STATE OF WASHINGTON
DEPARTMENT OF HEALTH
ADJUDICATIVE SERVICE UNIT

In re:	)	Docket No. 03-07-C-2002CN
	)	
GOOD SAMARITAN HOSPITAL,	)	FINDINGS OF FACT,
	)	CONCLUSIONS OF LAW
Petitioner.	)	AND FINAL ORDER
	)	

APPEARANCES:

Petitioner, Good Samaritan Hospital, by
Lane Powell Spears Lubersky LLP, per
Kathleen D. Benedict

Intervenor, Overlake Hospital Medical Center, by
Ogden Murphy Wallace PLLC, per
Donald W. Black

Intervenor, King County Public Hospital District No. 2,
dba Evergreen Hospital Medical Center, per
Livengood Carter Tjossem Fitzgerald & Alskog LLP, per
James S. Fitzgerald

Intervenor, Multicare Health Systems
dba Tacoma General Allenmore Hospital, by
Bennett Bigelow & Leedom, P.S., per
Stephen I. Pentz

Intervenor, Franciscan Health System-West,
dba St. Joseph Medical Center, by
Vandenberg Johnson & Gandara, P.S., per
Mark R. Patterson

Department of Health Certificate of Need Program, by
The Office of the Attorney General, per
Richard A. McCartan

PRESIDING OFFICER: John F. Kuntz, Health Law Judge

The Presiding Officer, through authority delegated to him by the Secretary of Health, conducted a hearing on December 8 - 9, and December 22, 2003, in Tumwater, Washington. On May 27, 2003, the Certificate of Need Program denied the open-heart surgery and percutaneous transluminal coronary angioplasty application filed by Good Samaritan Hospital. Remanded.

ISSUES

Did the Program correctly calculate "current capacity" in step one of the open-heart surgery need methodology when analyzing Good Samaritan's open-heart surgery facility application?

If the Program did not correctly calculate current capacity, must the Program engage in the rulemaking process under the Administrative Procedure Act (chapter 34.05 RCW) before correcting its current capacity computation?

Where it consistently followed a different interpretation of the current capacity definition when approving previous applications, is the Program estopped from computing the planning area's current capacity using the "correct" definition?

Must the Program provide for a specific recapture rate by regulation regarding the minimum volume standard under WAC 246-310-261(3)(c) before it can deny an open-heart surgery application?

SUMMARY OF DECISION

The Program did not correctly apply the need forecast methodology set forth in chapter 70.38 RCW and WAC 246-310-261 when analyzing Good Samaritan's open heart surgery application. The Program failed to calculate current capacity in a manner consistent with the regulatory definition set forth in WAC 246-310-261(5)(b) when calculating step one of the forecast need methodology.

The method of calculating current capacity is a question of law rather than an issue of fact, and the Program is not estopped from correcting its calculations consistent with the regulatory language even though it consistently calculated current capacity using a different interpretation of the same regulatory language. Given the regulation is unambiguous on its face, the Program is not required to engage in the APA rule-making process before interpreting the current capacity regulatory language to Good Samaritan's application.

PROCEDURAL HISTORY

On August 29, 2002, Good Samaritan filed a certificate of need application to establish open-heart surgery (OHS) and percutaneous transluminal coronary angioplasty (PTCA) services in its hospital. The Program issued its analysis denying Good Samaritan's application on May 27, 2003. Good Samaritan requested the Program reconsider its denial decision on June 4, 2003, and the Program denied this request on July 21, 2003. Good Samaritan appealed the Program's denial decision on July 28, 2003.

Overlake Hospital Medical Center (Overlake) and King County Public Hospital District No. 2, dba Evergreen Healthcare (Evergreen), moved to intervene and the parties filed a stipulation and agreed order allowing intervention on a limited basis on October 31, 2003. Multicare Health Systems (Multicare) and Franciscan Health Services-West (Franciscan) subsequently filed for, and were granted, intervention on a limited basis. Prehearing Order Nos. 2 and 3.

On November 14, 2003, the Program requested the matter be remanded to allow it to correct errors in the WAC 246-310-261 methodology which it allegedly made in analyzing Good Samaritan's application. The Program alleged it erred by excluding Harrison Memorial Hospital's OHS figures as required by WAC 246-310-261(4)(a); and failing to include diagnostic related groupings (DRG) 514 and 515 figures in its WAC 246-310-261(4)(a) calculations. Specifically, the Program argued neither the Huyck nor the Nidermayer forecast need methodology calculations were correct, as

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neither employee calculated current capacity using the required "highest hospital" figures. WAC 246-310-261(5)(b) defines current capacity as:

> A planning area's current capacity for open heart surgery *equals the sum of the highest reported annual volume for each hospital* within the planning area during the most recent three available three year data. (Italics added).

Based on the "highest hospital" calculation method, current capacity was calculated to be 5,837. This figure corrected two of the identified Program "mistakes":

1. Use of the highest hospital method, and

2. Failure to include the Harrison Hospital assumed volume of 255 in calculating current capacity.

By performing the net need methodology calculations using the corrected information, there was sufficient OHS services (a surplus capacity of 137) projected for the 2006 forecast year. Exhibit 2. Because a surplus existed, the Program would deny Good Samaritan's application pursuant to WAC 246-310-261(4)(g).

Good Samaritan opposed the remand request. It argued the Program did not make any calculation errors in performing its analysis and that allowing a remand at that point in the proceedings would not address the underlying merits of its legal challenge, but would generate a whole new analysis and a whole new round of appeals, which would unreasonably delay the determination regarding Good Samaritan's appeal.

The Presiding Officer denied the remand motion was denied on the basis that whether a calculation error had occurred was an issue of fact for determination at hearing. Prehearing Order No. 5.

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After testimony concluded on December 22, 2003, the hearing record remained open to allow Jody Carona to complete her testimony at the Overlake/Evergreen hearing in January 2004 and to include that testimony in this record.

The following exhibits were admitted at hearing (except as noted):

Exhibit 1: Certificate of Need Application file (admitted at prehearing)[1].

Exhibit 2: OHS Current Capacity (1999-2001), prepared December 3, 2003 (new methodology differing from the one attached to the Program's denial decision).

Exhibit 3: DRG 514 and 515 procedures by Hospital/State for 2001.

Exhibit 4: OHS Current Capacity (1999-2001), prepared December 3, 2003 (variation of Exhibit 2, taking into account DRG codes 514 and 515).

Exhibit 5: Calculation of Good Samaritan Hospital's Proposed OHS Program on Tacoma General Hospital.

Exhibit 6: Curriculum Vitae for Nayak L. Pollisar, Ph.D., dated September 22, 2003.

Exhibit 7: Regression analysis charts (using data from 1997 to 2001).

Exhibit 8: Charts regarding internal referral of cases; cumulative percentage of cases vs. average length of stay; and cumulative proportion of cases vs. DRG WT 2 for St. Joseph Medical Center and Tacoma General Hospital (re: acuity).

Exhibit 9: Comparison of Tacoma General Hospital and St. Joseph Medical Center on case acuity (DRG WT2).

Exhibit 10: Second Declaration of Charles Frank (with attachments) (admitted on a limited basis).

[1] Exhibit 1 pages are referred to using the application record (AR) page number. Hearing transcript pages are referred to using the report of proceeding (RP) page number.

Exhibit 11: Department of Health analysis granting OHS/PTCA certificate of need to St Joseph Hospital, dated April 15, 1993.

Exhibit 12: Department of Health analysis granting OHS/PTCA certificate of need to Harrison Memorial Hospital, dated November 2, 2001.

Portions of the record from *In re Overlake/Evergreen*, Docket No. 03-06-C-2005CN and selected exhibits were also admitted. This included Ms. Carona's testimony on January 9, 2004, and the following:

Exhibit 20: Open Heart Surgery Forecasts by HSA 1 Average Use Rates (1994 – 1997).

Exhibit 22: Analysis of Joint Certificate of Need Application from Northwest Hospital and University of Washington Medical Center.

Exhibit 23: Appendix I Open Heart Surgery Need Methodology per WAC (Northwest University application).

Exhibit 28: Settlement Proposal Analysis of the Joint Certificate of Need Application from Kadlec Medical Center and Kennewick General Hospital.

Exhibit 34 Forecast Need Methodology (1999 – 2001), prepared January 2, 2004.

Exhibit 35: Certificate of Need Open Heart Surgery Decisions 1993 – 2003 (Matrix regarding all open heart surgery decisions in Washington since the new rules (1992) became effective prepared by Jody Carona. Admitted for a limited purpose – illustrative purposes only.

Exhibit 37: CD rom disc prepared by Karen Nidermayer (CHARS data).

Exhibit 39: Memo from Joe Campo to the Open Heart Surgery Advisory Committee, dated August 7, 1991.

Exhibit 40: Steps 5 and 6A per Karen Nidermayer's Capacity Method (prepared January 7, 2004).

Exhibit 41: Adult Open Heart Surgery Discharges from Overlake Hospital Medical Center (1994 through 2001).

Exhibit 42: Kadlec Medical Center/Kennewick General Hospital Open-Heart Analysis – Reconciliation of Step C per DOH Analysis to CHARS data provided by DOH 1996 email file.

Exhibit 43: Harrison Memorial Hospital Open-Heart Analysis – Reconciliation of Step C per DOH Analysis to CHARS data provided by DOH on CD-Rom.

Exhibit 44: Recommended Standards and Forecasting Method for Certificate of Need Review of Open Heart Surgery Programs – Open Heart Surgery Advisory Committee September 1991.

Exhibit 45: Memo from Joe Campo to Open Heart Surgery Advisory Committee, dated August 26, 1991.

Exhibit 46: Summary and Analysis of Written Comments on Proposed Certificate of Need Rules on Open Heart Surgery and Nonemergent Interventional Cardiology Services.

The parties requested, and were granted, permission to file briefs in lieu of closing argument. Posthearing Order No. 1. The dates were extended in response to requests by the parties. Prehearing Order Nos. 2, 3 and 4. The hearing record was closed on April 23, 2004.

For purposes of this order, reference to the application record will be identified as "AR". The hearing transcript will be identified as "RP".

HEARING

Good Samaritan Hospital applied for a certificate of need application to establish an open-heart surgery (OHS) and percutaneous transluminal coronary angioplasty (PTCA) program on August 29, 2002. The Certificate of Need Program denied the application because it was not consistent with certificate of need review criteria. AR at

913. Following the Program's denial of its reconsideration request, Good Samaritan requested a hearing appealing the denial of its application.

Open heart surgery is a "tertiary service", defined as a specialized service meeting complicated medical needs of people and requiring sufficient patient volume to optimize provider effectiveness, quality of service and improved outcomes of care. WAC 246-310-010. Open-heart surgery is a specialized surgical procedure utilizing a heart-lung bypass machine. WAC 246-310-261(1). It does not include organ transplantation. OHS/PTCA applications are subject to concurrent review, that is a comparative analysis and evaluation of competing or similar projects in order to determine which of the projects may best meet identified needs. RCW 70.38.115(7). Applications must be submitted in August. WAC 246-310-132(2) (b). The OHS application fee is approximately twenty-five thousand dollars. AR at 2.

To assist potential applicants the Program creates an annual OHS need forecast using a seven-step methodology. WAC 246-310-261(4). The need forecast methodology calculates need using known open heart surgery volumes in the identified service area for the three years[2] prior to the application and calculates a current capacity figure based on that information. Relevant information is obtained from the Comprehensive Hospital Abstract Reporting System (CHARS), a database containing information on all surgeries reported by all hospitals within the state. RP at 21 – 22. The open-heart surgery codes or diagnostic related groupings (DRG 104 – 109[3])

[2] The three-year period is the three calendar years prior to the application, not the immediate three years prior to the application date.
[3] Per WAC 246-310-261(5)(e), the only open-heart surgery codes identified are DRG 104 – 108.

identify the relevant OHS surgeries. RP at 22. The CHARS data from the relevant three-year period is then used to forecast open-heart surgery service needs four years after the concurrent review process (for example, a 1992 review forecasts needs for 1996). WAC 246-310-261(a) through (g); WAC 246-310-261(5)(b).

Good Samaritan Hospital and Overlake/Evergreen submitted certificate of need applications for the same health service area (HSA 1) in August 2002, and review of the two applications was assigned to Karen Nidermayer. While submitted for the same health service area, the Good Samaritan and Overlake/Evergreen applications were determined to be "noncompeting" because they addressed separate geographic regions within the service area. Since they were noncompeting, the Program could grant both applications if sufficient need existed to support two additional OHS facilities in HSA 1.

Good Samaritan filed its application in August 2002 and relied on need information contained in the last available need forecast (1997 – 1999). This information projected a net need for an additional 727 OHS procedures in forecast year (2003). AR at 24, 1024. *See* WAC 246-310-261(5)(c). Because updated information was available, the Program calculated the need forecast based on the period 1999 – 2001, with the forecast year of 2006.

Program Analyst Randy Huyck prepared the initial need forecast prepared for the application. AR at 988. The forecast appears as Appendix A to the analysis. Under step 1 of the Huyck methodology, the current capacity volume was calculated as 5,171, based on the "highest calendar year" figure during the three-year analysis period. AR at 974. He then completed steps 2 through 6 of the methodology using that current

capacity figure and projected net need for the 2006 forecast year for an additional 529 OHS. This projected net need figure would allow the Program to grant both the Good Samaritan and Overlake/Evergreen applications, so long as all other relevant criteria were met.

Ms. Nidermayer did not use Mr. Huyck's methodology calculations in analyzing Good Samaritan's application and she prepared the need forecast which appears in the body of the analysis. Instead of using Mr. Huyck's "highest calendar year" approach she calculated the current capacity figure (5,208) using a "highest age categories" method (selecting the highest number from each of the four age categories within the three year period, the sum of which equals current capacity). Using the current capacity figure, Ms. Nidermayer calculated a forecast net need of 492 OHS procedures for the 2006 forecast year. AR at 924. This result suggested the Program might grant one, but not both, OHS applications.

Ms. Nidermayer learned to calculate current capacity using the "highest age" approach when she analyzed her first OHS application in 1995. She approached Joe Campo for guidance regarding the current capacity calculation. He advised her to ignore the "highest hospital" language of the regulation and use the "highest age" figures instead, as the "highest age" figures were more readily available from CHARS statistical information at that time. RP at 85 – 87. Ms. Nidermayer subsequently used the "highest age" figure to calculate the current capacity figure when analyzing OHS applications.[4]

[4] Ms. Carona, Good Samaritan's expert, asserts the CHARS data system consistently allowed retrieval of the "highest hospital" information during the relevant time period. RP at 494.

After calculating OHS need existed, Ms. Nidermayer reviewed Good Samaritan's application to see whether granting the application would reduce any existing facility below the 250 OHS standard. Good Samaritan referred ninety-nine percent of its OHS cases to two hospitals, Tacoma General and St. Joseph. Ms. Nidermayer analyzed whether granting Good Samaritan's application would reduce either facility's OHS volume below the 250 OHS minimum standard. RP at 352. In performing this analysis, Ms. Nidermayer calculated Good Samaritan would recapture 100% of its OHS referrals to Tacoma General and St. Joseph.

Ms. Nidermayer acknowledged in her analysis it was unlikely Good Samaritan would actually recapture 100% of its OHS referrals to those two facilities. However, the approach was consistent with the analysis procedure used in analyzing earlier OHS applications. RP at 352 – 353. Use of a 100% recapture rate in previous OHS application reviews did not reduce an existing program below the 250 OHS standard. RP at 354. In other words, Good Samaritan's application was the first time where applying the 100% rate reduced an existing program below the 250 OHS standard. RP at 355. Neither Program rule nor written policy requires using a 100% recapture rate. RP at 355.

Based on her reading of WAC 246-310-261(3)(c), Ms. Nidermayer believes it is the applicant's responsibility to provide the Program with its anticipated recapture rate. RP at 356. Good Samaritan did so in its application. RP at 353 – 354; AR at 22 – 23. Rather than use a 100% recapture rate, Good Samaritan adopted an approach based on a percentage of the market share volume for Tacoma General and St. Joseph

compared to the total OHS volume for Pierce County in 2001. Using that approach Good Samaritan found it would not reduce Tacoma General's or St. Joseph's OHS minimum volume below the 250 minimum standard.

Ms. Nidermayer reviewed and rejected Good Samaritan's approach as flawed and relied on the 100% recapture rate, consistent with her previous application analyses. RP at 357; AR at 927 – 928. While relying on the 100% approach she noted even if Good Samaritan were to recapture 75% of its referrals to Tacoma General, it would put Tacoma General's OHS volume right at the 250 OHS minimum standard. RP at 359; AR at 928. By rejecting Good Samaritan's recapture approach Ms. Nidermayer determined the application should be denied based on its failure to meet the standard of not reducing an existing program below the minimum standard of 250.

After deciding to deny the application for Good Samaritan's failure to meet the WAC 246-310-261(3)(c) standard, Ms. Nidermayer conducted an acuity analysis and regression analysis. Neither of those methods formed part of her decision to reject the application. RP at 399. While not relying on these analyses in reaching the ultimate decision, she chose to include them in her analysis of Good Samaritan's application.[5]

Ms. Nidermayer found that Good Samaritan would recover a larger percentage of its referrals from Tacoma General under her acuity analysis. RP at 367 – 384; AR at 928. At hearing Ms. Nidermayer clarified that part of her reasoning was St. Joseph might conduct higher acuity surgeries because it does more surgeries. RP at 376.

[5] It is unclear from the analysis why Ms. Nidermayer included this material when it was not used in making the ultimate decision.

Ms. Nidermayer also conducted a regression analysis showing the overall decline of OHS surgery numbers. RP at 391; AR at 929 – 930. Chapter 246-310 WAC does not require the Program conduct a regression analysis for OHS applications, and Ms. Nidermayer had not used this approach in analyzing prior OHS applications. RP at 391 – 392. She did not consider any other factors to explain the reduction in surgeries. RP at 393.

After working as a Certificate of Need Program employee for two years, Jody Carona created a consulting firm, Health Facilities Planning and Development, in 1981. Ms. Carona's firm has participated in five OHS applications since the 1992 rule change, including the Overlake/Evergreen application currently under appeal.

The first OHS analysis performed following the 1992 rule change was the St. Joseph application in 1993. RP at 483; Exhibit 11. This analysis used the "highest hospital" approach to calculate current capacity. RP at 484. This is consistent with the "correct" approach the Program sought to apply in its remand analysis. RP at 485; Exhibit 2. Ms. Carona used this highest hospital approach in the OHS application for Northwest University Hospital application in 1996. RP at 485. This was the first application the Program calculated using the "highest age" current capacity figure rather than the "highest hospital" approach used in the St. Joseph application. RP at 486; Exhibits 11 and 22.

Ms. Carona spoke with Ms. Nidermayer about recapturing Good Samaritan's OHS procedures relative to the recent Harrison Memorial application. Ms. Nidermayer agreed it was appropriate to go back to the Harrison Memorial application, look at where

it said it was going to pull their volumes and reduce those volumes from those providers and reassign those volumes to Harrison. RP at 492. This same approach was used in the Overlake/Evergreen OHS application.

When the OHS rule was last amended in 1992, Ms. Carona was involved in the rule-making process as a member of the technical advisory committee created to develop a forecasting methodology. RP at 522 – 523. Joe Campo, a Department employee participating as staff to the committee, prepared an agenda for the committee's final meeting on August 16, 1991. RP at 523 – 525; Exhibit 39. The committee considered four different approaches to counting current capacity. None of the four approaches was considered empirically superior to the other. RP at 525.

Ms. Carona defined capacity, for purposes of WAC 246-310-261, as the maximum amount of throughput volume the existing provider could accommodate. RP at 525. For health planning purposes such measurements are proxies or benchmarks to compare future need against current capacity. RP at 528. For the proxy to be useful in the health planning process, it must consistently provide a measurement of the capacity variable. RP at 528 – 529. Each of the three capacity measuring approaches (highest hospital, highest year and highest age) is a "reasonable" approach to count. RP at 529. However, Ms. Carona believes the highest hospital approach allows for significant or potentially significant overstatement of capacity, as shown by the one-year increase of OHS procedures by Virginia Mason under its contract to provide services to British Columbia in the early nineties. RP at 532. Ms. Carona notes the effect any such one-year spike in OHS procedures by any one hospital would

overstate capacity. Of the three approaches, she finds the highest year approach to be the most reasonable. RP at 532 – 533.

The Program previously processed an OHS application (St. Joseph) where it deducted the projected number of OHS surgeries projected by an application (St. Peter). RP at 537; Exhibit 11, page 9. That resembles the Program's approach in the Good Samaritan application. RP at 537; Exhibits 2 and 4.

Good Samaritan employed Charles Franc to evaluate the feasibility of expanding to include open-heart services. RP at 132. His assessment found an adequate number of patients being referred for cardiac surgery to meet the 250 state standard requirement. RP at 133. Mr. Franc's experience showed the analysis presented in the application (AR at 22 – 23) was an accurate approach to understanding what the ultimate outcome would be when a new program is introduced. RP at 135. Good Samaritan was projected to capture 70% of the primary service area and 28% of the secondary service area in the third year of operation. AR at 84; RP at 137 – 138. Combined, the average is closer to 55%. Based on input provided by a cardiologist the capture rate would likely be 80 – 85%. RP at 139.

Mr. Franc determined Good Samaritan could meet the 110% minimum volume standard following his work with the Cardiac Study Center – they documented 284 procedures, which is over the 275 minimum. RP at 141. Good Samaritan ended their analysis at this point, even though they referred more OHS procedures to other HSA 1 facilities during the 2001 period. RP at 141, 314 – 316.

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Consistent with its initial capture percentages, Mr. Franc determined that Good Samaritan would not capture OHS procedures such that it would draw St. Joseph or Tacoma General below the 250 OHS standard. RP at 142; AR at 863 – 867.

In conducting his analysis, Mr. Franc relied on the forecast need methodology analysis set forth in the Harrison Memorial and prior OHS applications. RP at 146. He finds the Program's "corrected" analysis (Exhibit 2) is inconsistent with the forecast methodology approach previously used by the Program forecast methodology approach. RP at 150.

Nayak Pollisar Ph.D. runs a statistical consultant business and consulted with Good Samaritan following the denial of their OHS application. He reviewed the data analysis portion of the Program's analysis, including its regression and acuity analysis. Dr. Pollisar disagreed with the Program's regression analysis, concluding the future was very uncertain because a graph of the five points used by the Program in its analysis was based on little data, with quite a bit of "scatter" among them. RP at 211. For the 1997 – 2001 period, the trend line for the OHS volume data falls within an interval or range rather than on a straight line. RP 212 – 214; Exhibit 7. He further concluded the Program's regression analysis is not useful for accurately projecting a future caseload and the amount of data presented does not say anything meaningful regarding the 2006 caseload. RP at 214. He performed a similar statistical analysis regarding the Program's acuity analysis regarding the Good Samaritan OHS cases referred to St. Joseph and Tacoma General. RP at 215 – 223; Exhibit 9. His analysis did not support the Program's theory that Good Samaritan may recapture the majority of its 182

referrals from Tacoma General Hospital because of the lower acuity of those cases. RP at 223.

Under a statistical analysis, Dr. Pollisar concludes the "highest hospital" interpretation is a worse case interpretation and it is unlikely that the maximum across the board for each hospital will be achieved. RP at 236 – 237. He also believes that the projected 255 Harrison Memorial Hospital OHS procedures are not additions to the OHS case load but represent a redistribution of cases already accounted in the grand total caseload. RP at 239. This does not preclude more cases or procedures being performed if a new facility is added. RP at 245.

LEGAL ANALYSIS

Appeal of Program Denial of Application

Chapter 70.38 RCW relates to the regulation of health care costs:

> In 1979, the Legislature enacted RCW 70.38 RCW, the State Health Planning and Resources Development Act, creating the certificate of need (CN) program. Laws of 1979, 1st Ex.Sess., ch. 181. The Legislature acted in response to the National Health Planning and Resources Development Act of 1974, Pub.L.No. 93-641, 88 Stat. 2225 (repealed 1986).
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> One purpose of the federal law was to control health care costs. Congress was concerned "that the marketplace forces in this industry failed to produce efficient investment in facilities and to minimize the costs of health care". *National Gerimedical Hospital & Gerontology Ctr. v. Blue Cross of Kansas City*, 452 U.S. 378, 386, 69 L.Ed.2d 89, 101 S.Ct. 2415 (1981). Congress endeavored to control costs by encouraging state and local health planning. It offered grants to state agencies provided the agencies met certain standards and performed certain functions. Among the specified functions was the administration of a CN program.

> The CN program seeks to control costs by ensuring better utilization of existing institutional health services and major medical equipment. Those health care providers wishing to establish or expand facilities or acquire certain types of equipment are required to obtain a CN, which is a nonexclusive license.

St. Joseph Hospital and Health Care Center v. Department of Health, 125 Wn.2d 733, 735 – 736 (1995).

Reduced to its simplest terms, the Certificate of Need Program controls health care costs by granting or denying certificate of need applications. An OHS applicant must show its application complies with the need methodology requirements set forth WAC 246-310-261(4), the standards set forth under WAC 246-310-261(3) and the general need requirements set forth in WAC 246-310-210 through 246-310-240.

The Program initially found OHS need existed in the relevant forecast year and did not deny Good Samaritan's application on that basis. The Department denied Good Samaritan's application because approving it would reduce Tacoma General's OHS program below the 250 OHS standard. As noted earlier, the Program has asserted that calculating current capacity using the correct method would result in its denying Good Samaritan's OHS application both because of a surplus of OHS capacity and because approving the application would reduce Tacoma General's OHS program below the 250 OHS standard.

The material facts regarding the need calculations are not in dispute. Mr. Huyck calculated current capacity as 5,171. Based on that, he projected a net need of 529 OHS procedures in the forecast year, sufficient to support two additional OHS applications for HSA 1. Ms. Nidermayer calculated a different current capacity figure of

5,208 OHS surgeries during the relevant three year volume period. Using this figure projected a net need of 492 additional OHS in HSA 1 for the 2006 forecast year. This need calculation would support at least one additional OHS program for HSA 1 and Ms. Nidermayer did not deny Good Samaritan's application on this basis.

After finding sufficient need existed to establish at least one OHS provider, Ms. Nidermayer examined whether Good Samaritan's application complied with the standards under WAC 246-310-261(3). Ninety-nine percent of Good Samaritan's previous OHS referrals went to two hospitals, St. Joseph Medical Center and Tacoma General. Assuming Good Samaritan would recapture 100% of its OHS referrals[6], the Program determined that granting Good Samaritan's application would reduce Tacoma General's OHS standard below the 250 minimum. Ms. Nidermayer denied the application on that basis.

In its application Good Samaritan used a different recapture rate calculation method and found it would recapture only 52.1% and 37.2% of its prior OHS referrals respectively. Under that method the application would not reduce either the St. Joseph or Tacoma General OHS volumes below the 250 minimum standard.
WAC 246-310-261(3)(c). Good Samaritan included a projected impact for Harrison Memorial Hospital in its analysis. The Program rejected Good Samaritan's approach, as the calculations were based on total volume figures that reversed Good Samaritan's actual referral patterns. The Program found Good Samaritan did not provide any

[6] Chapter 246-310 WAC does not provide a specific recapture rate for use in evaluating OHS applications.

rationale in the application to suggest that a reverse of the referral patterns was a reasonable assumption.

Although the Presiding Officer denied the Program's remand request,[7] the Program was allowed to introduce the proposed corrected figures at hearing. At the time the OHS regulations were last amended, three methods for calculating current capacity were considered (highest hospital, highest year or highest age). Each calculation method is considered a "reasonable" method for performing the calculation.

Under WAC 246-310-261(4) a seven-step process is used to determine the OHS net need for the forecast year. Before beginning the process the Program analyst must first calculate the "current capacity" as defined in WAC 246-310-261(5)(b). Following its decision to deny Good Samaritan's application the Program argued its analyst incorrectly calculated current capacity under WAC 246-310-261(5)(b), as the analysts used the "highest age" or "highest year" approach instead of the "highest hospital" approach. The Program argued the clear language of the current capacity definition in step 1 of the methodology requires using the "highest hospital" approach for calculating the need forecast in the present case. After the "highest hospital" approach was used by the Program in one analysis, Ms. Nidermayer began using the "highest age" methodology based on Joe Campo's recommendation. The question is whether this

[7] The Program had requested a remand because it determined it made "mistakes" in its analysis, including calculating current capacity using "highest age" rather than "highest hospital" figures, failing to include the Harrison Memorial OHS program in the current capacity calculations and failing to include figures from DRG 514 and 515 categories. During the Overlake/Evergreen) hearing Ms. Nidermayer concluded that DRG 514 and 515 should not be considered in the calculations, as the procedures in question do not require the use of a heart-lung machine. See Exhibit 38. Use of a heart-lung machine is required for OHS procedures. WAC 246-310-261(1).

Program action rises to the level of a "mistake" and if so, is the Program estopped from denying Good Samaritan's OHS application.

Good Samaritan argues the Program did not err in using "highest age" in its calculations. The Program merely interpreted "current capacity" to mean "highest age" and consistently followed this interpretation when analyzing this and previous OHS applications. Good Samaritan argues that the Program, having consistently interpreted "current capacity" in applying step 1 of the need forecast methodology in this fashion, must now follow this interpretation or notify the public of a "new" interpretation following the appropriate APA rule-making process. *Budget Rent a Car Corp. v. State of Washington*, 144 Wn.2d 889 (2001); *Alaska Professional Hunters v. Federal Aviation Administration*, 177 F.3d 1030 (D.C. Cir. 1999). Good Samaritan also argues that the Program, having failed to undertake rule-making, is now estopped from using the "highest hospital" methodology in analyzing Good Samaritan's application.

Good Samaritan also contends the Program erred in finding its OHS application would reduce an existing OHS provider (Tacoma General) below the 250 minimum standard in WAC 246-310-261(3)(c). Good Samaritan indicates that the assumption that it would recapture 100% of its OHS referrals to Tacoma General is unrealistic or unlikely, a position acknowledged by the Program. Good Samaritan contends its recapture calculations provide a more realistic approach.

Finally, Good Samaritan argues that the Program, having failed to establish a realistic recapture rate, incorporated the use of an acuity and regression analysis to support its finding that Good Samaritan's proposed OHS program will reduce Tacoma

General's existing program. Dr. Pollisar refutes Ms. Nidermayer's acuity analysis as well as her regression analysis as statistically flawed given the data upon which it was based. While discussed in the analysis, the Program contends its denial decision was not based on either the acuity or the regression analysis.

The Program contends neither the "highest age" nor "highest year" approach may be used in reviewing the present (and previous) applications, as "current capacity" means "the sum of the highest reported annual volume for each hospital". WAC 246-310-261(5)(b). Arguing that the regulatory language is clear on its face and the APA rule-making process is unnecessary, the Program contends its failure to use the "highest hospital" approach in reviewing previous applications does not require it to ignore the regulatory language in this case. Intervenors Multicare Health Systems (Tacoma General) and Franciscan Health System-West (St. Joseph) support this position.

Under a statutory interpretation analysis, the plain language in WAC 246-310-261(4)(a) clearly requires the new Harrison Memorial OHS program capacity be counted in its current capacity calculations. *See State v. J.P.*, 149 Wn.2d 444 (2003). While it did not include this OHS capacity in the original calculation in its analysis, the Program sought to correct that error at the time it filed its remand motion.

The Program argues estoppel cannot apply in situations (as here) where an agency has acted to reverse a prior erroneous legal interpretation. *Department of Ecology v. Campbell & Gwinn*, 146 Wn.2d 1 (2002); *Department of Ecology v. Theodoratus*, 135 Wn.2d 582 (1998). Applying the correct methodology approach (use

of “highest hospital” in calculating capacity) shows there is a surplus of OHS forecast need and thus no additional OHS program is required in HSA 1.

The Program argues Good Samaritan failed to demonstrate that its proposed program would not reduce an existing program (Tacoma General) below the 250 OHS minimum standard. In reaching this conclusion, the Program used a 100% recapture rate for Good Samaritan’s referrals to Tacoma General and St. Joseph. The Program argues even if a lower recapture rate is utilized (e.g., 85%) Good Samaritan’s application fails. Calculations using that recapture rate still reduce Tacoma General’s OHS procedures below the minimum 250 standard (e.g. to about 234, or 389 minus 85% of 182 referrals). Of greater importance, the Program contends Good Samaritan failed to completely document its referral data, choosing to stop at 284 referrals when more referrals existed during the report period.

Good Samaritan seeks to include four additional classes of surgeries in Tacoma General’s current volume (389). These classes include five out-of-state cases, eight defibrillator cases, twelve tracheotomy cases and forty-three projected cases (representing Tacoma General’s share of the projected 529 OHS procedures the Program projects for forecast year 2006). The Program does not seriously contest the addition of the five out-of-state cases, and points out adding these cases does not change the ultimate outcome even though WAC 246-310-261(5)(e) defines open heart surgeries as those performed under DRG code 104 through 108.

The Program argues the defibrillator cases were removed from the DRG 104 – 105 classifications because they were significantly different from other OHS procedures.

Even if these cases were included, Program argues that the impact still does not prevent reducing Tacoma General below the 250 OHS standard.

The Program argues WAC 246-310-261(5)(e) precludes consideration of the tracheotomy cases coded under DRG 483. The projected cases must be rejected because the revised methodology does not support a need for 529 additional OHS surgeries in 2006 and the plain language of WAC 246-310-261(3)(c) requires measuring whether Tacoma General's minimum standard would be reduced at any point, not just in the forecast year.

Good Samaritan argues a recent certificate of need decision imposes an evidentiary burden on both itself and the Program. *In re Auburn Regional Medical Center*, Docket No. 01-05-C-1052CN (February 20, 2003). That decision states, in relevant part:

> If it is the Program's position that the affected/interested party *must* provide it with information, and that the Program is not *required* to produce sufficient evidence in support of its decision, that decision is both misplaced and legally incorrect. The applicant must initially provide sufficient proof or documentation to support its application request. It *is* the Program's responsibility to ensure that the burden of proof (that is the burden of going forth with the evidence and the burden of persuasion on the relevant issue) is contained in its analysis and supports its certificate of need decision.

Auburn Regional, at 22 – 23 (Emphasis in original). The specific issue in *Auburn Regional* was that portion of WAC 246-310-201(1) regarding "facilities of the type proposed are not or will not be sufficiently available or accessible to meet that need" as it related to special need mothers. Auburn Regional (the applicant) received a certificate of need to operate a level II nursery and Multicare (the petitioner) contested

the Program's decision. Multicare contended the Program failed to evaluate or issue a written finding on whether existing level II services were sufficiently available or accessible – the Program contended that the affected or interested party had a positive duty to provide of solicit information from existing providers. The Program contended if the parties did not supply it with information it was not required to seek out the information in completing its analysis.

The applicant is responsible to establish that the application meets all criteria to support its application. WAC 246-10-606. Therefore Good Samaritan must first establish that it meets all applicable criteria and only then does the burden of persuasion shift to the Program. If the Program relies on evidence that is not submitted by the applicant then the Program must present sufficient evidence to support its decision. The Program can accomplish that by pointing to such evidence in the record or providing the necessary statistical analysis in support of the certificate of need regulations relied upon in reaching its decision. See WAC 246-310-200(2)(a).

To obtain an open heart surgery certificate of need the applicant must prove need exists using the forecast methodology under WAC 246-310-261(4), show it complies with the standards provided in WAC 246-310-261(3) and then show it complies with the general CON requirements. The Program initially found Good Samaritan met the need analysis but failed to meet the WAC 246-310-261(3)(a) standard. Following Good Samaritan's appeal the Program contends it did not meet either the need or standard requirements.[8]

[8] The parties agree if the applicant met the WAC 246-310-261(3)(c) standard it would meet the general CON standards. RP at 121.

The initial question is whether Good Samaritan meets the need requirement, that is, did it accurately compute current capacity in step 1 of the methodology? Answering that question requires a determination whether current capacity should be calculated using the "highest year", "highest age" or "highest hospital" approach. Ms. Carona testified any of the three methods is a "reasonable" approach to calculating current capacity. However:

A. "Current capacity" is defined as, or equals, the "sum of the highest reported annual volume for each hospital within the planning area during the most recent available three years data."

WAC 246-310-261(5)(b).

B. When interpreting a statute the court's primary objective is to determine the legislature's intent, and if clear, the court must afford the statute its plain meaning. *Gontmakher v. City of Bellevue*, 120 Wn.App. 365, 370 (2004) (citing *Department of Ecology v. Campbell & Gwinn, L.L.C*., 146 Wn.2d 1 (2002). Even if all of the three methods are a "reasonable" approach, the language in the regulation, if clear, controls. WAC 246-310-261(5)(b) clearly speaks to the "highest hospital" method. It refers to the sum of the highest reported annual volume for each hospital during the period, not the sum of highest reported annual volume for all hospitals during the period. Dr. Pollisar noted the Program's interpretation by *practice* was not consistent with the regulatory language. He testified that the *language* of the regulation was consistent with the highest hospital approach. RP at 243.[9]

[9] While Dr. Pollisar's testimony is not controlling on the legal issue, it is illustrative of, and supports, the Presiding Officer's legal determination on this issue.

C. There is nothing in the regulatory language supporting the use of "highest age" method used by Ms. Nidermayer.

D. The Program initially interpreted current capacity as meaning "highest hospital" following the adoption of the regulation.

The second issue regarding the calculation of current capacity is whether to include the Harrison Memorial volume figures in the computation.

WAC 246-310-261(4)(a) provides "[i]n those planning areas where a new program is being established, the assumed volume of that institution will be the greater of either the minimum volume standard or the estimated volume described in the approved application and adjusted by the department in the course of the review and approval". The Program argued that it was required to include Harrison Memorial's 255 OHS assumed volume in the current capacity calculations under WAC 246-310-261(4). Good Samaritan disagrees.

Good Samaritan does not dispute the language contained in the second sentence in WAC 246-310-261(4)(a) provides that any new program assumed volume be included in the calculations. It argues the Program has consistently interpreted that regulatory language to mean something else. Good Samaritan argues the Program's eight-year interpretation is consistent with the rule-making "legislative history" for chapter 246-310 WAC. Good Samaritan Hospital's Post Hearing Brief, page 34. It also argues that by the Program's use of the various interpretations it shows the language in the regulation is ambiguous. If a statute is subject to more than one interpretation,

statutory construction rules apply. *J.A. v. State*, 120 Wn.App. 654, 658 (2004) *citing Department of Ecology v. Campbell & Gwinn, L.L.C*., 146 Wn.2d 1 (2002).

Unless a statute is ambiguous, its meaning must be derived from the actual statutory language, and the statute must not be interpreted in a manner that renders any part thereof superfluous. *State v. Votava*, 149 Wn.2d 178, 183 – 184 (2003). It is inappropriate to look to the legislative history of a statute to determine its intent if the intent can clearly be divined by its plain language. *Shoop v. Kittatis County*, 149 Wn.2d 29, 36 (2003). As the regulatory language is clear on its face (a fact not disputed by Good Samaritan) it is unambiguous and therefore it is unnecessary to examine the "legislative history" behind the regulation. The fact the Program previously ignored the regulatory language does not change its responsibility to follow it.[10]

Good Samaritan argues the Program is estopped from changing its interpretation of the OHS need forecast methodology rule and must engage in the APA rule-making process to change its established interpretation. See *Alaska Professional Hunters v. Federal Aviation Administration*, 177 F.3d 1030 (D.C. Cir 1999) (*Alaska Hunters*). In that case the FAA advised Alaska hunting and fishing guides that they were exempt from regulations governing commercial pilots. It later changed its interpretation and advised guides that if they transported customers by aircraft they were no longer exempt. In that case, as here, the FAA contended they made a "mistake". The court was unpersuaded by that approach and focused on the reliance that the regulated

[10] There was an argument at hearing that if the Program's actions were ultra vires that might affect the earlier OHS decisions using the "incorrect" calculation standards. It is not necessary to rule on what effect an ultra vires issue has on other cases or applications here as that is beyond the scope of this appeal.

entities had placed on the FAA's long-standing interpretation. *Alaska Hunters*, 177 F.3d at 1035.

The present case differs from the holding in *Alaska Hunters* given the clear language of the regulation. It must be remembered that estoppel against the government is not favored. *Kramarevcky v. Department of Social and Health Services*, 122 Wn.2d 738, 743 (1993). Where the representations allegedly relied upon are matters of law, rather than matters of fact, equitable estoppel will not be applied. *Department of Ecology v. Theodoratus*, 135 Wn.2d 582, 599 – 600 (1998) (citing *Concerned Land Owners of Union Hill v. King County*, 64 Wn.App. 768 (1992). A person may not rely on a government agency's representation of the law if the status of the law may be independently verified by reference to the law itself. *Wellington River v. King County*, 121 Wn.App. 224, 236 -237 (2002). Here the Program's "mistake" resulted from its decision to ignore the plain language of the regulation because it believed the "highest age" date was more easily available from the CHARS database. The plain language of the regulation was independently verified, at one point, by Ms. Carona, but she chose to utilize the Program's mistake in subsequent applications.

Reasonable minds may differ whether the Program's conscious choice to ignore the regulatory language can be characterized as a mistake. No matter how it is characterized, the underlying representation relied upon here is how should current capacity be interpreted. This is a legal rather than factual issue. For that reason estoppel does not apply in the present case.

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Regarding the WAC 246-310-261(3)(c) standard issue, Good Samaritan disputes that granting its application will reduce Tacoma General's program below the OHS minimum standard. It points out there is no standard that outlines how to project the impact of a proposed open-heart surgery program on other programs. Good Samaritan utilizes an approach based on a market share percentage of volume for Tacoma General and St. Joseph compared to the total Pierce County OHS volume for 2001. AR at 22 – 23; 926 – 927. Currently there are no Department rules, policy or procedures addressing the process for measuring the recapture rate, except as it is discussed in previous OHS applications.

The Program argues Good Samaritan's approach is flawed because it includes OHS cases on Pierce County residents by all hospitals in the state, including patients referred to other facilities. The Program notes that such calculations are not relevant to Good Samaritan's referral pattern and using the total number of OHS cases on Pierce County residents reverses the referral pattern. The Program also notes that WAC 246-310-261(3) does not specify (or require) an applicant establish a recapture rate, only that an applicant show that establishing its program will not reduce an existing program below the 250 OHS minimum standard. Ms. Nidermayer contends the applicant must submit a recapture rate in its application. Good Samaritan contends this approach is in conflict with the burden of proof standard set forth in the Auburn Regional order.

Good Samaritan bears the initial burden of proving its application meets the required standards by showing it will not reduce an existing OHS program below the

minimum 250 OHS standard. In this case Good Samaritan provided what it determined was a reasonable approach to analyzing the recapture rate issue. The Program analyzed this approach and rejected it. In doing so the Program provided its reasons for that rejection.

The purpose of certificate of need adjudicative proceedings is not to supplant the certificate of need review process but to assure that the procedural and substantive rights of the parties have been observed and that the factual record supports the Program's analysis and decision. *See Ear, Nose, Throat and Plastic Surgery Associates, P.S*., Docket No. 00-09-C-1037CN (April 17, 2001), Prehearing Order No. 6 at page 8. The approach is similar to the standard used by the courts in reviewing administrative decisions. In reviewing matters within agency discretion, the court limits its function to assuring that the agency has exercised its discretion in accordance with the law, and shall not undertake to exercise the discretion that the legislature has placed in the agency. *Hillis v. Department of Ecology*, 131 Wn.2d 373, 400 (1997).

The Program's function in analyzing certificate of need applications is to determine whether an application meets the statutory and regulatory criteria. *See St. Joseph Hospital and Health Care Center v. Department of Health*, 125 Wn.2d 733, 735 – 735 (1995). Here the Program applied a 100% recapture rate consistent with its past practice. The Program acknowledged that it was unrealistic that Good Samaritan would recapture 100% of its referrals. It did consider the effect of how a lower recapture rate would effect Good Samaritan's referrals, however. The Program determined even if Good Samaritan recaptured its OHS referrals at a 75% rate, it would leave Tacoma

General's OHS standard right at the minimum 250 level. AR at 928. Had Good Samaritan recaptured its referrals at an 80 – 85% rate[11], its application would have been denied for failing to meet the WAC 246-310-261(3) standard.

The Program's approach was consistent with its past practice and does not appear to be an abuse of discretion under the reasonably prudent person evidentiary standard. RCW 34.05.452(1). It is therefore unnecessary to address whether a specific recapture rate must be established by regulation or further analyze the Program's regression analysis.

In its appeal Good Samaritan refers to materials submitted in its reconsideration request, which is part of the application record (AR 1113 – 1189). At hearing Tacoma General objected to the introduction of such information on the grounds it was not relevant to the Program's decision to deny Good Samaritan's application. RP at 338 – 343. Good Samaritan contends that any information contained as a part of the reconsideration process is part of the record and should be considered.

The purpose of the adjudicative proceeding is to contest a Department certificate decision. WAC 246-310-610(2). It is not a *de novo* hearing. So while the application record contains the materials submitted by Good Samaritan in its reconsideration request, it is not part of the Program's initial decision to deny the application. The documents submitted regarding reconsideration are relevant only to the extent Good Samaritan has argued that the Program should have amended or modified its decision

[11] Testimony of Dr. Needam Ward: I would think it (recapture rate) would be in the range of 80 to 85 percent, but that is not scientific – that is an estimate. RP at 459

on reconsideration. *See* WAC 246-310-560(6). Since reconsideration was denied, that material is not relevant in the appeal from the application denial.

Appeal of Reconsideration Decision

Good Samaritan requested the Program reconsider its decision denying Good Samaritan's application. Good Samaritan argued it had provided significant relevant information not previously considered which, with reasonable diligence, could not have been presented before the Program's decision and information on significant changes in factors or circumstances relied upon by the Program in making its findings and decisions. AR at 1125 – 1181. It then supplemented its reconsideration request by calculating the impact on Tacoma General and St. Joseph using the Huyck OHS projections. AR at 1182 – 1189.

Good Samaritan argued Tacoma General's OHS volume decline was not due to Good Samaritan's application but was a function of the competitive marketing and staffing at St. Joseph. It noted there was no new competing OHS program during a five year period (1997 – 2002) which would account why Tacoma General's volumes declined and St Joseph's volumes increased. AR at 1127 – 1128.

Good Samaritan expanded its initial audit beyond the 284 OHS patients referred by active medical staff and Mr. Franc noted this expanded audit or revised time period occurred following discussion with Program staff. RP at 153. It included patient referral information during the period May 31, 2002 through June 1, 2003, that showed changes in the percentage of OHS referrals to Tacoma General and St. Joseph. Good Samaritan argued the changes (decrease of referrals to Tacoma General and

corresponding increase in referrals to St . Joseph) were for the most part attributable to changes in physician staffing and referral patterns. AR 112- - 1129; RP at 154.

Based on the Program's forecast of an additional 492 OHS surgeries by the 2006 forecast year, Good Samaritan argued these projected surgeries would offset its patient recapture, as some of these surgeries would be performed at Tacoma General and St. Joseph. Using a percentage approach, and applying the percentages to the additional 492 OHS surgeries, the total overall numbers for Tacoma General and St. Joseph would increase, and these resulting increases would prevent the reduction of either Tacoma General or St. Joseph below the 250 minimum standard. This approach would work whether the recapture rate was calculated at 100%, 90% or 75% rate.

Finally, Good Samaritan raised issues regarding transportation difficulties critical to East Pierce County residents, and provided letters from state and local government officials to support the need for local intervention to allow both local access to both facilities and primary care physicians. AR at 1142 – 1143; 1114 – 1124.

The Program reviewed and rejected the reconsideration material and determined the issues raised did not meet the necessary grounds under WAC 246-310-560(2). AR at 1198. The Program is required to conduct a reconsideration hearing upon receipt of a written request within twenty-eight days of a decision on a certificate of need application. WAC 246-310-560(2)(a). Grounds for reconsideration include, but are not limited to:

> (i) Significant relevant information not previously considered by the Program which, with reasonable diligence, could not have been presented before it made the decision.

(ii) Information on significant changes in factors or circumstances relied upon by the Program in making findings or decisions.

(iii) Evidence the department failed to follow adopted procedures in reaching a decision.

WAC 246-310-560(2)(b).

After reviewing the information contained in Good Samaritan's reconsideration request, the Presiding Officer does not find the Program abused its discretion in denying the request.

I. FINDINGS OF FACT

1.1 Good Samaritan Hospital submitted an application to establish OHS/PTCA services in HSA 1 in August 2002. Analysis of this application was assigned to Program analyst Karen Nidermayer.

1.2 The need forecast methodology figures available at the time Good Samaritan filed its application were the 1997 – 1999 need figures. Under this need forecast the 2003 projected need for HSA 1 projected a need for an additional 726 OHS services. Randy Huyck then prepared an updated need projection using figures from the period 1999 – 2001.

1.3 Ms. Nidermayer did not use Mr. Huyck's methodology calculations in her analysis. She calculated the current capacity for the service area using the "highest age" figure and projected the net need in forecast year 2006 to be 492 additional surgeries. In calculating the net need figure she did not include the estimated volume for the Harrison Memorial Hospital application granted by the Program in November 2001.

1.4 Ms. Nidermayer examined and rejected Good Samaritan's approach and decided that granting Good Samaritan's application would reduce an existing HSA 1 program (Tacoma General) below the minimum 250 OHS standard required by WAC 246-310-261(3)(c). Ms. Nidermayer determined Good Samaritan did not provide compelling documentation that its method of evaluating impact was either valid or preferable to the Program's direct mathematical calculation to determining impact on existing providers.

1.5 Ms. Nidermayer relied on the direct mathematical method previously used by the Program in analyzing OHS applications. By subtracting 100% of Good Samaritan's OHS referrals to Tacoma General for 2001 (389 minus 182 referrals), she concluded Tacoma General's OHS number would be reduced to 207 patients, or below the 250 procedure requirement in WAC 246-310-261(3)(a). Even if Good Samaritan recaptured 75% of its OHS referrals to Tacoma General, it would leave Tacoma General at 250 OHS procedures, the minimum standard allowed under the regulation.

1.6 The Program made two mistakes in calculating "current capacity". It used the "highest age" rather than the "highest hospital" approach in calculating current capacity. The Program did not include the Harrison Memorial Hospital OHS assumed volume in calculating current capacity, in so doing misstated the open-heart surgery need in HSA 1 for the relevant forecast year.

1.7 Utilizing the "highest hospital" approach and calculating current capacity to include the OHS assumed volume of Harrison Memorial Hospital results in a surplus of OHS capacity of 137 in the forecast year 2006.

1.8 In the absence of need for additional OHS capacity, Good Samaritan's application failed to meet the PTCA requirements of WAC 246-310-262, and the general certificate of need requirement set forth in WAC 246-310-210.

1.9 In filing its application Good Samaritan represented that it referred 284 open-heart surgery cases during 2001. This number did not represent the total number of OHS surgeries, merely counting the 110% of the minimum volume standard (or 275) open heart surgeries under WAC 246-310-261(3)(d).

1.10 Good Samaritan requested the Program reconsider its denial decision and provided what it considered to be significant relevant information and changes. This included information regarding changes in physician staffing and referral patterns between Tacoma General and St. Joseph, data showing that projected increased OHS need offset patient recapture reducing Tacoma General's OHS below the required standard and transportation difficulties critical to East Pierce County residents. The Program denied Good Samaritan's request, finding the additional information did not comply with the requirements of WAC 246-310-560(2).

II. CONCLUSIONS OF LAW

2.1 The Department of Health is responsible for managing the certificate of need program under chapter 70.38 RCW. WAC 246-310-010. An applicant denied a certificate of need has the right to an adjudicative proceeding. WAC 246-310-610(1); RCW 34.05.413(2). A certificate applicant contesting a Department decision must file a written application for a proceeding within twenty-eight days of receipt of the

department's decision or reconsideration. WAC 246-310-610(2). Chapters 34.05 RCW and 246-10 WAC govern the proceeding[12]. WAC 246-310-610(3).

2.2 Within twenty-eight days of the Program's decision, and prior to a request for an adjudicative proceeding, the applicant may submit a written request for reconsideration of the Program's decision based upon a showing of good cause. WAC 246-310-560(1), (2) and (7). Good cause includes significant relevant information not previously considered which, with reasonable diligence, could not have been presented before the Program made its decision. WAC 246-310-560(2)(b)(i). Good Cause was not established in this matter.

2.3 Good Samaritan applied for, and was denied, a certificate of need application to establish an OHS and PTCA services. Good Samaritan requested reconsideration and this request was denied on July 21, 2003. Good Samaritan appealed the decision denying its application on July 28, 2003. Good Samaritan's hearing request is therefore timely.

2.4 The burden of proof in certificate of need cases is preponderance of the evidence. WAC 246-10-606. In all cases involving an application for licensure, the applicant shall establish it meets all applicable criteria. WAC 246-10-606. Evidence should be the kind "upon which reasonably prudent persons are accustomed to rely in the conduct of their affairs." WAC 246-10-606.

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[12] WAC 246-310-610(3) provides chapter 246-08 WAC governs the proceeding. 246-10 WAC has replaced chapter 246-08. WAC 246-10-101(3).

2.5 To be granted a certificate of need, an open-heart surgery program shall meet the standards in this section [246-310-261] in addition to applicable review criteria in WAC 246-310-210 through WAC 246-310-240. WAC 246-310-261(2).

2.6 A planning area's current capacity for open-heart surgeries equals the sum of the highest reported annual volume for each hospital within the planning area during the most recent available three years data. WAC 246-310-261(5)(b). In those planning areas where a new program is being established, the assumed volume of that institution will be the greater of either the minimum volume standard or the estimated volume described in the approved application and adjusted by the department in the course of review and approval. WAC 246-310-261(4)(a).

2.7 WAC 246-310-261(5)(b), as written, defines current capacity as the highest reported annual volume for each hospital, and requires the use of the "highest hospital" method in calculating that number. That number is then used to calculate step one of the forecast need methodology under WAC 246-310-261(4). Because the Program did not use the "highest hospital method to calculate current capacity, it failed to correctly calculate the OHS forecast need amount for the 2006 forecast year.

2.8 The second sentence in WAC 246-310-261(4)(a), requires calculating current capacity by including the minimum or estimated volume of a new program where such program is being established. A new program (the Harrison Memorial Hospital) was established in 2001 after Good Samaritan's application was filed and should have been used in calculating current capacity. The Program failed to do so and therefore

did not correctly calculate current capacity for the Good Samaritan application in its analysis.

2.9 The language in WAC 246-310-261(5)(a) is unambiguous and requires calculation of current capacity using the "highest hospital" method. The language in WAC 246-310-261(4)(a) is unambiguous, and requires the calculation of current capacity using the 255 OHS assumed volume of Harrison Memorial Hospital. For that reason it is not subject to the rules of statutory interpretation and must be applied by the Program as written. Because the issue raised on appeal speaks to a matter of law rather than an issue of fact, the Program is not estopped from correctly applying the language of the relevant regulation.

2.10 The Program reviewed Good Samaritan's reconsideration request and found it did not comply with the requirements of WAC 246-310-560(2). The evidence in the record does not support reversing the Program's decision to deny Good Samaritan's reconsideration request.

III. ORDER

Based on the foregoing Procedural History, Findings of Fact and Conclusions of Law, the Certificate of Need Program's determination denying Good Samaritan's open-heart surgery application is REVERSED and the application is REMANDED to the Program for processing consistent with this Order.

Dated this __19th ___ day of July, 2004.

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

NOTICE TO PARTIES

This order is subject to the reporting requirements of RCW 18.130.110, Section 1128E of the Social Security Act, and any other applicable interstate/national reporting requirements. If adverse action is taken, it must be reported to the Healthcare Integrity Protection Data Bank.

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

The Adjudicative Clerk Office
PO Box 47879
Olympia, WA 98504-7879

and a copy must be sent to:

Certificate of Need Program
PO 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 Clerk Office 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).

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 Clerk Office. 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).