Chapter 246-310 WAC
CERTIFICATE OF NEED

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WAC

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DISPOSITION OF SECTIONS FORMERLY CODIFIED IN THIS CHAPTER

246-310-002 Purpose of chapter 248-156 WAC. [Statutory Authority: RCW 43.70.040. WSR 91-02-049 (Order 121), recodified as § 246-310-002, filed 12/27/90, effective 1/31/91. Statutory Authority: RCW 70.38.025. WSR 81-09-060 (Order 1641), § 248-156-010, filed 4/20/81.] Repealed by WSR 92-02-018 (Order 224), filed 12/23/91, effective 1/23/92. Statutory Authority: RCW 70.38.135 and 70.38.919.

246-310-030 Index and procedures for adjustment. [Statutory Authority: RCW 43.70.040. WSR 91-02-049 (Order 121), recodified as § 246-310-030, filed 12/27/90, effective 1/31/91. Statutory Authority: RCW 70.38.025. WSR 81-09-060 (Order 1641), § 248-156-030, filed 4/20/81.] Repealed by WSR 92-02-018 (Order 224), filed 12/23/91, effective 1/23/92. Statutory Authority: RCW 70.38.135 and 70.38.919.

246-310-030A Tertiary services identification. [Statutory Authority: RCW 43.70.040. WSR 91-02-049 (Order 121), recodified as § 246-310-030A, filed 12/27/90, effective 1/31/91. Statutory Authority: Chapter 70.38 RCW. WSR 90-21-028 (Order 082), § 248-19-235, filed 10/9/90, effective 10/9/90.] Repealed by WSR 92-02-018 (Order 224), filed 12/23/91, effective 1/23/92. Statutory Authority: RCW 70.38.135 and 70.38.919.

246-310-060 Sanctions for violations. [Statutory Authority: RCW 43.70.040. WSR 91-02-049 (Order 121), recodified as § 246-310-060, filed 12/27/90, effective 1/31/91. Statutory Authority: RCW 70.38.135. WSR 81-09-012 (Order 210), § 248-19-250, filed 4/9/81, effective 5/20/81. Statutory Authority: Chapter 70.38 RCW. WSR 79-12-079 (Order 188), § 248-19-250, filed 11/30/79.] Repealed by WSR 97-20-101, filed 9/29/97, effective 10/30/97. Statutory Authority: RCW 43.70.040.

246-310-070 Periodic reports on development of proposals. [Statutory Authority: RCW 43.70.040. WSR 91-02-049 (Order 121), recodified as § 246-310-070, filed 12/27/90, effective 1/31/91. Statutory Authority: RCW 70.38.135. WSR 86-06-030 (Order 2344), § 248-19-260, filed 2/28/86; WSR 81-09-012 (Order 210), § 248-19-260, filed 4/9/81, effective 5/20/81. Statutory Authority: Chapter 70.38 RCW. WSR 79-12-079 (Order 188), § 248-19-260, filed 11/30/79.] Repealed by WSR 96-24-052, filed 11/27/96, effective 12/28/96. Statutory Authority: Chapter 70.38 RCW.

246-310-135 Ethnic minority nursing home bed pool—Procedures. [Statutory Authority: Chapter 70.38 RCW. WSR 96-24-052, § 246-310-135, filed 11/27/96, effective 12/28/96. Statutory Authority: RCW 70.38.135 (3)(c). WSR 92-05-057 (Order 244), § 246-310-135, filed 2/14/92, effective 3/16/92.] Repealed by WSR 97-20-101, filed 9/29/97, effective 10/30/97. Statutory Authority: RCW 43.70.040.

246-310-250 Open heart surgery. [Statutory Authority: RCW 70.38.135 and 70.38.919. WSR 92-02-018 (Order 224), § 246-310-250, filed 12/23/91, effective 1/23/92. Statutory Authority: RCW 43.70.040. WSR 91-02-049 (Order 121), recodified as § 246-310-250, filed 12/27/90, effective 1/31/91. Statutory Authority: Chapter 70.38 RCW. WSR 90-13-116 (Order 67), § 248-19-600, filed 6/21/90, effective 7/1/90.] Repealed by WSR 92-12-015 (Order 274), filed 5/26/92, effective 6/26/92. Statutory Authority: RCW 70.38.135(3).

246-310-262 Nonemergent interventional cardiology standard. [Statutory Authority: Chapter 70.38 RCW. WSR 96-24-052, § 246-310-262, filed 11/27/96, effective 12/28/96. Statutory Authority: RCW 70.38.135(3). WSR 92-12-015 (Order 274), § 246-310-262, filed 5/26/92, effective 6/26/92.] Repealed by WSR 09-01-113, filed 12/19/08, effective 12/19/08. Statutory Authority: RCW 70.38.128.

246-310-280 Kidney disease treatment centers—Definitions. [Statutory Authority: RCW 70.38.135. WSR 06-24-050, § 246-310-280, filed 12/1/06, effective 1/1/07. Statutory Authority: Chapter 70.38 RCW. WSR 96-24-052, § 246-310-280, filed 11/27/96, effective 12/28/96. Statutory Authority: RCW 70.38.135 (3)(c). WSR 93-13-015 (Order 367), § 246-310-280, filed 6/7/93, effective 7/8/93. Statutory Authority: RCW 70.38.135 and 70.38.919. WSR 92-02-018 (Order 224), § 246-310-280, filed 12/23/91, effective 1/23/92. Statutory Authority: RCW 43.70.040. WSR 91-02-049 (Order 121), recodified as § 246-310-280, filed 12/27/90, effective 1/31/91. Statutory Authority: RCW 70.38.919. WSR 90-16-058 (Order 073), § 248-19-701, filed 7/27/90, effective 8/27/90.] Repealed by WSR 17-04-062, filed 1/27/17, effective 1/1/18. Statutory Authority: RCW 70.38.135.

246-310-282 Kidney disease treatment centers—Concurrent review cycle. [Statutory Authority: RCW 70.38.135. WSR 06-24-050, § 246-310-282, filed 12/1/06, effective 1/1/07.] Repealed by WSR 17-04-062, filed 1/27/17, effective 1/1/18. Statutory Authority: RCW 70.38.135.

246-310-284 Kidney disease treatment centers—Methodology. [Statutory Authority: RCW 70.38.135. WSR 06-24-050, § 246-310-284, filed 12/1/06, effective 1/1/07.] Repealed by WSR 17-04-062, filed 1/27/17, effective 1/1/18. Statutory Authority: RCW 70.38.135.

246-310-286 Kidney disease treatment centers—Standards for planning areas without an existing facility. [Statutory Authority: RCW 70.38.135. WSR 06-24-050, § 246-310-286, filed 12/1/06, effective 1/1/07.] Repealed by WSR 17-04-062, filed 1/27/17, effective 1/1/18. Statutory Authority: RCW 70.38.135.

246-310-287 Kidney disease treatment centers—Exceptions. [Statutory Authority: RCW 70.38.135. WSR 06-24-050, § 246-310-287, filed 12/1/06, effective 1/1/07.] Repealed by WSR 17-04-062, filed 1/27/17, effective 1/1/18. Statutory Authority: RCW 70.38.135.

246-310-288 Kidney disease treatment centers—Tie-breakers. [Statutory Authority: RCW 70.38.135. WSR 06-24-050, § 246-310-288, filed 12/1/06, effective 1/1/07.] Repealed by WSR 17-04-062, filed 1/27/17, effective 1/1/18. Statutory Authority: RCW 70.38.135.

246-310-289 Kidney disease treatment centers—Relocation of facilities. [Statutory Authority: RCW 70.38.135. WSR 06-24-050, § 246-310-289, filed 12/1/06, effective 1/1/07.] Repealed by WSR 17-04-062, filed 1/27/17, effective 1/1/18. Statutory Authority: RCW 70.38.135.

246-310-350 Nursing home and continuing care retirement community definitions. [Statutory Authority: RCW 70.38.135 and 70.38.919. WSR 92-02-018 (Order 224), § 246-310-350, filed 12/23/91, effective 1/23/92. Statutory Authority: RCW 43.70.040. WSR 91-02-049 (Order 121), recodified as § 246-310-350, filed 12/27/90, effective 1/31/91. Statutory Authority: RCW 70.38.919. WSR 90-12-071 (Order 062), § 248-19-800, filed 6/1/90, effective 7/1/90.] Repealed by WSR 96-24-052, filed 11/27/96, effective 12/28/96. Statutory Authority: Chapter 70.38 RCW.

246-310-400 AIDS long-term care pilot facility review standards. [Statutory Authority: RCW 70.38.135 and 70.38.919. WSR 92-02-018 (Order 224), § 246-310-400, filed 12/23/91, effective 1/23/92. Statutory Authority: RCW 43.70.040. WSR 91-02-049 (Order 121), recodified as § 246-310-400, filed 12/27/90, effective 1/31/91. Statutory Authority: RCW 70.38.919. WSR 90-12-072 (Order 063), § 248-19-840, filed 6/1/90, effective 7/1/90.] Repealed by WSR 96-24-052, filed 11/27/96, effective 12/28/96. Statutory Authority: Chapter 70.38 RCW.

246-310-620 Certificate of need program reports. [Statutory Authority: RCW 43.70.040. WSR 91-02-049 (Order 121), recodified as § 246-310-620, filed 12/27/90, effective 1/31/91. Statutory Authority: RCW 70.38.135. WSR 81-09-012 (Order 210), § 248-19-490, filed 4/9/81, effective 5/20/81. Statutory Authority: Chapter 70.38 RCW. WSR 79-12-079 (Order 188), § 248-19-490, filed 11/30/79.] Repealed by WSR 98-21-084, filed 10/21/98, effective 11/21/98. Statutory Authority: Chapter 70.38 RCW.

246-310-630 Public access to records. [Statutory Authority: RCW 70.38.135 and 70.38.919. WSR 92-02-018 (Order 224), § 246-310-630, filed 12/23/91, effective 1/23/92. Statutory Authority: RCW 43.70.040. WSR 91-02-049 (Order 121), recodified as § 246-310-630, filed 12/27/90, effective 1/31/91. Statutory Authority: RCW 70.38.135. WSR 81-09-012 (Order 210), § 248-19-500, filed 4/9/81, effective 5/20/81. Statutory Authority: Chapter 70.38 RCW. WSR 79-12-079 (Order 188), § 248-19-500, filed 11/30/79.] Repealed by WSR 97-20-101, filed 9/29/97, effective 10/30/97. Statutory Authority: RCW 43.70.040.

WAC 246-310-001 Purpose of certificate of need program. The purpose of the certificate of need program has been established by the legislature in RCW 70.38.015.

[Statutory Authority: RCW 43.70.040. WSR 91-02-049 (Order 121), recodified as § 246-310-001, filed 12/27/90, effective 1/31/91. Statutory Authority: RCW 70.38.135. WSR 86-06-030 (Order 2344), § 248-19-210, filed 2/28/86; WSR 81-09-012 (Order 210), § 248-19-210, filed 4/9/81, effective 5/20/81. Statutory Authority: Chapter 70.38 RCW. WSR 79-12-079 (Order 188), § 248-19-210, filed 11/30/79.]

WAC 246-310-010 Definitions. For the purposes of chapter 246-310 WAC, the following words and phrases have the following meanings unless the context clearly indicates otherwise.

(1) "Acute care facilities" means hospitals and ambulatory surgical facilities.

(2) "Affected person" means an interested person who:

(a) Is located or resides in the applicant's health service area;

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

(c) Requested in writing to be informed of the department's decision.

(3) "Alterations," see "construction, renovation, or alteration."

(4) "Ambulatory care facility" means any place, building, institution, or distinct part thereof not a health care facility as defined in this section and operated for the purpose of providing health services to individuals without providing such services with board and room on a continuous twenty-four-hour basis. The term "ambulatory care facility" includes the offices of private physicians, whether for individual or group practice.

(5) "Ambulatory surgical facility" means any free-standing entity, including an ambulatory surgery center that operates primarily for the purpose of performing surgical procedures to treat patients not requiring hospitalization. This term does not include a facility in the offices of private physicians or dentists, whether for individual or group practice, if the privilege of using the facility is not extended to physicians or dentists outside the individual or group practice.

(6) "Applicant," means:

(a) Any person proposing to engage in any undertaking subject to review under chapter 70.38 RCW; or

(b) Any person or individual with a ten percent or greater financial interest in a partnership or corporation or other comparable legal entity engaging in any undertaking subject to review under chapter 70.38 RCW.

(7) "Bed banking" means the process of retaining the rights to nursing home bed allocations which are not licensed as outlined in WAC 246-310-395.

(8) "Bed supply" means within a geographic area the total number of:

(a) Nursing home beds which are licensed or certificate of need approved but not yet licensed or beds banked under RCW 70.38.111 (8)(a) or where the need is deemed met under RCW 70.38.115 (13)(b), excluding:

(i) Those nursing home beds certified as intermediate care facility for the mentally retarded (ICF-MR) the operators of which have not signed an agreement on or before July 1, 1990, with the department of social and health services department of social and health services to give appropriate notice prior to termination of the ICF-MR service;

(ii) New or existing nursing home beds within a CCRC which are approved under WAC 246-310-380(5); or

(iii) Nursing home beds within a CCRC which is excluded from the definition of a health care facility per RCW 70.38.025(6); and

(iv) Beds banked under RCW 70.38.115 (13)(b) where the need is not deemed met.

(b) Licensed hospital beds used for long-term care or certificate of need approved hospital beds to be used for long-term care not yet in use, excluding swing-beds.

(9) "Bed-to-population ratio" means the nursing home bed supply per one thousand persons of the estimated or forecasted resident population age seventy and older.

(10) "Capital expenditure": Except for WAC 246-310-280, capital expenditure means an expenditure, including a force account expenditure (i.e., an expenditure for a construction project undertaken by a nursing home facility as its own contractor), which, under generally accepted accounting principles, is not properly chargeable as an expense of operation or maintenance. The costs of any studies, surveys, designs, plans, working drawings, specifications, and other activities (including staff effort, consulting and other services which, under generally accepted accounting principles, are not properly chargeable as an expense of operation and maintenance) shall be considered capital expenditures. Where a person makes an acquisition under lease or comparable arrangement, or through donation, which would have required certificate of need review if the acquisition had been made by purchase, this acquisition shall be deemed a capital expenditure. Capital expenditures include donations of equipment or facilities to a nursing home facility, which if acquired directly by the facility, would be

subject to review under this chapter and transfer of equipment or facilities for less than fair market value if a transfer of the equipment or facilities at fair market value would be subject to the review.

(11) "Certificate of need" means a written authorization by the secretary's designee for a person to implement a proposal for one or more undertakings.

(12) "Certificate of need program" means that organizational program of the department responsible for the management of the certificate of need program.

(13) "Commencement of the project" means whichever of the following occurs first: In the case of a construction project, giving notice to proceed with construction to a contractor for a construction project provided applicable permits have been applied for or obtained within sixty days of the notice; beginning site preparation or development; excavating or starting the foundation for a construction project; or beginning alterations, modification, improvement, extension, or expansion of an existing building. In the case of other projects, initiating a health service.

(14) "Construction, renovation, or alteration" means the erection, building, remodeling, modernization, improvement, extension, or expansion of a physical plant of a health care facility, or the conversion of a building or portion thereof to a health care facility.

(15) "Continuing care contract" means a contract providing a person, for the duration of that person's life or for a term in excess of one year, shelter along with nursing, medical, health-related, or personal care services. The contract is conditioned on the transfer of property, the payment of an entrance fee to the provider of the services, or the payment of periodic charges for the care and services involved. A continuing care contract is not excluded from this definition because the contract is mutually terminable or because shelter and services are not provided at the same location.

(16) "Continuing care retirement community (CCRC)" means any of a variety of entities, unless excluded from the definition of health care facility under RCW 70.38.025(6), which provides shelter and services based on continuing care contracts with its residents which:

Maintains for a period in excess of one year a CCRC contract with a resident which provides or arranges for at least the following specific services:

(a) Independent living units;

(b) Nursing home care with no limit on the number of medically needed days;

(c) Assistance with activities of daily living;

(d) Services equivalent in scope to either state chore services or medicaid home health services;

(e) Continues a contract, if a resident is no longer able to pay for services;

(f) Offers services only to contractual residents with limited exception during a transition period; and

(g) Holds the medicaid program harmless from liability for costs of care, even if the resident depletes his or her personal resources.

(17) "Days" means calendar days. Days are counted starting the day after the date of the event from which the designated period of time begins to run. If the last day of the period falls on a Saturday, Sunday, or legal holiday observed by the state of Washington, a designated period runs until the end of the first working day following the Saturday, Sunday, or legal holiday.

(18) "Department" means the Washington state department of health.

(19) "Effective date of facility closure" means:

(a) The date on which the facility's license was relinquished, revoked or expired; or

(b) The date the last resident leaves the facility, whichever comes first.

(20) "Enhance the quality of life for residents" means, for the purposes of voluntary bed banking, those services or facility modifications which have a direct and immediate benefit to the residents. These include, but are not limited to: Resident activity and therapy facilities; family visiting rooms; spiritual rooms and dining areas. These services or facility modifications shall not include those that do not have direct and immediate benefit to the residents, such as: Modifications to staff offices; meeting rooms; and other staff facilities.

(21) "Established ratio" means a bed-to-population ratio of forty beds per one thousand persons of the estimated or forecast resident population age seventy and older established for planning and policy-making purposes. The department may revise this established ratio using the process outlined in WAC 246-310-370.

(22) "Estimated bed need" means the number of nursing home beds calculated by multiplying the planning area's forecasted resident population by the established ratio for the projection year.

(23) "Estimated bed projection" means the number of nursing home beds calculated by the department statewide or within a planning area, by the end of the projection period.

(24) "Ex parte contact" means any oral or written communication between any person in the certificate of need program or any other person involved in the decision regarding an application for, or the withdrawal of, a certificate of need and the applicant for, or holder of, a certificate of need, any person acting on behalf of the applicant or holder, or any person with an interest regarding issuance or withdrawal of a certificate of need.

(25) "Expenditure minimum" means one million dollars for the twelve-month period beginning with July 24, 1983, adjusted annually by the department according to WAC 246-310-900.

(26) "Health care facility" means hospitals, psychiatric hospitals, nursing homes, kidney disease treatment centers including free-standing dialysis units, ambulatory surgical facilities, continuing care retirement communities, hospices and home health agencies, and includes the facilities when owned and operated by a political subdivision or instrumentality of the state and other facilities as required by federal law and rules, but does not include any health facility or institution conducted by and for those who rely exclusively upon treatment by prayer or spiritual means in accordance with the creed or tenets of any well-recognized church or religious denomination, or any health facility or institution operated for the exclusive care of members of a convent as defined in RCW 84.36.800 or rectory, monastery, or other institution operated for the care of members of the clergy.

(a) In addition, the term "health care facility" does not include any nonprofit hospital:

(i) Operated exclusively to provide health care services for children;

(ii) Which does not charge fees for the services; and

(iii) If not contrary to federal law as necessary to the receipt of federal funds by the state.

(b) In addition, the term "health care facility" does not include a continuing care retirement community which:

(i) Offers services only to contractual residents;

(ii) Provides its residents a contractually guaranteed range of services from independent living through skilled nursing, including some form of assistance with activities of daily living;

(iii) Contractually assumes responsibility for costs of services exceeding the resident's financial responsibility as stated in contract, so that, with the exception of insurance purchased by the retirement community or its residents, no third party, including the medicaid program, is liable for costs of care even if the resident depletes personal resources;

(iv) Offers continuing care contracts and operates a nursing home continuously since January 1, 1988, or obtained a certificate of need to establish a nursing home;

(v) Maintains a binding agreement with the department of social and health services assuring financial liability for services to residents, including nursing home services, shall not fall upon the department of social and health services;

(vi) Does not operate, and has not undertaken, a project resulting in a number of nursing home beds in excess of one for every four living units operated by the continuing care retirement community, exclusive of nursing home beds; and

(vii) Has undertaken no increase in the total number of nursing home beds after January 1, 1988, unless a professional review of pricing and long-term solvency was obtained by the retirement community within the prior five years and fully disclosed to residents.

(27) "Health maintenance organization" means a public or private organization, organized under the laws of the state, which:

(a) Is a qualified health maintenance organization under Title XIII, Section 1310(d) of the Public Health Service Act; or

(b) Provides or otherwise makes available to enrolled participants health care services, including at least the following basic health care services: Usual physician services, hospitalization, laboratory, X-ray, emergency and preventive services, and out-of-area coverage;

(c) Is compensated (except for copayments) for the provision of the basic health care services listed in this subsection to enrolled participants by a payment made on a periodic basis without regard to the date the health care services are provided and fixed without regard to the frequency, extent, or kind of health service actually provided; and

(d) Provides physicians' services primarily:

(i) Directly through physicians who are either employees or partners of the organization; or

(ii) Through arrangements with individual physicians or one or more groups of physicians (organized on a group practice or individual practice basis).

(28) "Health service area" means a geographic region appropriate for effective health planning including a broad range of health services.

(29) "Health services" means clinically related (i.e., preventive, diagnostic, curative, rehabilitative, or palliative) services and includes alcoholism, drug abuse, and mental health services.

(30) "Home health agency" means an entity which is, or has declared its intent to become, certified as a provider of home health services in the medicaid or medicare program.

(31) "Hospice" means an entity which is, or has declared its intent to become, certified as a provider of hospice services in the medicaid or medicare program.

(32) "Hospital" means any institution, place, building or agency or distinct part thereof which qualifies or is required to qualify for a license under chapter 70.41 RCW, or as a psychiatric hospital licensed under chapter 71.12 RCW.

(33) "Inpatient" means a person receiving health care services with board and room in a health care facility on a continuous twenty-four-hour-a-day basis.

(34) "Interested persons" means:

(a) The applicant;

(b) Health care facilities and health maintenance organizations providing services similar to the services under review and located in the health service area;

(c) Third-party payers reimbursing health care facilities in the health service area;

(d) Any agency establishing rates for health care facilities and health maintenance organizations in the health service area where the proposed project is to be located;

(e) Health care facilities and health maintenance organizations which, in the twelve months prior to receipt of the application, have submitted a letter of intent to provide similar services in the same planning area;

(f) Any person residing within the geographic area to be served by the applicant; and

(g) Any person regularly using health care facilities within the geographic area to be served by the applicant.

(35) "Licensee" means an entity or individual licensed by the department of health or the department of social and health services. For the purposes of nursing home projects, licensee refers to the operating entity and those persons specifically named in the license application as defined under chapter 388-97 WAC.

(36) "Net estimated bed need" means estimated bed need of a planning area changed by any redistribution as follows:

(a) Adding nursing home beds being redistributed from another nursing home planning area or areas; or

(b) Subtracting nursing home beds being redistributed to another nursing home planning area or areas.

(37) "New nursing home bed" means a nursing home bed never licensed by the state or beds banked under RCW 70.38.115(13), where the applicant must demonstrate need for the previously licensed nursing home beds. This term does not include beds banked under RCW 70.38.111(8).

(38) "Nursing home" means any entity licensed or required to be licensed under chapter 18.51 RCW or distinct part long-term care units located in a hospital and licensed under chapter 70.41 RCW.

(39) "Obligation," when used in relation to a capital expenditure, means the following has been incurred by or on behalf of a health care facility:

(a) An enforceable contract has been entered into by a health care facility or by a person on behalf of the health care facility for the construction, acquisition, lease, or financing of a capital asset; or

(b) A formal internal commitment of funds by a health care facility for a force account expenditure constituting a capital expenditure; or

(c) In the case of donated property, the date on which the gift is completed in accordance with state law.

(40) "Offer," when used in connection with health services, means the health facility provides one or more specific health services.

(41) "Over the established ratio" means the bed-to-population ratio is greater than the statewide current established ratio.

(42) "Person" means an individual, a trust or estate, a partnership, any public or private corporation (including associations, joint stock companies, and insurance companies), the state, or a political subdivision or instrumentality of the state, including a municipal corporation or a hospital district.

(43) "Planning area" means each individual county designated by the department as the smallest geographic area for which nursing home bed need projections are developed, except as follows:

(a) Clark and Skamania counties shall be one planning area.

(b) Chelan and Douglas counties shall be one planning area.

(44) "Predevelopment expenditures" means capital expenditures, the total of which exceeds the expenditure minimum, made for architectural designs, plans, drawings, or specifications in preparation for the acquisition or construction of physical plant facilities. "Predevelopment expenditures" exclude any obligation of a capital expenditure for the acquisition or construction of physical plant facilities and any activity which the department may consider the "commencement of the project" as this term is defined in this section.

(45) "Professional review of continuing care retirement community pricing and long-term solvency" means prospective financial statements, supported by professional analysis and documentation, which:

(a) Conform to Principles and Practices Board Statement Number 9 of the Healthcare Financial Management Association, "Accounting and Reporting Issues Related to Continuing Care Retirement Communities"; and

(b) Project the financial operations of the continuing care retirement community over a period of ten years or more into the future; and

(c) Are prepared and signed by a qualified actuary as defined under WAC 284-05-060 or an independent certified public accountant, or are prepared by management of the continuing care retirement community and reviewed by a qualified actuary or independent certified public accountant who issues a signed examination or compilation report on the prospective financial statements; and

(d) Include a finding by management that the intended expansion project of the continuing care retirement project is financially feasible.

(46) "Project" means all undertakings proposed in a single certificate of need application or for which a single certificate of need is issued.

(47) "Project completion" for projects requiring construction, means the date the facility is licensed. For projects not requiring construction, project completion means initiating the health service.

(48) "Projection period" means the three-year time interval following the projection year.

(49) "Projection year" for nursing home purposes, means the one-year time interval preceding the projection period.

(50) "Public comment period" means the time interval during which the department shall accept comments regarding a certificate of need application.

(51) "Redistribution" means the shift of nursing home bed allocations between two or more planning areas or the shift of nursing home beds between two or more nursing homes.

(52) "Replacement authorization" means a written authorization by the secretary's designee for a person to implement a proposal to replace existing nursing home beds in accordance with the eligibility requirements in WAC 246-310-044 and notice requirements in WAC 246-310-396.

(53) "Resident population" for purposes of nursing home projects, means the number of residents sixty-five years of age and older living within the same geographic area which:

(a) Excludes contract holders living within a recognized CCRC:

(i) With approval for new nursing home beds under WAC 246-310-380(4); or

(ii) Excluded from the definition of a health care facility per RCW 70.38.025(6);

(b) Is calculated using demographic data obtained from:

(i) The office of financial management; and

(ii) Certificate of need applications and exemption requests previously submitted by a CCRC.

(54) "Secretary" means the secretary of the Washington state department of health or the secretary's designee.

(55) "State Health Planning and Resources Development Act" means chapter 70.38 RCW.

(56) "Statewide current ratio" means a bed-to-population ratio computed from the most recent statewide nursing home bed supply and the most recent estimate of the statewide resident population.

(57) "Swing beds" means up to the first five hospital beds designated by an eligible rural hospital which are available to provide either acute care or nursing home services.

(58) "Tertiary health service" means a specialized service meeting complicated medical needs of people and requires sufficient patient volume to optimize provider effectiveness, quality of service, and improved outcomes of care.

(59) "Transition period" means the period of time, not exceeding five years, between the date a CCRC is inhabited by a member, and the date it fully meets the requirements of a CCRC.

(60) "Under the established ratio" means the bed-to-population ratio is less than the statewide current established ratio.

(61) "Undertaking" means any action subject to the provisions of chapter 246-310 WAC.

(62) "Working days" excludes Saturdays, Sundays, and legal holidays observed by the state of Washington. Working days are counted in the same way as calendar days.

[Statutory Authority: RCW 70.38.115 and 70.38.135. WSR 17-08-097, § 246-310-010, filed 4/5/17, effective 5/6/17. Statutory Authority: RCW 70.38.135, 70.38.115, 70.41.030, chapters 70.38 and 70.41 RCW. WSR 14-02-040, § 246-310-010, filed 12/23/13, effective 1/23/14. Statutory Authority: RCW 70.38.135. WSR 08-19-018, § 246-310-010, filed 9/5/08, effective 10/6/08; WSR 06-24-050, § 246-310-010, filed 12/1/06, effective 1/1/07. Statutory Authority: Chapter 70.38 RCW. WSR 04-17-054, § 246-310-010, filed 8/10/04, effective 9/10/04; WSR 98-10-053, § 246-310-010, filed 4/29/98, effective 5/30/98; WSR 96-24-052, §

246-310-010, filed 11/27/96, effective 12/28/96. Statutory Authority: RCW 70.38.135 and 70.38.919. WSR 92-02-018 (Order 224), § 246-310-010, filed 12/23/91, effective 1/23/92. Statutory Authority: RCW 43.70.040. WSR 91-02-049 (Order 121), recodified as § 246-310-010, filed 12/27/90, effective 1/31/91. Statutory Authority: Chapter 70.38 RCW. WSR 90-17-086 (Order 081), § 248-19-220, filed 8/17/90, effective 9/17/90; WSR 90-02-093 (Order 023), § 248-19-220, filed 1/3/90, effective 2/3/90. Statutory Authority: RCW 70.38.135. WSR 88-15-021 (Order 2639), § 248-19-220, filed 7/11/88; WSR 86-06-030 (Order 2344), § 248-19-220, filed 2/28/86; WSR 84-07-014 (Order 2082), § 248-19-220, filed 3/14/84; WSR 81-09-012 (Order 210), § 248-19-220, filed 4/9/81, effective 5/20/81. Statutory Authority: Chapter 70.38 RCW. WSR 79-12-079 (Order 188), § 248-19-220, filed 11/30/79.]

WAC 246-310-020 Applicability of chapter 246-310 WAC. (1) The rules of this chapter apply to the following:

(a) The construction, development, or other establishment of a new health care facility:

(i) No new health care facility may be initiated as a health service of an existing health care facility without certificate of need approval as a new health care facility;

(ii) The provision of services by a home health agency or hospice to a county, on a regular and ongoing basis, that was not previously included in the home health agency or hospice service area shall be considered the development of a new home health agency or hospice;

(iii) Any certificate of need approved ambulatory surgical facility expanding the number of operating rooms is considered the construction, development or other establishment of a new ambulatory surgical facility. A certificate of need approved ambulatory surgical facility may not operate more than the number of operating rooms approved by the department identified on its certificate of need or approved in the department evaluation. However, expansion of the number of certificate of need approved operating rooms does not require certificate of need approval if the expansion:

(A) Was completed without certificate of need approval prior to the effective date of these rules; or

(B) Received approval to begin construction from department of health construction review services prior to the effective date of these rules.

(b) The sale, purchase, or lease of part or all of any existing hospital licensed under chapter 70.41 RCW or a psychiatric hospital licensed under chapter 71.12 RCW;

(c) A change in bed capacity of a health care facility increasing the total number of licensed beds or redistributing beds among acute care, nursing home care, and assisted living facility care, as defined under RCW 18.20.020, if the bed redistribution is effective for a period in excess of six months;

(d) Any new tertiary health services offered in or through a health care facility, and not offered on a regular basis by, in, or through such health care facility within the twelve-month period prior to the time the facility will offer such services:

(i) Tertiary services include the following:

(A) Specialty burn services. This is a service designed, staffed, and equipped to care for any burn patient regardless of the severity or extent of the burn. All staff and equipment necessary for any level of burn care are available;

(B) Intermediate care nursery and/or obstetric services level II. Intermediate care nursery is defined in chapter 246-318 WAC. A level II obstetric service is in an area designed, organized, equipped, and staffed to provide a full range of maternal and neonatal services for uncomplicated patients and for the majority of complicated obstetrical problems;

(C) Neonatal intensive care nursery and/or obstetric services level III. Neonatal intensive care nursery is defined in chapter 246-318 WAC. A level III obstetric service is in an area designed, organized, equipped, and staffed to provide services to the few women and infants requiring full intensive care services for the most serious type of maternal-fetal and neonatal illnesses and abnormalities. Such a service provides the coordination of care, communications, transfer, and transportation for a given region. Level III services provide leadership in preparatory and continuing education in prenatal and perinatal care and may be involved in clinical and basic research;

(D) Transplantation of specific solid organs, including, but not limited to, heart, liver, pancreas, lung, small bowel and kidney and including bone marrow. A transplantation service for each solid organ is considered a separate tertiary service;

(E) Open heart surgery and/or elective therapeutic cardiac catheterization including elective percutaneous translumenal coronary angioplasty (PTCA). Open heart surgery includes the care of patients who have surgery requiring the use of a heart lung bypass machine. Therapeutic cardiac catheterization means passage of a tube or other device into the coronary arteries or the heart chambers to improve blood flow. PTCA means the treatment of a narrowing of a coronary artery by means of inflating a balloon catheter at the site of the narrowing to dilate the artery;

(F) Inpatient physical rehabilitation services level I. Level I rehabilitation services are services for persons with usually nonreversible, multiple function impairments of a moderate-to-severe complexity resulting in major changes in the patient's lifestyle and requiring intervention by several rehabilitation disciplines. Services are multidisciplinary, including such specialists as a rehabilitation nurse; and physical, occupational, and speech therapists; and vocational counseling; and a physiatrist. The service is provided in a dedicated unit with a separate nurses station staffed by nurses with specialized training and/or experience in rehabilitation nursing. While the service may specialize (i.e., spinal cord injury, severe head trauma, etc.), the service is able to treat all persons within the designated diagnostic specialization regardless of the level of severity or complexity of the impairments and include the requirements as identified in chapter 246-976 WAC relating to level I trauma rehabilitation services;

(G) Specialized inpatient pediatric services. The service is designed, staffed, and equipped to treat complex pediatric cases for more than twenty-four hours. The service has a staff of pediatric specialists and subspecialists.

(ii) The department shall review, periodically revise, and update the list of tertiary services. The department shall change the tertiary services list following the procedures identified in WAC 246-310-035;

(iii) The offering of an inpatient tertiary health service by a health maintenance organization or combination of health maintenance organizations is subject to the provisions under chapter 246-310 WAC unless the offering is exempt under the provisions of RCW 70.38.111.

(e) Any increase in the number of dialysis stations in a kidney disease center;

(f) Any capital expenditure in excess of the expenditure minimum for the construction, renovation, or alteration of a nursing home. However, a capital expenditure, solely for any one or more of the following, which does not substantially affect patient charges, is not subject to certificate of need review:

(i) Communications and parking facilities;

(ii) Mechanical, electrical, ventilation, heating, and air conditioning systems;

(iii) Energy conservation systems;

(iv) Repairs to, or the correction of, deficiencies in existing physical plant facilities necessary to maintain state licensure, however, other additional repairs, remodeling, or replacement projects that are not related to one or more deficiency citations and are not necessary to maintain state licensure are not exempt from certificate of need review except as otherwise permitted by (f)(vi) of this subsection or RCW 70.38.115(13);

(v) Acquisition of equipment, including data processing equipment, not for use in the direct provision of health services;

(vi) Construction or renovation at an existing nursing home involving physical plant facilities, including administrative, dining, kitchen, laundry, and therapy areas, or support facilities, by an existing licensee who has operated the beds for at least one year;

(vii) Acquisition of land;

(viii) Refinancing of existing debt; and

(ix) Nursing home project granted a replacement authorization under WAC 246-310-044.

(g) Any expenditure for the construction, renovation, or alteration of a nursing home or change in nursing home services in excess of the expenditure minimum made in preparation for any undertaking subject to the provisions under chapter 246-310 WAC and any arrangement or commitment made for financing such undertaking;

(h) No person may divide a project in order to avoid review requirements under any of the thresholds specified under this section; and

(i) The department may issue certificates of need authorizing only predevelopment expenditures, without authorizing any subsequent undertaking for which the predevelopment expenditures are made.

(2) No person shall engage in any undertaking subject to certificate of need review unless:

(a) A certificate of need authorizing such undertaking is issued and remains valid; or

(b) An exemption is granted in accordance with the provisions of this chapter.

(3) If a nursing home or portion of a nursing home constructed or established under the authority of a certificate of need granted from the pool of nursing home beds for ethnic minorities according to the provisions of WAC 246-310-135 is sold or leased within ten years to a party not eligible for an award of such beds under the provisions of WAC 246-310-136(2):

(a) The purchaser or lessee may not operate those beds as nursing home beds without first obtaining a certificate of need for new beds; and

(b) The beds that were awarded from the special pool shall be returned to that pool.

[Statutory Authority: RCW 70.38.135. WSR 17-05-068, § 246-310-020, filed 2/13/17, effective 3/16/17. Statutory Authority: RCW 70.38.135 and 2012 c 10. WSR 14-08-046, § 246-310-020, filed 3/27/14, effective 4/27/14. Statutory Authority: Chapter 70.38 RCW. WSR 96-24-052, § 246-310-020, filed 11/27/96, effective 12/28/96. Statutory Authority: RCW 70.38.135 (3)(c). WSR 92-05-057 (Order 244), § 246-310-020, filed 2/14/92, effective 3/16/92. Statutory Authority: RCW 70.38.135 and 70.38.919. WSR 92-02-018 (Order 224), § 246-310-020, filed 12/23/92, effective 1/23/93. Statutory Authority: RCW 43.70.040. WSR 91-02-049 (Order 121), recodified as § 246-310-020, filed 12/27/90, effective 1/31/91. Statutory Authority: Chapter 70.38 RCW. WSR 90-21-028 (Order 082), § 248-19-231, filed 10/9/90, effective 10/9/90; WSR 89-23-098 (Order 019), § 248-19-231, filed 11/21/89, effective 12/22/89.]

WAC 246-310-035 Tertiary services identification. (1) The criteria in this section shall be used as guidelines when examining services to determine whether the service is considered a tertiary service.

(2) In determining whether a service is a tertiary service the department shall consider the degree to which the service meets the following criteria:

(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 service is characterized by relatively 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 outcomes of care; and

(g) Whether the service carries a significant risk or consequence.

(3) Periodically the department shall request review of proposed changes to the list of tertiary services identified in WAC 246-310-020. The periodic review shall be conducted as follows:

(a) The department shall send notice to all persons who have sent the certificate of need program a written request to be notified of the annual review of tertiary services.

(b) The notice shall contain the following:

(i) Identification of the thirty-day period during which written comments may be received. This thirty-day period shall be called the comment period;

(ii) The criteria listed in this section; and

(iii) The name and address of the person in the department to whom written comments are to be addressed.

(c) The written comments must address whether a service meets or partially meets the criteria in this section.

(d) Within sixty days after the close of the comment period the department shall determine whether to propose any changes to the list of tertiary services in chapter 246-310 WAC. This sixty-day period shall be called the consideration period.

(e) During the consideration period information may be exchanged between the department and persons proposing changes to the list of tertiary services in chapter 246-310 WAC.

(4) The department shall convene a technical work group at least every three years to do the following:

(a) Review the criteria listed in this section to determine whether the criteria appropriately define a tertiary service; and

(b) Propose any necessary changes to the list of tertiary services in WAC 246-310-020.

[Statutory Authority: Chapter 70.38 RCW. WSR 96-24-052, § 246-310-035, filed 11/27/96, effective 12/28/96. Statutory Authority: RCW 70.38.135 and 70.38.919. WSR 92-02-018 (Order 224), § 246-310-035, filed 12/23/91, effective 1/23/92.]

WAC 246-310-040 Exemptions from requirements for a certificate of need for health maintenance organizations. (1) Provisions for exemptions.

The secretary's designee shall grant an exemption from the requirements for a certificate of need for the offering of an inpatient institutional health service, the acquisition of major medical equipment for the provision of an institutional health service, or the obligation of a capital expenditure in excess of the expenditure minimum for the provision of an inpatient institutional health service to any entity meeting the eligibility requirements set forth in subsection (1)(a) of this section for such an exemption and submitting an application for an exemption meeting the requirements of subsection (1)(b) of this section.

(a) Eligibility requirements.

To be eligible for an exemption from the requirements for a certificate of need for the offering of an inpatient institutional health service, the acquisition of major medical equipment for the provision of an inpatient institutional health service, or the obligation of a capital expenditure in excess of the expenditure minimum for the provision of an institutional health service, an applicant entity shall be one of the following:

(i) A health maintenance organization or a combination of health maintenance organizations if:

(A) The organization or combination of organizations has, in the service area of the organization or the service areas of the organizations in the combination, an enrollment of at least fifty thousand individuals;

(B) The facility in which the service will be provided is or will be geographically located so the service will be reasonably accessible to such enrolled individuals; and

(C) At least seventy-five percent of the patients reasonably expected to receive the institutional health service will be individuals enrolled in such organization or organizations in the combination;

(ii) A health care facility if:

(A) The facility primarily provides or will provide inpatient health services;

(B) The facility is or will be controlled, directly or indirectly, by a health maintenance organization or a combination of health maintenance organizations which has, in the service area of the organization or service areas of the organizations in the combination, an enrollment of at least fifty thousand individuals;

(C) The facility is or will be geographically located so the service will be reasonably accessible to such enrolled individuals; and

(D) At least seventy-five percent of the patients reasonably expected to receive the institutional health service will be individuals enrolled with such organization or organizations in the combination; or

(iii) A health care facility (or portion thereof) if:

(A) The facility is or will be leased by a health maintenance organization or combination of health maintenance organizations which has, in the service area of the organization or the service areas of the organizations in the combination, an enrollment of at least fifty thousand individuals and, on the date the application for an exemption is submitted, at least fifteen years remain in the term of the lease;

(B) The facility is or will be geographically located so the service will be reasonably accessible to such enrolled individuals; and

(C) At least seventy-five percent of the patients reasonably expected to receive the institutional health service will be individuals enrolled with such organization;

(b) Requirements for an application for exemption.

An application for an exemption from a certificate of need shall meet the following requirements:

(i) The application for an exemption shall have been submitted at least thirty days prior to the offering of the institutional health service, acquisition of major medical equipment, or obligation of the capital expenditure to which the application pertains. A copy of the application for the exemption shall be sent simultaneously to the appropriate advisory review agencies.

(ii) A complete application shall be submitted in such form and manner as has been prescribed by the department. The information which the department prescribes shall include:

(A) All of the information required to make a determination that the applicant entity qualifies in accordance with subsection (1)(a) of this section; and

(B) A complete description of the offering, acquisition, or obligation to which the application pertains.

(2) Action on an application for exemption.

(a) Within thirty days after receipt of a complete application for exemption from certificate of need requirements, the department shall send the applicant a written notice the exemption has been granted or denied. A copy of such written notice shall be sent simultaneously to the appropriate advisory review agencies.

(b) The secretary's designee shall deny an exemption if he or she finds the applicant has not met the requirements of subsections (1)(a) and (b) of this section. Written notice of the denial shall include the specific reasons for the denial.

(c) In the case of an application for a proposed health care facility (or portion thereof) which has not begun to provide institutional health services on the date the application for an exemption is submitted, the secretary's designee shall grant the exemption if he or she determines the facility (or portion thereof) will meet the applicable requirements of subsection (1)(a) of this section when the facility first provides health services.

(d) If the secretary's designee fails to grant or deny an exemption in accordance with the provisions of this section within thirty days after receipt of a complete application for such exemption, the

applicant for the exemption may seek a writ of mandamus from superior court pursuant to chapter 7.16 RCW.

(3) Subsequent sale, lease, or acquisition of exempt facilities or equipment.

Subsequent sale, lease, or acquisition of exempt health care facilities (or portions thereof) or medical equipment for which an exemption was granted under the provisions of subsection (2) of this section, any acquisition of a controlling interest in such facility or equipment, and any use of such facility or equipment by a person other than the one to whom the exemption was granted, shall meet one of the following conditions:

(a) A certificate of need for the purchase, lease, acquisition of controlling interest in, or use of such facility or equipment, shall have been applied for and issued by the department; or

(b) The department shall have determined, after receipt of an application for an exemption, submitted in accordance with subsection (1) of this section, that the requirements of either subsection (1)(a)(i) or subsection (1)(a)(ii)(A) and (B) are met.

(4) The method of payment for services (i.e., prepaid or fee for service) shall not be considered relevant in determining whether an undertaking of a health maintenance organization qualifies for an exemption under this section.

[Statutory Authority: RCW 43.70.040. WSR 91-02-049 (Order 121), recodified as § 246-310-040, filed 12/27/90, effective 1/31/91. Statutory Authority: RCW 70.38.135. WSR 86-06-030 (Order 2344), § 248-19-405, filed 2/28/86; WSR 81-09-012 (Order 210), § 248-19-405, filed 4/9/81, effective 5/20/81.]

WAC 246-310-041 Exemption from requirements for a certificate of need for continuing care retirement communities' nursing home projects. (1) Provisions for exemptions.

The secretary's designee shall grant an exemption from the requirements for a certificate of need for the construction, development, or other establishment of a nursing home, or the addition of beds to an existing nursing home, that is owned and operated by a continuing care retirement community meeting the eligibility requirements of (a) of this subsection and submitting an application for an exemption meeting the requirements of (b) of this subsection.

(a) Eligibility requirements. To be eligible for an exemption under this section, an applicant entity shall demonstrate that:

(i) Nursing home services will be offered only to contractual residents;

(ii) Residents will be provided a contractually guaranteed range of services from independent living through skilled nursing, including some assistance with daily living activities;

(iii) The facility contractually assumes responsibility for the cost of services exceeding the residents financial responsibility under the contract, so that no third party, including the medicaid program, is liable for the costs of care, even if the resident depletes his or her personal resources. This exclusion does not pertain to insurance purchased by the retirement community or its residents;

(iv) The entity has offered continuing care contracts and has operated a nursing home continuously since January 1, 1988, or has obtained a certificate of need to establish a nursing home;

(v) A binding agreement is maintained with the state assuring that financial liability for services to residents, including nursing home services, will not fall upon the state;

(vi) It does not operate, and has not undertaken a project that would result in the ratio of nursing home beds to independent living units exceeding one nursing home bed for every four independent living units, exclusive of nursing home beds; and

(vii) It has obtained a professional review of pricing and long-term solvency of the applicant entity within the prior five years which was fully disclosed to residents.

(b) Requirements for an application for exemption. An application for an exemption from a certificate of need shall meet the following requirements:

(i) The application for an exemption shall be submitted at least thirty days prior to the commencement of construction, submitting an application for nursing home licensure, or commencing operation of a nursing home, whichever occurs first;

(ii) A complete application shall be submitted in such form and manner as has been prescribed by the department. The information which the department prescribes shall include:

(A) All of the information required to make a determination that the applicant entity qualifies in accordance with (a) of this subsection; and

(B) A complete description of the construction, development or other establishment of a nursing home, or the addition of nursing home beds to which the exemption application pertains.

(2) Action on an application for exemption.

(a) Within thirty days after receipt of a complete application for exemption from certificate of need requirements, the department shall send the applicant a written notice whether the exemption has been granted or denied.

(b) The secretary's designee shall deny an exemption if it is determined the applicant has not met the requirements of subsection (1)(a) and (b) of this section. Written notice of the denial shall include the specific reasons for the denial.

(3) Subsequent sale, lease, acquisition, or use of, part or all, of an exempt continuing care retirement community.

Subsequent sale, lease, acquisition or use of exempt continuing care retirement communities shall require prior certificate of need approval to qualify for licensure as a nursing home unless the department determines such sale, lease, acquisition, or use is by a continuing care retirement community that meets the conditions identified in subsection (1)(a) and (b) of this section.

[Statutory Authority: Chapter 70.38 RCW. WSR 96-24-052, § 246-310-041, filed 11/27/96, effective 12/28/96.]

WAC 246-310-042 Rural hospital and rural health care facility exemptions from certificate of need review. (1) Provisions for exemptions of qualified rural hospitals and rural health care facilities.

The secretary's designee shall grant an exemption from the requirement for a certificate of need for an increase in licensed bed capacity to a rural hospital meeting the eligibility requirements of (a) of this subsection and submitting an application for an exemption meeting the requirements of (c) of this subsection. The secretary's designee shall grant an exemption from the requirement for a certifi-

cate of need for the construction, development, or other establishment of a new hospital to a rural health care facility meeting the eligibility requirements of (b) of this subsection and submitting an application for an exemption meeting the requirements of (c) of this subsection.

(a) Eligibility requirements for a rural hospital exemption. To be eligible for an exemption from the requirements under this section, a rural hospital, shall demonstrate that:

(i) The applicant hospital meets the definition of a rural hospital as defined by the department;

(ii) The request is being made within three years of the date the beds licensed under chapter 70.41 RCW were reduced;

(iii) The increase in licensed beds will result in no more than had previously been licensed; and

(iv) The rural hospital became a rural primary care hospital under the provisions of Part A Title XVIII of the Social Security Act Section 1820, 42 U.S.C., 1395c et seq. after its licensure reduction.

(b) Eligibility requirements for a rural health care facility exemption. To be eligible for an exemption from the requirements under this section, a rural health care facility, shall demonstrate that:

(i) The applicant facility meets the definition of a rural health care facility under RCW 70.175.100;

(ii) The applicant facility was previously licensed as a hospital under chapter 70.41 RCW;

(iii) The request is being made within three years of the effective date of the rural health care facility license;

(iv) There will be no increase in the number of beds previously licensed under chapter 70.41 RCW and there is no redistribution in the number of beds used for acute care or long-term care;

(v) The rural health care facility has been in continuous operation; and

(vi) The rural health care facility has not been purchased or leased.

(c) Requirements for an application for exemption by a rural hospital or rural health care facility. An application for an exemption from a certificate of need shall meet the following requirements:

(i) The application for a rural hospital exemption shall be submitted at least thirty days prior to the effective date of the hospital license that increases the number of beds at the rural hospital or at the time an application is made to the department to increase the number of licensed beds at the rural hospital, whichever occurs first.

(ii) The application for a rural health care facility exemption shall be submitted at least thirty days prior to the effective date of the hospital license that converts the rural health care facility back to a hospital or at the time an application is made to the department to convert back to a hospital, whichever occurs first;

(iii) A complete application shall be submitted in such form and manner as has been prescribed by the department. The information which the department prescribes shall include:

All of the information required to make a determination that the rural hospital qualifies in accordance with (a) of this subsection or that the rural health care facility qualifies with (b) of this subsection.

(2) Action on an application for exemption by a rural hospital or rural health care facility.

(a) Within thirty days after receipt of a complete application for exemption from certificate of need requirements, the department

shall send the applicant a written notice whether the exemption request has been granted or denied.

(b) The secretary's designee shall deny an exemption if it is determined the applicant entity has not met the requirements of subsection (1)(a), (b), or (c) of this section. Written notice of the denial shall include the specific reasons for the denial.

[Statutory Authority: Chapter 70.38 RCW. WSR 96-24-052, § 246-310-042, filed 11/27/96, effective 12/28/96.]

WAC 246-310-043 Exemption from requirements for a certificate of need for nursing home bed conversions to alternative use. Provisions for exemptions.

The secretary's designee shall grant an exemption from the requirements for a certificate of need for the conversion of nursing home beds banked under the provisions of RCW 70.38.111(8) by a nursing home meeting the eligibility requirements of this section and submitting an application for an exemption which demonstrates the eligibility requirements have been met.

(1) Eligibility requirements. To be eligible for an exemption under this section, an applicant shall demonstrate that:

(a) The nursing home voluntarily reduced its licensed capacity to provide one or more alternative services, as identified in RCW 70.38.111(8), to reduce the number of beds per room to one or two in the nursing home, or otherwise enhance the quality of life for residents, as defined in WAC 246-310-010;

(b) The beds to be converted back to nursing home beds are to be licensed in the original facility;

(c) The nursing home has remained in continuous operation and has not been sold or leased during the bed banking time interval;

(d) Notice of intent to bank the nursing home beds was given as required by WAC 246-310-395; and

(e) The bed conversion occurs within four years of the bed banking, unless the department has granted a four year extension under WAC 246-310-580 in which case the bed conversion must occur within eight years of the original bed banking.

(2) Nursing homes proposing to establish, construct, or otherwise develop alternative services subject to certificate of need review under the provisions of RCW 70.38.105 shall obtain certificate of need approval prior to providing such services.

[Statutory Authority: Chapter 70.38 RCW. WSR 96-24-052, § 246-310-043, filed 11/27/96, effective 12/28/96.]

WAC 246-310-044 Exemption from requirements for a certificate of need for nursing home bed replacements. (1) Provisions for exemptions.

The secretary's designee shall grant a replacement authorization exempting a facility from the requirements for a certificate of need for the replacement of existing nursing home beds under the provisions of RCW 70.38.115 (13)(a) by a nursing home meeting the eligibility requirements of this section and submitting an application, following the notice requirements in WAC 246-310-397, which demonstrates the eligibility requirements have been met.

(2) Nursing home construction or renovation projects for the purpose of replacing nursing home beds within the same planning area, and which meet the eligibility requirements in subsection (3) of this section and the notification requirements in WAC 246-310-397, shall not be subject to certificate of need review. Projects meeting the above requirements would include, but are not limited to:

(a) Replacement of an existing facility at the same location;

(b) Construction of a new nursing home or facilities for the purpose of replacing beds in the same planning area;

(c) Renovation of an existing facility for the purpose of replacing beds; and

(d) Redistribution of all or a portion of existing beds to an existing or new nursing home or facilities in the same planning area.

(3) Eligibility requirements. To be eligible for an exemption under this section, an applicant shall demonstrate that:

(a) The applicant is the existing licensee (as defined in WAC 246-310-010) of all affected facilities and has operated the beds at all affected facilities for at least one year immediately preceding the replacement exemption request fulfilling the requirements as specified in WAC 246-310-397;

(b) The applicant will be the licensee at all affected facilities at the completion of the project except as allowed under the provisions of RCW 70.38.115(14);

(c) The project will not increase the total bed capacity of a planning area; and

(d) The nursing home beds being replaced will not provide nursing home services once the replacement beds are licensed.

(4) Projects must be commenced within two years following replacement authorization with a possibility of one six-month extension provided that substantial and continuing progress had been made toward commencement of the project as referenced in WAC 246-310-580.

[Statutory Authority: Chapter 70.38 RCW. WSR 98-10-053, § 246-310-044, filed 4/29/98, effective 5/30/98; WSR 96-24-052, § 246-310-044, filed 11/27/96, effective 12/28/96.]

WAC 246-310-045 Exemption from certificate of need requirements for a change in bed capacity at a residential hospice care center. (1) A change in bed capacity at a residential hospice care center shall not be subject to certificate of need review under this chapter if the department determined prior to June 1994 that the construction, development, or other establishment of the residential hospice care center was not subject to certificate of need review under this chapter.

(2) For purposes of this section, a "residential hospice care center" means any building, facility, place, or equivalent that opened in December 1996 and is organized, maintained, and operated specifically to provide beds, accommodations, facilities, and services over a continuous period of twenty-four hours or more for palliative care to two or more individuals, not related to the operator, who are diagnosed as being in the latter stages of an advanced disease that is expected to lead to death.

[Statutory Authority: Chapter 70.38 RCW. WSR 98-17-099, § 246-310-045, filed 8/19/98, effective 9/19/98.]

WAC 246-310-050 Applicability determination. (1) Any person wanting to know whether an action the person is considering is subject to certificate of need requirements (chapter 246-310 WAC) may submit a written request to the certificate of need program requesting a formal determination of applicability of the certificate of need requirements to the action.

(a) The written request shall include the nature and extent of any construction, changes in services, and the estimated total costs of the action.

(2) The department may request any additional written information that is reasonably necessary to make an applicability determination on the action.

(3) The department shall respond in writing to a request for an applicability determination within thirty days of receipt of the complete information needed for such determination. In the written response, the department shall state the reasons for its determination that the action is or is not subject to certificate of need requirements.

(4) Information or advice given by the department as to whether an action is subject to certificate of need requirements shall not be considered an applicability determination unless it is in written form in response to a written request submitted in accordance with provisions of this section.

(5) A written applicability determination on an action in response to a written request and based on written information shall be binding upon the department: Provided, The nature, extent, or cost of the action does not significantly change.

[Statutory Authority: Chapter 70.38 RCW. WSR 98-10-053, § 246-310-050, filed 4/29/98, effective 5/30/98; WSR 96-24-052, § 246-310-050, filed 11/27/96, effective 12/28/96. Statutory Authority: RCW 70.38.135 and 70.38.919. WSR 92-02-018 (Order 224), § 246-310-050, filed 12/23/91, effective 1/23/92. Statutory Authority: RCW 43.70.040. WSR 91-02-049 (Order 121), recodified as § 246-310-050, filed 12/27/90, effective 1/31/91. Statutory Authority: RCW 70.38.135. WSR 86-06-030 (Order 2344), § 248-19-240, filed 2/28/86; WSR 81-09-012 (Order 210), § 248-19-240, filed 4/9/81, effective 5/20/81. Statutory Authority: Chapter 70.38 RCW. WSR 79-12-079 (Order 188), § 248-19-240, filed 11/30/79.]

WAC 246-310-080 Letter of intent. Any person planning to propose an undertaking subject to certificate of need review shall submit a letter of intent as follows:

(1) The letter of intent shall include the following information:

(a) A description of the services proposed;

(b) The estimated cost of the proposed project;

(c) An identification of the service area.

(2) A letter of intent shall be valid for six months after the receipt of the letter by the department. If the applicant does not submit an application for the project as described in the letter within this time frame, a new letter of intent shall be required before the department accepts an application.

(3) In the event that the application proposes a project that is significantly different than that proposed in the letter of intent, the department shall consider the application the letter of intent and

no further action shall be taken until the end of the thirty-day letter of intent period.

(4) Expedited or regular review. Any person proposing an undertaking subject to an expedited or regular review shall submit a letter of intent at least thirty days prior to the submission of the application.

(5) Concurrent review.

(a) Any person proposing undertakings subject to concurrent review shall submit a letter of intent according to the applicable schedule.

(b) Within thirty days following the last day of the letter of intent submittal period, the department shall determine which of the proposed undertakings compete with other proposed undertakings. Two or more undertakings within the same concurrent review cycle may be competing when the proposed undertaking would be located in the same county or planning area and/or the undertakings propose nursing home beds to be allocated from the same statewide continuing care retirement community (CCRC) bed pool as defined in WAC 246-310-380. The department shall notify applicants of competing undertakings.

(c) In the event the department determines an application submitted under concurrent review is not competing, the department may convert the review to a regular review.

[Statutory Authority: Chapter 70.38 RCW. WSR 98-10-053, § 246-310-080, filed 4/29/98, effective 5/30/98; WSR 96-24-052, § 246-310-080, filed 11/27/96, effective 12/28/96. Statutory Authority: RCW 70.38.135 and 70.38.919. WSR 92-02-018 (Order 224), § 246-310-080, filed 12/23/91, effective 1/23/92. Statutory Authority: RCW 43.70.040. WSR 91-02-049 (Order 121), recodified as § 246-310-080, filed 12/27/90, effective 1/31/91. Statutory Authority: RCW 70.38.115. WSR 87-10-023 (Order 2487), § 248-19-270, filed 5/1/87. Statutory Authority: RCW 70.38.135. WSR 86-06-030 (Order 2344), § 248-19-270, filed 2/28/86; WSR 81-09-012 (Order 210), § 248-19-270, filed 4/9/81, effective 5/20/81. Statutory Authority: Chapter 70.38 RCW. WSR 79-12-079 (Order 188), § 248-19-270, filed 11/30/79.]

WAC 246-310-090 Submission and withdrawal of applications. (1) General.

(a) A person proposing an undertaking subject to review shall submit a certificate of need application in such form and manner and containing such information as the department has prescribed and published as necessary to such a certificate of need application.

(i) The information, which the department prescribes and publishes as required for a certificate of need application, shall be limited to the information necessary for the department to perform a certificate of need review and shall vary in accordance with and be appropriate to the category of review or the type of proposed project: Provided however, That the required information shall include what is necessary to determine whether the proposed project meets applicable criteria and standards.

(ii) Information regarding a certificate of need application submitted by an applicant after the department has given "notification of the beginning of review" in the manner prescribed by WAC 246-310-170 shall be submitted in writing to the department.

(iii) Except as provided in WAC 246-310-190, no information regarding a certificate of need application submitted by an applicant

after the conclusion of the public comment period shall be considered by the department in reviewing and taking action on a certificate of need application. An exception to this rule shall be made when, during its final review period, the department finds an unresolved pivotal issue requires submission of further information by an applicant and the applicant agrees to an extension of the review period in order to resolve this issue as provided for in WAC 246-310-160 (2)(b), 246-310-150 (2)(c), and 246-310-140(4). The department shall give public notice of such request for additional information through the same newspaper in which the "notification of beginning of review" for the project was published. The notice shall identify the project, the nature of the unresolved issue and the information requested of the applicant, and shall state the period of time allowed for receipt of written comments from interested persons.

(b) A person submitting a certificate of need application shall submit one original and one copy of the application to the certificate of need program of the department.

(c) On or before the last day of the applicable screening period for a certificate of need application, as prescribed in subsections (2) and (3) of this section, the department shall send a written notice to the person submitting the application stating whether or not the application has been declared complete. If an application has been found to be incomplete, the notice from the department shall specifically identify the portions of the application where the information provided has been found to be insufficient or indefinite and request supplemental information needed to complete the application.

(d) The department shall not request any supplemental information of a type not prescribed and published as being necessary to a certificate of need application for the type of project being proposed. The department may request clarification of information provided in the application.

(e) A response to the department's request for information to supplement an incomplete application shall be written.

(2) Screening and prereview activities.

(a) The department shall, within a fifteen working-day period for emergency, expedited, and regular reviews, screen the application to determine whether the information provided in the application is complete and as explicit as is necessary for a certificate of need review. This screening period shall begin on the first day after the department has received the application. In the event that the application is lacking significant information relating to the review criteria, the department may, upon notification, reserve the right to screen the application again upon receipt of the applicant's original response unless the applicant exercises option (c)(iii) of this subsection.

(b) The department shall return an incomplete certificate of need application to the person submitting the application if the department has not received a response to a request for the supplemental information sent in accordance with subsection (1)(c) of this section within forty-five days for emergency, expedited, and regular reviews unless extended by mutual agreement, and within one month for concurrent review after such request was sent.

(c) For emergency, expedited, and regular reviews, a person submitting a response to the department's request for supplemental information to complete a certificate of need application within forty-five days after the request was sent by the department, in accordance with

subsection (1)(c) of this section, shall have the right to exercise one of the following options:

(i) Submission of written supplemental information and a written request that the information be screened and the applicant be given opportunity to submit further supplemental information if the department determines that the application is still incomplete;

(ii) Submission of written supplemental information with a written request that review of the certificate of need application begin without the department notifying the applicant as to whether the supplemental information is adequate to complete the application; or

(iii) Submission of a written request that the application be reviewed without supplemental information.

(d) The department shall not accept responses to the department's screening letters later than ten days after the department has given "notification of beginning of review."

(e) For concurrent review a person submitting a response to the department's request for supplemental information to complete a certificate of need application within one month after the request was sent by the department, in accordance with subsection (1)(c) of this section, shall submit written supplemental information or a written request that the incomplete application be reviewed. The review shall begin in accordance with the published schedule.

(f) After receipt of a request for review of a certificate of need application, submitted in accordance with subsection (2)(c)(ii) or (iii) of this section, the department shall give notification of the beginning of review in the manner prescribed for a complete application in WAC 246-310-170.

(g) If a person requests the screening of supplemental information in accordance with subsection (2)(c)(i) of this section, such screening shall be carried out in the same number of days and in the same manner as required for an application in accordance with the provisions of subsection (1)(c) and (2)(a) of this section. The process of submitting and screening supplemental information may be repeated until the department declares the certificate of need application complete, the applicant requests that review of the incomplete application begin, or the one hundred twentieth day after the beginning of the first screening period for the application, whichever occurs first. The department shall return an application to the applicant if it is still incomplete on the one hundred twentieth day after the beginning of the first screening period and the applicant has not requested review of such incomplete application.

(3) Withdrawal of applications.

A certificate of need application shall be withdrawn from the certificate of need process if the department receives a written request for withdrawal of the application from the person submitting the application at any time before final action on such application has been taken by the secretary's designee.

(4) Resubmission of applications withdrawn or returned as incomplete.

A submission of a new certificate of need application shall be required for a certificate of need review of any undertaking for which the department has returned an incomplete application in accordance with subsection (2)(b) of this section, or for which a certificate of need application has been withdrawn in accordance with subsection (3) of this section. The content of the application should be updated as necessary before resubmission.

[Statutory Authority: Chapter 70.38 RCW. WSR 98-10-053, § 246-310-090, filed 4/29/98, effective 5/30/98; WSR 96-24-052, § 246-310-090, filed 11/27/96, effective 12/28/96. Statutory Authority: RCW 70.38.135 and 70.38.919. WSR 92-02-018 (Order 224), § 246-310-090, filed 12/23/91, effective 1/23/92. Statutory Authority: RCW 43.70.040. WSR 91-02-049 (Order 121), recodified as § 246-310-090, filed 12/27/90, effective 1/31/91. Statutory Authority: RCW 70.38.135. WSR 86-06-030 (Order 2344), § 248-19-280, filed 2/28/86; WSR 81-09-012 (Order 210), § 248-19-280, filed 4/9/81, effective 5/20/81. Statutory Authority: Chapter 70.38 RCW. WSR 79-12-079 (Order 188), § 248-19-280, filed 11/30/79.]

WAC 246-310-100 Amendment of certificate of need applications. (1) The following changes to an application may be considered by the department an amendment of an application:

(a) The addition of a new service or elimination of a service included in the original application.

(b) The expansion or reduction of a service included in the original application.

(c) An increase in the bed capacity.

(d) A change in the capital cost of the project or the method of financing the project.

(e) A significant change in the rationale used to justify the project.

(f) A change in the applicant.

(2) Direct responses to screening questions will not be considered amendments.

(3) Amendments to certificate of need applications shall include information and documentation consistent with the requirements of WAC 246-310-090 (1)(a)(i) and (b).

(4) Application for emergency review. If an applicant changes an application during the screening period, the department shall determine whether the changed application constitutes a new application. An application changed during the review period shall be considered a new application.

(5) An application for expedited or regular review may be changed during the screening period or the public comment period.

(a) If an application is changed during the screening period or within the ten-day grace period following the beginning of review, the department shall determine whether the changed application constitutes an amended application. The applicant may submit written information to the department within five working days of receiving the department's determination indicating why the change should not be considered an amendment.

(b) The department shall respond within five working days of receiving the applicant's written information concerning whether the application changes constitute an amendment.

(c) When an application has been amended, the review period may be extended for a period not to exceed forty-five days.

(6) An application for concurrent review may be amended according to the following provisions:

(a) The department shall determine when an application has been amended.

(b) An amendment may be made through the first forty-five days of the concurrent review process. When the department determines an ap-

plicant has amended an application, the review period for all applications reviewed concurrently shall be extended by a single thirty-day period. The forty-five days for amendments shall be divided as follows:

(i) During the first thirty days an applicant or applicants may amend an application one or more times.

(ii) When an amendment has been made to an application in the first thirty days, all applicants may make one final amendment during the remaining fifteen days of the forty-five day period.

(iii) The department shall send written notice to all applicants when an amendment to an application is submitted.

(iv) If no amendment has been made to any application through the thirty-day period, no amendments may be made during the subsequent fifteen-day period.

(c) Any information submitted after the amendment period which has not been requested in writing by the department shall be returned to the person submitting the information and shall not be considered in the review of the application.

[Statutory Authority: Chapter 70.38 RCW. WSR 96-24-052, § 246-310-100, filed 11/27/96, effective 12/28/96. Statutory Authority: RCW 70.38.135 and 70.38.919. WSR 92-02-018 (Order 224), § 246-310-100, filed 12/23/91, effective 1/23/92. Statutory Authority: RCW 43.70.040. WSR 91-02-049 (Order 121), recodified as § 246-310-100, filed 12/27/90, effective 1/31/91. Statutory Authority: RCW 70.38.135. WSR 86-06-030 (Order 2344), § 248-19-295, filed 2/28/86.]

WAC 246-310-110 Categories of review. (1) In the review of any certificate of need application, one of the following review processes shall be used: Regular review, concurrent review, emergency review, or expedited review.

(2) Determination of review process.

The department shall determine which review process will be used in the review of a given certificate of need application.

(a) Emergency review.

(i) An emergency review may, with the written consent of the appropriate advisory review agencies, be conducted when an immediate capital expenditure is required in order for a health care facility to maintain or restore basic and essential patient services.

(ii) The department may determine an application submitted for emergency review does not qualify for such review. Such a determination and notification to the applicant shall be made within five days after receipt of the application. When the department makes a determination that an application is not subject to emergency review procedures, the application will be reviewed under another review process appropriate for the type of undertaking proposed. The department will notify the applicant of the other process under which the application will be reviewed.

(b) Expedited review.

An expedited review shall be conducted on a certificate of need application for the following:

(i) Projects proposed for the correction of deficiencies as described in WAC 246-310-480, except projects for the repair to or correction of deficiencies in the physical plant necessary to maintain state licensure, which are exempt from review by the provisions of WAC 246-310-020, if they do not substantially affect patient charges.

(ii) Demonstration or research projects: Provided, That such projects do not involve a change in bed capacity or the provision of a new tertiary health service.

(iii) Acquisition of an existing health care facility.

(iv) Projects limited to predevelopment expenditures.

(c) Regular review process.

The regular review process shall be used for any application unless the department has determined the emergency, expedited, or concurrent review process will be used in the review of such application. The regular review process will also be used to review applications for projects solely for the purposes listed in WAC 246-310-020 determined by the department to substantially affect patient charges, unless the project qualifies for an expedited review under subsection (2)(a)(i) of this section.

(d) Concurrent review process.

The concurrent review process shall be used for all applications determined to be competing in accordance with WAC 246-310-120.

[Statutory Authority: Chapter 70.38 RCW. WSR 96-24-052, § 246-310-110, filed 11/27/96, effective 12/28/96. Statutory Authority: RCW 70.38.135 and 70.38.919. WSR 92-02-018 (Order 224), § 246-310-110, filed 12/23/91, effective 1/23/92. Statutory Authority: RCW 43.70.040. WSR 91-02-049 (Order 121), recodified as § 246-310-110, filed 12/27/90, effective 1/31/91. Statutory Authority: RCW 70.38.135. WSR 86-06-030 (Order 2344), § 248-19-300, filed 2/28/86; WSR 81-09-012 (Order 210), § 248-19-300, filed 4/9/81, effective 5/20/81. Statutory Authority: Chapter 70.38 RCW. WSR 79-12-079 (Order 188), § 248-19-300, filed 11/30/79.]

WAC 246-310-120 Concurrent review process. (1) Projects for which the department may establish concurrent review schedules are identified in RCW 70.38.115(7). An annual concurrent review has been scheduled for competing projects proposing:

(a) New nursing homes, not using bed allocations banked under the provisions of RCW 70.38.115(13);

(b) Nursing home bed additions, not using bed allocations banked under the provisions of RCW 70.38.115(13);

(c) The redistribution of beds from the following facility and service categories to nursing home beds:

(i) Acute care;

(ii) Assisted living facility; or

(iii) Intermediate care for the mentally retarded.

(2) Procedures for the concurrent review process shall be as follows:

(a) Submittal of initial applications.

(i) Each applicant shall submit one original and one copy of the application to the department.

(ii) Each applicant if requested in writing shall provide a copy of his or her application to the applicant of each other competing application.

(b) Screening of the initial applications.

(i) The department shall screen each initial application during the screening period of the applicable concurrent review cycle schedule.

(ii) The screening period shall begin on the first working day following the last day of the initial application submittal period for the applicable concurrent review cycle schedule.

(iii) The department by, the end of the screening period of the applicable concurrent review cycle schedule, shall send a written request for supplemental information to each applicant.

(iv) Each applicant, by the end of the final application submittal period, shall respond to the department's written request for supplemental information in one of the following ways:

(A) Submitting the requested written supplemental information; or

(B) Submitting a written request that the incomplete application be reviewed without supplemental information.

(c) Reviewing of final applications.

(i) The department shall commence the review of competing applications on the date prescribed for the applicable concurrent review cycle schedule.

(ii) The total number of days in the public comment and final review periods shall not exceed one hundred and thirty-five, unless extended in accordance with subsection (2)(d) of this section.

(iii) The public comment period shall be a maximum of ninety days from the beginning of the review period, unless the public comment period is extended in accordance with subsection (2)(d) of this section. The first sixty days of the public comment period is reserved for receiving public comment and conducting a public hearing, if requested. The remaining thirty days shall be reserved for the applicant or applicants to provide rebuttal statements to written or oral statements submitted during the first sixty-day period. Any affected person shall also be provided the opportunity to provide rebuttal statements to written or oral statements submitted during the first sixty-day period.

(iv) The department shall conclude its final review and the secretary's designee shall take action on a certificate of need application within forty-five days after the end of the public comment period, unless extended in accordance with subsection (2)(d) of this section.

(d) Extending review of final applications.

(i) The public comment period shall be extended in accordance with the provisions of WAC 246-310-100.

(ii) The final review period may be extended by the department under the following provisions:

(A) The department informs each applicant of the competing applications of the existence of an unresolved pivotal issue.

(B) The department may make a written request for additional information from one or more of the applicants of the competing applications.

(C) The department shall specify in the written request a deadline for receipt of written responses.

(D) Each applicant receiving such written request may provide a written response within the specified deadline.

(E) The department may extend the final review period for all competing applications up to thirty days after the receipt of the last response to the department's request for additional information or after the specified deadline, whichever occurs first.

[Statutory Authority: RCW 70.38.135 and 2012 c 10. WSR 14-08-046, § 246-310-120, filed 3/27/14, effective 4/27/14. Statutory Authority: Chapter 70.38 RCW. WSR 98-10-053, § 246-310-120, filed 4/29/98, effec-

tive 5/30/98; WSR 96-24-052, § 246-310-120, filed 11/27/96, effective 12/28/96. Statutory Authority: RCW 70.38.135 and 70.38.919. WSR 92-02-018 (Order 224), § 246-310-120, filed 12/23/91, effective 1/23/92. Statutory Authority: RCW 43.70.040. WSR 91-02-049 (Order 121), recodified as § 246-310-120, filed 12/27/90, effective 1/31/91. Statutory Authority: RCW 70.38.115. WSR 87-10-023 (Order 2487), § 248-19-327, filed 5/1/87. Statutory Authority: RCW 70.38.135. WSR 86-06-030 (Order 2344), § 248-19-327, filed 2/28/86.]

WAC 246-310-130 Nursing home concurrent review cycles. (1) The department shall review concurrently during review cycles established under subsection (5) of this section the following:

(a) New nursing homes beds not using bed allocations banked under the provisions of RCW 70.38.115(13);

(b) Redistribution of beds from the following facility or service categories to skilled nursing care beds:

(i) Acute care;

(ii) Assisted living facility care.

(2) Undertakings by continuing care retirement communities (CCRCs), as defined in this section which do not propose or are not operating within a transition period as defined in this section during development, and which meet the following conditions, shall be reviewed under the regular review process per WAC 246-310-160:

(a) The number of nursing home beds requested in a single undertaking shall not exceed sixty; and

(b) After project completion, the number of nursing home beds, including those with which the CCRC contracts, shall not exceed one bed for each four independent living units within the CCRC. In computing this ratio, only independent living units of the CCRC already existing, and/or scheduled for completion at the same time as the proposed nursing home beds under the same financial feasibility plan, shall be counted.

(3) The annual nursing home concurrent review consists of the following cycles:

(a) One of the annual cycles is reserved for the review of competing applications submitted by or on behalf of:

(i) CCRCs applying for nursing home beds available from the statewide CCRC allotment as described in WAC 246-310-380(5); and

(ii) CCRCs which propose or are operating within a transition period during development and are not applying for nursing home beds available from any nursing home planning area.

(b) Two other cycles are established for review of competing applications for nursing home beds needed. The nursing home planning areas are divided into two separate groups.

(4) The department shall use the following nursing home concurrent review application filing procedures:

(a) Each applicant shall:

(i) File the required number of copies of each application as specified in the application information requirements; and

(ii) Mail or deliver the application so that the department receives it no later than the last day for initial application receipt as prescribed in the schedule for that concurrent review cycle.

(b) The department shall:

(i) Only review applications for which a letter of intent, as described in WAC 246-310-080, was mailed or delivered to the department

before the last day for receipt of letters of intent as indicated below;

(ii) Begin screening all applications received during the initial application period on the first working day following the close of that period; and

(iii) Return to the applicant any application received after the last day of the initial application receipt period.

(5) The schedules for the annual nursing home bed concurrent review cycles shall be as follows:

(a) For those applications described in subsection (3)(a) of this section, the concurrent review cycle schedule shall be as follows:

(i) Period for receipt of letters of intent shall begin on the first working day of June and end on the first working day of July;

(ii) Period for receipt of initial applications shall begin on the first working day of July and end on the first working day of August;

(iii) End of initial application completeness screening period is the first working day of September;

(iv) End of final application receipt period is the first working day of October; and

(v) Beginning of concurrent review period is October 16 or first working day after that date.

(b) For competing applications submitted for nursing home beds available for the Chelan/Douglas, Clallam, Clark/Skamania, Cowlitz, Grant, Grays Harbor, Island, Jefferson, King, Kittitas, Klickitat, Okanogan, Pacific, San Juan, Skagit, Spokane, and Yakima nursing home planning areas, the concurrent review cycle schedule shall be as follows:

(i) Period for receipt of letters of intent shall begin on the first working day of July and end on the first working day of August;

(ii) Period for receipt of initial applications shall begin on the first working day of August and end on the first working day of September;

(iii) End of initial application completeness screening period is the first working day of October;

(iv) End of final application receipt period is the first working day of November; and

(v) Beginning of concurrent review period is November 16 or first working day after that date.

(c) For competing applications submitted for nursing home beds available for the Adams, Asotin, Benton, Columbia, Ferry, Franklin, Garfield, Kitsap, Lewis, Lincoln, Mason, Pend Oreille, Pierce, Snohomish, Stevens, Thurston, Wahkiakum, Walla Walla, Whatcom, and Whitman nursing home planning areas, the concurrent review cycle schedule shall be as follows:

(i) Period for receipt of letters of intent shall begin on the first working day of August and end on the first working day of September;

(ii) Period for receipt of initial applications shall begin on the first working day of September and end on the first working day of October;

(iii) End of initial application completeness screening period is the first working day of November;

(iv) End of final application receipt period is the first working day of December; and

(v) Beginning of concurrent review period is December 16 or first working day after that date.

[Statutory Authority: RCW 70.38.135 and 2012 c 10. WSR 14-08-046, § 246-310-130, filed 3/27/14, effective 4/27/14. Statutory Authority: Chapter 70.38 RCW. WSR 96-24-052, § 246-310-130, filed 11/27/96, effective 12/28/96. Statutory Authority: RCW 70.38.135 and 70.38.919. WSR 92-02-018 (Order 224), § 246-310-130, filed 12/23/91, effective 1/23/92. Statutory Authority: RCW 43.70.040. WSR 91-02-049 (Order 121), recodified as § 246-310-130, filed 12/27/90, effective 1/31/91. Statutory Authority: RCW 70.38.115. WSR 88-24-026 (Order 2736), § 248-19-328, filed 12/2/88. Statutory Authority: RCW 70.38.115 and 70.38.135. WSR 88-04-047 (Order 2591), § 248-19-328, filed 1/29/88. Statutory Authority: RCW 70.38.115. WSR 87-10-023 (Order 2487), § 248-19-328, filed 5/1/87.]

WAC 246-310-132 Open heart surgery concurrent review cycle. (1) The department shall review new open heart surgery services using the concurrent review cycle in this section.

(2) Certificate of need applications shall be submitted and reviewed according to the following schedule and procedures.

(a) Letters of intent shall be submitted between the first working day and last working day of July of each year.

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

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

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

(e) The public review and comment period for applications shall begin on November 16 of each year. In the event that November 16 is not a working day in any year, then the public review and comment period shall begin on the first working day after November 16.

(f) The public comment period shall be 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 affected person shall 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 shall be limited to sixty days, unless extended according to the provisions of WAC 246-310-120 (2)(d).

(3) 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.

[Statutory Authority: Chapter 70.38 RCW. WSR 98-10-053, § 246-310-132, filed 4/29/98, effective 5/30/98; WSR 96-24-052, § 246-310-132, filed 11/27/96, effective 12/28/96. Statutory Authority: RCW 70.38.135. WSR 92-16-081 (Order 293) § 246-310-132, filed 8/4/92 effective 9/4/92; WSR 91-17-011 (Order 188), § 246-310-132, filed 8/12/91, effective 8/28/91.]

WAC 246-310-136 Ethnic minority nursing home bed pool—Considerations for review of applications. (1) The department shall consider the following factors in the course of reviewing and making decisions on applications for construction or establishment of nursing home beds for ethnic minorities.

(a) Conformance with applicable review criteria in WAC 246-310-210, 246-310-220, 246-310-230, and 246-310-240;

(b) Which competing applications best meet identified needs, consistent with the purpose of concurrent review as stated in RCW 70.38.115(7).

(c) The relative degree to which the long-term care needs of an ethnic minority among Washington residents are not otherwise being met. This includes consideration of the legislature's finding that certain ethnic minorities have special cultural, language, dietary, and other needs not generally met by existing nursing homes which are intended to serve the general population;

(d) The percentage of low-income persons who would be served by the proposed project; and

(e) The impact of the proposal on the area's total need for nursing home beds.

(2) To be eligible to apply for and receive an award of beds from the ethnic nursing home bed pool, an application must be to construct, develop, or establish a new nursing home or add beds to an existing nursing home that:

(a) Shall be owned and operated by a nonprofit corporation. At least fifty percent of the board of directors of the corporation are members of the ethnic minority the nursing home is intended to serve;

(b) Shall be designed, managed, and administered to serve the special cultural, language, dietary, and other needs of the ethnic minority; and

(c) Shall not discriminate in admissions against persons who are not members of the ethnic minority whose special needs the nursing home is designed to serve.

(3) An applicant not awarded beds in a concurrent review shall not be given preference over other applicants in any subsequent concurrent review on the basis of the prior review and decision when that applicant submits a new application for another review.

[Statutory Authority: Chapter 70.38 RCW. WSR 96-24-052, § 246-310-136, filed 11/27/96, effective 12/28/96. Statutory Authority: RCW 70.38.135 (3)(c). WSR 92-05-057 (Order 244), § 246-310-136, filed 2/14/92, effective 3/16/92.]

WAC 246-310-140 Emergency review process. (1) The emergency review process shall not exceed fifteen working days from the beginning of the review period.

(2) The department shall complete its final review and the secretary's designee shall make his or her decision on an emergency certificate of need application within fifteen working days after the beginning of the review period unless the department extends its final review period in accordance with the provisions of subsection (3) of this section.

(3) If an issue, which is pivotal to the decision of the secretary's designee remains unresolved, the department may make one request for additional information from the person submitting the appli-

cation. The department may extend its final emergency review period up to but not exceeding ten days after receipt of the applicant's written response to the department's request for information.

[Statutory Authority: Chapter 70.38 RCW. WSR 96-24-052, § 246-310-140, filed 11/27/96, effective 12/28/96. Statutory Authority: RCW 43.70.040. WSR 91-02-049 (Order 121), recodified as § 246-310-140, filed 12/27/90, effective 1/31/91. Statutory Authority: RCW 70.38.135. WSR 86-06-030 (Order 2344), § 248-19-350, filed 2/28/86; WSR 82-19-055 (Order 244), § 248-19-350, filed 9/15/82; WSR 81-09-012 (Order 210), § 248-19-350, filed 4/9/81, effective 5/20/81. Statutory Authority: Chapter 70.38 RCW. WSR 79-12-079 (Order 188), § 248-19-350, filed 11/30/79.]

WAC 246-310-150 Expedited review process. (1) The expedited review process shall not exceed fifty days from the beginning of the review period unless extended in accordance with the provisions of subsection (2) of this section.

(a) The public comment period shall be limited to thirty days. The first twenty days of the public comment period shall be reserved for receiving public comments. The remaining ten days shall be for the applicant or applicants to provide rebuttal statements to written or oral statements submitted during the first twenty-day period. Any affected person shall also be provided the opportunity to provide rebuttal statements to written or oral statements submitted during the first twenty-day period.

(b) The department shall complete its final review and the secretary's designee shall make his or her decision on a certificate of need application under an expedited review within twenty days of the end of the public comment period.

(2) The review period for an expedited review may be extended according to the following provisions:

(a) The review period may be extended an additional forty-five days in accordance with WAC 246-310-100. The department may grant further extensions to this review period: Provided, The person submitting the certificate of need application gives written consent to further extension.

(b) If an issue, which is pivotal to the decision of the secretary's designee remains unresolved, the department may make one request for additional information from the person submitting the application. The department may extend its final expedited review period up to but not exceeding thirty days after receipt of the applicant's written response to the department's request for information.

(c) The department may extend its final review period upon receipt of a written request of the person submitting the application: Provided however, That such an extension shall not exceed sixty days.

[Statutory Authority: Chapter 70.38 RCW. WSR 98-10-053, § 246-310-150, filed 4/29/98, effective 5/30/98; WSR 96-24-052, § 246-310-150, filed 11/27/96, effective 12/28/96. Statutory Authority: RCW 70.38.135 and 70.38.919. WSR 92-02-018 (Order 224), § 246-310-150, filed 12/23/91, effective 1/23/92. Statutory Authority: RCW 43.70.040. WSR 91-02-049 (Order 121), recodified as § 246-310-150, filed 12/27/90, effective 1/31/91. Statutory Authority: RCW 70.38.135. WSR 86-06-030 (Order 2344), § 248-19-340, filed 2/28/86; WSR 82-19-055 (Order 244), § 248-19-340, filed 9/15/82; WSR 81-09-012 (Order 210), § 248-19-340,

filed 4/9/81, effective 5/20/81. Statutory Authority: Chapter 70.38 RCW. WSR 79-12-079 (Order 188), § 248-19-340, filed 11/30/79.]

WAC 246-310-160 Regular review process. (1) The regular review process shall not exceed ninety days from the beginning of the review period and shall be conducted in accordance with this section unless the review period is extended in accordance with the provisions of subsection (2) of this section.

(a) The public comment period shall be limited to forty-five days. The first thirty-five days of the public comment period shall be reserved for receiving public comments and conducting a public hearing, if requested. The remaining ten days shall be reserved for the applicant to provide rebuttal statements to written or oral statements submitted during the first thirty-five day period. Any affected person shall also be provided the opportunity to provide rebuttal statements to written or oral statements submitted during the first thirty-five day period.

(b) The department shall complete its final review and the secretary's designee shall make a decision on a certificate of need application within forty-five days of the end of the public comment period.

(2) The review period for a regular review may be extended according to the following provisions:

(a) The public comment period may be extended for up to an additional forty-five days in accordance with WAC 246-310-100. The department may grant further extensions to this review period: Provided, The person submitting the certificate of need application gives written consent to such further extensions.

(b) If an issue, which is pivotal to the decision of the secretary's designee remains unresolved, the department may make one request for additional information from the person submitting the application. The department may extend its final review period up to but not exceeding thirty days after receipt of the applicant's written response to the department's request for information.

(c) The department may extend either the public comment period or the department's final review period upon receipt of a written request of the person submitting the application: Provided however, That such an extension shall not exceed ninety days.

[Statutory Authority: Chapter 70.38 RCW. WSR 98-10-053, § 246-310-160, filed 4/29/98, effective 5/30/98; WSR 96-24-052, § 246-310-160, filed 11/27/96, effective 12/28/96. Statutory Authority: RCW 70.38.135 and 70.38.919. WSR 92-02-018 (Order 224), § 246-310-160, filed 12/23/91, effective 1/23/92. Statutory Authority: RCW 43.70.040. WSR 91-02-049 (Order 121), recodified as § 246-310-160, filed 12/27/90, effective 1/31/91. Statutory Authority: RCW 70.38.135. WSR 86-06-030 (Order 2344), § 248-19-330, filed 2/28/86; WSR 82-19-055 (Order 244), § 248-19-330, filed 9/15/82; WSR 81-09-012 (Order 210), § 248-19-330, filed 4/9/81, effective 5/20/81. Statutory Authority: Chapter 70.38 RCW. WSR 79-12-079 (Order 188), § 248-19-330, filed 11/30/79.]

WAC 246-310-170 Notification of beginning of review. (1) Notice required.

The department shall provide written notification of the beginning of the review of a certificate of need application and notification of the beginning of the review of a proposed withdrawal of a cer-

tificate of need to interested persons and any other person submitting a written request that the person's name be on the mailing list for such notice. Notification of the beginning of the review of a certificate of need application shall be provided through a newspaper of general circulation in the health service area of the project.

(2) Specific notice requirements.

(a) The department shall give "notification of the beginning of review" of an application after the department has received an application or the applicant's request, submitted in accordance with WAC 246-310-090 (2)(c), that review of the application begin. Such notice shall be given according to the following requirements:

(i) Emergency review.

When an application is being reviewed under the emergency review process, required notices shall be given within five working days following the receipt of a complete application or the applicant's written request that review of the application begin.

(ii) Expedited and regular review.

When an application is being reviewed under the expedited or regular review process, required notices shall be given within five working days of a declaration that the application is complete or the applicant's request that review of the application begin.

(b) The department shall give notification of the beginning of the review of a proposed withdrawal of a certificate of need when the department determines there may be good cause to withdraw a certificate of need.

(c) The notices shall include:

(i) The procedures for receiving copies of applications, supplemental information and department decisions;

(ii) A general description of the project;

(iii) In the case of a proposed withdrawal of a certificate of need, the reasons for the proposed withdrawal;

(iv) The proposed review schedule;

(v) The period within which one or more interested persons may request a public hearing;

(vi) The name and address of the agency to which a request for a public hearing should be sent;

(vii) The manner in which notification will be provided of the time and place of any hearing so requested;

(viii) Notice that any interested person wishing to receive notification of a meeting on the application called by the department after the end of the public comment period shall submit a written request to the department to receive notification of such meetings; and

(ix) The period within which any interested person may request notification of the meetings referenced in subsection (2)(c)(viii) of this section.

(d) The notices to other interested persons shall be mailed on the same date the notice to the public is mailed to the newspaper for publication.

(3) Beginning of review.

(a) Review of a certificate of need application under the expedited or regular review process shall begin on the day the department sends notification of the beginning of review to the general public and other interested persons unless the department has received a written request from the applicant pursuant to WAC 246-310-090 (2)(c)(iii), in which case review shall begin upon receipt of such request.

(b) Review of certificate of need applications under the concurrent review process shall begin fifteen days after the conclusion of the published time period for the submission of final applications subject to concurrent review.

(c) Review of a certificate of need application under emergency review shall begin on the first day after the date on which the department has determined the application is complete, or has received a written request to begin review submitted by the applicant in accordance with WAC 246-310-090 (2)(c).

(d) Review of a proposed withdrawal of a certificate of need shall begin on the day the department sends notification of the beginning of review to the general public and to other interested persons.

[Statutory Authority: Chapter 70.38 RCW. WSR 98-10-053, § 246-310-170, filed 4/29/98, effective 5/30/98; WSR 96-24-052, § 246-310-170, filed 11/27/96, effective 12/28/96. Statutory Authority: RCW 70.38.135 and 70.38.919. WSR 92-02-018 (Order 224), § 246-310-170, filed 12/23/91, effective 1/23/92. Statutory Authority: RCW 43.70.040. WSR 91-02-049 (Order 121), recodified as § 246-310-170, filed 12/27/90, effective 1/31/91. Statutory Authority: RCW 70.38.135. WSR 86-06-030 (Order 2344), § 248-19-310, filed 2/28/86; WSR 81-09-012 (Order 210), § 248-19-310, filed 4/9/81, effective 5/20/81. Statutory Authority: Chapter 70.38 RCW. WSR 79-12-079 (Order 188), § 248-19-310, filed 11/30/79.]

WAC 246-310-180 Public hearings. (1) "Opportunity for a public hearing," as used in this section, shall mean a public hearing will be conducted if a valid request for such a hearing has been submitted by one or more interested persons.

(2) The department shall provide opportunity to interested persons for a public hearing on:

(a) A certificate of need application under review, unless the application is being reviewed according to the emergency or expedited review processes; and

(b) The proposed withdrawal of a certificate of need.

(3) To be valid, a request for a public hearing on a certificate of need application or on the proposed withdrawal of a certificate of need shall:

(a) Be submitted in writing;

(b) Be received by the department within fifteen days after the date on which the department's "notification of beginning of review" for the particular certificate of need application or proposed withdrawal of a certificate of need was published in a newspaper of general circulation; and

(c) Include identification of the particular certificate of need application or proposed certificate of need withdrawal for which the public hearing is requested and the full name, complete address, and signature of the person making the request.

(4) The department shall give written notice of a public hearing conducted pursuant to this section.

(a) Written notice shall be given to interested persons and the public at least fifteen days prior to the beginning of the public hearing.

(b) The notices shall include: Identification of the certificate of need application or certificate of need on which the public hearing

is to be conducted and the date, time, and location of the public hearing.

(c) Notice to the general public to be served by the proposed project to which the certificate of need application or certificate of need pertains shall be through a newspaper of general circulation in the health service area of the proposed project. The notices to other interested persons shall be mailed on the same date the notice to the public is mailed to the newspaper for publication.

(5) In a public hearing on a certificate of need application or on a proposed withdrawal of a certificate of need, any person shall have the right to be represented by counsel and to present oral or written arguments and evidence relevant to the subject matter of the hearing. Any person affected by the matter may conduct reasonable questioning of persons who make relevant factual allegations.

(6) The department shall maintain a verbatim record of a public hearing and shall not impose fees for the hearing.

(7) The department shall not be required to conduct a public hearing on a certificate of need application being reviewed according to the emergency or expedited review procedures.

(8) The department may conduct a public hearing in the absence of a request as identified in subsection (3) of this section, if the department determines it is in the best interest of the public.

[Statutory Authority: Chapter 70.38 RCW. WSR 98-10-053, § 246-310-180, filed 4/29/98, effective 5/30/98; WSR 96-24-052, § 246-310-180, filed 11/27/96, effective 12/28/96. Statutory Authority: RCW 70.38.135 and 70.38.919. WSR 92-02-018 (Order 224), § 246-310-180, filed 12/23/91, effective 1/23/92. Statutory Authority: RCW 43.70.040. WSR 91-02-049 (Order 121), recodified as § 246-310-180, filed 12/27/90, effective 1/31/91. Statutory Authority: RCW 70.38.135. WSR 86-06-030 (Order 2344), § 248-19-320, filed 2/28/86; WSR 81-09-012 (Order 210), § 248-19-320, filed 4/9/81, effective 5/20/81. Statutory Authority: Chapter 70.38 RCW. WSR 79-12-079 (Order 188), § 248-19-320, filed 11/30/79.]

WAC 246-310-190 Ex parte contacts. (1) There shall be no ex parte contacts as defined in WAC 246-310-010 after whichever of the following occurs last:

(a) The conclusion of a public hearing held in accordance with WAC 246-310-180, or

(b) The end of the public comment period.

(2) Any of the following communications shall not be considered ex parte contacts:

(a) A communication regarding the procedure or process of the review.

(b) A communication made in a meeting open to the public requested by the department and reasonable notice of the meeting has been given to the applicant, all applicants in a concurrent review, and all persons having previously requested in writing to be notified of all such meetings or written requests for information concerning a specific application for certificate of need or a specific proposed withdrawal of a certificate of need.

(c) A written request for information made by the department and provided to all persons specified in subsection (2)(b) of this section.

(d) A response to a request made by the department in a meeting held in accordance with subsection (2)(b) of this section or in response to subsection (2)(c) of this section, and submitted to the department and to all persons specified in subsection (2)(b) of this section.

[Statutory Authority: Chapter 70.38 RCW. WSR 96-24-052, § 246-310-190, filed 11/27/96, effective 12/28/96. Statutory Authority: RCW 70.38.135 and 70.38.919. WSR 92-02-018 (Order 224), § 246-310-190, filed 12/23/91, effective 1/23/92. Statutory Authority: RCW 43.70.040. WSR 91-02-049 (Order 121), recodified as § 246-310-190, filed 12/27/90, effective 1/31/91. Statutory Authority: RCW 70.38.135. WSR 86-06-030 (Order 2344), § 248-19-326, filed 2/28/86.]

WAC 246-310-200 Bases for findings and action on applications. (1) The findings of the department's review of certificate of need applications and the action of the secretary's designee on such applications shall, with the exceptions provided for in WAC 246-310-470 and 246-310-480 be based on determinations as to:

(a) Whether the proposed project is needed;

(b) Whether the proposed project will foster containment of the costs of health care;

(c) Whether the proposed project is financially feasible; and

(d) Whether the proposed project will meet the criteria for structure and process of care identified in WAC 246-310-230.

(2) Criteria contained in this section and in WAC 246-310-210, 246-310-220, 246-310-230, and 246-310-240 shall be used by the department in making the required determinations.

(a) In the use of criteria for making the required determinations, the department shall consider:

(i) The consistency of the proposed project with service or facility standards contained in this chapter;

(ii) In the event the standards contained in this chapter do not address in sufficient detail for a required determination the services or facilities for health services proposed, the department may consider standards not in conflict with those standards in accordance with subsection (2)(b) of this section; and

(iii) The relationship of the proposed project to the long-range plan (if any) of the person proposing the project.

(b) The department may consider any of the following in its use of criteria for making the required determinations:

(i) Nationally recognized standards from professional organizations;

(ii) Standards developed by professional organizations in Washington state;

(iii) Federal medicare and medicaid certification requirements;

(iv) State licensing requirements;

(v) Applicable standards developed by other individuals, groups, or organizations with recognized expertise related to a proposed undertaking; and

(vi) The written findings and recommendations of individuals, groups, or organizations with recognized expertise related to a proposed undertaking, with whom the department consults during the review of an application.

(c) At the request of an applicant, the department shall identify the criteria and standards it will use prior to the submission and

screening of a certificate of need application: Provided however, That when a person requests identification of criteria and standards prior to the submission of an application, the person shall submit such descriptive information on a project as is determined by the department to be reasonably necessary in order to identify the applicable criteria and standards. The department shall respond to such request within fifteen working days of its receipt. In the absence of an applicant's request under this subsection, the department shall identify the criteria and standards it will use during the screening of a certificate of need application. The department shall inform the applicant about any consultation services it will use in the review of a certificate of need application prior to the use of such consultation services.

(d) Representatives of the department or consultants whose services are engaged by the department may make an on-site visit to a health care facility, or other place for which a certificate of need application is under review, or for which a proposal to withdraw a certificate of need is under review when the department deems such an on-site visit is necessary and appropriate to the department's review of a proposed project.

[Statutory Authority: Chapter 70.38 RCW. WSR 96-24-052, § 246-310-200, filed 11/27/96, effective 12/28/96. Statutory Authority: RCW 70.38.135 and 70.38.919. WSR 92-02-018 (Order 224), § 246-310-200, filed 12/23/91, effective 1/23/92. Statutory Authority: RCW 43.70.040. WSR 91-02-049 (Order 121), recodified as § 246-310-200, filed 12/27/90, effective 1/31/91. Statutory Authority: RCW 70.38.135. WSR 85-05-032 (Order 2208), § 248-19-360, filed 2/15/85; WSR 81-09-012 (Order 210), § 248-19-360, filed 4/9/81, effective 5/20/81. Statutory Authority: Chapter 70.38 RCW. WSR 79-12-079 (Order 188), § 248-19-360, filed 11/30/79.]

WAC 246-310-210 Determination of need. The determination of need for any project shall be based on the following criteria, except these criteria will not justify exceeding the limitation on increases of nursing home beds provided in WAC 246-310-810.

(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 assessment of the conformance of a project with this criterion shall include, but need not be limited to, consideration of the following:

(a) In the case of a reduction, relocation, or elimination of a service, the need the population presently served has for the service, the extent to which the need will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination, or relocation of the service on the ability of low-income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care;

(b) In the case of health services or facilities proposed to be provided, the efficiency and appropriateness of the use of existing services and facilities similar to those proposed;

(c) In the case of an application by an osteopathic or allopathic facility the need for and the availability in the community of services and facilities for osteopathic and allopathic physicians and their patients, and the impact on existing and proposed institutional

training programs for doctors of osteopathy and medicine at the student, internship, and residency training levels; and

(d) In the case of a project not involving health services, the contribution of the project toward overall management and support of such services.

(2) All residents of the service area, including low-income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly are likely to have adequate access to the proposed health service or services. The assessment of the conformance of a project with this criterion shall include, but not be limited to, consideration as to whether the proposed services makes a contribution toward meeting the health-related needs of members of medically underserved groups which have traditionally experienced difficulties in obtaining equal access to health services, particularly those needs identified in the applicable regional health plan, annual implementation plan, and state health plan as deserving of priority. Such consideration shall include an assessment of the following:

(a) The extent to which medically underserved populations currently use the applicant's services in comparison to the percentage of the population in the applicant's service area which is medically underserved, and the extent to which medically underserved populations are expected to use the proposed services if approved;

(b) The past performance of the applicant in meeting obligations, if any, under any applicable federal regulations requiring provision of uncompensated care, community service, or access by minorities and handicapped persons to programs receiving federal financial assistance (including the existence of any unresolved civil rights access complaints against the applicant);

(c) The extent to which medicare, medicaid, and medically indigent patients are served by the applicant; and

(d) The extent to which the applicant offers a range of means by which a person will have access to its services (e.g., outpatient services, admission by house staff, admission by personal physician).

(3) The applicant has substantiated any of the following 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.

(4) The project will not have an adverse effect on health professional schools and training programs. The assessment of the conformance of a project with this criterion shall include consideration of:

(a) The effect of the means proposed for the delivery of health services on the clinical needs of health professional training programs in the area in which the services are to be provided; and

(b) If proposed health services are to be available in a limited number of facilities, the extent to which the health professions schools serving the area will have access to the services for training purposes.

(5) The project is needed to meet the special needs and circumstances of enrolled members or reasonably anticipated new members of a health maintenance organization or proposed health maintenance organization and the services proposed are not available from nonhealth maintenance organization providers or other health maintenance organizations in a reasonable and cost-effective manner consistent with the basic method of operation of the health maintenance organization or proposed health maintenance organization. In assessing the availability of health services from these providers, the department shall consider only whether the services from these providers:

(a) Would be available under a contract of at least five years' duration;

(b) Would be available and conveniently accessible through physicians and other health professionals associated with the health maintenance organization or proposed health maintenance organization (for example - whether physicians associated with the health maintenance organization have or will have full staff privileges at a nonhealth maintenance organization hospital);

(c) Would cost no more than if the services were provided by the health maintenance organization or proposed health maintenance organization; and

(d) Would be available in a manner administratively feasible to the health maintenance organization or proposed health maintenance organization.

(6) For nursing home projects including distinct part long-term care units located in a hospital and licensed under chapter 70.41 RCW, the following criterion shall apply in addition to those found in WAC 246-310-380.

(a) In the case of an application for new nursing home beds, the department shall find no need if the state is at or above the statewide estimated bed need, except as referenced in WAC 246-310-380(5). However, the department may put under review and subsequently approve or deny applications that propose to redistribute nursing home beds to a planning area under the established ratio. The department may also consider applications that propose to add beds in planning areas under the established ratio using beds banked and for which the need for the beds is not deemed met, under the provisions of RCW 70.38.115(13). For the above projects, the need for such projects, shall, in part, be determined using individual planning area estimated bed need numbers.

(b) If the state is below the statewide estimated bed need or for those projects referenced above, the department shall determine the need for nursing home beds, including distinct part long-term care units located in a hospital licensed under chapter 70.41 RCW, based on:

(i) The availability of other nursing home beds in the planning area to be served; and

(ii) The availability of other services in the planning area to be served. Other services to be considered include, but are not limited to: Assisted living facilities (as defined in chapter 18.20 RCW); enhanced adult residential care (as defined in chapter 74.39A RCW); adult residential care (as defined in chapter 74.39A RCW); adult family homes (as defined in chapter 70.128 RCW); hospice, home health and home care (as defined in chapter 70.127 RCW); personal care services (as defined in chapter 74.09 RCW); and home and community services provided under the community options program entry system waiver (as referenced in chapter 74.39A RCW). The availability of other services shall be based on data which demonstrates that the other services are

capable of adequately meeting the needs of the population proposed to be served by the applicant. The following variables should be evaluated in this analysis when available:

(A) The current capacity of nursing homes and other long-term care services;

(B) The occupancy rates of nursing homes and other long-term care services over the previous two-year period;

(C) Proposed residential care projects scheduled to be completed within the same period of time indicated on the nursing home certificate of need application; and

(D) The ability of the other long-term care services to serve all people regardless of payor source.

[Statutory Authority: RCW 70.38.135 and 2012 c 10. WSR 14-08-046, § 246-310-210, filed 3/27/14, effective 4/27/14. Statutory Authority: Chapter 70.38 RCW. WSR 96-24-052, § 246-310-210, filed 11/27/96, effective 12/28/96. Statutory Authority: RCW 70.38.135 and 70.38.919. WSR 92-02-018 (Order 224), § 246-310-210, filed 12/23/91, effective 1/23/92. Statutory Authority: RCW 43.70.040. WSR 91-02-049 (Order 121), recodified as § 246-310-210, filed 12/27/90, effective 1/31/91. Statutory Authority: RCW 70.38.135. WSR 85-05-032 (Order 2208), § 248-19-370, filed 2/15/85; WSR 81-09-012 (Order 210), § 248-19-370, filed 4/9/81, effective 5/20/81. Statutory Authority: Chapter 70.38 RCW. WSR 79-12-079 (Order 188), § 248-19-370, filed 11/30/79.]

WAC 246-310-220 Determination of financial feasibility. The determination of financial feasibility of a project shall be based on the following criteria.

(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.

[Statutory Authority: RCW 43.70.040. WSR 91-02-049 (Order 121), recodified as § 246-310-220, filed 12/27/90, effective 1/31/91. Statutory Authority: Chapter 70.38 RCW. WSR 79-12-079 (Order 188), § 248-19-380, filed 11/30/79.]

WAC 246-310-230 Criteria for structure and process of care. A determination that a project fosters an acceptable or improved quality of health care shall be based on the following criteria.

(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. The assessment of the conformance of a project to this criterion shall include but not be limited to consideration as to whether:

(a) The applicant or licensee has no history, in this state or elsewhere, of a criminal conviction which is reasonably related to the applicant's competency to exercise responsibility for the ownership or operation of a health care facility, a denial or revocation of a license to operate a health care facility, a revocation of a license to practice a health profession, or a decertification as a provider of services in the medicare or medicaid program because of failure to comply with applicable federal conditions of participation; or

(b) If the applicant or licensee has such a history, whether the applicant has affirmatively established to the department's satisfaction by clear, cogent and convincing evidence that the applicant can and will operate the proposed project for which the certificate of need is sought in a manner that ensures safe and adequate care to the public to be served and conforms to applicable federal and state requirements.

[Statutory Authority: Chapter 70.38 RCW. WSR 96-24-052, § 246-310-230, filed 11/27/96, effective 12/28/96. Statutory Authority: RCW 43.70.040. WSR 91-02-049 (Order 121), recodified as § 246-310-230, filed 12/27/90, effective 1/31/91. Statutory Authority: RCW 70.38.135. WSR 81-09-012 (Order 210), § 248-19-390, filed 4/9/81, effective 5/20/81. Statutory Authority: Chapter 70.38 RCW. WSR 79-12-079 (Order 188), § 248-19-390, filed 11/30/79.]

WAC 246-310-240 Determination of cost containment. A determination that a proposed project will foster cost containment shall be based on the following criteria:

(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; and

(b) The project will not have an unreasonable impact on the costs and charges to the public of providing health services by other persons.

(3) The project will involve appropriate improvements or innovations in the financing and delivery of health services which foster cost containment and which promote quality assurance and cost effectiveness.

[Statutory Authority: RCW 43.70.040. WSR 91-02-049 (Order 121), recodified as § 246-310-240, filed 12/27/90, effective 1/31/91. Statutory Authority: RCW 70.38.135. WSR 86-06-030 (Order 2344), § 248-19-400, filed 2/28/86; WSR 81-09-012 (Order 210), § 248-19-400, filed 4/9/81, effective 5/20/81. Statutory Authority: Chapter 70.38 RCW. WSR 79-12-079 (Order 188), § 248-19-400, filed 11/30/79.]

WAC 246-310-260 Kidney transplantation. (1) Kidney transplantation is a tertiary service as listed in WAC 246-310-020.

(2) To receive approval a kidney transplant center must meet the following standards in addition to applicable review criteria in WAC 246-310-210, 246-310-220, 246-310-230, and 246-310-240.

(a) A center shall perform at least fifteen transplants annually by the fourth year of operation.

(b) A center shall document that it will meet the requirements of membership to the United Network for Organ Sharing (UNOS) or its successor organization.

[Statutory Authority: RCW 70.38.135 and 70.38.919. WSR 92-02-018 (Order 224), § 246-310-260, filed 12/23/91, effective 1/23/92. Statutory Authority: RCW 43.70.040. WSR 91-02-049 (Order 121), recodified as § 246-310-260, filed 12/27/90, effective 1/31/91. Statutory Authority: RCW 70.38.919. WSR 90-16-058 (Order 073), § 248-19-601, filed 7/27/90, effective 8/27/90.]

WAC 246-310-261 Open heart surgery standards and need forecasting method. (1) Open heart surgery means a specialized surgical procedure (excluding organ transplantation) which utilizes a heart-lung bypass machine and is intended to correct congenital and acquired cardiac and coronary artery disease.

(2) Open heart surgery is a tertiary service as listed in WAC 246-310-020. To be granted a certificate of need, an open heart surgery program shall 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.

(3) Standards.

(a) A minimum of two hundred fifty open heart surgery procedures per year shall be performed at institutions with an open heart surgery program.

(b) Hospitals applying for a certificate of need shall demonstrate that they can meet one hundred ten percent of the minimum volume standard. To do so, the applicant hospital must provide written documentation, which is verifiable, of open heart surgeries performed on patients referred by active medical staff of the hospital. The volume of surgeries counted must be appropriate for the proposed program (i.e., pediatric and recognized complicated cases would be excluded).

(c) No new program shall be established which will reduce an existing program below the minimum volume standard.

(d) Open heart surgery programs shall have at least two board certified cardiac surgeons, one of whom shall be available for emergency surgery twenty-four hours a day. The practice of these surgeons shall be concentrated in a single institution and arranged so that each surgeon performs a minimum of one hundred twenty-five open heart surgery procedures per year at that institution.

(e) Institutions with open heart surgery programs shall have plans for facilitating emergency access to open 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).

(f) In the event two or more hospitals 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 cardiovascular and support services; and

(v) Facilitating emergency access to care.

(g) Hospitals granted a certificate of need have three years from the date the program is initiated to establish the program and meet these standards.

(h) These standards should be reevaluated in at least three years.

(4) Steps in the need forecasting method. The department will develop a forecast of need for open heart surgery every year using the following procedures.

(a) Step 1. Based upon the most recent three years volumes reported for the hospitals within each planning area, compute the planning area's current capacity and the percent of out-of-state use of the area's hospitals. In those planning areas where a new program is being established, the assumed volume of that institution will be the greater of either the minimum volume standard or the estimated volume described in the approved application and adjusted by the department in the course of review and approval.

(b) Step 2. Patient origin adjust the three years of open heart surgery data, and compute each planning area's age-specific use rates and market shares.

(c) Step 3. 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 surgeries expected to be performed on the residents of each planning area.

(d) Step 4. Apportion the forecasted surgeries among the planning areas in accordance with each area's average market share for the last three years of the four planning areas. This figure equals the forecasted number of state residents' surgeries expected to occur within the hospitals in each planning area. In those areas where a newly approved program is being established, an adjustment will be made to reflect anticipated market share shifts consistent with the approved application.

(e) Step 5. Increase the number of surgeries expected to occur within the hospitals in each planning area in accordance with the percent of surgeries 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 surgeries expected to occur within the hospitals in each planning area.

(f) Step 6. Calculate the net need for additional open heart surgery services by subtracting the current capacity from the total forecasted surgeries.

(g) Step 7. If the net need is less than the minimum volume standard, no new programs shall be assumed to be needed in the planning area. However, hospitals may be granted certificate of need approval even if the forecasted need is less than the minimum volume standard, provided:

(i) The applying hospital can meet all the other certificate of need criteria for an open heart surgery program (including documented evidence of capability of achieving the minimum volume standard); and

(ii) There is documented evidence that at least eighty percent of the patients referred for open heart surgery by the medical staff of the applying hospital are referred to institutions more than seventy-five miles away.

(5) 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 fifteen to forty-four year olds, forty-five to sixty-four year olds, sixty-five to seventy-four year olds, and seventy-five and older.

(b) Current capacity. A planning area's current capacity for open heart surgeries equals the sum of the highest reported annual volume for each hospital within the planning area during the most recent available three years data.

(c) Forecast year. Open heart surgery service needs shall be based on forecasts for the fourth year after the certificate of need open heart surgery concurrent review process. The 1992 reviews will be based on forecasts for 1996.

(d) Market share. The market share of a planning area represents the percent of a planning area's total patient origin adjusted surgeries that were performed in hospitals located in that planning area. The most recent available three years data will be used to compute the age-specific market shares for each planning area.

(e) Open heart surgeries. Open heart surgeries are defined as DRGs 104 through 108, inclusive. All pediatric surgeries (ages fourteen and under) are excluded.

(f) Out-of-state use of planning area hospitals. The percent of out-of-state use of hospitals within a planning area will equal the percent of total surgeries 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 planning area hospitals.

(g) Patient origin adjustment. A patient origin adjustment of open heart surgeries provides a count of surgeries performed on the residents of a planning area regardless of which planning area the surgeries were performed in. (Surgeries can be patient origin adjusted by using the patient's zip code reported in the CHARS database.)

(h) Planning areas. Four regional health service areas will be used as planning areas for forecasting open heart surgery service needs.

(i) Health service area "one" includes the following counties: Clallam, Island, Jefferson, King, Kitsap, Pierce, San Juan, Snohomish, Skagit, and Whatcom.

(ii) Health service area "two" includes the following counties: Cowlitz, Clark, Grays Harbor, Klickitat, Lewis, Mason, Pacific, Skamania, Thurston, and Wahkiakum.

(iii) Health service area "three" includes the following counties: Benton, Chelan, Douglas, Franklin, Grant, Kittitas, Okanogan, and Yakima.

(iv) Health service area "four" includes Adams, Asotin, Columbia, Ferry, Garfield, Lincoln, Pend Oreille, Stevens, Spokane, Walla Walla, and Whitman.

(v) Use rate. The open heart surgery use rate equals the number of surgeries performed on the residents of a planning area divided by the population of that planning area. The most recent available three

years data is used to compute an averaged annual age-specific use rate for the residents of each of the four planning areas.

(6) The data source for open heart surgeries is the comprehensive hospital abstract reporting system (CHARS), office of hospital and patient data, department of health.

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

[Statutory Authority: RCW 70.38.135(3). WSR 92-12-015 (Order 274), § 246-310-261, filed 5/26/92, effective 6/26/92.]

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.]

WAC 246-310-270 Ambulatory surgery. (1) To receive approval, an ambulatory surgical facility must meet the following standards in addition to applicable review criteria in WAC 246-310-210, 246-310-220, 246-310-230, and 246-310-240.

(2) The area to be used to plan for operating rooms and ambulatory surgical facilities is the secondary health services planning area.

(3) Secondary health services planning areas are: San Juan, Whatcom, East Skagit, Whidbey-Fidalgo, Western North Olympic, East Clallam, East Jefferson, North Snohomish, Central Snohomish, East Snohomish, Southwest Snohomish, Kitsap, North King, East King, Central King, Southwest King, Southeast King, Central Pierce, West Pierce, East Pierce, Mason, West Grays Harbor, Southeast Grays Harbor, Thurston, North Pacific, South Pacific, West Lewis, East Lewis, Cowlitz-Wahkiakum-Skamania, Clark, West Klickitat, East Klickitat, Okanogan, Chelan-Douglas, Grant, Kittitas, Yakima, Benton-Franklin, Ferry, North Stevens, North Pend Oreille, South Stevens, South Pend Oreille, Southwest Lincoln, Central Lincoln, Spokane, Southwest Adams, Central Adams, Central Whitman, East Whitman, Walla Walla, Columbia, Garfield, and Asotin.

(4) Outpatient operating rooms should ordinarily not be approved in planning areas where the total number of operating rooms available for both inpatient and outpatient surgery exceeds the area need.

(5) When a need exists in planning areas for additional outpatient operating room capacity, preference shall be given to dedicated outpatient operating rooms.

(6) An ambulatory surgical facility shall have a minimum of two operating rooms.

(7) Ambulatory surgical facilities shall document and provide assurances of implementation of policies to provide access to individuals unable to pay consistent with charity care levels provided by hospitals affected by the proposed ambulatory surgical facility. The amount of an ambulatory surgical facility's annual revenue utilized to finance charity care shall be at least equal to or greater than the average percentage of total patient revenue, other than medicare or medicaid, that affected hospitals in the planning area utilized to provide charity care in the last available reporting year.

(8) The need for operating rooms will be determined using the method identified in subsection (9) of this section.

(9) Operating room need in a planning area shall be determined using the following method:

(a) Existing capacity.

(i) Assume the annual capacity of one operating room located in a hospital and not dedicated to outpatient surgery is ninety-four thousand two hundred fifty minutes. This is derived from scheduling forty-four hours per week, fifty-one weeks per year (allowing for five weekday holidays), a fifteen percent loss for preparation and clean-up time, and fifteen percent time loss to allow schedule flexibility. The resulting seventy percent productive time is comparable to the previously operating hospital commission's last definition of "billing minutes" which is the time lapse from administration of anesthesia until surgery is completed.

(ii) Assume the annual capacity of one operating room dedicated to ambulatory surgery is sixty-eight thousand eight hundred fifty minutes. The derivation is the same as (a)(i) of this subsection except for twenty-five percent loss for prep/clean-up time and scheduling is for a thirty-seven and one-half hour week. Divide the capacity minutes by the average minutes per outpatient surgery (see (a)(vii) of this subsection). Where survey data are unavailable, assume fifty minutes per outpatient surgery, resulting in a capacity for one thousand three hundred seventy-seven outpatient surgeries per room per year.

(iii) Calculate the total annual capacity (in number of surgeries) of all dedicated outpatient operating rooms in the area.

(iv) Calculate the total annual capacity (in number of minutes) of the remaining inpatient and outpatient operating rooms in the area, including dedicated specialized rooms except for twenty-four hour dedicated emergency rooms. When dedicated emergency operating rooms are excluded, emergency or minutes should also be excluded when calculating the need in an area. Exclude cystoscopic and other special purpose rooms (e.g., open heart surgery) and delivery rooms.

(b) Future need.

(i) Project number of inpatient and outpatient surgeries performed within the hospital planning area for the third year of operation. This shall be based on the current number of surgeries adjusted for forecasted growth in the population served and may be adjusted for trends in surgeries per capita.

(ii) Subtract the capacity of dedicated outpatient operating rooms from the forecasted number of outpatient surgeries. The difference continues into the calculation of (b)(iv) of this subsection.

(iii) Determine the average time per inpatient and outpatient surgery in the planning area. Where data are unavailable, assume one hundred minutes per inpatient and fifty minutes per outpatient surgery. This excludes preparation and cleanup time and is comparable to "billing minutes."

(iv) Calculate the sum of inpatient and remaining outpatient (from (b)(ii) of this subsection) operating room time needed in the third year of operation.

(c) Net need.

(i) If (b)(iv) of this subsection is less than (a)(iv) of this subsection, divide their difference by ninety-four thousand two hundred fifty minutes to obtain the area's surplus of operating rooms used for both inpatient and outpatient surgery.

(ii) If (b)(iv) of this subsection is greater than (a)(iv) of this subsection, subtract (a)(iv) of this subsection from the inpatient component of (b)(iv) of this subsection and divide by ninety-four thousand two hundred fifty minutes to obtain the area's shortage of inpatient operating rooms. Divide the outpatient component of (b)(iv) of this subsection by sixty-eight thousand eight hundred fifty to obtain the area's shortage of dedicated outpatient operating rooms.

[Statutory Authority: RCW 70.38.135 and 70.38.919. WSR 92-02-018 (Order 224), § 246-310-270, filed 12/23/91, effective 1/23/92. Statutory Authority: RCW 43.70.040. WSR 91-02-049 (Order 121), recodified as § 246-310-270, filed 12/27/90, effective 1/31/91. Statutory Authority: RCW 70.38.919. WSR 90-16-058 (Order 073), § 248-19-700, filed 7/27/90, effective 8/27/90.]

WAC 246-310-290 Hospice services——Standards and need forecasting method. The following rules apply to any in-home services agency licensed or an applicant intending to become licensed to provide hospice services, and intending to become a medicare certified or medicaid contracted service provider in a designated planning area.

(1) The definitions in this subsection apply throughout this section unless the context clearly indicates otherwise:

(a) "ADC" means average daily census and is calculated by:

(i) Multiplying projected annual hospice agency admissions by the most recent average length of stay in Washington, based on the most recent data reported to the Centers for Medicare and Medicaid Services (CMS) to derive the total annual days of care;

(ii) Dividing the total calculated in (a)(i) of this subsection by three hundred sixty-five (days per year) to determine the ADC.

(b) "Average length of stay" means the average covered days of care per person for Washington state as reported by CMS.

(c) "Base year" means the most recent calendar year for which hospice survey data is available as of September 30th of each year.

(d) "CMS" means the Centers for Medicare and Medicaid Services.

(e) "Current supply of hospice providers" means all providers of hospice services that have received certificate of need approval to provide services within a planning area. State licensed only and volunteer hospices are excluded from the current supply of hospice providers.

(f) "Hospice services" means symptom and pain management provided to a terminally ill person, and emotional, spiritual and bereavement support for the terminally ill person and family in a place of temporary or permanent residence provided under the direction of an interdisciplinary team composed of at least a registered nurse, social worker, physician, spiritual counselor, and a volunteer.

(g) "OFM" means the Washington state office of financial management.

(h) "Planning area" or "service area" means an individual geographic area designated by the department for which hospice need projections are calculated. For the purposes of hospice services, planning area and service area have the same meaning.

(i) "Projection year" means the third calendar year after the base year. For example, reviews using 2016 survey data as the base year will use 2019 as the projection year.

(2) The department will review a hospice application using the concurrent review cycle described in subsection (3) of this section, except when the sole hospice provider in the service area ceases operation. Applications to meet this need may be accepted and reviewed in accordance with the regular review process described in WAC 246-310-110 (2)(c).

(3) Applications must be submitted and reviewed according to Table A:

Table A

		Application Submission Period			Department Action	Application Review Period		
Concurrent Review Cycle	Letters of Intent Due	Receipt of Initial Application	End of Screening Period	Applicant Response	Beginning of Review	Public Comment	Rebuttal	Ex Parte Period
Cycle 1 (Chelan, Douglas, Clallam, Clark, Skamania, Cowlitz, Grant, Grays Harbor, Island, Jefferson, King, Kittitas, Klickitat, Okanogan, Pacific, San Juan, Skagit, Spokane, and Yakima).	Last working day of **November** of each year.	Last working day of **December** of each year.	Last working day of **January** of each year.	Last working day of **February** of each year.	**March 16** of each year or the first working day thereafter.	**45-Day** public comment period (including public hearing). Begins **March 17** or the first working day thereafter.	**30-Day** rebuttal period. Applicant and affected person response to public comment.	**75-Day** ex parte period. Department evaluation and decision.
Cycle 2 (Adams, Asotin, Benton, Columbia, Ferry, Franklin, Garfield, Kitsap, Lewis, Lincoln, Mason, Pend Oreille, Pierce, Snohomish, Stevens, Thurston, Wahkiakum, Walla Walla, Whatcom, and Whitman).	Last working day of **December** of each year.	Last working day of **January** of each year.	Last working day of **February** of each year.	Last working day of **March** of each year.	**April 16** of each year or the first working day thereafter.	**45-Day** public comment period (including public hearing). Begins **April 17** or the first working day thereafter.	**30-Day** rebuttal period. Applicant and affected person response to public comment.	**75-Day** ex parte period. Department evaluation and decision.

(4) Pending certificate of need applications. A hospice service application submitted prior to the effective date of these rules will be reviewed and action taken based on the rules that were in effect on the date the application was received.

(5) The department will notify applicants fifteen calendar days prior to the scheduled decision date if it is unable to meet the decision deadline on the application(s). In that event, the department will establish and commit to a new decision date.

(6) When an application initially submitted under the concurrent review cycle is deemed not to be competing, the department may convert the review to a regular review process.

(7) Current hospice capacity will be determined as follows:

(a) For hospice agencies that have operated in a planning area for three years or more, current hospice capacity is calculated by determining the average number of unduplicated admissions for the last three years of operation;

(b) For hospice agencies that have operated (or been approved to operate) in a planning area for less than three years, an ADC of thirty-five and the most recent Washington average length of stay data will be used to calculate assumed annual admissions for the hospice agency as a whole for the first three years to determine current hospice capacity. If a hospice agency's reported admissions exceed an ADC of thirty-five, the department will use the actual reported admissions to determine current hospice capacity;

(c) For a hospice agency that is no longer in operation, the department will use the historical three-year admissions to calculate the statewide use rates, but will not use the admissions to calculate planning area capacity;

(d) For a hospice agency that has changed ownership, the department will use the historical three-year admissions to calculate the

statewide use rates, and will use the admissions to calculate planning area capacity.

(8) Need projection. The following steps will be used to project the need for hospice services.

(a) Step 1. Calculate the following two statewide predicted hospice use rates using department of health survey and vital statistics death data:

(i) The percentage of patients age sixty-five and over who will use hospice services. This percentage is calculated by dividing the average number of unduplicated admissions over the last three years for patients sixty-five and over by the average number of past three years statewide total deaths age sixty-five and over.

(ii) The percentage of patients under sixty-five who will use hospice services. This percentage is calculated by dividing the average number of unduplicated admissions over the last three years for patients under the age of sixty-five by the average number of past three years statewide total deaths under sixty-five.

(b) Step 2. Calculate the average number of total resident deaths over the last three years for each planning area by age cohort.

(c) Step 3. Multiply each hospice use rate determined in Step 1 by the planning areas average total resident deaths determined in Step 2, separated by age cohort.

(d) Step 4. Using the projected patients calculated in Step 3, calculate a use rate by dividing projected patients by the three-year historical average population by county. Use this use rate to determine the potential volume of hospice use by the projected population by the two age cohorts identified in Step 1, (a)(i) and (ii) of this subsection using OFM data.

(e) Step 5. Combine the two age cohorts. Subtract the most recent three-year average hospice capacity in each planning area from the projected volumes calculated in Step 4 to determine the number of projected admissions beyond the planning area capacity.

(f) Step 6. Multiply the unmet need from Step 5 by the statewide average length of stay as determined by CMS to determine unmet need patient days in the projection years.

(g) Step 7. Divide the unmet patient days from Step 6 by 365 to determine the unmet need ADC.

(h) Step 8. Determine the number of hospice agencies in the planning areas that could support the unmet need with an ADC of thirty-five.

(9) If the department becomes aware of a facility closure fifteen calendar days or more prior to the letter of intent submission period, the department will update the methodology for the application cycle. If a closure occurs fewer than fifteen calendar days prior to the letter of intent submission period, the department will not update the methodology until the next year.

(10) In addition to demonstrating numeric need under subsection (7) of this section, applicants must meet the following certificate of need requirements:

(a) Determination of need under WAC 246-310-210;

(b) Determination of financial feasibility under WAC 246-310-220;

(c) Criteria for structure and process of care under WAC 246-310-230; and

(d) Determination of cost containment under WAC 246-310-240.

(11) To conduct the superiority evaluation to determine which competing applications to approve, the department will use only the

criteria and measures in this section to compare two or more applications to each other.

(a) The following measures must be used when comparing two or more applications to each other:

(i) Improved service to the planning area;

(ii) Specific populations including, but not limited to, pediatrics;

(iii) Minimum impact on existing programs;

(iv) Greatest breadth and depth of hospice services; and

(v) Published and publicly available quality data.

(b) An application will be denied if it fails to meet any criteria under WAC 246-310-210, 246-310-220, 246-310-230, or 246-310-240 (2) or (3).

(12) The department may grant a certificate of need for a new hospice agency in a planning area where there is not numeric need.

(a) The department will consider if the applicant meets the following criteria:

(i) All applicable review criteria and standards with the exception of numeric need have been met;

(ii) The applicant commits to serving medicare and medicaid patients; and

(iii) A specific population is underserved; or

(iv) The population of the county is low enough that the methodology has not projected need in five years, and the population of the county is not sufficient to meet an ADC of thirty-five.

(b) If more than one applicant applies in a planning area, the department will give preference to a hospice agency that proposes to be physically located within the planning area.

(c) The department has sole discretion to grant or deny application(s) submitted under this subsection.

(13) Any hospice agency granted a certificate of need for hospice services must provide services to the entire county for which the certificate of need was granted.

(14) Failure to operate the hospice agency as approved in the certificate of need may be a basis for revocation or suspension of a hospice agency's certificate of need, or other appropriate action.

[Statutory Authority: RCW 70.38.135 and 70.38.115. WSR 18-19-051, § 246-310-290, filed 9/14/18, effective 10/15/18. Statutory Authority: Chapters 70.127 and 70.38 RCW. WSR 03-07-096, § 246-310-290, filed 3/19/03, effective 4/19/03.]

WAC 246-310-295 Hospice care center—Standards. The following rules apply to any in-home services agency licensed to provide hospice services, that is or has declared an intent to become additionally licensed to provide hospice care center services.

(1) Definitions.

(a) "Applicant" means an in-home services agency licensed to provide hospice services under chapter 246-335 WAC.

(b) "Hospice care center" means a homelike, noninstitutional facility where hospice services are provided, and that meet the requirements for operation under RCW 70.127.280 and chapter 246-335 WAC.

(2) The department shall review hospice care center applications using the concurrent review cycle in this section.

(3) Applications must be submitted and reviewed according to the following schedule and procedures.

(a) Letters of intent must be submitted between the first working day and last working day of October of each year.

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

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

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

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

(f) The public comment period is limited to ninety days, unless extended under WAC 246-310-120 (2)(d). The first sixty days of the public comment period must be reserved for receiving public comments and conducting a public hearing, if requested. The remaining thirty days must 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 applying hospice agency'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, shall 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 under WAC 246-310-120 (2)(d).

(4) 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.

(5) If an application initially submitted under the concurrent review cycle is deemed not to be competing, the department may convert the review to a regular review process.

(6) An applicant must provide the following documentation to demonstrate that the applicant's existing patient base is sufficient to support the creation of the hospice care center.

(a) Step 1. Determine the average total days of care provided in the applicant's preceding three years of operation. If the applicant has been in operation for less than three years, assume an ADC of thirty-five to calculate potential days of care;

(b) Step 2. Multiply the above average days of care by the applicant's annual percentage of patients requiring care in settings other than their private home to estimate the number of potential patient days. If the applicant has been in operation for less than three years, multiply the potential days of care by the statewide percentage of hospice patients requiring care in settings other than their private home;

(c) Step 3. Divide the estimated number of patient days by three hundred sixty-five (days per year) to estimate the average daily census for the applicant;

(d) Step 4. Assume a minimum occupancy of sixty-five percent to determine the number of beds the applicant could request in their application.

(7) If applying for more beds than provided for in subsection (6) of this section, the applicant must provide documentation, methodology and assumptions that support the applicant's ability to sustain the additional beds.

(8) The following occupancy requirements apply to all applicants:

(a) The average occupancy rate of the beds in the center must be projected to be at least fifty percent for the first three years following completion of the project;

(b) A minimum occupancy rate of sixty-five percent should be maintained after the first three years of operation; and

(c) If applying to add beds to an existing hospice care center the applicant must document that the average occupancy of the beds in the hospice care center was at least eighty percent for the nine months immediately preceding the submittal of the proposal.

(9) The applicant must document that they can maintain the minimum occupancy rate and still meet the following requirements:

(a) No more than forty-nine percent of the hospice agency's patient care days, in the aggregate on a biennial basis, can be provided in the hospice care center, under RCW 70.127.280; and

(b) The maximum number of beds in a hospice care center is twenty, under chapter 70.127 RCW.

(10) Failure to operate the hospice care center in accordance with the application relied upon by the department in making its decision may be grounds for revocation or suspension of a center's certificate of need, or other appropriate action.

[Statutory Authority: Chapters 70.127 and 70.38 RCW. WSR 03-07-096, § 246-310-295, filed 3/19/03, effective 4/19/03.]

WAC 246-310-360 Nursing home bed need method. For all applications where the need for nursing home beds is not deemed met as identified in RCW 70.38.115(13), the following mathematical calculation will be used as a guideline and represent only one component of evaluating need:

(1) The department shall calculate the statewide and planning area specific estimated bed need for the projection year by multiplying the estimated statewide and planning area specific resident population for the projection year by the established ratio;

(2) The department shall then calculate the projected current supply ratio statewide and for each planning area. The current supply ratio shall be computed from the most recent bed supply and the projection year estimate of resident population.

(3) The department shall next determine the areas of the state that will be under the established ratio, or over the established ratio in the projection year by comparing each planning area's projected current supply ratio to the established ratio.

(4) The department shall compare the most recent statewide bed supply with the statewide estimated bed need.

(a) If the current statewide bed supply is greater than or equal to the statewide estimated bed need, then calculation of statewide need for new beds ends.

(b) If the current statewide bed supply is less than the statewide estimated bed need, the department shall determine the difference

between the statewide estimated bed need and the statewide current bed supply, which shall be called statewide available beds.

(i) If the number of statewide available beds is large enough, the department shall assign to each planning area under the established ratio the number of beds necessary to bring it up to the established ratio in the projection year.

(ii) If the number of statewide available beds is insufficient to assign each planning area under the established ratio the number of new beds necessary to bring it up to the established ratio, the department shall assign to each planning area under the established ratio a proportion of statewide available beds equal to the ratio of that planning area's bed need to reach the established ratio to the total beds required for all planning areas under the established ratio to reach the established ratio in the projection year.

(iii) The department shall not assign more new beds to a planning area than the number which, when added to the planning area's bed supply, will raise the planning area's bed-to-population ratio to the greater of the established ratio and the statewide current ratio.

[Statutory Authority: Chapter 70.38 RCW. WSR 96-24-052, § 246-310-360, filed 11/27/96, effective 12/28/96. Statutory Authority: RCW 43.70.040. WSR 91-02-049 (Order 121), recodified as § 246-310-360, filed 12/27/90, effective 1/31/91. Statutory Authority: RCW 70.38.919. WSR 90-12-071 (Order 062), § 248-19-805, filed 6/1/90, effective 7/1/90.]

WAC 246-310-370 Nursing home bed need method revision. (1) The department shall review the projection method and may make changes in accordance with the following process:

(a) The appropriate consumer and provider representatives and the department of social and health services shall be notified of the department's plan to evaluate the projection method and be provided information on the process for participating in the evaluation;

(b) Proposed revisions to the projection method shall be developed in consultation with the responding representatives. An opportunity for public comment on the proposed revisions to the projection method will be provided prior to filing the proposed rules.

(2) When reviewing the projection method the department shall consider the following:

(a) The national bed-to-population ratio and the bed-to-population ratios of other states judged by the aging and adult services administration of the department of social and health services to have reasonable and progressive long-term care policies;

(b) Data and information provided by provider and consumer representatives;

(c) State governmental policy goals for distributing scarce resources between nursing homes and other institutional or community based services;

(d) The effects of developments in the delivery or financing of long-term care services on nursing home bed need; and

(e) Progress in developing other long-term care services for the statewide resident population.

[Statutory Authority: Chapter 70.38 RCW. WSR 96-24-052, § 246-310-370, filed 11/27/96, effective 12/28/96. Statutory Authority: RCW 43.70.040. WSR 91-02-049 (Order 121), recodified as § 246-310-370,

filed 12/27/90, effective 1/31/91. Statutory Authority: RCW 70.38.919. WSR 90-12-071 (Order 062), § 248-19-806, filed 6/1/90, effective 7/1/90.]

WAC 246-310-380 Nursing home bed need standards. (1) The department shall use the following rules in conjunction with the certificate of need review criteria contained in WAC 246-310-210(1) for applications proposing the following:

(a) Construction, development, or other establishment of a new nursing home;

(b) Increase in the licensed bed capacity of a nursing home or a hospital long-term care unit;

(c) Change in license category of beds from the following to nursing home or hospital long-term care unit beds:

(i) Acute care; or

(ii) Assisted living facility care;

(2) The department shall comply with the following time schedule for developing bed need projections:

(a) By the last working day in January of each year, the department shall recalculate the estimated bed projection for each planning area.

(b) By the last working day in January of each year, the department shall provide the aging and adult services administration of the department of social and health services with the estimated bed need for each planning area, pending the department's decisions on applications submitted during the previous year's nursing home concurrent review cycles.

(c) By the last working day in January of each year, the department shall rank order planning areas from lowest to highest by the projected current supply ratio.

(d) By the first working day of June of each year, the department shall calculate the net estimated bed need for each planning area.

(3) The estimated bed projections for the projection period, listed by planning area will be updated annually and distributed to interested parties. When a planning area's estimated bed projection is less than the planning area's bed supply as defined by WAC 246-310-350(4), no beds can be added until the statewide established ratio is reached, except as allowed in this section.

(4) The department shall limit to three hundred the total number of nursing home beds approved for all CCRCs which propose or are operating within a transition period.

(a) These three hundred beds available for CCRCs during transition periods shall be in addition to the net nursing home beds needed in all of the planning areas.

(b) All nursing home beds approved for CCRCs which propose or are operating within a transition period shall be counted as beds within this three hundred bed limitation unless and until the CCRC fully complies with all provisions of the CCRCs performance standards.

(5) The department shall not issue certificates of need approving more than the net estimated bed need indicated for a given planning area, unless:

(a) The department finds such additional beds are needed to be located reasonably close to the people they serve; and

(b) The department explains such approval in writing.

[Statutory Authority: RCW 70.38.135 and 2012 c 10. WSR 14-08-046, § 246-310-380, filed 3/27/14, effective 4/27/14. Statutory Authority: Chapter 70.38 RCW. WSR 96-24-052, § 246-310-380, filed 11/27/96, effective 12/28/96. Statutory Authority: RCW 70.38.135. WSR 91-15-018 (Order 179), § 246-310-380, filed 7/10/91, effective 8/10/91. Statutory Authority: RCW 43.70.040. WSR 91-02-049 (Order 121), recodified as § 246-310-380, filed 12/27/90, effective 1/31/91. Statutory Authority: RCW 70.38.919. WSR 90-12-072 (Order 063), § 248-19-810, filed 6/1/90, effective 7/1/90.]

WAC 246-310-390 Nursing home bed need adjustments. (1) The department shall use the procedures described in this section to make adjustments to planning area net estimated bed need.

(2) For planning areas for which a nursing home review is scheduled or is ongoing, the department shall use the following procedures to adjust a planning area's net estimated bed need between April tenth or the first working day thereafter and the last working day in January of the following year.

(a) Where an increase in the bed supply of a planning area results in a reduction in net estimated bed need, the department shall use the following procedures:

(i) When a reduction in net estimated bed need occurs prior to the date of beginning of review for the applicable concurrent review cycle, the department shall:

(A) Inform, in writing, all persons from whom the department has received an application and/or a valid letter of intent of the reduction; and

(B) Explain the procedures for withdrawing or amending a certificate of need application.

(ii) When a reduction in net estimated bed need occurs after the date of beginning of review for the applicable concurrent review cycle, the department shall use the need projected at the time the review began in reaching a decision on each affected application.

(b) Where a decrease in the bed supply of a planning area results in the increase in net estimated bed need, the department shall:

(i) Use the following policies:

(A) If such a decrease in the bed supply would result in a planning area being under the established ratio, the department shall:

(I) Assign to the planning area only enough beds for the planning area to reach the established ratio in the projection year, but not to exceed the number of beds which closed; and

(II) Redistribute any remaining beds to planning areas statewide through the next scheduled recalculation of estimated projections for all planning areas.

(B) If such decrease in the bed supply would not make a planning area under the established ratio, the department shall redistribute any remaining beds to planning areas statewide through the next scheduled recalculation of baseline projections for all planning areas.

(ii) Subject to the provisions of (b)(i) of this subsection, use the following procedures:

(A) When an increase in net estimated bed need can be made prior to the last day on which the department can accept amendments to applications under review, the department shall:

(I) Notify all affected applicants in writing; and

(II) Explain to each affected applicant the procedures for amending a certificate of need application.

(B) When an increase cannot be made prior to the last day on which the department can accept amendments to applications under review, the department shall include the increased net estimated bed need in any subsequent decisions on each affected application or the next applicable concurrent review cycle, whichever occurs first.

(3) For planning areas for which a nursing home review is not scheduled or ongoing, the department shall use the following procedures to adjust a planning area's net estimated bed need between April tenth or the first working day thereafter and the last working day in January of the following year:

(a) If a decrease in the bed supply would make a planning area under the established ratio, the department shall:

(i) Assign to the planning area only enough beds for the planning area to reach the established ratio in the projection year; and

(ii) Redistribute any remaining beds to planning areas statewide through the next scheduled recalculation of baseline projections for all planning areas.

(b) If such decrease in the bed supply would not result in a planning area being under the established ratio, the department shall redistribute any remaining beds to planning areas statewide through the next scheduled recalculation of baseline projections for all planning areas.

[Statutory Authority: Chapter 70.38 RCW. WSR 96-24-052, § 246-310-390, filed 11/27/96, effective 12/28/96. Statutory Authority: RCW 43.70.040. WSR 91-02-049 (Order 121), recodified as § 246-310-390, filed 12/27/90, effective 1/31/91. Statutory Authority: RCW 70.38.919. WSR 90-12-072 (Order 063), § 248-19-811, filed 6/1/90, effective 7/1/90.]

WAC 246-310-395 Nursing home bed banking for alternative use notice requirements. In the case of a nursing home licensee, requesting to convert some of the nursing home beds to an alternative use, as defined in RCW 70.38.111(8), or reduce the number of beds per room to two or one, or otherwise enhance the quality of life for residents and preserve the right to later convert the original portion of the facility back to skilled nursing care, the nursing home shall give notice of intent to preserve its conversion options to the department of health.

(1) Notice of the nursing homes intent to preserve conversion options shall be given to the department of health no later than thirty days after the effective date of the license modification made by the nursing home licensing authority. Such notices shall be signed by the licensee and include the following:

(a) A description of the alternative service to be provided or a description of how the proposed bed banking will have a direct and immediate benefit to the quality of life of the residents and a listing of the number of beds, by room number;

(b) A projected timeline for implementation; and

(c) In the event the nursing home licensee, as defined by WAC 246-310-010, is not the nursing home owner, the licensee shall document whether the building owner has a secured interest in the beds.

- If the building owner does have a secured interest in the beds, the licensee shall provide a written statement, signed by the building owner, indicating approval of the bed reduction.
- If the building owner does not have a secured interest in the beds, the licensee shall provide documentation showing that the building owner has been notified of the bed reduction.

(2) The department shall notify the nursing home, as to whether the proposal meets the requirements of RCW 70.38.111 (8)(a) and if conversion rights are recognized. The nursing home does not forfeit its right to bank beds under this section if the department does not respond within this thirty-day time frame, nor does the nursing home obtain rights that it otherwise would not have under applicable statutes or rules if the department does not respond within the thirty-day time frame.

(3) The licensee shall notify the department of health at the time the alternative service or services commences.

(4) In the event the facility decides to modify the room numbers or alternative uses for the beds that have been banked, notification to the department is necessary to assure continued compliance with RCW 70.38.111 (8)(a) and WAC 246-310-395.

(5) Notice of intent to convert beds back to nursing home bed use shall be given to the department of health and the department of social and health services a minimum of ninety days prior to the effective date of the licensure modification made by the nursing home licensing authority reflecting the restored beds unless construction is required to convert the beds back. In the event the beds are not converted back to nursing home beds within sixty days of the date stated in the notice of intent, a notice of intent will need to be resubmitted a minimum of ninety days prior to the effective date of the licensure modification.

(6) In the event construction is required to convert beds back to nursing home bed use, notice shall be given to the department of health and department of social and health services a minimum of one year prior to the effective date of licensure modification made by the nursing home licensing authority reflecting the restored beds. The same life and safety code requirements as existed at the time the nursing home voluntarily reduced its licensed beds shall be complied with unless waivers from such requirements were issued, in which case the converted beds shall reflect the conditions or standards that then existed pursuant to the approved waivers. In the event the beds are not converted back to nursing home beds within sixty days of the date stated in the notice of intent, a notice of intent will need to be resubmitted a minimum of one year prior to the effective date of the licensure modification. The term "construction," as used in this section, is limited to those projects that are expected to equal or exceed the expenditure minimum amount, as determined under chapter 70.38 RCW.

(7) Prior to any license modification to convert beds back to nursing home beds under this section, the licensee must demonstrate that the nursing home meets the certificate of need exemption requirements under WAC 246-310-043.

[Statutory Authority: Chapter 70.38 RCW. WSR 98-17-099, § 246-310-395, filed 8/19/98, effective 9/19/98; WSR 98-10-053, § 246-310-395, filed 4/29/98, effective 5/30/98; WSR 96-24-052, § 246-310-395, filed 11/27/96, effective 12/28/96.]

WAC 246-310-396 Nursing home bed banking requirements for full facility closure. In the case of a nursing home licensee, as defined in WAC 246-310-010 ceasing operation as a nursing home or any other party who has secured an interest in the beds and requesting to retain the nursing home bed allocation, pursuant to RCW 70.38.115 (13)(b), the licensee or other party who has secured an interest in the beds shall give notice to the department of health.

(1) Notice of the nursing homes intent to retain the nursing home bed allocation shall be given to the department of health no later than thirty days after the effective date of the homes closure. Such notices shall be signed by the licensee and include the following:

(a) The name of the facility ceasing operation;

(b) The number of beds in the bed allocation to be retained;

(c) Documentation of the effective date of the facility closure;

(d) The name, address, and telephone number of a contact person;

(e) Documentation as to whether the applicant is the licensee who has operated the beds for at least one year immediately preceding the reservation of the beds; and

(f) In the event the nursing home licensee, as defined by WAC 246-310-010, is not the nursing home owner, the licensee shall document whether the building owner or other party has a secured interest in the beds.

- If the building owner or other party does have a secured interest in the beds, the licensee shall provide a written statement, signed by the building owner or other party, indicating approval of the facility's closure.
- If the building owner or other party does not have a secured interest in the beds, the licensee shall provide documentation showing that the building owner or other party has been notified of the facility's closure.

(2) Notice shall be in written form addressed to the certificate of need program and signed by an authorized representative of the nursing home or other party who has secured an interest in the beds.

(3) The department shall respond within thirty days of the notice confirming that the rights to the bed allocation have been retained and the date the retained bed right will expire, provided no certificate of need is issued to replace the beds. The nursing home does not forfeit its right to bank beds under this section if the department does not respond within the thirty-day time frame, nor does the nursing home obtain rights that it otherwise would not have under applicable statutes or rules if the department does not respond within the given time frame.

(4) Certificate of need review shall be required for any party who has reserved the nursing home beds except that the need criteria shall be deemed met when the applicant is the licensee who has operated the beds for at least one year immediately preceding the reservation of the beds, and who is replacing the beds in the same planning area.

[Statutory Authority: Chapter 70.38 RCW. WSR 98-10-053, § 246-310-396, filed 4/29/98, effective 5/30/98; WSR 96-24-052, § 246-310-396, filed 11/27/96, effective 12/28/96.]

WAC 246-310-397 Nursing home bed replacement notice requirements. In the case of a nursing home licensee wanting to replace

nursing home beds pursuant to WAC 246-310-044, the nursing home shall give notice of intent to replace the beds to the department of health.

Notice of the nursing home licensees intent to replace the nursing home beds shall be given to the department a minimum of thirty days prior to initiating the replacement project. Such notices shall be signed by the licensee and include the following:

(1) Documentation that the applicant is the existing licensee at all affected facilities and has operated the beds at all affected facilities for at least one year immediately preceding the replacement exemption request fulfilling the notice requirements of this section;

(2) An affidavit from the applicant that the applicant intends to be the licensee at all affected facilities at the time of project completion. This affidavit shall include a statement that the applicant acknowledges the project can not be completed if the applicant is not the licensee at the time of project completion except as allowed for under the provisions of RCW 70.38.115(14);

(3) In the event the nursing home licensee, as defined by WAC 246-310-010, is not the nursing home owner, the licensee shall document whether the building owner has a secured interest in the beds.

(a) If the building owner does have a secured interest in the beds, the licensee shall provide a written statement, signed by the building owner, indicating approval of the bed replacement. In the event that the licensee is unable to complete the replacement project, as referenced in RCW 70.38.115(14), the building owner shall be permitted to complete the project.

(b) If the building owner does not have a secured interest in the beds, the licensee shall provide documentation showing that the building owner has been notified of the proposed project. In the event that the licensee is unable to complete the replacement project, as referenced in RCW 70.38.115(14), the building owner shall not be permitted to complete the project.

(4) The number of beds currently licensed at each affected facility and the number of licensed beds to be replaced at each affected facility;

(5) Geographic location of both the existing nursing home beds and the proposed replacement beds;

(6) Documentation that the nursing home beds being replaced will not be used for nursing home services once the replacement beds are licensed;

(7) A projected timeline for completion of the project; and

(8) Estimated capital expenditure. (This figure will be used by department of social and health services as part of the rate calculation.)

[Statutory Authority: Chapter 70.38 RCW. WSR 98-17-099, § 246-310-397, filed 8/19/98, effective 9/19/98; WSR 96-24-052, § 246-310-397, filed 11/27/96, effective 12/28/96.]

WAC 246-310-410 Swing bed review standards. (1) The department shall use the following rules, in addition to those under WAC 246-310-380 to interpret the certificate of need review criteria contained in WAC 246-310-210, 246-310-220, 246-310-230, and 246-310-240 for applications by hospitals proposing an increase in the number of designated swing beds.

(2) Swing beds are defined as up to the first five hospital beds, so designated by an eligible rural hospital, which are available to

provide either acute care or long-term care nursing services as required.

(3) Hospitals proposing swing bed projects shall:

(a) Be located in geographic areas of the state defined by the United States Bureau of the Census as a nonstandardized metropolitan statistical area; and

(b) Have total licensed bed capacity not exceeding one hundred.

(4) Hospitals shall demonstrate ability to meet minimum medicare standards of care for rural hospital swing beds.

[Statutory Authority: Chapter 70.38 RCW. WSR 96-24-052, § 246-310-410, filed 11/27/96, effective 12/28/96. Statutory Authority: RCW 70.38.135 and 70.38.919. WSR 92-02-018 (Order 224), § 246-310-410, filed 12/23/91, effective 1/23/92. Statutory Authority: RCW 43.70.040. WSR 91-02-049 (Order 121), recodified as § 246-310-410, filed 12/27/90, effective 1/31/91. Statutory Authority: RCW 70.38.919. WSR 90-12-072 (Order 063), § 248-19-860, filed 6/1/90, effective 7/1/90.]

WAC 246-310-470 Review and action on health maintenance organization projects. (1) Undertakings requiring a certificate of need.

A certificate of need shall be required for any undertaking which, in accordance with WAC 246-310-020, is subject to the provisions of chapter 246-310 WAC, unless an exemption has been granted for such undertaking under the provisions of WAC 246-310-040.

(2) Required approval.

The secretary's designee shall issue a certificate of need for a proposed project if the certificate of need applicant for the proposed project is a health maintenance organization or a health care facility controlled (directly or indirectly) by a health maintenance organization and the department finds the proposed project meets the criteria set forth in WAC 246-310-210(5).

(3) Sale, acquisition, or lease of facilities or equipment for which a certificate of need has been issued.

A health care facility (or portion thereof) for which a certificate of need has been issued under the provisions of this section shall not be sold or leased and a controlling interest in such facility or in a lease of the facility shall not be acquired unless an exemption or a certificate of need for such sale, lease, or acquisition has been granted by the secretary's designee.

[Statutory Authority: Chapter 70.38 RCW. WSR 96-24-052, § 246-310-470, filed 11/27/96, effective 12/28/96. Statutory Authority: RCW 70.38.135 and 70.38.919. WSR 92-02-018 (Order 224), § 246-310-470, filed 12/23/91, effective 1/23/92. Statutory Authority: RCW 43.70.040. WSR 91-02-049 (Order 121), recodified as § 246-310-470, filed 12/27/90, effective 1/31/91. Statutory Authority: RCW 70.38.135. WSR 86-06-030 (Order 2344), § 248-19-410, filed 2/28/86; WSR 81-09-012 (Order 210), § 248-19-410, filed 4/9/81, effective 5/20/81. Statutory Authority: Chapter 70.38 RCW. WSR 79-12-079 (Order 188), § 248-19-410, filed 11/30/79.]

WAC 246-310-480 Projects proposed for the correction of deficiencies. (1) For the purposes of this section, "correction of deficiencies" shall mean one or more of the following:

(a) Eliminating or preventing imminent safety hazards as defined by federal, state, or local fire, building, or life safety codes or regulations; or

(b) Complying with state licensing standards; or

(c) Complying with accreditation or certification standards which must be met to receive reimbursement under Titles XVIII or XIX of the Social Security Act.

(2) An application submitted for a project limited to the correction of deficiencies, as defined in subsection (1) of this section, shall be approved unless the department finds that:

(a) The applicant was provided sufficient advanced notification of such deficiencies to allow for ongoing correction; or

(b) The project would result in the substantial modification or replacement of an existing health care facility and the licensee would not be exempt under WAC 246-310-044.

(3) An application submitted for the correction of deficiencies shall be reviewed under the expedited review process, in accordance with WAC 246-310-150, unless it qualifies for emergency review in accordance with WAC 246-310-140.

(4) An application reviewed under the provisions of this section shall be approved only to the extent the capital expenditure is needed for the correction of the deficiency.

(5) If the department finds any portion of the project or the project as a whole is not needed for the correction of deficiencies, such portion or entire project shall be reviewed in accordance with WAC 246-310-200, 246-310-210, 246-310-220, 246-310-230, and 246-310-240.

(6) If the department finds a proposed capital expenditure is needed to correct deficiencies, as defined in subsection (1) of this section, the criteria in WAC 246-310-210 shall not be applied to the consideration of the project.

[Statutory Authority: Chapter 70.38 RCW. WSR 96-24-052, § 246-310-480, filed 11/27/96, effective 12/28/96. Statutory Authority: RCW 70.38.135 and 70.38.919. WSR 92-02-018 (Order 224), § 246-310-480, filed 12/23/91, effective 1/23/92. Statutory Authority: RCW 43.70.040. WSR 91-02-049 (Order 121), recodified as § 246-310-480, filed 12/27/90, effective 1/31/91. Statutory Authority: RCW 70.38.135. WSR 86-06-030 (Order 2344), § 248-19-415, filed 2/28/86; WSR 81-09-012 (Order 210), § 248-19-415, filed 4/9/81, effective 5/20/81.]

WAC 246-310-490 Written findings and actions on certificate of need applications. (1) Written findings.

(a) The findings of the department's review of a certificate of need application shall be stated in writing and include the basis for the decision of the secretary's designee as to whether a certificate of need is to be issued or denied for the proposed project.

(b) In making its findings and taking action on a certificate of need application, the department shall use all criteria contained in chapter 246-310 WAC applicable to the proposed project.

(i) The written findings shall identify any criterion the department has decided is not applicable to the particular project and give the reason for such decision.

(ii) The secretary's designee may deny a certificate of need if the applicant has not provided the information which is necessary to a determination that the project meets all applicable criteria and which

the department has prescribed and published as necessary to a certificate of need review of the type proposed: Provided however, That the department has requested such information in a screening letter sent in accordance with WAC 246-310-090 (1)(c).

(c) The department shall make written findings on the extent to which the project meets the criteria set forth in WAC 246-310-210 (1) and (2) when the secretary's designee issues a certificate of need directly related to the provision of health services, or beds: Provided however, That no such written finding shall be necessary for projects for the correction of deficiencies of the types described in WAC 246-310-480 and for projects proposed by or on behalf of a health maintenance organization or a health care facility controlled, directly or indirectly, by a health maintenance organization.

(d) When, as a part of concurrent review proceedings, the secretary's designee makes a decision to approve an application or applications and to disapprove other competing applications, he or she shall provide a specific written statement of reasons for determining the approved application or applications to be superior.

(2) Separability of application and action.

When a certificate of need application is for multiple services or multiple components or the proposed project is to be multiphased, the secretary's designee may take individual and different action on separable portions of the proposed project.

(3) Conditional certificate of need.

(a) The secretary's designee in making his or her decision on a certificate of need application may decide to issue a conditional certificate of need if the department finds the project is justified only under specific circumstances: Provided however, That conditions shall relate directly to the project being reviewed and to review criteria.

(b) When the department finds a project for which a certificate of need is to be issued does not satisfy the review criteria set forth in WAC 246-310-210 (1) and (2), the secretary's designee may impose a condition or conditions that the applicant take affirmative steps so as to satisfy those review criteria. In evaluating the accessibility of the project, the current accessibility of the facility as a whole shall be taken into consideration.

(c) The conditions attached to a certificate of need may be released by the secretary's designee upon the request of the health care facility or health maintenance organization for which the certificate of need was issued.

(i) The request must include information needed by the department demonstrating the conditions are no longer valid and the release of such conditions would be consistent with the purpose of chapter 70.38 RCW.

(ii) A request for the removal of a condition must be submitted in accordance with WAC 246-310-090 and will be reviewed in accordance with the regular or expedited review procedures described in WAC 246-310-160 or 246-310-150.

(4) Distribution of written findings and statement of decision.

(a) A copy of the department's written findings and statement of the decision of the secretary's designee on a certificate of need application shall be sent to:

(i) The person submitting the certificate of need application;

(ii) In the case of a project proposed by a health maintenance organization, the appropriate regional office of the United States Department of Health and Human Services; and

(iii) When the secretary's designee issues a certificate of need for a project which does not satisfy the review criteria set forth in WAC 246-310-210 (1) and (2), the appropriate regional office of the Department of Health and Human Services.

(b) The written findings and statement of the decision of the secretary's designee on a certificate of need application shall be available to others requesting the certificate of need unit to provide access to a copy of such findings and statement.

[Statutory Authority: Chapter 70.38 RCW. WSR 96-24-052, § 246-310-490, filed 11/27/96, effective 12/28/96. Statutory Authority: RCW 70.38.135 and 70.38.919. WSR 92-02-018 (Order 224), § 246-310-490, filed 12/23/91, effective 1/23/92. Statutory Authority: RCW 43.70.040. WSR 91-02-049 (Order 121), recodified as § 246-310-490, filed 12/27/90, effective 1/31/91. Statutory Authority: RCW 70.38.135. WSR 86-06-030 (Order 2344), § 248-19-420, filed 2/28/86; WSR 81-09-012 (Order 210), § 248-19-420, filed 4/9/81, effective 5/20/81. Statutory Authority: Chapter 70.38 RCW. WSR 79-12-079 (Order 188), § 248-19-420, filed 11/30/79.]

WAC 246-310-500 Issuance, suspension, denial, revocation, and transfer of a certificate of need. (1) The secretary's designee shall issue a certificate of need to the applicant.

(a) The secretary's designee shall issue a certificate of need for:

(i) The proposed project, or

(ii) A separable portion of the proposed project.

(b) When the certificate of need is issued for a separable portion of the proposed project, the secretary's designee shall provide written notice to the applicant stating the reasons for the department's action.

(c) The secretary's designee shall issue a certificate of need only when the department finds that the project or the separable portion of the proposed project is consistent with the applicable criteria contained in chapter 246-310 WAC.

(d) In issuing a certificate of need, the secretary's designee shall:

(i) Specify the maximum capital expenditure which may be obligated under the certificate, and

(ii) Prescribe the cost components to be included in determining the capital expenditure which may be obligated under such certificate.

(2) The secretary's designee may issue a conditional certificate of need for a proposed project or a separable portion of the proposed project.

(a) The conditions attached to a certificate of need must directly relate to the project being reviewed.

(b) The conditions must directly relate to criteria contained in chapter 246-310 WAC.

(3) The department shall apply the following provisions when suspending a certificate of need.

(a) The secretary's designee may suspend a certificate of need for cause which shall include, but not be limited to:

(i) Suspicion of fraud,

(ii) Misrepresentation,

(iii) False statements,

(iv) Misleading statements,

(v) Evasion or suppression of material fact in the application for a certificate of need or any of its supporting materials.

(b) The secretary's designee shall issue an order which states the reason for any suspension of a certificate of need to the person to whom the certificate of need had been issued.

(c) A suspension of a certificate of need shall not exceed one hundred twenty calendar days.

(i) Prior to the expiration of the suspension the department shall:

(A) Review the facts and circumstances relevant to the suspension;

(B) Reinstate, amend, or revoke the certificate of need; and,

(ii) Send written notice of its decision on a suspended certificate of need to the person to whom the certificate of need had been issued.

(4) The secretary's designee shall send written notification of denial of a certificate of need to the applicant submitting the certificate of need application stating the reasons for the denial.

(5) When a proposed project or separable portion of the proposed project is denied a certificate of need, the department shall not accept another certificate of need application for the same project or separable portion unless the department determines:

(a) There is a substantial change in existing or proposed health facilities or services in the area to be served by the project; or

(b) There is a substantial change in the need for the facilities or services of the type proposed in the area to be served by the project; or

(c) One year has lapsed since the submission of the application for the certificate of need subject to regular review which was denied or the next scheduled concurrent review cycle permits the submission of applications.

(6) The department shall apply the following provisions in the revocation of a certificate of need.

(a) The secretary's designee may revoke a certificate of need for cause which shall include the following:

(i) Fraud,

(ii) Misrepresentation,

(iii) False statements,

(iv) Misleading statements, and

(v) Evasion or suppression of material facts in the application of a certificate of need, or in any of its supporting materials.

(b) When the secretary's designee revokes a certificate of need, the secretary's designee shall provide written notice of revocation to the person to whom the certificate of need was issued, including a statement of the reasons for such revocation.

(7) The department shall apply the following procedures in transferring or assigning a certificate of need.

(a) The department shall consider a request to transfer or assign a certificate of need valid only when:

(i) The person to whom the certificate of need was originally issued, or personal representative, where the holder is deceased, submits to the department a written request that the certificate of need be transferred to another person and gives the full name and complete address of the other person; and

(ii) The person to whom the current holder of the certificate of need wishes to transfer the certificate sends an application for such

transfer on a form and in such a manner as prescribed and published by the department.

(b) The department shall review applications for transfer or assignment of a certificate of need according to the:

(i) Expedited review procedures in WAC 246-310-150; or

(ii) Regular review procedures in WAC 246-310-160.

(c) The secretary's designee shall base his or her decision to approve or deny an application to transfer or assign a certificate of need on:

(i) The demonstrated ability of the person wishing to acquire the certificate of need to undertake, complete, and operate the project in accordance with the following review criteria:

(A) WAC 246-310-220 (1) and (3), and

(B) WAC 246-310-230 (1), (3), and (5).

(ii) The continuing conformance of the project with all other applicable review criteria.

(d) When the person submitting an application to transfer or assign a certificate of need proposes to modify the project description or the maximum capital expenditure, the department shall inform in writing such person that a new or amended certificate of need is required.

(e) When the department denies an application for transfer or assignment of a certificate of need, the department shall inform in writing the person who submitted the application of the reasons for such denial.

(f) The department shall not transfer or assign any certificate of need issued after February 1, 1988, except when:

(i) Prior to completion of the project, death or divorce of one or more persons holding a certificate renders it impossible or impractical to complete the project in the absence of a transfer or assignment; or

(ii) After commencement, a substantial portion of the project has been completed by the original holder of the certificate.

(g) The department shall not transfer or assign a certificate of need under subsection (7)(f)(i) and (ii) of this section when the authorized project is to be relocated.

(h) When the department transfers a certificate of need for a project which has not been commenced, the transferred certificate of need shall have a validity period of two years from the date of issue with the provision for one six-month extension if the holder can demonstrate to the satisfaction of the secretary's designee that substantial and continuing progress towards commencement has been made.

[Statutory Authority: Chapter 70.38 RCW. WSR 96-24-052, § 246-310-500, filed 11/27/96, effective 12/28/96. Statutory Authority: RCW 70.38.135. WSR 91-05-093 (Order 143), § 246-310-500, filed 2/20/91, effective 3/23/91. Statutory Authority: RCW 43.70.040. WSR 91-02-049 (Order 121), recodified as § 246-310-500, filed 12/27/90, effective 1/31/91. Statutory Authority: RCW 70.38.115. WSR 89-02-040 (Order 2745), § 248-19-440, filed 12/30/88. Statutory Authority: RCW 70.38.135. WSR 86-06-030 (Order 2344), § 248-19-440, filed 2/28/86; WSR 81-09-012 (Order 210), § 248-19-440, filed 4/9/81, effective 5/20/81. Statutory Authority: Chapter 70.38 RCW. WSR 79-12-079 (Order 188), § 248-19-440, filed 11/30/79.]

WAC 246-310-560 Provision for reconsideration decision. (1) Any interested or affected person may, for good cause shown, request a public hearing for the purpose of reconsideration of the decision of the secretary's designee on a certificate of need application or withdrawal of a certificate of need.[1]

(2) The department shall conduct a reconsideration hearing if it finds the request is in accord with the following requirements:

(a) The request for a reconsideration hearing shall be written, be received by the department within twenty-eight days of the department's decision on the certificate of need application or withdrawal of the certificate of need, state in detail the grounds which the person requesting the hearing believes to show good cause, and be signed by the person making the request.

(b) Grounds which the department may deem to show good cause for a reconsideration hearing shall include but not be limited to the following:

(i) Significant relevant information not previously considered by the department which, with reasonable diligence, could not have been presented before the department made its decision;

(ii) Information on significant changes in factors or circumstances relied upon by the department in making its findings and decision; or

(iii) Evidence the department materially failed to follow adopted procedures in reaching a decision.

(3) Scheduling of a reconsideration hearing shall occur within thirty days after receipt of an approved request for a hearing.

(4) Notification of a public reconsideration hearing on a certificate of need application or withdrawal of a certificate of need shall be sent prior to the date of such hearing by the department to the following:

(a) The person requesting the reconsideration hearing;

(b) The person submitting the certificate of need application which is under reconsideration or the holder of the certificate of need;

(c) Health care facilities and health maintenance organizations located in the health service area where the project is proposed to be located providing services similar to the services under review;

(d) In the case of a concurrent review, other applicants competing as described in WAC 246-310-080; and to

(e) Other persons requesting the department to send them such notification.

(5) The department shall, within forty-five days after the conclusion of a reconsideration hearing, make written findings stating the basis of the decision made after such hearing.

(6) The secretary's designee may, upon the basis of the department's findings on a reconsideration hearing, issue or reissue, amend, revoke, or withdraw a certificate of need or impose or modify conditions on a certificate of need for the project about which the reconsideration hearing was conducted.

(7) An applicant requesting a reconsideration hearing under the provisions of this section does not forfeit his or her rights to an adjudicative appeal under the provisions of WAC 246-310-610.

Note: [1]No fee will be charged for a reconsideration hearing.

[Statutory Authority: Chapter 70.38 RCW. WSR 98-10-053, § 246-310-560, filed 4/29/98, effective 5/30/98; WSR 96-24-052, § 246-310-560, filed

11/27/96, effective 12/28/96. Statutory Authority: RCW 70.38.135 and 70.38.919. WSR 92-02-018 (Order 224), § 246-310-560, filed 12/23/91, effective 1/23/92. Statutory Authority: RCW 43.70.040. WSR 91-02-049 (Order 121), recodified as § 246-310-560, filed 12/27/90, effective 1/31/91. Statutory Authority: RCW 70.38.135. WSR 86-06-030 (Order 2344), § 248-19-430, filed 2/28/86; WSR 81-09-012 (Order 210), § 248-19-430, filed 4/9/81, effective 5/20/81. Statutory Authority: Chapter 70.38 RCW. WSR 79-12-079 (Order 188), § 248-19-430, filed 11/30/79.]

WAC 246-310-570 Circumstances for which an amended certificate of need is required. (1) An amended certificate of need shall be required for any of the following modifications of a project for which a certificate of need was issued and has been submitted in accordance with subsection (2) of this section:

(a) An addition of a new service;

(b) An expansion of a service beyond that which was included in the certificate of need application on which the issuance of the certificate of need was based;

(c) An increase in the inpatient bed capacity;

(d) The modification or release of a condition placed on a certificate of need;

(e) A significant reduction in the scope of a project for which a certificate of need has been issued without a commensurate reduction in the cost of the project, or the project cost increases (as represented in bids on a construction project or final cost estimate or estimates acceptable to the person to whom the certificate of need was issued) when the total of such increases exceeds twelve percent or fifty thousand dollars, whichever is greater, over the maximum capital expenditure specified by the secretary's designee in issuing the certificate of need: Provided however, That the review of such reductions or cost increases shall be restricted to the continued conformance of the project with the criteria contained in WAC 246-310-220 and 246-310-240; or

(f) A change in the approved site.

(2) An application to amend a certificate of need shall be submitted and the certificate of need will be issued or denied prior to project completion except for projects involving construction. For projects involving construction, an amendment application may be submitted up to ninety days after project completion provided the applicant meets the following eligibility requirements:

(a) Eligibility requirements for a ninety-day extension to submit an application to amend a certificate of need.

(i) The applicant has submitted quarterly reports and updated the capital expenditures as required in WAC 246-310-590;

(ii) The quarterly progress reports identified that the actual construction costs had exceeded twelve percent or fifty thousand dollars (whichever is greater) of the approved capital expenditure; and

(iii) The department did not notify the applicant in writing that an amended certificate of need was needed.

(b) In the event the applicant has submitted quarterly progress reports as identified in (a)(i) of this subsection and the reports did not reflect that the actual construction costs had exceeded the approved capital expenditure, the applicant would only be eligible for a ninety-day extension if the applicant can document:

(i) All costs in excess of twelve percent or fifty thousand dollars (whichever is greater) of the approved capital expenditure were totally unforeseen as documented by a signed affidavit from the contractor; and

(ii) That all the excess costs were incurred after the submission of the last quarterly progress report preceding the projects' completion.

(3) An application for an amended certificate of need shall be submitted in accordance with the provisions of WAC 246-310-090.

(4) An application for an amended certificate of need may be reviewed under the expedited review process set forth in WAC 246-310-150.

(5) The department shall provide a written determination as to the requirement for an amended certificate of need within twenty-one days after receipt of a request for such determination.

[Statutory Authority: Chapter 70.38 RCW. WSR 96-24-052, § 246-310-570, filed 11/27/96, effective 12/28/96. Statutory Authority: RCW 70.38.135 and 70.38.919. WSR 92-02-018 (Order 224), § 246-310-570, filed 12/23/91, effective 1/23/92. Statutory Authority: RCW 43.70.040. WSR 91-02-049 (Order 121), recodified as § 246-310-570, filed 12/27/90, effective 1/31/91. Statutory Authority: RCW 70.38.135. WSR 86-06-030 (Order 2344), § 248-19-450, filed 2/28/86; WSR 81-09-012 (Order 210), § 248-19-450, filed 4/9/81, effective 5/20/81. Statutory Authority: Chapter 70.38 RCW. WSR 79-12-079 (Order 188), § 248-19-450, filed 11/30/79.]

WAC 246-310-580 Validity and extensions. (1) A certificate of need shall be valid for two years: Provided, That one six-month extension may be made if the certificate holder can demonstrate that substantial and continuing progress toward commencement of the project has been made.

(2) In the case of a project involving construction, substantial and continuing progress shall include one of the following:

(a) When review and approval by the department of the final plans for construction is required, the submission of working drawings;

(b) When plan approval is not required by the department, receipt of copies of the working drawings for construction; or

(c) In the event working drawings have not been submitted, the applicant must demonstrate that he or she has made continuous progress toward commencement of the project.

(3) A project for which a certificate of need has been issued shall be commenced during the validity period for the certificate of need.

(4) Applications for extensions of the validity period of certificates of need shall be submitted to the department at least one hundred twenty calendar days before the expiration of the certificate of need, and shall contain such information as may be required by the department to determine the extent of progress toward commencement of construction or other action necessary to a project.

(5) An application for an extension of a certificate of need submitted less than one hundred twenty calendar days before the expiration of the certificate of need shall not be reviewed, unless the applicant can demonstrate to the satisfaction of the department unforeseen occurrences during the last one hundred twenty days of the valid-

ity period of the certificate of need prevented commencement of construction as previously anticipated by the applicant.

(6) Commencement of the project shall not be undertaken after the expiration of the certificate of need unless a new certificate of need application has been reviewed and a new certificate of need has been issued by the secretary's designee.

(7)(a) In the case of a request by a nursing home to extend its conversion rights to beds banked under the provisions of RCW 70.38.111(8) for an additional four years, the nursing home must meet the following requirements:

(i) The request shall be made a minimum ninety days prior to the end of the four-year validity period of the original bed banking request.

(ii) The nursing home shall demonstrate it has complied with the applicable notification requirements under WAC 246-310-395;

(iii) The nursing home has and is currently meeting the exemption requirements in WAC 246-310-043; and

(iv) The nursing home has implemented the alternative service or services identified in the bed banking request. If the service or services have not been implemented, an explanation of why such services have not been implemented and rationale for why the department should grant its extension request.

(b) The department shall notify the nursing home within thirty days of the extension request as to whether an extension of the nursing home's conversion rights is recognized. The nursing home does not forfeit its right to extend its conversion rights under this section if the department does not respond within this time frame, nor does the nursing home obtain rights that it otherwise would not have under applicable statutes or rules if the department does not respond within the time frame.

[Statutory Authority: Chapter 70.38 RCW. WSR 96-24-052, § 246-310-580, filed 11/27/96, effective 12/28/96. Statutory Authority: RCW 43.70.040. WSR 91-02-049 (Order 121), recodified as § 246-310-580, filed 12/27/90, effective 1/31/91. Statutory Authority: RCW 70.38.135. WSR 86-06-030 (Order 2344), § 248-19-460, filed 2/28/86. Statutory Authority: Chapter 70.38 RCW. WSR 79-12-079 (Order 188), § 248-19-460, filed 11/30/79.]

WAC 246-310-590 Monitoring of approved projects. (1) The department shall monitor the costs and components of approved projects to assure conformance with certificates of need that have been issued.

(2) The department shall require periodic progress reports from those applicants to whom certificates of need have been issued.

(a) Progress reports shall be required quarterly.

(b) Progress reports shall be submitted in the form and manner prescribed and published by the department.

(3) Information required on approved projects may include:

(a) Actual project costs;

(b) Changes in the project;

(c) Financing arrangements, different than approved under the certificate of need;

(d) Project commencement date;

(e) Progress toward completion of construction; and

(f) Project completion date.

(4) The information required on approved projects may vary according to the nature of the projects.

(5) Progress reports on a project for which a particular certificate of need has been issued shall terminate when the project has been completed and the department finds it has received all the information necessary to determine the project has been completed in accordance with the certificate of need which had been issued and the provisions of chapter 246-310 WAC.

[Statutory Authority: Chapter 70.38 RCW. WSR 96-24-052, § 246-310-590, filed 11/27/96, effective 12/28/96. Statutory Authority: RCW 70.38.135 and 70.38.919. WSR 92-02-018 (Order 224), § 246-310-590, filed 12/23/91, effective 1/23/92. Statutory Authority: RCW 43.70.040. WSR 91-02-049 (Order 121), recodified as § 246-310-590, filed 12/27/90, effective 1/31/91. Statutory Authority: RCW 70.38.135. WSR 86-06-030 (Order 2344), § 248-19-470, filed 2/28/86. Statutory Authority: Chapter 70.38 RCW. WSR 79-12-079 (Order 188), § 248-19-470, filed 11/30/79.]

WAC 246-310-600 Withdrawal of a certificate of need. (1) The secretary's designee may withdraw a certificate of need if the department determines that the holder of a certificate is not meeting the timetable specified in the certificate of need application for completing the project and is not making a good-faith effort to meet such timetable.

(2) In reviewing a proposed withdrawal of a certificate of need, the department shall adhere to the provisions of WAC 246-310-170, 246-310-180, 246-310-190, and 246-310-560.

(3) The review period for a proposed withdrawal of a certificate of need shall not exceed ninety days unless extended by the department to allow sufficient time for the conduct of a public hearing pursuant to the provisions of WAC 246-310-180. Such extension shall not exceed thirty days.

(4) The findings of the department's review of a proposed withdrawal of a certificate of need shall be stated in writing and include the basis for the decision of the secretary's designee as to whether the certificate of need is to be withdrawn for a proposed project. A copy of the department's written findings and statement of the decision of the secretary's designee on the proposed withdrawal of a certificate of need shall be sent to:

(a) The holder of the certificate of need;

(b) In the case of a project proposed by a health maintenance organization, the appropriate regional office of the United States Department of Health and Human Services.

(5) The written findings and statement of the decision of the secretary's designee on the proposed withdrawal of a certificate of need shall be available to others requesting the certificate of need unit to provide access to a copy of such findings and statement.

(6) When a certificate of need is for multiple services or multiple components or the proposed project is to be multiphased, the secretary's designee may take individual and different action regarding withdrawal of the certificate of need on separable portions of the certificate of need.

[Statutory Authority: Chapter 70.38 RCW. WSR 96-24-052, § 246-310-600, filed 11/27/96, effective 12/28/96. Statutory Authority: RCW 70.38.135

and 70.38.919. WSR 92-02-018 (Order 224), § 246-310-600, filed 12/23/91, effective 1/23/92. Statutory Authority: RCW 43.70.040. WSR 91-02-049 (Order 121), recodified as § 246-310-600, filed 12/27/90, effective 1/31/91. Statutory Authority: RCW 70.38.135. WSR 86-06-030 (Order 2344), § 248-19-475, filed 2/28/86; WSR 81-09-012 (Order 210), § 248-19-475, filed 4/9/81, effective 5/20/81.]

WAC 246-310-610 Adjudicative proceeding. (1) An applicant denied a certificate of need or a certificate holder whose certificate was suspended or revoked has the right to an adjudicative proceeding.

(2) A certificate applicant or holder contesting a department certificate decision shall within twenty-eight days of receipt of the department's decision or reconsidered decision:

(a) File a written application for an adjudicative proceeding by a method showing proof of receipt with the Adjudicative Clerk Office, Department of Health, 2413 Pacific Avenue, P.O. Box 47879, Olympia, WA 98504-7879; and

(b) Include in or with the application:

(i) A specific statement of the issue or issues and law involved;

(ii) The grounds for contesting the department decision; and

(iii) A copy of the contested department decision.

(3) The proceeding is governed by the Administrative Procedure Act (chapter 34.05 RCW), this chapter, and chapter 246-08 WAC. If a provision in this chapter conflicts with chapter 246-08 WAC, the provision in this chapter governs.

(4) Any health care facility or health maintenance organization that:

(a) Provides services similar to the services provided by the applicant and under review pursuant to this subsection;

(b) Is located within the applicant's health service area; and

(c) Testified or submitted evidence at a public hearing held pursuant to RCW 70.38.115(9), shall be provided an opportunity to present oral or written testimony and argument in a proceeding under RCW 70.38.115 (10)(a) provided that the health care facility or health maintenance organization had, in writing, requested to be informed of the department's decision. If the department desires to settle with the applicant prior to the conclusion of the adjudicative proceeding, the department shall so inform the health care facility or health maintenance organization and afford them the opportunity to comment, in advance, on the proposed settlement.

[Statutory Authority: Chapter 70.38 RCW. WSR 98-10-053, § 246-310-610, filed 4/29/98, effective 5/30/98; WSR 96-24-052, § 246-310-610, filed 11/27/96, effective 12/28/96. Statutory Authority: RCW 70.38.135 and 70.38.919. WSR 92-02-018 (Order 224), § 246-310-610, filed 12/23/91, effective 1/23/92. Statutory Authority: RCW 43.70.040. WSR 91-02-049 (Order 121), recodified as § 246-310-610, filed 12/27/90, effective 1/31/91. Statutory Authority: Chapter 34.05 RCW, RCW 34.05.220 (1)(a), 70.38.135 and 1989 1st ex.s. c 9 § 607. WSR 90-06-019 (Order 039), § 248-19-480, filed 2/28/90, effective 3/1/90. Statutory Authority: RCW 70.38.135. WSR 86-06-030 (Order 2344), § 248-19-480, filed 2/28/86; WSR 82-19-055 (Order 244), § 248-19-480, filed 9/15/82; WSR 81-09-012 (Order 210), § 248-19-480, filed 4/9/81, effective 5/20/81. Statutory Authority: Chapter 70.38 RCW. WSR 79-12-079 (Order 188), § 248-19-480, filed 11/30/79.]

WAC 246-310-700 Adult elective percutaneous coronary interventions (PCI) without on-site cardiac surgery. Purpose and applicability of chapter. Adult elective percutaneous coronary interventions are tertiary services as listed in WAC 246-310-020. To be granted a certificate of need, an adult elective PCI program must meet the standards in this section and WAC 246-310-715, 246-310-720, 246-310-725, 246-310-730, 246-310-735, 246-310-740, and 246-310-745 in addition to applicable review criteria in WAC 246-310-210, 246-310-220, 246-310-230, and 246-310-240. This chapter is adopted by the Washington state department of health to implement chapter 70.38 RCW and establish minimum requirements for obtaining a certificate of need and operating an elective PCI program.

[Statutory Authority: RCW 70.38.128. WSR 09-01-113, § 246-310-700, filed 12/19/08, effective 12/19/08.]

WAC 246-310-705 PCI definitions. For the purposes of this chapter and chapter 70.38 RCW, the words and phrases below will have the following meanings unless the context clearly indicates otherwise:

(1) "Concurrent review" means the process by which applications competing to provide services in the same planning area are reviewed simultaneously by the department. The department compares the applications to one another and these rules.

(2) "Elective" means a PCI performed on a patient with cardiac function that has been stable in the days or weeks prior to the operation. Elective cases are usually scheduled at least one day prior to the surgical procedure.

(3) "Emergent" means a patient needs immediate PCI because, in the treating physician's best clinical judgment, delay would result in undue harm or risk to the patient.

(4) "Percutaneous coronary interventions (PCI)" means invasive but nonsurgical mechanical procedures and devices that are used by cardiologists for the revascularization of obstructed coronary arteries. These interventions include, but are not limited to:

(a) Bare and drug-eluting stent implantation;

(b) Percutaneous transluminal coronary angioplasty (PTCA);

(c) Cutting balloon atherectomy;

(d) Rotational atherectomy;

(e) Directional atherectomy;

(f) Excimer laser angioplasty;

(g) Extractional thrombectomy.

(5) "PCI planning area" means an individual geographic area designated by the department for which adult elective PCI program need projections are calculated. For purposes of adult elective PCI projections, planning area and service area have the same meaning. The following table establishes PCI planning areas for Washington state:

Planning Areas: Planning areas that utilize zip codes will be administratively updated upon a change by the United States Post Office, and are available upon request.	
1.	Adams, Ferry, Grant, Lincoln, Pend Oreille, Spokane, Stevens, Whitman, Asotin
2.	Benton, Columbia, Franklin, Garfield, Walla Walla
3.	Chelan, Douglas, Okanogan

Planning Areas: Planning areas that utilize zip codes will be administratively updated upon a change by the United States Post Office, and are available upon request.	
4.	Kittitas, Yakima, Klickitat East (98620, 99356, 99322)
5.	Clark, Cowlitz, Skamania, Wahkiakum, Klickitat West (98650, 98619, 98672, 98602, 98628, 98635, 98617, 98613)
6.	Grays Harbor, Lewis, Mason, Pacific, Thurston
7.	Pierce East (98304, 98321, 98323, 98328, 98330, 98338, 98360, 98371, 98372, 98373, 98374, 98375, 98387, 98390, 98391, 98443, 98445, 98446, 98580)
8.	Pierce West (98303, 98327, 98329, 98332, 98333, 98335, 98349, 98351, 98354, 98388, 98394, 98402, 98403, 98404, 98405, 98406, 98407, 98408, 98409, 98416, 98418, 98421, 98422, 98424, 98430, 98433, 98438, 98439, 98444, 98447, 98465, 98466, 98467, 98498, 98499)
9.	King East (98001, 98002, 98003, 98004, 98005, 98006, 98007, 98008, 98010, 98011, 98014, 98019, 98022, 98023, 98024, 98027, 98028, 98029, 98030, 98031, 98032, 98033, 98034, 98038, 98039, 98042, 98045, 98047, 98051, 98052, 98053, 98055, 98056, 98057, 98058, 98059, 98065, 98072, 98074, 98075, 98077, 98092, 98224, 98288)
10.	King West (98040, 98070, 98101, 98102, 98103, 98104, 98105, 98106, 98107, 98108, 98109, 98112, 98115, 98116, 98117, 98118, 98119, 98121, 98122, 98125, 98126, 98133, 98134, 98136, 98144, 98146, 98148, 98155, 98158, 98166, 98168, 98177, 98178, 98188, 98195, 98198, 98199)
11.	Snohomish
12.	Skagit, San Juan, Island
13.	Kitsap, Jefferson, Clallam
14.	Whatcom

[Statutory Authority: RCW 70.38.128. WSR 09-01-113, § 246-310-705, filed 12/19/08, effective 12/19/08.]

WAC 246-310-710 Concurrent review. The department shall review new adult elective percutaneous coronary intervention (PCI) services using the concurrent review cycle according to the following table:

Concurrent Review Cycle:

Application Submission Period	Letters of Intent Due	First working day through last working day of January of each year.
	Receipt of Initial Application	First working day through last working day of February of each year.
	End of Screening Period	Last working day of March of each year.
	Applicant Response	Last working day of April of each year.

Department Action	Beginning of Review Preparation	May 1 through May 15	
Application Review Period	Public Comment Period (includes public hearing if requested)	60-Day Public Comment Period	Begins May 16 of each year or the first working day after May 16.
	Rebuttal Period	30-Day Rebuttal period	Applicant and affected party response to public comment.
	Ex parte Period	45-Day Ex parte period	Department evaluation and decision.

(1) If the department is unable to meet the deadline for making a decision on the application, it will notify applicants fifteen days prior to the scheduled decision date. In that event, the department will establish a new decision date.

(2) The department may not accept new applications for a planning area if there are any pending applications in that planning area filed under a previous concurrent review cycle, or applications submitted prior to the effective date of these rules that affect any of the new planning areas, unless the department has not made a decision on the pending applications within the review timelines of nine months for a concurrent review and six months for a regular review.

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

[Statutory Authority: RCW 70.38.128. WSR 09-01-113, § 246-310-710, filed 12/19/08, effective 12/19/08.]

WAC 246-310-715 General requirements. The applicant hospital must:

(1) Submit a detailed analysis of the impact that their new adult elective PCI services will have on the Cardiovascular Disease and Interventional Cardiology Fellowship Training programs at the University of Washington, and allow the university an opportunity to respond. New programs may not reduce current volumes at the University of Washington fellowship training program.

(2) Submit a detailed analysis of the projected volume of adult elective PCIs that it anticipates it will perform in years one, two and three after it begins operations. All new elective PCI programs must comply with the state of Washington annual PCI volume standards of (two hundred) by the end of year three. The projected volumes must be sufficient to assure that all physicians working only at the applicant hospital will be able to meet volume standards of fifty PCIs per year. If an applicant hospital fails to meet annual volume standards, the department may conduct a review of certificate of need approval for the program under WAC 246-310-755.

(3) Submit a plan detailing how they will effectively recruit and staff the new program with qualified nurses, catheterization laboratory technicians, and interventional cardiologists without negatively affecting existing staffing at PCI programs in the same planning area.

(4) Maintain one catheterization lab used primarily for cardiology. The lab must be a fully equipped cardiac catheterization laboratory with all appropriate devices, optimal digital imaging systems, life sustaining apparati, intra-aortic balloon pump assist device (IABP). The lab must be staffed by qualified, experienced nursing and technical staff with documented competencies in the treatment of acutely ill patients.

(5) Be prepared and staffed to perform emergent PCIs twenty-four hours per day, seven days per week in addition to the scheduled PCIs.

(6) If an existing CON approved heart surgery program relinquishes the CON for heart surgery, the facility must apply for an amended CON to continue elective PCI services. The applicant must demonstrate ability to meet the elective PCI standards in this chapter.

[Statutory Authority: RCW 70.38.135 and 70.38.115. WSR 18-07-102, § 246-310-715, filed 3/20/18, effective 4/20/18. Statutory Authority: RCW 70.38.128. WSR 09-01-113, § 246-310-715, filed 12/19/08, effective 12/19/08.]

WAC 246-310-720 Hospital volume standards. (1) Hospitals with an elective PCI program must perform a minimum of two hundred adult PCIs per year by the end of the third year of operation and each year thereafter.

(2) The department shall only grant a certificate of need to new programs within the identified planning area if:

(a) The state need forecasting methodology projects unmet volumes sufficient to establish one or more programs within a planning area; and

(b) All existing PCI programs in that planning area are meeting or exceeding the minimum volume standard.

[Statutory Authority: RCW 70.38.135 and 70.38.115. WSR 18-07-102, § 246-310-720, filed 3/20/18, effective 4/20/18. Statutory Authority: RCW 70.38.128. WSR 09-01-113, § 246-310-720, filed 12/19/08, effective 12/19/08.]

WAC 246-310-725 Physician volume standards. Physicians performing adult elective PCI procedures at the applying hospital must perform a minimum of fifty PCIs per year. Applicant hospitals must provide documentation that physicians performed fifty PCI procedures per year for the previous three years prior to the applicant's CON request.

[Statutory Authority: RCW 70.38.135 and 70.38.115. WSR 18-07-102, § 246-310-725, filed 3/20/18, effective 4/20/18. Statutory Authority: RCW 70.38.128. WSR 09-01-113, § 246-310-725, filed 12/19/08, effective 12/19/08.]

WAC 246-310-730 Staffing requirements. The applicant hospital must:

(1) Employ a sufficient number of properly credentialed physicians so that both emergent and elective PCIs can be performed.

(2) Staff its catheterization laboratory with a qualified, trained team of technicians experienced in interventional lab procedures.

(a) Nursing staff should have coronary care unit experience and have demonstrated competency in operating PCI related technologies.

(b) Staff should be capable of endotracheal intubation and ventilator management both on-site and during transfer if necessary.

[Statutory Authority: RCW 70.38.128. WSR 09-01-113, § 246-310-730, filed 12/19/08, effective 12/19/08.]

WAC 246-310-735 Partnering agreements. The applicant hospital must have a signed written agreement with a hospital providing on-site cardiac surgery. This agreement must include, at minimum, provisions for:

(1) Coordination between the nonsurgical hospital and surgical hospital's availability of surgical teams and operating rooms. The hospital with on-site surgical services is not required to maintain an available surgical suite twenty-four hours, seven days a week.

(2) Assurance the backup surgical hospital can provide cardiac surgery during all hours that elective PCIs are being performed at the applicant hospital.

(3) Transfer of all clinical data, including images and videos, with the patient to the backup surgical hospital.

(4) Communication by the physician(s) performing the elective PCI to the backup hospital cardiac surgeon(s) about the clinical reasons for urgent transfer and the patient's clinical condition.

(5) Acceptance of all referred patients by the backup surgical hospital.

(6) The applicant hospital's mode of emergency transport for patients requiring urgent transfer. The hospital must have a signed transportation agreement with a vendor who will expeditiously transport by air or land all patients who experience complications during elective PCIs that require transfer to a backup hospital with on-site cardiac surgery.

(7) Emergency transportation beginning within twenty minutes of the initial identification of a complication.

(8) Evidence that the emergency transport staff are certified. These staff must be advanced cardiac life support (ACLS) certified and have the skills, experience, and equipment to monitor and treat the patient en route and to manage an intra-aortic balloon pump (IABP).

(9) The hospital documenting the transportation time from the decision to transfer the patient with an elective PCI complication to arrival in the operating room of the backup hospital. Transportation time must be less than one hundred twenty minutes.

(10) At least two annual timed emergency transportation drills with outcomes reported to the hospital's quality assurance program.

(11) Patient signed informed consent for adult elective (and emergent) PCIs. Consent forms must explicitly communicate to the patients that the intervention is being performed without on-site surgery backup and address risks related to transfer, the risk of urgent surgery, and the established emergency transfer agreements.

(12) Conferences between representatives from the heart surgery program(s) and the elective coronary intervention program. These conferences must be held at least quarterly, in which a significant num-

ber of preoperative and post-operative cases are reviewed, including all transport cases.

(13) Addressing peak volume periods (such as joint agreements with other programs, the capacity to temporarily increase staffing, etc.).

[Statutory Authority: RCW 70.38.128. WSR 09-01-113, § 246-310-735, filed 12/19/08, effective 12/19/08.]

WAC 246-310-740 Quality assurance. The applicant hospital must submit a written quality assurance/quality improvement plan specific to the elective PCI program as part of its application. At minimum, the plan must include:

(1) A process for ongoing review of the outcomes of adult elective PCIs. Outcomes must be benchmarked against state or national quality of care indicators for elective PCIs.

(2) A system for patient selection that results in outcomes that are equal to or better than the benchmark standards in the applicant's plan.

(3) A process for formalized case reviews with partnering surgical backup hospital(s) of preoperative and post-operative elective PCI cases, including all transferred cases.

(4) A description of the hospital's cardiac catheterization laboratory and elective PCI quality assurance reporting processes for information requested by the department or the department's designee. The department of health does not intend to require duplicative reporting of information.

[Statutory Authority: RCW 70.38.128. WSR 09-01-113, § 246-310-740, filed 12/19/08, effective 12/19/08.]

WAC 246-310-745 Need forecasting methodology. For the purposes of the need forecasting method in this section, the following terms have the following specific meanings:

(1) "Base year" means the most recent calendar year for which December 31 data is available as of the first day of the application submission period from the department's CHARS reports or successor reports.

(2) "Current capacity" means the sum of all PCIs performed on people (aged fifteen years of age and older) by all certificate of need approved adult elective PCI programs, or department grandfathered programs within the planning area. To determine the current capacity for those planning areas where a new program has operated less than three years, the department will measure the volume of that hospital as the greater of:

(a) The actual volume; or

(b) The minimum volume standard for an elective PCI program established in WAC 246-310-720.

(3) "Forecast year" means the fifth year after the base year.

(4) "Percutaneous coronary interventions" means cases as defined by diagnosis related groups (DRGs) as developed under the Centers for Medicare and Medicaid Services (CMS) contract that describe catheter-based interventions involving the coronary arteries and great arteries of the chest. The department will exclude all pediatric catheter-based therapeutic and diagnostic interventions performed on persons fourteen

years of age and younger are excluded. The department will update the list of DRGs administratively to reflect future revisions made by CMS to the DRG to be considered in certificate of need definitions, analyses, and decisions. The DRGs for calendar year 2008 applications will be DRGs reported in 2007, which include DRGs 518, 555, 556, 557 and 558.

(5) "Use rate" or "PCI use rate," equals the number of PCIs performed on the residents of a planning area (aged fifteen years of age and older), per one thousand persons.

(6) "Grandfathered programs" means those hospitals operating a certificate of need approved interventional cardiac catheterization program or heart surgery program prior to the effective date of these rules, that continue to operate a heart surgery program. For hospitals with jointly operated programs, only the hospital where the program's procedures were approved to be performed may be grandfathered.

(7) The data sources for adult elective PCI case volumes include:

(a) The comprehensive hospital abstract reporting system (CHARS) data from the department, office of hospital and patient data;

(b) The department's office of certificate of need survey data as compiled, by planning area, from hospital providers of PCIs to state residents (including patient origin information, i.e., patients' zip codes and a delineation of whether the PCI was performed on an inpatient or outpatient basis); and

(c) Clinical outcomes assessment program (COAP) data from the foundation for health care quality, as provided by the department.

(8) The data source for population estimates and forecasts is the office of financial management medium growth series population trend reports or if not available for the planning area, other population data published by well-recognized demographic firms.

(9) The data used for evaluating applications submitted during the concurrent review cycle must be the most recent year end data as reported by CHARS or the most recent survey data available through the department or COAP data for the appropriate application year. The forecasts for demand and supply will be for five years following the base year. The base year is the latest year that full calendar year data is available from CHARS. In recognition that CHARS does not currently provide outpatient volume statistics but is patient origin-specific and COAP does provide outpatient PCI case volumes by hospitals but is not currently patient origin-specific, the department will make available PCI statistics from its hospital survey data, as necessary, to bridge the current outpatient patient origin-specific data shortfall with CHARS and COAP.

(10) Numeric methodology:

Step 1. Compute each planning area's PCI use rate calculated for persons fifteen years of age and older, including inpatient and outpatient PCI case counts.

(a) Take the total planning area's base year population residents fifteen years of age and older and divide by one thousand.

(b) Divide the total number of PCIs performed on the planning area residents over fifteen years of age by the result of Step 1 (a). This number represents the base year PCI use rate per thousand.

Step 2. Forecasting the demand for PCIs to be performed on the residents of the planning area.

(a) Take the planning area's use rate calculated in Step 1 (b) and multiply by the planning area's corresponding forecast year population of residents over fifteen years of age.

Step 3. Compute the planning area's current capacity.

(a) Identify all inpatient procedures at certificate of need approved hospitals within the planning area using CHARS data;

(b) Identify all outpatient procedures at certificate of need approved hospitals within the planning area using department survey data; or

(c) Calculate the difference between total PCI procedures by certificate of need approved hospitals within the planning area reported to COAP and CHARS. The difference represents outpatient procedures.

(d) Sum the results of (a) and (b) or sum the results of (a) and (c). This total is the planning area's current capacity which is assumed to remain constant over the forecast period.

Step 4. Calculate the net need for additional adult elective PCI procedures by subtracting the calculated capacity in Step 3 from the forecasted demand in Step 2. If the net need for procedures is less than two hundred, the department will not approve a new program.

Step 5. If Step 4 is greater than two hundred, calculate the need for additional programs.

(a) Divide the number of projected procedures from Step 4 by two hundred.

(b) Round the results down to identify the number of needed programs. (For example: 375/200 = 1.875 or 1 program.)

[Statutory Authority: RCW 70.38.135 and 70.38.115. WSR 18-07-102, § 246-310-745, filed 3/20/18, effective 4/20/18. Statutory Authority: RCW 70.38.128. WSR 09-01-113, § 246-310-745, filed 12/19/08, effective 12/19/08.]

WAC 246-310-750 Tiebreaker. If two or more applicant hospitals are competing to meet the same forecasted net need, the department shall consider which facility's location provides the most improvement in geographic access. Geographic access means the facility that is located the farthest in statue miles from an existing facility authorized to provide PCI procedures.

[Statutory Authority: RCW 70.38.128. WSR 09-01-113, § 246-310-750, filed 12/19/08, effective 12/19/08.]

WAC 246-310-755 Ongoing compliance with standards. If the department issues a certificate of need (CON), it will be conditioned to require ongoing compliance with the CON standards. Failure to meet the standards may be grounds for revocation or suspension of a hospital's CON, or other appropriate licensing or certification actions.

(1) Hospitals granted a certificate of need must meet:

(a) The program procedure volume standards within three years from the date of initiating the program; and

(b) QA standards in WAC 246-310-740.

(2) The department may reevaluate these standards every three years.

[Statutory Authority: RCW 70.38.128. WSR 09-01-113, § 246-310-755, filed 12/19/08, effective 12/19/08.]

WAC 246-310-800 Kidney disease treatment centers——Definitions. The definitions in this section apply to WAC 246-310-800 through 246-310-833, unless the context clearly indicates otherwise:

(1) "Affiliate" or "affiliated" means:

(a) Having at least a ten percent but less than one hundred percent ownership in a kidney dialysis facility;

(b) Having at least a ten percent but less than one hundred percent financial interest in a kidney dialysis facility; or

(c) Three years or more operational management responsibilities for a kidney dialysis facility.

(2) "Base year" means the most recent calendar year for which December 31 data is available as of the letter of intent submission date from the *Northwest Renal Network's Modality Report*.

(3) "Capital expenditures," as defined by *Generally Accepted Accounting Principles* (GAAP), means expenditures made to acquire tangible long-lived assets. Long-lived assets represent property and equipment used in a company's operations that have an estimated useful life greater than one year. Acquired long-lived assets are recorded at acquisition cost and include all costs incurred necessary to bring the asset to working order. Capital expenditure includes:

(a) A force account expenditure or acquisition (i.e., an expenditure for a construction project undertaken by a facility as its own contractor).

(b) The costs of any site planning services (architect or other site planning consultant) including, but not limited to, studies, surveys, designs, plans, working drawings, specifications, and other activities (including applicant staff payroll and employee benefit costs, consulting and other services which, under GAAP or Financial Accounting Standards Board (FASB) may be chargeable as an operating or nonoperating expense).

(c) Construction cost of shelled space.

(d) Building owner tenant improvements including, but not limited to: Asbestos removal, paving, concrete, contractor's general conditions, contractor's overhead and profit, electrical, heating, ventilation and air conditioning systems (HVAC), plumbing, flooring, rough and finish carpentry and millwork and associated labor and materials, and utility fees.

(e) Donations of equipment or facilities to a facility.

(f) Capital expenditures do not include routine repairs and maintenance costs that do not add to the utility of useful life of the asset.

(4) "Concurrent review" means the process by which applications competing to provide services in the same planning area are reviewed simultaneously by the department.

(5) "Dialysis facility report (DFR)" means the kidney dialysis facility reports produced annually for Centers for Medicare and Medicaid Services (CMS). The DFR is provided to individual dialysis facilities and contains summary data on each facility compiled from multiple sources. The DFR facilitates comparison of patient characteristics, treatment patterns, transplantation rates, hospitalization rates, and mortality rates to local and national averages.

(6) "Dialysis facility compare (DFC) report" means the kidney dialysis facility compare quarterly report that is produced by CMS and posted on the medicare DFC website. This report provides information about statistically measurable practice patterns in kidney disease

treatment facilities including, but not limited to, mortality, hospitalization, late shifts, and availability of home training.

(7) "End-of-year data" means data contained in the fourth quarter modality report or successor report from the Northwest Renal Network.

(8) "End-of-year in-center patients" means the number of in-center hemodialysis (HD) and self-dialysis training patients receiving in-center kidney dialysis at the end of the calendar year based on end-of-year data.

(9) "Exempt isolation station" means one certificate of need approved certified station per facility dedicated to patients requiring medically necessary isolation. This station may not be used for nonisolation treatments. This one approved station is included in the kidney dialysis facility's total CMS certified station count. However, for purposes of certificate of need, this one isolation station is not included in the facility's station count for projecting future station need or in calculating existing station use. Providers may operate more than one isolation station, but only one is excluded from the facility's station count for purposes of projecting future station need and in calculating existing station use.

(10) "Kidney disease treatment center" or "kidney dialysis facility" means any place, institution, building or agency or a distinct part thereof equipped and operated to provide services, including outpatient dialysis. In no case will all stations at a given kidney disease treatment center or kidney dialysis facility be designated as self-dialysis training stations. For purposes of these rules, kidney disease treatment center and kidney dialysis facility have the same meaning.

(11) "Maximum treatment floor area square footage" means the sum of (a), (b), (c), and (d) of this subsection:

(a) One hundred fifty square feet multiplied for each general use in-center station and each nonisolation station;

(b) Two hundred square feet multiplied for each isolation station and each permanent bed station as defined in subsection (14) of this section;

(c) Three hundred square feet for future expansion of two in-center treatment stations; and

(d) Other treatment floor space is seventy-five percent of the sum of (a), (b), and (c) of this subsection.

As of the effective date of these rules, maximum treatment floor area square footage identified in a successful application cannot be used for future station expansion, except as provided in (c) of this subsection. For example, the applicant may use the maximum allowable treatment floor area square footage. The number of stations may include one isolation station, one permanent bed station, eight general use in-center stations, two future expansion stations, and maximum other treatment floor space. In this example, the total maximum treatment floor area square footage in this example would equal three thousand three hundred twenty-five square feet.

(12) "Operational" means the date when the kidney dialysis facility provides its first dialysis treatment in newly approved certificate of need stations, including relocated stations.

(13) "Patients per station" means the reported number of in-center patients at the kidney dialysis facility divided by counted certificate of need approved stations. The results are not rounded up. For example, 4.49 is not rounded to 4.5.

(14) "Permanent bed station" means a bed that would commonly be used in a health care setting.

(15) "Planning area" or "service area" means an individual geographic area designated by the department for which kidney dialysis station need projections are calculated. For purposes of kidney dialysis projects, planning area and service area have the same meaning. Each county is considered a separate planning area, except for the planning subareas identified for King, Snohomish, Pierce, and Spokane counties. If the United States Postal Service (USPS) changes zip codes in the defined planning areas, the department will update areas to reflect the revisions to the zip codes to be included in the certificate of need definitions, analyses and decisions. Post office boxes are not included.

(a) King County is divided by zip code into twelve planning areas as follows:

KING ONE	KING TWO	KING THREE
98028 Kenmore	98101 Business District	98070 Vashon
98103 Green Lake	98102 Eastlake	98106 White Center/West Seattle
98105 Laurelhurst	98104 Business District	98116 Alki/West Seattle
98107 Ballard	98108 Georgetown	98126 West Seattle
98115 View Ridge/ Wedgwood	98109 Queen Anne	98136 West Seattle
98117 Crown Hill	98112 Madison/ Capitol Hill	98146 West Seattle
98125 Lake City	98118 Columbia City	98168 Riverton
98133 Northgate	98119 Queen Anne	
98155 Shoreline/ Lake Forest Park	98121 Denny Regrade	
98177 Richmond Beach	98122 Madrona	
98195 University of Washington	98134 Harbour Island	
	98144 Mt. Baker/ Rainier Valley	
	98199 Magnolia	

KING FOUR	KING FIVE	KING SIX
98148 SeaTac	98003 Federal Way	98011 Bothell
98158 SeaTac	98023 Federal Way	98033 Kirkland
98166 Burien/ Normandy Park		98034 Kirkland
98188 Tukwila/ SeaTac		98052 Redmond
98198 Des Moines		98053 Redmond
		98072 Woodinville
		98077 Woodinville

KING SEVEN	KING EIGHT	KING NINE
98004 Bellevue	98014 Carnation	98055 Renton
98005 Bellevue	98019 Duvall	98056 Renton
98006 Bellevue	98024 Fall City	98057 Renton
98007 Bellevue	98045 North Bend	98058 Renton
98008 Bellevue	98065 Snoqualmie	98059 Renton
98039 Medina	98027 Issaquah	98178 Skyway
98040 Mercer Island	98029 Issaquah	
	98074 Sammamish	
	98075 Sammamish	

KING TEN	KING ELEVEN	KING TWELVE
98030 Kent	98001 Auburn	98022 Enumclaw
98031 Kent	98002 Auburn	
98032 Kent	98010 Black Diamond	
98038 Maple Valley	98047 Pacific	
98042 Kent	98092 Auburn	
98051 Ravensdale		

(b) Pierce County is divided into five planning areas as follows:

PIERCE ONE	PIERCE TWO	PIERCE THREE
98354 Milton	98304 Ashford	98329 Gig Harbor
98371 Puyallup	98323 Carbonade	98332 Gig Harbor
98372 Puyallup	98328 Eatonville	98333 Fox Island
98373 Puyallup	98330 Elbe	98335 Gig Harbor
98374 Puyallup	98360 Orting	98349 Lakebay
98375 Puyallup	98338 Graham	98351 Longbranch
98390 Sumner	98321 Buckley	98394 Vaughn
98391 Bonney Lake		

PIERCE FOUR	PIERCE FIVE
98402 Tacoma	98303 Anderson Island
98403 Tacoma	98327 DuPont
98404 Tacoma	98387 Spanaway
98405 Tacoma	98388 Steilacoom
98406 Tacoma	98430 Tacoma
98407 Ruston	98433 Tacoma
98408 Tacoma	98438 Tacoma
98409 Lakewood	98439 Lakewood
98416 Tacoma	98444 Parkland
98418 Tacoma	98445 Parkland
98421 Tacoma	98446 Parkland
98422 Tacoma	98447 Tacoma
98424 Fife	98467 University Place
98443 Tacoma	98498 Lakewood
98465 Tacoma	98499 Lakewood
98466 Fircrest	98580 Roy

(c) Snohomish County is divided into three planning areas as follows:

SNOHOMISH ONE	SNOHOMISH TWO	SNOHOMISH THREE
98223 Arlington	98201 Everett	98012 Mill Creek/ Bothell
98241 Darrington	98203 Everett	98020 Edmonds/ Woodway
98252 Granite Falls	98204 Everett	98021 Bothell
98271 Tulalip Reservation/ Marysville	98205 Everett	98026 Edmonds
98282 Camano Island	98208 Everett	98036 Lynnwood/ Brier
98292 Stanwood	98251 Gold Bar	98037 Lynnwood
	98224 Baring	98043 Mountlake Terrace
	98258 Lake Stevens	98087 Lynnwood
	98270 Marysville	98296 Snohomish
	98272 Monroe	
	98275 Mukilteo	

SNOHOMISH ONE	SNOHOMISH TWO	SNOHOMISH THREE
	98288 Skykomish	
	98290 Snohomish	
	98294 Sultan	

(d) Spokane County is divided into two planning areas as follows:

SPOKANE ONE	SPOKANE TWO
99001 Airway Heights	99003 Chattaroy
99004 Cheney	99005 Colbert
99011 Fairchild Air Force Base	99006 Deer Park
99012 Fairfield	99009 Elk
99016 Greenacres	99021 Mead
99018 Latah	99025 Newman Lake
99019 Liberty Lake	99026 Nine Mile Falls
99022 Medical Lake	99027 Otis Orchards
99023 Mica	99205 Spokane
99030 Rockford	99207 Spokane
99031 Spangle	99208 Spokane
99036 Valleyford	99217 Spokane
99037 Veradale	99218 Spokane
99201 Spokane	99251 Spokane
99202 Spokane	
99203 Spokane	
99204 Spokane	
99206 Spokane Valley	
99212 Spokane Valley	
99216 Spokane/Spokane Valley	
99223 Spokane	
99224 Spokane	

(16) "Projection year" means the fifth calendar year after the base year. For example, reviews using 2015 end-of-year data as the base year will use 2020 as the projection year.

(17) "Quality incentive program" or "QIP" means the end-stage renal disease (ESRD) quality incentive program (QIP) administered by the Centers for Medicare and Medicaid Services (CMS). The QIP measures kidney dialysis facility performance based on outcomes assessed through specific performance and quality measures that are combined to create a total performance score (TPS). The QIP and TPS are updated annually and are publicly available on the CMS DFC website.

(18) "Quintile" means any of five groups into which a population can be divided according to the distribution of values of a particular variable.

(19) "Resident in-center patients" means in-center hemodialysis (HD) patients who reside within the planning area. If more than fifty percent of a kidney dialysis facility's patients reside outside Washington state, these out-of-state patients would be considered resident in-center patients.

(20) "Shelled space" means space that is constructed to meet future needs; it is a space enclosed by a building shell but otherwise unfinished inside unless the space designated for future needs is part of an existing, finished building prior to an applicant's proposed project. In that case, there is no requirement to degrade the space. The shelled space may include:

(a) Electrical and plumbing that will support future needs;

(b) Insulation;

(c) Sheet rock that is taped or other similar wall coverings that are otherwise unfinished; and

(d) Heating, ventilation, and air conditioning.

(21) "Training services" means services provided by a kidney dialysis facility to train patients for home dialysis. Home training spaces are not used to provide in-center dialysis treatments. Spaces used for training are not included in the facility's station count for projecting future station need or in calculating existing station use. Stations previously designated as "training stations" may be used as in-center dialysis stations and will continue to be included in the facility's current station count for projecting future station need or in calculating existing station use. For the purpose of awarding the point for home training in the superiority criteria section (WAC 246-310-823), training services include the following:

(a) Home peritoneal dialysis (HPD); and

(b) Home hemodialysis (HHD).

[Statutory Authority: RCW 70.38.135. WSR 17-04-062, § 246-310-800, filed 1/27/17, effective 1/1/18.]

WAC 246-310-803 Kidney disease treatment facilities—Data reporting requirements. (1) By February 15th or the first working day thereafter of each year, each provider will electronically submit the following data elements for each of its kidney dialysis facilities in the state of Washington and each out-of-state kidney dialysis facility that might be used in an application review during the next year (an out-of-state kidney dialysis facility may be used as one of the three closest facilities for a future project during the next year pursuant to WAC 246-310-827):

(a) Cost report data for the most recent calendar or fiscal year reporting period for which data is available reported to the Centers for Medicare and Medicaid Services (CMS) that is used to calculate net revenue per treatment; and

(b) Data reported to providers by CMS for the most recent calendar or fiscal year reporting period for which data is available to identify the percentage of nursing home patients and the average number of comorbid conditions.

(2) A provider's failure to submit complete data elements identified in subsection (1)(a) and (b) of this section in the format identified by the department for a facility by the deadline in subsection (1) of this section or whose data for a facility is not complete on the DFC report or QIP report (medicare website) will result in automatic rejection of concurrent review applications for that provider until the following year's data report deadline unless an exemption is granted pursuant to subsection (3) of this section. Corrections to the DFC report, as noted in WAC 246-310-827(7) do not require the filing on an exemption.

(3) A provider may request an exemption from subsection (2) of this section in writing by the first working day in March. The exemption request must demonstrate that reasonable efforts were made to timely submit the required data elements in subsection (1)(a) and (b) of this section. An exemption request based on missing data in the DFC report or QIP report should demonstrate the absence of data is not the result of failure to report to medicare. The department has sole discretion to grant these exemptions. The department will review all sub-

mitted exemption requests and respond with a decision by the first working day in April.

(4) Within ten working days, providers must report to the department the date that kidney dialysis stations first became operational for the following:

(a) New kidney dialysis facility;

(b) Stations added to an existing kidney dialysis facility; or

(c) Relocated stations of a kidney dialysis facility.

(5) The department will confirm it has received the required data in subsections (1) and (4) of this section as well as any exemption requests in subsection (3) of this section via email within ten working days of receipt.

(6) The department will publish on its website the date that the stations in subsection (4) of this section became operational.

[Statutory Authority: RCW 70.38.135. WSR 17-04-062, § 246-310-803, filed 1/27/17, effective 1/1/18.]

WAC 246-310-806 Kidney disease treatment facilities—Concurrent review cycles. The department will review kidney dialysis facility applications using the concurrent review cycles described in this section, unless the application was submitted as described in subsection (9) of this section. There are four concurrent review cycles each year.

(1) Applicants must submit applications for review according to the following table:

		Application Submission Period			Department Action	Application Review Period		
Concurrent Review Cycle	Letters of Intent Due	Receipt of Initial Application	End of Screening Period	Applicant Response	Beginning of Review	Public Comment Period (includes public hearing if requested)	Rebuttal Period	Exparte Period
Special Circumstances 1	First working day of **April** of each year.	First working day of **May** of each year.	**May 15** or the first working day thereafter.	**June 15** or the first working day thereafter.	**June 22** or the first working day thereafter.	**30-Day** Public comment period (including public hearing). Begins **June 23** or the first working day thereafter.	**7-Day** Rebuttal period. Applicant and affected party response to public comment.	**15-Day** Exparte period. Department evaluation and decision.
Nonspecial Circumstance Cycle 1	First working day of **May** of each year.	First working day of **June** of each year.	Last working day of **June**.	Last working day of **July**.	**August 5** or the first working day thereafter.	**30-Day** Public comment period (including public hearing). Begins **August 6** or the first working day thereafter.	**30-Day** Rebuttal period. Applicant and affected party response to public comment.	**75-Day** Exparte period. Department evaluation and decision.

		Application Submission Period			Department Action	Application Review Period		
Concurrent Review Cycle	Letters of Intent Due	Receipt of Initial Application	End of Screening Period	Applicant Response	Beginning of Review	Public Comment Period (includes public hearing if requested)	Rebuttal Period	Exparte Period
Special Circumstances 2	First working day of **October** of each year.	First working day of **November** of each year.	**November 15** or the first working day thereafter.	**December 15** or the first working day thereafter.	**December 22** or the first working day thereafter.	**30-Day** Public comment period (including public hearing). Begins **December 23** or the first working day thereafter.	**7-Day** Rebuttal period. Applicant and affected party response to public comment.	**15-Day** Exparte period. Department evaluation and decision.
Nonspecial Circumstances Cycle 2	First working day of **November** of each year.	First working day of **December** of each year.	Last working day of **December**.	Last working day of **January**.	**February 5** or the first working day thereafter.	**30-Day** Public comment period (including public hearing). Begins **February 6** or the first working day thereafter.	**30-Day** Rebuttal period. Applicant and affected party response to public comment.	**75-Day** Exparte period. Department evaluation and decision.

(2) The department should complete a nonspecial circumstance concurrent review cycle within nine months, which begins the first day after letters of intent are due for that particular review cycle. The department should complete the regular review process within six months, which begins the first day after the letters of intent are due for that particular review cycle.

(3) The department will notify applicants fifteen days prior to the scheduled decision date if it is unable to meet the decision deadline on the applications. In that event, the department will establish and commit to a new decision date.

(4) When two or more applications are submitted for the same planning area, the department will first evaluate each application independently for meeting the applicable standards described in WAC 246-310-210, 246-310-220, 246-310-230, and 246-310-240. If two or more applications independently meet those four standards, the department will apply the superiority criteria in WAC 246-310-827 to determine the superior application under WAC 246-310-240(1).

(5) An applicant receiving points for the purposes of the superiority criteria under WAC 246-310-827 (3)(e), (f), or (g) may only apply for station need in one planning area per review cycle.

(6) An applicant receiving points for purposes of the superiority criteria under WAC 246-310-827 (3)(e), (f), or (g) must operate the newly awarded stations for a period of time long enough to have a full year of data reporting medicare cost report worksheets and a full year of data reporting the dialysis facility report prior to any future applications.

(7) The department will not accept new nonspecial circumstance applications for a planning area if there are any nonspecial circumstance applications for which the certificate of need program has not made a decision in that planning area filed under a previous concurrent review cycle. This restriction does not apply if the department

has not made a decision on the pending applications within the review timelines of nine months for a concurrent review and six months for a regular review. This restriction also does not apply to special circumstance applications.

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

(9) Pending certificate of need applications. Kidney dialysis facility applications submitted prior to the effective date of these rules will be reviewed and action taken based on the rules that were in effect on the date the applications were received.

[Statutory Authority: RCW 70.38.135. WSR 17-04-062, § 246-310-806, filed 1/27/17, effective 1/1/18.]

WAC 246-310-809 One-time exempt isolation station reconciliation. (1) The department will identify each certificate of need approved kidney dialysis facility and the total number of certificate of need approved stations as of the effective date of these rules.

(2) The department will make a one-time administrative station adjustment to each kidney dialysis facility to add one station as an approved exempt isolation station for those facilities that were approved prior to the effective date of these rules.

(3) The department will notify each kidney dialysis facility of its adjusted certificate of need approved station count.

[Statutory Authority: RCW 70.38.135. WSR 17-04-062, § 246-310-809, filed 1/27/17, effective 1/1/18.]

WAC 246-310-812 Kidney disease treatment facilities—Methodology. A kidney dialysis facility that provides hemodialysis or peritoneal dialysis, training, or backup must meet the following standards in addition to applicable review criteria in WAC 246-310-210, 246-310-220, 246-310-230, and 246-310-240.

(1) Applications for new stations may only address projected station need in the planning area in which the facility is to be located.

(a) If there is no existing facility in an adjacent planning area, the application may also address the projected station need in that planning area.

(b) Station need projections must be calculated separately for each planning area within the application.

(2) Data used to project station need must be the most recent five-year resident end-of-year in-center patient data available from the Northwest Renal Network as of the letter of intent submission date, concluding with the base year at the time of application.

(3) Projected station need must be based on 4.8 resident in-center patients per station (4.8 planning area) for all planning areas except Adams, Columbia, Douglas, Ferry, Garfield, Jefferson, Kittitas, Klickitat, Lincoln, Okanogan, Pacific, Pend Oreille, San Juan, Skamania, Stevens, Wahkiakum, and Whitman counties. The projected station need for these exception planning areas must be based on 3.2 resident in-center patients per station (3.2 planning area).

(4) The number of dialysis stations projected as needed in a planning area will be determined by using the following methodology:

(a) Determine the type of regression analysis to be used to project resident in-center station need by calculating the annual growth rate in the planning area using the end-of-year number of resident in-center patients for each of the previous six consecutive years, concluding with the base year.

(i) If the planning area has experienced less than six percent growth in any of the previous five annual changes calculations, use linear regression to project station need; or

(ii) If the planning area has experienced six percent or greater growth in each of the previous five annual changes, use nonlinear (exponential) regression to project station need.

(b) Project the number of resident in-center patients in the projection year using the regression type determined in (a) of this subsection. When performing the regression analysis use the previous five consecutive years of end-of-year data concluding with the base year. For example, if the base year is 2015, use end-of-year data for 2011 through 2015 to perform the regression analysis.

(c) Determine the number of dialysis stations needed to serve resident in-center patients in the planning area in the projection year by dividing the result of (b) of this subsection by the appropriate resident in-center patient per station number from subsection (3) of this section. In order to assure access, fractional numbers are rounded up to the nearest whole number. For example, 5.1 would be rounded to 6.0. Rounding to a whole number is only allowed for determining the number of stations needed.

(d) To determine the net station need for a planning area, subtract the number calculated in (c) of this subsection from the total number of certificate of need approved stations located in the planning area. This number does not include the one department recognized exempt isolation station defined in WAC 246-310-800(9). For example, a kidney dialysis facility that is certificate of need approved and certified for eleven stations would subtract the one exempt isolation station and use ten stations for the methodology calculations.

(5) Before the department approves new in-center kidney dialysis stations in a 4.8 planning area, all certificate of need counted stations at each facility in the planning area must be operating at 4.5 in-center patients per station. However, when a planning area has one or more facilities with stations not meeting the in-center patients per stations standard, the department will consider the 4.5 in-center patients per station standard met for those facilities when:

(a) All stations for a facility have been in operation for at least three years; or

(b) Certificate of need approved stations for a facility have not become operational within the timeline as represented in the approved application. For example, an applicant states the stations will be operational within eight months following the date of the certificate of need approval. The eight months would start from the date of an uncontested certificate of need approval. If the certificate of need approval is contested, the eight months would start from the date of the final department or judicial order. However, the department, at its sole discretion, may approve a one-time modification of the timeline for purposes of this subsection upon submission of documentation that the applicant was prevented from meeting the initial timeline due to circumstances beyond its control.

Both resident and nonresident patients using the kidney dialysis facility are included in this calculation. Data used to make this calculation must be from the most recent quarterly modality report from the Northwest Renal Network as of the letter of intent submission date.

(6) Before the department approves new in-center kidney dialysis stations in a 3.2 planning area, all certificate of need counted stations at each facility in the planning area must be operating at or above 3.2 in-center patients per station. If the certificate of need approval is contested, the eight months would start from the date of the final department or judicial order. However, when a planning area has facilities with stations not meeting the in-center patients per station standard, the department will consider the 3.2 in-center patients per station standard met for those facilities when:

(a) All stations for a facility have been in operation for at least three years; or

(b) Certificate of need approved stations for a facility have not become operational within the timeline as represented in the approved application. For example, an applicant states the stations will be operational within eight months following the date of the certificate of need approval. The eight months would start from the date of an uncontested certificate of need approval. However, the department, at its sole discretion, may approve a one-time modification of the timeline for the purposes of this subsection upon submission of documentation that the applicant was prevented from meeting the initial timeline due to circumstances beyond its control.

Both resident and nonresident patients using the kidney dialysis facility are included in this calculation. Data used to make this calculation must be from the most recent quarterly modality report from the Northwest Renal Network as of the letter of intent submission date.

(7) When there are relocated stations within a planning area pursuant to WAC 246-310-830(3) and data is not available for the relocated stations, the department will use the station use rate from the previous location as reported on the last quarterly modality report from Northwest Renal Network.

(8) If a provider, including any affiliates, submits multiple applications for projected need in a planning area, the department will use the following process:

(a) Each application will be scored as an individual application to determine superiority.

(b) The sum of the stations requested in the applications cannot exceed the projected need at the time of applications in the planning area.

[Statutory Authority: RCW 70.38.135. WSR 17-04-062, § 246-310-812, filed 1/27/17, effective 1/1/18.]

WAC 246-310-815 Kidney disease treatment facilities——Financial feasibility. (1) The kidney dialysis facility must demonstrate positive net income by the third full year of operation.

(a) The calculation of net income is subtraction of all operating and nonoperating expenses, including appropriate allocated and overhead expenses, amortization and depreciation of capital expenditures from total revenue generated by the kidney dialysis facility.

(b) Existing facilities. Revenue and expense projections for existing facilities must be based on that facility's current payor mix and current expenses.

(c) New facilities.

(i) Revenue projections must be based on the net revenue per treatment of the applicant's three closest dialysis facilities.

(ii) Known expenses must be used in the pro forma income statement. Known expenses may include, but are not limited to, rent, medical director agreement, and other types of contracted services.

(iii) All other expenses not known must be based on the applicant's three closest dialysis facilities.

(iv) If an applicant has no experience operating kidney dialysis facilities, the department will use its experience in determining the reasonableness of the pro forma financial statements provided in the application.

(v) If an applicant has one or two kidney dialysis facilities, revenue projections and unknown expenses must be based on the applicant's operational facilities.

(2) An applicant proposing to construct finished treatment floor area square footage that exceeds the maximum treatment floor area square footage defined in WAC 246-310-800(11) will be determined to have an unreasonable impact on costs and charges and the application will be denied. This does not preclude an applicant from constructing shelled space.

[Statutory Authority: RCW 70.38.135. WSR 17-04-062, § 246-310-815, filed 1/27/17, effective 1/1/18.]

WAC 246-310-818 Special circumstances one- or two-station expansion—Eligibility criteria and application process. (1) The department will approve one or two additional special circumstance stations for an existing kidney dialysis facility (facility) if it meets the following criteria, regardless of whether the need methodology in WAC 246-310-812 projects a need for additional stations in the planning area:

(a) For 4.8 planning areas, the facility has operated at or above an average of 5.0 patients per station for the most recent six consecutive month period preceding the letter of intent submission date for which data is available. Data used to determine patients per station must be obtained from the Northwest Renal Network; or

(b) For 3.2 planning areas, the facility has operated at or above an average of 3.5 patients per station for the most recent six consecutive month period preceding the letter of intent submission date for which data is available. Data used to determine patients per station must be obtained from the Northwest Renal Network; and

(c) The facility can accommodate one or two additional stations within its existing building, which may include shelled space. If renovation is needed to accommodate the additional station(s), renovation must be within the existing building.

(2) The department may approve special circumstance station expansions even if other kidney dialysis facilities not owned or affiliated with the applicant in the planning area are below the minimum patients per station operating thresholds set by WAC 246-310-812 (5) or (6).

(3) A facility approved for two special circumstance stations under subsection (1) of this section is not eligible for further special circumstance expansions under this subsection until the department awards additional nonspecial circumstances kidney dialysis stations in the planning area.

(4) As of the effective date of these rules, a facility that has relocated all or part of its stations may not request a special circumstance one- or two-station expansion until three years have lapsed from the date the stations become operational. The three-year prohibition applies to any new kidney dialysis facility or facilities whose station count is changed by the relocation of stations. The three-year prohibition will be retrospectively applied only to kidney dialysis facilities that were approved for partial or complete relocation after January 1, 2015.

(5) For 4.8 planning areas, a facility is ineligible for a special circumstance one- or two-station expansion if the owner or affiliate has approved certificate of need stations in the planning area that have operated below an average of 4.5 patients per station for the most recent six consecutive month period preceding the letter of intent submission date. Data used to calculate patients per station must be obtained from the Northwest Renal Network.

(6) For 3.2 planning areas, a facility is ineligible for a special circumstance one- or two-station expansion if the owner or affiliate has approved certificate of need stations in the planning area that have operated below an average of 3.2 patients per station for the most recent six consecutive month period preceding the letter of intent submission date. Data used to calculate patients per station must be obtained from the Northwest Renal Network.

(7) For 4.8 planning areas, a special circumstance one- or two-station expansion will not be approved if, with the requested new station(s), the applicant's kidney dialysis facility would fall below a calculated 4.5 patients per station. Data used to make this calculation is the average patients per station from subsection (1)(a) of this section.

(8) For 3.2 planning areas, a special circumstance one- or two-station expansion will not be approved if, with the requested new stations(s), the applicant's kidney dialysis facility would fall below a calculated 3.0 patient per station. Data used to make this calculation is the average patients per station from subsection (1)(b) of this section.

(9) If a provider operates one or more kidney dialysis facilities within a planning area and applies for a special circumstance one- or two-station expansion in the planning area the department will not accept a letter of intent from that provider for additional stations to meet projected planning area need in the next nonspecial circumstance concurrent review cycle.

(10) Station(s) approved under this section must be operational within six months of approval, otherwise the approval is revoked.

(11) The department will provide a special circumstance one- or two-station expansion application form that incorporates the criteria for certificate of need approval. The application will not be approved unless the criteria are met. Special circumstances applications are evaluated independently of one another and accordingly without reference to the superiority criteria set forth in WAC 246-310-827. Therefore, multiple special circumstances applications may be approved in the same planning area during the same concurrent review cycle.

(12) Applicants must submit special circumstance one- or two-station expansion applications according to the schedule set forth in WAC 246-310-806(1).

(13) Special circumstance station applications will be treated as approved and will reduce net station need in the planning area when no nonspecial circumstance applications decisions are pending within the planning area. Special circumstance application approvals will not result in a reduction of net station need in the planning area when nonspecial circumstance application approvals decisions are pending within the planning area.

[Statutory Authority: RCW 70.38.135. WSR 17-04-062, § 246-310-818, filed 1/27/17, effective 1/1/18.]

WAC 246-310-821 Kidney disease treatment facilities—Standards for planning areas without an existing facility. (1) Columbia, Ferry, Garfield, Klickitat, Lincoln, Pend Oreille, San Juan, Skamania, Stevens, Wahkiakum, and Whitman counties do not have an existing kidney dialysis facility as of the effective date of these rules. The department will award the first project proposing to establish a facility in each of these planning areas as follows:

(a) A minimum of four stations, provided the project meets applicable review criteria and standards; and

(b) The facility must be projected to operate at 3.2 in-center patients per station by the third full year of operation. For purposes of this subsection, the applicant may supplement data obtained from the Northwest Renal Network with other documented demographic and utilization data to demonstrate station need.

(2) Once a county no longer qualifies under subsection (1) of this section, the county remains a 3.2 in-center patient per station county. As of the effective date of these rules, Adams, Douglas, Jefferson, Kittitas, Okanogan, Pacific, and Stevens counties are also identified as 3.2 in-center patient per station counties.

[Statutory Authority: RCW 70.38.135. WSR 17-04-062, § 246-310-821, filed 1/27/17, effective 1/1/18.]

WAC 246-310-824 Kidney disease treatment centers—Exceptions. The department will not approve new stations in a planning area if the projections in WAC 246-310-812(4) show no net need, and will not approve more than the number of stations projected as needed unless:

(1) The proposed project qualifies under WAC 246-310-818 for special circumstances one- or two-station expansions; or

(2) All other applicable review criteria and standards have been met; and

(3) One or more of the following have been met:

(a) The department finds the additional stations are needed to be located reasonably close to the people they serve; or

(b) Existing dialysis stations in the kidney dialysis facility requesting the exception are operating at 5.5 patients for a 4.8 planning area or, 3.7 patients per station for the 3.2 planning areas. Data used to make this calculation must be from the most recent quarterly modality report from the Northwest Renal Network as of the letter of intent submission date; or

(c) The applicant documents a significant change in ESRD treatment practice has occurred, affecting dialysis station use in the planning area; and

(4) The department finds that exceptional circumstances exist within the planning area and explains the approval of additional stations in writing.

[Statutory Authority: RCW 70.38.135. WSR 17-04-062, § 246-310-824, filed 1/27/17, effective 1/1/18.]

WAC 246-310-827 Kidney disease treatment facilities—Superiority criteria. For purposes of determining which of the competing applications should be approved, the criteria in this section will be used as the only means for comparing two or more applications to each other. No other criteria or measures will be used in comparing two or more applications to each other under any of the applicable subcriteria within WAC 246-310-210, 246-310-220, 246-310-230 or 246-310-240.

(1) An application will be denied if it fails to meet any criteria under WAC 246-310-210, 246-310-220, 246-310-230, or 246-310-240 (2) or (3).

(2) An application will be denied if the applicant has one or more kidney dialysis facilities in the planning area not meeting the 4.5 or 3.2 in-center patients per station standards required in WAC 246-310-812 (5) or (6) as of the most recent quarterly report from the Northwest Renal Network as of the date of the letter of intent.

(3) When available, Washington facilities must be used as comparables, as follows:

(a) For existing kidney dialysis facilities proposing to expand, use data for the existing facility plus the next two closest Washington facilities as comparables owned by or affiliated with the applicant as measured by a straight line. Straight lines will be calculated using "Google Maps" or equivalent mapping software (mileage calculated out to two decimal points, no rounding).

(b) For new kidney dialysis facilities, use data for the next three closest facilities as comparables owned by or affiliated with the applicant as measured by a straight line from the proposed new kidney dialysis facility location. Straight lines will be calculated using "Google Maps" or equivalent mapping software (mileage calculated out to two decimal points, no rounding).

(c) The number of applications per concurrent review cycle that rely on the same three comparables is limited to two.

(d) If complete medicare data is not available for any of the kidney dialysis facilities and a facility has been granted a department exemption in WAC 246-310-803(3), then that facility will not be used as a comparable and the next closest facility should be used as a comparable.

(e) If the applicant currently does not own or is not affiliated with any kidney dialysis facility, the department will assign the following points:

(i) The median quintile points for those superiority measures using quintiles (excluding net revenue per treatment);

(ii) Two points for standardized mortality ratio (SMR);

(iii) Two points for standardized hospitalization ratio (SHR); and

(iv) Any remaining points for other measures will be based on the representations made in the application.

(f) If the applicant owns or is affiliated with one existing kidney dialysis facility in total, the department will assign the facility's actual points as follows:

(i) The actual quintile points for those superiority measures using quintiles;

(ii) The actual points for SMR;

(iii) The actual points for SHR; and

(iv) Any remaining points for other measures will be based on the representations made in the application.

(g) If the applicant owns or is affiliated with two existing kidney dialysis facilities in total, the department will average the facility's scores as follows:

(i) The average quintile points for those superiority measures using quintiles;

(ii) The average points for SMR;

(iii) The average points for SHR; and

(iv) The average of the remaining points for other measures will be based on the representations made in the applications.

(4) The following table identifies the data measures and the data sources:

Data Item	Source
Home peritoneal dialysis and home hemodialysis training (Yes or No)	DFC report
Shift beginning after 5:00 p.m.? (Yes or No)	DFC report
Nursing home residents percentage (quintile)	Dialysis facility report (DFR)
Average number of comorbidities claimed (quintile)	Dialysis facility report (DFR)
Standardized mortality ratio performance (SMR) (better than expected, as expected, worse than expected)	DFC report - 4 year
Standardized hospitalization ratio performance (SHR) (better than expected, as expected, worse than expected)	DFC report - 1 year
Medicare total performance score (quintile)	QIP report
Net revenue per treatment (quintile)	Department calculation from medicare cost report. Divide total revenue by total treatments.

(5) The department will obtain the medicare QIP total performance scores (QIP Report) and the kidney dialysis facility compare reports (DFC Report) from the medicare website on the first working day in February.

(6) The department will determine the quintile scores and nonquintile scores. The department will calculate the quintile scores using the following process for each quintile measure:

(a) For all kidney dialysis facilities for which data is available, sort the facilities from most favorable to least favorable according to the identified data.

(b) Use the percent rank formula using Excel to create the percentile ranking for each kidney dialysis facility in the data set. The array used in the formula is the data set of available facility data identified for that measure.

(c) Assign quintile and nonquintile scores using the following methods:

(i) Quintile measures. For nursing home resident percentage, number of comorbidities, and QIP total performance score measures, the department will determine the quintile scores using the following process:

(A) Dialysis facilities with a percentile ranking of eighty percent or higher get five points.

(B) Dialysis facilities with a percentile ranking less than eighty percent and greater than or equal to sixty percent get four points.

(C) Dialysis facilities with a percentile ranking less than sixty percent and greater than or equal to forty percent get three points.

(D) Dialysis facilities with a percentile ranking less than forty percent and greater than or equal to twenty percent get two points.

(E) Dialysis facilities with a percentile ranking below twenty percent get one point.

(ii) Quintile measure. For the net revenue per treatment measure, the department will determine the quintile scores using the following process:

(A) Dialysis facilities with a percentile ranking of eighty percent or higher get one point.

(B) Dialysis facilities with a percentile ranking less than eighty percent and greater than or equal to sixty percent get two points.

(C) Dialysis facilities with a percentile ranking less than sixty percent and greater than or equal to forty percent get three points.

(D) Dialysis facilities with a percentile ranking less than forty percent and greater than or equal to twenty percent get four points.

(E) Dialysis facilities with a percentile ranking below twenty percent get five points.

(F) Hospitals that do not have a cost report may submit net revenue per treatment actuals from the previous year. Hospitals must also submit a signed attestation stating the net revenue per treatment data is accurate.

(iii) Nonquintile measures. The department will determine the nonquintile scores using the following process:

(A) Dialysis facilities that offer training services are given one point.

(B) Dialysis facilities that offer a shift that begins after 5 p.m. are given one point.

(C) The department will determine SMR points for dialysis facilities as follows:

(I) "Better than expected" get four points.

(II) "As expected" get two points.

(III) "Worse than expected" get 0 points.

(D) The department will determine SHR points for dialysis facilities as follows:

(I) "Better than expected" get four points.

(II) "As expected" get two points.

(III) "Worse than expected" get 0 points.

(E) The department will assign two points for an "as expected" score for dialysis facilities missing only SMR data from the DFC report, provided the facility was granted an exception under WAC 246-310-803(3).

(7) The department will publish the data set including resulting scores and quintiles for all kidney dialysis facilities for review no later than March 15th or the first working day thereafter. The data set, including resulting scores and quintiles, will remain open for review and any person may propose the correction of data to the department for seven calendar days. Correction of data may be proposed as follows:

(a) Training services (HPD and HHD): The department will accept a copy of a medicare certification for training services (HPD and HHD) as evidence that a kidney dialysis facility provides these services, regardless of what is represented in the DFC report.

(b) Data related to a shift beginning after 5 p.m.: The department will accept an attestation that a facility either operates a shift beginning after 5 p.m. or will operate that shift if there is a need, regardless of what is represented in the DFC report.

(c) The department will publish the final data set, including resulting scores and quintiles, no later than the first working day in April.

(8) The department will do the following analysis in order to determine the superior application:

(a) Create the comparable kidney dialysis facility set for each application per subsection (3) of this section.

(b) Determine the individual measure scores for each application by taking the simple average of the comparable scores for each measure.

(c) Determine the total score in the following manner according to the table below:

Data Items:	**Calculation of Points**	**Score**
Home training	The average score of comparable facilities rounded up to two decimal places.	
Shift beginning after 5 p.m.	The average score of comparable facilities rounded up to two decimal places.	
Nursing home residents	Average quintile score of comparable facilities rounded up to two decimal places.	
Average number of comorbid conditions	Average quintile score of comparable facilities multiplied by 1.25 and rounded up to two decimal places.	

Data Items:	Calculation of Points	Score
Standardized mortality ratio	Average score of comparable facilities rounded up to two decimal places.	
Standardized hospitalization ratio	Average score of comparable facilities rounded up to two decimal places.	
QIP total performance score	Average quintile score of comparable facilities multiplied by 2.0 and rounded up to two decimal places.	
Net revenue per treatment	Average quintile score of comparable facilities rounded down to two decimal places.	
Total score	Sum each of these individual average scores to arrive at total score.	

(9) The application with the highest total score will be the superior alternative for the purpose of meeting WAC 246-310-240(1).

(10) After applying the superiority criterion in this section, if applications are tied, the department will use the following process to determine the superior alternative:

(a) An applicant that was assigned points under subsection (3)(e) of this section in the superiority analysis will be considered the superior alternative; if no applicant was assigned points under subsection (3)(e) of this section, apply (b) of this subsection:

(b) The applicant with the highest average QIP total performance score will be considered the superior alternative;

(c) If applications have the same average QIP total performance score, the applicant with the lowest average net revenue per treatment will be considered the superior alternative.

[Statutory Authority: RCW 70.38.135. WSR 17-04-062, § 246-310-827, filed 1/27/17, effective 1/1/18.]

WAC 246-310-830 Kidney disease treatment facilities—Relocation of facilities. (1) When an existing facility proposes to relocate any of its stations to another planning area, a new health care facility is considered to be established under WAC 246-310-020 (1)(a).

(2) When an existing kidney dialysis facility proposes to relocate a portion but not all of its stations within the same planning area, a new health care facility is considered to be established under WAC 246-310-020 (1)(a).

(3) When an existing kidney dialysis facility proposes to relocate a portion but not all of its stations to an existing facility, it will be considered a station addition under WAC 246-310-020 (1)(e).

(4) When an entire existing kidney dialysis facility proposes to relocate all of its stations within the same planning area, a new

health care facility is not considered to be established under WAC 246-310-020 (1)(a) if:

(a) The existing kidney dialysis facility ceases operation after the relocation;

(b) No new stations are added to the replacement kidney dialysis facility. The maximum treatment floor area square footage as defined in WAC 246-310-800 (11)(a) is limited to the number of certificate of need stations that were approved at the existing facility;

(c) There is no break in service between the closure of the existing kidney dialysis facility and the operation of the replacement facility;

(d) The existing facility has been in operation for at least five years at its present location; and

(e) The existing kidney dialysis facility has not been purchased, sold, or leased within the past five years.

(5) Station use rates at new facilities created by the total relocation of an existing facility or the partial relocation of an existing facility should not be a barrier to the addition of new stations projected as needed for the planning area. In 4.8 planning areas, the station use rate will be counted as 4.5 in-center patients per station. If the department has had to count the station use at 4.5 under the need methodology described in WAC 246-310-812(5), the facility may not request additional stations at the new facility for three years from the date the stations become operational or the facility meets the 4.5 station use standard, whichever comes first. Data used to make this determination will be the most recent Northwest Renal Network quarterly modality report available as of the letter of intent submission date.

(6) Station use rates at new facilities created by the total relocation of an existing facility or the partial relocation of an existing facility should not be a barrier to the addition of new stations projected as needed for the planning area. In 3.2 planning areas, the station use rate will be counted as 3.2 in-center patients per station. If the department has had to count the station use at 3.2 under the need methodology described in WAC 246-310-812(6), the facility may not request additional stations at the new facility for three years from the date the stations become operational or the facility meets the 3.2 station use standard, whichever comes first. Data used to make this determination will be the most recent Northwest Renal Network quarterly modality report available as of the letter of intent submission date.

[Statutory Authority: RCW 70.38.135. WSR 17-04-062, § 246-310-830, filed 1/27/17, effective 1/1/18.]

WAC 246-310-833 One-time state border kidney dialysis facility station relocation. (1) When an existing owner-operator of a Washington state kidney dialysis facility is also the owner-operator of a kidney dialysis facility in a contiguous Idaho or Oregon county, the department will not consider a facility that combines the Washington facility and the out-of-state facility to be a new health care facility under WAC 246-310-020(1) provided all of the following criteria are satisfied:

(a) The Washington state kidney dialysis facility is located in Asotin, Benton, Clark, Columbia, Cowlitz, Garfield, Klickitat, Pend Oreille, Skamania, Wahkiakum, Walla Walla, or Whitman counties;

(b) The kidney dialysis facility is the sole provider of dialysis services in the Washington state county;

(c) The kidney dialysis facility is the sole provider of dialysis services in the contiguous Idaho or Oregon county;

(d) The replacement kidney dialysis facility will be located in the same county or planning area as the current Washington state facility;

(e) Both existing kidney dialysis facilities cease operation;

(f) There is no break in service between the closure of the existing kidney dialysis facilities and the operation of the replacement facility;

(g) There has been no change in ownership of either the Washington kidney dialysis facility or out-of-state kidney dialysis facility for at least five years prior to applying for the exemption under this section;

(h) Each existing kidney dialysis facility has been operated by the current provider for a minimum of five years prior to applying for the exemption under this section;

(i) Each existing kidney dialysis facility has been operating at its current location for a minimum of five years prior to applying for the exemption under this section;

(j) The department has not granted a previous exemption under the provisions of this section; and

(k) The number of stations at the replacement kidney dialysis facility does not exceed the total of:

(i) All stations from the Washington state kidney dialysis facility; and

(ii) Using the 4.8 patients per station standard, the stations necessary for the number of patients receiving dialysis at the out-of-state kidney dialysis facility as reported on the most recent Northwest Renal Network quarterly modality report.

(2) Once a Washington state provider has requested and received its one-time exemption under the provisions of this section, the kidney dialysis facility's "resident in-center patient" will have the same meaning as all patients at the facility.

[Statutory Authority: RCW 70.38.135. WSR 17-04-062, § 246-310-833, filed 1/27/17, effective 1/1/18.]

WAC 246-310-900 Capital expenditure minimum adjustment procedures. These rules and regulations are adopted pursuant to RCW 70.38.025 (6) and (12) for the purpose of establishing the index to be used and procedures for making adjustments to the "expenditure minimum" for capital expenditures which are subject to the requirements of the certificate of need program established under the provisions of chapter 70.38 RCW.

(1) Index to be used. For the purposes of the certificate of need program, the United States Department of Commerce Composite Construction Cost Index shall be used in the annual adjustments of the following:

The "expenditure minimum" as this term is defined in RCW 70.38.025 and WAC 246-310-010.

(2) Procedure for adjustment.

(a) On or before the first day of each January, the department shall adjust and publish the adjusted expenditure minimum for capital

expenditures. Such adjusted minimums shall be in effect during the entire calendar year for which they are established.

(b) The adjustments in the minimums shall be based on the changes which occurred in the Department of Commerce Composite Construction Cost Index during the twelve month period ending the preceding October.

(c) The adjusted minimums shall be published by the department by public notice in one or more newspapers of general circulation within the state and through a written notice sent to each health care facility subject to the requirements of the certificate of need program, and each statewide organization of such health care facilities.

[Statutory Authority: Chapter 70.38 RCW. WSR 96-24-052, § 246-310-900, filed 11/27/96, effective 12/28/96. Statutory Authority: RCW 70.38.135 and 70.38.919. WSR 92-02-018 (Order 224), § 246-310-900, filed 12/23/91, effective 1/23/92.]

WAC 246-310-990 Certificate of need review fees. (1) An application for a certificate of need under chapter 246-310 WAC must include payment of a fee consisting of the following:

(a) A review fee based on the facility/project type;

(b) If more than one facility/project type applies to an application, the review fee for each type of facility/project must be included.

Facility/Project Type	Review Fee
Ambulatory Surgical Centers/Facilities	$20,427.00
Amendments to Issued Certificates of Need	$12,874.00
Emergency Review	$8,286.00
Exemption Requests	
• Continuing Care Retirement Communities (CCRCs)/Health Maintenance Organization (HMOs)	$8,286.00
• Bed Banking/Conversions	$1,347.00
• Determinations of Nonreviewability	$1,925.00
• Hospice Care Center	$1,733.00
• Nursing Home Replacement/ Renovation Authorizations	$1,733.00
• Nursing Home Capital Threshold under RCW 70.38.105 (4)(e) (Excluding Replacement/ Renovation Authorizations)	$1,733.00
• Rural Hospital/Rural Health Care Facility	$1,733.00
Extensions	
• Bed Banking	$770.00
• Certificate of Need/Replacement Renovation Authorization Validity Period	$770.00
Home Health Agency	$24,666.00
Hospice Agency	$21,968.00
Hospice Care Centers	$12,874.00

Facility/Project Type	Review Fee
Hospital (Excluding Transitional Care Units-TCUs, Ambulatory Surgical Center/Facilities, Home Health, Hospice, and Kidney Disease Treatment Centers)	$40,470.00
Kidney Disease Treatment Centers	$25,054.00
Nursing Homes (Including CCRCs and TCUs)	$46,253.00

(2) The fee for amending a pending certificate of need application is determined as follows:

(a) If an amendment to a pending certificate of need application results in the addition of one or more facility/project types, the review fee for each additional facility/project type must accompany the amendment application;

(b) If an amendment to a pending certificate of need application results in the removal of one or more facility/project types, the department shall refund to the applicant the difference between the review fee previously paid and the review fee applicable to the new facility/project type; or

(c) If an amendment to a pending certificate of need application results in any other change as identified in WAC 246-310-100, a fee of two thousand sixty dollars must accompany the amendment application.

(3) If a certificate of need application is returned by the department under WAC 246-310-090 (2)(b) or (e), the department shall refund seventy-five percent of the review fees paid.

(4) If an applicant submits a written request to withdraw a certificate of need application before the beginning of review, the department shall refund seventy-five percent of the review fees paid by the applicant.

(5) If an applicant submits a written request to withdraw a certificate of need application after the beginning of review, but before the beginning of the ex parte period, the department shall refund one-half of all review fees paid.

(6) If an applicant submits a written request to withdraw a certificate of need application after the beginning of the ex parte period the department shall not refund any of the review fees paid.

(7) Review fees for exemptions and extensions are nonrefundable.

[Statutory Authority: Chapter 43.70 RCW, RCW 70.38.105(5), and 2011 1st sp.s. c 50. WSR 12-11-062, § 246-310-990, filed 5/15/12, effective 6/15/12. Statutory Authority: RCW 43.70.250, 70.38.105, 18.46.030, 70.127.090, 43.70.040. WSR 08-12-036, § 246-310-990, filed 5/30/08, effective 7/1/08. Statutory Authority: RCW 43.70.250 and 70.38.105(5). WSR 03-22-020, § 246-310-990, filed 10/27/03, effective 11/27/03. Statutory Authority: Chapters 70.127 and 70.38 RCW. WSR 03-07-096, § 246-310-990, filed 3/19/03, effective 4/19/03. Statutory Authority: RCW 70.38.105 and 2002 c 371. WSR 02-14-051, § 246-310-990, filed 6/27/02, effective 7/28/02. Statutory Authority: RCW 70.38.105(5) and 43.70.110. WSR 01-15-094, § 246-310-990, filed 7/18/01, effective 8/18/01. Statutory Authority: RCW 70.38.105(5). WSR 99-23-089, § 246-310-990, filed 11/16/99, effective 12/17/99. Statutory Authority: Chapter 70.38 RCW. WSR 96-24-052, § 246-310-990, filed 11/27/96, effective 12/28/96. Statutory Authority: RCW 70.38.135, 43.70.250 and 70.38.919. WSR 92-02-018 (Order 224), § 246-310-990, filed 12/23/91, effective 1/23/92. Statutory Authority: RCW 43.70.040. WSR 91-02-049

(Order 121), recodified as § 246-310-990, filed 12/27/90, effective 1/31/91. Statutory Authority: Chapter 70.38 RCW. WSR 90-15-001 (Order 070), § 440-44-030, filed 7/6/90, effective 8/6/90. Statutory Authority: RCW 43.20A.055. WSR 89-21-042 (Order 2), § 440-44-030, filed 10/13/89, effective 11/13/89; WSR 87-16-084 (Order 2519), § 440-44-030, filed 8/5/87; WSR 87-12-049 (Order 2494), § 440-44-030, filed 6/1/87; WSR 84-13-006 (Order 2109), § 440-44-030, filed 6/7/84; WSR 83-21-015 (Order 2037), § 440-44-030, filed 10/6/83. Statutory Authority: 1982 c 201. WSR 82-13-011 (Order 1825), § 440-44-030, filed 6/4/82.]