STATE OF WASHINGTON
DEPARTMENT OF HEALTH
ADJUDICATIVE SERVICE UNIT

In Re: Certificate of Need Application of:	)	Docket No. 04-07-C-2005CN
	)	
	)	FINDINGS OF FACT,
SWEDISH MEDICAL CENTER	)	CONCLUSIONS OF LAW,
	)	AND FINAL ORDER
	)	

APPEARANCES:

Petitioner, University of Washington Medical Center by
Kathleen D. Benedict, PLLC, per
Kathleen D Benedict, Attorney at Law

Intervener, Swedish Medical Center, by
Bennett, Bigelow & Leedom, per
Stephen I. Pentz, Attorney at Law

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

PRESIDING OFFICER: Zimmie Caner, Health Law Judge

This is the University of Washington Medical Center's (the University) appeal of the Department of Health Certificate of Need Program's (the Program) issuance of a certificate of need (CON) to Swedish Medical Center (Swedish) for a liver transplant program. Program Affirmed.

ISSUES

1. Whether Swedish's application contains sufficient information demonstrating that it meets all applicable criteria for a liver transplant program CON.

2. Whether the Program's written analysis contains sufficient information that supports its decision to issue the Swedish liver transplant program CON.

3. Whether a preponderance of evidence supports the University's appeal; that the Swedish CON application does not met the requisite CON criteria, and/or the Program's written analysis does not support the issuance of the Swedish CON.

HEARING

During the hearing on January 25, 26, 27, February 3 and 4, 2005, Swedish presented the testimony of Randall Huyck, CON Program Analyst, Janis Sigman, CON Program Manager, William Marks, M.D., Swedish's Director of Organ Transplant Program and Director of Life Center Northwest, Rolland Dickson, M.D., Mayo Jacksonville Clinic Director of Transplantation Research, Marquis Hart, M.D., University of California San Diego Director of Transplant Program, and Charles M. Miller, M.D., Cleveland Clinic Foundation Transplant Program Director.

The University presented the testimony of: Robert Carithers, M.D., University's Vice Chairman for the Department of Surgery, Jorge Reyes, M.D., University's Division Chief of Transplant Surgery, James Perkins, M.D., the University's Vice Chairman of the Department of Surgery, John Hamm, M.D., Oregon Health & Sciences University Division Chief of Liver and Pancreas Transplantation, Amadeo Marcos, M.D., University of Pittsburgh Transplant Surgery Division Chief, John Fung, M.D., Cleveland Clinic Foundation General Surgery Department Chairman and Transplant Center Director, Sally Aungier, United Network for Organ Sharing (UNOS) Member Services Manager, and Jody Corona, Health Care Consultant.

A copy of the Program's 1,548 page administrative record (AR) regarding the Program's review of the Swedish CON application was admitted as Exhibit 1. Exhibits 2 through 10 were admitted during the hearing.

Pursuant to an agreement of the parties during the hearing, the November 6, 2003 administrative public hearing tapes were transcribed. The transcript was filed and admitted as Exhibit 11 on March 15, 2005. This transcript is a part of the administrative record.

Closing arguments were presented through briefs. The final brief was filed on May 3, 2005. Due to conflicts in schedule, the Health Law Judge issued an order extending the time to issue the final order.

OFFERS OF PROOF

The University filed an offer of proof filed on February 18, 2005 and Swedish filed a responding offer of proof on March 4, 2005.[1] Pursuant to an oral ruling during the

[1] During the hearing, the University moved for reconsideration of the ruling in Prehearing Order No. 4 regarding the admission of new evidence that is not a part of the administrative record. The administrative record was closed on November 24, 2003. After consideration of the University's brief in support of its motion for reconsideration and after consideration of the parties' oral argument, the Health Law Judge denied the motion on the record. The various procedural options for offer of proof were discussed during the hearing, and the parties decided to file written offers of proof pursuant to deadlines set forth by the Health Law Judge.

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.[2]

"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

[2] AR 771-780.

both adult and pediatric patients.[3] 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.[4] 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.[5] 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.

[3] 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.

[4] 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.

[5] 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.[6] 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

[6] AR 734.

rather than subjective findings.[7] 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.[8]

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.[9] 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.[10] 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.[11] 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

[7] 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).
[8] AR 737 and 560.
[9] AR 560.
[10] 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.
[11] 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.

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[12] 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.[13]

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:

[12] There are approximately 59 organ procurement organizations. Life Center Northwest is the local organ procurement organization for the University.
[13] 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.[14] 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.[15] 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.[16]

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 it discretion to determine whether the donor liver matches the patient's needs. In doing so, the liver's quality and function is

[14] AR 45-48, 618 and testimony of Drs. Marks, Dickson, Hart and Miller.
[15] All but two of the "exported" livers (between 1999- 2002) were successfully transplanted
[16] 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.[17] 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

[17] 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.[18]

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.[19] 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.[20] All but 2 of the exported livers were successful upon transplantation.[21] All of these livers would probably not have been

[18] See AR 22-23, the testimony of Dr Dickson, Day 4 at 49 and Dr. Millller, Day 4 at 115-116.
[19] 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.
[20] See footnote #10.
[21] 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.[22] 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[23] and the mandatory MELD export for "Status 1" non local patients.[24] 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%.[25]

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.[26] 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.

[22] 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

[23] Children's may also reject offered donor livers, but no evidence was presented regarding any donor livers Children's may have rejected.

[24] In 2002, only seven of the thirty exported livers were mandatory exports from Life Center Northwest.

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

[26] AR 738.

patients with less conservative, more innovative wait list/treatment protocols, and through outreach/education of patients and heath 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".[27] 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.[28] 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.[29] As Dr. Dickson stated; "WWAMI region is grossly

[27] AR 605, 608-619, 764-7.
[28] AR 618.
[29] AR 45-8, 618.

underrepresented in persons on the wait list per million residents, falling only below Georgia" [30]

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.[31]

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.[32] However, increased cost or lack of

[30] 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.

[31] 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.

[32] 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.[33]

1.27 In evaluating potential adverse impact on the University's program, one must rely on the minimum standards set by UNOS and ASTS.[34] 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.[35] 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.

[33] There are approximately 120 UNOS approved liver transplant programs of which approximately 44 have fellowship training programs.
[34] 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.
[35] 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.[36] 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.[37] 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.[38] 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.[39] The 5 % national annual growth rate in liver transplants during

[36] 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.
[37] 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.
[38] AR 36.
[39] 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.[40] A liver transplant program requires available staff twenty-four hours a day seven days a week.

[40] Swedish transplant program started 1993 and presently includes pancreas, kidney, and bone marrow. These programs have demonstrated innovations such as steroid free immunosupression 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.[41] Swedish's existing transplant program includes three board-certified surgeons[42], 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.[43] 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.[44] 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

[41] Board certified in surgery, urology or osteopathic surgery. AR 779, 943, 947.
[42] 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.
[43] 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.
[44] 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.[45]

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.

[45] 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.[46]

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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[46] 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.[47]

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:

[47] 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.[48]

[48] 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.[49]

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 heath care costs and charges to the public. WAC 246-310-220(2) and WAC 246-310-240(2)(b).

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[49] 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.

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 23rd day of August, 2005.

/s/
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

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

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

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).