WAC 246-310-263 Pediatric cardiac surgery and interventional treatment center standards and need forecasting method. (1) A pediatric cardiac surgery and interventional treatment center is a hospital providing comprehensive pediatric cardiology care, including medical and surgical diagnosis and treatment.

(2) Pediatric cardiac surgery and interventions includes, but is not limited to: All pediatric surgery of the heart (excluding organ transplantation) and the great vessels in the chest; all pediatric catheter-based nonsurgical therapeutic and diagnostic interventions in the heart and great vessels in the chest; and invasive pediatric electrophysiologic procedures.

(3) Pediatric cardiac surgery and interventional procedure is a tertiary service as listed in WAC 246-310-020. To be granted a certificate of need for a pediatric cardiac surgery and interventional treatment center, a hospital must meet the standards in this section in addition to applicable review criteria in WAC 246-310-210, 246-310-220, 246-310-230, and 246-310-240.

(4) The department must review new pediatric cardiac surgery and interventional center applications using the concurrent review cycle in this section.

(a) Applicants must submit letters of intent between the first working day and last working day of August of each year.

(b) Initial applications must be submitted between the first working day and last working day of September of each year.

(c) The department shall screen initial applications for completeness by the last working day of October of each year.

(d) Responses to screening questions must be submitted by the last working day of November of each year.

(e) The public review and comment period for applications begins on December 16 of each year. If December 16 is not a working day in any year, then the public review and comment period begins on the first working day after December 16.

(f) The public comment period is limited to ninety days, unless extended according to the provisions of WAC 246-310-120 (2)(d). The first sixty days of the public comment period shall be reserved for receiving public comments and conducting a public hearing, if requested. The remaining thirty days shall be for the applicant or applicants to provide rebuttal statements to written or oral statements submitted during the first sixty-day period. Any interested person that:

(i) Is located or resides within the applicant's health service area;

(ii) Testified or submitted evidence at a public hearing; and

(iii) Requested in writing to be informed of the department's decision, must also be provided the opportunity to provide rebuttal statements to written or oral statements submitted during the first sixty-day period.

(g) The final review period is limited to sixty days, unless extended according to the provisions of WAC 246-310-120.

(5) The department may convert the review of an application that was initially submitted under the concurrent review cycle to a regular review process if the department determines that the application does not compete with another application.

(6) Any letter of intent or certificate of need application submitted for review in advance of this schedule, or certificate of need application under review as of the effective date of this section,

shall be held by the department for review according to the schedule in this section.

(7) Standards.

(a) A minimum of one hundred pediatric cardiac surgical procedures (seventy-five with extracorporeal circulation) per year and a minimum of one hundred fifty catheterizations must be performed at a hospital with a pediatric cardiac surgery and interventional treatment center by the third year of operation and each year thereafter.

(b) Hospitals applying for a pediatric cardiac surgery and interventional center certificate of need must demonstrate that they can meet one hundred ten percent of the minimum volume standards. The applicant hospital must provide data from CHARS demonstrating:

(i) The zip codes served by the applying hospital;

(ii) The percentage of the total hospital admissions for children ages zero through nineteen served by the applying hospital in each of the applicable zip codes during the most recent available three years data. Expired patients will not be counted;

(iii) The number of pediatric heart surgeries, number of therapeutic and diagnostic interventions and invasive electrophysiologic procedures performed in these zip codes during the most recent available three years data. The percentage established in (b)(ii) of this subsection shall then be applied to the number of pediatric heart surgeries, interventions and invasive electrophysiologic procedures. This number must be equal to or greater than one hundred ten percent of the minimum volume standards.

(c) The department will not grant a certificate of need to a new center if:

(i) The new center will reduce any existing center below one hundred ten percent of any one of the minimum volume standards; or

(ii) Reduces the volumes of any existing center that has not yet met any one of the minimum volume standards; or

(iii) Fails to meet any one of the center's minimum volume standards.

(d) At time of initiating the program, and thereafter, the director of the pediatric cardiac surgery and interventional center must be a U.S. board certified pediatric cardiologist.

(e) At time of initiating the program, and thereafter, pediatric cardiac surgery and interventional centers must have at least two U.S. board certified or board eligible cardiac surgeons on the staff. At least one of the required surgeons must be certified by the American Board of Thoracic Surgery. Board eligible status must not extend beyond five years.

(f) The program must provide twenty-four hour coverage.

(g) Hospitals with a pediatric cardiac surgery and interventional center must have plans for facilitating emergency access to heart surgery services at all times for the population they serve. These plans should, at minimum, include arrangements for addressing peak volume periods (such as joint agreements with other programs, the capacity to temporarily increase staffing, etc.), and the maintenance of or affiliation with emergency transportation services (including contingency plans for poor weather and known traffic congestion problems).

(h) Hospitals with a pediatric cardiology surgery and interventional center must provide a copy of the hospital's QI plan that includes/incorporates a section specific to the pediatric cardiac surgery and interventional center.

(i) If a certificate of need is issued, it will be conditioned, at a minimum, to require ongoing compliance with the certificate of

need standards. Failure to meet the conditioned standards may be grounds for revocation or suspension of a hospital's certificate of need, or other appropriate licensing or certification action.

(j) In the event two or more centers are competing to meet the same forecasted net need, the department shall consider the following factors when determining which proposal best meets forecasted need:

(i) The most appropriate improvement in geographic access;

(ii) The most cost efficient service;

(iii) Minimizing impact on existing programs;

(iv) Providing the greatest breadth and depth of pediatric cardiovascular and support services; and

(v) Facilitating emergency access to care.

(k) Hospitals granted a certificate of need have three years from the date of initiating the program to meet the center procedure volume standards.

(l) These standards should be reevaluated every three years.

(8) Need forecasting method. The data used for evaluating applications submitted during the concurrent review cycle will be the most recent three years CHARS data available at the close of the application submittal period for that review cycle. Separate forecasts are to be made for heart surgery, interventions and electrophysiological procedures.

(a) Step 1. Compute the planning area's current capacity. When a new center is being established, the assumed volume of that center will be the greater of the actual volume or the minimum volume standards or the estimated volumes described in the approved application, including any adjustments made by the department in the course of review and approval.

(b) Step 2. Compute the percent of out-of-state use of the area's hospitals.

(c) Step 3. Compute the planning area's average age-specific use rates.

(d) Step 4. Multiply the planning area's age-specific use rates by the area's corresponding forecast year population. The sum of these figures equals the forecasted number of pediatric cardiac surgical and interventional procedures expected to be performed on Washington pediatric residents.

(e) Step 5. Increase the number of pediatric cardiac surgical and interventional procedures expected to occur within the planning area in accordance with the percent of procedures calculated as occurring in those hospitals on out-of-state residents, based on the average of the last three years. This figure equals the total forecasted number of procedures expected to occur within the hospital's planning area.

(f) Step 6. Calculate the net need for additional pediatric cardiac centers by subtracting the current capacity from the total forecasted pediatric cardiac surgical and interventional procedures.

(g) Step 7. The department will not grant a certificate of need for a new center if the need is less than the minimum volume standards. An exception may be made and a certificate of need granted if (g)(i) and (ii) of this subsection can be met:

(i) The applying hospital can meet all the other certificate of need criteria for a pediatric cardiac surgery and interventional treatment center (including documented evidence of capability of achieving the minimum volume standard); and

(ii) At least eighty percent of the results identified in subsection (7)(b)(iii) of this section for pediatric cardiac services received pediatric cardiac services more than seventy-five miles away.

(9) For the purposes of the forecasting method in this section, the following terms have the following specific meanings:

(a) Age-specific categories. The categories used in computing age-specific values will be zero through fourteen, fifteen through nineteen year olds.

(b) Current capacity. The planning area's current capacity for pediatric cardiac surgical and interventional procedures equals the sum of the highest reported annual volume for each hospital with an approved pediatric cardiac surgical and interventional center within the planning area. When a new center is being established, the assumed volumes of that center will be the greater of the actual volume or minimum volume standards or the estimated volumes described in the approved application, including any adjustments made by the department in the course of review and approval.

(c) Forecast year. Pediatric cardiac surgery and interventional service needs shall be based on forecasts for the fourth year after the certificate of need pediatric cardiac surgery and interventional concurrent review process.

(d) Pediatric cardiac surgery and intervention. Pediatric cardiac surgery and intervention means diagnosis related groups (DRGs) 104-111 and 115-116, as developed under the Centers for Medicare and Medicaid Services (CMS) contract. All adult cardiac procedures (ages twenty-one and over) are excluded. The department will update the list of codes administratively to reflect future revisions made by CMS to the DRGs to be considered in certificate of need definitions, analyses and decisions. The department's updates to DRGs will be based on the definition of pediatric heart surgery contained in subsection (2) of this section.

(e) Out-of-state use of planning area hospitals. The percent of out-of-state use of hospitals within the planning area will equal the percent of total pediatric cardiac surgery and interventional procedures occurring within the planning area's hospitals that were performed on patients from out-of-state (or on patients whose reported zip codes are invalid). The most recent available three years data will be used to compute out-of-state use of Washington hospitals.

(f) Planning area. For the purpose of pediatric cardiac surgery and intervention, the planning area is the state of Washington.

Use rate. The pediatric cardiac surgery and interventional use rate equals the number of procedures performed on the pediatric residents of the planning area.

(10) The data source for pediatric cardiac surgery and interventional procedures is the comprehensive hospital abstract reporting system (CHARS), office of hospital and patient data, department of health.

(11) The data source for population estimates and forecasts is the office of financial management population trends reports.

[Statutory Authority: Chapter 70.38 RCW and State Court of Appeals, Case # 23480-7-11. WSR 04-24-016, § 246-310-263, filed 11/22/04, effective 12/23/04.]