

NO. 80264-5

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**IN THE SUPREME COURT  
OF THE STATE OF WASHINGTON**

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UNIVERSITY OF WASHINGTON MEDICAL CENTER,

Respondent,

v.

SWEDISH MEDICAL CENTER

and

WASHINGTON STATE DEPARTMENT OF HEALTH,

Appellants,

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**APPELLANT DEPARTMENT OF HEALTH'S BRIEF**

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## I. INTRODUCTION

In 2003, Swedish Health Services (Swedish) applied to the Department of Health (Department) for a Certificate of Need under RCW 70.38 to offer a new liver transplant program. The University of Washington Medical Center (University) currently operates the only liver transplant program in Washington. Swedish submitted information in support of its application. In 2003, the University submitted information in opposition to Swedish's application. After conducting a public hearing and reviewing all information submitted by many interested persons, in June 2004, the Department granted Swedish's application. Since that date, there have been two adjudicative proceedings under the Administrative Procedures Act (RCW 34.05) and two judicial reviews before the superior court. The second judicial review resulted in the superior court denying Swedish's application. Both the Department and Swedish appeal the denial.

This Court should reverse the superior court's decision and affirm the Department's decision to grant the Swedish liver transplant Certificate of Need application. The 2003 evidence available and reviewed by the Department at the time of its decision on the application demonstrated that a second liver transplant program is needed because it would allow more Washingtonians to receive life-saving liver transplants and would spur

competition and innovation in the field. The 2003 evidence available and reviewed by the Department also demonstrated that a second program would not prevent the University from continuing to operate a viable liver transplant program.

## II. ASSIGNMENTS OF ERROR

First Assignment of Error. The superior court erred in overturning the Department's decision to grant Swedish's Certificate of Need application on grounds that the Health Law Judge (HLJ) on remand limited the University's right to present evidence in the adjudicative proceeding to evidence that existed as of December 31, 2003, five weeks after the close of the period in which the Department accepted information on the application from interested persons.

Second Assignment of Error. The superior court erred in overturning the Department's decision to grant Swedish's Certificate of Need application on grounds that, under RCW 70.38.115 and WAC 246-310-210, the application did not address adverse effects of approving of the application on the University's existing liver transplant program, even though the University had an opportunity to address adverse effects during the application process, and even though the Department evaluated adverse effects in making its decision.

### III. ISSUES

1. Swedish applied to the Department of Health for a Certificate of Need to start a liver transplant program. The University currently operates the state's only program. The evidence was that some Washington-donated livers are not transplanted at the University and are sent to other states for use; that the University's "wait list" and number of transplants performed is far below the national average; and that a second program would spur healthy competition and innovation. Did substantial evidence support the HLJ's finding of "need" for a second transplant program at Swedish?

2. Under RCW 70.38 and WAC 246-310, the Department of Health received information from Swedish and from interested parties, including the University, on the Swedish application. On November 24, 2003, the Department "closed" the record following submission of "rebuttal" from Swedish and the University under WAC 246-310-160(1). Based on all the information received, the Department approved the application. The University requested an adjudicative proceeding to contest the approval. Did the HLJ properly exercise her discretion in limiting the evidence at the adjudicative proceeding to evidence that existed as of December 31, 2003?

3. The superior court found that the HLJ erred in imposing the December 31, 2003 cutoff date for evidence and reversed the Department's decision to grant the Certificate of Need to Swedish. If this Court finds that the cutoff date was in error, should it remand to the Department under RCW 34.05.562(2)(b) to take additional evidence?

4. In considering whether to approve the Swedish application, under RCW 70.38.115 and WAC 246-310-210, the Department was required to assess whether approval would adversely affect the University's liver transplant program. Should Swedish's application have been denied because the application did not contain an adverse-effect assessment, even though the University had a full and fair opportunity to provide such an assessment to the Department during the application process?

#### **IV. STATEMENT OF CASE**

##### **A. Overview Of Certificate Of Need Law**

RCW 70.38 and WAC 246-310 require health care providers to apply to the Department of Health (Department) for a Certificate of Need prior to establishing certain types of new facilities or services in the state. "Liver transplant programs" are one type of service that requires

Certificate of Need review.<sup>1</sup> The Department's Certificate of Need Program (Program) reviews applications and determines whether they should be approved or denied.

A primary purpose of the Certificate of Need law is to promote public health by assuring "accessible" health services to "promote, maintain, and assure the health of all citizens in the state." RCW 70.38.015(1).

RCW 70.38 and WAC 246-310 contain provisions for the Program to collect information from the applicant and the public on a Certificate of Need application. An applicant must submit certain information to the Program related to its proposed new program. RCW 70.38.115(6). The Program may request additional information. *Id.* The Program must notify the public of the application filing. WAC 246-310-170(1). Any person may submit written comments and other material supporting or opposing the application. WAC 246-310-160(1)(a). If requested, the Program must hold a public hearing on the application. WAC 246-310-180.<sup>2</sup> Following

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<sup>1</sup> "Tertiary services" are subject to Certificate of Need review. RCW 70.38.105(4)(f). Department rules define tertiary services to include liver transplant programs. WAC 246-310-020(1)(d)(i)(D).

<sup>2</sup> The public hearing is not conducted under the Administrative Procedures Act (RCW 34.05). The public hearing is an opportunity for interested persons to provide oral and written comment to assist the Program in evaluating whether to approve or deny the application.

public comment and hearing, the applicant and affected parties may provide rebuttal information to the Program. WAC 246-310-160(1)(a).

After collecting the information from the applicant, affected parties, and the public, the Program must issue a written evaluation either approving or denying the Certificate of Need application. WAC 246-310-190(1)(b); WAC 246-310-490. The applicant must satisfy four criteria: Need (WAC 246-310-210); Financial Feasibility (WAC 246-310-220); Structure and Process of Care (WAC 246-310-230); and Cost Containment (WAC 246-310-240).

If an application is denied, the applicant may request an adjudicative hearing to contest the denial. RCW 70.38.115(10)(a). If an application is approved, a competitor of the applicant may request an adjudicative proceeding pursuant to RCW 34.05.422(1)(b) to contest the approval.<sup>3</sup> These adjudicative proceedings are conducted under the Administrative Procedures Act (RCW 34.05).

## **B. History Of Litigation**

The University of Washington Medical Center in Seattle (University) operates the state's only liver transplant program. 1st AR at 1029. In June 2003, Swedish Health Services in Seattle (Swedish) applied

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<sup>3</sup> An Appendix is attached containing a flow chart of the basic steps of the Certificate of Need application review process and excerpts from the administrative records and the clerk's papers.

for a Certificate of Need to establish its own liver transplant program. 1st AR at 1023-1262.<sup>4</sup>

During public comment, the University submitted 158 pages of material opposing the application. 1st AR at 1406-1564, 1573-1627. On November 24, 2003, following the public comment, the University (1st AR at 1572-1632) and Swedish (1st AR at 1633-89) submitted rebuttal pursuant to WAC 246-310-160(1)(a). Under this rule, the Program allowed no further submissions from the parties and “closed” the application record.

In June 2004, after evaluating the information in the application record received through November 24, 2003, the Program issued an evaluation approving the Swedish application to start a new liver transplant program. 1st AR at 1796-1811. The Department issued Certificate of Need #1288 to Swedish, authorizing Swedish to begin providing liver transplants to patients. 1st AR at 1816. The University filed a request for adjudicative proceeding to contest the approval. 1st AR at 1-31.<sup>5</sup>

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<sup>4</sup> There are two administrative records in this case. This brief refers to the record related to the original adjudicative proceeding as “1st AR.” The record related to the remand adjudicative proceeding is referred to as “2d AR.”

<sup>5</sup> At the same time, the University filed a Petition for Judicial Review to contest the approval. CP at 7-37. The Department filed a motion to dismiss for the University’s failure to first exhaust its administrative remedy of requesting an adjudicative proceeding. CP at 977-1039. The superior court in October 2004 declined to entertain the Petition on

The University sought a stay in superior court to prevent Swedish from implementing its liver transplant program. The superior court in October 2004 issued a stay pending completion of the adjudicative proceeding that had been filed by the University. CP at 1040-42. Swedish filed a motion for discretionary review of the stay, which was denied by the Court of Appeals in March 2005. CP at 1043-46.

Meanwhile, in the adjudicative proceeding, the University moved for summary judgment. 1st AR at 63-91. The Health Law Judge (HLJ) denied the motion. 1st AR at 285-92. On January 25-27 and February 3-4, 2005, the HLJ held a five-day hearing. 1st AR at 3121-4127. Swedish called six witnesses and the University eight. 1st AR at 995 (App. at 2). The HLJ limited the evidence to information that had been presented to the Program during the application review process up through November 24, 2003. The parties submitted their final post-hearing briefs in May 2005. 1st AR at 882-990.

In August 2005, the HLJ issued a written decision affirming the Program's decision to approve Swedish's application. 1st AR 994-1018 (App. at 2-25). In her decision, the HLJ noted that liver transplants were life-saving operations, and that the University was the only provider in Washington. *Id.* at 997. She found that the University accepts for  

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grounds that the University had failed to exhaust its administrative remedy. CP at 1040-42.

transplants healthier patients than do peer institutions; that the University's "wait list" of eligible patients is shorter than would be expected; and that the University had been performing fewer transplants than would be expected given Washington's population. *Id.* at 1001, 1006. Relying on expert testimony, she also found that a second program at Swedish would spur healthy competition and innovation that would benefit Washington liver transplant patients. *Id.* 1001, 1003, 1009. Based on these findings, she found that Washington "needed" the state's second liver transplant program proposed by Swedish. *Id.* at 1005, 1007. She further found that a new Swedish program would not affect the University's ability to maintain a viable liver transplant fellowship program of its own.

Following the HLJ's affirmation of the approval of the Certificate of Need in August 2005, the University filed a Petition for Judicial Review. In September 2005, Swedish moved in superior court to lift the stay that had prevented Swedish from implementing its liver transplant program. CP at 1047. The Department supported Swedish's motion. CP at 1048-53. The superior court lifted the stay. CP at 1054.

In January 2006, at the hearing on the University's Petition for Judicial Review, the superior court ruled that the HLJ had improperly prevented the University from presenting new evidence – evidence not

presented to the Program during the application review process – in response to the November 24, 2003 rebuttal information submitted by Swedish. 2d AR at 11-12 (App. at 26-27). The superior court remanded to the Department to take additional evidence and reconsider whether the Swedish application should be approved based on the additional evidence.

Id.

Following the superior court's remand, the University moved the superior court to re-impose the stay to prevent Swedish from implementing its liver transplant program. CP at 1055-84. The superior court denied the motion. CP at 1091-92. The University filed a motion for discretionary review of the stay, which was denied by the Court on Appeals. CP at 1093-98.

In August 2006, the HLJ conducted a remand adjudicative proceeding and allowed the University to offer new evidence in response to Swedish's November 24, 2003 rebuttal. 2d AR at 1917-2124. The University argued that it should be allowed to introduce any additional evidence that came into existence up until the time of the August 2006 remand hearing. 2d AR at 230-31, 233, 236. However, the HLJ ruled that the remand evidence must have been in existence as of December 31, 2003, a date approximately five weeks after the Swedish rebuttal evidence

had been submitted to the Program and was made available to the University. 2d AR at 286-89; 2d AR at 1906-1913 (App. at 29-36).

At the remand adjudicative proceeding, the University's witnesses admitted that they could not provide any new evidence to defeat the Swedish application, without being allowed to testify about evidence that came into existence after the December 31, 2003 evidentiary cutoff imposed by the HLJ.<sup>6</sup> 2d AR at 1981, 1992-93, 2018. Since no new evidence was offered by the University at the remand hearing, the HLJ issued a written decision again affirming approval of Swedish's application. 2d AR at 1906-13 (App. at 29-36).

The University filed another Petition for Judicial Review.<sup>7</sup> CP at 272-294, 376-388. When the case proceeded to hearing, the superior court ruled that the HLJ had erred in imposing the December 31, 2003 evidence cutoff, and also that Swedish's application should be denied because Swedish had not assessed the effect of its proposed program on the

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<sup>6</sup> After the HLJ made her evidentiary ruling, the University moved to disqualify the HLJ for bias in the middle of the remand hearing, a motion that was denied. 2d AR at 1967-1978. The superior court upheld the denial. RP at 69.

<sup>7</sup> In February 2007, before the case proceeded to hearing on the second Petition For Judicial Review, the University moved for summary judgment, arguing that Swedish had failed to implement its August 2004 Certificate of Need within the two-year "validity period" specified by RCW 70.38.125(2), and therefore the Certificate of Need had expired. CP at 1099-1122. The Department opposed the motion on grounds that the "validity period" would not start running until the appeal was resolved. CP at 1123-57. The Department also opposed the motion on the alternative grounds that the two-year validity period was not over because the two-year clock had not run during the 481 days in which Swedish had been judicially stayed from implementing its program. *Id.* The superior court denied the University's summary judgment motion. CP at 1158.

University's existing program. CP at 863-72 (App. 38-40). Both Swedish and the Department appeal the superior court's decision to deny the Swedish application.<sup>8</sup> The superior court stayed its invalidation of Swedish's Certificate of Need #1288 pending the appellate review, though Swedish is stayed from actually performing transplants until the appeal is resolved. CP at 949-50.

## V. ARGUMENT

The University's challenge to the HLJ's order granting Swedish's Certificate of Need application raises three main issues. Part (A) of this Argument explains that evidence from 2003 showed "need" for a second liver transplant program in Washington. Part (B) explains that the University was properly prevented at the adjudicative proceeding from opposing Swedish's 2003 application with evidence that came into existence after December 31, 2003. Part (C) explains that approval of the Swedish program would not adversely affect the University's ability to continue to operate a viable liver transplant program.

### A. **The HLJ Correctly Found That The Proposed Swedish Liver Transplant Application Met The Certificate Of Need Criteria**

A Certificate of Need applicant must satisfy four criteria: Need (WAC 246-310-210); Financial Feasibility (WAC 246-310-220); Structure

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<sup>8</sup> Swedish filed for Direct Review to the Supreme Court. The Department filed in the Court of Appeals.

and Process of Care (WAC 246-310-230); and Cost Containment (WAC 246-310-240). In June 2004, the Program found that Swedish met the four criteria and approved the liver transplant application. 1st AR at 1796-1811. In July 2005, in the first adjudicative proceeding, the HLJ upheld the approval. 1st AR at 994-1018 (App. 2-25). On remand in August 2006, the HLJ again upheld the approval. 2d AR at 1906-1913 (App. 29-36).

The University has challenged the HLJ's findings that Swedish satisfied the Need criterion under WAC 246-310-210 and the Structure and Process of Care criterion under WAC 246-310-230. CP at 300-75.

**1. The Standard Of Review Of The HLJ's Findings Is Whether They Are Supported By Substantial Evidence**

The appellate court reviews the validity of the agency's decision, not the superior court's decision. U.S. West Communications v. Utilities and Transportation Commission, 134 Wn.2d 48, 56, 949 P.2d 1321 (1997). The HLJ's factual findings on the Certificate of Need criteria must be upheld by the Court if they are supported by "substantial evidence when viewed in light of the whole record." RCW 34.05.570(3)(e). Substantial evidence means "evidence in sufficient quantum to persuade a fair-minded person of the truth of the declared premise." Miller v. City of Tacoma, 138 Wn.2d 318, 323, 979 P.2d 429 (1999). The agency's

decision is supported by substantial evidence if a “fair-minded” person could have reached the same decision, even if the reviewing court would have reached a different decision on its own. Callecod v. Washington State Patrol, 84 Wn. App. 663, 676 n. 9, 929 P.2d 510 (1997).

The reviewing court accords substantial deference to agency views when an agency determination is based heavily on factual matters that are complex, technical, and close to the heart of the agency’s expertise. Hillis v. Department of Ecology, 131 Wn.2d 373, 396, 932 P.2d 139 (1997). The decision of the Department, as the agency entrusted by the legislature to decide complex Certificate of Need applications, is entitled to substantial deference.

Evidence must be viewed in the “light most favorable to . . . the party who prevailed in the highest forum that exercised fact-finding authority.” University Place v. McGuire, 144 Wn.2d 640, 652, 30 P.2d 453 (2001). In this case, that party was Swedish. Finally, as the party challenging the findings, the University has the burden of proving the invalidity of the findings. RCW 34.05.570(1)(a).

**2. Substantial Evidence Shows That Swedish Had Demonstrated “Need” For Its Liver Transplant Program**

A Certificate of Need applicant must show “the need that the population served or to be served by the services has for such services.”

RCW 70.38.115(2)(a); WAC 246-310-210(1). Substantial evidence supports the HLJ's finding that "need" exists for the Swedish liver transplant program because the new program will provide life-saving liver transplants to patients who would otherwise be denied services. Indeed there can be no greater justification of "need" for a proposed service than the actual saving of lives.

A liver transplant operation gives the average recipient twelve additional years of life. 1st AR at 1811; 1st AR at 1011, ¶1.34 (App. at 18). The University wields unfettered control over the process by which a person suffering from liver disease becomes eligible for and then receives a liver transplant in Washington. The University operates the only liver transplant program in the five-state "WWAMI" region of Washington, Wyoming, Alaska, Montana, and Idaho. 1st AR at 997, ¶1.3 (App. at 4). With 8.8 million residents, WWAMI is the most populous region in the country that is served by only one liver transplant program. 1st AR at 1343.

Any person suffering from liver disease may apply to receive a liver transplant from the University. Persons deemed eligible under University protocols are placed on a "wait-list." 1st AR at 1004, ¶1.22 (App. at 11). They are assigned a "MELD score" based on the severity of their illness. The score determines their priority on the wait list, with

sicker patients having higher priority when a liver comes available for transplantation. 1st AR at 999-1003, ¶¶ 1.5, 1.9, 1.12, 1.18 (App. 6-10).

Meanwhile, health care facilities in the WWAMI region notify the “local procurement organization” whenever they come into possession of a donated liver. 1st AR 1000, ¶1.10 (App. at 7). The local procurement organization generally must first offer the liver to the University, which then decides whether the particular liver is a suitable “match” for someone on the wait list. 1st AR 1000, ¶1.11 (App. at 7). If there is no suitable match, the local procurement organization offers the liver to a different program for transplantation outside the WWAMI region. *Id.* A Washington patient who is unable to receive a liver transplant through the University has the option of either foregoing a transplant or seeking a transplant at a facility located outside the state.

Under the “need” criterion, the Department may not approve a new health care service provider unless existing providers are inadequately meeting the public need for the service. In this case, in approving the Swedish application, the HLJ found “need” for a second liver transplant program in Washington based on the following conclusions:

[T]he statistical analysis indicates that the University has been too conservative and less innovative in its approach. As a result, healthier patients with lower MELD scores and insufficient numbers of patients have been placed on the University’s liver transplant wait list, and too many donors

have been ‘turned down’ by the University. These statistics indicate that the University’s conservative approach has underserved patients suffering from end stage liver disease who warrant a place on the wait list and/or patients on the wait list who would be a reasonable recipient of a ‘rejected’ donor liver . . . [Footnotes omitted.]

The University has not performed as many transplants as would be expected considering the rate of liver disease and the population of WWAMI or Washington.

1st AR 1001, ¶¶ 1.13, 1.14 (App. at 8). These conclusions are supported by substantial evidence, as explained below.

**a. Compared With Peer Institutions, The University Denies Sicker Patients The Opportunity For A Liver Transplant By Not Placing Them On Its Wait List**

As discussed above, each patient on the wait list is assigned a “MELD score” that indicates the severity of the particular patient’s illness in terms of threat to life. A low score indicates a healthier patient, while a higher score indicates a sicker patient. The HLJ found that the MELD scores of patients on the University’s wait list indicate the University is “too conservative” in determining eligibility for a liver transplant. 1st AR 1001, ¶1.13 (App. at 8). This finding is supported by substantial evidence in the record.

Data presented by Swedish compared the MELD scores of the University patients at time of transplant with scores of patients at peer institutions. 1st AR at 1644. The data show 70 percent of the University

patients have MELD scores that fall within the healthier ranges of 11-20 and 21-30, while a significant lower percentage of transplant patients at peer institutions fall within the healthier ranges. The difference is most striking in the 11-20 range: 52 percent of the University's transplant recipients score in that range, compared to just 20-27 percent in that range at peer institutions. At the administrative hearing, Rolland Dickson, M.D., of the Jacksonville (Fla.) Mayo Clinic, and Charles Miller, M.D., professor of surgery at the Cleveland Clinic, both testified that the MELD scores demonstrate that the University has chosen more often to transplant healthier patients than do peer institutions. 1st AR at 3783, 3853. In other words, too many sicker patients in Washington have been forced either to leave the state for a transplant or forego a transplant.<sup>9</sup>

**b. Compared With Other States, The University's Wait List Is Short. The Consequence Is That Some Washington-Donated Livers Are "Exported" For Use Out Of State, And Too Many Patients Needing A Liver Transplant Are Never Given An Opportunity To Receive One At The University**

The length of the wait list indicates how many persons are deemed "eligible" for transplantation by the program. 1st AR at 1647. In the adjudication proceeding, the length of the University's wait list was an

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<sup>9</sup> The HLJ found another indication of the University limiting transplants to patients with less severe illness is University's low "retransplant" rate when compared to statistics nationally and from peer institutions. 1st AR at 1004, footnote 22. Retransplant is more common for sicker patients.

important issue. The HLJ found that a longer wait list means a better chance that a particular liver offered to the University by the local procurement organization will “match” a University patient. 1st AR at 1004, 1006, ¶¶ 1.19, 1.24 (App. at 11, 13). The HLJ also noted the serious consequences for patients failing to qualify for the University’s wait list: lacking necessary information or resources to obtain treatment elsewhere, they “may die.” 1st AR at 1006-07, ¶1.25 (App. at 13-14).

The HLJ noted that between 1999 and 2002, 98 livers were electively “exported” by the University because there was no “match” for a wait-listed patient – and only two of those were not successfully transplanted elsewhere. 1st AR at 1651; 1st AR at 1003, ¶1.19 (App. at 10). A longer wait list could reduce the number of livers that are exported from Washington for transplantation elsewhere by increasing the opportunities for matching patients and donors in Washington.

The HLJ further found evidence that the wait list is too short in the number of Washington-donated livers sent elsewhere for transplantation. The HLJ noted that the WWAMI region’s local procurement organization, Life Center Northwest, which provides organs to the University, has a 27 percent out-of-state “export” rate, compared to just 10-15 percent for local procurement organizations in comparable areas. 1st AR at 1651-52; 1st AR at 1004, ¶1.20 (App. at 11).

Moreover, the University's wait list is strikingly short when compared nationally. Based on data provided by Swedish (1st AR at 1648), the HLJ found that the number of persons nationally on a liver transplant wait list in 2002 is 60 per million. 1st AR at 1005, ¶1.23 (App. at 12). In the University's WWAMI region, the rate is just 14 per million or one-fourth the national average. This compares unfavorably with other states: California (106 per million); Maryland (82 per million); North Carolina (55 per million); Tennessee (48 per million); Virginia (46 per million); Arizona (38 per million); and Georgia (17 per million). *Id.* The HLJ found credible Dr. Dickson's testimony (1st AR at 3788-89) that these figures show the WWAMI region served by the University is "grossly underrepresented" in terms of numbers of patients on a wait list. 1st AR at 1006, ¶1.23 (App. at 13).

The HLJ concluded that these statistics from other states indicate that the University "should have many more patients on its wait list." 1st AR at AR 1006, ¶1.24 (App. at 13). According to the HLJ, the shortness of the wait list indicates that some patients are indeed "falling through the cracks," as alleged by Swedish. 1st AR at 1005, ¶1.22 (App. at 12). Washingtonians will benefit from a second liver transplant program that will allow more patients to gain placement on a wait list.

**c. The University Has Not Performed As Many Transplants As Would Be Expected, Based On National Data, Indicating That A Second Program Is Needed in Washington**

The HLJ also found that the University had performed fewer transplants than would have been expected. 1st AR at 1001, ¶1.14 (App. at 8). This finding is supported by substantial evidence. In the two years preceding the Swedish application, 2001 and 2002, the University performed 71 and 79 transplants. 1st AR at 1068; 1st AR at 1008, ¶1.30 (App. at 15). Swedish calculated that based on the national transplant rate, 111 Washington residents should have received transplants in 2001 (1st AR at 1048) – 40 more than the number who actually did.<sup>10</sup> These statistics are substantial evidence of the need for a second liver transplant program in Washington.

**d. A Second Liver Transplant Program Would Spur Competition And Innovation, Leading To More Patients Receiving Transplants, and Offering Patients A Choice of Where To Receive A Transplant**

Approving a second liver transplant program might be unnecessary under the Certificate of Need law if it would simply result in two separate programs sharing a fixed and limited number of potential liver transplants,

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<sup>10</sup> For 2001, the University conceded that only nine Washington residents received transplants out of state. 1st AR at 1412. Swedish also presented evidence that incidence of liver disease in Washington is not lower than the national average. 1st AR at 1064.

without increasing the total number of transplants that could be performed in the state. However, the HLJ correctly found that is not the case here:

A second program is needed for patient choice/competition that will promote innovation and discourage complacency, resulting in the treatment of a higher percentage of sick patients and better use of donor organs . . .

Medical literature concludes that programs in areas with competing liver transplant program treat less sick people and those programs in areas with competition treat patients at significantly higher MELD scores. Liver transplantation is a relatively new field, therefore innovation is important. 'Collegial competition' between two facilities with good reputations such as Swedish and the University will generate better ideas, thereby improving the quality of care to the point where Washington may start importing more organs than it exports.

The addition of a new liver transplant program is not a 'zero sum game'. Any Swedish transplant would not necessarily subtract from the University's volume. As Dr. Dickson and Dr. Miller explained, more that one program in a service area results in the performance of a greater number of transplants because competition promotes additional transplants. Additional transplants are the result of competition/innovation because more than one provider determines who qualifies for a transplant, is interested in promoting organ donations, and is available during peak demand within the service area.

1st AR at 1001, 1003, 1009, ¶¶ 1.13, 1.18, 1.31 (App. at 8, 10, 16).

The HLJ's findings are supported by the evidence. Dr. Dickson of the Mayo Clinic testified as follows:

[I]t's my feeling that a second program will actually improve the qualify of the other program, that competition and actually having another program in the state forces the

program to be more innovative, to take better care of the referring physicians, to take better care of their patients . . . And I suspect, given the numbers, that a large number of patients are falling through the cracks that the population is better served by having a second program . . . . My guess is that transplants in the entire state and region will increase, and it will be better service, both to the provider sent the patient and to the patient and their family.

[T]here is, indeed, at some point a saturation of organs that will come available. However, my review of the data suggests that Washington [is] nowhere near that point. My experience has been that expanding the donor pool, both by using what was considered marginal donors in the past, which I think there's plenty of data . . . from our experience here, that those organs when used in correct circumstances work as well, that expansion could be done in that way. Living donors can be used to expand the pool. My understanding is that there are no living donors being used, and then on novel techniques, such as split livers.

1st AR at 3792-95. Dr. Miller of the Cleveland Clinic testified that approval of new centers in New York resulted in greater total transplant volume and higher quality service. 1st AR at AR 3858. Dr. Miller testified that having more than one program in an area allows providers to better respond in periods of peak demand for transplantation. Id. He predicted that both the University and Swedish could have "excellent programs" and that "competition will drive excellence" because that is what has "happened all over the country." Id. at 3859.

Regarding the University's argument about a limited number of available livers for transplantation, the University itself elicited further

testimony from Dr. Miller on cross examination. He testified that his experience shows having competition means that providers will find more types of livers to be suitable for transplantation, meaning more patients will receive transplants. He predicted that a second liver transplant in Washington may result in the state becoming a “net importer” rather than a “net exporter” of donated livers. 1st AR at 3862-64. The HLJ adopted Dr. Miller’s opinion as a finding. 1st AR at 1002-03, ¶1.17 (App. at 9-10).

The HLJ relied on the opinions of Swedish’s experts on the benefits of competition, finding them more credible than the University’s experts who decried competition. On a Petition for Judicial Review, a court does not “weigh credibility” of experts. U.S. West, 134 Wn.2d at 62. An administrative law judge is better positioned than a reviewing court to judge witness credibility. Discipline of White, 149 Wn.2d 707, 725, 72 P.3d 173 (2003).

In addition to the expert testimony, a study introduced by Swedish, and not rebutted by the University, concluded that liver transplant programs having competition “perform transplantation on patients at higher MELD scores [sicker patients] than centers without competition.” 1st AR at 1768. The HLJ cited this study to support her decision. 1st AR at 1002, footnote 17 (App. at 9).

As an example of benefits of competition, the HLJ found that the University has been “slow to respond” to the option of using livers donated after cardiac death as a means to increase the number of transplants performed on Washington residents. 1st AR at 1002, ¶1.16 (App. at 9).

Finally, given the need for a second program, the HLJ noted that a second program will for the first time offer Washington patients an in-state “choice” of where to obtain a liver transplant. She found that having a choice will allow patients to select the best provider for them, and possibly reduce the necessity of patients having to leave the state for a transplant. 1st AR at 1009, ¶2.8 (App. at 16).

### **3. The University’s Concerns About The Adequacy Of Swedish’s Proposed Staffing Are Without Merit**

WAC 246-310-230(1) requires that Swedish, as the applicant, must demonstrate that its program will have a “sufficient supply of qualified staff.” The University has argued that the Swedish application fails this criterion and therefore should have been denied. CP at 322-24. Specifically, the University has argued that Swedish’s plan to hire a single liver transplant surgeon and single hepatologist for the first three years is insufficient. It also claims that Swedish’s Dr. Marks and Dr. Florence are

not qualified under the United Network for Organ Sharing (UNOS) standards to be liver transplant surgeons.

The University's arguments are factually incorrect. In its application, Swedish stated that it "plans to recruit and hire an appropriately skilled hepatologist and a liver transplant surgeon." 1st AR at AR 1068. In its rebuttal statement, Swedish further stated that its "budget accommodates a new surgeon and a new physician dedicated to liver care because we intend to add senior level, state of the art leaders in the field to our faculty." 1st AR at 1662. Contrary to the University's argument, Swedish never stated that either Dr. Marks or Dr. Florence would serve as the UNOS-qualified liver transplant surgeon.

Swedish's application contained a detailed explanation of proposed staffing for its program. 1st AR at 1660-62. The HLJ found the staffing would be "adequate." 1st AR at 1009, ¶1.32 (App. at 16). It led her to reasonably conclude that the requirements of WAC 246-310-230, related to quality of care, were satisfied. 1st AR at 1017, ¶2.16 (App. at 24). The University's accusation that Swedish plans to operate with unqualified staff is without merit.

**B. The HLJ Properly Limited The Evidence That The University Could Present In The Adjudicative Proceeding**

As stated above, Swedish applied for its liver transplant program Certificate of Need in June 2003. During the application process, in September 2003, as allowed by WAC 246-310-160, the University submitted voluminous information opposing the application. 1st AR at 1023-1262. Following the public comment, Swedish (1st AR at 1633-89) and the University (1st AR at 1572-1632) both were allowed to submit “rebuttal” information to the Department. Swedish’s rebuttal claimed that the University’s program was under-serving the public’s need for liver transplants, and therefore its new program was needed in the state. The rebuttal comments were submitted on November 24, 2003. Under WAC 246-310-160(1), the parties were given no further opportunity to present information prior to the Department rendering a decision on the application. In effect, the application record – including the application material, public comment by interested parties including the University, and rebuttal by the University and Swedish – “closed” on November 24, 2003.

Relying on information in the application record, the Program in issued its decision in June 2004 to approve the application and issue Certificate of Need #1288 to Swedish. 1st AR at 1796-1811. The

University requested an adjudicative proceeding before the Department's HLJ to contest the decision. 1<sup>st</sup> AR at 1-31. At the hearing in January 2005, the HLJ prevented the University from presenting new information that it had failed to provide to the Program during its review of the application. 1st AR at 290. Likewise, at the hearing, the HLJ upheld the University's objections when Swedish attempted to present information it had not provided to the Program during the application process. 1st AR at 3187, 3201.

The HLJ's role was to decide whether the Program had reached the correct decision based on the information provided by Swedish and the University during the application process. In other words, the HLJ did not permit the parties to use the adjudicative hearing to "restart" the fact-gathering process that formed the application record on which the Program based its contested decision.

When the HLJ upheld the Program's approval of the application (1st AR at 994-1018 (App. at 2-25)), the University filed a Petition for Judicial Review. CP at 7-37. In the superior court, the University claimed that the HLJ had improperly excluded evidence it attempted to offer at the hearing in response to Swedish's November 24, 2003 rebuttal information. The University claimed that the exclusion was improper because

Department rules did not allow the University to respond to the Swedish rebuttal during the Certificate of Need review process.<sup>11</sup>

The superior court remanded and directed the Department to allow the University to respond to the Swedish rebuttal, and then to reconsider its decision to approve the application in light of the additional evidence. 2d AR at 11-12 (App. at 26-27). In its oral ruling, the superior court declined to provide any direction on the scope of the new evidence that should be admitted by the Department upon remand. 2d AR at 260-261. (The Department does not challenge the validity of the superior court's remand order, and this Court need not address its validity.)

At the August 2006 remand hearing, the HLJ allowed the University to present additional evidence in response to the "rebuttal" information that Swedish had submitted on November 24, 2003. The University argued that it should be allowed to introduce additional evidence that came into existence at any time up until the August 2006 remand hearing. 2d AR at 230-31, 233, 236. The HLJ rejected the University's argument and ruled that any new information must have been

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<sup>11</sup> The HLJ held the rules did allow the University to respond to the rebuttal during the Certificate of Need review process by requesting "reconsideration" of the Program's August 2004 decision under WAC 246-310-560, prior to requesting an adjudicative proceeding to contest the decision. The University had failed to request reconsideration under WAC 246-310-560. The superior court rejected the HLJ's ruling that the University should have used the reconsideration process to respond to the Swedish rebuttal.

in existence as of December 31, 2003. 2d AR at 286-289; 2d AR at 1906-1913. This date was about five weeks after the November 24, 2003 Swedish rebuttal that the University wanted an opportunity to respond to – a period much longer than the 10 days under WAC 246-310-160(1)(a) given to Swedish to present its rebuttal following the public comment on its application. The HLJ explained her decision to limit the evidence:

The December 31, 2003 date was selected by the HLJ because it provided the University with an opportunity to respond to the new theory raised in Swedish's November 2003 rebuttal statement, and at the same time set a reasonable date that does not deviate unnecessarily far from the closure of the public input stage of the administrative record.

If no date was set as the University requested, new information could be submitted that did not exist at the time the Program made its decision [on June 17, 2004]. Such a ruling could result in a revolving door of litigation with additional information submitted for the first time during the adjudicative or judicial stages. This may be of special advantage when the interested party is a potential competitor who may want additional time to change the manner in which it provides health care. Closure is needed so a revolving door of delayed responses does not unreasonably draw out the process. Late presentation of facts and data would result in an increased number of appeals/remands and delays in the resolution of Certificate of Need appeals.

The purpose of the Certificate of Need adjudicative appeals is not to supplant the certificate of need application process but to assure that the procedural and substantive rights of the parties were observed and that the factual record supports the Program's analysis and decision. The December 31, 2003 cut off date for evidence during the

remand hearing is reasonable and consistent with the facts at hand and the Certificate of Need regulatory framework.

2d AR at 1910-11 (App. at 33-37).

At the August 2006 remand hearing, given the December 31, 2003 evidence cut off, University witnesses stated they could not provide any additional information that would assist in defeating Swedish's application. 2d AR at 1981, 1992-93, 2018. Having received no new evidence, the HLJ on remand issued a decision that again upheld the Program's decision to grant the Swedish application. 2d AR at 1906-13 (App. at 29-36).

On judicial review, the superior court found that the December 31, 2003 cutoff was improper, and ruled for the first time that no evidence cutoff date should have been applied at the August 2006 remand hearing. CP at 863-72 (App. at 38-40). The superior court reversed the Department's decision to grant Swedish's application and effectively terminated the application. *Id.*

**1. The HLJ's Evidence Cutoff Date Was A "Relevancy" Ruling, Reviewable By This Court Under The "Abuse Of Discretion" Standard**

Under RCW 34.05.452(1), the HLJ may exclude "irrelevant" evidence from the adjudicative proceeding. The HLJ in effect ruled that evidence not in existence as of December 31, 2003 was irrelevant in

determining whether Swedish's 2003 application should be granted.<sup>12</sup> The reason for this determination was that post-2003 information was not available when the Program was collecting the information for making its decision on the application. 2d AR at 286-289, 2d AR at 1906-1913 (App. at 29-36). Evidence "too remote . . . in point of time" may be excluded as "irrelevant." Roberts v. ARCO, 88 Wn.2d 887, 893, 568 P.2d 764 (1977).

Evidentiary rulings in administrative hearings, including relevancy rulings, are reviewed under the abuse of discretion standard. Port of Seattle v. Pollution Control Hearings Board, 151 Wn.2d 568, 642, 90 P.3d 659 (2004). The standard also is used by appellate courts to review relevancy determinations by superior courts. In re Detention of Turay, 139 Wn.2d 379, 986 P.2d 790 (1999).

Abuse of discretion is a narrow standard of review that is satisfied only when a ruling is "untenable" or "manifestly unreasonable." State v. Cannon, 130 Wn.2d 313, 922 P.2d 1293 (1996). A ruling is not arbitrary and capricious if there is "room for two opinions . . . even though the

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<sup>12</sup> In her ruling, 2d AR at 1910-11, the HLJ held that evidence that came into existence after December 31, 2003 would be "too far away" from the time when the Program was receiving information on Swedish's application. The HLJ did not expressly use the term "irrelevant" in excluding the evidence. However, in argument before the HLJ, Swedish asserted that the evidentiary cutoff was premised on "relevancy." 2d AR at 85. Moreover, RCW 34.05.452(1) allows the exclusion of evidence only for unreliability, privileged communications, irrelevancy, immateriality, and undue repetitiveness. Clearly, the basis for the HLJ's ruling was relevancy (or materiality) in that she deemed facts coming into existence after December 31, 2003 were not germane to deciding whether Swedish's 2003 application should be approved.

reviewing court may believe it to be erroneous.” Rios v. Department of Labor and Industries, 145 Wn.2d 483, 501, 39 P.3d 961 (2002). For reasons discussed below, the HLJ’s December 31, 2003 evidentiary cutoff was not an abuse of discretion.

**2. The Evidence Cutoff Was Reasonably Based On The Structure Of The Certificate Of Need Process, On Assuring Public Access To Needed Health Services, And On Fairness To Applicants**

The reasonableness of the December 31, 2003 evidence cutoff is demonstrated by recapping the critical dates in this case. Swedish applied in June 2003. Over the next five months, the Program collected information from Swedish and the University in 2003 about the application. The last opportunity for Swedish to present evidence was its rebuttal submitted on November 24, 2003. In June 2004, the Program issued its decision under RCW 70.38.115(1) and WAC 246-310-490 approving the Swedish application, relying on information provided by Swedish and the University. The University then requested an adjudicative proceeding, which was held in January-February 2005, and the HLJ upheld the approval of Swedish’s application.

On remand, the HLJ ruled that any new information presented by the University at the August 2006 remand hearing should relate to the period of time – 2003 – in which the Program collected information in

order to decide whether to approve Swedish's application consistent with RCW 70.38.115(1) and WAC 246-310-490. The HLJ's role was to assess whether the facts in existence at the time of the Program's 2003 review of the application justified approval of the application. Accordingly, the HLJ reasonably imposed a December 31, 2003 evidence cutoff in making her decision whether to approve the 2003 application.

The HLJ's ruling limiting new evidence is particularly reasonable given the structure of the Certificate of Need process under RCW 70.38 and WAC 246-310. As discussed above, the statutes and rules allow the applicant and interested members of the public to submit information at various stages in the Certificate of Need review process. This entire process would be eviscerated if the University – in an attempt to strip Swedish of its Certificate of Need – was allowed in the adjudicative proceeding to introduce evidence that did not even exist at the time when the Program made its contested decision. Allowing newly-developed evidence in the adjudicative proceeding would provide a disincentive for interested parties to participate in the public process by which the Program gathers information upon which to make its decision. In short, the filing of a request for adjudicative proceeding should not “restart” the statutorily-required rigorous fact gathering that already has taken place and that has led to the approval or denial of an application that is being reviewed.

Case law supports the Department's position. In a telecommunications rate case, this Court has held that when an agency receives prefiled testimony, rebuttal, and briefs pursuant to a statutory process, and then "closes" the record, the agency's decision and the court's review of the decision is based on facts in the record and not on facts developed after the "record closes." U.S. West, 134 Wn.2d at 52, 72-73.<sup>13</sup> Likewise, the fact-gathering process under RCW 70.38 and WAC 246-310 establishes a "record" upon which the Department's Certificate of Need decision should be decided.

In Old Dominion Electric Cooperative v. Virginia Electric & Power Company, 237 Va. 385, 377 S.E.2d 422 (1989), a rate case, the State Corporation Commission based its decision on the record compiled by the parties in a proceeding conducted by a hearing examiner, and would not allow introduction of new information that subsequently came into existence. In upholding the Commission's ruling under the abuse of discretion standard, the Virginia Supreme Court held:

At best, the rate case gives the Commission a view of the operations of a utility at a moment in time. The next moment events may have changed. We agree with the

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<sup>13</sup> Based on the record, the Utilities and Transportation Commission (UTC), issues a "final decision" that is not subject to challenge by requesting an adjudicative proceeding. In this respect, the UTC process is different than the Certificate of Need process, where the Program's decision may be reviewed in an adjudicative proceeding. However, in both cases, the agencies establish a record, based on input from the parties under a statutory process, upon which a decision is made whether to grant an application.

Commission that it would cause delay and confusion to reopen a complex record of this kind to substitute actual figures for projected figures. Therefore, we hold that the commission did not abuse of discretion in refusing to reopen the record.

Id. at 397. Likewise, the HLJ did not abuse her discretion when she excluded evidence that came into existence after December 31, 2003, which was after the time in which the Program collected information from the parties on which to base its decision whether to approve Swedish application.

Establishing an evidence cutoff serves the legislative intent of promoting the health of Washington citizens by assuring they have adequate on-going “access” to health services through the Certificate of Need process. RCW 70.38.015(1). The cutoff means that “need” for a service is judged at a particular point in time when a new provider attempts to enter the marketplace by filing a Certificate of Need application. It means that existing providers must oppose a Certificate of Need application based on the access to their services at the time of application, rather than based on the changes to access that are made in response to an application. It prevents existing providers from simply waiting to change the access to their services until a competitor happens to file an application. The public interest is served by encouraging existing providers to offer on-going accessible services that meet the health care

needs of Washington residents if they hope to prevent the Department from finding need for a new provider.

It is against the public interest to discourage new providers from filing Certificate of Need applications by allowing existing providers to defeat their applications in an adjudicative proceeding by developing facts that did not even exist when an application was under review by the Program. Without a cutoff, existing providers would have an interest in prolonging the Certificate of Need appeal process as long as possible – preventing new providers from offering new services – to allow them to make changes in their program in an attempt to defeat the Certificate of Need application. That is precisely what the University has attempted in this case. Such delays do not serve the legislative goal of assuring that the public has ongoing “access” to needed health services.

The HLJ’s ruling also promotes the public interest by assuring fairness to the applicant. In other contexts, this Court has held that an applicant has a due process right to have its application decided under the law in effect at the time of application. Friends of the Law v. King County, 123 Wn.2d 518, 522, 869 P.2d 1056 (1994) (land use application); Northern Pacific Transport Company v. Utilities & Transportation Commission, 69 Wn.2d 471, 474-75, 418 P.2d 735 (1966) (transportation route application). The principle is that it would be

fundamentally unfair to allow “shifting of the proverbial goal posts during the application review process.” East Reclamation Company v. Bjornsen, 125 Wn. App. 432, 437, ¶ 11, 105 P.3d 94 (2005).

Likewise, a Certificate of Need application should be decided based on the facts in existence at the time of Program’s application review process. In upholding this principle, the HLJ’s December 31, 2003 evidence cut-off assures due process fundamental fairness to Swedish. In 2003, Swedish filed a Certificate of Need application and submitted to a time-consuming and expensive review process required by RCW 70.38 and WAC 246-310. Through that process, Swedish persuaded the Program that its proposed program was “needed” because the 2003 facts showed that the University was under-serving the demand for liver transplants in Washington.

It would be fundamentally unfair to Swedish – and contrary to the public interest in having access to needed services – to allow the University to introduce post-2003 information in an attempt to strip Swedish of its Certificate of Need by alleging that changes in the University’s program make the Swedish program no longer approvable. In the adjudicative proceeding, Swedish was entitled to have the merits of its application judged on facts that existed at the time its application was reviewed by the Program – not on facts that came into being afterwards.

That entitlement is particularly evident here since by revising its liver transplant program, the University had the ability under the superior court's ruling to belatedly change the facts in an attempt to take away the Certificate of Need that Swedish had won during the application process.

**3. The Superior Court's Constitutional And Statutory Reasons For Reversing The HLJ's Evidentiary Ruling Do Not Withstand Scrutiny**

The superior court ruled that the December 31, 2003 cutoff was an "artificial deadline" which "violates due process." CP at 863-64 (App. at 38-39). Neither the University nor the superior court cited support for the proposition that an agency violates due process when it bases its decision only on information that was in existence at the time an application was under review by the agency. In any event, for argument sake, even if HLJ's evidentiary ruling were erroneous, the error would not be of constitutional magnitude. The December 31, 2003 date represented the HLJ's determination of what evidence was "relevant" in the adjudicative proceeding under RCW 34.05.452(1). If an HLJ abuses discretion in excluding evidence, the remedy under RCW 34.05.562(2) is remand of the case to the agency to hear the previously-excluded evidence. Neither the University nor the superior court cited authority for the proposition that a relevancy determination that is overturned on appeal amounts to a due process violation.

Furthermore, while the superior court held that the HLJ could set an evidence cutoff date, it found that December 31, 2003 was an “artificial” date. As demonstrated above, the date was not “artificial” or otherwise inappropriate. The date was the end of the year in which the Program collected information on which to base its decision whether to approve Swedish’s 2003 Certificate of Need application. Moreover, the date was more than one month after Swedish’s November 24, 2003 rebuttal. The length of time until the end of 2003 was a fair period, especially considering that Swedish had only ten days to prepare its rebuttal following the public hearing on the application. WAC 246-310-160(1).

In support of its decision, the superior court also relied on RCW 34.05.449(2) which requires an HLJ to allow parties “to respond, present evidence and argument, conduct cross examination, and submit rebuttal evidence.” However, RCW 34.05.449(2) does not override the HLJ’s authority under RCW 34.05.452(1) to exclude “irrelevant” evidence, as she did when she imposed the December 31, 2003 evidence cutoff for deciding whether Swedish’s 2003 application should be approved. During the two adjudicative proceedings over six days, the University received all the rights prescribed under RCW 34.05.449(2). Those rights do not include a right to present evidence judged irrelevant

because it does not relate to the time period in which Swedish's application was under review by the Program.

Finally, the superior court also relied on RCW 34.05.461(4), stating that "findings of fact shall be based exclusively on evidence of record in the adjudicative proceeding . . . ." The HLJ in fact did base her decision exclusively on facts introduced in the adjudicative proceeding, as required by RCW 34.05.461(4), and the University does not argue otherwise. This statute, of course, did not prohibit the HLJ from excluding evidence that she found irrelevant because it came into existence after the 2003 time period in which the Program collected information to decide whether to grant the application. In fact, this statute would prohibit findings based on evidence that is excluded as irrelevant, because such evidence is not in the record. The superior court's reliance on RCW 34.05.461(4) is misplaced.

**4. If The HLJ Selected In Incorrect Evidence Cutoff Date, This Court Should Remand To The HLJ To Take Additional Evidence If Necessary**

The HLJ held the adjudicative proceeding in January 2005. The superior court ruled in January 2006 that the HLJ had improperly limited the evidence at the January-February 2005 adjudicative proceeding. 2d AR at 11-12 (App. at 26-27). The superior court remanded to the Department to take additional evidence, but declined to provide further guidance for

the remand proceeding. On remand, the HLJ limited the new evidence to evidence that was in existence on December 31, 2003. If this Court agrees with the superior court that the December 31, 2003 date was impermissibly limiting, then under RCW 34.05.562(2)(b) the proper remedy would to specify the correct cutoff date and remand the case to the Department with instructions to consider additional evidence as appropriate.

If, strictly for argument sake, December 31, 2003 was not the proper evidence cutoff, the proper cutoff would be June 30, 2004, the date of the Program's decision to grant the Certificate of Need to Swedish. That is the decision reviewed by the HLJ. Under RCW 34.05.562(2)(b) the remand evidence must relate "to the validity of agency action at the time it was taken." (Emphasis added.) Evidence that relates to facts after that date may not be considered in determining the validity of the HLJ's order. U.S. West, 134 Wn.2d at 72-73. ,

**C. The HLJ Correctly Determined That The Needed Swedish Liver Transplant Program Will Not Have An Adverse Effect On The University's Program**

**1. The Superior Court Misinterpreted The Law Regarding Assessment Of Adverse Effects**

Rather than remand for a second time, the superior court held that Swedish's application for a new liver transplant program should be denied

because it failed to address the impact of a new program on the University's program. RCW 70.38.115(2)(d) states in part:

The department shall consider the [Certificate of Need] application in terms of its impact on existing and proposed institutional training programs for doctors of osteopathic medicine and surgery and medicine at the student, internship, and residency level . . .

(Emphasis added.) Additionally, WAC 246-310-210 states:

The determination of need [by the Department<sup>14</sup>] for any project shall be based on the following criteria . . .

(4) The project will not have an adverse effect on health profession schools. The assessment of the conformance of a project with this criterion shall include consideration of:

(a) The effect of the means proposed for the delivery of health services on the clinical needs of health profession training programs in the areas in which the services are to be provided; and

(b) If the proposed health care services are to be available in a limited number of facilities, the extent to which the health profession schools in the area will have access to the service for training purposes.

The superior court's holding that Swedish was obliged to assess the impact on the University's program is a misinterpretation of RCW 70.38.115(2)(d) and WAC 246-310-210(4). The statute and the rule do not require the applicant to address the impact on the University's program. Instead, both laws require the Department, based on information

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<sup>14</sup> WAC 246-310-200(2) expressly states that the WAC 246-310-210 criterion shall be used "by the Department" in making the required determinations.

in the record, to assess adverse impact on the University's program (WAC 246-310-210(4)) and specifically on the training programs (RCW 70.38.115(2)(d)).

In the application form, the Program gave Swedish the opportunity to assess the impact to the University, and Swedish declined. 1st AR at 1056-57. However, the Program never required an assessment by Swedish in the application form.<sup>15</sup> The reason is straightforward: under RCW 70.38.115(2)(d) and WAC 246-310-210(4) the duty to conduct an assessment is on the Department, not on the applicant. In Certificate of Need cases, the Department's interpretation of the law is entitled to "considerable weight" on judicial review. St. Joseph Hospital v. Department of Health, 125 Wn.2d 733, 743, 887 P.2d 891 (1995). It would be terribly unfair to deny an application for failing to undertake an assessment that the Department never required of the applicant.

In reality, an applicant, like Swedish, is not even in a position to assess impact on the University. It would be unreasonable to require Swedish to attempt to acquire detailed knowledge about the University's program, and then venture an "adverse effect" assessment on someone else's program. If such a requirement existed, the University could have

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<sup>15</sup> As pointed out in its brief, outside the application form, Swedish did address adverse effects in other written submissions to the Program (1st AR at 1653-55, 1668-69, 1687) and at the adjudicative proceeding. 1st AR at 3819-20.

defeated the application simply by withholding information, making it impossible for Swedish to perform a meaningful assessment. Because it has knowledge of its own program, the University undeniably is best positioned to present evidence to the Department regarding adverse effects. During the Certificate of Need review process in 2003, the University was provided the opportunity to submit any information it deemed relevant to assist the Program in evaluating adverse impacts to the University's program.

Both the Program and the HLJ performed the required "adverse effect" evaluation by considering the information provided by the University and Swedish during the application process and at the adjudicative proceeding.

**2. Substantial Evidence Supports The HLJ's Finding That A New Liver Transplant Program At Swedish Will Not Adversely Affect The University**

The HLJ found insufficient evidence of an adverse effect on the University to justify denial of the Swedish application, a finding that is supported by substantial evidence.

In orchestrating massive public comment opposing the application, the University did not allege that approval of the Swedish program would adversely affect a University liver transplant "fellowship" program. 1st AR at 1406-1564, 1573-1632. In fact, the University never mentioned its

fellowship program. The HLJ made an uncontested finding that in 2003 the University had one liver transplant fellow. 1st AR at 1007, ¶1.26 (App. at 14).<sup>16</sup>

Accordingly, under WAC 246-310-210(4), the HLJ evaluated whether approval of the Swedish application would have an adverse effect on the University's one-fellowship program. Under the applicable national standards of the United Network for Organ Sharing (UNOS) and the American Society of Transplant Surgeons (ASTS), a liver transplant training program must perform 50 liver transplants annually, and a program fellow must participate in 45 transplants either as a primary surgeon or first assistant over a two-year period. 1st AR at 1007, ¶1.27 (App. at 14); 1st AR at 1978-79.

The HLJ found that the University's one-fellow program could continue to operate "well above" the two UNOS/ASTS standards, even if the Swedish application is approved, for the following reasons:

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<sup>16</sup> At the superior court in February 2007, the University claimed it had been "authorized" for a second fellow in Fall 2004. CP at 319. (No evidence presented to the superior court showed that a second fellow is actually at the University.) This is the type of new evidence that the HLJ properly excluded as having come into existence after December 31, 2003. In fact, this alleged authorization for a second fellow occurred even after the HLJ made her contested decision in June 2004 to approve Swedish's application, as the University admits. CP at 319.

- The University performed the following number of transplants: 67 in 1998; 94 in 1999; 71 in 2000; 79 in 2001; and 104 in 2002. 1st AR at 1008, ¶1.30 (App. at 15).

- Nationally, the number of liver transplants is expected to grow five percent each year. 1st AR at 1008, ¶1.30 (App. at 15); 1st AR at 1090.

- Swedish's plan is to perform the following number of transplants in its first five years of operation: 0-18-32-42-48. 1st AR at 1008, ¶1.29 (App. at 15); 1st AR at 1084.

- The current number of transplants now performed in Washington will increase with the addition of Swedish's program, with different selection and treatment protocols, with innovation, with recruitment of new donors, and with expected population increases. 1st AR at 1009, 1015, ¶¶ 1.31, 2.11 (App. at 16, 22).

Furthermore, the HLJ found that many viable academic medical centers perform fewer transplants than the University has performed in recent years. 1st AR at 1008, ¶1.28 (App. at 15); 1st AR at 1421-36 ("removals for transplant" column indicates the number of transplants per facility).

In response, the University has not argued that approval of the Swedish application would cause the University to fall below the UNOS/ASTS standards for a one-fellowship program. Instead, the

University has taken the position that it would be adversely impacted by any potential reduction in the number of transplants performed at the University. The HLJ addressed this argument by deferring to the expertise reflected in UNOS/ASTS standards:

The University has a fellowship liver transplant education and training program with one fellow. The University argues that its existing transplant volume levels are necessary to maintain quality training and research programs. That argument is asking the health law judge to set new minimum standards for a liver transplant program after expert medical organizations have done so. That would be inappropriate. UNOS and the American Society of Transplant Surgeons (ASTS) are clearly better qualified to determine minimum volumes needed to sustain a fellowship training program.

1st AR at 1007, ¶1.26 (App. at 14). The HLJ made a reasoned finding that approval of Swedish's application would not cause the University to fall below the UNOS/ASTS volume standards. In any event, the University's "minimum volume" argument must fail because the University has not even attempted to identify an alternative minimum volume standard. Instead, the University has taken the inflexible position that it must remain the state's only liver transplant program no matter how many transplants might be capable of being performed on Washingtonians in future years and no matter what benefits to patients might be realized by creation of a second program.

The University's untenable argument is that any potential volume reduction would cause an adverse effect and therefore preclude in perpetuity the approval of a second liver transplant program in Washington. WAC 246-310-210(4) should not be so broadly construed in the University's favor to chock off competition.

The HLJ noted that the University touted the "excellence" of its program in earlier years when it was performing as few as 67 liver transplants per year. 1st AR at 1008, ¶1.30 (App. at 15). Given this positive self-assessment, how can the University claim it must continue to perform all of the increasing number of liver transplants in Washington in order to maintain the excellence of its liver transplant program?

Finally, the University has argued that the Department under WAC 246-310-210(4) failed to take into account adverse effects to its "research programs" that would result from a new liver transplant program at Swedish. CP at 320-22. However, in its extensive public comment, the University never identified a single research project that would be affected, let alone a research project that somehow depends on the University maintaining its status as the state's only liver transplant program. If such evidence existed, of course, it would be in the University's possession, and the University could have presented it to the Department during the Certificate of Need application process.

## VI. CONCLUSION

Based on the foregoing, the Department of Health respectfully requests the Court affirm the decision of the Health Law Judge to grant Swedish's application for a Certificate of Need to start a new liver transplant program because:

(1) In making her decision, the Health Law Judge properly limited the relevant evidence admissible in the remand adjudicative proceeding; and

(2) The Health Law Judge properly found that the application satisfied the four criteria in WAC 246-310-210 through WAC 246-310-240. The new Swedish program will increase the number of life-saving liver transplants performed in Washington, and will not prevent the University from continuing to operate a viable program.

RESPECTFULLY SUBMITTED this 5 day of November, 2007.

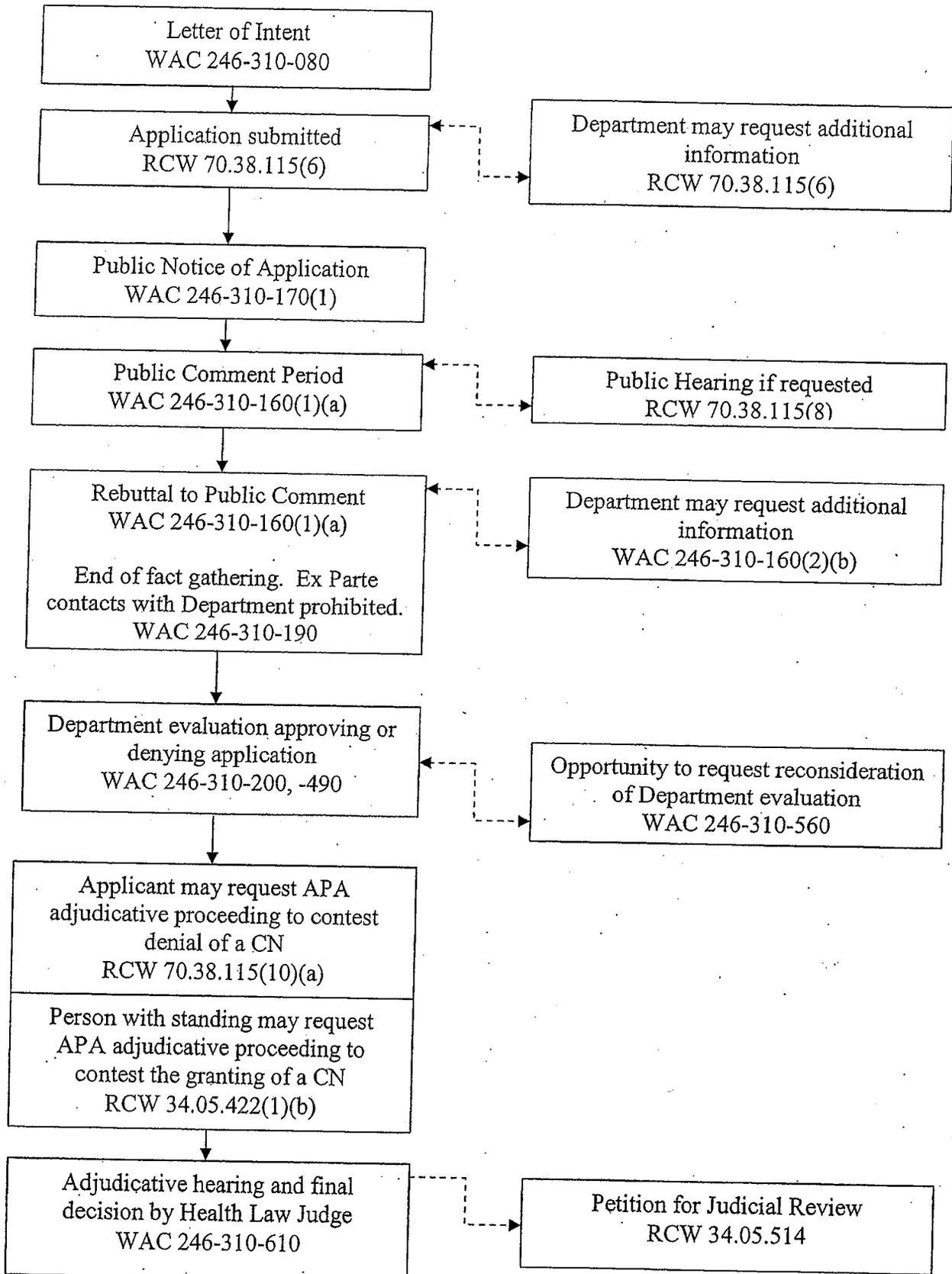
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# APPENDIX

# CN Application "Regular" Review





hearing and pursuant to Prehearing Order No. 4 regarding the closure of the administrative record, the offers of proof are rejected. Even if the offers of proof were admitted, the findings of fact in this order would not substantially change, and the conclusions of law and order would not be modified as a result the consideration of the offers of proof.

## I. FINDINGS OF FACT

1.1 Swedish applied to the Program for a CON to establish an adult liver transplant program that would provide liver transplant services, including pre-screening/testing, complete inpatient care and follow-up treatment. The Swedish program would be located in Seattle, Washington where the University's existing transplant program is located. The Program granted Swedish a liver transplant program CON. The University is contesting the Program's decision to grant the CON.

1.2 The Program's written analysis addressed the CON criteria regarding "need", "financial feasibility", "structure and process (quality) of care" and "cost containment" that support the issuance of the Swedish CON. The "need" analysis addresses accessibility of liver transplant care from the University and the potential adverse effects a Swedish liver transplant program would have on the University's clinical, training and research programs.<sup>2</sup>

### "Need"

1.3 The University provides adult liver transplant services and Children's Regional Hospital & Medical Center provides pediatric liver transplant services. These facilities work together to coordinate split liver or cut down liver procedures involving

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<sup>2</sup> AR 771-780.

both adult and pediatric patients.<sup>3</sup> The University is the only facility providing adult liver transplant services to patients in Washington, Wyoming, Alaska, Montana and Idaho (WWAMI) who do not seek treatment elsewhere.<sup>4</sup> The University is an institution with a good reputation regarding the treatment of patients and the education of medical students and fellows. But, a comparison of statistics regarding population, liver disease/death and transplant rates of the University to other programs indicates that the University is not meeting the needs of Washington or WWAMI region.

1.4 The allocation of donor livers is based upon the severity of the illness. The statistical analysis demonstrates that the University has failed to provide liver transplant services to a sufficient number of sicker patients, or transplant a sufficient total number of patients. These shortcomings are particularly apparent when the University's statistics are compared with similar regions and the University's peer liver transplant programs.<sup>5</sup> There is a need for a second facility in this service area to serve those qualified patients who are not wait-listed or transplanted by the University.

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<sup>3</sup> There are basically four liver transplant procedures; donor liver transplant, a cut down donor liver transplant to fit into a smaller patient, a split donor liver transplant into two patients and live donor transplant, a portion of live donor's liver is transplanted into a patient. The later procedure places a healthy donor at risk, and therefore is done less frequently. The live donor procedure requires two surgical teams, one for the donor and one for the recipient patient, therefore a new program such as Swedish's would not only lack the experience but the staffing levels to conduct such a procedure. It was unclear from the evidence how long before Swedish would perform live donor transplants. The University has only performed one live donor transplant.

<sup>4</sup> Some Washington patients seek treatment from Oregon Health & Sciences University in Portland for insurance or veteran benefit coverage or because they live close to Portland in southwest Washington. WWAMI patients may also seek treatment elsewhere to be close to family/friends, for benefit coverage, or because other facilities have less conservative wait list selection criteria and/or transplantation protocols related to the acceptance of donor livers and matching patients to donor livers.

<sup>5</sup> Peer programs are those with similar size, quality of care and are serving a similar patient population/market. AR 605, 613-622.

1.5 The allocation of donor livers is a critical factor in the needs analysis for Washington and WWAMI. To understand the importance of the "sickest" first treatment standard for liver transplantation and donor liver allocation, one needs to understand its brief history. Prior to the existing donor liver allocation system, donor livers were allocated by length of time that a patient's name was on a wait list. Some patients were placed on waiting lists before they were very sick or before they needed a transplant, resulting in healthier patients receiving transplants first. As a result some sicker wait list patients with a shorter wait list time were dying unnecessarily.

1.6 To solve this problem, the Institute of Medicine recommended in 1999 that liver allocation could be improved with a new allocation system that focuses on the severity of the patient's illness rather than patient's wait list time. In response to this recommendation, the Department of Health & Human Services created the Organ Procurement and Transplantation Network (OPTN) to improve donor organ procurement and to assure fair distribution of organs, primarily based upon medical urgency.<sup>6</sup> OPTN awarded the contract to establish the allocation system and a scientific registry to United Network for Organ Sharing (UNOS).

***New allocation system: Model for End-Stage Liver Disease (MELD)***

1.7 In February 2002, after careful evaluation and studies predicting mortality related to liver disease, UNOS adopted the Model for End-Stage Liver Disease (MELD). The MELD system is an evidence based system relying on objective lab test results

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<sup>6</sup> AR 734.

rather than subjective findings.<sup>7</sup> This system satisfied the recommendation made by the Institute of Medicine and the Department of Health and Human Services that emphasizes disease severity rather than time on wait lists.<sup>8</sup>

1.8 The MELD system generally dictates that the sickest patients on the wait lists are transplanted first, unless the patient's condition deteriorates so much that it is highly likely the patient will die even with a transplant. The transplant program such as the University makes that decision and removes those patients from its list.<sup>9</sup> The question in the case at hand is whether the University is treating/placing the sickest patients on its wait list or is it to some degree "cherry picking" its patients and donor livers? To answer this question one must understand the MELD allocation system.

1.9 The MELD system of allocation is divided into six basic levels pursuant to the severity of the illness (mortality risk) and the location of the patient in relation to the donated liver.<sup>10</sup> In an attempt to maintain fair, current and accurate information regarding the patient's life expectancy without a transplant, the MELD system requires regular reassessment of patients.<sup>11</sup> The reassessment is completed by a review of the patient's new lab test results that may result in a new MELD score and a new place on

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<sup>7</sup> The lab test results used to help calculate the MELD score are the values for Creatinine (kidney function), Bilirubin (liver's bile secretion function) and IRN (liver's blood clotting function).

<sup>8</sup> AR 737 and 560.

<sup>9</sup> AR 560.

<sup>10</sup> Six MELD levels of mortality risk: 1. local "Status 1" patients with a life expectancy less than 7 days without transplant, 2. regional "Status 1" patients, 3. local patients in descending order of mortality risk scores, the probability of pre-transplant death, 4. regional patients in descending order of mortality risk scores, 5. national "Status 1" patients, and 6. national patients in descending order of mortality risk status. AR 560.

<sup>11</sup> The MELD mortality risk status is divided into five tiers for reassessment and transplant priority purposes: 1. Status 1 patients are reassessed every 7 days, 2. Patients with a MELD score 25 or greater are reassessed every 7 days, 3. Patients with a MELD score between 24-18 are reassessed every month, 4. Patients with MELD scores between 18-11 are reassessed every 3 months, and 4. Patients with MELD scores between 10-0 are reassessed every 12 months.

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the MELD priority list. These MELD scores are entered into the UNOS system that helps quickly determine the allocation of donor organs pursuant to the MELD system with current information.

1.10 Health care facilities of liver donors notify the local organ procurement organization of donor liver availability and provide the clinical information that is necessary to offer the liver to a transplant facility such as to University. The local organ procurement organization<sup>12</sup> responsible for the distribution of the donor liver contacts the facility with the patient(s) qualified under the MELD system to receive the donated liver. If there is no "Status 1" regional (non-local) patient with priority, the donor liver is offered to the local transplant program such as the University.

1.11 If a local transplant program such as the University rejects the organ, the organ procurement organization goes down the MELD priority list contacting the non local program with the patient(s) next qualified to receive a donor liver under the MELD allocation system. A local liver transplant program uses its discretion/protocols to determine whether a donor liver is an appropriate match to its wait list patient(s) qualified to receive the organ under the MELD system. The local liver transplant program may or may not accept the donated organ after reviewing the information regarding the donor and the donated organ.<sup>13</sup>

1.12 The MELD system provides an objective standard to prioritize patients once they are on the wait list, but the system does not set forth criteria to determine:

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<sup>12</sup> There are approximately 59 organ procurement organizations. Life Center Northwest is the local organ procurement organization for the University.

<sup>13</sup> AR 572.

- a. which patients should be placed on the list,
- b. which donor livers should be accepted or rejected by a liver transplant program, or
- c. which match is appropriate - donor liver to a particular patient on the wait list.

1.13 Within these areas of discretion, the statistical analysis indicates that the University has been too conservative and less innovative in its approach.<sup>14</sup> As a result, healthier patients with lower MELD scores and an insufficient number of patients have been placed on the University's liver transplant wait list, and too many donor livers have been "turned down" by the University.<sup>15</sup> The statistics indicate that the University's conservative approach has under-served patients suffering from end stage liver disease who warrant a place on the wait list and/or patients on the wait list who would be a reasonable recipient of a "rejected" donor liver.<sup>16</sup>

#### **Patient choice/competition**

1.14 The University has not performed as many transplants as would be expected considering the rate of liver disease and the population of WWAMI or Washington. A second program is needed for patient choice/competition that will promote innovation and discourage complacency, resulting in the treatment of a higher percentage of sicker patients and better use of donor organs. The Swedish program would provide this needed choice/competition.

1.15 The transplant program uses its discretion to determine whether the donor liver matches the patient's needs. In doing so, the liver's quality and function is

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<sup>14</sup> AR 45-48, 618 and testimony of Drs. Marks, Dickson, Hart and Miller.

<sup>15</sup> All but two of the "exported" livers (between 1999- 2002) were successfully transplanted

<sup>16</sup> AR 614 and the testimony of Drs. Marks, Dickson, Hart and Miller.

evaluated based upon clinical information such as age, fat content/body mass index, cold ischemic time, illicit drug/alcohol use and the cause or the donor's death. The program needs to assess the risk of transplant failure resulting in the need for retransplantation, excessive hardship on the recipient and high post operative recovery cost.

1.16 A program's acceptance standards of donor livers affect the number of patients who receive livers. For example, livers donated after cardiac death were routinely rejected until innovative treatment disclosed that some livers donated after cardiac death could be successfully transplanted. This innovation greatly increased the pool of usable donor organs. The University was slow to respond to this innovation, and therefore deprived patients of transplants with viable livers donated after cardiac death. Dr. Marks, as Director of Life Center Northwest, the local organ procurement organization, was frustrated at the University's slow acceptance of this type of donor liver.

1.17 Medical literature concludes that programs in areas without competing liver transplantation programs treat less sick patients and those programs in areas with competition treat patients at significantly higher MELD scores.<sup>17</sup> Liver transplantation is a relatively new field, therefore innovation is important. "Collegial competition" between two facilities with good reputations such as Swedish and the University will generate

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<sup>17</sup> Schaffer, Kulkarni, Harper, Millis & Cronin, The Sickest First? Disparities with Model for End-State Liver Disease-Based Organ Allocation: One Region's Experience, *Liver Transpl.* 2003:9:1211-1215. This article concludes that competing centers create patient choice, "programs performed transplantation on patients at a significantly higher MELD score than transplant service areas dominated by a single center." The study upon which this article is based included approximately 10% of the nations liver transplants including transplant service areas that had one transplant provider comparing areas with multiple providers. AR 734-738.

better ideas, increase innovation and decrease complacency, therefore improving the quality of care and expanding the organ pool to the point where Washington may start importing more organs than it exports.<sup>18</sup>

1.18 In evaluating patients, the MELD system directs the treatment of the sickest patients first whenever medically practical, whether it is placing a patient on a wait list or matching a patient to a donor liver. The University transplants a higher percentage of patients with lower MELD score patients than its peers.<sup>19</sup> Competition stimulates facilities to be more innovative, provide better care, reach out and treat sicker patients (higher MELD scores). The addition of the Swedish program will provide patients with a choice, and therefore a greater opportunity for the sicker patients to be wait listed and transplanted as intended by the MELD liver allocation system, and recommended by the Institute of Medicine and the Department of Health & Human Services.

#### **Export/import of donor livers**

1.19 The University rejected approximately 126 donor livers from 1999 through 2002, 98 of which were elective exports under the MELD system. Approximately 28 were exports for "Status 1" patients, mandatory exports pursuant to the MELD allocation system that is based upon mortality risk.<sup>20</sup> All but 2 of the exported livers were successful upon transplantation.<sup>21</sup> All of these livers would probably not have been

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<sup>18</sup> See AR 22-23, the testimony of Dr Dickson, Day 4 at 49 and Dr. Miller, Day 4 at 115-116.

<sup>19</sup> Despite the fact that the University transplant a higher percentage of patients with lower MELD scores, the University's transplant patient three year survival rate is lower that its peers who treat a higher percentage of sicker patients with higher MELD scores. AR 614 and 617.

<sup>20</sup> See footnote #10.

<sup>21</sup> Statistics regarding transplant success for longer periods of time were not present, because UNOS did not collect that data (other than data regarding transplantation of livers donated after cardiac death).

exported if more patients were on the list, and/or the University used less conservative criteria to accept/match donor livers to patients.<sup>22</sup> A longer wait list provides a larger pool, therefore increasing the probability of a compatibility match of donor liver to patient.

1.20 Life Center Northwest, the local organ procurement organization's export rate is composed of the donor livers rejected by the University<sup>23</sup> and the mandatory MELD export for "Status 1" non local patients.<sup>24</sup> Life Center Northwest's 27% export rate is close to the 25% national average, but that is not a reasonable figure for comparison purposes. Life Center Northwest's export rate should be compared with organ procurement organizations with similarities such as population served and similar programs served. These comparable organ procurement organizations have much lower export rates from approximately 10% to 15%.<sup>25</sup>

#### **Number of Patients on the University's Wait List**

1.21 There are an unknown number of patients with undiagnosed liver disease, patients diagnosed but never referred to a transplant center and patients evaluated by a transplant center but not listed for transplantation.<sup>26</sup> Swedish proposes to reach these

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During this period of time more patients on the University wait list may have survived through innovations such as earlier utilization of livers donated after cardiac death. AR 601, 620.

<sup>22</sup> One factor used to analyze the University's conservative, less innovative approach is its retransplantation rate as compared to the University's peer programs; Stanford 13%, University of Pittsburg 13%, UCLA 13% and Baylor 7%. The national retransplantation rate is 9%. The University's low 2.8% retransplant rate is probably the result the University transplanting more patients with lower MELD scores than its peers transplant. AR 23.

<sup>23</sup> Children's may also reject offered donor livers, but no evidence was presented regarding any donor livers Children's may have rejected.

<sup>24</sup> In 2002, only seven of the thirty exported livers were mandatory exports from Life Center Northwest.

<sup>25</sup> These four comparable organ procurement organizations serve the San Francisco Bay area, Los Angeles County, Nebraska and Colorado. AR 621-622.

<sup>26</sup> AR 738.

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patients with less conservative, more innovative wait list/treatment protocols, and through outreach/education of patients and health care providers. Through these methods, Swedish should increase the number of patients who are wait-listed and/or eligible to receive a liver transplant.

1.22 The population, liver disease and deaths statistics indicate that patients in Washington state and WWAMI region are "falling through the cracks".<sup>27</sup> Some patients may choose to be treated elsewhere for family support, veteran/insurance coverage reasons, but the statistics indicate that more patients should be on the University's wait list, and the number of exported livers should not be as large as it is. Patients probably come to Washington as some patients leave to be close to friends or family for support during the transplant process. Therefore, this factor may not be significant in the statistical analysis as the University asserts.

1.23 The average number of residents on wait list per million residents is 60 nationally, 14 in the WWAMI region, 38 in Arizona, 106 in California, 17 in Georgia, 82 in Maryland, 47 in Missouri, 55 in North Carolina, 48 in Tennessee and 46 in Virginia.<sup>28</sup> Washington is comparable to North Carolina with an 8.2 million population. The University serves the WWAMI region that has an 8.8 million population (6 million in Washington alone). North Carolina has a 251 patient wait list, and the University has only 127 patients on its list.<sup>29</sup> As Dr. Dickson stated; "WWAMI region is grossly

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<sup>27</sup> AR 605, 608-619, 764-7.

<sup>28</sup> AR 618.

<sup>29</sup> AR 45-8, 618.

underrepresented in persons on the wait list per million residents, falling only below Georgia<sup>30</sup>

1.24 These comparisons indicate that the University should have many more patients on its wait list. In light of these statistics, Drs. Marks, Miller, Hart and Dickson are more credible and persuasive than the experts presented by the University. The addition of a second program is needed for patient choice/competition that will result in increased innovation, decreased complacency and improved volume and quality of care. Even though the University on average performs transplants on its wait list patients at a faster rate, there should not be such a large discrepancy with its wait list size. A shorter list will result in patients being transplanted faster since the patients do not have as much competition on the shorter list. The wait list size does not dictate the number of transplants, but the longer the wait list the more varied the patients' needs (matching criteria of patient to donor liver). Therefore a longer wait list will probably result in higher use of the available donor livers and a lower donor liver export rate.<sup>31</sup>

1.25 Patients who are turned down by the University and not placed on its wait list can seek care from another facility out-of-state.<sup>32</sup> However, increased cost or lack of

<sup>30</sup> Day 4 at 44-5. Dr. Dickson's point is supported by indicated by Table 5 at AR 617 that shows the average number of resident on wait list per million residents nationally is 60, 14 in the WWAMI region, 38 in Arizona, 106 in California, 17 in Georgia, 82 in Maryland, 47 in Missouri, 55 in North Carolina, 48 in Tennessee and 46 in Virginia. AR 618.

<sup>31</sup> A number of physicians who refer patients to the University's program find that their patients receive good treatment, and that their patients do not have to seek care elsewhere. A number of those practitioners were trained or closely affiliated with the University. It would be reasonable to conclude that they have similar standards as the University. Letters submitted by these physicians fail to address many of the issues raised by the statistical analysis such as wait list size and MELD scores discrepancies. AR 501-528 and 651-658.

<sup>32</sup> See Dr. Green's testimony at 21 of Exhibit 11 and Dr. Dickson's testimony regarding patients who migrated out of state for liver transplants.

information may result in patients not seeking out-of-state care. As a result these patients may die.

### **Minimum volume standards**

1.26 The University has a fellowship liver transplant education and training program with one fellow. The University argues that its existing transplant volume levels are necessary to maintain quality training and research programs. That argument is asking the health law judge to set new minimum standards for a liver transplant program after expert medical organizations have done so. That would be inappropriate. UNOS and the American Society of Transplant Surgeons (ASTS) are clearly better qualified to determine minimum volumes needed to sustain a fellowship training program.<sup>33</sup>

1.27 In evaluating potential adverse impact on the University's program, one must rely on the minimum standards set by UNOS and ASTS.<sup>34</sup> UNOS and ASTS require a liver transplant training program to perform 50 liver transplants annually and a liver transplant fellow must participate in 45 liver transplants as primary surgeon or as first assistant over a two year period.<sup>35</sup> In light of the number of University transplants, the potential for the increase in the number of transplants, the University's annual transplant volume should remain well above the minimum volumes set by the experts through UNOS and ASTS.

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<sup>33</sup> There are approximately 120 UNOS approved liver transplant programs of which approximately 44 have fellowship training programs.

<sup>34</sup> Even if the University's program were to expand to two fellows, the University would probably perform more than the requisite number of transplants for a training program with the addition of competing transplant program.

<sup>35</sup> AR 943.

1.28 In assessing the potential impact on the University's fellowship training program, one should compare it with other well know peer academic programs. These programs have annual volumes that are comparable or lower than the University.

1.29 There are no minimum volume standards for liver transplant programs without a fellowship training program. One study concludes that transplant outcomes are better at high volume programs but find no clear minimal threshold volume.<sup>36</sup> Another study regarding minimum volume standards concluded that liver transplant programs under 20 transplants a year experienced higher mortality rates, and that the mortality rates varied little when programs performed twenty or more transplant annually.<sup>37</sup> Swedish projects that its new program will be performing 18 transplants during its second year of operation, 32 in its third year, 42 in its fourth year and 48 in its fifth year.<sup>38</sup> Swedish will be soon above 20 transplants a year, and the statistical analysis indicates that the University will remain well above 20 transplants a year.

1.30 To evaluate the potential adverse effect, one needs to review the national and local upward trends in the number of liver transplants, liver disease and population. The University stated that it had an excellent program when its volumes were even lower than the volumes in 2003 and 2004. The University performed approximately 68 transplants in 1998, 67 transplants in 1999, 93 in 2000, 71 in 2001, 79 in 2002, 104 in 2003 and 126 in 2004.<sup>39</sup> The 5 % national annual growth rate in liver transplants during

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<sup>36</sup> AR 1178-1185, Axelrod, Guidinger, McCullough, Liechtman, Punch, Merion, Association of Center Volume with Outcome after Liver and Kidney Transplantation, Am J of Transplantation 1999; 4: 920-7.

<sup>37</sup> AR 780, 1518-1522, Edwards, Roberts, McBride, Schulak, Hunsicker, The Effect of the Volume of Procedures at Transplantation Centers on Mortality After Liver Transplantation, N Engl J Med 199, 341: 2049-53.

<sup>38</sup> AR 36.

<sup>39</sup> Dr. Carithers on direct examination, Day 3 at 19 and AR 70, 1068.

this same period probably will continue. Also, a new program at Swedish will increase the total number of liver transplants through innovation and competition.

1.31 The addition of a new liver transplant program is not a "zero sum game". Any Swedish transplant would not necessarily subtract a transplant from the University's volume. As Dr. Dickson and Dr. Miller explained, more than one program in a service area results in the performance of a greater total number of transplants because competition promotes additional transplants. Additional transplants are the result of competition/innovation because more than one provider determines who qualifies for a transplant, is interested in promoting organ donations, and is available during peak demand within the service area. Therefore, the addition of a second program to this service area will not result in the creation of an unneeded program leading to mediocrity and low volumes for both programs.

#### **Adequate Staffing levels**

1.32 Swedish's proposed liver transplant program includes adequate staffing levels for the projected transplant volumes, and clinical care/assessment before and after the transplant. Staffing levels need to take into account the patients who are assessed but who are not placed on a list, and those who are placed on the list but who do not receive a transplant.<sup>40</sup> A liver transplant program requires available staff twenty-four hours a day seven days a week.

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<sup>40</sup> Swedish transplant program started 1993 and presently includes pancreas, kidney, and bone marrow. These programs have demonstrated innovations such as steroid free immunosuppression for kidney transplantation, the first facility in the Northwest to offer this protocol. The University now provides this treatment but in a different fashion, therefore offering a patient a choice in care. AR 630-1.

1.33 Swedish's proposal includes a new hepatologist and liver transplant surgeon who will work with the existing staff. UNOS liver transplant program standards require one qualified liver transplant surgeon on site.<sup>41</sup> Swedish's existing transplant program includes three board-certified surgeons<sup>42</sup>, a urologist, a nephrologist and six rotating nephrologists. It also includes residents in training, transplant nursing staff with special training and assignments, a transplant pharmacist, a transplant pathologist, a transplant infections disease group, a social worker, a data manager and a research fellow. Some of the existing staff members will work with the new liver transplant program in addition to the existing program since it will be part of the Swedish transplant program.

#### **Financial Feasibility**

1.34 Because Swedish will use existing transplant program facility and staff with the addition of two physicians, equipment and training, the initial capital costs are relatively small.<sup>43</sup> Swedish can appropriately finance the proposed liver transplant program from existing Swedish funds and projected income, and the project will not result in an unreasonable impact on the cost and charges for liver transplant health care services.<sup>44</sup> The Swedish program will probably result in an increase in the overall health care costs in Washington, but not as a result of unnecessary duplication. This increase

<sup>41</sup> Board certified in surgery, urology or osteopathic surgery. AR 779, 943, 947.

<sup>42</sup> UNOS requires a liver transplant program to have one qualified transplant surgeon on site. UNOS qualified transplant surgeon must be board certified by either American Boards of Surgery or Urology, the American Board of Osteopathic Surgery, or their foreign equivalent.) Two of Swedish's transplant surgeons are certified by the American Board of Surgery. AR 779.

<sup>43</sup> Swedish service agreements with the local organ procurement organization, the local blood bank demonstrates its relationships with ancillary and support service providers currently serving other Swedish programs and that it will continue the relationship to support a liver transplant program.

<sup>44</sup> AR 56-66 (pro forma budget and volume/revenue projections), and AR 776-781.

will result from the increased number of Washington residents receiving transplants. Liver transplants on average extends a life by 12 years, therefore the increased costs are not unreasonable.<sup>45</sup>

## II. CONCLUSIONS OF LAW

### Purpose of the Health Planning & Development Act

2.1 In response to the 1974 National Health Planning and Resources Development Act, the Washington legislature adopted Washington's 1979 Health Planning & Development Act creating the certificate of need program. Chapter 70.38 RCW and *St. Joseph Hospital & Health Care Center v. Department of Health*, 125 Wn2d 733, 735-736 (1995). One of the purposes of the federal and state health care planning acts was to control health care costs. *Id.* Both legislative bodies were concerned that competition in health care "had a tendency to drive health care cost up rather than down, and government therefore needed to restrain marketplace forces. *Id.* at 741. The CON regulations are therefore designed in part to control rapid rising health care cost by limiting competition within the health care industry". *Id.*

2.2 The CON statutory scheme protects existing facilities from competition "unless a need for additional services" can be demonstrated. *Id.* at 742. Swedish's CON will meet a public need of increasing number of liver transplants and need for more innovative/less conservative program that will not adversely affect the University's program and may also improve the quality of care at both facilities.

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<sup>45</sup> AR 781.

2.3 The CON statutory requirements limit provider entry into the health care markets so the development of 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).

2.4 The Department of Health (the Program) is responsible for managing the CON chapter under chapter 70.38 RCW. RCW 70.38.105(1). Certificates of Need shall be issued or denied in accordance with Health Planning & Development Act and the Department rules which establish the review procedures and criteria for the CON program in chapter 246-310 WAC. RCW 70.38.115(1).

2.5 This health planning process must consider the "cost-effectiveness and cost-benefit analysis" and provide accessible health care services "while controlling excessive increases in costs". RCW 70.38.015(1) and (5).

#### **Liver Transplant Programs**

2.6 Liver transplantation programs are hospital-based "tertiary services" that are subject to CON review. WAC 246-310-020(1)(d)(i)(D). The Department rules do not set minimum standards for liver transplant facilities, unlike kidney facilities that must perform at least 15 transplants by its fourth year of operation, and must meet the United Network for Organ Sharing (UNOS) requirements for organ sharing.

WAC 246-310-260(2)(a)(b). Even though the Department rules are silent on the issue of minimum volumes for liver transplant centers, UNOS and the American Society of Transplant Surgeons (ASTS) have minimum standards/volumes for liver transplant fellowship training programs. It is unreasonable for the CON Program or a Health Law

Judge to create standards that conflict with the well researched standards set by these expert organizations. UNOS and ASTS do not have minimum volume standards for a liver transplant program that does not include a fellowship training program. After review of available literature regarding liver transplant volumes and outcomes, the CON Program reasonably concluded that Swedish and the University would meet minimum volumes that results in good quality of care in their liver transplant programs.<sup>46</sup>

2.7 The general CON criteria apply to a liver transplant program application.

An applicant for a CON shall establish that it meets all applicable criteria:

WAC 246-10-606. The CON Program then renders a decision whether to grant a CON in a written analysis that must contain sufficient information supporting its decision.

RCW 70.38.115(2) and WAC 246-310-200 outline the criteria that the CON Program must address in determining whether it should grant or deny a CON. Those criteria are "need" (WAC 246-310-210), "financial feasibility" (WAC 246-310-220), "structure and process (quality) of care" (WAC 246-310-230), and "cost containment"

(WAC 246-310-240). The Program's written analysis contains sufficient information regarding "need", "financial feasibility", "structure and process (quality) of care" and "cost containment" criteria that support the issuance of the Swedish CON. Swedish's application established that it met the requisite criteria.

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<sup>46</sup> AR 780

**Need – WAC 246-310-210**

2.8 A preponderance of the evidence supports Program's conclusion that there is a need for Swedish's proposed liver transplant facility. As stated in WAC 246-310-210(1):

The population served or to be served has need for the project and other services and facilities of the type proposed are not or will not be sufficiently available or accessible to meet that need... (Emphasis added)

Patient choice may be used under this criteria when evidence demonstrates a public need for a second transplant facility, and when that facility does not adversely affect the existing facility. St. Joseph at 742. There is a need for a second facility. The lack of patient choice resulted in some patients not receiving necessary and proper care or traveling longer distances to obtain care.<sup>47</sup>

2.9 Because The CON Program does not have a rule or established numeric needs projection methodology for liver transplant services, Swedish provided a rational and verifiable analysis of need. Swedish's need analysis examined national and local liver disease/mortality and transplant program statistics, and demonstrated that the existing facility is not meeting the transplant needs of all eligible transplant recipients.

2.10 A preponderance of the evidence supports The CON Program's conclusion that the Swedish program will not have an adverse effect on University's research and training programs. The pertinent part of WAC 246-310-210 states:

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<sup>47</sup> The University cites the *Olympic Peninsula Kidney Center* decision. Docket No. 04-06-C-2003CN (2005). Contrary to the University's argument, the decision held that patient choice is a legitimate CON factor in the review of CON applications whenever there is need and the facilities would provide the patients with a realistic choice. In *Olympic*, the geographic distance between the dialysis facilities in question precluded a realistic patient choice, therefore competition/patient choice was found to be unsupported by the facts, unlike the case at hand.

The determination of need for any project shall be based on the following criteria...

(4) The program will not have an adverse affect on health professional schools and training programs. The assessment of the conformance of the project with this criterion shall include consideration of:

(a) The effect of the means proposed for the delivery of health services on clinical needs of health professional training program in the area in which the services are to be provided; and

(b) If the proposed health services are to be available in a limited number of facilities, the extent to which the health professional schools serving the area will have access to the services for training purposes. (Emphasis added)

2.11 Analysis under subsection (a) indicates that the addition of Swedish's competing program, with different selection criteria and treatment protocols will increase the number of Washington patients on wait lists and the number of liver transplants. Innovation and less conservative protocols will increase the use of the existing donor livers. Population increases and education/recruitment of new donors will increase the overall size of the donor pool. In light of these factors, the literature regarding minimum volume standards and UNOS minimum volume standards, a new Swedish liver transplant program should not have an adverse effect on the University's training or research programs as well as its clinical program. The simple reduction of the total number of transplants is not sufficient evidence of adverse affect in light of UNOS/ASTS standards and the statistical analysis regarding population, liver disease and liver transplants.<sup>48</sup>

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<sup>48</sup> University argues that WAC 246-310-210(3) applies. This subsection addresses applications that contain proposed training and/or research programs; therefore it does not apply to the Swedish application. Subsection (4) addresses applications that may affect existing training programs and research programs and therefore subsection (4) applies to the case at hand.

2.12 Subsection (b) does not apply since the University has its own liver transplant program and therefore will not need to have "access to the services for training purposes".

**Financial Feasibility – WAC 246-310-220**

2.13 A preponderance of the evidence supports the Program's conclusion that Swedish's proposed liver transplant program is "financially feasible" because: 1) the capital and operating project costs can be met; 2) the costs of the project will not result in "an unreasonable impact" on the costs and charges for health care services; and 3) "the project can be appropriately financed." WAC 246-31-220(1)-(3).

2.14 The Swedish program will increase in the overall health care costs in Washington, but not as a result of "unnecessary construction or duplication". WAC 246-210-220(2). This increase will result from an increased number of transplants. This increased cost is not unreasonable, because a liver transplants extends a life by approximately 12 years.<sup>49</sup>

2.15 The initial capital costs are relatively small, and Swedish intends on using existing transplant program facility and staff with the addition of two physicians, equipment and training. Therefore, Program reasonably concluded that Swedish's transplant program "will not have an unreasonable impact" on the health care costs and charges to the public. WAC 246-310-220(2) and WAC 246-310-240(2)(b).

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<sup>49</sup> AR 781.

### **Structure and Process (Quality) of Care – WAC 246-310-230**

2.16 A preponderance of the evidence supports the Program's conclusion that Swedish's proposed program will foster an "acceptable or improved quality of care" because the Swedish program will have sufficient staff, appropriate relationships with needed ancillary and support services, and "will not result in an unwarranted fragmentation of services". WAC 246-310-230(1)-(5).

2.17 Swedish's liver transplant program will not result in unwarranted fragmentation of services because the University will maintain volumes well above the "low volume standard" associated with higher mortality rates. In addition, a Swedish program should decrease fragmentation because fewer patients will probably travel out of state to receive a liver transplant.

### **Cost Containment – WAC 246-310-240**

2.18 A preponderance of the evidence support Program's conclusion regarding "cost containment." As stated in WAC 246-310-240:

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... (Emphasis added)

A second facility will probably provide services to the types of patients who have been denied access in the past, and provide more "efficient" (not having to travel out of state) or "effective" care (qualified patients not receiving a place on wait list and/or transplants). WAC 246-310-240.

2.19 The party appealing the CON Program decision has the burden of proof in the adjudicative proceeding. The standard of proof is a preponderance of the evidence.

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WAC 246-10-606. Evidence should be the kind that "reasonably prudent persons are accustomed to rely in the conduct of their affairs." RCW 34.05.461(4). Sufficient evidence was present to support Program's decision to grant a CON to Swedish for a liver transplant program. University failed to present a preponderance of the evidence that supports its appeal regarding the issuance of the Swedish CON.

### III. ORDER

Based on the foregoing findings of fact and conclusions of law, the Program's issuance of Swedish's CON for a liver transplant facility is affirmed.

Dated this 23<sup>rd</sup> day of August, 2005.

  
\_\_\_\_\_  
ZIMMIE CANER, Health Law Judge  
Presiding Officer

### NOTICE TO PARTIES

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:

Adjudicative Service Unit  
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

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	Time: <u>9:00 a.m.</u>
	Judge/Calendar: <u>Tabor</u>

**FILED**

JAN 13 2006

SUPERIOR COURT  
BETTY J. GOULD  
THURSTON COUNTY CLERK

SUPERIOR COURT OF WASHINGTON FOR THURSTON COUNTY

UNIVERSITY OF WASHINGTON  
MEDICAL CENTER.

No. 04-2-01506-2

Petitioner,

ORDER GRANTING UNIVERSITY OF  
WASHINGTON MEDICAL CENTER'S  
REQUEST TO ACCEPT ADDITIONAL  
EVIDENCE OR, IN THE  
ALTERNATIVE, REMAND TO THE  
DEPARTMENT OF HEALTH TO TAKE  
ADDITIONAL EVIDENCE

v.

WASHINGTON STATE DEPARTMENT  
OF HEALTH,

Respondent.

SWEDISH MEDICAL CENTER.

Intervenor.

THIS MATTER having come on for hearing before the above-entitled Court on December 23, 2005, upon Petitioner University of Washington Medical Center's ("UWMC's") Request to Accept Additional Evidence or, in the Alternative, Remand to the Department of Health CON Program, the Petitioner appearing by and through its attorneys of record, Kathleen D. Benedict and Sally G. Garratt of Benedict Garratt, PLLC, Respondent Washington State Department of Health appearing by and through its attorney of record, Richard McCartan, Assistant Attorney General; and Intervenor Swedish Medical Center appearing by and through its attorney of record, Stephen I. Pentz

ORDER GRANTING UWMC'S  
REQUEST TO ACCEPT EVIDENCE

BENEDICT GARRATT, PLLC  
235 Fourth Avenue East, Suite 200  
Olympia, Washington 98506  
Telephone (360) 236-9858  
Facsimile (360) 943-4427

1 of Bennett Bigelow & Leedom, P.S.; and the Court having reviewed the records and files  
2 herein and being fully informed in the premises, now, therefore, it is hereby

3 ORDERED as follows:

- 4 (1) The UWMC's request to accept new evidence is granted.
- 5 (2) This matter is remanded to the Health Law Judge, and the Health Law  
6 Judge shall decide whether or not to hear the information and take the additional  
7 testimony ~~requested by UWMC~~ <sup>KB SP RM</sup> or remand the matter to the Department's Certificate of  
8 Need Program to hear the information and take the additional testimony.
- 9 (3) <sup>UWMC alleges KB RM</sup> It appears information was excluded that would assertedly counter  
10 findings by the Department, the Health Law Judge, or both.
- 11 (4) Fundamental fairness and due process require that if there is new  
12 information placed in an administrative record, a party has the right to respond and that  
13 right to respond was not given to UWMC under the circumstances.
- 14 (5) The offer of proof submitted in the administrative proceeding below  
15 informed the court of the substance of the excluded testimony but does not go into  
16 sufficient detail to substitute for the testimony itself. Therefore, the administrative  
17 proceeding must be reopened in order to receive the information in the form of additional  
18 testimony.
- 19 (6) UWMC was not required to request reconsideration of the Certificate of  
20 Need Program's Analysis and decision prior to offering additional evidence to counter  
21 new information contained in the Rebuttal submission of Swedish. Thus, at the  
22 adjudicative proceeding, UWMC was not prohibited from responding to the rebuttal  
23 submission submitted by Swedish because it did not seek reconsideration.

24 DATED this 13 day of January, 2006.

GARY R. TABOR

25 JUDGE

26 ORDER GRANTING UWMC'S  
REQUEST TO ACCEPT EVIDENCE

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Presented by:

BENEDICT GARRATT, PLLC

By: Kathleen D. Benedict  
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Attorneys for Petitioner  
University of Washington Medical Center

ROB McKENNA  
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BENNETT BIGELOW & LEEDOM, P.S.

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Stephen I. Pentz, WSBA #14089  
Attorneys for Intervenor  
Swedish Medical Center

ORDER GRANTING UWMC'S  
REQUEST TO ACCEPT EVIDENCE

3

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requested a copy of the application and any other information submitted to Program regarding the Swedish application.

1.2 On July 30, 2003, the University requested a public hearing regarding Swedish's application. Prior to and during the public hearing, the University and other interested parties submitted written comments and documents regarding the Swedish application. During the November 6, 2003 public hearing, the University and Swedish presented testimony and documents. On November 24, 2003, pursuant to WAC 246-310-160(1)(a), the University and Swedish submitted rebuttal documents to oral and written information submitted during the public hearing. Swedish raised a new theory within its rebuttal statement regarding patients falling through the cracks. On November 24, 2003, the rebuttal period ended and Program closed the period for public/party input.

1.3 On June 30, 2004, Program issued Swedish a CN to establish a liver transplant program for adult patients. Pursuant to RCW 70.38.115(10), the University filed a request for an adjudicative proceeding protesting the issuance of this CN.<sup>1</sup>

1.4 During the January 25, 26, 27, February 3 and 4, 2005 administrative hearing before a Health Law Judge (HLJ), the University presented the testimony of six physicians, a health care consultant, and a staff member with United Network for Organ

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<sup>1</sup> Prior to the adjudicative appeal, the University participated in the administrative application review process as an "affected party" (defined in WAC 246-130-010) contesting Swedish's application for a liver transplant program CN.

Sharing.<sup>2</sup> Swedish presented the testimony of five physicians, the Program analyst, and the Program manager. Eleven exhibits were admitted two of which included a copy of Program's 1,548 page administrative record (AR) and the transcript of the public hearing regarding Programs' review of the Swedish application.

1.5 During the 2005 adjudicative proceeding, the HLJ concluded that the University failed to exhaust its administrative remedies by its failure to request reconsideration of Program's decision; and that reconsideration was the appropriate procedure to submit additional facts and data in respond to Swedish's November 2003 rebuttal statement.<sup>3</sup> As a result, the HLJ sustained objections regarding the presentation of facts and data that were not a part of the administrative record. During the 2005 administrative hearing, the University made an offer of proof in the form of the proposed exhibits. Swedish made a responding offer of proof.

1.6 On August 23, 2005, the HLJ issued Findings of Fact, Conclusions of Law and Final Order (Final Order) that affirmed Program's approval of Swedish's CN application for a liver transplant program. The HLJ concluded that even if the offers of proof were admitted as evidence, the findings of fact in the Final Order would not

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<sup>2</sup> The University's expert witnesses disagreed with Swedish's theory that patients are falling through the cracks and that Swedish's proposed liver transplant program is needed.

<sup>3</sup> Within 28 days of the Program's decision, any interested or affected person may, for good cause shown, request a public hearing for the purpose of reconsideration" of the decision on a certificate of need application. WAC 246-310-560(1). Good cause for a reconsideration hearing include but is not limited to:

(i) Significant relevant information not previously considered by the department which, with reasonable diligence, could not have been presented before the department made its decision; ... (iii) Evidence the department materially failed to follow adopted procedures in reaching a decision.

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

The HLJ concluded in Prehearing Order No. 4 that subsections (i) and (iii) encompass the University's arguments for a remand and additional hearing; and that the reconsideration procedure is more efficient for all parties consuming less time and expense than pursuing a remand through an adjudicative appeal.

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substantially change, and the conclusions of law and order would not be modified.

The University appealed this Final Order to Thurston County Superior Court.

1.7 On January 13, 2006, Superior Court Judge Gary R. Tabor held that the HLJ erred. Judge Tabor held that the University did not lose its right to present additional evidence in response to Swedish's rebuttal at the adjudicative proceeding by failing to request reconsideration of Program's decision. In his remand order Judge Tabor outlined the scope of the remand:

(5) The offer of proof submitted in the administrative proceeding below informed the court of the substance of the excluded testimony but does not go into sufficient detail to substitute for the testimony itself. Therefore, the administrative proceeding must be reopened in order to receive the information in the form of additional testimony.

1.8 During a March 2006 status conference and in Post-Hearing Order No. 1, the HLJ ruled that the evidence will be presented in the following order during the remand hearing;

1. The University may submit evidence in response to the Swedish's November 24, 2003 Rebuttal Statement that was submitted to Program.<sup>4</sup>
2. Swedish may submit evidence in response to the University's evidence admitted during the remand hearing.
3. The University may submit evidence in response to Swedish's evidence admitted during the remand hearing.<sup>5</sup>

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<sup>4</sup> The University was not limited to oral testimony although such a limitation could have been issued pursuant to paragraph 5 of Judge Tabor's remand order.

<sup>5</sup> The Program did not request the opportunity to present any evidence

1.9 Under the Washington Administrative Procedures Act (APA) chapter 34.05 RCW, a HLJ shall provide parties an opportunity to present evidence to the extent necessary for full disclosure of all the relevant facts and issues. RCW 34.05.449(2). The HLJs shall regulate the course of the proceedings in conformity with applicable rules and the prehearing order if any. RCW 34.05.449(1). In doing so the HLJ may restrict a party's opportunity to present evidence. RCW 34.05.449.

1.10 During the March 2006 status conference and in Post Hearing order No 1, the HLJ set a May 5, 2006 deadline for the filing of witness lists and proposed exhibits,<sup>6</sup> and limited the evidence to information that relies on facts and data that existed as of December 31, 2003.<sup>7</sup> This date is approximately five weeks after the rebuttal statements were submitted to Program, and five weeks after Program "closed" the public input stage pursuant to WAC 246-310-160. The public input stage is closed so Program may review and analyze an application with all the information that the applicant, interested parties and the public deem relevant and submit to Program.<sup>8</sup>

1.11 The December 31, 2003 date was selected by the HLJ because it provided the University with an opportunity to respond to the new theory raised in

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<sup>6</sup> Evidence that is not submitted in advance as ordered by the presiding officer should not be admitted in the absence of a "clear showing that the offering party has good cause for his or her failure to produce the evidence sooner, unless it is submitted for impeachment purposes". WAC 10-08-140(2)(a),(b). The purpose of the deadline is to provide the parties with sufficient time to prepare for hearing.

<sup>7</sup> During a May 18, 2006 prehearing conference, the HLJ granted the University a May 18th extension of time to submit additional exhibits that were not filed by the May 5<sup>th</sup> deadline. The parties were also granted a May 22<sup>nd</sup> extension of time to present redacted versions of timely filed exhibits (redacting the post 2003 data). The University did not provide good cause for its failure to file a number of its proposed exhibits by the extended deadline.

<sup>8</sup> The remand order did not address whether facts and data that did not exist at the time of Program's record "closure" should be admitted during the remand adjudicative proceeding.

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Swedish's November 2003 rebuttal statement, and at the same time set a reasonable date that does not deviate unnecessary far from the closure of the public input stage of the administrative record. If no date was set as the University requested, new information could be submitted that did not exist at the time the Program made its decision. Such a ruling could result in a revolving door of litigation with additional information submitted for the first time during the adjudicative and judicial stages. As a result, applicants and/or interested parties may tactically benefit from postponing the submission of additional facts until the adjudicative or judicial stages. This may be of special advantage when the interested party is a potential competitor who may want additional time to change the manner in which it provides health care. Closure is needed so a revolving door of delayed responses does not unreasonable draw out the process. Late presentation of facts and data would result in an increase number of appeals/remands and delays in the resolution of CN appeals. The purpose of CN adjudicative appeals is not to supplant the certificate of need application review process but to assure that the procedural and substantive rights of the parties were observed and that the factual record supports Program's analysis and decision.<sup>9</sup> The December 31, 2003 cut off date for evidence during the remand hearing is reasonable and consistent with the facts at hand and the CN regulatory framework.<sup>10</sup>

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<sup>9</sup> See page 8 Prehearing Order No. 6, Order on Motion for Partial Summary Judgment In re the Certification of Need Application of Ear, Nose, Throat and Plastic Surgery Association, Inc., Docket No. 00-09-C-1027CN.

<sup>10</sup> The CN applicant has the burden to provide information necessary to grant the requested CN. WAC 246-310-090. Interested parties may comment on the application and parties may provide rebuttal information. WAC 246-310-060, -180. Program shall complete its final review and make its decision on

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## II. REMAND HEARING

2.1 The remand hearing was scheduled for a three day hearing on June 6-8, 2006.

2.2 On June 6<sup>th</sup> the University rested after presenting its exhibits and the testimony of Robert Carithers, M.D. and James Perkins, M.D. Their testimony was extremely limited because they stated that they could not dispute the new theory raised in the November 2003 Swedish rebuttal without post 2003 facts and data.

2.3 None of the University's proposed exhibits were admitted because they were not timely filed,<sup>11</sup> contained post 2003 facts and data, and/or lacked proper foundation.

2.4 Swedish did not present any rebuttal evidence due to the limited evidence presented by the University.

2.5 The parties submitted closing arguments through briefs.

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the application within 45 days of the end of the public comment period, unless the public comment period is extended in accordance with the rules. WAC 246-310-160. A party may request reconsideration of the program's decision. WAC 246-310-560. Program's decision to grant or deny an application for a CN must be in writing and include the findings that are the basis of Program's decision. WAC 246-310-490(1).

<sup>11</sup> The University argues in its closing brief that deadlines are not applied in other CN adjudicative proceedings to preclude exhibits, and therefore the University is not being fairly treated. This is not true. This HLJ rejects exhibits that are not timely filed by deadlines set in prehearing orders when a party objects to the admission of the untimely identified exhibit. These deadlines would be meaningless unless so applied, and the failure to reject untimely identified exhibits would place the complying party at a strategic disadvantage.

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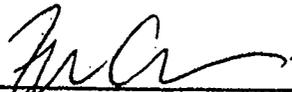
Docket No. 04-07-C-2005CN

001912

### III. ORDER

The August 23, 2005 Findings of Fact, Conclusions of Law and Final Order that affirmed Program's issuance of Swedish's CN for a liver transplant facility is  
**AFFIRMED.**

Dated this 15<sup>th</sup> day of August, 2006.

  
\_\_\_\_\_  
ZIMMIE CANER, Health Law Judge  
Presiding Office

### NOTICE TO PARTIES

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:

Adjudicative Service Unit  
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 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,

FINAL ORDER ON REMAND  
AFFIRMING FINDINGS OF FACT,  
CONCLUSIONS OF LAW AND  
FINAL ORDER DATED  
AUGUST 23, 2005

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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 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).

**FINAL ORDER ON REMAND  
AFFIRMING FINDINGS OF FACT,  
CONCLUSIONS OF LAW AND  
FINAL ORDER DATED  
AUGUST 23, 2005**

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	Date: 05/11/07
	Time: 9:00 a.m.
	Judge/Calendar: Tabor

FILED  
 SUPERIOR COURT  
 THURSTON COUNTY, WASH.  
 07 MAY 11 AM 10:34  
 BETTY J. GOULD, CLERK  
 BY \_\_\_\_\_  
 DEPUTY

SUPERIOR COURT OF WASHINGTON FOR THURSTON COUNTY

UNIVERSITY OF WASHINGTON  
 MEDICAL CENTER.

No. 04-2-01506-2

Petitioner,

ORDER GRANTING PETITION FOR  
 JUDICIAL REVIEW AND REVERSING  
 AWARD OF CERTIFICATE OF NEED  
 NO. 1288

v.

WASHINGTON STATE DEPARTMENT  
 OF HEALTH,

Respondent.

This matter came before The Honorable Gary R. Tabor on April 13, 2007, on the University of Washington Medical Center's Second Amended Petition for Judicial Review of the "Final Order on Remand Affirming Findings of Fact, Conclusions of Law and Final Order Dated August 23, 2005" (Agency Order). With this Agency Order, the Department of Health Law Judge had awarded Certificate of Need No. 1288 to Swedish Health Services for a liver transplant program.

The Court considered the records and written submissions of the parties, including: (a) University of Washington Medical Center's Second Amended Petition for Judicial Review or, in the Alternative, Petition for Judicial Review; (b) Brief in Support of University of Washington Medical Center's Second Amended Petition for Review; (c) Response Brief of Swedish Health Services; (d) Department of Health's Trial Brief;

ORDER GRANTING PETITION FOR JUDICIAL  
 REVIEW AND REVERSING AWARD OF  
 CERTIFICATE OF NEED NO. 1288

BENEDICT GARRATT POND, PLLC  
 1235 Fourth Avenue East, Suite 200  
 Olympia, Washington 98506  
 Telephone: (360) 236-9858  
 Facsimile: (360) 943-4427

P-AlternateOrder granting PR.doc

1 (e) University of Washington Medical Center's Consolidated Reply Brief in Support of  
2 its Second Amended Petition for Judicial Review; (f) Declaration of Sally Gustafson  
3 Garratt in Support of UWMC's Reply Brief in Support of Petition for Judicial Review;  
4 (g) University of Washington Medical Center's Second Request to Accept Additional  
5 Evidence or, in the Alternative, Remand to the Department of Health CON Program to  
6 Take Additional Evidence; (h) Supplement to Brief in Support of University of  
7 Washington Medical Center's Second Amended Petition for Review and Submission of  
8 Supplemental Authority; (i) Response Brief of Swedish in Opposition to UWMC's  
9 "Second Request to Accept Additional Evidence or, in the Alternative, Remand to the  
10 Department of Health CON Program to Take Additional Evidence"; (j) Department of  
11 Health's Memorandum Opposing UWMC Request to Accept Additional Evidence; and  
12 (k) University of Washington Medical Center's Consolidated Reply Brief in Support of  
13 Its Second Amended Petition for Judicial Review; and the Court further considered the  
14 administrative and superior court record herein. Having considered the evidence and  
15 hearing arguments of counsel, now, therefore, it is hereby ORDERED AND  
16 ADJUDGED THAT:

17 1. This Court has jurisdiction over the Second Amended Petition for Review  
18 pursuant to RCW 34.05.570(3).

19 2. This Court has the authority pursuant to RCW 34.05.574(1) to (a) affirm  
20 the agency action or (b) order an agency to take action required by law, order an agency  
21 to exercise discretion required by law, set aside agency action, enjoin or stay the agency  
22 action, remand the matter for further proceedings, or enter a declaratory judgment order.

23 3. The Second Amended Petition for Review is granted, <sup>the matter will not be</sup> ~~and the appropriate~~  
24 ~~remedy is to set aside the Agency Order.~~ ~~The Agency Order~~ awarding Certificate of  
25 Need No. 1288 to Swedish Health Services is reversed for the reasons detailed in the  
26 Court's oral decision attached hereto as Exhibit A:

KB  
remanded  
instead  
the Court  
is setting  
aside the  
agency order

the matter will not be

ORDER GRANTING PETITION FOR JUDICIAL  
REVIEW AND REVERSING AWARD OF  
CERTIFICATE OF NEED NO. 1288

2

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P-AlternateOrder granting PER due

1 a. The Agency Order is in violation of constitutional due process  
2 provisions and is set aside pursuant to RCW 34.05.570(3)(a);

3 b. The agency has engaged in unlawful procedure in its decision-  
4 making process and has failed to follow the decision-making procedure proscribed by  
5 law, and its Agency Order is set aside pursuant to RCW 34.05.570(3)(c);

6 c. The agency has erroneously interpreted and applied the law, and its  
7 Agency Order is set aside pursuant to RCW 34.05.570(3)(d);

8 d. The Agency Order is arbitrary and capricious and is set aside  
9 pursuant to RCW 34.05.570(3)(i);

10 *Alternatively, the Court stated that Swedish did*  
11 *not in its CON application address any potential impacts on*  
12 *existing or proposed institutional training programs as required*  
13 *terms of its impact on existing and proposed institutional training programs for doctors of*  
14 *osteopathic medicine and surgery and medicine at the student, internship, and residency*  
15 *training levels" as required by RCW 70.38.115.*  
16 *4. The Court stays the effect of the decision for a one-week*  
17 *period to more fully address*  
18 *Swedish's motion for stay.*

19 Dated this 11 day of May, 2007.

*[Signature]*  
The Honorable Gary R. Fabor

20 Presented by:  
21 BENEDICT GARRATT POND, PLLC

22 *Kathleen D. Benedict*  
Kathleen D. Benedict, WSBA #07763  
23 Attorneys for Petitioner

24 *Notice of presentation waived;*  
25 *All objections preserved =*  
26 *[Signature]*  
*Peter Ehrlichman*  
*for Swedish*

*[Signature]*  
Richard A. McCartan  
ASSIT Attorney General

ORDER GRANTING PETITION FOR JUDICIAL  
REVIEW AND REVERSING AWARD OF  
CERTIFICATE OF NEED NO. 1288

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