No. 46384-9-II

COURT OF APPEALS, DIVISION II
OF THE STATE OF WASHINGTON

DAVITA HEALTHCARE PARTNERS INC.,

Appellant,

v.

WASHINGTON STATE DEPARTMENT OF HEALTH
and NORTHWEST KIDNEY CENTERS,

Respondents.

# OPENING BRIEF OF DAVITA HEALTHCARE PARTNERS INC.

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## I. INTRODUCTION

This judicial review proceeding relates to the Certificate of Need ("CON") decision of the Washington State Department of Health (the "Department") to approve the CON application of DaVita HealthCare Partners Inc. ("DaVita") to establish a new kidney disease treatment center in Des Moines and to deny the competing CON application of Northwest Kidney Centers ("NKC") to expand its existing kidney disease treatment center in SeaTac. DaVita and NKC are well-regarded providers of dialysis services and the Department determined that the proposed DaVita and NKC projects each satisfied all applicable CON requirements. Because the number of dialysis stations projected to be needed in the planning area would not allow for approval of both projects, however, the Department was required to, and did, apply the regulatory "tie-breakers" set forth in WAC 246-310-288 to determine which application would be approved. DaVita won under the tie-breakers, and the Department accordingly approved DaVita's application and denied NKC's competing application.

This decision was reversed by Health Law Judge Frank Lockhart (the "HLJ"), the presiding officer in the subsequent adjudicative proceeding commenced by NKC. The HLJ's reversal was based on his

erroneous legal conclusion that he was not required to use the regulatory tie-breaker standards as the basis to compare the applications.

The HLJ instead compared the projects based on the applicants' respective projections of revenue per treatment, effectively a function of the reimbursement rates DaVita and NKC have negotiated with commercial insurers, and the applicants' respective capital budgets. The HLJ determined that on average DaVita would receive higher reimbursement from commercial insurers than would NKC. The HLJ approved NKC's application and denied DaVita's application on the ground that NKC would provide lower-cost dialysis, as measured by this revenue-per-treatment statistic, and the ground that expanding NKC's existing facility would cost NKC less than building DaVita's new facility would cost DaVita.

The tie-breaker standards set forth in WAC 246-310-288 balance several criteria, including the scope of services to be provided in a facility, capital costs, geographic diversity of facilities, and provider choice. These are the criteria selected by the Department, based on input from dialysis providers during the rulemaking process, and adopted in regulation. Capital cost is worth one tie-breaker point out of nine; commercial reimbursement rates are not part of the analysis at all, for good reasons. The HLJ's conclusion that he could disregard the tie-breaker regulation,

and instead conduct a comparative evaluation based on ad hoc criteria, constituted legal error.

DaVita respectfully requests that the Court determine that the Department must, as a matter of law, use the tie-breaker regulation as the basis to compare competing kidney dialysis facility applications. The HLJ's order to the contrary should be set aside and the Department's original decision approving DaVita's application and denying NKC's application, based on the regulatory tie-breakers, should be reinstated.

## II. ASSIGNMENT OF ERROR

The HLJ erred by denying DaVita's application, and approving NKC's application, based on a comparison of the projects under criteria other than those set forth in WAC 246-310-288.

## III. ISSUES PERTAINING TO ASSIGNMENT OF ERROR

A. Whether the Department must choose between competing CON applications to establish or expand kidney disease treatment centers based on the regulatory tie-breaker criteria set forth in WAC 246-310-288, or whether the Department may instead compare such applications based on ad hoc criteria.

B. Whether a proposed kidney disease treatment center may be denied as having an unreasonable impact on the costs and charges for health services, under WAC 246-310-220(2), because its capital cost

and/or projected revenue per treatment is higher than that of a competing application, rather than by a comparison of the projects under the tie-breaker criteria set forth in WAC 246-310-288.

C. Whether a proposed kidney disease treatment center may be denied as an inferior alternative, under WAC 246-310-240(1), because its capital cost and/or projected revenue per treatment is higher than that of a competing application, rather than by a comparison of the projects under the tie-breaker criteria set forth in WAC 246-310-288.

## IV. STATEMENT OF THE CASE

### A. Kidney dialysis saves lives.

The loss of kidney function is normally irreversible. End-Stage Renal Disease ("ESRD") is a stage of advanced kidney impairment. There are approximately 382,000 ESRD patients in the United States. For these individuals, there are only two methods of sustaining life: dialysis or kidney transplantation. AR 2098.

Dialysis refers to the removal of toxins, fluids, and salt from the blood of ESRD patients by artificial means. ESRD patients generally require dialysis at least three times a week for the rest of their lives. AR 2098. Each treatment takes about four hours. AR 1630.

## B. Medicare covers almost all ESRD dialysis patients.

Since 1972, the federal government has provided universal coverage for dialysis treatment under the Medicare ESRD program, regardless of age or financial circumstances. Under this system, Congress establishes Medicare rates for dialysis treatments, related supplies, lab tests and medications. AR 2098. For a patient not covered by an employer group health plan, Medicare becomes the primary payor either immediately or after a three-month waiting period. For a patient covered by an employer group health plan, Medicare generally becomes the primary payor after thirty-three months, which includes the three-month waiting period, or earlier if the patient's employer group health plan coverage terminates. AR 2102.

Thus, Medicare is the primary payor for almost all ESRD patients, except for the relatively short period of time where a commercial policy remains the primary payor before Medicare takes over. Importantly, this means that the reimbursement rates for the vast majority of dialysis treatments are set by Congress. At DaVita, which provides dialysis to approximately 125,000 patients nationwide, approximately 80% of patients are covered by Medicare and another 9% are covered by other government-based programs. AR 2098.

### C. Certificate of Need approval is required to establish or expand kidney dialysis facilities.

In Washington, healthcare providers must obtain CON approval from the Department before establishing or expanding certain types of healthcare facilities or providing certain types of healthcare services. *See* RCW 70.38.105(4); WAC 246-310-020(1). The Department will issue a CON only if it determines that the proposed facility or service is needed by the population to be served and satisfies certain other criteria. *See* RCW 70.38.115(2); WAC 246-310-200.

Kidney dialysis facilities are among the types of healthcare facilities requiring CON approval. *See* RCW 70.38.105(4)(a), RCW 70.38.025(6), WAC 246-310-020(1)(a), WAC 246-310-010(26); *see also* WAC 246-310-280(6) & (7) (defining "kidney dialysis facility"). Applications to establish kidney dialysis facilities are reviewed on one of four quarterly review cycles, which allows for concurrent review of competing applications to meet the same need in a particular planning area. *See* WAC 246-310-282.

### D. The Department has adopted a "tie-breaker" rule governing competing kidney dialysis facility applications.

The Department is required to evaluate CON applications based on the standards set forth in its regulations. *See* WAC 246-310-200(2)(a)(i). All CON applications, not just kidney dialysis facility applications,

generally are reviewed under the basic criteria of "need," "financial feasibility," "structure and process of care," and "cost containment." *See* WAC 246-310-200 (bases for findings); WAC 246-310-210 (need); WAC 246-310-220 (financial feasibility); WAC 246-310-230 (structure and process of care); WAC 246-310-240 (cost containment). However, the Department also has adopted more specific criteria for review of certain types of projects, including kidney dialysis facilities. *See* WAC 246-310-280 *et seq.*

Until recently, the regulations governing kidney dialysis facility applications did not provide specific standards for comparative evaluation of two or more competing applications—i.e., the criteria on which the Department should choose between two or more qualifying projects, when there is not sufficient projected need to warrant approval of both. Therefore, the Department relied upon the general CON criterion that "[s]uperior alternatives, in terms of cost, efficiency, or effectiveness, are not available or practicable" to determine which project should be approved. WAC 246-310-240(1). As might be expected, evaluating competing applications under a general "superiority" standard resulted, in practice, in ad hoc standards.

This Court's opinion in *DaVita, Inc. v. Department of Health*, 137 Wn. App. 174, 151 P.3d 1095 (2007), arose out of just such a situation. In

an evaluation of the competing applications of DaVita and Olympic Peninsula Kidney Center ("OPKC") to establish new dialysis facilities, the Department determined that both applications satisfied all CON criteria, and therefore it had to determine which was "superior." The Department determined that the DaVita project was superior to the OPKC project, because it would add a new choice of provider in the planning area. *See DaVita*, 137 Wn. App. at 178.

The HLJ in the adjudicative proceeding commenced by OPKC determined that, to the contrary, the OPKC project was superior to the DaVita project, because commercial reimbursement rates and operating expenses would be lower at OPKC's facility than at DaVita's facility and OPKC could open a new facility more quickly than could DaVita. *See id.* at 179-80. Because the HLJs were, at that time, the Department's final decision-makers on CON applications, the superiority criteria selected by the HLJ trumped the superiority criteria selected by the Department in its evaluation. *See id.* at 186.

This historical approach—in which comparative review of competing kidney dialysis facility applications was conducted on ad hoc standards; applicants could not know on what basis competing applications would be evaluated; and the criteria varied from application to application and from decision-maker to decision-maker—persisted for

years. It finally was eliminated for kidney disease treatment center applications, or should have been, when the Department adopted WAC 246-310-288, which became effective on January 1, 2007.

The Department's tie-breaker rule identifies nine objective criteria, each of which is worth one point. *See* WAC 246-310-288. They are (1) provision of training services; (2) provision of a private room for patients requiring isolation; (3) provision of a permanent bed station; (4) provision of an evening shift; (5) provision of the number of stations projected to be needed; (6) role as a historical provider; (7) lowest capital expenditure; (8) geographic diversity; and (9) provider choice. *See id.* Whichever applicant receives more points is awarded the CON. If the applicants remain tied after application of the tie-breakers, the Department will approve both applications and award stations as equally as possible among them, without exceeding the total number of stations projected for the planning area. *See id.*

The Department's rulemaking history underscores that the tie-breaker rule was adopted to provide "clarity and consistency for applicants because they will know how stations will be awarded in the event of a tied decision." *See* Significant Analysis, Rules Concerning Kidney Dialysis Treatment Centers, Revision of WAC 246-[3]10-010 and 280, July 2006, at 5-6; *see also* The Report of the ESRD Methodology Stakeholders

Committee to the Washington State Department of Health, December 9, 2005, at 4 (recommending that "[t]he decision-making criteria that are applied in comparative processes are clear, delineated in advance to the applicants and affected parties, and commonly understood by all").[1]

The adoption of the tie-breaker rule accomplished this. As the Department explained in its evaluation in this matter, "[t]he tie-breaker criteria are objective measures used to compare competing projects and make the determination between two or more approvable projects which is the best alternative." AR 2448. The Department accordingly uses the tie-breakers as the exclusive basis to compare competing kidney dialysis facility applications. AR 2449-50. This is in contrast to some other types of CON applications, e.g., applications to build new hospitals, which still must be compared under the general "superiority" standard. AR 1513.

### E. DaVita and NKC each apply to meet the need for additional dialysis stations in King County Planning Area #4.

King County Planning Area #4 is a geographic area south of Seattle containing Burien, Des Moines, Normandy Park, SeaTac, and Tukwila. *See* WAC 246-310-280(9)(a) (defining planning area). More than 100,000 people live in the planning area. AR 1791. It currently is

[1] Palmer Pollock, NKC's Vice-President of Planning, was a member of the committee that made this recommendation. *See id.* at 2; *see also* Application Record ("AR") 1558-59 (Mr. Pollock's hearing testimony) (Q: "And isn't it true that the committee tried to identify what it considered to be the most important factors in evaluating one applicant against another? A: "I believe that's a fair statement.").

served by a single kidney disease treatment center, NKC's 25-station facility in SeaTac. AR 2430. Based on the Department's projections, five additional dialysis stations are needed in the planning area. AR 2429-30.

On May 31, 2011, DaVita and NKC each submitted CON applications to meet this need. AR 2426. DaVita amended its application on June 30, 2011. AR 2426. DaVita applied to build a new, 5-station facility in Des Moines. AR 1773-2293. NKC applied to add five stations to its existing facility in SeaTac. AR 2477-2616.

Between July 1 and September 15, 2011, the Department requested and obtained additional information from DaVita and NKC relating to their respective applications. AR 2296-2307; 2621-31. The Department began concurrent review of the applications on September 16, 2011. AR 2308-09. Between September 16 and December 15, 2011, the Department conducted a public-comment process. AR 2310-2417. The application record closed on December 15, 2011, the deadline for the applicants' rebuttal comments. AR 2308.

DaVita and NKC each are highly-regarded, high-quality providers of kidney dialysis services, with extensive experience applying for CONs to establish or expand dialysis facilities in Washington. At the time of the applications at issue, DaVita operated twenty-five dialysis facilities in Washington, and many more in forty-two other states and the District of

Columbia. AR 2422. NKC operated fifteen dialysis facilities in Washington. AR 2422.

### F. The Department grants DaVita's application and denies NKC's application based on the regulatory tie-breaker standards.

On February 9, 2012, the Department issued its evaluation of the DaVita and NKC applications. AR 2420-56. The Department determined that both applications would satisfy all applicable review criteria as stand-alone applications. Therefore, the Department applied the nine regulatory tie-breaker criteria under WAC 246-310-288. AR 2449-53.

DaVita and NKC both qualified for five of the tie-breaker points: training services, private room, permanent bed station, evening shift, and meeting need. AR 2452.

NKC also qualified for the economies of scale tie-breaker point, because the cost of adding five stations to NKC's existing facility would be less than the cost of building the new, 5-station facility proposed by DaVita. Therefore, NKC received a total of six tie-breaker points. AR 2452.

DaVita also qualified for the geographic access tie-breaker point, because its proposed facility would be at least three miles away from the next closest existing facility, as well as the provider choice tie-breaker point, because NKC was the exclusive provider of dialysis services in the

planning area and DaVita's proposed facility would add a second choice of provider. Therefore, DaVita received a total of seven tie-breaker points. AR 2452.

Because DaVita prevailed under the regulatory tie-breaker criteria, seven points to six points, the Department approved DaVita's application and denied NKC's application. AR 2427.

### G. In the adjudicative proceeding commenced by NKC, the Department defends its reliance upon the regulatory tie-breakers.

On March 8, 2012, NKC commenced an adjudicative proceeding to challenge the Department's decision. AR 1-48. DaVita intervened. AR 60-61. The HLJ conducted the requested hearing on December 5-6, 2012. AR 1191.

Karen Nidermayer, the CON Program Analyst who wrote the Department's evaluation, explained in her hearing testimony the genesis of the tie-breaker regulation:

> The Certificate of Need Program underwent an extensive rulemaking process for dialysis facilities. Participants in that rulemaking included Department of Health staff as well as representation from all of the dialysis providers in the community. And as a group, they sat down and determined what they believed would be tiebreaker points, what are important for comparing applications to each other to determine which is the better application.

AR 1414.

She testified that, from the Department's perspective, the specific tie-breaker regulation was intended to supersede the general superiority standard as the basis on which competing dialysis facility applications must be compared:

> That WAC [246-310-240] was established long before the [WAC 246-310]-288 tiebreaker criteria. ... Previous to -288 ... the Program had no specific guidelines or standards that it could use to compare dialysis applications, and so 288 was created specifically for the review of applications, one or more applications for a planning area specific to dialysis.

AR 1452-53.

She also explained each of the tie-breaker points and how they were applied in this matter, resulting in the Department's determination that DaVita prevailed under the tie-breaker criteria and therefore must be awarded the CON. AR 1414-19.

When asked about NKC's argument that the Department should have determined "superiority" in this matter based on which facility is projected to receive lower reimbursement rates from commercial insurers, Ms. Nidermayer testified that the Department did not consider this alleged basis for comparison at all, because it is not one of the tie-breaker criteria adopted by the Department in regulation. AR 1423. She further explained that the Department would be unequipped, in any event, to make an accurate comparison of providers' respective commercial reimbursement

rates, because rates are privately negotiated and guarded by providers as confidential, proprietary information. AR 1424. Finally, she confirmed that the Department has never attempted to conduct such an analysis. AR 1424.

### H. The HLJ reverses the Department's decision, grants NKC's application, and denies DaVita's application, based on criteria other than the regulatory tie-breakers.

The HLJ identified two differences between the projects which he determined were of particular significance: (1) the difference between what it would cost NKC to add five stations to its existing facility and what it would cost DaVita to build a new, five-station facility, and (2) the difference between projected net revenue per treatment at the two facilities.

First, the HLJ found that it would cost DaVita approximately $2 million to build its proposed new facility, whereas it would cost NKC approximately $100,000 to add five stations to its existing facility. AR 1203. DaVita's $2 million capital budget was not remarkable in itself. Indeed, NKC spent more than this to build its SeaTac facility. AR 1476-77. However, it was significant to the HLJ to the extent that it would cost DaVita more to build a new facility than it would cost NKC to expand its existing facility.

Lower capital expenditure is, in fact, one of the tie-breaker criteria. *See* WAC 246-310-288(2)(a) ("economies of scale"). Within the tie-breaker regulation, however, lower capital expenditure (favoring expansion of existing facilities) is balanced against geographic diversity of facilities and provider choice (favoring new facilities). *See* WAC 246-310-288(2)(c) & (d). The Department properly awarded the economies of scale tie-breaker point to NKC. AR 2458. However, the HLJ determined that lower capital costs could be used as a basis for comparison to the *exclusion* of the other tie-breaker criteria.

Second, the HLJ found that DaVita would receive higher reimbursement from commercial insurers for dialysis services provided at its proposed facility than NKC receives from commercial insurers for dialysis services provided at its existing facility. However, the HLJ did not make any findings as to what the actual rates would be, or quantifying the difference between them. AR 1203.[2]

Because NKC's project had a lower capital budget, and NKC projected lower commercial reimbursement rates, the HLJ found that (1) DaVita's project would have an "unreasonable" impact on the costs and

[2] As described above, most dialysis treatment is covered by Medicare, at rates set by Congress, which would be the same for DaVita and NKC. Therefore, the difference in the applicants' projected net revenue per treatment is a function of the reimbursement rates they each have negotiated with commercial insurers, for the small number of patients not covered by government-sponsored plans.

charges for health services, and accordingly failed WAC 246-310-220(2), and (2) there was a "superior alternative" to DaVita's project, and that DaVita's project accordingly failed WAC 246-310-240(1). AR 1203-04. The HLJ's determinations were not based on consideration of DaVita's application as a stand-alone project, but only in comparison to NKC's application. AR 1200-01 ("The only question is: is the impact on the costs of health services 'unreasonable'? And the answer is, it depends. *It depends on the alternatives.*"); AR 1203-04 ("The Presiding Officer finds that, *given the alternative (NWKC)*, the project proposed by DaVita has an unreasonable impact on health care costs[.]"); AR 1204 ("*In comparing the two applications*, NWKC is the superior alternative.") (emphasis added).

The HLJ determined that the regulatory tie-breakers do not need to be used if one project is deemed to be superior to the other on some other ground. AR 1205 ("[O]ne never gets to the tie-breaker in a concurrent evaluation if one applicant is found to be superior to the other."). Therefore, because he determined that NKC's application was superior based on lower capital costs and lower projected revenue per treatment, he approved NKC's application over DaVita's application on these criteria, and did not apply the regulatory tie-breakers. AR 1205.

## I. The Department and DaVita request reconsideration, which the HLJ denies.

The Department and DaVita sought reconsideration of the HLJ's decision. AR 1232-63; AR 1214-30. The Department documented in detail the numerous errors reflected in the HLJ's order. The Department warned that the HLJ had come up with "a significant new policy for the Department":

> This new policy attacks the wisdom of WAC 246-310-288 – adopted in consultation with kidney dialysis providers, including NKC – which (for good reason) makes commercial rates a non-factor in distinguishing the merits of competing applications. The HLJ is steering the Department into uncharted territory, as there is no record of any regulatory agency in the United States ever having blocked a health care provider from market participation due to the commercial rates that insurance companies voluntarily choose to pay to the provider through negotiation. ... Any movement by the Department in this bold new direction should be undertaken only through rule-making with public input – and not through an HLJ decision in an adjudicative proceeding, especially when the proceeding did not explore the rate-setting issue in any depth.

AR 1259.

Finally, in an extraordinary step, the Department publicly expressed its concern with having to defend in the courts the HLJ's "casting aside the Department's objective tiebreaker rule, in favor of his own subjective superiority analysis." AR 1350. The Department identified the challenge of defending on appeal a decision in which "the

HLJ has offered only the thinnest rationale for disregarding and not giving effect to the Department's own tiebreaker rule[.]" AR 1350. Despite the Department's objections, the HLJ denied the reconsideration motions. AR 1375-80.

**J. Internal Department review of HLJ decisions was not available at the time of the HLJ's order in this matter.**

The CON procedures were amended, effective July 28, 2013, to allow for administrative review of HLJ decisions. A provider whose application has been denied by an HLJ may now seek review of the HLJ decision by a final decision-maker appointed by the Secretary of Health. *See* RCW 18.130.050; WAC 246-310-701; *see also* Engrossed Substitute House Bill 1381, 63rd Leg., Reg. Sess. (Wash. 2013).

The Department advocated for this new procedure precisely so that the Department could ensure consistency in its decision-making. *See* Senate Bill Report, ESHB 1381, March 28, 2013, at 3 ("Having the internal review with the Secretary will help ensure the policy approach is consistent across the agency and across the different administrative law judges. ... DOH supports providing an opportunity for the Secretary to complete a final review of administrative proceedings. The administrative law proceedings can still be formally appealed but this would provide

another level of review and may help avoid some appeals.") (Staff Summary of Public Testimony).

Unfortunately, this new procedure did not become available until a few weeks after the HLJ's reconsideration order was issued, so DaVita was not able to seek review of the HLJ's decision by a final Department decision-maker appointed by the Secretary of Health.

**K. DaVita seeks judicial review of the HLJ's decision.**

DaVita sought judicial review of the HLJ's decision in Thurston County Superior Court. On May 16, 2014, the Superior Court affirmed the HLJ's decision. DaVita now seeks judicial review in this Court.

## V. STANDARD OF REVIEW

The Court reviews the HLJ's decision pursuant to the judicial review standards set forth in the Administrative Procedure Act (the "APA"). The Court reviews the HLJ's decision directly, not the Superior Court's order. *See Postema v. Pollution Control Hearings Bd.*, 142 Wn.2d 68, 77, 11 P.3d 726 (2000).

Because the HLJ's decision was an agency order in an adjudicative proceeding, the Court reviews it pursuant to RCW 34.05.570(3), which provides that the Court may grant relief on, inter alia, the following grounds:

- The agency has engaged in unlawful procedure or decision-making process, or has failed to follow a prescribed procedure;
- The agency has erroneously interpreted or applied the law;
- The order is not supported by evidence that is substantial when viewed in light of the whole record before the court;
- The order is inconsistent with a rule of the agency unless the agency explains the inconsistency by stating facts and reasons to demonstrate a rational basis for inconsistency; or
- The order is arbitrary or capricious.

*See* RCW 34.05.570(3)(c), (d), (e), (h) & (i).

If the Court determines that relief should be granted from the HLJ's decision on any of these grounds, the Court may grant, inter alia, the following relief:

- Order the agency to take action required by law;
- Set aside agency action; or
- Enter a declaratory judgment order.

*See* RCW 34.05.574(1)(b).

This judicial review proceeding relates to the correct interpretation of the Department's regulations governing competing kidney dialysis facility CON applications. "The interpretation of a regulation is a question of law reviewed de novo." *Grays Harbor Energy, LLC v. Grays Harbor County*, 175 Wn. App. 578, 583, 307 P.3d 754 (2013). "When

interpreting a regulation," the court follows "the same rules" it uses "to interpret a statute." *Id.*

## VI. ARGUMENT

### A. The Department is required to apply the standards set forth in the CON regulations.

"It is well-settled law in Washington that public agencies must follow their own rules and regulations." *Samson v. City of Bainbridge Island*, 149 Wn. App. 33, 44, 202 P.3d 334 (2009). Here, the Department promulgated a tie-breaker rule as the basis on which the Department would conduct comparative evaluations of competing kidney dialysis applications; accordingly, the Department is required to use those tie-breakers for that purpose. Indeed, the CON rules explicitly require that the Department do so. *See* WAC 246-310-200(2) (regulatory criteria "shall be used by the department in making the required determinations"); *see also* WAC 246-310-200(2)(a) ("In the use of criteria for making the required determinations, the department shall consider ... the consistency of the proposed project with service or facility standards contained in this chapter").

This Court's opinion in *Children's Hospital and Medical Center v. Department of Health*, 95 Wn. App. 858, 975 P.2d 567 (1999), illustrates this principle in the CON context. In that case, Seattle Children's Hospital challenged the Department's determination that Tacoma General Hospital,

which already was a provider of adult open heart surgery, was not required to obtain CON approval to also provide pediatric open heart surgery. The Department argued that the omission of "pediatric open heart surgery" from the list of tertiary services requiring CON approval, in WAC 246-310-020(1)(d)(i), meant that pediatric open heart surgery is no longer a separate tertiary health service apart from general open heart surgery. *Id.*, at 868. This Court rejected the Department's argument, finding that the Department's own regulations required it to consider the factors set forth under WAC 246-310-035(2) to determine whether pediatric open heart surgery is a tertiary service. The Court explained:

> [T]he Department acknowledges that it did not examine these factors in making its decision in this case, and we note that the courts are charged with ensuring that administrative agencies follow the law and appropriate procedures. In reviewing whether the Department has followed the law, we independently examine these 'tertiary service' factors *because the Department's own regulation provides that it 'shall' consider these factors* and the record shows that it did not.

*Id.* (emphasis added; internal citations omitted). Similarly, the Department's own regulations require it to use the tie-breaker criteria set forth in WAC 246-310-288 to decide between competing kidney dialysis facility applications and, in this case, the HLJ did not do so.

### B. Under the plain language of the regulations, the regulatory tie-breakers are the only permissible basis to compare competing kidney dialysis facility applications.

"If the meaning of a rule is plain and unambiguous on its face" the Court should "give effect to that plain meaning." *Overlake Hosp. Ass'n v. Dep't of Health*, 170 Wn.2d 43, 52, 239 P.3d 1095 (2010). "To ascertain a regulation's plain meaning" the court looks "to the ordinary meaning of its text." *Grays Harbor Energy*, 175 Wn. App. at 584. It also considers "the context in which the regulation appears, related regulations and statutes, and the statutory scheme of which the regulation is a part." *Id.*

On its face, the tie-breaker regulation requires that the criteria it sets forth must be used to compare competing kidney dialysis facility applications:

> If two or more applications meet all applicable review criteria and there is not enough station need projected for all applications to be approved, the department *will* use tie-breakers to determine which application or applications will be approved. The department *will* approve the application accumulating the largest number of points.

WAC 246-310-288 (emphasis added). "In construing statutes and court rules, the words 'will' and 'shall' are mandatory, while words like 'may' are permissive and discretionary." *State v. Stivason*, 134 Wn. App. 648, 656, 142 P.3d 189 (2006). Therefore, the Department is required to use the tie-breakers to choose between competing kidney dialysis facility

applications, and to approve the application which receives the higher number of tie-breaker points.

### C. Under the principles of regulatory interpretation, the regulatory tie-breakers are the only permissible basis to compare competing kidney dialysis facility applications.

The HLJ perceived a conflict between WAC 246-310-288, requiring that "the department will use tie-breakers," and WAC 246-310-240(1), which requires that an application should be approved only if "[s]uperior alternatives, in terms of cost, efficiency, or effectiveness, are not available or practicable." The HLJ interpreted these regulations to mean that the Department must first determine whether one of the applications is superior to the other, and only if neither can be said to be superior, apply the tie-breakers. AR 1205.

If the Court determines that there is, in fact, an ambiguity in the Department's regulations, the Department should, consistent with the principles of regulatory interpretation, conclude that the tie-breakers must be used to determine which application is "superior." At least seven such principles are applicable here: (1) the Court should give effect to the legislative intent underlying the enabling statute; (2) the Court should give effect to the agency's intent in adopting the regulation; (3) a more specific regulation supersedes a more general one; (4) a more recent regulation trumps an older one; (5) the Court should not interpret a regulation in a

way which renders provisions superfluous; (6) the Court should avoid an interpretation of a regulation that leads to an absurd result; and (7) regulations should be interpreted in a way that harmonizes all provisions.

### 1. The Court should look to the Legislature's intent in creating the CON system.

The Court's "paramount concern" when interpreting a regulation "is to ensure that the regulation is interpreted in a manner that is consistent with the underlying policy" of the enabling statute. *Overlake Hosp. Ass'n*, 170 Wn.2d at 52. The Supreme Court has held that the "overriding purpose of the [CON] program" is "promotion and maintenance of *access* to health care services for all citizens." *Id.* at 55 (emphasis added). While "controlling the cost of medical care" is also a priority, it is "of secondary significance" compared to access. *Id.*

The tie-breaker rule promotes access through *most* of the tie-breaker criteria selected by the Department. The "patient geographical access" point does so most directly, but so do the training services, private room, permanent bed station, evening shift, and provider choice points. *See* WAC 246-310-288. Thus, the Department's tie-breaker rule is entirely consistent with the legislative intent underlying the enabling statute.

The HLJ's interpretation of the regulations, by comparison, would permit, and in this case resulted in, cost-control being not only the primary consideration, but the *only* consideration. The HLJ determined that NKC's project should be approved over DaVita's project based solely on lower capital costs and lower commercial reimbursement ("secondary" priorities, per the Supreme Court's opinion in *Overlake*), without regard to how DaVita's new facility would promote access to care (the "overriding" priority, per the Supreme Court's opinion in *Overlake*). Indeed, the HLJ inaccurately characterized "the purpose of CN authority" as "to control health care costs," which contradicts the Supreme Court's holding in *Overlake* regarding legislative intent, that the "overriding purpose" of the CON system is to promote access, with cost-control being of secondary significance. AR 1205.

**2. The Court should look to the agency's intent in adopting the tie-breaker rule.**

Second, without adding to or subtracting from the clear language of a regulation, the Court should construe a regulation to give effect to the agency's intent in adopting it. *See Dep't of Licensing v. Cannon*, 147 Wn.2d 41, 57, 50 P.3d 627 (2002). The Department's intent in adopting the tie-breaker rule was to replace, for kidney dialysis facility applications, the general "superiority" standard with objective, transparent criteria.

This is confirmed by the rulemaking history, as well as by the hearing testimony of the CON Program Analyst, described above. Indeed, this point was emphasized by the Department in its reconsideration motion to the HLJ:

> [T]he tiebreakers – which identify specific comparative criteria – were adopted in order to avoid the problems with conducting the type of a highly-subjective superiority review that occurred in *DaVita v. Dep't of Health*, 137 Wn. App. 174, 151 P.3d 1095 (2007). Hence, it is uncontested that *the HLJ's decision – conducting a superiority analysis rather than applying the tiebreakers – is contrary to the intent of the Department in adopting the tiebreakers* as the new means for conducting a comparative review of kidney dialysis applications.

AR 1349 (emphasis added; original emphasis omitted); *see also* AR 1235 ("Without a doubt, the Final Order – in effect elevating lower commercial rates to a 'super' tiebreaker – *destroys the intent* behind WAC 246-310-288, and therefore should be reconsidered.") (emphasis added); *id.*, n.5 ("The objective WAC 246-310-288 tiebreakers were adopted on the heels of the decision in *DaVita v. Dep't of Health*, 137 Wn. App. 174, 151 P.3d 1095 (2007). The case showed the extreme difficulty of the Department trying to adopt non-defined factors to distinguish between qualified applicants. The WAC 246-310-288 tiebreakers were intended to remove this difficulty. The HLJ decision takes the Department right back to the difficult days prior to adoption of WAC 246-310-288.").

The HLJ suggested in his order denying the reconsideration motions that if that was the Department's intent, it should have repealed WAC 246-310-240(1). AR 1377. However, the general superiority standard remains in effect for *other* types of CON-reviewable projects, i.e., those for which specific comparative-review criteria have not been adopted. It is only for kidney dialysis applications that it has been replaced by the specific tie-breaker criteria.

The Court should interpret WAC 246-310-288 consistently with the Department's intent in adopting it. To permit dialysis applications to continue to be compared based on ad hoc criteria would defeat the whole point of the tie-breaker rule, which was to provide "clarity and consistency for applicants because they will know how stations will be awarded in the event of a tied decision." *See* Significant Analysis, Rules Concerning Kidney Dialysis Treatment Centers, Revision of WAC 246-[3]10-010 and 280, July 2006.

### 3. The specific tie-breaker criteria supersede the general superiority standard.

Third, "[a] specific statute will supersede a general one when both apply." *Kustura v. Dep't of Labor and Indus.*, 169 Wn.2d 81, 88, 233 P.3d 853 (2010). Thus, where the Department has adopted a general rule that the "superior" alternative should be approved with respect to CON

applications, and a specific rule identifying the criteria on which two competing dialysis applications must be compared, the specific rule must be given effect.

**4. The more recent tie-breaker rule trumps the earlier superiority rule.**

Fourth, "[i]f there is an apparent conflict between two provisions, the more specific and more recently enacted statute is preferred." *Am. Legion Post #149 v. Dep't of Health*, 164 Wn.2d 570, 585-86, 192 P.3d 306 (2008). Thus, where the Department has adopted a new, specific rule which clearly governs comparative review of dialysis applications, it must be interpreted to trump an older, general rule which arguably governs comparative review of dialysis applications.

**5. Conducting a superiority analysis based on criteria other than the tie-breakers renders the tie-breaker regulation superfluous.**

Fifth, "[s]tatutes must be interpreted and construed so that all the language used is given effect, with no portion rendered meaningless or superfluous." *State v. Hirschfelder*, 170 Wn.2d 536, 543, 242 P.3d 876 (2010); s*ee also Viet ex rel. Nelson v. Burlington Northern Santa Fe Corp.*, 171 Wn.2d 88, 113, 249 P.3d 607 (2011) (rejecting proposed interpretation "that would render superfluous a provision of a statute").

Under the HLJ's interpretation of the regulations, the Department only reaches the tie-breakers if neither application can be deemed

"superior." And "superiority," according to the HLJ's orders in this case, can be established merely through demonstrating lower commercial reimbursement rates and/or lower capital costs. Thus, unless two projects have *exactly* the same capital budgets, which would never be the case when an expansion application is competing with a new-facility application, and two applicants have negotiated *exactly* the same reimbursement rates with all commercial insurers, which is impossible to imagine, one project could be deemed superior, based on the standards used by the HLJ in this matter, and the tie-breakers will not be reached. Thus, the HLJ's interpretation renders the tie-breaker rule superfluous.

This can be illustrated by one of two superiority criteria relied upon by the HLJ: capital costs. Lower capital cost already is one of the nine tie-breaker criteria. *See* WAC 246-310-288(2)(a). However, because the HLJ determined that NKC's project was superior to DaVita's project based on capital cost, the HLJ did not balance this against the other tie-breaker criteria. Thus, by the logic of the HLJ's decision, *any* of the tie-breaker points identified in WAC 246-310-288 could be extracted and used as the sole basis of comparison. For example, if the Department is permitted to approve one applicant over another based solely on capital costs (WAC 246-310-288(2)(a)), which favored NKC in this matter, the Department also would be permitted to approve one applicant over another

based solely on adding geographic diversity of facilities or provider choice (WAC 246-310-288(2)(c) and (d)), which would have favored DaVita in this matter.

If "superiority" is determined based on reference to criteria outside the tie-breaker, or based on some but not all of the tie-breaker criteria, the tie-breaker rule itself becomes superfluous.

**6. A regulation should be interpreted in a way that avoids absurd results.**

Sixth, the Court should "avoid interpreting a statute in a way that leads to an absurd result[.]" *North Central Wash. Respiratory Care Servs., Inc. v. Dep't of Revenue*, 165 Wn. App. 616, 624, 268 P.3d 972 (2011). If the Court affirms the HLJ's interpretation of the regulations, the Department is—in its own words—"right back to the difficult days prior to adoption of WAC 246-310-288," when competing dialysis facility applications were decided based on ad hoc standards which the applicants did not know in advance, and sometimes changed during the application process, as they did during the previous *DaVita* matter. AR 1235, n.5. It would be absurd to interpret the tie-breaker rule in a way that renders it meaningless.

### 7. Using the tie-breakers as the basis for the superiority analysis harmonizes the provisions.

Finally, the Court should "harmonize" statutes and regulations "whenever possible." *In re Combs*, 176 Wn. App. 112, 117, 308 P.3d 763 (2013). The Department correctly harmonizes the "superior alternative" language with the new tie-breaker rule by using the tie-breakers as the criteria by which to determine which application is superior. AR 2447-48. This approach is consistent with the principles of regulatory interpretation discussed above: the more specific regulation supersedes the more general language; the more recent rule trumps the older rule; and no language is rendered superfluous. The Department still is conducting a superiority analysis; it simply is using the objective criteria stated in the tie-breaker regulation on which to judge superiority, rather than ad hoc standards.

## D. The HLJ's comparative review based on capital costs and projected revenue per treatment was improper.

The HLJ approved NKC's application based upon his determinations that NKC's capital costs were lower than DaVita's and that NKC's reimbursement rates from commercial insurers were lower than DaVita's.

With respect to capital costs, this is an appropriate basis for comparison, but only as one of nine tie-breakers. The tie-breaker rule mandates a balancing of several criteria. The Department cannot choose

to use only one of the criteria, to the exclusion of the others. *See* WAC 246-310-288(2)(a) (only "1 point" to be awarded for "economies of scale" out of nine possible points).

With respect to reimbursement rates, this is not a proper basis for comparison at all. In adopting the regulation at issue, the Department chose not to include reimbursement rates as one of the tie-breaker criteria. The record does not explain why lower revenue per treatment was not selected as one of the tie-breaker criteria. However, there are good reasons to believe that it would be an inaccurate measure of actual cost. Jason Bosh, the DaVita Vice-President with responsibility for all of DaVita's Washington facilities, testified at the hearing in this matter that most of the healthcare cost associated with ESRD patients is *not* for dialysis; it is for hospitalizations, surgeries, and other more-expensive care. Thus, a higher commercial reimbursement rate *for dialysis* may reflect the fact that an insurer is willing to pay more to a particular dialysis provider because that provider's quality of care reduces the patient's *total* healthcare costs (e.g., fewer hospitalizations and surgeries). Accordingly, a higher reimbursement rate for dialysis actually may be an indication of lower total healthcare costs, and thus lower premiums. AR 1631-32.

Moreover, choosing who provides dialysis services in Washington based solely on who can do so at the "lowest cost," as NKC appears to

advocate, is a potentially treacherous approach, as discussed above and as the Department explained in its reconsideration motion. AR 1242.

Therefore, if the Court determines that the Department must, as a matter of law, use the WAC 246-310-288 tie-breakers to choose between competing kidney dialysis facility applications, the HLJ's decision was based on legal error and should be set aside.

### E. The HLJ's "unreasonable impact" finding also is not supported by substantial evidence.

The HLJ's conclusion that DaVita's project would have an unreasonable impact on healthcare costs was erroneous for the additional reason that to be "unreasonable," an action must be outside a *range* of reasonable actions. *See, e.g., US West Commc'ns, Inc. v. Wash. Utilities & Transp. Comm'n*, 134 Wn.2d 74, 116, 949 P.2d 1337 (1997) (considering the "range of reasonableness" for telephone rates). The HLJ made no findings that DaVita's capital costs or revenue per treatment were objectively unreasonable, only that they were higher than NKC's respective capital costs and revenue per treatment figures. The HLJ instead converted a "reasonableness" standard into a binary comparison, where whichever of two providers of similar services charges more is, de facto, "unreasonable." Additionally, there was no evidence of actual impact of the costs to build DaVita's facility, or the differential between

the commercial reimbursement rates received by DaVita and NKC, on healthcare costs, which is what the regulation requires. *See* WAC 246-310-220(2) ("The costs of the project, including any construction costs, will probably not result in an unreasonable *impact* on the costs and charges for health services.") (emphasis added).

Thus, not only did the HLJ err as a matter of law in relying on the capital-cost and reimbursement-rate differentials as the basis for comparative review, there was not even substantial evidence supporting his findings on these issues. *See Little v. King*, 160 Wn.2d 696, 705, 161 P.3d 345 (2007) ("mere speculation is not substantial evidence"); *Weyerhaeuser v. Pierce County*, 124 Wn.2d 26, 35-36, 873 P.2d 498 (1994) (hearing examiner's factual findings were "clearly inadequate" where those findings failed to deal "fully and properly" with all evidence).

**F. The Court should set aside the HLJ's decision.**

The Court should grant relief from the HLJ's decision on the grounds that (1) by failing to use the tie-breaker rule to compare the DaVita and NKC applications the HLJ engaged in unlawful procedure or decision-making process, or failed to follow a prescribed procedure; (2) by concluding that the Department is not required to use the tie-breaker rule, if one project can be deemed "superior" to the other based on other criteria, the HLJ erroneously interpreted or applied the law; (3) the HLJ's

determinations that NKC's expansion was superior to DaVita's new facility and that DaVita's new facility would have an unreasonable impact on healthcare costs was not supported by evidence that is substantial when viewed in light of the whole record; (4) the HLJ's order is inconsistent with the tie-breaker rule; and (5) the HLJ's order is arbitrary and capricious. *See* RCW 34.05.570(3)(c), (d), (e), (h), and (i). Specifically, the Court should order that the Department must use its tie-breaker rule as the basis to compare competing kidney dialysis facility applications and set aside the HLJ's decision, which would reinstate the Department's original decision approving DaVita's application and denying NKC's application based on the tie-breaker rule. *See* RCW 34.05.574(1).

## VII. CONCLUSION

For years, the Department struggled with the lack of specific criteria on which to decide between competing kidney dialysis facility CON applications, and providers endured the uncertainty, inconsistency, and inevitable litigation that resulted from the Department's use of ad hoc standards in the absence of specific criteria. The Department solved this problem in 2007, when the tie-breaker rule went into effect. The tie-breaker rule was the culmination of more than a year of work, and consultation with dialysis providers, including NKC, about what criteria should be used to compare competing applications. The HLJ's decision, if

allowed to stand, would mean that the tie-breaker rule is meaningless, and that any CON Program analyst; any HLJ reviewing a CON Program evaluation; or, now, any Review Officer reviewing an HLJ's initial order, can select whatever criteria he or she wishes as the basis of comparison. This is precisely what the new regulation was supposed to prevent. The HLJ's decision based on ad hoc criteria should be set aside, and the Department's original decision, based on the regulatory tie-breakers, should be reinstated.

Respectfully submitted this 24th day of September 2014.

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# Appendix

## WAC 246-310-288

Agency filings affecting this section

# Kidney disease treatment centers—Tie-breakers.

If two or more applications meet all applicable review criteria and there is not enough station need projected for all applications to be approved, the department will use tie-breakers to determine which application or applications will be approved. The department will approve the application accumulating the largest number of points. If sufficient additional stations remain after approval of the first application, the department will approve the application accumulating the next largest number of points, not to exceed the total number of stations projected for a planning area. If the applications remain tied after applying all the tie-breakers, the department will award stations as equally as possible among those applications, without exceeding the total number of stations projected for a planning area.

(1) The department will award one point per tie-breaker to any applicant that meets a tie-breaker criteria in this subsection.

(a) ***Training services (1 point)***:

(i) The applicant is an existing provider in the planning area and either offers training services at the facility proposed to be expanded or offers training services in any of its existing facilities within a thirty-five mile radius of the existing facility; or

(ii) The applicant is an existing provider in the planning area that offers training services in any of its existing facilities within thirty-five miles of the proposed new facility and either intends to offer training services at the new facility or through those existing facilities; or

(iii) The applicant, not currently located in the planning area, proposes to establish a new facility with training services and demonstrates a historical and current provision of training services at its other facilities; and

(iv) Northwest Renal Network's most recent year-end facility survey must document the provision of these training services by the applicant.

(b) ***Private room(s) for isolating patients needing dialysis (1 point).***

(c) ***Permanent bed stations at the facility (1 point).***

(d) ***Evening shift (1 point)***: The applicant currently offers, or as part of its application proposes to offer at the facility a dialysis shift that begins after 5:00 p.m.

(e) ***Meeting the projected need (1 point)***: Each application that proposes the number of stations that most closely approximates the projected need.

(2) Only one applicant may be awarded a point for each of the following four tie-breaker criteria:

(a) ***Economies of scale (1 point)***: Compared to the other applications, an applicant demonstrates its proposal has the lowest capital expenditure per new station.

(b) ***Historical provider (1 point)***:

(i) The applicant was the first to establish a facility within a planning area; and

(ii) The application to expand the existing facility is being submitted within five years of the opening of its facility; or

(iii) The application is to build an additional new facility within five years of the opening of its first facility.

(c) ***Patient geographical access (1 point)***: The application proposing to establish a new facility within a planning area that will result in services being offered closer to people in need of them. The department will award the point for the facility located farthest away from existing facilities within the planning area provided:

(i) The facility is at least three miles away from the next closest existing facility in planning areas that qualify for 4.8 patients per station; or

(ii) The facility is at least eight miles from the next closest existing facility in planning areas that qualify for 3.2 patients per station.

(d) ***Provider choice (1 point)***:

(i) The applicant does not currently have a facility located within the planning area;

(ii) The department will consider a planning area as having one provider when a single provider has multiple facilities in the same planning area;

(iii) If there are already two unrelated providers located in the same planning area, no point will be awarded.

[Statutory Authority: RCW 70.38.135. WSR 06-24-050, § 246-310-288, filed 12/1/06, effective 1/1/07.]

## CERTIFICATE OF SERVICE

I certify that today I caused to be served the foregoing document on the following persons by the method so indicated:

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I declare under penalty of perjury under the laws of the State of Washington that the foregoing is true and correct.

Signed this 24th day of September, 2014, at Seattle, Washington.

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