conference. See Prehearing Order No. 2.

- Exhibit 4: Analysis of the Certificate of Need Application Submitted by Providence Health System-Washington Proposing to Establish a Neonatal Intensive Care Nursery and Level III Obstetric Services at Providence Everett Medical Center, Everett.
- Exhibit 5: Evaluation of Exhibit 11: Public documents, authority and reference materials, including but not limited to: Certificate of Need Program, Health Law Judge, and Court Decisions.
- Exhibit 12: SWMC Level III NICU Project. RMC Consulting SWMC Adjudicative Hearing Utilization Exhibit (NICU Discharges: January-September 2006 for Legacy Salmon Creek).
- Exhibit 13: Washington State Health Plan, Volume 1, Health Principles, Goals and Strategies (Title Page only) (Approved May 12, 1987).
- Exhibit 14: Volume II, State Health Plan, page B-5 (May 1987).
- Exhibit 15: Washington State Health Plan, Volume 2, Performance Standards for Health Facilities and Services (Approved May 12, 1987).

Following a discussion with the parties on October 15, 2007, the Presiding Officer did not admit Exhibit 2 through Exhibit 11 offered by Southwest.² The Presiding Officer admitted Exhibit 12. The Program withdrew its offer of admission of Exhibit 14. The Program did not offer for admission at hearing Exhibits 13 and 15. Exhibits 13, 14, and 15 were therefore not admitted at hearing.³

The Presiding Officer allowed the parties to submit briefs in lieu of closing arguments. The final brief was submitted on December 5, 2007, at which time the

² Transcript Record (TR), Vol I, page 11.

³ TR, Vol II, pages 482 – 486.

hearing record was closed. On April 17, 2008, the Presiding Officer extended the date for the issuance of the final order to May 15, 2008. See Post Hearing No. 1.

Based on the evidence presented, the Presiding Officer enters the following:

I. FINDINGS OF FACT

Introduction

1.1 When applying for a certificate of need, the applicant must submit sufficient information to show the necessity of the relevant service or facility. That showing of necessity is call need. An applicant generally proves need for the service exists by: (1) obtaining historical statistical information regarding the past use of the service; and (2) using the historical statistical information to project what will be the need for the service in the future given the expected increase of the population. Any assumptions regarding the projections are examined to see if the assumptions, in fact, support the projections. Testing the assumptions is necessary to develop health services in a planned, orderly fashion, and to avoid the unnecessary duplication or fragmentation of services.⁴

1.2 Any certificate of need application is nothing more than a snapshot in time. While the historical statistical information used in most need applications is known, the assumptions or projections are less certain. Though mathematical calculations are used in most determinations whether need exists, the process does not have the mathematical precision such calculation might suggest.

⁴ See RCW 70.38.015(2).

1.3 In fact, a certificate of need application is not a simple multiple-page form that the applicant fills out and submits with the appropriate fee. Rather the application (which actually begins with the applicant filing a letter of intent prior to filing the application) is merely the starting point in the process. By the time the Program issues its decision or analysis on a certificate of need application, the “application record” compiled by the Program runs into the thousands of pages.⁵

1.4 The first step is determining whether Southwest submitted sufficient information to support its application to establish an additional obstetric service (characterized as a Level III service) for the defined health service area.⁶ The next step is determining whether the Program, in reviewing the Southwest application, supplied sufficient information to support its decision to approve or deny the application.

1.5 In the most basic terms, there are three levels of medical or obstetric services that can be provided to a newborn or neonate.⁷ Level I care represents obstetric services provided to normal newborns. A health care facility does not need to obtain a certificate of need to provide obstetric services to normal newborns. Level II care (intermediate care) represents the next highest level of obstetric services. Level II care is subdivided into two subcategories (Level IIA and IIB). Level III care (intensive care) represents the highest level of obstetric services.

⁵ The Southwest application file is 1,393 pages in length.

⁶ A “health service area” means a geographic region appropriate for effective health planning including a broad range of health services. WAC 246-310-010(29). “Health services” means clinically related (i.e. preventative, diagnostic, curative, rehabilitative, or palliative) services and includes alcoholism, drug abuse, and mental health services. WAC 246-310.010(29).

⁷ A “newborn” or “neonate” means a newly born infant under twenty-eight days of age. WAC 246-320-010(62).

1.6 The reason that a certificate of need is required to provide Level II and Level III obstetric services is because these two levels of medical care are considered “tertiary health services,” or a specialized service meeting complicated medical needs of people, and which require sufficient patient volume to optimize provider effectiveness, quality of service, and improved outcomes of care.⁸ The parties do not dispute that providing neonatal intensive care or Level III services is a tertiary health service.

1.7 Level III is subdivided into three subcategories (Level IIIA, IIIB, and IIIC). The difference between Level IIIB services (which Southwest is currently authorized to provide), and Level IIIA services (which Southwest is seeking authority to provide), is a subtle distinction.⁹ In fact, the medical status of a newborn or neonate can fluctuate between the two levels of care on any given day. Both Level IIIB and Level IIIA anticipate the use of mechanical ventilation, differing only in the length of time or duration of use (Level IIIB less than 24 hours; Level IIIA for longer than 24 hours). Even though the distinction is subtle, and even though the medical status of a newborn or neonate may fluctuate between the two levels of care, an applicant like Southwest must still apply for a certificate of need before providing Level III obstetric services on a regular basis.¹⁰

⁸ See RCW 70.38.025(14) and WAC 246-310-010(58).

⁹ There are some weight and age requirements which determine whether care is Level IIIB or Level IIIA. See AR 640 (Neonatal Patients: Services and Capabilities).

¹⁰ A facility authorized to provide Level II obstetric services may provide Level III services on an emergency basis (emergent patients or non-scheduled Level III deliveries).

1.8 A Level III certificate of need application must meet the four basic criteria set forth in statute and regulation.¹¹ In addition to the statutory and regulatory requirements, there exists a guideline that provides a key measurement or proxy measurement (known as “average daily census”) in determining whether additional need exists for Level III services. The average daily census guideline is found in the Washington State Perinatal Level of Care (LOC) Guidelines (the LOC Guidelines). See AR 637 – 656. The average daily census proxy measurement requires or recommends that the service facility or hospital provide care for an average of ten patients requiring the Level II/Level III services on a daily basis.

1.9 Obtaining the average daily census figure is a multi-step calculation, which includes measuring such factors as the number of births, patient discharges, the number of patient days for each level of care, and length of stay of the patient. See AR 24 – 26; AR 1062 – 1063, and 1066 – 1067. While the LOC Guidelines are not regulatory in nature, certificate of need applicants consider the LOC Guidelines as a useful tool in determining whether additional obstetric services and capabilities are needed.¹²

Previous Southwest/Legacy Application History

1.10 A complete understanding of the current Southwest application to provide Level III services requires a look at recent Program decisions regarding certificate of need applications filed by Southwest Washington Medical Center (Southwest) and

¹¹ See RCW 70.38.115(2) and WAC 246-310-210 through WAC 246-310-240.

¹² Southwest reviewed and/or contributed to the 2005 version of the LOC Guidelines used in this analysis. AR 656.

Legacy Salmon Creek Hospital (Legacy Salmon Creek) in 2001 – 2002. Legacy submitted an application for a certificate of need to establish a new 220-bed acute care hospital, Legacy Salmon Creek, in Clark County, Vancouver, Washington in March 2001. Legacy Salmon Creek intended to provide services including medical, surgical, emergent, radiation, oncology, and basic obstetric services. AR 665. In addition to offering basic obstetric service care (or Level I care), Legacy Salmon Creek proposed to provide intermediate obstetric care (or Level II care), and neonatal intensive care (or Level III care). AR 665-666.

1.11 The Legacy Salmon Creek Level II and Level III services were described as follows:

The combined level II and level III service area would include a traditional nursery of 10 bassinets; in addition, the NICU would have 15 single rooms, each with a bassinet, for a combined total of 25 bassinets. Overall, LHS-Clark County would have 35 bassinets used for obstetric services – 10 in the normal newborn nursery; 10 in the NICU nursery; and 15 in the single NICU rooms.

AR 666.

1.12 On March 15, 2002, the Program approved the Legacy Salmon Creek certificate of need application. AR 657. There was no appeal from the Program's decision granting the Legacy Salmon Creek certificate of need application. As a result, the Legacy Salmon Creek facility was awarded 25 Level II and Level III beds. The Legacy Salmon Creek hospital opened on August 22, 2005.

1.13 In April 2001, Southwest filed a certificate of need to add 82 acute care beds to its hospital, for a total of 442 licensed acute care beds, in Clark County,

Vancouver, Washington. AR 693. Included in this bed total was a 10-bed intermediate care nursery (or Level II beds). Southwest's certificate of need application did not include a request to establish any neonatal intensive care nursery (Level III) beds.

1.14 On March 15, 2002, the Program approved the Southwest certificate of need application. There was no appeal filed regarding the Program's decision granting the certificate of need. As a result, Southwest was allowed to add the 82 acute care beds to its hospital. None of the 82 acute care beds authorized under the Southwest 2001 application included neonatal intensive care unit (or Level III care) beds.

Current Southwest Application History

1.15 On September 22, 2005, or approximately one month following the opening of the Legacy Salmon Creek neonatal intensive care nursery, Southwest filed a certificate of need application to establish a Level III Neonatal Intensive Care Unit in Clark County, Washington. Southwest identified Clark and Skamania counties as its service area. Legacy Salmon Creek sought and received affected person status.¹³ AR 463 and AR 492.

1.16 A neonatal intensive care nursery is defined as:

[a]n area designed, organized, equipped, and staffed for constant nursing, medical care, and treatment of high-risk infants (neonates or newborns)¹⁴ who may require:

¹³ An "affected person" means an interested person who: (a) Is located or resides in the applicant's health service area; (b) Testified at a public or submitted written evidence; and (c) Requested in writing to be informed of the department's decision. WAC 246-310-010(2). An "interested person" includes health care facilities providing services similar to the services under review and located in the health service area. See WAC 246-310-010(34).

¹⁴ A "neonate" or "newborn" means a newly born infant under 28 days of age. WAC 246-320-010(62).

- (a) Continuous ventilatory support, twenty-four hours per day;
- (b) Intravenous fluids or parenteral nutrition;
- (c) Preoperative and postoperative monitoring when anesthetic other than local is administered;
- (d) Cardiopulmonary or other life support on a continuous basis.¹⁵

1.17 Subsequent to receiving its certificate of need in 2002, Southwest made capital improvements to expand and remodel its 10-bed special care nursery to an 18-bed special care nursery. More specifically, Southwest remodeled the nursery from 10 bassinets¹⁶ in an open ward to 18 separate patient rooms available to provide obstetric services. In its 2005 certificate of need application, Southwest did not seek an increase above the 18-bed facility authorized for its intermediate care (Level II) unit. Rather, Southwest anticipated that it would provide Level III services within the 18 beds already authorized.

1.18 The Program screened the Southwest application, which consists of a review of the application and the submission of the Program's questions regarding the application to Southwest for clarification on two occasions. Following the application screening, the Program accepted written public comments on the Southwest application. Southwest could have requested a public hearing regarding the public comment process but did not do so.¹⁷ The Program did not conduct one. After receiving all of the documents submitted regarding the application, including rebuttal documents submitted by Southwest, the Program closed the file and began its review.

¹⁵ WAC 246-320-010(63).

¹⁶ A bassinet is a small crib or bed.

¹⁷ See WAC 246-310-180.

1.19 On April 21, 2006, the Program issued its certificate of need review. The Program concluded the Southwest application was not consistent with the certificate of need criteria and denied the application. AR 460 – 487. The Program found that the Southwest application met some of the sub-criteria.¹⁸ AR 473 – 487. However, the Program determined that Southwest failed to prove that need existed for additional Level III services in Clark – Skamania health service area as required under WAC 246-310-210(1). Stated another way, the Program determined that there existed sufficient capacity to provide Level III services in the health service area identified by Southwest. As the Program determined Southwest failed to prove that additional need was required in the health service area, the Program concluded Southwest could not meet the financial feasibility criteria in WAC 246-310-220(2). More specifically, because Southwest could not show need existed for another Level III facility, the costs of this project would result in an unnecessary impact on the costs and charges for health services in the community. AR 475.

1.20 On May 17, 2006, Southwest submitted a request for reconsideration of the Program’s denial decision, and submitted additional documentation in support of the request. In its reconsideration request, Southwest identified its service area as Clark, Cowlitz, and Wahkiakum counties. The Program granted the reconsideration request. Unlike the original review, a public hearing was conducted on September 28, 2006. After reviewing all of the reconsideration documentation, including the Southwest

¹⁸ The Program determined Southwest met the sub-criteria set forth in: WAC 246-310-210(2); WAC 246-310-220(1) and (3); and WAC 246-310-230(1), (2), (3) and (5).

rebuttal documentation following the public hearing, the Program closed the reconsideration file and commenced its review.

1.21 Following its review, the Program issued its reconsideration decision and denied the Southwest application on November 27, 2006. Southwest appealed the decision. AR 1239 – 1256. As with its original determination, the Program determined that Southwest did not show sufficient need existed to grant the application. AR 1248 – 1255. Unlike its original determination, the Program found that Southwest's failure to prove need existed for an additional Level III facility required a finding that Southwest did not prove that it met any of the financial feasibility, structure and process of care, and cost containment criteria under WAC 246-310-220, WAC 246-310-230, and WAC 246-310-240 respectively. AR 1255 – 1256.

Need

1.22 Whether sufficient need exists to establish or increase the amount of Level III services (the tertiary health service in question here) in a given service area is determined by a measurement of services necessary, and not by the number of beds available to provide the service. The level of obstetric services needed and the number of available beds are distinct measurements. The level of obstetric services required is measured using a proxy measurement, which is a figure known as the average daily census. More specifically, how many patients of a specific identified type are hospitalized on any given day at the facility in question? To calculate the average daily census, the applicant reviews historical statistical data regarding the number of patient discharges of an identified group of patients for one year, divided by 365 days.

Southwest used historical statistical data obtained from the Department of Health Office of Comprehensive Hospital Abstract Reporting System (CHARS), which provides the historical trends in patient discharges, and length of stay of newborn patients within the relevant major diagnostic category (MDC) #15.

1.23 A major diagnostic category or MDC is, as its name suggests, a category of information regarding patient discharge statistics. Here the specific category (MDC #15) represents a grouping of diagnostic related groups (DRGs). More specifically, MDC #15 includes diagnostic code numbers 385 – 391:

DRG Definition Level of Care

385: Neonates, died or transferred to another acute care facility	Level III
386: Extreme Immaturity or Respiratory Distress Syndrome, Neonate	Level III
387: Prematurity with Major Problems	Level II or III
388: Prematurity without Major Problems	Level II
389: Full Term Neonates with Major Problems	Level II
390: Neonates with Other Significant Problems	Level I or II
391: Normal Newborn	Level I

As indicted in the above DRG table, patient discharges identified by the DRG 385 and 386 diagnostic codes measure Level III obstetric services. Patient discharges under the DRG 387 diagnostic code can measure, but do not always measure, that the patient was provided with Level III obstetric services.

1.24 Southwest correctly points out that a determination of need for additional Level III services is a measure of services and not of the beds where the services are provided. While the need for Level III services, as requested by Southwest, measures services and not the number of beds, the number of available beds does have some effect on the need analysis. Whether a facility such as Southwest can provide a service

depends, at least in part, on whether a bed exists in which the hospital can provide the service. This bed number contributes to an understanding of the discharge data from which the average daily census figures are obtained to determine the need for the Level III services.

1.25 Southwest provided projections for the average daily census requirements in the Clark – Skamania service area. AR 25. Southwest first obtained discharge data for the 1999 – 2004 period for Level II and Level III services. AR 25. Southwest then projected an average daily census of 17.6 for the combined Level II and Level III services in 2006, with an increase to an average daily census to 20.4 by 2010. Dividing the average daily census in half, each facility (Legacy Salmon Creek and Southwest) could potentially maintain an average daily census of 10.2. If both Legacy Salmon Creek and Southwest could maintain an average daily census figure of 10.2, then both facilities would appear to comply with the LOC Guidelines. See AR 640.

1.26 The Southwest assumption that both Southwest and Legacy Salmon Creek would each maintain the average daily census discharge figure of 10.2 (or an equal split of the projected average daily census figure of 20.4 in 2010) is, however, undercut by Southwest's own projection regarding the recapture or retention of Level III service patients. Southwest calculated that its average daily census for Level II and Level III services the period 2005 – 2010 would grow from 6.6 in 2006, to 17.1 by 2010. AR 26. So comparing the average daily census figure of 17.1 in 2010, and contrasting it with the Clark – Skamania service area average daily census of 20.4, the remaining average daily census of Level II and III newborn or neonate patients left available for

Legacy Salmon Creek to provide treatment services to would be 3.3 patients. An average daily census figure of 3.3 patients would not allow Legacy Salmon Creek to maintain the sufficient patient volume to optimize provider effectiveness, quality of services, and improved outcomes of care necessary for providing tertiary health services. Southwest's own statistical information undercut its argument that need existed in the Clark – Skamania health service area.

1.27 In addition to the average daily census discharge numbers for the 2006 – 2010 period, Southwest considered the number of available bed numbers in the health service area in its need analysis. Southwest determined that it would be necessary to have 24 Level II/Level III beds available in 2006, increasing to 28 beds being necessary in 2010. The Southwest calculations that additional need existed in the Clark – Skamania health service area assumed that the Legacy Salmon Creek facility had only 15 available Level II and III beds with which to provide services. More specifically, the Southwest figures showing need for additional Level III services was calculated using 33 beds (that is, 15 Legacy Salmon Creek and 18 Southwest beds).

1.28 In actuality, there existed anywhere between 35 beds (25 at Legacy Salmon Creek and 10 at Southwest) to 43 beds (25 beds at Legacy Salmon Creek; 18 beds at Southwest) in the Clark – Skamania health service area. Looking at the total number of available Level II and Level III beds in the Clark – Skamania health service area, there currently were sufficient beds available to meet need in the service area.

1.29 In calculating its average daily census figures, Southwest included 100 percent of the discharge data for the DRG 387 group to support its calculations that need exists to support its application. There are only one to two percent of DRG 387 patients that normally qualify as Level III patients according to Southwest's medical expert, Dr. Linda Wallen. TR 360. For its need calculations to be valid, Southwest would need to submit information or evidence that supports the assumption that it can capture the remaining 99 to 98 percent of the discharge information from the DRG 387 group as Level III discharges. It did not do so. Absent an evidentiary showing that it can capture 100 percent of that diagnostic research group, any assumption based on that capture rate is not supportable.

1.30 In its remand request, Southwest redefined its health service area to Clark, Cowlitz, and Wahkiakum counties.¹⁹ AR 880 – 882. As with its original application, Southwest did not intend to establish additional beds. Southwest only intended to increase the level of medical/obstetric care provide in the 18-bed Level II unit to allow for Level III services. AR 882.

1.31 Southwest noted that it currently provided Level III services on an emergent basis, and possessed the capacity to provide mechanical ventilation, consistent with the change in the LOG Guidelines in 2005. See AR 851 – 852. Because of its experience with providing emergent Level III services, Southwest did not anticipate it would require additional medical resources, training, or an increase in staffing to provide services that met the Level III service guidelines. Southwest

¹⁹ Cowlitz-Wahkiakum counties are considered one service area. See AR 1250.

considered its resources and/or staffing were currently sufficient to meet the Level III service standards. Despite this experience, Southwest does not currently possess a Level III certificate of need. To do so, Southwest must prove that need exists for additional Level III services, just the same as any other applicant.

1.32 Similar to its calculations in the original application, Southwest included 100 percent of the entire number of patient discharges from the DRG 387 discharge category in Clark County in support of its average daily census (ADC) statistical analysis. AR 1062. As Southwest's medical expert testified that one to two percent of the DRG 387 group would be Level III patients,²⁰ assuming the capture of 100 percent of the DRG 387 discharges is not a supportable presumption. Without stronger evidence in support of its position on this factor alone, the Southwest application for additional need should fail. This analysis would be the same regarding Southwest's argument regarding the capture of the entire DRG 387 discharges for Cowlitz-Wahkiakum Counties. AR 1066.

1.33 By choosing the Clark, Cowlitz – Wahkiakum health service area, Southwest does increase the average daily census figure over that existing in the Clark – Skamania health service area previously identified in its original application. While the average daily census figure is increased, so is the capacity for treating patients who fall within the DRG #15 categories. The capacity for treating Level II/

²⁰ Dr. Linda Wallen. TR 360.

Level III patients is increased because another facility, Peace Health St. John Medical Center (St. John Medical) in Cowlitz County, must be included in the available capacity to treat the patients within the DRG #15 group.

1.34 By defining the health service area as Clark, Cowlitz, and Wahkiakum counties, the total number of Level II and Level III beds in the area is 46. AR 1252. This increased number of beds results from the inclusion of six additional Level II capacity beds located at the St. John Medical.²¹ As Southwest continued to compute its bed count using the assumption that Legacy Salmon Creek has only 15 Level II/Level III beds available, any bed count computation by Southwest continues to undercount the actual Level II/Level III beds available. Based strictly on the available bed count, Southwest's argument that further need exists must fail.

1.35 In addition to proving that the population to be served has need for the Level III services, Southwest must also show there are not services sufficiently available to meet that need. Southwest has not done so. There is the Legacy Salmon Creek facility within the defined health service area to address the current need for Level III services. Southwest did not prove that Legacy Salmon Creek was unable to meet the actual average daily census figures existing at the time of the application. Southwest also did not prove its average daily census figures (inflated by including 100 percent of the DRG 387 patient discharge numbers) were accurate. Southwest did not prove that the current bed capacity within the health service area hospital cannot meet the existing

²¹ Wahkiakum County does not have a hospital.

Level III services. Without sufficient evidence showing that other services and facilities are not or will not be, available to meet that need, Southwest's application must fail.

1.36 Southwest sought to provide continuity of care by obtaining the ability to provide Level III services, and thereby enable one team of providers to serve the needs of neonates with one standard of care and without a break in care due to transfer. In the best of all worlds, all facilities would be able to do so. Every facility that can show need should be allowed to provide the continuity of care anticipated or sought by Southwest. What the record shows is that the neonates were receiving continuity of care during the relevant time period, just not at the one facility. Neither Southwest witness Karla Rowe nor Dr. Linda Waller testified that neonate patients at Southwest suffered any loss of continuity of care because of the current requirement to transfer those patients receiving Level III services.

Charity Care/Access to Services

1.37 Southwest provided, in its application, its current admission and charity care policy. AR 116 – 133. Southwest provided sufficient financial information regarding its charity and uncompensated care to allow access to health care services to all residents of the health service area. AR 315 – 316. The financial information regarding the percentage of charity care was consistent with the regional charity care percentage for the Southwest Washington region. AR 591 – 601. Such charity and uncompensated care would allow access to medical services for low-income, racial and ethnic minorities, handicapped, and other underserved groups.

Financial Feasibility

1.38 The Southwest Level II nursery remodel from the 10-bed nursery to the 18-bed nursery was funded through a \$2.4 million philanthropic donation. For that reason, there were no anticipated capital construct or special equipment costs required by Southwest to provide the requested Level III services. Southwest spent \$50,000 as its capital investment in the project, which reflected the certificate of need application fee and the consulting fees associated with the application. AR 10 – 12. Given that there is a \$50,000 outlay, and the capital expenditure came from funds which were available to it at the time of the application, Southwest could adequately fund the Level III project.²² See AR 501.

1.39 The Department of Health Office of Hospital and Patient Data Systems (OHPDS) evaluated the financial information provided by Southwest. AR 498 – 502. For this application OHPDS performed a financial ratio analysis method, including a long term debt to equity ratio, and the total operating expenses to total operating revenue ratio. Following its analysis, OHPDS found the hospital had an above average financial foundation and that was unlikely to change in the near future.

Structure and Process of Care

1.40 As it intended the co-location of the proposed Level III services within its currently existing Level II service facility, Southwest anticipated that it would only need to add three additional full time employees (FTEs) to its facility. Most of the key

²² See AR 501.

personnel were already providing Level IIB services, which Southwest argued was essentially the same skill set necessary to provide Level IIIA services. AR 36 – 37.

1.41 In addition to the analysis that it would not be required to add more than three additional FTEs to enable it to provide Level IIIA services, Southwest created a detailed comparison of the LOC Guidelines and its own capabilities regarding the Level IIB and Level IIIA services. AR 103 – 114. Southwest already had in place a policy/procedure for the transportation of Level III patients. AR 236-237. Southwest appeared to consider, at least in 2005, a patient transfer agreement with Legacy Salmon Creek. See AR 238 – 243. This agreement was executed between the parties in August 2006. See AR 331 – 337.

1.42 The LOC Guidelines describes two stages of Level II care services (Level IIA and IIB) and three stages of Level III care services (Level IIIA, IIIB, and IIIC). AR 639. Following the LOC Guidelines recommended approach, Southwest would need to provide Level IIB services before providing Level IIIA services. As Southwest was providing Level IIB services at the time of its application, it met this requirement.

1.43 In analyzing the Southwest application, the Program reviewed Department of Health, Office of Health Care surveys for the period 2003 through 2005. AR 484. Based on those survey results, the Program determined that the Southwest compliance history would support a finding that Southwest would continue to operate in conformance with all relevant state and federal regulations in the event it provided Level III services. AR 485.

Cost Containment

1.44 Southwest considered three alternatives approaches to its proposed project to provide new Level III services in the Clark – Skamania health service area. The three alternatives were: (1) provide only Level IIB services, which would maintain the status quo; (2) develop a neonatal intensive care unit that provided Level III services which exceeded Level IIIA capabilities; or (3) develop Level IIIA services, consistent with its intention in the application. AR 39 – 41. Southwest determined that establishing the Level IIIA services as projected in its application was the superior alternative, and the Office of Hospital and Patient Data Systems (OHPDS) staff determined that Southwest’s decision to establish Level IIIA services was an appropriate selection. AR 501 – 502.

1.45 Additionally, OHPDS determined that the costs, scope and methods of construction, and energy conservation were reasonable. The total capital invested in the project (\$50,000) for the 18-bed project were within the past construction costs reviewed by OHPDS. From a fiscal standpoint, Southwest would appear to satisfy the cost containment criteria.

1.46 Whether a facility can justify criteria from a fiscal standpoint is only one view of the criteria. As with the need criteria, there is a requirement to determine if superior alternatives are not available or practicable. So, the fiscal analysis performed by OHPDS for the Southwest application answers the question whether, of the three choices provided, it meets the cost criteria requirement. It does not completely answer the question whether *any* superior alternatives are not available or practicable. When

considered from this perspective, the choice does not fully consider whether there exists a sufficient Level III service alternative within the health service area. Here, such an alternative exists, specifically Legacy Salmon Creek.

1.47 Southwest eventually considered the transfer of Level III patients to the Legacy Salmon Creek facility. AR 116 – 118. Southwest determined, based on its own need projections, that Legacy Salmon Creek had insufficient capacity to accommodate the projected increased need for Level III services. As a result, newborns or neonates would need to be transferred to Portland area hospitals. This analysis failed on two grounds: (1) Southwest presented insufficient evidence as a part of its application to support the increased need for Level III services; and (2) Southwest failed to provide evidence that it was transporting newborns or neonates in numbers that precluded Legacy Salmon Creek from meeting the existing Level III needs in the health service area. The numbers discussed at hearing (three to four transfers) do not appear beyond the capacity at Legacy Salmon Creek at the time of the application. TR 366, line 25.

II. CONCLUSIONS OF LAW

General Certificate of Need Requirement

2.1 A certificate of need is a non-exclusive license to allow health care providers to establish or expand facilities or acquire certain types of equipment. See *St. Joseph Hospital v. Department of Health*, 125 Wn.2d 733, 736 (1995). The Program seeks to control health care costs under chapter 70.38 RCW by ensuring better utilization of existing institutional health services and major medical equipment. See *St. Joseph Hospital v. Department of Health*, 125 Wn.2d at 736. The development

of health services and resources should be accomplished in a planned, orderly fashion consistent with identified priorities and without unnecessary duplication or fragmentation. RCW 70.38.015(2). The certificate of need process grew out of the government concern “that the marketplace forces in this industry failed to produce efficient investment in facilities and to minimize the costs of health care.” *St. Joseph Hospital v. Department of Health*, 125 Wn.2d at 735-736.

2.2 The applicant bears the burden of establishing that the application meets all applicable criteria by a preponderance of the evidence. WAC 246-10-606. Evidence in a certificate of need hearing shall be the kind of evidence upon which reasonable prudent persons are accustomed to rely upon in the conduct of their affairs. WAC 246-10-606. Relevant evidence for certificate of need applications purposes means evidence that existed at the time of the application was submitted to the Program for consideration in that application.

2.3 Upon the receipt of a certificate of need application, the Program reviews the application to determine whether the application met the required criteria. The Program then issues its written decision, which must contain sufficient information to support the Program’s decision. WAC 246-310-200(2); see WAC 246-310-490; see also *In re Auburn Medical Research Center*, Docket No. 01-05-C-1052CN (February 20, 2003). The Program’s analysis need not be a recitation of the entire application record, so long as it contains sufficient summary of the information used in reaching the decision.

- 2.4 To obtain a certificate of need regarding a project an applicant must show:
- (a) Whether the proposed project is needed;
 - (b) Whether the proposed project will foster containment of the costs of health care;
 - (c) Whether the proposed project is financially feasible; and
 - (d) Whether the propose project will meet the criteria for structure and process of care identified in WAC 246-310-230.

WAC 246-310-200(1). The above criteria are addressed in WAC 246-310-210 (determination of need); WAC 246-310-220 (determination of financial feasibility); WAC 246-310-230 (criteria for structure and process of care); and WAC 246-310-240 (determination of cost containment).

2.5 In the event the chapter 246-310 WAC standards do not address what is required to determine whether a proposed service is needed in sufficient detail, the applicants and/or Program may consider standards developed by organizations with recognized expertise related to the proposed undertaking. See WAC 246-310-200(2). Such standards may be found in the LOC Guidelines. When read in conjunction with the WAC 246-310-210 through WAC 246-310-240 criteria, the LOC Guidelines provides a reference for hospitals applying for Level II or Level III services.

Southwest Certificate of Need Application

2.6 Southwest applied for a certificate of need to operate a neonatal intensive care unit and provide Level III obstetric services. A neonatal intensive care unit is considered a “tertiary health service,” which is defined to mean:

[a] specialized service meeting complicated medical needs of people and requires sufficient patient volume to optimize provider effectiveness, quality of service, and improved outcomes of care.

RCW 70.38.025(14) and WAC 246-310-010(58). The parties do not dispute that a Level III obstetric service is a tertiary health service.

2.7 The Southwest application must meet the requirements or criteria set forth in WAC 246-310-200(1). The first criterion (WAC 246-310-210) speaks to need. WAC 246-310-210(1) and (2) apply to the Southwest application.²³ Those subsections state:

The determination of need for any project shall be based on the following criteria, except these criteria will not justify exceeding the limitation on increases of nursing home beds provided in WAC 246-310-810.

(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 the need. The assessment of the conformance of a project with this criterion shall include, but need not be limited to, consideration of the following:*

(b) *In the case of health services or facilities proposed to be provided, the efficiency and appropriateness of the use of existing services and facilities similar to those propose;*

WAC 246-310-210(1) (emphasis added).

2.8 Based on Findings of Fact 1.5 through 1.37, 1.46, and 1.47, Southwest fails to show that additional need exists for Level III services, and fails to show that Level III services are not sufficiently available or accessible to meet the existing need. The Southwest application fails to meet the applicable WAC 246-310.210(1) criteria.

²³ The Program did not address the criteria contained in subsections WAC 246-310-210(3), (4), (5), and (6) in considering the Southwest certificate of need application and they are not relevant to further discussion. See AR 464 and 1244.

2.9 WAC 246-310-210(2) provides, in relevant part:

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.

WAC 246-310-210(2).

2.10 Based on Finding of Fact 1.37, Southwest provided sufficient financial evidence to provide adequate access to the proposed Level III health service. The Southwest application met the applicable WAC 246-310-210(2) criteria.

2.11 The financial feasibility criteria are found in WAC 246-310-220:

The determination of financial feasibility of a project shall be based on the following criteria.

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

(2) The costs of the project, including any construction costs, will probably not result in an unreasonable impact on the costs and changes for health services.

(3) The project can be appropriately financed.

2.12 Based on Findings of Fact 1.38 through 1.39, Southwest met the criteria set forth in WAC 246-310-220.

2.13 The structure and process of care criteria are set forth in WAC 246-310-230. The relevant portions of that regulation state:

A determination that a project fosters an acceptable or improved quality of health care shall be based on the following criteria.

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

(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.

(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.

(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.

(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.²⁴

2.14 Based on an analysis of the five sub-criteria, Southwest met four of these five WAC 246-310-230 criteria. More specifically:

- A. Based on Finding of Fact 1.40 through 1.41, Southwest met the applicable WAC 246-310-230(1) criteria.
- B. Based on Findings of Fact 1.40 through 1.42, Southwest met the applicable WAC 246-310-230(2) criteria.
- C. Based on Finding of Fact 1.43, Southwest met the applicable WAC 246-310-230(3) criteria.
- D. Based on Findings of Fact 1.5 through 1.37, 1.46 and 1.47, Southwest did not meet the applicable WAC 246-310.230(4) criteria.
- E. Based on Finding of Fact 1.43, Southwest met the applicable WAC 246-310-230(5) criteria.

²⁴ The sub-criteria contained in WAC 246-310-230(5) (a) and (b) are not applicable to the Southwest certificate of need application.

Southwest did not meet the applicable WAC 246-310-230 criteria by not meeting all five of the sub-criteria.

2.15 WAC 246-310-240 set forth the criteria regarding cost containment in this matter.²⁵ The relevant portion of that regulation states:

A determination that a proposed project will foster cost containment shall be based on the following criteria:

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

WAC 246-310-240(1).

2.16 Based on Findings of Fact 1.5 through 1.37, and 1.44 through 1.47, Southwest did not meet the applicable WAC 246-310-240(1) criteria.

Southwest Due Process/Constitutional Arguments

2.17 Southwest raises due process and constitutional issues in its closing brief. See Southwest Washington Medical Center's Post-Hearing Closing Brief, pages 32-34. More specifically, Southwest argues the Program's denial of its certificate of need application is the result of the Program's inconsistent application/interpretation of vague and/or non-existent need methodology. Southwest Washington Medical Center's Post-Hearing Brief, page 32, lines 19 – 20. To the extent Southwest contends the certificate of need statutes and/or regulations are invalid or unconstitutional, those arguments or issues are preserved for appeal. See WAC 246-10-602(3)(c) and (4).

²⁵ The sub-criteria contained in WAC 246-310-240(2) and (3) are not applicable to the Southwest certificate of need application

III. ORDER

Based on the foregoing Findings of Fact and Conclusions of Law, the Southwest Washington Medical Center certificate of need to establish a Level III neonatal intensive care unit in Clark County, Washington, is DENIED.

Dated this __6__ day of May, 2008.

_____/s/_____
JOHN F. KUNTZ, Health Law Judge
Presiding Officer

NOTICE TO PARTIES

Either party may file a **petition for reconsideration**. RCW 34.05.461(3); RCW 34.05.470. The petition must be filed within 10 days of service of this Order with:

Adjudicative Service Unit
P.O. Box 47879
Olympia, WA 98504-7879

and a copy must be sent to:

Certificate of Need Program
P.O. Box 47852
Olympia, WA 98504-7852

The petition must state the specific grounds upon which reconsideration is requested and the relief requested. The petition for reconsideration is considered denied 20 days after the petition is filed if the Adjudicative Service Unit has not responded to the petition or served written notice of the date by which action will be taken on the petition.

A **petition for judicial review** must be filed and served within 30 days after service of this order. RCW 34.05.542. The procedures are identified in chapter 34.05 RCW, Part V, Judicial Review and Civil Enforcement. A petition for reconsideration is not required before seeking judicial review. If a petition for reconsideration is filed, however, the 30-day period will begin to run upon the resolution of that petition. RCW 34.05.470(3).

FINDINGS OF FACT,
CONCLUSIONS OF LAW
AND FINAL ORDER

Page 30 of 31

Docket No. 06-12-C-2002CN
Master Case No. M2008-117728

The order remains in effect even if a petition for reconsideration or petition for review is filed. "Filing" means actual receipt of the document by the Adjudicative Service Unit. RCW 34.05.010(6). This Order was "served" upon you on the day it was deposited in the United States mail. RCW 34.05.010(19).