

**RECONSIDERATION EVALUATION OF THE CERTIFICATE OF NEED
APPLICATION SUBMITTED ON BEHALF OF CHILDREN’S HOSPITAL AND
REGIONAL MEDICAL CENTER PROPOSING TO ESTABLISH A PEDIATRIC
AMBULATORY SURGERY CENTER IN EAST KING COUNTY**

PROJECT DESCRIPTION

Children’s Hospital and Regional Medical Center (Children’s) is owned by Children’s Health Care System, a Washington not-for-profit, public benefit 501(c)(3) tax exempt organization, founded in 1907 as Children’s Orthopedic Hospital. Children’s provides health care services through its main hospital campus in Seattle’s Laurelhurst neighborhood, through local satellite clinics, via partnerships with other hospitals in Washington, Alaska, Montana and Idaho and a home care agency.

Children’s is a tertiary provider of pediatric care that draws patients from throughout Washington, Alaska, Idaho and Montana for acute care, hematology/oncology, infectious disease, organ transplantation, rehabilitation, cardiology, and other specialized pediatric services. Children’s also currently operates a pediatric specialty outpatient center in Bellevue on the Overlake Hospital Medical Center campus. [Application, p9; Children’s website]

BACKGROUND INFORMATION ON THE PROJECT

On June 6, 2008, Children’s submitted its Certificate of Need application to establish an ambulatory surgery center in Bellevue. The ASC plans to include two operating rooms and one GI procedure room with shelved in space for additional capacity. Children’s intends to operate the facility under the hospital’s license. The ASC intends to offer outpatient surgery exclusively to pediatric patients from 0-14 years. [Application, p9-10]

The anticipated date of commencement of construction of the facility is April, 2009. The facility is expected to begin serving patients in June, 2010. Under this timeline, the first full year of operation is projected to be calendar year 2011. The estimated capital expenditure for this project is \$19,176,407 and is a compilation of the individual costs detailed below. [Initial application, p13 & 27]

Breakdown Of Estimated Capital Costs	Cost	% Of Total
Land Costs	\$1,577,398	8%
Equipment Costs	\$1,995,044	10%
Tenant Improvements	\$12,528,171	65%
Planning Fees	\$1,683,010	9%
Financing Costs	\$150,244	1%
Applicable Taxes	\$1,242,540	6%
Total Estimated Capital Cost	\$19,176,407	100%

On December 6, 2008, the Program denied Children’s application primarily based on its failure to meet the criteria related to numeric need. On December 24, 2008, Children’s submitted its

“Request for Reconsideration” in response to the Department’s denial, which included information related to the need criteria. The Program granted Children’s reconsideration request and the reconsideration hearing was conducted on January 14, 2009. This document is the evaluation of the reconsideration information.

APPLICABILITY OF CERTIFICATE OF NEED LAW

This project is subject to Certificate of Need review as the establishment of a new health care facility under the provisions of Revised Code of Washington (RCW) 70.38.105(4)(a) and Washington Administrative Code (WAC) 246-310-020(1)(a).

APPLICATION CHRONOLOGY

A chronological summary of the initial review and this reconsideration review is below.

Initial Review

April 14, 2008	Letter of Intent Submitted
June 6, 2008	Application Submitted
June 7, 2008 through August 11, 2008	Department ’s Pre-Review Activities <ul style="list-style-type: none">• screening activities and responses
August 12, 2008	Department Begins Review of the Application
October 6, 2008	Public Hearing / End of Public Comment
October 21, 2008	Rebuttal Documents Received at Department
December 5, 2008	Department 's Anticipated Decision Date
January 5, 2009	Department 's Updated Decision Date
December 16, 2008	Department 's Actual Decision Date

Reconsideration Review

December 18, 2008	Applicant Submits Reconsideration Request to Secretary of Health
December 24, 2008	Applicant Submits Request to Program for Reconsideration
December 24, 2008	Reconsideration request granted
January 14, 2009	Reconsideration Public Hearing Conducted in Tumwater <ul style="list-style-type: none">• public comments submitted at the public hearing
January 30, 2009	Rebuttal Documents Received at Department
March 16, 2009	Department 's Anticipated Reconsideration Decision Date
February 27, 2009	Department 's Actual Decision Date

CRITERIA EVALUATION

The review for a reconsideration project is limited to only those criteria that were denied in the initial evaluation. To obtain approval for this project, Children's must demonstrate compliance with the relevant criteria found in WAC 246-310-210 (need); WAC 246-310-220 (financial feasibility); WAC 246-310-230 (structure and process of care); and WAC 246-310-240 (cost containment).

AFFECTED PERSONS

Throughout the initial review of this project, the two entities sought and received affected person status under WAC 246-310-010. During the reconsideration review, only one of the entities maintained their affected person status. The entities are listed below with the applications noted accordingly:

- Swedish Medical Center – A current provider of healthcare in the planning area (Initial Application)
- Mr. David Plummer – A resident of Bellevue, Washington (Initial and Reconsideration Application)

SOURCE INFORMATION REVIEWED

Initial Review

- Children's Certificate of Need application submitted June 6, 2008
- Children's supplemental information dated August 11, 2008
- Public comment received throughout the review of the application
- Public hearing documents received at the October 6, 2008, public hearing
- The Children's rebuttal comments received October 21, 2008
- East King County ASC and/or operating room utilization survey responses
- Historical charity care data obtained from the Department of Health's Office of Hospital and Patient Data Systems (2004, 2005, and 2006 summaries)
- Population data obtained from the Office Financial Management based on year 2000 census published November 2007
- Financial feasibility and cost containment evaluation prepared by the Department of Health's Office of Hospital and Patient Data Systems (November 20, 2008)
- Licensing and/or survey data provided by the Department of Health's Office of Health Care Survey
- Data obtained from Children's Hospital webpage (www.seattlechildrens.org)

Reconsideration Review

- Children's Hospital and Regional Medical Center's Reconsideration Request dated December 24, 2008
- Comment submitted to the Certificate of Need Program office between December 25, 2008 though January 14, 2009
- Public comment received at the January 14, 2009 public hearing in Tumwater

- Rebuttal comments from Children’s Hospital and Regional Medical Center received January 30, 2009
- Population estimates and forecasts obtained from the Claritas, Inc.

CONCLUSION

For the reasons stated in this evaluation, the application submitted on behalf of Children’s Hospital and Regional Medical Center proposing to establish a new 2 OR ASC in the city of Bellevue within the East King County planning area is consistent with applicable criteria of the Certificate of Need Program, provided Children’s Hospital and Regional Medical Center agrees to the following condition.

Condition

The two new OR’s within the proposed ASC be operated solely to provide care to pediatric patients between the ages of 0 and 14 years.

The approved capital expenditure associated with this project is \$19,176,407.

RECONSIDERATION EVALUATION

A. Need (WAC 246-310-210)

Based on the source information reconsidered, the Department determines that the Children's application has met the applicable need criteria in WAC 246-310-210 and the ambulatory surgery standards and methodology in WAC 246-310-270.

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

The Program uses the numeric methodology found in WAC 246-310-270 for determining the need for additional ASCs in Washington State. The numeric methodology provides a basis of comparison of existing OR capacity for both outpatient and inpatient OR's in a planning area using the current utilization of existing providers. The methodology separates Washington State into 54 separate secondary health services planning areas. The Children's ASC would be located in the East King County planning area.

The methodology estimates OR need in a planning area using multi-steps as defined in WAC 246-310-270(9). This methodology relies on a variety of assumptions and initially determines existing capacity of dedicated outpatient and mixed-use operating rooms in the planning area, subtracts this capacity from the forecast number of surgeries to be expected in the planning area in the target year, and examines the difference to determine:

- a) whether a surplus or shortage of OR's is predicted to exist in the target year, and
- b) if a shortage of OR's is predicted, the shortage of dedicated outpatient and mixed-use rooms are calculated.

Initial Evaluation Summary

In the initial application, Children's acknowledged that the need calculations as required by WAC 246-310-270(9) produces a surplus capacity for the planning area. Children's relied upon a series of extraordinary circumstances to warrant exceeding the numeric need projections. The applicant believes these extraordinary circumstances provide the basis for the Department to approve a project which would ordinarily be denied. The applicant produced a version of the numeric need methodology which was based upon assumptions derived from the extraordinary circumstances. Their method computes the need sufficient to support approval of 2 new OR's to serve the East King County 0-14 patient population. The Department determined that the applicant did not demonstrate that the population to be served has need for the project or that other services and facilities of the type proposed are not or will not be sufficiently available or accessible to meet that need. In conclusion, the project failed to meet the applicable criteria under WAC 246-310-210 and WAC 246-310-270. [Application, p17-19 & Supplemental Information p3; Initial Evaluation, p9 & Appendix A]

Reconsideration Evaluation

East King Use Rate

In the initial evaluation, the Department counted the procedures reported in survey data from responding ambulatory surgery centers within the planning area as part of the need calculations. Not included were procedures conducted on East King residents 0-14 at the applicant's Laurelhurst campus in the neighboring North King planning area. The application identified a total of 1,283 cases for patients residing in the East King planning area which would be appropriate candidates for the procedures offered at the proposed ASC. [Application, p22]

A more detailed evaluation of the East King planning areas OR capacity and its availability for performing pediatric cases is found later in the analysis. However, based on the results of that evaluation, the Department concluded it was appropriate to include these 1,283 cases in the use rate calculations of the planning area.

In reconsideration documents, Children's contends that the number of cases projected for the proposed ASC can be increased further. The applicant's methodology includes the historical volume of patients from non-East King planning areas that currently schedule procedures at the Laurelhurst campus. The applicant reports that an additional 1,062 procedures would be candidates for relocation to the Bellevue facility. [Children's Reconsideration Hearing Testimony, p5]

The Department does not concur. Including these non-East King County residents in determining a use rate intended for East King County residents is not appropriate. That use rate would be artificially increased and projections could only be maintained through the active relocation of non-East king County patients.

After the inclusion of the East King residents and a correction in previously reported case totals¹ in the original evaluation, the use rate increased from 10.88 to 22.63 per 1000 residents aged 0-14 in East King County. [Reconsideration Evaluation, Appendix A]

Capacity

In the initial evaluation, the Program based current capacity upon available mixed-use and dedicated OR's reported in survey data from responding ambulatory surgery centers within the planning area. Survey returns indicated that the two respondents were operating a total of 13 operating rooms². The additional data provided in these surveys resulted in a calculated average of 23.68 minutes per case. [Initial Evaluation, p9 & Appendix A]

In the methodology provided by the applicant, the capacity for pediatric care was assumed to be zero, and the average minutes per case equaled 57.7 minutes. Children's maintains that the capacity for pediatric care in the planning area is zero since there are no dedicated pediatric facilities in the area. Further, the disparity in average minutes per case is attributable to the complexity of the cases Children's is proposing versus the less time

¹ Appendix A of the Initial Evaluation errantly included 50 cases for both Snoqualmie and Group Health hospitals in the use rate calculations. These were corrected to read zero for both facilities.

² Evergreen Hospital reported 8 mixed use OR's and Overlake ASC reported 5 dedicated outpatient rooms.

consuming procedures identified in the survey respondent’s case mix. The Department rejects Children’s assertions that no pediatric capacity exists within the planning area. The Department must consider survey returns reporting pediatric procedures, representing some available capacity. [Application Supplemental information, p3]

To determine what capacity for pediatric OR space should be applied, the Department calculated the surplus availability of OR space in excess of the usage reported in survey returns. WAC 246-310-270 identifies the assumed maximum annual capacity for mixed-use and dedicated OR’s, the Department established the maximum potential minutes of usage for the responding providers and subtracted the reported usage. The balance, adjusted for the reported pediatric use, identifies what surplus capacity may be available for potential pediatric cases. The results are reported below.

Table 1
Calculated Available Capacity for East King County

Hospital	OR’s	WAC Capacity³	Max WAC Capacity	Reported Use	Less 0-14 Minutes	Adjusted Minutes	Available Minutes	Avail Capacity⁴
Evergreen	8	94,250	754,000	714,146	1,882	712,264	41,736	0.443
Overlake	5	68,850	344,250	397,110	22,625	374,485	-30,235	-0.439

The calculations consider the current procedures performed on predominately adult population (15 years or older) and provide what capacity may remain available in the reported 13 OR’s for pediatric focused care. The capacity for Evergreen Hospital is nominal, but does constitute available capacity. It is appropriate to include this capacity for mixed-use OR’s. The results for Overlake indicate that they are performing at standards exceeding the assumed capacity cited in rule. Due to the negative result, there is no capacity available to attribute to dedicated OR space.

Department’s Reconsideration Methodology

Given that the ASC would be located in East King County, the Department will apply the methodology to that health service planning area. There are 35 providers in the East King County planning area. The providers are listed below. [Application p6; CN historical files; Licensing/ASPEN database]

³ Capacity assumptions cited in WAC 46-310-270 differ for mixed-use and dedicated OR space.

⁴ Established by dividing the Available Minutes by the WAC Capacity Assumptions

East King Planning Area Providers

Hospital

Evergreen Hospital Medical Center
Overlake Hospital Medical Center

Snoqualmie Valley Hospital
Swedish Issaquah Hospital **

Freestanding ASCs

Aesthetic Eye Associates
Bellevue Spine Specialist
Bellevue Urology Associates
Bel-Red Ambulatory Surgical Facility
Center For Plastic Surgery
Cosmetic Surgery & Dermatology of Issaquah
Eastside Endoscopy Center
Eastside Podiatry
Eastside Urology Ambulatory Surgery Center
Evergreen Endoscopy Center
Evergreen Orthopedic Surgery Center *
Evergreen Surgery Center *
Evergreen Surgical Clinic
Foot Surgical Center Of Issaquah
Henri P Gaboriau MD, Inc
Issaquah Day Surgery *

Northwest Nasal Sinus *
Overlake Surgery Center *
Pacific Cataract And Laser Institute
Redmond Foot Care Associates
Remington Plastic Surgery, P.S
Sam Naficy MD PS Inc
Skin Surgery Center
Specialty Eyecare Center
Swedish – Bellevue **
Swedish Issaquah ASC **
Virginia Mason – Bellevue
Virginia Mason – Issaquah
Virginia Mason - Kirkland
WA Ctr. for Reproductive Med
Washington Sports Medicine Assoc.

* CN Approved Freestanding Facilities

** CN Approved - Not Yet Operational

As shown above, the Department requested utilization information from 33 of the facilities identified above.⁵ The survey requested case data for patients 0-14 separate from total ASC utilization totals. Responses were received from eight of the facilities.⁶ Two of surveys provided both capacity (5 outpatient & 8 mixed use) and procedure data for the 0-14 age group.⁷

As identified previously, the 35 facilities include four hospitals and 31 ASCs. Of the four hospitals, three are operational while the Swedish Issaquah facility is forecasted to begin providing service in 2013. OR capacity will be applied according to the calculated capacity results detailed in the reconsideration discussion above.

Of the remaining 31 ASCs, 24 are located within a solo or group practice (considered an exempt ASC) and therefore, the use of these ASCs is restricted to physicians that are employees or members of the clinical practices that operate the facilities. Therefore, these 24 facilities do not meet the ASC definition found in WAC 246-310-010 and the ORs are not included in the capacity calculations of available ORs for the East King planning area.

⁵ The program excluded two facilities which are CN approved, but not yet operational.

⁶ Utilization surveys containing information particular to patients aging 14 years or less were received from the Overlake ASC, Evergreen Healthcare and Virginia Mason-Bellevue. Responses which stated that no pediatric care were returned by Virginia Mason – Issaquah, Eastside Urology, Stephens Plastic Surgery, Skin Surgery Center, and Eastside Endoscopy.

⁷ A total of 13 ORs were identified: 5 outpatient rooms at Overlake and 8 mixed use rooms at Evergreen.

The seven remaining ASCs are facilities meeting the definition in WAC 246-310-010 and the OR capacity reported for these ASCs will be included with the existing hospitals in the capacity calculations of available ORs for the East King planning area.⁸

To complete the reconsideration of this section, the Department relied on the following assumptions to apply its methodology.

Assumption	Data Used
Planning Area	East King County
Population Estimates and Forecasts	Data calculated from Claritas, Inc. data for 0-14 years of age in the applicable zip codes of the service area for 2000, 2008, & 2013. 2007 population = 100,672 2011 population = 103,328
Use Rate	Divide reported pediatric (0-14) surgical cases by estimated 2007 pediatric population results in the service area. Use rate of 22.63/1,000
Percent of surgery ambulatory vs. inpatient	Based on DOH 2007 survey results, 97.4% outpatient setting; 2.6% inpatient setting
Average minutes per case	Based on DOH 2007 survey results, Outpatient cases = 44 minutes; Inpatient cases = 69 minutes
OR Annual capacity in minutes	68,850 outpatient surgery minutes; 94,250 inpatient or mixed-use surgery minutes
Existing providers	Based on 2008 listing of East King County providers

The Program’s application of the numeric methodology, using available out-migration of East King County pediatric cases from the planning area and available OR capacity, indicates a need for 1.45 dedicated outpatient ORs for the East King planning area in year 2011. Since the calculated need results in a fraction of a second OR, need would be sufficient to substantiate approval of up to 2 additional operating rooms to provide pediatric-focused ambulatory surgical care in East King. The Program’s reconsideration methodology is attached to this evaluation as Appendix A.

In the initial review of this project, the Program received comments related to the impact Children’s project would have on the existing providers. Of the providers that responded, many indicated either no or little impact on their existing ASCs if the Children’s project were approved. In the initial and reconsideration reviews of this project, concerns were raised regarding the estimates used in the population forecasts of the planning area.

When the Department produces an ASC need methodology, population estimates are required. In this particular analysis, the estimates also need to be categorized by zip code and age group. The Department agrees that age specific population data, reported separately by

⁸ Swedish – Bellevue and Issaquah are currently under appeal

zip code, is not available from the Washington Office of Financial Management. Therefore, to obtain the population projections, the Department utilized population estimates and projections developed by Claritas, Inc., a recognized source of demographic information.

In conclusion, this reconsideration of numeric need for pediatric focused OR capacity in the East King planning area has been demonstrated. Children's submitted an application proposing to meet the demonstrated need for pediatric-focused care with a new ASC containing 2 new operating rooms. If this project is approved, the Department would include a condition that the 2 new OR's within the proposed ASC be operated solely to provide care to pediatric patients between the ages of 0 and 14 years. Provided Children's agrees to this condition, this sub-criterion would be met.

(3) The applicant has substantiated any of the special needs and circumstances the proposed project is to serve.

(a) The special needs and circumstances of entities such as medical and other health professions schools, multidisciplinary clinics and specialty centers providing a substantial portion of their services or resources, or both, to individuals not residing in the health service areas in which the entities are located or in adjacent health service areas.

(b) The special needs and circumstances of biomedical and behavioral research projects designed to meet a national need and for which local conditions offer special advantages.

(c) The special needs and circumstances of osteopathic hospitals and nonallopathic services

Initial Evaluation Summary

In response to this criterion, Children's application references that a long term affiliation and proximity to the University of Washington School of Medicine provides a primary component to facilitate these efforts. Children's projects that the establishment of ASC services in Bellevue will shift outpatient activity from the main campus. This shift of outpatient services is expected to facilitate training and educational opportunities for medical students and allow Children's to "further differentiate itself from other area providers". [Application, p26 & 32]

The Department agreed that Children's has had a long term affiliation with area hospitals and is a resource for teaching and technology. However, upon review of the information submitted for this project, none appeared to substantiate that this project would increase the opportunities beyond what is currently available in the area. This sub-criterion was not met.

Reconsideration Evaluation

Upon review of the materials submitted as part of the initial review, Children's identified a series of practice guidelines which would be implemented in the proposed facility. These efforts center on building/equipment design and advancing pediatric anesthesiology practices which are planned into the design of the proposed facility. With acceptance of the condition stated in the need section above, the construction of this new facility may better address the need and circumstances facing the pediatric patients this project is proposing to serve. This sub-criterion is met. [October 21, 2008 Applicant Rebuttal Documents, p10]

B. Financial Feasibility (WAC 246-310-220)

Based on the source information reviewed and the applicant's agreement to the condition stated at the conclusion of the need portion of this reconsideration evaluation, the Department determines that the Children's Hospital and Regional Medical Center application meets the financial feasibility criteria in WAC 246-310-220.

- (1) The immediate and long-range capital and operating costs of the project can be met.
- (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.
- (3) The project can be appropriately financed.

Initial Evaluation Summary

In its December 16, 2008 evaluation, the Department concluded that Children's project met two of the three sub-criteria outlined above. The sub-criterion not met – (2) above - related to the project's failure to meet the need criteria. [Initial evaluation, p11-14]

Reconsideration Evaluation

Based on information provided during the reconsideration review, the Department concluded that Children's application met all applicable need criteria. As a result, the Department's conclusion under (2) above would be met, along with the other two sub-criteria.

C. Structure and Process (Quality) of Care (WAC 246-310-230)

Based on the source information reviewed and the applicant's agreement to the condition stated at the conclusion of the need portion of this reconsideration evaluation, the Department determines that Children's application meets the structure and process (quality) of care criteria in WAC 246-310-230.

- (1) A sufficient supply of qualified staff for the project, including both health personnel and management personnel, are available or can be recruited.
- (2) The proposed service(s) will have an appropriate relationship, including organizational relationship, to ancillary and support services, and ancillary and support services will be sufficient to support any health services included in the proposed project.
- (3) There is reasonable assurance that the project will be in conformance with applicable state licensing requirements and, if the applicant is or plans to be certified under the Medicaid or Medicare program, with the applicable conditions of participation related to those programs.
- (4) The proposed project will promote continuity in the provision of health care, not result in an unwarranted fragmentation of services, and have an appropriate relationship to the service area's existing health care system.
- (5) There is reasonable assurance that the services to be provided through the proposed project will be provided in a manner that ensures safe and adequate care to the public to be served and in accord with applicable federal and state laws, rules, and regulations.

Initial Evaluation Summary

In its December 16, 2008 evaluation, the Department concluded that Children's project met four of the five sub-criteria outlined above. The sub-criterion not met – (4) above - related to the project's failure to meet the need criteria. [Initial evaluation, pp14-17]

Reconsideration Evaluation

Based on information provided during the reconsideration review, the Department concluded that Children's application met all applicable need criteria. As a result, the department's conclusion under (4) above would be met, along with the other four sub-criteria.

D. Cost Containment (WAC 246-310-240)

Based on the source information reviewed and the applicant's agreement to the condition stated at the conclusion of the need portion of this reconsideration evaluation, the Department determines that the Children's ASC application meets the cost containment criteria in WAC 246-310-240.

- (1) Superior alternatives, in terms of cost, efficiency, or effectiveness, are not available or practicable.
- (2) In the case of a project involving construction:
 - (a) The costs, scope, and methods of construction and energy conservation are reasonable;
 - (b) The project will not have an unreasonable impact on the costs and charges to the public of providing health services by other persons.

Initial Evaluation Summary

In its December 16, 2008 evaluation, the Department concluded that Children's project did not meet either of the two sub-criteria outlined above. The failure in these cost containment criterion related to the project's failure to meet the need criteria. [Initial evaluation, pp14-17]

Reconsideration Evaluation

Based on information provided during the reconsideration review, the Department concluded that Children's application met all applicable need criteria. As a result, the department's conclusion under sections (1) and (2) above would be met.

Appendix A