

Chapter 14:

Certificate of Need

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Ms. Zana, a Seattle native, received a B.A. in Business Administration in 2004 from the University of Washington. She received her law degree, *magna cum laude*, from Seattle University School of Law in 2007, where she served as Business & Marketing Editor of the Seattle University Law Review. During law school, Ms. Zana also externed for Judge Zilly in the United States District Court for the Western District of Washington.

Chapter Outline

14.1 Chapter Summary14-2

14.2 History and Rationale for Certificate of Need.....14-2

14.3 Certificate of Need and Anti-Trust Challenge14-3

14.4 Who Needs to Apply for a Certificate of Need?14-3

14.4.1 Facilities Requiring a Certificate of Need.....14-3

14.4.2 Certificate of Need Exemptions and Determinations of Non-Reviewability14-4

14.5 Certificate of Need Review Criteria14-5

14.5.1 Need.....14-5

14.5.2 Financial Feasibility.....14-6

14.5.3 Structure and Process of Care14-7

14.5.4 Cost Containment.....14-7

14.6 Certificate of Need Categories of Review.....14-7

14.6.1 Regular Review.....14-8

14.6.2 Expedited Review14-8

14.6.3 Concurrent Review14-8

14.6.4 Emergency Review14-9

14.6.5 General Timelines of Certificate of Need Applications14-9

14.7 Certificate of Need Application Process.....14-10

14.7.1 Letter of Intent14-10

14.7.2 Application.....14-10

14.7.3 Affected and Interested Persons.....14-11

14.7.4 Screening14-12

14.7.5 Amendment of a Certificate of Need Application.....14-12

14.7.6 Beginning of Review14-12

14.7.7 Public Hearings14-13

14.7.8 Ex Parte Contact and Unresolved Pivotal Issues.....14-13

14.7.9 Evaluation of the Certificate of Need Application.....14-13

14.7.10 Conditional Certificates of Need.....14-14

14.7.11 Reconsideration.....14-14

14.7.12 Amended Certificates of Need.....14-15

14.7.13 Suspension, Revocation and Transfer14-15

14.7.14 Monitoring14-16

14.7.15 Withdrawal.....14-16

14.8 Rules for Specific Facilities and Services14-16

14.8.1 Hospitals14-16

14.8.2 Kidney Disease Treatment Centers14-17

14.8.3 Ambulatory Surgery Facilities14-17

14.8.4 Nursing Homes14-18

14.8.5 Hospice Services.....14-18

14.8.6 Swing Beds14-19

14.8.7 Tertiary Services14-19

14.9 Adjudicative Process and Judicial Review14-19

14.9.1 Appeal of a CN Decision14-19

14.9.2 Standing14-20

14.9.3 Authority of the HLJ.....14-21

14.9.4 Judicial Review of HLJ Decision.....14-22

14.9.5 Construction of Facility Pending Adjudicative and Judicial Review.....14-22

14.10 Rule Making Process14-23

Volume 2: Regulation of Healthcare Practitioners and Entities

14.1 Chapter Summary

In the state of Washington, health care providers are required to obtain a certificate of need (“CN”) from the Department of Health (“DOH”) prior to commencing construction and operation of certain health care facilities and services. Facilities including hospitals, nursing homes, home health and hospice agencies, kidney dialysis centers, and free standing ambulatory surgery centers must apply for a CN before beginning major projects. These major projects include adding new beds, establishing new tertiary services, opening new facilities, or building dialysis stations.

The stated goals of the Washington CN program are to “promote, maintain, and assure the health of all citizens in the state, to provide accessible health services, health manpower, health facilities, and other resources while controlling excessive increases in costs.”¹ Starting in 2010, CN determinations must be made in a manner consistent with the statewide health resources strategy.² Access, quality, and cost-effectiveness of the projects requiring review are additional goals of the statutory scheme. These goals are assessed through the application of four criteria: need,³ financial feasibility,⁴ structure and process of care,⁵ and cost containment.⁶ A successful CN application must satisfy the requirements of all four of these criteria.

The purpose of this chapter is to present a general overview of the CN regulations and the operation of the CN Program by providing a brief description of the application process, evaluations performed by the CN Program, determinations of non-reviewability, requests for reconsideration and appeals to adjudicative and judicial proceedings. Any applicant for a CN is advised to independently review the specific CN-related rules and regulations. In recent years, the issuance of a CN has become a highly litigious topic due to the involvement of stakeholders, such as competing entities. Therefore, this chapter will also identify some of the legal issues affecting the CN process.

14.2 History and Rationale for Certificate of Need

Managing rising health care costs has been a priority for the federal government and the State of Washington since the 1970’s. In order to combat these rising costs the federal government and the State of Washington instituted CN regulations. Though the federal government has since dropped the requirement that states institute CN laws, 36 states and the District of Columbia have continued their CN programs.⁷ A CN is a non-exclusive license granted to health facility applicants by the state, allowing them to commence building and developing their health services and programs. Grant of a CN is not a license for the operation of the health care facility. Hospitals and other medical facilities must still obtain a license from the State. In order to receive a CN, an applicant must show that there is a need for this health service, and that the appropriate tools are available to provide quality care and access using the least costly method.

The driving force behind CN is the belief that CN can limit health care expenditures. The theory behind the CN statutory scheme is that regular market forces are not able to control healthcare costs, therefore lead to excess supply and needless duplication of services and facilities. Moreover there are aspects of the healthcare marketplace that encourage overinvestment that would not normally occur in an efficient market. The CN statutes endeavor “to control costs by ensuring better utilization of existing institutional health services and major medical equipment.”⁸ Improving health care quality and increasing access to health care facilities are additional objectives of the CN program. Whether or not the CN program is successful in these objectives is the subject of some controversy among both providers and academics.⁹

¹ RCW 70.38.015.

² See RCW 43.370 *et seq.* The statewide health resources strategy is currently under development.

³ WAC 246-310-210.

⁴ WAC 246-310-220.

⁵ WAC 246-310-230.

⁶ WAC 246-310-240.

⁷ National Conference of State Legislatures,

<http://www.ncsl.org/IssuesResearch/Health/CONCertificateofNeedStateLaws/tabid/14373/Default.aspx>.

⁸ *St. Joseph Hosp. & Health Care Center v. Dep’t of Health*, 125 Wn.2d 733, 736, 887 P.2d 891 (1995).

⁹ This is generally not an issue in CN litigation before a Health Law Judge.

In Washington, DOH Facilities and Services Licensing Division administers the CN Program. The CN Program hosts a helpful website, <http://www.doh.wa.gov/hsqa/fsl/CertNeed/default.htm>, which provides, among other things, application forms, contact information, methodologies determining numeric need, CN Program statutes and regulations, a list of pending applications and an archive of previous evaluations dating from 2004. The CN statutory scheme is codified in Chapter 70.38 RCW and DOH regulations are located in Chapter 246-310 WAC.

14.3 Certificate of Need and Anti-Trust Challenges

In May 2010, the Eastern District of Washington upheld Washington's CN statutes against claims that the statutory scheme violated the Sherman Anti-trust Act and the dormant Commerce Clause.¹⁰ Yakima Valley Memorial Hospital filed a claim to enjoin enforcement, by the CN Program, of regulations limiting the number of hospitals that could perform elective percutaneous coronary interventions. The Court found that the CN statutes did not violate the Sherman Anti-trust Act because the CN statutes did not delegate any market authority to private actors and therefore were immune from anti-trust challenges.¹¹ The court also rejected the dormant Commerce Clause argument, because the CN statutes were authorized by Congress in the National Health Planning and Resource Development Act ("NHPDA") passed in 1974. Though the NHPDA was repealed by the Regan Administration, the repeal eliminated only the requirement to enact CN legislation, not the authority.¹² Accordingly, the Washington State CN Program was a permissible burden on interstate commerce.

14.4 Who Needs to Apply for a Certificate of Need?

14.4.1 Facilities Requiring a Certificate of Need

RCW 70.38 articulates the goals of the CN Program, appoints DOH as the administrator of the CN Program, and describes what services are and are not covered by the CN statutes.

The following facilities and projects are subject to CN review:¹³

1. The construction, development, or other establishment of a new health care facility. A new health care facility includes hospitals, psychiatric hospitals, nursing homes, kidney disease treatment centers including freestanding dialysis units, ambulatory surgical facilities (not including in-office facilities), continuing care retirement communities, hospices and home health agencies;¹⁴
2. The sale, purchase, or lease of part or all of any existing hospital as defined in RCW 70.38.025;
3. Any capital expenditure for the construction, renovation, or alteration of a nursing home that substantially changes the services or is above the expenditure minimum (\$1,000,000 in 1989 adjusted for construction cost inflation thereafter);¹⁵
4. Additions or re-distributions among categories of health facility bed capacity;¹⁶

¹⁰ *Yakima Valley Memorial Hospital v. Dept. of Health*, 2010 WL 2181148 (E.D. Wash. May 25, 2010).

¹¹ *Id.* at *4-5.

¹² *Id.* at *9.

¹³ RCW 70.38.105.

¹⁴ WAC 246-310-010. A health care facility includes public hospital districts and other hospitals operated by a state or other political subdivision but does not include a 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.

¹⁵ The following types of projects are excluded (provided they are not otherwise subject to review and do not affect patient charges): communications and parking facilities; mechanical, electrical, ventilation, heating and air conditioning systems; energy conservation systems; repairs necessary to maintain state licensure; acquisition of equipment which will not be used in the direct provision of health services; construction or renovation of an existing nursing home involving physical plant facilities (in operation for at least one year); acquisition of land; and refinancing of existing debt. RCW 70.38.105(4)(d).

¹⁶ A change in bed capacity of a health care facility which increases the total number of licensed beds or redistributes beds among acute care, nursing home care, and boarding home care if the bed redistribution is to be effective for a period in excess of six months. RCW 70.38.105(4)(e).

Volume 2: Regulation of Healthcare Practitioners and Entities

5. Any new tertiary health services which are offered in or through a health care facility that were not offered at such facility within the prior twelve-month period;¹⁷
6. 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 CN review;¹⁸ and
7. Any increase in the number of dialysis stations in a kidney disease center.¹⁹

Health care facilities already possessing a CN for one type of facility must apply for an additional CN if desiring to provide new services that require CN Program approval.²⁰ For example, a hospital that plans to operate an intermediate care nursery (obstetric services Level II) or a neonatal intensive care nursery (obstetric services Level III) must apply for a CN for those services, even if it already operates a lower level obstetric service. In addition, a health care entity that operates an existing facility, such as a hospital, must apply for a CN specific to any new location it wishes to operate, regardless of whether the facility functions under an existing hospital license.²¹

14.4.2 Certificate of Need Exemptions and Determinations of Non-Reviewability

RCW 70.38.111 identifies the following services as exempted from the CN requirements:

1. A health maintenance organization (HMO), a combination of HMO's, and a health care facility operated by an HMO if certain conditions are met. These conditions are quite detailed and are fully described in RCW 70.38.111(1)-(4) and WAC 246-310-040.²²
2. 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 that meets certain conditions as specified in RCW 70.38.111(5) and WAC 246-310-041.
3. A rural hospital and a rural health care facility that wishes to increase the number of licensed beds within three years of a reduction in those beds if certain qualifications are met as specified in RCW 70.38.111(6) and (7) and WAC 246-310-042.
4. A nursing home that had voluntarily reduced the number of licensed beds to enhance its services or quality of life for its residents may increase the number of nursing home beds to the previously licensed capacity without applying for a CN provided that certain conditions detailed in RCW 70.38.111(8) and WAC 246-310-043 are met.
5. Replacement of nursing home beds as described in RCW 70.38.115(13) and (14) and WAC 246-310-044.²³

Applicants who are not sure whether a CN is required may apply to the CN Program for an applicability determination. The request must be in writing and must include the "nature and extent of any construction, changes in services, and the estimated total costs of the action."²⁴ The CN Program may request additional information, but must issue a written response within 30 days after receipt of the complete information. In its response, the CN Program must include reasons for its determination that the action is not subject to CN requirements. This decision is binding upon the CN Program unless the nature, extent or cost of the action

¹⁷ WAC 246-310-020(1)(d).

¹⁸ Expenditures of preparation shall include expenditures for architectural designs, plans, working drawings, and specifications. The CN Program may issue CNs permitting predevelopment expenditures, only, without authorizing any subsequent undertaking with respect to which such predevelopment expenditures are made. RCW 70.38.105(4)(g).

¹⁹ WAC 246-310-020(1)(e).

²⁰ See *Centennial Villas, Inc. v. Dep't of Health and Social Serv.*, 47 Wn. App. 42, 733 P.2d 564 (1987) (existing nursing home required to apply for a CN before operating a home health care service).

²¹ See *Multicare Health Sys. v. Dep't of Health*, 118 Wn. App. 597, 77 P.3d 363 (2003) (requiring that a hospital system apply for a CN before constructing a new hospital, even if a single hospital license will encompass both facilities).

²² See also RCW 70.38.115(3) and WAC 246-310-470 regarding HMO CN applications.

²³ See also WAC 246-310-397.

²⁴ WAC 246-310-050.

significantly changes. Determination of non-reviewability (“DNR”) requests include in-office ambulatory surgery centers,²⁵ mergers and affiliations of health facility systems and relocation of CN approved facilities.

Ambulatory surgical facilities operated in the offices of private physicians or dentists are not required to obtain a CN, provided that the privilege to use the facility is not extended to physicians or dentists outside the individual or group practice.²⁶ These facilities should apply for a DNR.²⁷ Timeshare arrangements, in which a group practice or individual physician shares the use of an ambulatory surgery facility with another group practice or individual physician, each of which has a contractual agreement to use the facility exclusively at specified periods of time, are not required to obtain a CN but must get a DNR. In addition, the CN Program has issued DNR’s for ambulatory surgical facilities owned by a hospital system and used exclusively by the employed doctors of that hospital system.²⁸

14.5 Certificate of Need Review Criteria

Once an application is submitted the CN Program reviews the application for compliance with four criteria:

1. Whether the proposed project is needed (“Need”);
2. Whether the proposed project will foster containment of the costs of health care (“Cost Containment”);
3. Whether the proposed project is financially feasible (“Financial Feasibility”); and
4. Whether the proposed project will meet the criteria for structure and process of care (“Structure and Process of Care”).²⁹

When evaluating these criteria the CN Program will also consider the availability of alternative uses of project resources for the provision of other health services, the extent to which residents of the area will have access to the proposed service, and the need for facilities for osteopathic and allopathic physicians.³⁰ Additionally, the CN Program will evaluate the effect the proposed project will have on established services and facilities, including institutional training programs, osteopathic hospitals, nonallopathic services and children’s hospitals, as well as the quality of care provided by the applicant in the past (if the applicant operates other facilities or services).³¹ Hospital applicants will also be evaluated as to whether the hospital meets or exceeds the regional average level of charity care.³² “Improvements or innovations in the financing and delivery of health services which foster cost containment and serve to promote quality assurance and cost-effectiveness” will also be assessed.³³ The CN Program will analyze construction projects for the costs and methods used in the proposed construction as well as the impact on the cost of providing those health services and the charges to the public for provision of those services.³⁴ Nursing home applications will also be evaluated based on the availability of other nursing home beds in the planned area and the availability of other services available in the community.³⁵

14.5.1 Need

Though not explicitly stated in the statutes or regulations, need is the primary focus of CN evaluations and the first criteria evaluated. Depending on the type of application, the CN Program uses specified mathematical

²⁵ Applicants for DNR’s for ambulatory surgery centers can find the application at:

<http://www.doh.wa.gov/hsqa/FSL/certneed/Docs/Apps/ASCEXempApp.pdf>.

²⁶ WAC 246-310-010(5).

²⁷ WAC 246-310-050. The CN Program lists the DNRs beginning in 2009 on its website:

<http://www.doh.wa.gov/hsqa/FSL/certneed/DORArch2009.htm>.

²⁸ See DNR related to MultiCare Health System’s Day Surgery of Gig Harbor (2005); see also ASC decisions related to Kennewick General Hospital and Virginia Mason.

²⁹ WAC 246-310-200; Need - WAC 246-310-210; Financial Feasibility - WAC 246-310-220; Structure and Process of Care - WAC 246-310-230; Cost Containment - WAC 246-310-240.

³⁰ RCW 70.38.115(2)(d).

³¹ RCW 70.38.115(2).

³² RCW 70.38.115(2)(j).

³³ RCW 70.38.115(g).

³⁴ RCW 70.38.115(e).

³⁵ RCW 70.38.115(k).

Volume 2: Regulation of Healthcare Practitioners and Entities

formulas and methodologies to determine need. These methodologies are further described in this Chapter. When evaluating need the CN Program considers the following:

1. The need the population served or to be served has for the project and the ability of other services or facilities to accommodate this need;
2. The availability of the proposed service to underserved groups (i.e. racial and ethnic minorities, handicapped persons, etc.);
3. The substantiation by the applicant of any special needs and circumstances the proposed project is to serve;
4. The impact of the proposed project on health professional schools and training programs;³⁶
5. The necessity of the project for the special needs and circumstances of enrolled members of HMO's; and
6. Specific criteria related to nursing homes.³⁷

Careful preparation of the Need section is required, as it is the most highly contested criteria in CN-related litigation. In addition, often a determination of no-need will have a direct effect on the determination of the other CN criteria. Based on a finding of no-need the CN Program may decide that the applicant cannot fulfill the other criteria.³⁸

The applicant's past performance in providing charity care and care to underserved groups is also evaluated in the Need section. Applicants are requested to submit charity care policies as part of the application. Previous charity care expenditures of applicant hospitals are often compared to the planning area averages for charity care. As a condition of CN issuance, the CN Program has often required applicants to provide charity care in an amount comparable to the average amount given in the planning area.³⁹

14.5.2 Financial Feasibility

The determination of Financial Feasibility is based on the following criteria:

1. The ability of the applicant to meet the immediate and long range capital and operating costs of the project;
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 ability of the applicant to appropriately finance the project.⁴⁰

In the Financial Feasibility section, the CN Program analyzes the applicant's financial statements and projections as well as any contracts related to the project (i.e. lease agreements, purchase and sale agreements and medical director agreements).⁴¹ For hospitals the CN Program will evaluate Financial Feasibility by looking at financial ratios provided by the Office of Hospital and Patient Data Systems. "The financial ratios utilized are 1) long-term debt to equity ratio; 2) current assets to current liabilities ratio; 3) assets financed by

³⁶ The Supreme Court has recognized that an applicant is not in the best position to provide a meaningful analysis of the impact a proposed program will have on a potential competitor. The Supreme Court explains that "the wise applicant should attempt to show the impact on existing training programs, but it is not fatal to the application that the applicant does not have detailed information on that impact." *Univ. of Wash. Med. Ctr v. Wash. State Dep't of Health*, 164 Wn.2d 95, 107, 187 P.3d 243 (2008).

³⁷ WAC 246-310-210.

³⁸ See for example Evaluation of Overlake Hospital Medical Center application for 120 beds in East King County, (CN05-04) (2005).

³⁹ See for example Evaluation of Auburn Regional Medical Center application for 13 geropsychiatric beds in Southeast King County (CN09-17) (2009).

⁴⁰ WAC 246-310-220.

⁴¹ Additional items evaluated by the CN Program include real estate issues, control of property, need to obtain a binding commitment letter from the lessor.

liabilities ratio; 4) total operating expense to total operating revenue ratio; and 5) debt service coverage ratio. If a project's ratios are within the expected value range, the project can be expected to be financially feasible."⁴² These same ratios are analyzed for nursing home applications.⁴³

14.5.3 Structure and Process of Care

This criterion focuses on the quality of health care services provided by the applicant and proposed in the evaluation. The CN Program evaluates:

1. The availability of a sufficient supply of staff;
2. The relationship the proposed service has with ancillary and support services sufficient to support the proposed health service (i.e. assistance from hospitals);
3. Assurance that the project is in conformance with state licensing requirements and requirements under the Medicaid and Medicare programs, if applicable;
4. The ability of the proposed project to 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. Assurance that the proposed project will be provided in a manner that ensures safe and adequate care in accordance with state and federal laws.⁴⁴

The CN Program will investigate whether the applicant or licensee has a criminal conviction or a previous revocation of a license to operate a health care facility or practice a health profession that is reasonably related to the operation of a health care facility, this includes a decertification as a provider of services in the Medicare or Medicaid programs because of the failure to comply with applicable federal conditions of participation. If the applicant does have such a history the CN Program will determine if the applicant has affirmatively established that the applicant can and will operate the proposed project in a manner that ensures safe and adequate care and in compliance with state and federal law.⁴⁵

14.5.4 Cost Containment

The CN Program determines whether an applicant fulfills the Cost Containment criterion by assessing:

1. Whether superior alternatives, in terms of cost, efficiency, or effectiveness, are available or practicable;
2. In a proposed construction project the reasonableness of the costs, scope, and methods of construction and energy conservation and the impact this proposed project would have on the costs and charges to the public;
3. The ability of the project to 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.⁴⁶

As the factors above illustrate, the analysis of Cost Containment and Financial Feasibility are interrelated.

14.6 Certificate of Need Categories of Review

Once an application is submitted there are four review categories that the CN Program may use to evaluate the application.⁴⁷

⁴² Evaluation of Evergreen Healthcare's application for 80 new beds in East King County, CN08-042 (2008).

⁴³ Evaluation of Manor Care of Salmon Creek application for 120 bed skilled nursing center in Clark County, CN08-04 (2008).

⁴⁴ WAC 246-310-230.

⁴⁵ WAC 246-310-230.

⁴⁶ WAC 246-310-240.

⁴⁷ WAC 246-310-110.

Volume 2: Regulation of Healthcare Practitioners and Entities

14.6.1 Regular Review

This is the standard review procedure utilized by the CN Program and should not exceed 90 days unless otherwise extended.⁴⁸ The CN Program will accept public comments on the application for the first 35 days, and rebuttal comments from the applicant or any other affected party for 10 days following the close of public comments.⁴⁹ The CN Program then has 45 days to complete its evaluation unless the review process is extended. The CN Program routinely extends the evaluation timeline.

The CN Program may grant an extension for an additional 45 days if the applicant requests to amend the application. Additional extensions are allowed upon written approval of the applicant.⁵⁰ If the CN Program declares an unresolved pivotal issue then the CN Program may extend the review period up to 30 days following receipt of the applicant's response.⁵¹ The CN Program may also extend its final review upon written request of the applicant, but this extension shall not exceed 90 days.⁵²

14.6.2 Expedited Review

Expedited Review is utilized when the application is for a correction of deficiencies,⁵³ demonstration or research projects not involving a change in bed capacity or a new tertiary health service, acquisition of an existing health care facility, or a project limited to predevelopment expenditures.⁵⁴

The Expedited Review process shall not exceed 50 days.⁵⁵ The CN Program will accept public comments on the application for the first 20 days, and rebuttal comments from the applicant or any other affected party for 10 days following the close of public comments.⁵⁶ The CN Program then has 20 days to complete its evaluation unless the review process is extended. The CN Program may grant an extension for an additional 45 days if the applicant requests to amend the application. Additional extensions are allowed upon written approval of the applicant.⁵⁷ If the CN Program declares an unresolved pivotal issue then the CN Program may extend the review period up to 30 days following receipt of the applicant's response.⁵⁸ The CN Program may also extend its final review upon written request of the applicant, but this extension shall not exceed 60 days.⁵⁹

14.6.3 Concurrent Review

The Concurrent Review process is used when there are competing applications for the same proposed service. The CN Program employs a comparative analysis and evaluation of the competing projects in addition to the regular review of the four CN criteria.⁶⁰

The CN Program has created concurrent review cycles for certain types of applications. Applicants for these proposed projects must submit the applications in accordance with those review cycles so that the CN Program can review all competitive applications at the same time.⁶¹ The following projects have concurrent review

⁴⁸ WAC 246-310-160. For further information on unresolved pivotal issues see Section 14.7.8.

⁴⁹ Affected persons may also submit rebuttal comments to any public comments submitted during the first 35-day period. For more information regarding affected persons see Section 14.7.3.

⁵⁰ WAC 246-310-100(5), WAC 246-310-160(2)(a).

⁵¹ WAC 246-310-160(2)(b).

⁵² WAC 246-310-160(2)(c).

⁵³ WAC 246-310-480 governs applications for corrections of deficiencies, which include the elimination or prevention of imminent safety hazards, compliance with state licensing standards, and compliance with accreditation and certification standards which must be met to receive Medicare and Medicaid reimbursement. If the proposed project is for a correction of deficiencies then WAC 246-310-480 should be further consulted.

⁵⁴ WAC 246-310-110(2)(b).

⁵⁵ WAC 246-310-150.

⁵⁶ Affected persons may also submit rebuttal comments to any public comments submitted during the first 20-day period.

⁵⁷ WAC 246-310-100(5), WAC 246-310-150(2)(a).

⁵⁸ WAC 246-310-150(2)(b).

⁵⁹ WAC 246-310-150(2)(c).

⁶⁰ WAC 246-310-120 provides a detailed description of the concurrent review process. *See also* RCW 70.38.115(7).

⁶¹ For a concurrent review cycle timeline visit: <http://www.doh.wa.gov/hsqa/FSL/certneed/Docs/ConcurrentReviewCycles.pdf>.

cycles: Nursing Homes;⁶² Open Heart Surgery;⁶³ Kidney Disease Treatment Centers;⁶⁴ and Percutaneous Coronary Intervention (PCI).⁶⁵

14.6.4 Emergency Review

An Emergency Review is performed when an immediate capital expenditure is required in order for a health care facility to maintain or restore basic and essential patient services.⁶⁶ The emergency review period shall not exceed 15 working days from the beginning of the review period unless the CN Program extends the review period.⁶⁷ The CN Program may only extend this period if it has made a request for additional information to resolve an unresolved pivotal issue. This extension cannot exceed 10 days after receipt of the applicant’s written response.⁶⁸

14.6.5 General Timelines of Certificate of Need Applications⁶⁹

Application Activity	Regular Review	Expedited Review	Concurrent Review
Submission of Letter of Intent	Minimum of 30 days prior to application submission (six month validity from date of receipt).	Minimum of 30 days prior to application submission (six month validity from date of receipt).	Submitted in conformance with published schedule for type of project under review. Good for only one review cycle.
Submission of Application	After 30 days has lapsed and no later than six months after the Department’s receipt of Letter of Intent.	After 30 days has lapsed and no later than six months after the Department’s receipt of Letter of Intent.	Submitted in conformance with published schedule for type of project under review.
Application Screening	Within 15 working days after application submission.	Within 15 working days after application submission.	Within 30 days after application submission.
Applicant Response (Applicant may request the screening & response activity be conducted a second time.)	Within 45 days of receiving Department’s request for additional information. (Additional responses to screening letters will be accepted up to 10 days after the notice of Beginning of Review.)	Within 45 days of receiving Department’s request for additional information. (Additional responses to screening letters will be accepted up to 10 days after the notice of Beginning of Review.)	Within 30 days of receiving Department’s request for additional information.
Formal Review Period (Formal review begins on fifth)	A total of 90 days First 35 days open to general public comment and conducting a public hearing	A total of 50 days First 20 days open to general public comment. Last 10 days open for	A total of 135 days First 60 days open to general public comment and conducting a public hearing if

⁶² WAC 246-310-130.

⁶³ WAC 246-310-132.

⁶⁴ WAC 246-310-282.

⁶⁵ WAC 246-310-710.

⁶⁶ WAC 246-310-110(2)(a). If DOH determines that the application does not qualify for emergency review it must submit this determination within five days after receiving the application and notify the applicant which type of review will be used instead.

⁶⁷ WAC 246-310-140(1).

⁶⁸ WAC 246-310-140(2), (3).

⁶⁹ Provided on the CN Program website, <http://www.doh.wa.gov/hsqa/FSL/certneed/Review.htm>.

Application Activity	Regular Review	Expedited Review	Concurrent Review
working day after applicant’s request to begin review, or the Department declares the application complete.)	<p>if requested.</p> <p>Last 10 days open for applicant/ interested persons rebuttal statements submitted during first 35 days of public comment period</p> <p>Last 45 days exparte period. Department is preparing written analysis and decision.</p>	<p>applicant/ interested persons rebuttal statements submitted during first 20 days of public comment period.</p> <p>No public hearing conducted on projects qualifying for expedited review.</p> <p>Last 20 days exparte period. Department is preparing written analysis and decision.</p>	<p>requested.</p> <p>Last 30 days open for applicant/ interested persons rebuttal statements submitted during first 60 days of public comment period</p> <p>Last 45 days exparte period. Department is preparing written analysis and decision.</p>

14.7 Certificate of Need Application Process

Certificate of Need Applications can be found on the CN Program website at:

<http://www.doh.wa.gov/hsqa/FSL/certneed/Appl.htm>. The CN Program also provides a list of consultants that can assist applicants with the process.

14.7.1 Letter of Intent

The first step in the CN application process is the submission of a Letter of Intent to the CN Program.⁷⁰ The Letter of Intent shall include a description of the proposed services or facility, the estimated cost of the project, and the identification of the service area. The applicant should submit the Letter of Intent at least 30 days prior to the submission of the application; the applicant then has six months in which to submit the application. If the project described in the application is significantly different than the project described in the letter of intent, the CN Program will consider the application to be the new letter of intent and no action will be taken until the end of the 30 day period.⁷¹ The CN Program has determined in the past that a significant difference can equal a 12% increase in capital expenditures.⁷² Applicants for concurrent review should submit the Letter of Intent according to the applicable schedule. The CN Program will determine which of the proposed projects qualify for concurrent review and notify the applicants. If the CN Program determines that there are no competing applications it will convert the review of that application to the regular review process.

14.7.2 Application

The applicant must submit one original and one copy of the application to the CN Program along with the appropriate fee.⁷³ There are three common components of CN applications:

1. Applicant Description - this section requests information about the entity applying for the CN.
2. Project Description - this section requests information about the proposed project, including information regarding patient mix, financing of the project and capital expenditures, and documentation that the applicant has sufficient interest in the proposed site.
3. Project Rationale - this section describes the four CN criteria of Need, Financial Feasibility, Structure and Process of Care, and Cost Containment.

The applicant provides its analysis of the appropriate Need methodology within the Project Rationale section of the application. The formula used to evaluate Need varies depending on the type of project.⁷⁴ Not

⁷⁰ WAC 246-310-080.

⁷¹ WAC 246-310-080(3).

⁷² See for example CN Program’s rejection of Franciscan Health System’s CN application for a kidney dialysis facility, March 13, 2007; decision affirmed by Thurston County Superior Court decision, Cause No. 07-2-00628-9.

⁷³ For a list of fees see WAC 246-310-990.

uncommonly, a CN applicant may request phased installation of the proposed project or facility; for example a hospital requesting additional beds may open the beds according to a phased timetable as opposed to commencing service all at once.⁷⁵ Applicants often propose a phased implementation when there is not an immediate need for the amount of service being proposed, but the need does exist a few years in the future.

14.7.3 Affected and Interested Persons

Affected and interested persons status allows persons to provide comments to the CN Program. “Interested persons” include a broader subset of interested parties, including “affected persons.” Interested persons include:

1. The applicant;
2. Health care facilities and health maintenance organizations providing services similar to the services under review and located in the health service area;
3. Third-party payers reimbursing health care facilities in the health service area;
4. 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;
5. 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;
6. Any person residing within the geographic area to be served by the applicant; and
7. Any person regularly using health care facilities within the geographic area to be served by the applicant.⁷⁶

Interested persons are allowed to provide comments to the application and unresolved pivotal issues,⁷⁷ receive notification of the beginning of the review period,⁷⁸ request a public hearing,⁷⁹ request reconsideration,⁸⁰ provide rebuttal comments on pediatric cardiac surgery and interventional treatment centers, as well as hospice services and hospice care applications provided certain criteria are met.⁸¹

Affected persons are interested persons who:

1. Are located or reside in the applicant's health service area;
2. Testify at a public hearing or submit written evidence; and
3. Request in writing to be informed of the Department's decision.⁸²

Along with the rights provided to interested persons, affected persons are granted the following additional privilege: ability to provide rebuttal statements in a regular, concurrent, or expedited review process.

Persons wishing to request affected person status must send a written request to the CN Program requesting such status. It is recommended that this letter be sent immediately following the receipt of the CN application. Following receipt of this letter the CN Program will copy the affected party on all correspondence between the CN Program and the applicant.

⁷⁴ For a list of methodologies see: <http://www.doh.wa.gov/hsqa/FSL/certneed/Method.htm>.

⁷⁵ See Evaluation of Franciscan Health Services, St Francis Hospital, CN07-03, request for a CN for an additional 36 beds, the first 18 beds to be operational in January 2010, the second 18 beds to be operational in January 2012 (2007).

⁷⁶ WAC 246-310-010(34).

⁷⁷ WAC 246-310-090(1)(a)(iii).

⁷⁸ WAC 246-310-170(1).

⁷⁹ WAC 246-310-170(2)(c)(v).

⁸⁰ WAC 246-310-560(1).

⁸¹ WAC 246-310-263(f), WAC 246-310-290(f), WAC 246-310-295(f). The criteria require that the interested person: a) be located or reside within the applicant's health service area; b) testify or submit evidence at a public hearing; and c) request in writing to be informed of the Department's decision.

⁸² WAC 246-310-010(2).

Volume 2: Regulation of Healthcare Practitioners and Entities

Standing of affected persons is further discussed in Section 14.9.

14.7.4 Screening

Within 15 days following the receipt of the application, the CN Program may request additional information to enable its evaluation of the proposed project.⁸³ The applicant then has 45 days to respond with the requested supplemental information.⁸⁴ The applicant may respond in one of three ways: 1) submit the supplemental information and request that the application be screened again to determine if the application is still incomplete; 2) submit the supplemental information and request that the review of the CN application begin without any further request for supplemental information; or 3) submit a written request that the CN Program proceed without supplemental information.⁸⁵

14.7.5 Amendment of a Certificate of Need Application

The following changes to a CN application may be considered an amendment to the application:

1. The addition of a new service or elimination of a service included in the original application.
2. The expansion or reduction of a service included in the original application.
3. An increase in the bed capacity.
4. A change in the capital cost of the project or the method of financing the project.
5. A significant change in the rationale used to justify the project.
6. A change in the applicant.⁸⁶

An application for expedited or regular review may be amended during the screening period or the public comment period; amendments will not be admitted after that period.⁸⁷ If the CN Program determines that the application has been amended, the review period may be extended for up to an additional 45 days.⁸⁸

14.7.6 Beginning of Review

Once the CN Program has received the application and any screening responses from the applicant, the CN Program will send to the applicant and any interested persons a notification of the beginning of review.⁸⁹ Affected and interested persons⁹⁰ must submit a written request to be notified of any action and communications between the CN Program and the applicant. To maintain affected person status the party must

⁸³ WAC 246-310-090.

⁸⁴ Except for concurrent review applicants who must respond within one month. WAC 246-310-090(2)(b).

⁸⁵ WAC 246-310-090(c).

⁸⁶ WAC 246-310-100.

⁸⁷ See Evaluation of Good Samaritan Hospital, CN05-09, page 18, revision in capital costs not accepted because such a revision requires an amendment which may not be submitted after the screening and public comment periods have ended.

⁸⁸ See WAC 246-310-100 regarding amendments during the concurrent and emergency review periods.

⁸⁹ WAC 246-310-170.

⁹⁰ WAC 246-310-010 provides the following definitions:

(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.

(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.

submit testimony or evidence at or before the public hearing. The Notice of Beginning of Review shall be given within five working days following the receipt of a complete application or request by the applicant that review begin.⁹¹ Review of expedited and regular review applications shall begin on the day the CN Program sends out the Notice of Beginning of Review. Review of concurrent review applications shall begin 15 days after the conclusion of the review cycle. The CN Program shall review emergency review applications one day after the application is deemed complete.

14.7.7 Public Hearings

Upon request by one or more interested persons or upon the CN Program's own initiative, the CN Program will hold a public hearing.⁹² A request is valid provided it is submitted in writing, is received within 15 days of the Notice of Beginning of Review, identifies the application and includes the name, address, and signature of the person making the request. The CN Program will provide notice of the public hearing at least 15 days before the hearing. During the public hearing the CN Program will preside over the meeting, and maintain a verbatim record of the public hearing. Public hearings on expedited or emergency review applications are not required. Public comments are often submitted at or prior to the public hearing. After the first 35 days of the public comment period, the applicant or any affected or interested persons have 10 days to submit rebuttal comments.

Any party has the right to be represented by counsel and to present oral or written arguments and evidence at the public hearing. Affected persons may also ask questions at the public hearing.⁹³ Typically the public hearings are non-adversarial and consist of presentations by the applicant, community members, community providers, and other facilities affected by the application.

14.7.8 Ex Parte Contact and Unresolved Pivotal Issues

The CN Program will not consider any information submitted by the applicant following the close of the public comment period.⁹⁴ The one exception to this rule is when the CN Program declares an unresolved pivotal issue which requires additional information and the applicant agrees to an extension of the review period. If an unresolved pivotal issue is declared, the CN Program will provide public notice of the issue and will allow public comments from interested persons.

Ex parte contact following the end of the public comment period is not allowed except for communication regarding the procedure or process of review or communications by the CN Program which are made open to the public and may include a written request and responses regarding the application.⁹⁵

14.7.9 Evaluation of the Certificate of Need Application

The CN Program evaluates a CN application by determining if the application meets the Need, Financial Feasibility, Structure and Process of Care, and Cost Containment criteria. When evaluating the CN application, the CN Program takes into account the application, screening responses and public comments, including any rebuttal comments. To evaluate the application, the CN Program may employ standards developed by a variety of sources including but not limited to Washington state professional organizations, federal standards, state licensing requirements and nationally recognized standards. When issuing a CN, the CN Program will specify the maximum capital expenditure and the cost components associated with that expenditure for which the applicant is allowed to expend in constructing the CN approved project.⁹⁶

Depending on the type of application, the CN Program may determine that only a certain number of beds, operating rooms or dialysis stations are needed in the proposed facility.⁹⁷ For example, the CN Program may determine that a planning area does not need the number of acute care beds a hospital applicant has requested.⁹⁸

⁹¹ Contents of the Notice of Beginning of Review are described in WAC 246-310-170(c).

⁹² WAC 246-310-180.

⁹³ WAC 246-310-180(5).

⁹⁴ WAC 246-310-090; WAC 246-310-190.

⁹⁵ WAC 246-310-190.

⁹⁶ WAC 246-310-500(1)(d).

⁹⁷ See WAC 246-310-500(1).

⁹⁸ See Evaluation of Providence Everett Medical Center, CN06-24, granting 106 acute care beds as opposed to the 166 requested (2006).

Volume 2: Regulation of Healthcare Practitioners and Entities

The CN Program may choose to grant a CN for a modified number of beds, as opposed to granting the entire request.

If the CN Program denies a CN, the applicant may request reconsideration or an adjudicative proceeding.⁹⁹ If the CN Program denies a proposed project, then it shall not accept another CN application for the same project unless there is a substantial change in the existing facilities or services in the planning area or the need for such facilities or services or one year has passed since the submission of the application.¹⁰⁰

Once granted, a CN is valid for two years unless the CN Program grants a six month extension.¹⁰¹ During this two year period the project must be commenced, but does not need to be completed.¹⁰² Applications for an extension must be submitted at least 120 days before the expiration of the CN (unless there are unforeseen circumstances).¹⁰³

Review of previous evaluations will aid future applicants in determining how the CN Program will evaluate new applications. The CN Program website contains Archives of previous CN decisions from 2004 to the present.¹⁰⁴

14.7.10 Conditional Certificates of Need

The CN Program may issue a conditional CN if it determines that the project is justified only under specific circumstances and if the conditions directly relate to the project being reviewed and the review criteria.¹⁰⁵ If the CN Program determines that the application does not meet the need criteria or the accessibility criteria outlined in WAC 246-310-210(1) and (2), it may impose conditions that the applicant take affirmative steps to satisfy those review criteria. The CN Program may, upon request, release the conditions. A request to release these conditions must include information demonstrating that the conditions are no longer valid and that the release of the conditions would be consistent with the CN Program. Such a request would be submitted pursuant to the submission guidelines of WAC 246-310-090. A common condition required by the CN Program is that the applicant meet or exceed the average amount of charity care provided in the planning area.¹⁰⁶

14.7.11 Reconsideration

Following a decision by the CN Program to either grant or deny the CN, any interested or affected person, including the applicant, may request a public hearing for the purpose of reconsideration.¹⁰⁷ The request must be submitted in writing within 28 days of the decision and must show good cause for reconsideration. Grounds for good cause shall include, but are not limited to, the following:

1. Significant relevant information not previously considered by the Department which, with reasonable diligence, could not have been presented before the Department made its decision;
2. Information on significant changes in factors or circumstances relied upon by the Department in making its findings and decision; or

⁹⁹ See *infra* Section 14.7 and Section 14.9.

¹⁰⁰ WAC 246-310-500(5), unless it is a concurrent review and the concurrent review cycle permits the submission of applications.

¹⁰¹ WAC 246-310-580. To receive an extension the applicant must show that “substantial and continuing progress toward commencement of the project has been made.” “Substantial and continuing progress” is further defined in WAC 246-310-580(2).

¹⁰² WAC 246-310-580.

¹⁰³ WAC 246-510-580(4)-(5), for information regarding extensions granted to nursing homes for conversion of banked beds see WAC 246-510-580(7).

¹⁰⁴ <http://www.doh.wa.gov/hsqa/FSL/certneed/archive.htm>.

¹⁰⁵ WAC 246-310-490(3).

¹⁰⁶ See e.g., Swedish Health Services Remand Evaluation, CN04-47, granting a CN for a 175-bed hospital in Issaquah, King County (2007); Proliance Surgeons, Inc. Reconsideration Evaluation, CN06-17, granting a CN for a free-standing ASC in Skagit County (2006).

¹⁰⁷ WAC 246-310-560.

3. Evidence the Department materially failed to follow adopted procedures in reaching a decision.¹⁰⁸

The reconsideration hearing shall occur within 30 days of the receipt of a request and the CN Program shall properly notify all interested and affected parties. The CN Program also accepts written public comments at the public hearing (or prior to the public hearing) and allows rebuttal comments. Within 45 days after the reconsideration hearing the CN Program shall issue a decision. The CN Program may decide to issue or deny the CN, revoke, amend, or impose or modify conditions. An applicant requesting a reconsideration hearing does not forfeit any rights it may have to an adjudicative appeal.

14.7.12 Amended Certificates of Need

An amended CN is required for any of the following modifications to a project.

1. An addition of a new service;
2. An expansion of a service;
3. An increase in the inpatient bed capacity;
4. The modification or release of a condition placed on a certificate of need;
5. 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 total project cost increases exceeds 12% or \$50,000, whichever is greater, over the maximum capital expenditure;¹⁰⁹ or
6. A change in the approved site.¹¹⁰

An application to amend a CN should be submitted prior to the completion of the project, except under specific circumstance for construction projects, and should be in accordance with the submission guidelines in WAC 246-310-090.¹¹¹ An application for an amended CN may be reviewed under the expedited review process. The CN Program shall provide a written determination of whether an amended CN is needed within 21 days after the receipt of a request for such a determination.

What this rule does not specify is when the CN Program must require the applicant to submit an amended CN application. Though an applicant must submit the amendment prior to project completion (except in certain circumstances involving new construction) the rule is vague regarding whether the application can be submitted following substantial completion or at any other point in the process.

14.7.13 Suspension, Revocation and Transfer

The CN Program may revoke or suspend a CN for cause, which shall include, but is not limited to:

1. Suspicion of fraud (or determination of fraud for revocation),
2. Misrepresentation,
3. False statements,
4. Misleading statements,
5. Evasion or suppression of a material fact in the application for a CN or any of its supporting materials.¹¹²

¹⁰⁸ WAC 246-310-560(b)(i)-(iii).

¹⁰⁹ The review of such reductions or cost increases shall be restricted to the continued conformance of the project with the criteria contained in the Financial Feasibility and Cost Containment requirements.

¹¹⁰ WAC 246-310-570(1).

¹¹¹ WAC 246-310-570(2). For information regarding amendments to construction projects see WAC 246-310-570(2).

¹¹² WAC 246-310-500(3)(a).

Volume 2: Regulation of Healthcare Practitioners and Entities

Upon revocation or suspension, the CN Program shall issue an order which states the reason for the revocation or suspension. A suspension shall not exceed 120 days, during which time the CN Program shall determine whether to reinstate, amend or revoke the CN.

Provisions regarding transfer of a CN are described in WAC 246-310-500(7). A transfer of a CN will not be issued unless, prior to the completion of the project, death or divorce makes it impossible or impractical to complete the project in the absence of a transfer, or after commencement of the project a substantial portion of the project has been completed by the original holder of the application.

14.7.14 Monitoring

Following the issuance of a CN, the CN Program will monitor the project to ensure conformance with the terms of the CN¹¹³ through quarterly progress reports submitted by the applicant. These progress reports must be submitted in a form as required by the CN Program and may contain updates to the actual project costs, changes in the project, financing arrangements, project commencement date, progress towards completion and the project completion date. The progress reports shall terminate upon completion of the project and when the CN Program finds that it has received all necessary information to determine that the project was completed.

14.7.15 Withdrawal

The CN Program may withdraw a CN if it determines that the holder of a CN is not meeting the timetable specified in the CN application for completion of the project and is not making a good faith effort to meet the timetable.¹¹⁴ The review period for a withdrawal is 90 days unless a 30-day extension is granted and includes a public hearing. The CN Program will issue written findings explaining its determination of whether to withdraw the CN. The program may decide to withdraw only a part of a CN related to specific services of the project when there are multiple components of a project.

14.8 Rules for Specific Facilities and Services

14.8.1 Hospitals

The 1987 State Health Plan provides the Need methodology used to determine the need for additional acute care and psychiatric beds. Though the State Health Plan sunset in 1989, the CN Program still utilizes this methodology to determine bed need.¹¹⁵ The bed need methodology is quite complicated and requires projections for the planning area population. The application of the bed need methodology is often the target of affected parties' comments. Whether this is the sole method for calculating bed need has yet to be determined. In computing the bed need methodology applicants use patient data from the Office of Hospital and Patient Data Systems, which is obtained using the Comprehensive Hospital Abstract Reporting System (CHARS).¹¹⁶ Applicants should use the last full year of CHARS data available at the time of the submission of the application. The CN Program may also consider additional factors outside of the numeric methodology when determining bed need.¹¹⁷

When projecting bed need, the CN Program projects seven years in the future.¹¹⁸ If the project is phased, an additional three years may be considered.¹¹⁹ The CN Program evaluates the need of the planning area through at least three years following projected completion of the project. Additionally, the CN Program analyzes the financial ratios, submitted in the financial feasibility section, for at least three years following the completion of the project to ensure the financial viability of the project. For new hospital applications, the CN Program will

¹¹³ WAC 246-310-590.

¹¹⁴ WAC 246-310-600.

¹¹⁵ As of the writing of this chapter, the CN Program has initiated workshops to review the current acute care bed need methodology to propose new rules.

¹¹⁶ This can be obtained online at: <http://www.doh.wa.gov/ehsphl/hospdata/chars.htm>.

¹¹⁷ For an example see the Reconsideration Evaluation of Kennewick General Hospital, August 21, 2002; *see also* 1987 State Health Plan page C-28.

¹¹⁸ 1987 State Health Plan page C-30.

¹¹⁹ *See* Providence Everett Medical Center Evaluation, CN06-24.

apply a longer planning horizon.¹²⁰ Typically, the CN Program will grant a CN for the number of beds needed as determined by the bed need methodology. However, in the situation of an application for a new facility, the CN Program has allowed some surplus beds because of the costs associated with building a new facility and the expectation that a new facility does not operate at full capacity when the hospital first opens.¹²¹

14.8.2 Kidney Disease Treatment Centers

WAC 246-310-280 through -289 describe in detail the application requirements for kidney disease treatment centers (“Dialysis Centers”) providing hemodialysis or peritoneal dialysis. As mentioned above, Dialysis Centers are reviewed under a concurrent review cycle.¹²² Since multiple applications are often submitted for the same planning area, the CN Program on occasion must evaluate the tie breaking factors in determining which applicant should receive the CN, these factors are described in WAC 246-310-288. The methodology, described in WAC 246-310-284, uses patient data available from the Northwest Renal Network as of the first day of the application submission period and applies a form of regression analysis to determine the forecast of station need.¹²³ Proposed facilities must reasonably project to be operating at 4.8 in-center patients per station in certain highly populated planning areas, and 3.2 in-center patients per station in less populated planning areas.¹²⁴

14.8.3 Ambulatory Surgery Facilities

An “Ambulatory Care Facility” is defined as “any place, building, institution, or distinct part thereof not a health care facility” that is “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.”¹²⁵ An “Ambulatory Surgical Facility” (“ASF”) includes all free-standing facilities, including an Ambulatory Surgery Center (“ASC”), “that operates primarily for the purpose of performing surgical procedures to treat patients not requiring hospitalization. A CN is not required for a facility in the offices of private physicians or dentists, whether for an individual or group practice, if the privilege of using the facility is not extended to physicians or dentists outside the individual or group practice.”¹²⁶ ASC’s licensed under a hospital’s license but located outside of the hospital’s main facility are required to apply for a CN.¹²⁷

When analyzing an ASF application, the CN Program evaluates the total number of operating rooms available in the planning area and whether additional operating rooms are needed.¹²⁸ The methodology for determining need is provided in WAC 246-310-270. The number of surgeries and the number of minutes for each surgery are calculated based on survey data submitted by ASC’s, hospitals, and in-office facilities in the planning area. Both inpatient and outpatient operating rooms are included in the need evaluation. However, when determining the number of operating rooms in a planning area, operating rooms used specifically for special purposes, such as open heart surgery or endoscopy are excluded.¹²⁹ When calculating the ASF methodology, the applicant may include surgeries performed in exempt facilities when determining the need for additional operating rooms, but exclude these same facilities when determining the number of operating rooms in the planning area.¹³⁰

¹²⁰ See Legacy Health System, evaluation for a new hospital in Clark County and Level III NICU, March 15, 2002, DOH applied a twenty year planning horizon.

¹²¹ See Swedish Health Service, Remand Evaluation for a hospital in Issaquah, CN04-47, page 16.

¹²² WAC 246-310-282.

¹²³ Exponential regression analysis is used if the planning area has experienced more than 6% of patient growth. Linear regression analysis is used if the planning area has experienced less than 6% of patient growth.

¹²⁴ WAC 246-310-284(6).

¹²⁵ WAC 246-310-010(4).

¹²⁶ WAC 246-310-010(5).

¹²⁷ In 1996, WAC 246-310-010 defining “ambulatory surgical facilities” was modified to delete the provision that the facility was not a part of a hospital. Legislative history of the modification indicates that the CN Program wanted to create a level playing field between hospitals and non-hospitals wishing to operate an ASC; see also Application for Determination of Non-Reviewability- Ambulatory Surgical Centers.

¹²⁸ WAC 246-310-270.

¹²⁹ WAC 246-310-270(9)(a)(iv); see also Evaluation of Western Washington Endoscopy Centers, LLC, CN08-41, application for three dedicated endoscopy operating rooms (2008).

¹³⁰ *Overlake Hospital Association v. Dep’t of Health*, 2010 WL 3705227 (Washington Supreme Court, Sept. 23, 2010).

Volume 2: Regulation of Healthcare Practitioners and Entities

An application for an ASF must contain a minimum of two operating rooms. Applicants for ASF's must document that they can provide charity care at levels consistent with the charity care levels provided by hospitals in the planning area.¹³¹

14.8.4 Nursing Homes

CN approval for new nursing home beds or the redistribution of beds to skilled nursing care beds is performed under a concurrent review cycle.¹³² The numeric bed need methodology for nursing homes is defined in WAC 246-310-360.¹³³ The CN Program may consider certain revisions to the need methodology based on: 1) the national (and other state) bed-to-population ratios; 2) data and information provided by the provider and consumer representatives; 3) state government policy goals regarding distribution of resources between nursing homes and other community based services; 4) the effects of developments in delivery and financing of long-term care services; and 5) progress in developing other long-term care services.¹³⁴

Unlike hospitals, nursing homes are allowed to “bank” nursing home beds.¹³⁵ A nursing home which voluntarily decides to reduce its number of beds in order to provide other services may convert the facility back and reopen those beds without applying for a new CN provided that the number of beds does not exceed the original license, the facility has been in continuous operation and the facility has not been purchased or leased. Additionally, the conversion must occur no later than four years after the reduction, however this may be extended by the CN Program for an additional four years if good cause is shown.¹³⁶ Special notice requirements for nursing homes intending to bank beds or reopen beds are outlined in WAC 246-310-395.

If a nursing home decides to cease operation, the licensee or another party with a secured interest in the beds may reserve its interest in the beds for up to eight years or until a CN to replace those beds is issued.¹³⁷ Notice to retain these beds must be given no later than 30 days after the effective date of the nursing home's closure. CN review is required for any party who has reserved the nursing home beds, except the need criteria will be deemed met if the applicant is the licensee who has operated the beds for at least one year preceding the reservation of the beds, and is replacing the beds in the same planning area.

Nursing homes dedicated to providing care to ethnic minorities are granted a specific exception to the normal nursing home CN requirements.¹³⁸ Based on findings that certain ethnic minorities use nursing home care at a lower rate than the general population due to special cultural, language, dietary and other needs, the Legislature decided to establish a special pool of nursing home beds (no more than 250 beds) designed to serve the needs of these ethnic minorities. To be eligible for this special pool of nursing home beds the applicant must: 1) be owned or operated by a nonprofit corporation in which at least fifty percent of the board of directors are members of the ethnic minority; 2) develop a nursing home to serve the special needs of that ethnic community; and 3) not discriminate in admissions against persons who are not members of the ethnic minority.¹³⁹ In evaluating an application the CN Program shall consider the four CN criteria as well as: 1) whether the long-term care needs of an ethnic minority are not otherwise being met; 2) the percentage of low-income persons who will be served by the proposed nursing home; and 3) the impact of the application on the area's total need for nursing home beds.¹⁴⁰

14.8.5 Hospice Services

A concurrent review process is used for hospice services applications. Applicants must demonstrate that they can meet a minimum average daily census of 35 patients by the third year of operation.¹⁴¹ The CN Program may grant an exception if the applicant can commit to maintain Medicare certification, commits to serve one or

¹³¹ See e.g. Evaluation of the Doctor's Clinic ASC application, CN08-01 (2008).

¹³² WAC 246-310-130, this WAC includes continuing care retirement communities.

¹³³ See WAC 246-310-380, -390 for additional bed need standards.

¹³⁴ WAC 246-310-370.

¹³⁵ See RCW 70.38.111(8) and WAC 246-310-395.

¹³⁶ RCW 70.38.111(8)(c).

¹³⁷ RCW 70.38.115(13)(b) and WAC 246-310-396.

¹³⁸ RCW 70.38.220.

¹³⁹ RCW 70.38.220(4).

¹⁴⁰ See WAC 246-310-136.

¹⁴¹ WAC 246-310-290(6).

more counties that do not have any Medicare certified providers, and can document financial feasibility. Both the need methodology and guidelines for assessing competing applications are contained within WAC 246-310-290 and WAC 246-310-295.

In 2009 the Legislature amended RCW 70.38.111 to allow certain hospice agencies to operate without first obtaining a CN. These hospice agencies must be designed to serve unique religious or cultural needs of a religious group or ethnic minority and commit to furnishing hospice services in a manner aimed at meeting those religious or cultural needs. Additionally, the hospice agency must: 1) operate a facility that offers a “comprehensive continuum of long-term care services,”¹⁴² 2) have had these facilities for at least 10 continuous years prior to the establishment of the hospice agency; 3) have a census of no more than 40 patients; 4) commit to coordinating the hospice programs with the community as appropriate; 5) commit to obtaining and maintaining Medicare certification; 6) only serve patients located in the same county as the majority of the long-term care services offered by that agency; and 7) not sell or transfer the hospice agency to another agency. The CN Program shall include the patient census of these exempted organizations in future CN need calculations.

14.8.6 Swing Beds

Swing beds are defined as up to five hospital beds, designated in an eligible rural hospital, which are available to provide either acute care or long-term care nursing services.¹⁴³ Applicants for swing bed projects must be located in a nonstandardized metropolitan statistical area and cannot have capacity for more than 100 licensed beds. Additionally, hospitals must meet the minimum Medicare standards for rural hospital swing beds.

14.8.7 Tertiary Services

WAC 246-310-020 defines tertiary services to include the following: specialty burn services, intermediate care nursery and obstetric services (Level II), neonatal intensive care nursery and obstetric services (Level III), transplantation of specific solid organs, open heart surgery and elective therapeutic cardiac catheterization, including elective percutaneous transluminal coronary angioplasty (PTCA), inpatient physical rehabilitation services (Level I) and specialized inpatient pediatric services, including pediatric cardiac surgery and interventional treatment,¹⁴⁴ and elective percutaneous coronary interventions (PCI).¹⁴⁵ The CN Program may make changes to this list of tertiary services.¹⁴⁶

The CN Program has provided application guidelines for certain tertiary services, including requiring that an applicant prove that it can perform a certain volume of procedures in order to meet the need criteria.¹⁴⁷ CHARS data is often utilized in performing these calculations.¹⁴⁸ Certain tertiary services, such as open heart surgery applications and PCI are subject to concurrent review.¹⁴⁹

14.9 Adjudicative Process and Judicial Review

The Washington Administrative Procedure Act (WAPA)¹⁵⁰ and the CN Program’s administrative procedure for adjudicative proceedings govern the adjudicative process.¹⁵¹ This section describes the adjudicative and judicial review process, as well as issues related to standing and the authority of the HLJ.

14.9.1 Appeal of a CN Decision

An applicant denied a CN or a certificate holder whose CN was suspended or revoked has a right to an adjudicative proceeding.¹⁵² A request for adjudicative proceeding must be made within 28 days of receipt of the

¹⁴² This includes, at a minimum, “a licensed, Medicare-certified nursing home, assisted living, independent living, day health, and various community-based support services.” RCW 70.38.111(9).

¹⁴³ WAC 246-310-410.

¹⁴⁴ WAC 246-310-263.

¹⁴⁵ WAC 246-310-710 through -755.

¹⁴⁶ WAC 246-310-035.

¹⁴⁷ See for example WAC 246-310-260 and WAC 246-310-261.

¹⁴⁸ See for example WAC 246-310-261 and WAC 246-310-740.

¹⁴⁹ WAC 246-310-132 and WAC 246-310-710.

¹⁵⁰ RCW 34.05.

¹⁵¹ See RCW 34.05 and WAC 246-10.

¹⁵² WAC 246-310-610.

Volume 2: Regulation of Healthcare Practitioners and Entities

CN Program's decision. The burden of proof in an adjudicative proceeding is the preponderance of the evidence standard and must be established by the applicant.¹⁵³ Any health care facility or HMO that provides similar services to the applicant, is located in the applicant's health service area, and testified or provided evidence at a public hearing, shall have the opportunity to present testimony and argument in an adjudicative proceeding provided that the entity requested to be informed of the CN Program's decision. If the CN Program decides to settle with the applicant then the affected health care facility shall have an opportunity to comment in advance on the proposed settlement. Additionally, notice must be given to affected parties when a stipulation to reopen review of a CN application is agreed upon by an applicant and the CN Program.¹⁵⁴

Under the WAPA, judicial review is of the final agency action. If the CN decision was appealed to an administrative hearing, the final agency action is the decision made by the HLJ.¹⁵⁵ Following a decision by the HLJ the contesting party has 30 days to file a request for judicial review.¹⁵⁶

A reviewing court may grant relief from an agency decision only in limited circumstances. These circumstances include:

1. The agency has engaged in unlawful procedure or decision-making process, or has failed to follow a prescribed procedure;
2. The agency has erroneously interpreted or applied the law;
3. The order is not supported by evidence that is substantial when viewed in light of the whole record before the court;
4. The order is inconsistent with a rule of the agency unless the agency explains the inconsistency by stating facts and reasons to demonstrate a rational basis for inconsistency; or
5. The order is arbitrary or capricious.¹⁵⁷

An agency's determination is overturned only if the factual findings are clearly erroneous, however the legal conclusions are reviewed de novo.¹⁵⁸

14.9.2 Standing

The question of standing to appeal a CN decision is one of the most highly contested issues in CN litigation. It is clear that an applicant who has been denied a CN has standing to request an adjudicative hearing and review of the CN decision by a Health Law Judge (HLJ).¹⁵⁹ Additionally, affected parties have the ability to intervene in adjudicative proceedings.¹⁶⁰ What has yet to be fully resolved is whether an affected party has standing to appeal to an adjudicative proceeding the grant of a CN or a DNR decision.

The Washington Supreme Court case *St. Joseph* is the touchstone decision discussing the standing of affected parties, in particular, competing facilities.¹⁶¹ In *St. Joseph*, the Supreme Court addressed the question of whether a competing entity had the ability to request judicial review of a decision granting a CN. The WAPA allows a person who is "aggrieved or adversely affected" by an agency action to request judicial review.¹⁶² The

¹⁵³ WAC 246-10-606.

¹⁵⁴ See *St. Joseph's*, 125 Wn.2d at 744.

¹⁵⁵ See *DaVita, Inc. v. Wash. State Dep't of Health*, 137 Wn. App. 174, 181, 151 P.3d 1095 (2007).

¹⁵⁶ RCW 34.05.542(3).

¹⁵⁷ RCW 34.05.570(3). Some of the circumstances have been excluded based on their applicability.

¹⁵⁸ *DaVita*, 137 Wn. App. at 181.

¹⁵⁹ WAC 246-310-610.

¹⁶⁰ RCW 70.38.115(10).

¹⁶¹ *St. Joseph Hosp. & Health Care v. Dep't of Health*, 125 Wn.2d 733, 887 P.2d 891 (1995).

¹⁶² RCW 34.05.530. A person is "aggrieved or adversely affected" if the following conditions are present:

- (1) The agency action has prejudiced or is likely to prejudice that person;
- (2) That person's asserted interests are among those that the agency was required to consider when it engaged in the agency action challenged; and
- (3) A judgment in favor of that person would substantially eliminate or redress the prejudice to that person caused or likely to be caused by the agency action.

Supreme Court applied the federal zone of interest test which focuses on whether the Legislature intended the agency to protect the competing party's interests. Relying on the purposes behind CN legislation, including the idea that "competition had a tendency to drive health care costs up rather than down," the Supreme Court determined that competing facilities were in the statutory zone of interest.¹⁶³ From a policy viewpoint, the Supreme Court determined that whereas an applicant has motivation to challenge a decision to deny a CN, a competitor is the only entity that has the motivation to seek review when the CN Program grants a CN.

Though *St. Joseph* gave competitors the right to request judicial review, it did not clearly provide this same right to adjudicative proceedings. In 1998, HLJ Eric Schmidt determined that competing entities have the right to request an adjudicative proceeding following the grant of a CN.¹⁶⁴ Judge Schmidt relied on *St. Joseph's* analysis, RCW 34.05.422(1)(b) and a second Supreme Court case, *Trades Council*,¹⁶⁵ in which the Supreme Court used *St. Joseph's* analysis to determine that competing providers have standing to request an adjudicative proceeding. Though Judge Schmidt's decision has been widely contested, it has been upheld multiple times.¹⁶⁶

St. Joseph and Judge Schmidt's decision grant standing to competitors for review of CN decisions; however, neither of these opinions address whether standing exists pertaining to DNR determinations. It still remains to be determined whether a competitor may request an adjudicative proceeding to review a DNR decision.¹⁶⁷

As a practical matter it is advisable for an affected party to file a request for adjudicative proceeding and judicial proceeding simultaneously in order to protect its ability to contest a CN decision. Though it is clear that a competitor has the right to judicial review, a right to an administrative hearing is not absolute.

14.9.3 Authority of the HLJ

In CN cases, the HLJ acts as a presiding officer, who takes evidence, listens to oral arguments and issues findings and conclusions. As such, the HLJ is the agency's fact finder.¹⁶⁸ The HLJ does not need to give deference to the analysis performed by the CN Program analysts or the CN Program's decision.¹⁶⁹ For example, in adjudicative proceedings before the HLJ competing applicants would both bear the burden of proof of establishing that its own application meets the applicable CN criteria, even if the CN Program determined

¹⁶³ *St. Joseph*, 125 Wn.2d at 741.

¹⁶⁴ See *In Re the Certificate of Need Joint Application of University of Washington Medical Center and Health Resources Northwest d/b/a Northwest Hospital*, Prehearing Order No. 3: Order on Joint Motions to Dismiss, Docket No. 97-07-C-1004CN, March 16, 1998.

¹⁶⁵ *Seattle Building & Construction Trades Council v. The Apprenticeship & Training Council*, 129 Wn.2d 787, 920 P.2d 581 (1996).

¹⁶⁶ See e.g., *In re: Certificate of Need Application of DaVita Inc., to establish a 12-station Dialysis Center in Tacoma, Washington*, No. 07-08-C-2009CN, Prehearing Order No. 2: Order Denying DaVita's Motion to Dismiss for Lack of Standing; *In re: Certificate of Need Application of Franciscan Health Care*, No. 07-07-C-2005CN, Amended Scheduling Order/Notice of Hearing; *In re the Certificate of Need Application of: Ear, Nose, Throat and Plastic Surgery Associates, P.S.*, No. 00-09-C-1037CN, Prehearing Order No. 6: Order on Motion for Partial Summary Judgment; *In re Certificate of Need Decision by Department of Health regarding Valley Orthopedic Surgery Center, LLC*, No. 02-07-C-1072CN; *In Re Certificate of Need Application of Swedish Medical Center*, No. 03-06-C-2001CN, Amended Findings of Fact, Conclusions of Law and Final Order; *In re: Certificate of Need Application of Manor of Meadow Park, Inc., to Establish Nursing Home in City of Lacey, Thurston County*, No. 06-03-C-2005CN, Prehearing Order No. 2 Order Regarding Consolidation and Continuance.

¹⁶⁷ The only published opinion discussing the reviewability of DNR determinations is a footnote in *Children's Hospital and Medical Center v. Washington State Department of Health*.¹⁶⁷ *Children's* acknowledges the anomaly which allows public hearings and comment periods during the CN process, but fails to provide an opportunity for an aggrieved party to contest a DNR. *Children's* notes that the only remedy for an aggrieved party is to request judicial review. *Children's Hospital and Medical Center v. Washington State Department of Health*, 95 Wn. App. 858, 862 n.4, 975 P.2d 567 (1999). However, in an unpublished opinion, the Court of Appeals appears to acknowledge a competitor's right to request an adjudicative proceeding of a DNR decision. See *Multicare Health System v. Department of Health*, 2008 WL 4868881, *5 (2008) (unpublished opinion).

¹⁶⁸ *Id.* at 182.

¹⁶⁹ *Id.* at 183.

Volume 2: Regulation of Healthcare Practitioners and Entities

that one application was superior to the other.¹⁷⁰ However, if the HLJ's decision to disregard the Program's decision is an arbitrary agency action then judicial relief may be appropriate.¹⁷¹

The HLJ also has wide discretion as to what evidence is admitted at the administrative hearing.¹⁷² The HLJ has the discretion to only allow evidence that was submitted prior to or during the public comment period, or to allow evidence that came into existence after the close of the public comment period. In dicta the Supreme Court noted that requiring an HLJ to admit evidence after a decision has been issued by the CN Program "would undermine the statutory objective of expeditious decision making and prevent meaningful public input on the evidence."¹⁷³ Though ultimately the decision of what evidence the HLJ shall admit during an adjudicative proceeding is at the discretion of the HLJ, it is advisable to submit all relevant evidence (for both applicants and interested parties) during the public comment period.

In CN related litigation previous adjudicative decisions are often cited and used as precedent. Though not binding in other adjudicative proceedings or judicial proceedings they are often persuasive.

14.9.4 Judicial Review of HLJ Decision

In *Providence Hospital of Everett v. Department of Social & Health Services*, the Supreme Court outlined the standards of review for CN cases:

1. We review the entire administrative record.
2. The agency decision is presumed correct and the challenger bears the burden of proof.
3. We do not retry factual issues and accept the administrative findings unless we determine them to be clearly erroneous, that is, the entire record leaves us with a definite and firm conviction that a mistake has been made. Important here is the corollary principle that the existence of credible evidence contrary to the agency's findings is not sufficient in itself to label those findings clearly erroneous.
4. The error of law standard permits this court to substitute its interpretation of the law for that of the agency, but we accord substantial deference to the agency's interpretation, particularly in regard to the law involving the agency's special knowledge and expertise.
5. To find an agency's decision to be arbitrary and capricious we must conclude that the decision is the result of willful and unreasoning disregard of the facts and circumstances.¹⁷⁴

The party challenging the CN Program's and HLJ's decision has "the burden of demonstrating the invalidity of [the] agency[']s action."¹⁷⁵ Deference is given to the CN Program or HLJ when it is exercising the agency's special knowledge and expertise.¹⁷⁶ For example, when the CN Program applies a complex mathematical formula deference is given to the agency's interpretation and expertise.¹⁷⁷ However, when the actions of the CN Program are arbitrary, capricious and contrary to law, deference is not given.¹⁷⁸

14.9.5 Construction of Facility Pending Adjudicative and Judicial Review

Following the issuance of a CN, if the applicant proceeds with construction while the CN is contested by affected parties, the applicant likely proceeds at its own risk.¹⁷⁹ Likewise, applicants have argued that the

¹⁷⁰ *Id.* at 185.

¹⁷¹ *Id.* at 184.

¹⁷² *Univ. of Wash. Med. Ctr. v. Wash. State Dep't of Health*, 164 Wn.2d 95, 104, 187 P.3d 243 (2008).

¹⁷³ *Id.*

¹⁷⁴ *Providence Hosp. of Everett v. Dep't of Soc. & Health Servs.*, 112 Wn.2d 353, 355-56, 770 P.2d 1040 (1989) (citations omitted).

¹⁷⁵ RCW 34.05.570(1).

¹⁷⁶ *Univ. of Wash. Med. Ctr. v. Wash. State Dep't of Health*, 164 Wn.2d 95, 102, 187 P.3d 243 (2008).

¹⁷⁷ *Odyssey Healthcare v. Wash. State Dep't of Health*, 145 Wn. App. 131, 143, 185 P.3d 652 (2008).

¹⁷⁸ *Children's Hosp. & Med. Ctr. v. Wash. State Dep't of Health*, 95 Wn. App. 858, 871, 975 P.2d 567 (1999).

¹⁷⁹ *See In re: Franciscan Health Systems, dba St. Joseph Medical Center Certificate of Need application for a 14 Station Kidney Dialysis Center in Spanaway Washington*, Prehearing Order No. 2: Order Denying Stay, Docket No. 04-06-C-2005CN, September 2, 2004.

construction and operation of a CN facility makes an adjudicative proceeding moot. No appellate court has decided the matter. Pursuant to HLJ decisions, “an adjudicative proceeding does not become moot once a contested certificate of need is operational.”¹⁸⁰ Accordingly, if a contesting party succeeds in an adjudicative proceeding in reversing the CN Program’s grant of a CN the fact that the facility has been built and is operational is irrelevant.

A contesting party is also not required to obtain a stay order preventing the applicant from commencing construction. In previous adjudicative proceedings, contesting parties have requested that an HLJ issue a stay order precluding the applicant from commencing the project. The contesting parties have argued that a stay order is necessary in order to “protect the potential fruits of its appeal and to avoid rendering the appeal process meaningless.”¹⁸¹ However, previous adjudicative decisions have determined that a stay is not required because a CN is a nonexclusive license,¹⁸² and as such “funds expended on a mere license do not create a valuable, compensable property right, as the license may be revoked.”¹⁸³ If a CN was deemed to be invalid, regardless of whether the facility was fully constructed, no rights would be conferred on the CN holder and the entity would not be allowed to continue operation.¹⁸⁴ However, despite these decisions, practitioners should consider requesting a stay to preserve their arguments.

14.10 Rule Making Process

DOH is often engaging in new rule making regarding CN. DOH adheres to the rule making procedures outlined in the WAPA, RCW 34.05.310 *et. seq.* The public is encouraged to comment on the proposed rules. Notices of proposed rules are located on the CN Program website at: <http://www.doh.wa.gov/hsqa/FSL/certneed/proprules.htm>. Public comments regarding the proposed rules are also posted on the website. The CN Program also publishes the date for public hearings on the proposed rules on its website.

¹⁸⁰ *In re the Certificate of Need Application of: Sacred Heart Medical Center*, Prehearing Order No. 5: Order Denying Petitioner’s Motion to Dismiss, Docket No. 00-11-C-1002CN, at 9, April 17, 2002.

¹⁸¹ *In re: Franciscan Health Systems, dba St. Joseph Medical Center Certificate of Need application for a 14 Station Kidney Dialysis Center in Spanaway Washington*, Prehearing Order No. 2: Order Denying Stay, Docket No. 04-06-C-2005CN, at 4, September 2, 2004. The criteria outlined in *Purser v. Rahm* has been used to determine if a stay should be issued. This criteria includes “(1) whether the issue presented by the appeal is debatable, and (2) whether a stay is necessary to preserve for the movant the fruits of a successful appeal, considering the equities of the situation.” *Purser v. Rahm*, 104 Wn.2d 159, 177, 702 P.2d 1196 (1985).

¹⁸² *Children’s Hospital and Medical Center v. Dep’t of Health*, 95 Wn. App. 858, 865-66, 975 P.2d 567 (1999).

¹⁸³ *In re: Franciscan Health Systems, dba St. Joseph Medical Center Certificate of Need application for a 14 Station Kidney Dialysis Center in Spanaway Washington*, Prehearing Order No. 2: Order Denying Stay, Docket No. 04-06-C-2005CN, at 4-5, September 2, 2004; *see also In re: Certificate of Need Application of DaVita, Inc. to establish a Kidney Dialysis Facility in Bellevue, King County*, Prehearing Order No. 5: Order Denying Motion to Dismiss, Docket No. 03-09-C-2000CN, August 9, 2004.

¹⁸⁴ *Id.*