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No. 80264-5
IN THE SUPREME COURT
OF THE STATE OF WASHINGTON

UNIVERSITY OF WASHINGTON MEDICAL CENTER,

Respondent,

vs.

WASHINGTON STATE DEPARTMENT OF HEALTH

and

SWEDISH MEDICAL CENTER,

Appellants

SWEDISH'S REPLY BRIEF

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I. INTRODUCTION

Liver transplantation in Washington State is noteworthy for at least two reasons. First, Washington residents die from liver disease at rates above the national average, but receive liver transplants at rates significantly below the national average. This suggests that too few Washington residents are receiving transplants. Second, Washington has only one liver transplant program. No other program anywhere in the country is the sole provider of liver transplants for a region as large as that served by the University of Washington Medical Center (the “UW”). This suggests the reason that too few Washington residents receive transplants: “monopolist” providers tend to be more conservative in their approach, and accordingly accept fewer patients and donated livers, than are providers who face “competition.”

Washington State easily can support two liver transplant programs. Indeed, it needs two programs, as the Department of Health (the “Department”) has repeatedly determined. Moreover, the program to be established by Swedish Health Services (“Swedish”) will in no way “harm” the UW’s program; to the contrary, “competing” programs at the UW and Swedish—two of the most respected healthcare providers in the region—will make both programs better. This Court should affirm the Department’s decision approving Swedish’s proposed program. The Department’s findings were supported by substantial evidence, and the Health Law Judge’s evidentiary rulings in the adjudicative hearing on Swedish’s application were not an abuse of discretion.

II. ARGUMENT

A. **Substantial Evidence Supports The Department's Determination That Washington Needs A Second Liver Transplant Program.**

1. **The Court should not reweigh the evidence before the Department.**

The UW invites this Court to reweigh the evidence on which the Department based its determination that Washington needs a second liver transplant program, and even asks the Court to consider new evidence that was not before the Department. UW's Response Brief ("Resp. Br.") at 6, 9, 12. For determinations such as the Department's approval of Swedish's application, "the judiciary does not have the responsibility of...weighing the evidence[.]" Apostle v. City of Seattle, 77 Wn.2d 59, 63, 459 P.2d 792 (1969). That responsibility instead belongs to the Department.

This Court should review the Department's determination that Washington needs a second liver transplant program only to determine whether it is supported by substantial evidence. See id.; see also Premera v. Kreidler, 133 Wn. App. 23, 32, 131 P.3d 930 (2006) (court will "not weigh the evidence or substitute [its] judgment for that of the agency"); Callecod v. Wash. State Patrol, 84 Wn. App. 663, 676, 929 P.2d 510 (1997) (court should determine whether "any fair-minded" person could have ruled as the agency did). Where, as here, there is substantial evidence to support the Department's determination, the Department's decision must be upheld regardless of whether the Court would have made the same determination. The Court also should decline to consider new evidence that was not part of the record before the Department.

2. The Department did not simply rely on the nationwide transplant rate to find need.

Throughout its review of Swedish's application, the fundamental issue before the Department was "whether approval of a liver transplant program at [Swedish] will allow patients to receive liver transplants who would not otherwise be served by the existing program at [the UW]." AR 1805 (Appendix, Ex. D). In order to properly assess this issue, the Department did not simply apply the nationwide transplant rate to Washington's population, as the UW contends. Resp. Br. at 23-26. Instead, the Department's need determination was based on its extensive review of documents, public comment, testimony by witnesses called by both Swedish and the UW, and independent research. The record below reveals that the Department conducted a careful review at every stage.

For instance, before the Department issued its initial decision approving Swedish's application on June 17, 2004, the Department, through its Certificate of Need Program (the "Program"), reviewed and analyzed Swedish's two-hundred page application and supporting exhibits (AR 1023-1262); Swedish's detailed responses to the Program's screening questions (AR 1268-1325); more than two hundred pages submitted by the UW in opposition to Swedish's application during the public comment period (AR 1409-1564; 1573-1627); public hearing testimony from twelve UW witnesses and nine Swedish witnesses (AR 3036-3120); Swedish's rebuttal statement and supporting exhibits (AR 1628-1795, Appendix, Ex. F); and the UW's rebuttal statement and supporting exhibits (AR 1573-1627). In addition to analyzing the extensive evidence submitted by both

Swedish and the UW, the Program also conducted independent research, and considered information and statistics obtained from institutions such as the United Network for Organ Sharing (“UNOS”), the Organ Procurement and Transplant Network (“OPTN”), the Scientific Registry of Transplant Recipients, the Washington State Cancer Registry, the Department of Health and Human Services, and the American Cancer Society. AR 1799 (Appendix, Ex. D); see also AR 1830-2622.

After careful review of the aforementioned evidence, the Program concluded that a second liver transplant program would increase Washington residents’ access to liver transplantation. Although it is not possible to briefly summarize all of the information supporting this decision, the initial need determination generally was based on the Program’s finding that there is an increasing need for liver transplant procedures due to population growth in Washington and increasing rates of hepatitis C and hepatocellular carcinomas, frequent causes of need for liver transplants (AR 1801-1802, Appendix, Ex. D); that the existence of only one transplant center, and therefore only one set of selection criteria for transplant recipients and donor organs, restricts the ability of area residents to receive transplants (Id. at 1804); that regions such as the Bay Area, where there are three successful liver transplant programs, demonstrate that having more than one liver transplant program increases patient access due to variation in selection criteria (Id. at 1803); and that the UW does not perform living-donor transplants, although this procedure allows patients access whose MELD scores or other factors may not allow

them to obtain a liver transplant at the UW (Id.).¹ The fundamental basis for the Program's need determination was thus that a second program would allow Washington residents who would not receive transplants at the UW access to this life-saving procedure.

Like the Program, the Department's Health Law Judge (the "HLJ") also conducted a careful review of evidence prior to determining there is need for a second liver transplant facility in Washington. For instance, in addition to the 1,548-page administrative record compiled during the Program's review of Swedish's application, the HLJ considered five days of testimony from eight UW witnesses and six Swedish witnesses, additional exhibits, and extensive post-hearing briefing submitted by Swedish, the Program, and the UW, before issuing a Final Order approving Swedish's liver transplant program on August 23, 2005. AR 994 et. seq. (Appendix, Ex. C)² Far from a "simple mathematical formula," the Department's decision was based on substantial evidence that Washington is underserved by having only one transplant facility.

¹ Although the UW claims it performs living donor transplants, it had only performed one such procedure at the time of Swedish's application, and, indeed, publicly stated in 2003 that it would not perform living donor procedures. AR 1672 (Appendix, Ex. F); AR 1344.

² During the June 6, 2006 remand hearing, the HLJ was prepared to hear testimony from multiple UW and Swedish witnesses, and to consider any new evidence which complied with the HLJ's evidentiary rulings. For instance, prior to the remand hearing, the UW identified 17 witnesses who would possibly testify during the remand. AR (Remand) 912. However, during the remand hearing, the UW presented only two witnesses, both of whom testified that they could not dispute Swedish's application without using post-2003 information. AR (Remand) 1912 (Appendix, Ex. B). The evidence considered by the HLJ in affirming the August 23, 2005 Final Order upon remand was accordingly limited by the UW's failure to present any admissible evidence. Id.

3. The rate of liver disease in Washington shows need for a second program.

The rate of liver disease in Washington supports the Department's determination that a second program is needed. Significantly, although the population served solely by the UW is the largest population in the country with only one transplant facility, incidence of chronic liver disease in Washington is equivalent to incidence rates for the rest of the nation, and the death rates from liver disease in Washington exceed those for the nation. AR 1634-35 (Appendix, Ex. F). In addition, Washington residents' need for liver transplantation is likely to increase because of increasing rates of hepatitis C and hepatocellular carcinoma, which are frequent causes of need for liver transplants. AR 1802 (Appendix, Ex. D).

Although Washington residents are not healthier than residents in other states with respect to mortality from liver disease, the UW performs significantly fewer transplants than would be expected based on national averages. AR 1634 (Appendix, Ex. F). As discussed in Swedish's opening brief, the UW performed one-fourth the number of liver transplants as would be expected based on UNOS national transplant rates. AR 1970-71. Indeed, over 500 Washington residents die each year from liver disease, but less than 20 of these deaths occur in patients awaiting transplantation on the UW's waiting list. *Id.* at 1640. The UW's low transplant rate demonstrates that the UW is not meeting the needs of Washington residents.

4. A comparison of MELD scores illustrates need for a second program.

The Department's finding that a second liver transplant program is needed was also supported by evidence showing the UW transplants less sick, or lower MELD-score, patients. AR 1001 (Appendix, Ex. C). The HLJ compared the MELD-score ranges of the UW's patients with the MELD score ranges of the UW's peers. When compared with "centers of excellence," such as Stanford, the University of California, Los Angeles ("UCLA"), the University of California, San Francisco, California Pacific Medical Center, and the University of Colorado, the UW transplants the lowest percentage of the sickest, or MELD 31-40, patients. AR 1644 (Appendix, Ex. F).³ Notably, unlike the UW, each of the aforementioned centers face competition from additional liver transplant programs within their state. AR 1422-24. As the sole provider for a five-state region, the UW is not forced by "competition" to seek out more complex cases.

The UW attempts to rebut the Department's determination that sicker patients lack sufficient access to the UW's program by arguing that it is more appropriate to look at MELD-score data for patients at the time of registration, rather than at the time of transplant. Resp. Br. at 26-27. However, a comparison of the UW's MELD scores at the time of registration with the national average reveals that 50.5% of the UW's patients fall within the MELD 11-20 range, while only 38.4% of patients

³ During the first administrative hearing, the medical director of the UW's liver transplant program confirmed that the aforementioned five programs are peers of the UW. AR 3554. The HLJ's comparison of the UW with UW's "peer centers of excellence" was thus appropriate.

fall within this range on average nationally. AR 1494. The UW's high percentage of low MELD-score patients at the time of registration is further exacerbated by the UW's position as the sole provider in Washington, and the UW's low transplant rate despite the incidence of liver disease and mortality in Washington. Given the size and relative health of the population it serves, the UW's MELD-score statistics, even when measured at the time of registration, show that sicker patients do not have adequate access to the UW's program.

5. The UW's export rate illustrates need for a second program.

The HLJ's need determination was also supported by evidence establishing that the UW is overly selective when rejecting, or "exporting," livers. This finding was based on the extremely high success rate of organs rejected by the UW (98.4% of the livers the UW exported between 1999 and 2002 were successfully transplanted elsewhere),⁴ the number of patients on the UW's waiting list who die while awaiting transplant (64 patients on the UW's waiting list died awaiting transplant during the same time period the UW rejected 126 livers), and a comparison between the UW's export rate with export rates in other areas

⁴ The UW attempts to discount the high success rate of the livers it exported with the claim of Dr. John Ham, division chief of liver and pancreas transplantation at Oregon Health and Science University, that, of the 26 livers that were exported from Washington to Oregon in 2001, only two were deemed as being of the "quality" necessary to be transplantable. Resp. Br. at 29-30, n.19. However, as Dr. Marks explained during the adjudicative hearing, Dr. Ham never examined the exported livers in question himself, and data from the organ procurement organization representing the UW, Life Center Northwest, established that all but 2 of the 124 livers rejected by the UW between 1999 and 2002 were successful upon transplantation. AR 3901-02.

(the UW's export rate in 2002 was 27.8%, while comparable donor service areas had export rates of 10-15.6%). AR 1651 (Appendix, Ex. F).

The UW contends that its export rate should be compared to the national average, rather than other specific areas. However, a comparison of the UW's export rate with the national average is inapposite because there are great disparities between donor service areas throughout the country. AR 3183-84. The national export rate includes donor services areas without active transplant centers, such as Mississippi, where every donated liver must be exported, as well as centers that exist in highly populated regions with a number of competitive programs, particularly in the Northeast. AR 1651 (Appendix, Ex. F). In such regions, there is a greater likelihood of having a Status 1 recipient in a neighboring region, thus mandating liver export. Id.⁵ This is not the case in Washington. AR 3184. Indeed, of the 126 livers the UW rejected between 1999 and 2002, only 28 were mandatory Status 1 exports. Id.

To properly evaluate the UW's export rate, the HLJ thus compared the UW with organ procurement organizations serving similarly sized programs, in similar markets to that of the UW. AR 1004 (Appendix, Ex.

⁵ Status 1 patients are those patients deemed likely to die within seven days without a liver transplant. AR 3150. Under the national liver transplantation system, Status 1 patients within a donor service area have the first priority for any donated livers. AR 3152. If there are no Status 1 patients within the donor service area, then all centers within a contiguous region must be contacted, and a donated liver must be exported if there are any Status 1 within the contiguous region. AR 3152-53. The UW's region, or Region 6, includes only Hawaii and Oregon. Id. The UW's export rate is thus less likely to be effected by mandatory Status 1 patients, as the number of centers who could put a call on Status 1 patients is relatively small. AR 3184.

C); AR 1651 (Appendix, Ex. F). When compared with donor service areas represented by a dominant high-volume center with some expertise, like the UW, the UW's export rate can be properly evaluated. AR 1651 (Appendix, Ex. F); AR 3185. Specifically, areas comparable to the UW's had export rates from approximately 10 to 15.6% in 2002, while the UW's export rate during this period was 27.8%. Id. at 1652; AR 1004 (Appendix, Ex. C).

6. The length of the UW's waiting list shows need for a second program.

The Department's decision is also supported by the fact that the UW's waiting list length is too short. The UW contends that waiting list length is not an adequate representation of whether a community is served or underserved because "unless you reach a certain threshold in the MELD score, which is how you prioritize patients, the patients that are listed with a low MELD score are unlikely to get transplanted." Resp. Br. at 27. However, as the HLJ determined, a longer waiting list represents more varied patients' needs and greater opportunity for matching patients with donor livers. AR 1006 (Appendix, Ex. C). If more people were represented on the UW's waiting list, there would be greater opportunity for transplanting, rather than exporting, available donor livers. Id. Moreover, as Dr. Rolland Dickson, medical director of solid organ transplantation and research at the Mayo Clinic in Jacksonville testified during the administrative hearing, "in order to get access to liver transplants, you need to be evaluated and placed on a waiting list." AR

3789 (Appendix, Ex. G). As previously discussed, the UW's waiting list includes a disproportionate number of healthier patients. By not listing sicker patients, the UW eliminates such patients' opportunity for transplantation in Washington.

Because the number and transplantation criteria of patients evaluated by the UW, but not listed for transplantation, is unknown, the only way to determine whether the UW's waiting list is too short is to compare its length with what would be expected based on the population the UW serves. AR 1004 (Appendix, Ex. C). Specifically, although the national waiting list rate is 60 residents per million, the UW's waiting list length is only 14 residents per million. *Id.* at 1005. That the UW's waiting list is one-fourth the length that would be expected based on the national rate is particularly significant when considering the UW is the only facility in the nation serving such a large population by itself, and given that Washington's mortality rate from liver disease is higher than the nationwide average.

The HLJ also compared the UW to other facilities serving similar populations. For instance, North Carolina has a population of 8.2 million, which is close to the 8.8 million served by the UW. AR 1648 (Appendix, Ex. F); AR 3166. In stark contrast to the UW's waiting list of 127 patients in 2002, North Carolina had 451 patients awaiting transplant on its waiting lists in 2002. AR 3166. Incidentally, North Carolina has three successful liver transplant facilities. AR 3166-67

7. Competition would increase the transplant rate and Washington residents' access to transplants.

The HLJ's need determination was also supported by substantial evidence that a second transplant facility in Washington would allow more residents access to transplantation by increasing competition. AR 1001-03 (Appendix, Ex. C). Both Dr. Charles Miller, director of the liver transplant program at the Cleveland Clinic, and Dr. Dickson, testified at length regarding the benefits of competition. This testimony showed that the addition of a second transplant facility in Washington would improve the quality of the UW's program, and with it, increased patient access to transplantation.

Medical research shows that liver transplant programs in areas with competition treat patients with significantly higher MELD scores, thereby increasing sicker patients' access to liver transplants. Competition would force the UW, like other facilities facing competition, to seek out more complex cases, i.e., patients with higher MELD scores, in order to receive donor organs. AR 1656 (Appendix, Ex. F).

Competition would also increase access to transplantation by bringing living-donor transplantation to Washington. *Id.* Because patients with high MELD scores are much more likely to receive cadaver livers, patients with liver tumors who are not yet ill (and therefore have low MELD scores) may never receive a donor liver in the early stages of their disease, when a transplant is still possible. *Id.* at 1657. In such cases, a living donor may be the only chance for survival. *Id.* Washington residents currently lack access to this procedure. Because it does not face

competition, the UW is not forced to improve and expand its program through use of new procedures such as living-donor transplantation. The UW claims it performs living donor transplants where medically appropriate. Resp. Br. at 14. However, at the time of Swedish's application, the UW had performed only one such procedure.⁶ AR 1672 (Appendix, Ex. F).

In its response brief, the UW also focuses on (1) the merits of living donor transplants and (2) whether Swedish, in the early stages of its program, would be able to perform living-donor transplants, split liver procedures, and cut-down liver procedures. Resp. Br. at 9-10, 14. Both arguments miss the fundamental point: the opening of Swedish's program will spur both Swedish and the UW to innovate and constructively compete in order to deliver the best services possible to Washington residents. A second liver transplant program in Washington would allow for alternative donor criteria, transplant candidate selection, and treatment programs, and would thus provide greater flexibility and local access to care. AR 1655-60 (Appendix, Ex. F). As a result, the universe of transplant candidates and of donor organs will be expanded.

8. Anecdotal evidence also shows need for a second program.

Finally, the UW places great weight on the testimony it presented from local gastroenterologists, and suggests that the Department's need

⁶ Moreover, Dr. James Perkins, director of the UW's transplant program, publicly stated in 2003 that the UW will not perform living-donor transplants because, in his opinion, there was no need for this type of procedure. AR 1344.

determination lacks evidentiary support because Swedish did not present similar anecdotal evidence. Resp. Br. at 24-25. To the contrary, in addition to the substantial statistical and comparative evidence provided by Swedish, testimony from area residents and physicians also demonstrates that Washington residents lack access to the UW's program.

For example, Jerry Metcalf, a Washington resident whose fifteen year-old daughter was denied a transplant at the UW, participated in the public comment process. AR 1383-84; AR 1701-02; AR 3098-3104. After Mr. Metcalf's daughter, Erin, was turned away by the UW because she did not meet its selection criteria, Erin received a successful transplant at UCLA. AR 1383. The transplant at UCLA was possible only because the Metcalfs personally researched and found a transplant program willing to accept their daughter, and were able to bear the substantial expense of renting a private airplane (required to fly Erin to Los Angeles the moment a liver became available), accommodations for Erin's three-month recovery period, and lost wages resulting from having one parent stay in Los Angeles to care for Erin while she recovered. Id. Unlike the Metcalfs, many Washington residents who are denied transplants at the UW do not have the resources required to obtain transplants elsewhere. A second program here would increase access to this life-saving procedure for all Washington residents.

In addition to Mr. Metcalf, Swedish spoke to other area residents who had to leave the region to obtain transplants, as well as to local gastroenterologists who expressed concern that some of their patients must

leave the area for transplantation due to lack of access to the UW. AR 1343; 1381; 1394; 1399. The Director of Life Alaska Donor Services, Bruce Zalneraitis, also expressed support for Swedish's program because some donor livers from Alaska could have been used by the UW but were not, and more livers from his Center could be used if there were a second program with different selection criteria. AR 1652 (Appendix, Ex. F).

Thus, in addition to the extensive statistical and comparative evidence showing need for a second liver transplant facility, as well as the undisputed evidence establishing that competition would increase Washington residents' access to transplantation, evidence obtained from area residents and providers also supports the Department's determination that there is need for a second liver transplant program in Washington.

B. Substantial Evidence Supports The Department's Finding That The UW's Program Will Not Be Adversely Impacted By Swedish's Program.

To assess need, the Department's regulations require the Department to determine that the proposed facility will not have an adverse effect on health professional schools and training programs. WAC 246-310-210(4). Although the UW attempts to alter the standard of review regarding this issue, the Department's determination that Swedish's proposed program would not adversely impact the UW was a finding of fact. AR 1007-09 (Appendix, Ex. C). Under the Washington Administrative Procedure Act (the "APA"), findings of fact are reviewed under the substantial evidence standard. RCW 34.05.570(3)(e).

Substantial evidence supports the Department's finding that a new liver transplant program at Swedish would not adversely effect the UW.

1. The Department did not simply consider minimum accreditation requirements when determining that Swedish's program would not adversely impact the UW.

The UW's assertion that the HLJ converted minimum accreditation requirements for a liver transplant fellowship program into the maximum she could consider under the law is inaccurate. Resp. Br. at 30.⁷ In order to assess adverse impact, the HLJ considered extensive evidence beyond minimum accreditation requirements. For instance, the HLJ compared the UW with transplant programs (both academic and non-academic) throughout the nation. Such a comparison was appropriate, and, indeed, necessary, because the UW's inflexible position throughout this proceeding has been that any reduction in the number of transplants it performs would adversely impact its ability to maintain research and training programs. AR 1007-08 (Appendix, Ex. C). As discussed in Swedish's Opening Brief, the UW, as a result of its monopoly status in a large region, performs far more liver transplants than many other major academic programs. In 2002, the UW performed 79 transplants, compared

⁷ In support of this assertion, the UW selectively quotes the HLJ's Final Order, and claims the HLJ stated a consideration beyond the minimum 50 transplants per year needed for program accreditation was unnecessary because such an argument asked the HLJ to set new minimum standards for a liver transplant program after expert medical organizations had done so. Id. at 33. In truth, however, the HLJ actually stated that the UW's argument that its existing transplant volumes were necessary to maintain quality training and research programs was untenable in light of UNOS and American Society of Transplant Surgeons ("ASTS") accreditation standards. AR 1007 (Appendix, Ex. C).

to 58 at USC, 48 at Georgetown, 47 at the University of North Carolina, 40 at Johns Hopkins, 40 at Iowa, 35 at Duke, and 32 at the University of Illinois. AR 1422-36. It simply is not credible for the UW to claim that its training and research programs will be jeopardized, even if it really believes it will “lose” some transplants to Swedish, in light of the volumes at these other successful programs.⁸ A comparison between the UW’s volumes and those at other programs supports the Department’s conclusion that a second transplant facility at Swedish would not adversely impact the UW.⁹ However, even had the Department only considered the UNOS and ASTS minimum volumes, such consideration would have provided adequate support for the Department’s adverse impact determination because the only specific training-related programs the UW ever identified that would be affected by the opening of Swedish’s program were the UW’s UNOS-approved liver transplant surgery training program and its ASTS-approved liver transplant surgery fellowship program. The Department’s consideration of UNOS and ASTS standards to evaluate the UW’s adverse impact claim was thus appropriate.

⁸ Moreover, as the HLJ explained in her Final Order, liver transplantation is not a “zero sum game” where any transplant performed at Swedish would necessarily subtract a transplant from the UW’s volume. AR 1009 (Appendix, Ex. C). Instead, “more than one program in a service area results in the performance of a greater total number of transplants because competition promotes additional transplants.” Id.

⁹ In addition to this comparative evidence, substantial evidence supporting the Department’s adverse impact determination also included the UW’s statement that it had an excellent program even when it was only performing 67 transplants per year (AR 1008)(Appendix, Ex. C); that a second liver transplant program would actually increase the total number of transplants performed in Washington (Id. at 1009); and that the UW’s transplant number had increased at a rate of 5% per year, and would likely continue to increase in the future. Id. at 1008.

2. The UW's "Progression Argument" is without support.

In its response brief, the UW claims that an annual volume of 120 transplants is necessary in order to meet training requirements. Resp. Br. at 33. The only support the UW offers for this contention is the post-administrative proceeding declaration of Dr. Jorge Reyes, chief of the division of transplant surgery at the UW, which states that a transplant volume of 120 annual transplants is necessary because fellows must begin with less difficult surgeries and then progress to more difficult surgeries. Id. (citing AR (Remand) 26).¹⁰

The UW's "progression" argument is untenable. The UNOS and ASTS minimum volume standards require a research fellow to perform a minimum of forty-five liver transplants over a two-year period as primary surgeon or first assistant. AR 3362-63.¹¹ Moreover, there are typically two surgeons on every liver transplant, a primary surgeon and first assistant. AR 3832 (Appendix, Ex. J). If a research fellow acts as a first assistant, this would count towards the forty-five transplants. Id. Thus, because the UW performed 79 transplants in 2002 and 104 transplants in

¹⁰ Dr. Reyes's December 16, 2005, declaration, provided four months after the HLJ issued her original decision, is the first time the UW provided the Department with a specific minimum volume requirement.

¹¹ In addition to the UNOS minimum volume requirement, administrative hearing testimony also shows that the UW's 120 minimum volume estimate is untenable. For instance, Dr. Marquis Hart, director of transplant services at the University of California, San Diego, offered expert opinion testimony that a volume of "between 45 and 50 liver transplants" annually is sufficient to maintain training programs in both liver transplant surgery and hepatology. AR 3819 (Appendix, Ex. J). Dr. Hart also testified that a medical program "that does anywhere close to 45 to 50 [liver transplants] certainly would meet the academic needs for medical students and residents." Id. at 3820.

2003, there were 183 opportunities during that two-year period for a liver transplant fellow to satisfy the UNOS liver transplant requirement of forty-five transplants in two years. AR 1008 (Appendix, Ex. C). The substantial volume of transplants the UW performs above the UNOS minimum guarantees that the UW's fellow has adequate opportunity to begin with less difficult, and progress to more difficult, surgeries.¹²

3. Swedish and the Department conducted the required impact assessment.

Finally, the Superior Court's ruling that Swedish was required to assess the impact on the UW's program misapplies RCW 70.38.115(2)(d) and WAC 246-310-210(4). Neither the statute nor the regulation requires the applicant to assess adverse impact.¹³ Instead, both provisions require the Department, not the applicant, to conduct an adverse-impact assessment. As described above, the Department carefully considered whether Swedish's program would adversely impact the UW, and properly determined that the UW would not be adversely effected by the addition of a second liver transplant facility in Washington.¹⁴

¹² Although the UW did not have a second fellow until after the Department issued Swedish's certificate of need, the HLJ determined that, given the aforementioned information, the UW's program would not be adversely impacted even if the UW were to add a second fellow. AR 1007, n.34 (Appendix, Ex. C).

¹³ RCW 70.38.115(2)(d) states: "The department shall consider the application in terms of its impact on existing and proposed institutional training programs...". (emphasis added). Similarly, WAC 246-310-210(4) provides that the Department's "determination of need for any project" shall include whether the project will "have adverse effect on health professional schools and training programs."

¹⁴ In addition, although not required to do so under either statute or regulation, Swedish did address adverse impact in its written submissions to the Department (AR 1653-55, 1668-69, 1687) (Appendix, Ex. F), and through testimony at the adjudicative proceeding (AR 3819-20) (Appendix, Ex. J).

C. The HLJ's Evidentiary Ruling Was Not An Abuse of Discretion.

The UW erroneously contends that the HLJ's evidentiary rulings are reviewed de novo, and cites Port of Seattle v. Pollution Control Hearings Board, 151 Wn.2d 568, 593, 90 P.3d 659 (2004) in support. Resp. Br. at 34. However, the Court in Port of Seattle explicitly held that evidentiary rulings are reviewed under the "abuse of discretion" standard. 151 Wn.2d at 642. Under the abuse of discretion standard, the HLJ's evidentiary rulings should be reversed only if "no reasonable person would take" the same view as the HLJ. T.S. v. Boy Scouts of Amer., 157 Wn.2d 416, 424, 138 P.3d 1053 (2006) (emphasis added).

1. The HLJ's ruling was consistent with both the purpose of the remand and the APA.

The HLJ's evidentiary ruling was not an abuse of discretion because it was consistent with both the scope and purpose of the remand hearing, and was well within the HLJ's discretion under the APA. To get around this, the UW mischaracterizes the evidentiary ruling at issue. The purpose of the remand hearing was to allow the UW an opportunity to respond to the new theory the UW claimed Swedish raised in its November 24, 2003 rebuttal statement. AR (Remand) 2 (stating, "if there is new information placed in the administrative records, a party has the right to respond[.]"). During the remand hearing, the HLJ did not require that any evidence the UW presented be tied to some reference in the Program's public record, as the UW contends. Resp. Br. at 34-5. Instead, in light of the Superior Court's remand order, the HLJ ruled that the UW

could present any relevant evidence in response to Swedish's rebuttal, including evidence that was not contained within the original Program record, provided that such evidence did not post-date the December 31, 2003 closing of the record. AR (Remand) 288 (Appendix, Ex. E).

The APA gives an administrative law judge discretion to control the scope of an adjudicative proceeding. See RCW 34.05.449(1) (“The presiding officer shall regulate the course of the proceedings, in conformity with applicable rules and the prehearing order, if any.”). The presiding officer need only admit evidence “to the extent necessary for full disclosure of all relevant facts and issues. . . .” RCW 34.05.449(2) (emphasis added). Moreover, the APA also specifically provides that evidence presented in an administrative proceeding may be limited by “materiality, relevance, and non-redundancy.” RCW 34.05.452(1). The cut-off date limited evidence to that which was relevant and material to the purpose of the remand hearing: allowing the UW an opportunity to respond to Swedish's November, 2003 rebuttal statement, which the UW did not have an opportunity to do at that time. Evidence which did not even exist when Swedish submitted its rebuttal statement—and which the UW therefore could not possibly have used to respond to Swedish's rebuttal statement—was properly excluded as immaterial and irrelevant.

2. The HLJ's ruling was based on longstanding Department policy.

The CN statute is designed to promote the health of Washington residents by assuring adequate and on-going access to health services.

RCW 70.38.015(1). To evaluate a CN application, the Department “closes” the record so that the Program can timely evaluate the available information and make a decision. This means that existing providers must oppose a CN application based on the facts as they exist at the time the Program evaluates the application. The Department’s longstanding policy of closing the record after the public comment period prevents existing providers from simply waiting to change their own services until after a competitor has filed an application, undergone the Program’s evaluation, and received a CN. Contrary to the UW’s claim, the HLJ’s evidentiary ruling did not attempt to create a new type of hearing, but instead was consistent with the Department’s practice in every CN proceeding. Resp. Br. at 34.

3. The cases cited by the UW do not support its position.

The UW analogizes the HLJ’s December 31, 2003 evidentiary cut-off to the evidentiary rulings at issue in Port of Seattle v. Pollution Control Hearings Board, 151 Wn.2d at 597-8. However, the Pollution Control Hearings Board (“PCHB”) is expressly permitted, under both state and federal statute, to consider evidence outside of the Department of Ecology (“DOE”) record. Id. at 596-7. Additionally, the PCHB rules state that its hearings should be conducted de novo, while the certificate of need guidelines merely state that the HLJ may conduct the hearing de novo, meaning there is no right to a hearing in which evidence that was not

available to the Program may be submitted. Id. at 596; WAC 246-10-602(2).¹⁵

Division II's decision in DaVita, Inc. v. Dep't of Health, 137 Wn. App. 174, 151 P.3d 1095(2007), has no relevance whatsoever to the HLJ's evidentiary rulings in this case. In DaVita, the Court of Appeals reviewed the certificate of need regulatory scheme and observed that "the presiding officer . . . takes the evidence, listens to oral argument, and issues her own findings and conclusions." DaVita, 137 Wn. App. at 182. Moreover, the HLJ may "conduct[] the hearing de novo" and "need not give any particular deference to the Program analysts" as she is "the agency's final decision maker on CN applications." Id. at 182-83. None of this is disputed.¹⁶

Finally, the UW's reliance on Marlboro Park Hospital v. Dep't of Health and Environmental Control, 358 S.C. 573, 595 S.E.2d 851 (2004), is misplaced. In Marlboro Park, the South Carolina court determined that a South Carolina statute prohibiting the ALJ from considering issues that were not before the certificate of need staff did not bar consideration of evidence that was not before the staff. Id. at 578-79. Because the South Carolina legislature had specifically determined the information that

¹⁵ Further, unlike the PCHB, there is no statutory or regulatory provision precluding the HLJ from excluding new information as irrelevant. Instead, RCW 34.05.452(1) explicitly authorizes exclusion of irrelevant evidence at an adjudicative proceeding.

¹⁶ Moreover, "de novo" refers to the standard of review, not an evidentiary standard. WAC 246-10-602(2) provides that "[t]he presiding officer may . . . [c]onduct the hearing de novo" (standard of review). RCW 34.05.452(1) provides that "[t]he presiding officer may exclude evidence that is irrelevant, immaterial, or unduly repetitious" (evidentiary limitations). These are not inconsistent.

was—and was not—to be considered by the ALJ, the Court determined the ALJ properly admitted evidence which was not before the staff. In Washington, by contrast, there is no regulatory or statutory provision mandating information to be considered in an adjudicative proceeding. The HLJ's exclusion of post-December 31, 2003 information was consistent with relevant Washington law.

D. If The Court Determines Additional Evidence Should Have Been Considered, It Should Remand.

The UW fails to explain how, or even whether, any of the evidence it claims was improperly excluded would change the HLJ's determination with respect to need or adverse impact. However, if this Court determines the HLJ's December 31, 2003 evidentiary ruling was an abuse of discretion, the appropriate remedy is to remand to the HLJ with instructions to admit specific, wrongfully excluded evidence and issue a new decision. RCW 34.05.562(2)(c) (remand is appropriate if an agency has improperly excluded evidence at the adjudicative proceeding).¹⁷

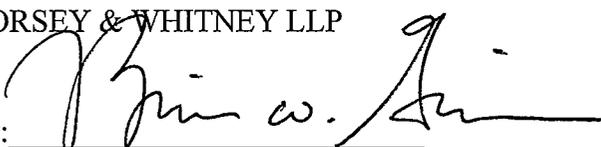
¹⁷ The UW's attempt to analogize the adverse-impact issue to the doctrine of invited error, *see* Resp. Br. at 45-47, is misplaced, because neither the Department nor Swedish failed to meet the burden of production or proof with respect to adverse impact. The UW's reliance on Weyerhaeuser v. Pierce County, 124 Wn.2d 26, 873 P.2d 498 (1994) is also misplaced. Unlike here, the zoning action at issue in Weyerhaeuser was not governed by the APA or the remand provision of RCW 34.05.562(2)(c). Moreover, the decision at issue in Weyerhaeuser did not involve the improper exclusion of evidence, but was instead concerned with hearing examiner error such as a failure to make sufficient findings or to allow cross-examination. *Id.* at 37. By contrast, the HLJ allowed five days of cross-examination during the first administrative hearing (and was prepared to allow another five days of testimony during the remand, had the UW chosen to present any evidence), and her findings are supported by substantial evidence.

III. CONCLUSION

The UW essentially asks this Court to second-guess the Department's factual determinations that Washington needs a second liver transplant program and that Swedish's program will not adversely impact the UW. The Court should not do so. Substantial evidence supports the Department's decision on Swedish's application. Swedish respectfully requests that this Court reverse the Superior Court and affirm the Department's decision to award a Certificate of Need to Swedish.

Respectfully submitted this 15th day of February 2008.

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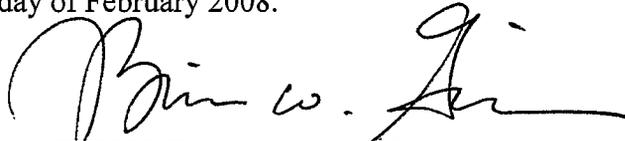
PROOF OF SERVICE

I caused a copy of the foregoing Swedish's Reply Brief, to be served today, by first-class mail, on:

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