

**STATE OF WASHINGTON
DEPARTMENT OF HEALTH
ADJUDICATIVE SERVICE UNIT**

In Re:)	Master Case No. M2011-1684
)	
DETERMINATION OF REVIEWABILITY))	FINDINGS OF FACT,
#11-24 REGARDING SACRED HEART))	CONCLUSIONS OF LAW
MEDICAL CENTER AND CHILDREN'S))	FINAL ORDER
HOSPITAL PEDIATRIC KIDNEY))	
TRANSPLANT PROGRAM,))	
)	
PROVIDENCE HEALTH & SERVICES-))	
WASHINGTON,))	
)	
Petitioners.))	
_____))	

APPEARANCES:

Petitioner, Providence Sacred Health & Services – Washington, d/b/a Sacred Heart Medical Center and Children’s Hospital (Sacred Heart), by Foster Pepper PLLC, per Christopher G. Emch and Lori K. Nomura, Attorneys at Law

Petitioner, Providence Health & Services – Washington (Providence), by Bennett Bigelow & Leedom, PS, per Lisa Dobson Gould, Attorney at Law

Department of Health Certificate of Need Program (Program), by Office of the Attorney General, per Richard A. McCartan and Mark H. Calkins, Assistant Attorneys General

Intervenor, Seattle Children’s Hospital (Seattle Children’s), by Ogden Murphy Wallace PLLC, per Donald W. Black and E. Ross Farr, Attorneys at Law

PRESIDING OFFICER: John F. Kuntz, Review Judge

The Presiding Officer conducted a hearing on July 19-20, 2012, in Tumwater, Washington.

FINDINGS OF FACT,
CONCLUSIONS OF LAW
AND FINAL ORDER

ISSUES

Whether Sacred Heart's request for a determination of non-reviewability¹ regarding its pediatric kidney transplant service should be granted?

SUMMARY OF THE PROCEEDINGS

Sacred Heart presented the testimony of: Jo Ann McCleary; Keith Georgeson, M.D.; and Okechukwu Ojogho, M.D. The Program presented the testimony of: Patrick Healy, M.D., Division Chief of Pediatric Transplantation, Seattle Children's Hospital; and Janis Sigman, Certificate of Need Program Manager. Counsel for Seattle Children's monitored the hearing pursuant to the Order Granting Petition to Intervene (Prehearing Order No. 4). Seattle Children's did not present any witness testimony or exhibits, but was permitted to submit post-hearing briefs pursuant to the prehearing order.

The Presiding Officer admitted the following exhibits at hearing:

Program Exhibits

- Exhibit P-1: The 458-page Program Record (AR).
- Exhibit P-2: Copy of web site for Scientific Registry of Transplant Recipients, visited on July 5, 2012.
- Exhibit P-3: Copy of Organ Procurement and Transplant network – Transplants in the United States by Recipient Age, visited on June 28, 2012.
- Exhibit P-4: Copy of Organ Procurement and Transplant network – Transplants by Donor Type, visited on June 28, 2012.

¹ The parties have referred to this matter as both a "determination of reviewability" and a "determination of non-reviewability." For the sake of consistency, the Presiding Officer will use "determination of non-reviewability" in his decision. A determination of non-reviewability is the threshold decision as to whether a facility or service is subject to a certificate of need. See WAC 246-310-050.

- Exhibit P-5: Copy of Program Summary for Sacred Heart Medical Center.
- Exhibit P-6: Copy of web site of organdonor.gov – Organ Donation: The Process, visited on June 21, 2012.
- Exhibit P-7: Copy of web site of organdonor.gov – Organ Transplantation: The Process, visited on June 21, 2012.
- Exhibit P-8: Copy of Department of Health Facility Reported Waitlist Registration and Transplants by Year and Age.
- Exhibit P-9: Copy of website of Organ Procurement and Transplantation Network – Waiting List Additions Age by Listing Year.

Sacred Heart Exhibits

- Exhibit S-1: Unredacted or partially redacted copies of patient records previously disclosed in the Administrative Record.
- Exhibit S-1A: Complete copy of unredacted or partially redacted copies of patient records previously disclosed.
- Exhibit S-1B: Illustrative Charts from Sacred Heart Medical Center & Children's Hospital regarding all pediatric kidney transplant patients.
- Exhibit S-1B1: Less than 21 years of age at referral/list date (includes duration of post-transplant care for kidney received as a pediatric patient).
- Exhibit S-1B2: Less than 21 years of age at referral/list date (includes duration of post-transplant care for kidney received as a pediatric patient through age 21).
- Exhibit S-1B3: Less than 18 years of age at referral/list date (includes duration of post-transplant care for kidney received as a pediatric patient through age 18).
- Exhibit S-1B4: Less than 18 years of age at referral/list date (includes duration of post-transplant care for kidney received as a pediatric patient (to age 18)).
- Exhibit S-1C: Heart Beat (a Sacred Heart Medical Center Publication), Volume 28, No. 2, April/May 1990.

- Exhibit S-1D: Curriculum Vitae for Jo Ann McCleary, RN, MN, CNN, CCTC.
- Exhibit S-1E: Physician Profile: Keith E. Georgeson, M.D.
- Exhibit S-1F: Curriculum Vitae Okechukwu N. Ojogho, M.D., MMM, FACS.
- Exhibit S-2: Printout from Seattle Children's website, www.seattlechildrens.org, regarding Seattle Children's Transplant Program, dated July 3, 2012.
- Exhibit S-4: Letter from the Children's Orthopedic Hospital and Medical Center to Frank Chestnut, Supervisor, Certificate of Need Unit, dated March 19, 1984, regarding kidney transplant program and Certificate of Need reviewability.
- Exhibit S-13: Centers for Medicare and Medicaid Service's (CMS) Notice to Transplant Programs: Application and Approval for Adults and Pediatric Transplant Programs, dated December 14, 2007, which was obtained at CMS website at <http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandCompliance/downloads/Programsservin gadultsand ped.pdf>.
- Exhibit S-14: Petitioner's Requests for Admission to the Department of Health with Department of Health Responses, dated April 30, 2012 (Department of Health Certification, dated June 15, 2012).

The Presiding Officer denied admission of the following exhibits based on lack of relevance:

- Exhibit S-3: Application for a Certificate of Need by Seattle Children's Hospital to the Department of Health, dated May 19, 2010.
- Exhibit S-5: Letter from Kristina Sparks, Supervisor, Certificate of Need Program to the Children's Orthopedic Hospital and Medical Center, dated April 9, 1984, regarding kidney transplant program and Certificate of Need reviewability.
- Exhibit S-6: Four single page printouts from the Organ Procurement and Transplantation website, <http://optn.transplant.hrsa.org>, dated June 29, 2012, regarding organ transplants at Seattle Children's Hospital.

- Exhibit S-7: The Department of Health's Findings for Certificate of Need Application Submitted on Behalf of Children's Hospital and Regional Medical Center, Seattle, Proposing to Establish an Intestinal Transplant Program, dated June 15, 2005.
- Exhibit S-8: A printout from the Department of Health's Certificate of Need Program's "Active Appeals" publication, dated January 3, 2012, from the "Monthly Report and Performance" section of the Certificate of Need Program's website, www.doh.wa.gov/hsqa/FSL/certneed.
- Exhibit S-9: A printout from the Department of Health's Certificate of Need Program's "Active Appeals" publication, dated March 5, 2012, from the "Monthly Reports and Performance" section of the Certificate of Need's website, www.doh.wa.gov/hsqa/FSL/certneed.
- Exhibit S-10: A printout from the Department of Health's Certificate of Need Program's "Active Appeals" publication, dated April 25, 2012, from the "Monthly Reports and Performance" section of the Certificate of Need Program's website, www.doh.wa.gov/hsqa/FSL/certneed.
- Exhibit S-11: A printout from the Department of Health's Certificate of Need Program's "Active Appeals" publication, dated May 4, 2012, from the "Monthly Reports and Performance" section of the Certificate of Need Program's website, www.doh.wa.gov/hsqa/FSL/certneed.
- Exhibit S-12: A printout from the Department of Health's Certificate of Need Program's "Active Appeals" publication, dated June 1, 2012, from the "Monthly Reports and Performance" section of the Certificate of Need Program's website, www.doh.wa.gov/hsqa/FSL/certneed.

The parties were given the opportunity to file post hearing briefs in lieu of closing argument. The parties were required to file opening briefs by August 17, 2012, and closing briefs by August 24, 2012. See Post-Hearing Order No. 1; see *also* RCW 34.05.461(7).² The hearing record was closed August 24, 2012.

² The Program filed a Correction of Certificate of Need Program's Response to Providence Health & Services – Washington's Post-Hearing Brief on August 29, 2012. This was to correct an inadvertent scrivener's error and did not extend the closing of the hearing record.

I. FINDINGS OF FACT

1.1 A certificate of need is a non-exclusive license for health care providers wishing to establish new facilities.

Tertiary Health Services

1.2 A certificate of need is required to establish a new tertiary health service. A tertiary health service is a specialized service meeting complicated medical needs of patients and requiring sufficient patient volume to optimize provider effectiveness, quality of service, and improved outcomes of care. See WAC 246-310-010(58); see also RCW 70.38.105(3) (requirement for certificate of need). A new tertiary health service is a new service that is not offered by, in, or through a health care facility within the 12-month period prior to the time such services would be offered. See RCW 70.38.105(4)(f). A tertiary health service includes specialized inpatient pediatric services. See WAC 246-310-020(1)(d)(i)(G).

1.3 Where a procedure or service is considered a tertiary health service, normally there is a statute or regulation that notifies applicants or the public what constitutes a sufficient patient volume to optimize provider effectiveness (that is, how many procedures must be performed annually to ensure the provider can effectively provide the tertiary health service). For example, WAC 246-310-263(7) specifies that a provider must perform a minimum of one hundred pediatric cardiac surgical procedures per year to maintain his or her effectiveness at such procedures.³ There is currently no

³ Other examples include adult kidney transplants (at least 15 transplants annually by the fourth year of operation under WAC 246-310-260) and open heart surgery procedures (250 procedures per year under WAC 246-310-261).

statute or regulation that specifying how many pediatric kidney transplant procedures a provider must perform regarding pediatric kidney transplant procedures. There are no minimum volume standards under the Center for Medicare and Medicaid Services or the United Network of Organ Sharing. In fact, the Center for Medicare and Medicaid Services does not require a separate certification in order to provide kidney transplant services to both pediatric and adult patients.

1.4 In addition, there is no statute or regulation defining what age group is included in the pediatric kidney transplant procedure category.⁴ There are at least two logical age cutoffs: 18 years of age (the age of majority; a cutoff date that is not related to any treatment criteria) and 21 years of age (the age cutoff used by some transplant programs, given the chronic nature of renal (kidney) disease).⁵ However the age cutoff is defined, it is clear that once a pediatric patient receives a kidney transplant, he or she will require medical services for the life of the kidney.

1.5 Despite the lack of specific regulatory standards setting what constitutes sufficient patient volume or what is the appropriate age cutoff for pediatric kidney transplants, it is clear that the pediatric kidney transplant is a tertiary health service and a facility must have a certificate of need to perform the procedure.

1.6 A pediatric kidney transplant consists of more than the actual transplant surgery (the surgery to replace the pediatric patient's diseased or nonfunctioning organ

⁴ In fact, the term "pediatric" is not defined in the chapter 246-310 WAC regulations. See TR 417, lines 14-20 (Janis Sigman direct testimony).

⁵ There was expert testimony at the hearing that age is less of a factor than the weight of the patient and the expertise of the surgeon.

with a healthy or functioning organ from a live or deceased donor.) A pediatric kidney transplant includes a broad range of services, both during the pre-transplant phase and the post-transplant phase. A non-exclusive list includes: determining whether the patient qualifies for a kidney transplant; finding a donor kidney; harvesting a donor kidney in tandem with a recipient's transplant⁶ (when the kidney is obtained from a live donor for transplantation into a recipient); psychological counseling surrounding the kidney transplant process; and supportive medical care (laboratory work; pharmacy and medications; and dietary considerations) throughout the life of the transplant patient. While a transplant surgery is the most obvious part of the pediatric kidney transplant process, it is not the only indicator of a facility's work in performing pediatric kidney transplant services. As WAC 246-310-035(2)(d) indicates, a tertiary health service can be broader than a procedure.

Sacred Heart Determination of Non-Reviewability

1.7 Sacred Heart applied for a certificate of need to establish a kidney dialysis program with the Department of Social and Health Services (the Department of Health Certificate of Need Program's (Program)'s predecessor agency) in 1980. Sacred Heart's application noted that "[w]e are especially aggressive in seeking transplantation for children and adults up to 50 years of age." At the time of its application, Sacred Heart's intention was to provide kidney transplant services to patients as young as ten years old.

⁶ Retrieval of a kidney from a cadaver (a dead body or corpse) is performed in Washington by a separate state organization, even if the organ will be transplanted to a recipient in the same facility. A certificate of need is not required to remove a kidney from a cadaver

1.8 The Department of Social and Health Services issued Certificate of Need No. 605-0 (CN 605-0) for kidney transplant services to Sacred Heart on April 15, 1981. See AR 19 and 147. CN 605-0 describes the project as “[d]evelopment of renal transplant surgery program, with purchase of two kidney perfusion systems at \$23,415.” CN 605-0 is silent regarding what the age cutoff is for Sacred Heart to perform kidney dialysis services; neither does CN 605-0 impose any conditions or age limitations. However, what is clear is that Sacred Heart has performed pediatric kidney transplants since 1981, and the Program was aware that Sacred Heart was performing pediatric kidney transplants since 1981.

1.9 In August 2010, the Department of Health’s (DOH) Investigations and Inspection Office, acting on behalf of the United States Department of Health and Human Services/Centers for Medicare and Medicaid Services (CMS), conducted a survey of the Sacred Heart hospital facility. On August 30, 2010, the DOH Investigation and Inspection Office notified Sacred Heart by email that Sacred Heart would need to apply for a pediatric kidney transplant certificate of need before it can be certified by CMS. AR 201.

1.10 On October 25, 2010, CMS issued to Sacred Heart a letter that stated “[t]he Pediatric Kidney Only program was not surveyed because the program was not in full operation and providing services to patients at the time of the survey [Sacred Heart] can resubmit an application for the Pediatric Kidney Only program once it has met State CON requirements and is operational.” AR 221-222.

1.11 By letter dated March 22, 2011, Sacred Heart sought a determination of non-reviewability from the Program. See AR -128. The Program requested additional or supplemental information, which Sacred Heart provided. On November 22, 2011, the Program notified Sacred Heart of its determination and advised Sacred Heart that it would need to file a certificate of need application for the specialized inpatient pediatric service. AR 243-244. The Program's determination stated:

In 1981, Sacred Heart received a CN to perform kidney transplants. The issued CN arguably made no differentiation between adult and kidney transplants. However, in 1989, the legislature amended RCW 70.38.105(4)(f) to require CN approval for:

“Any new tertiary services...which were not offered by [the] health care facility...within the twelve month period prior to the time such services would be offered.”

Pursuant to information from Sacred Heart, the hospital between 1989 and 2008 performed twelve pediatric kidney transplants. The hospital apparently has not performed any such transplants since 2008. Nor, during that period, has Sacred Heart maintained a “wait list” of children needing kidney transplants, or otherwise offered the service.

Hence, under the definition in RCW 70.38.105(4)(f), the 12-month lapse in providing the service would require Sacred Heart to obtain a “specialized inpatient pediatric service” CN under WAC 246-310-020(1)(d)(i)(G) in order to offer pediatric kidney transplant.

AR 243-244 (emphasis in original; footnotes in original omitted).

At the hearing, the Program reaffirmed that this determination of non-reviewability only applied to Sacred Heart's ability to perform pediatric kidney transplantation services;

it did not address or limit Sacred Heart's ability to perform adult kidney transplants under CN 605-0 issued in 1981.⁷

1.12 On December 16, 2011, Sacred Heart filed a request for reconsideration with the Program. On December 26, 2011, Sacred Heart filed an Application for Adjudicative Proceeding with the Adjudicative Service Unit to contest the Program's determination of non-reviewability.⁸

1.13 Sacred Heart has performed 12 pediatric transplant procedures since 1989. The most recent pediatric transplantation procedure was performed in 2008. See Exhibit P-3.

1.14 Since 1988, Washington health care facilities other than Sacred Heart have provided pediatric kidney transplantation services. These facilities include: Seattle Children's Medical Center (241 transplants); University of Washington Medical Center (4 transplants); Virginia Mason Medical Center (16 transplants); and Swedish Medical Center (9 transplants). When Sacred Heart applied for its determination of non-reviewability in March 2011, only Seattle Children's had performed pediatric kidney transplantation within the preceding 12-month period. See AR page 13, Footnote 26.

1.15 The evidence at hearing shows that none of the above-identified health care facilities have been required to obtain a pediatric kidney transplantation certificate of need, or another pediatric kidney transplantation certificate of need, as a result of a

⁷ The parties do not dispute that Sacred Heart has a certificate of need to perform adult kidney transplantation.

⁸ Sacred Heart filed a request for reconsideration on December 16, 2011. It then filed its request for adjudicative proceeding on or about December 19, 2011. The Program chose to address the appeal and did not respond to the reconsideration request. See Program's Post-Hearing Brief, page 4, lines 16-18.

12-month lapse in performing pediatric kidney transplant surgeries at their respective facilities.

1.16 Seattle Children's does not hold a certificate of need to provide kidney transplant services for pediatric patients. See Hearing Transcript (TR) page 340, line 23 through page 341, line 18, lines 14-19 (testimony of Dr. Healy); see also TR 460, lines 14-19 (Janis Sigman testimony).

1.17 The expert testimony at the hearing shows:

A. Pediatric transplant surgeries are infrequent in number.

B. There is no defined number of procedures that constitutes a sufficient patient volume to optimize provider effectiveness regarding the number of pediatric transplant surgeries in Washington.

C. Pediatric kidney transplantation consists of more services than just the actual transplant surgery.

D. Pediatric kidney transplantation is more a factor of the patient's weight than it is of the patient's age.

E. A physician with a certification of completion of an approved kidney transplant surgery fellowship is qualified to perform both pediatric and adult kidney transplantation services.

II. CONCLUSIONS OF LAW

Evidence in Certificate of Need Decisions

2.1 The Department of Health is authorized and directed to implement the Certificate of Need Program. RCW 70.38.105(1). The applicant must show its

application meets all of the applicable criteria or, as in the present case, must show that it qualified for a determination of non-reviewability. WAC 246-10-606(2). The standard of proof in certificate of need matters is a preponderance of the evidence. See WAC 246-10-606. Admissible evidence in certificate of need hearings is the kind of evidence on which reasonably prudent persons are accustomed to rely in the conduct of their affairs. See RCW 34.05.452(1).

Presiding Officer as Agency Fact-Finder

2.2 The Presiding Officer (on delegated authority from the Secretary of Health) is the agency's fact-finder and final decision maker. *DaVita v. Department of Health*, 137 Wn. App. 174, 182 (2007) (*DaVita*). The Presiding Officer considers the Program's written analysis in reaching his decision but is not required to defer to the Program analyst's decision or expertise. *DaVita*, 137 Wn. App. at 182-183. The Presiding Officer engages in a de novo review of the record because the Presiding Officer is the final decision maker. See *University of Washington Medical Center v. Department of Health*, 164 Wn. 2d 95, 103 (2008) (citing to *DaVita* decision).

2.3 In acting as the Department's final decision maker, the Presiding Officer reviewed the applicable record. This includes reviewing any supporting data obtained from the relevant organizations for the tertiary health care service, such as the Uniform Network of Organ Sharing (UNOS) and the Organ Procurement and Transplantation Network (OPTN) contained as a part of the application record. The Presiding Officer also reviewed the hearing transcripts and the closing briefs submitted by the parties in lieu of closing argument as authorized under RCW 34.05.461(7).

Applicability Determination

2.4 Any person wanting to know whether an action is subject to certificate of need requirements may submit a written request for a formal determination of non-reviewability. WAC 246-310-050(1). The Program must respond in writing to such a request and must state the reasons for its determination. WAC 246-310-050(3). A certificate of need evaluation analyzes whether the applicant meets all of the relevant criteria for the applied-for certificate. A determination of non-reviewability is not a detailed evaluation; it anticipates that if a certificate of need is required, the applicant will complete the detailed application process at that time.

2.5 The first question that must be addressed is whether Sacred Heart's performing pediatric kidney transplant procedures constitutes a tertiary health service. WAC 246-310-010(58) defines "tertiary health service" to mean:

A specialized service meeting complicated medical needs of people and requires sufficient patient volume to optimize provider effectiveness, quality of care, and improved outcomes of care.

There are a number of criteria that can be used to determine whether a service is a tertiary health service. WAC 246-310-035(2) provides a non-exclusive list, which includes:

- (a) Whether the service is dependent on the skills and coordination of specialties and subspecialties. Including, but not limited to, physicians, nurses, therapists, social workers;
- (b) Whether the service requires immediate access to an acute care hospital;
- (c) Whether the services is characterized few providers;
- (d) Whether the service is broader than a procedure;

- (e) Whether the service has a low use rate;
- (f) Whether consensus supports or published research shows that sufficient volume is required to impact structure, process, and outcome of care; and
- (g) Whether the service carries a significant risk or consequence.

Finally, WAC 246-310-020(1)(d)(i)(G) lists that tertiary health services includes:

Specialized inpatient pediatric services. The service is designed, staffed, and equipped to treat complex pediatric cases for more than 24 hours. The service has a staff of pediatric specialists and subspecialists.

See also Children's Hospital and Medical Center v. Department of Health, 95 Wn. App. 858, 866-867 (1999).⁹

2.6 Based on Findings of Fact 1.2 through 1.7, the Presiding Officer concludes that performing a pediatric kidney transplant constitutes a tertiary health service. Because it is a tertiary health service, Sacred Heart must have a certificate of need to perform pediatric kidney transplant procedures.

CN 605-0

2.7 The next question is whether Sacred Heart currently possesses a pediatric kidney transplant certificate of need or whether it must now apply for a certificate of need to perform pediatric transplantation services. The facts show that Sacred Heart was awarded CN 605-0 in 1981. Sacred Heart's record shows it failed to perform a kidney transplant procedure within the 12-month-period prior to its request for a determination of non-reviewability.

⁹ Adult kidney transplantation is a tertiary health service. WAC 246-310-260. While not the primary basis for his decision, the Presiding Officer concludes that if an adult kidney transplant procedure is a tertiary health service, it follows that pediatric kidney transplant procedures must be a tertiary health service as well.

2.8 CN 605-0 describes the project as “[d]evelopment of renal transplant surgery program.” On its face, CN 605-0 does not state whether it includes or excludes pediatric kidney transplant services; neither does CN 605-0 have any express limitations or conditions regarding the age of kidney transplant service recipient.

2.9 What is clear is that: (1) Sacred Heart fully intended to perform pediatric kidney transplant procedures and the services supporting them; (2) Sacred Heart notified the Program of its intention to perform pediatric kidney transplant procedures on patients as young as 14 years of age in its application for CN 605-0; and (3) the Program was fully aware that Sacred Heart continuously performed pediatric kidney transplant operations from 1981 through 2010. In addition, Sacred Heart performed or provided the services that accompany such operations. At the time of the application, the Program did not require facilities to obtain separate certificate of need authorization for the adult and pediatric kidney transplant operations and services. Based on the totality of the evidence available, the Presiding Officer concludes CN 605-0 authorized Sacred Heart to conduct pediatric kidney transplant procedures at least through the period 1981 through October 2010.

RCW 70.38.105(4)(f)

2.10 The next question is whether a health care facility that once possessed a certificate of need to perform pediatric kidney transplant procedures (or any other tertiary health service) is ever required to obtain a new certificate of need.¹⁰ The issue whether

¹⁰ This decision does not address those situations where the Program seeks to suspend or revoke a certificate of need under WAC 246-310-500.

a facility must obtain another or new certificate of need rests on the interpretation of the language set forth in RCW 70.38.105(4)(f). That statute reads:

The following shall be subject to certificate of need review under this chapter:

....

Any *new* tertiary health services which are not offered in or through a health care facility or rural health care facility licensed under RCW 70.175.100, *and* which were not offered on a regular basis by, in, or through such health care facility or rural health care facility within the twelve month period prior to the time such services would be offered. (Emphasis added).

2.11 Clearly a tertiary health service requires a certificate of need. The question then becomes what is a “new” tertiary health service under RCW 70.38.105(4)(f). The term “new” is not defined for purposes of RCW 70.38.105(4)(f). The Presiding Officer concludes that the rules of statutory construction can be used to resolve the issue.

2.12 In *City of Olympia v. Drebeck*, 156 Wn. 2d 289 (2006), the Washington Supreme Court set forth the principles of statutory construction. The Court stated:

The aim of statutory interpretation is “to discern and implement the intent of the legislature.” A reviewing “court is required, whenever possible, *to give effect to every word in a statute.*” Where the meaning of a provision is “plain on its face, then the court must give effect to that plain meaning as an expression of legislative intent.” A provision’s plain meaning may be ascertained by an “examination of the statute in which the provision at issue is found, as well as related statutes or other provisions of the same act in which the provision is found.” ...Only when the plain, unambiguous meaning cannot be derived through such an inquiry will it be “appropriate [for a reviewing court] to resort to aids to construction, including legislative history.”

City of Olympia v. Drebeck, 156 Wn. 2d at 295 (internal citations omitted) (emphasis added).

2.13 As one of the relevant terms (“new”) is undefined, RCW 70.38.105(4)(f) is ambiguous. So the correct interpretation of RCW 70.38.105(4)(f) turns on how the term “new” is defined and how that defined term assists in the interpretation of the entire section. A dictionary may be used to determine the plain and ordinary meaning of statutory words that are not defined. *Labor & Industries v. Gongyin*, 154 Wn. 2d 38, 45 (2005). “New” is defined as “never existing before; appearing, thought of, developed, made, produced, etc. for the first time.” Webster’s New College Dictionary, page 970 (2009). For a tertiary health service to be “new,” it must be a service that was never existed before or being produced for the first time.

2.14 Once the term “new” is defined, the term must be read in conjunction with the remaining language within RCW 70.38.105(4)(f). In other words, the service: (1) must be new (a service that never existing before); (2) it must be a tertiary health service; and (3) it must not be offered on a regular basis (offered on a regular basis in the preceding 12-month period). All three elements must be present for RCW 70.38.105(4)(f) to apply; a new certificate of need is not required if all three elements are not present

2.15 While Sacred Heart did not perform a pediatric kidney transplant surgery in the preceding 12-month period (the one before its request for a determination of non-reviewability), it is clear the tertiary health service Sacred Heart is offering to perform is not “new” to it. Sacred Heart has performed pediatric kidney transplant procedures (a tertiary health service) since 1981, albeit not as frequently as some other facilities. While there have been 12-month lapses in Sacred Heart performing the pediatric kidney

transplant surgery, its attempt to continue to offer the pediatric kidney transplant procedures and services cannot be considered as new.¹¹

Interpretation of RCW 70.38.105(4)(f)

2.16 The evidence shows that the Program has not consistently applied the interpretation of RCW 70.38.105(4)(f) that it seeks to apply to Sacred Heart on a consistent basis throughout the period 1981 to the present. For example, Seattle Children’s Hospital (the provider that performs the largest number of pediatric kidney transplant procedures in Washington) does not possess a certificate of need to perform that tertiary health service. Additionally, other facilities that perform pediatric kidney transplant procedures in Washington have had similar 12-month breaks in offering or performing the procedure without being required to obtain a certificate of need or a new certificate of need.

2.17 In *Christopher v. SmithKline Beecham Corp.*, ___ U.S. ___, 132 S.Ct. 2156, 183 L.Ed. 153 (2012), the United States Supreme Court was asked to review Department of Labor (DOL) regulations enacted to implement the Fair Labor Standards Act.

2.18 The Supreme Court ruled that the petitioners (pharmaceutical sales representatives) did qualify as outside salesmen. In reaching this decision, the Supreme Court did not defer to the DOL interpretation, determining that to defer to the DOL previously unannounced interpretation of its regulation would seriously undermine the

¹¹ Sacred Heart argues that the Program cannot revoke CN 605-0 without cause. See RCW 70.38.125. The Program argues it is not revoking CN 605-0, but merely requiring Sacred Heart to obtain a new certificate of need. Given his interpretation of RCW 70.38.105(4)(f), the Presiding Officer need not address the revocation issue.

principle that agencies should provide regulated parties fair warning of the conduct a regulation prohibits or requires. *Christopher v. SmithKline Beecham Corp*, 132 S. Ct. 2167. The Supreme Court stated:

It is one thing to expect regulated parties to conform their conduct to an agency's interpretation once the agency announces them; it is quite another to require regulated parties to divine the agency's interpretations in advance or else be held liable when the agency announces its interpretations for the first time in an enforcement proceeding and demands deference.

Christopher v. SmithKline Beechem Corp, 132 S.Ct. 2168.

2.19 The *SmithKline Beecham* case is on point in this matter. The Program denied Sacred Heart's request for non-reviewability on an interpretation of RCW 70.38.105(4)(f) not previously announced or applied. That the Program has not previously interpreted RCW 70.38.105(4)(f) to require other pediatric kidney transplant facilities to obtain a certificate of need after a 12-month period with no pediatric kidney transplantation is clear, given that it has never enforced RCW 70.38.105(4)(f) against any other Washington health care provider that performs pediatric kidney transplant procedures. The University of Washington Medical Center, Swedish Medical Center, and Virginia Mason Medical Center all currently perform pediatric kidney transplants.¹² All of them have experienced 12-month periods in which they did not perform pediatric kidney transplants. Yet none of these facilities has been required to obtain a certificate of need or a new certificate of need.

2.20 RCW 70.38.105(4)(f) does not require a facility that holds a certificate of need to provide a tertiary health service to obtain a new or successor certificate of need

¹² See AR page 10 and AR page 13, footnote 26.

merely because there is a 12-month gap in providing the service. The Presiding Officer concludes the language of RCW 70.38.105(4)(f) does not prevent Sacred Heart from conducting pediatric kidney transplant surgeries under CN 605-0.¹³ But even if the language of RCW 70.38.105(4)(f) could be read in the manner the Program interprets it, the United States Supreme Court's holding in *SmithKline Beecham Corp* argues against enforcing it for the first time in this administrative proceeding.

Sufficient Patient Volume

2.21 In addition to the correct interpretation of RCW 70.38.105(4)(f), it appears that a concern regarding Sacred Heart's request for a determination of non-compliance resulted in part because of Sacred Heart's failure to complete a sufficient number of pediatric kidney transplant procedures on an annual basis. Normally, whether an applicant meets the sufficient patient volume standard for a tertiary health service is determined by comparing the number of procedures performed by the facility or applicant to the numerical standard set forth in the regulatory standard.

2.22 There are complicating factors at work here. First, expert testimony makes clear that pediatric kidney transplant surgeries are infrequent in number. Second, there is no defined number of procedures that constitutes what is a "sufficient patient volume

¹³ There are policy reasons to reject the interpretation of RCW 70.38.105(4)(f) the Program argues for. The legislature declared one of Washington's public policy is to provide accessible health services. See RCW 70.38.015(1) and (5). If a health care facility, through no fault of its own, does not perform a pediatric kidney transplant surgery during any 12-month period, it will affect the public's accessibility to the service. If a facility must complete the application process that facility will be unavailable during the 12 to 18 months it takes to complete the application. That is especially true where, as here, pediatric kidney transplantation is an infrequent procedure.

to optimize provider effectiveness” in Washington.¹⁴ Unlike adult kidney transplantation, there is currently no specific definition that defines what constitutes a pediatric kidney transplant program. See WAC 246-310-260 (for adults, the number is 15 transplants annually). So there is not now, nor has there ever been, any regulation or statute notifying providers how many pediatric kidney transplants must be performed on an annual basis.¹⁵ Third, pediatric kidney transplantation consists of more than the actual transplant surgery. See WAC 246-310-035(2)(d). So even though it has not performed pediatric kidney transplant surgeries as frequently as other facilities, Sacred Heart has conducted the other pre-surgery and post-surgery activities that constitute a part of the pediatric kidney transplant services. Finally, the term “pediatric” is not consistently defined in certificate of need regulations. See WAC 246-310-263(9)(a) (age specific categories are zero through 14; 15 through 19).

2.23 In fact, age is not the defining factor in performing pediatric kidney transplantation. In other words, it does not matter whether a pediatric patient age cutoff is 18-years-old or 21-years-old. Expert testimony from Dr. Ojogho and Dr. Georgeson shows both: (1) it is the patient’s weight, rather than the patient’s age, is key in determining whether to perform a kidney transplant; and (2) a physician with a certification of completion of an approved kidney transplant surgery fellowship is qualified to perform both pediatric and adult kidney transplantation. It follows from these conclusions that if a facility performs sufficient adult kidney transplantation services, it

¹⁴ See WAC 246-310-010(58) (definition of “tertiary health service”).

¹⁵ See WAC 246-310-260(2)(a).

performs a sufficient number to qualify a facility to perform pediatric kidney transplantation as well.

2.24 Having so stated, the Presiding Officer concludes that it is more appropriate for both the patient age cutoff and sufficient volume cutoff to be set in regulation. That method allows a full discussion of all of the relevant policy issues. Based on the evidence before him, and consistent with the United States Supreme Court's holding in the *SmithKline Beechem* case, it is more appropriate for these issues to be set in regulation.

Conclusion

2.25 Based on the totality of the evidence and his interpretation of RCW 70.38.105(4)(f), the Presiding Officer concludes that Sacred Heart is not required to obtain a "new" certificate of need in order to continue performing pediatric kidney transplantation services. Its determination of non-reviewability is granted.

III. ORDER

Based on the foregoing Findings of Fact and Conclusions of Law, it is ORDERED:

3.1 Sacred Heart's request for a determination of non-reviewability under WAC 246-310-050 is GRANTED. Sacred Heart is not required to obtain a new certificate of need to perform pediatric kidney transplant procedures and services.

3.2 Sacred Heart's request for reconsideration under WAC 246-310-560 is DISMISSED as moot.

Dated this 30 day of October, 2012.

_____/s/_____
JOHN F. KUNTZ, Review Judge
Presiding Officer

NOTICE TO PARTIES

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

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

Adjudicative Service Unit
P.O. Box 47879
Olympia, WA 98504-7879

and a copy must be sent to:

Certificate of Need Program
P.O. Box 47852
Olympia, WA 98504-0109

The petition must state the specific grounds for reconsideration and what relief is requested. WAC 246-10-704. The petition is denied if the Adjudicative Service Unit does not respond in writing within 20 days of the filing of the petition.

A **petition for judicial review** must be filed and served within 30 days after service of this order. RCW 34.05.542. The procedures are identified in chapter 34.05 RCW, Part V, Judicial Review and Civil Enforcement. A petition for reconsideration is not required before seeking judicial review. If a petition for reconsideration is filed, the above 30-day period does not start until the petition is resolved. RCW 34.05.470(3).

FINDINGS OF FACT,
CONCLUSIONS OF LAW
AND FINAL ORDER

The order is in effect while a petition for reconsideration or review is filed. "Filing" means actual receipt of the document by the Adjudicative Service Unit. RCW 34.05.010(6). This order is "served" the day it is deposited in the United States mail. RCW 34.05.010(19).

For more information, visit our website at <http://www.doh.wa.gov/hearings>.