



PROPOSED RULE MAKING

CR-102 (June 2012)

(Implements RCW 34.05.320)

Do **NOT** use for expedited rule making

Agency: Department of Health

- ☒ **Preproposal Statement of Inquiry was filed as WSR 15-14-070 ; or**
☐ **Expedited Rule Making--Proposed notice was filed as WSR ; or**
☐ **Proposal is exempt under RCW 34.05.310(4) or 34.05.330(1).**

- ☒ **Original Notice**
☐ **Supplemental Notice to WSR**
☐ **Continuance of WSR**

Title of rule and other identifying information: (Describe Subject)

WAC 246-310-020 - Applicability of chapter 246-310 WAC. The Department of Health (department) is proposing revisions addressing the expansion of Certificate of Need (CoN)-approved ambulatory surgical facility (ASF) operating rooms.

Hearing location(s): Town Center 2 - Room 145
 111 Israel Road SE
 Tumwater WA 98501

Date: 10/19/16

Time: 1:00PM

Submit written comments to:

Name: Katherine Hoffman
 Address: Certificate of Need
 P.O. Box 47852
 Olympia WA 98504-7852
 e-mail: <https://fortress.wa.gov/doh/policyreview>
 fax 360-236-2321 by (date) 10/19/2016

Assistance for persons with disabilities: Contact

Katherine Hoffman by 10/12/2016

TTY (800) 833-6388 or () 711

Date of intended adoption: 10/26/16

(Note: This is **NOT** the **effective** date)

Purpose of the proposal and its anticipated effects, including any changes in existing rules:

The addition of operating rooms to an existing CoN-approved ASF within a designated planning area is currently not specifically addressed in WAC 246-310-020. The proposed rule revision would specify that the addition of operating rooms to existing CoN-approved ASF constitutes the construction, development or other establishment of a new health care facility pursuant to RCW 70.38.105(4)(a).

Reasons supporting proposal:

Previously, the department allowed ASFs to add a small number of operating rooms without CoN review. The department found this was inconsistent with the intent and purpose of RCW 70.38.105(4)(a). In 2014, representatives of an ASF requested a technical assistance meeting with the department about the significant expansion of their CoN-approved ASF, and were advised a CoN was required. The ASF challenged the department's statutory interpretation of RCW 70.38.105(4)(a) in Thurston County Superior Court. The court ordered that the department's interpretation should be in rule to be enforceable.

Statutory authority for adoption:

RCW 70.38.135

Statute being implemented:

RCW 70.38.105

Is rule necessary because of a:

- Federal Law? ☐ Yes ☒ No
 Federal Court Decision? ☐ Yes ☒ No
 State Court Decision? ☐ Yes ☒ No
 If yes, CITATION: ☒ Yes ☐ No
 The Polyclinic and Swedish Health
 Services v. Department of Health, Thurston
 County Superior Court Cause #14-2-
 01413-6

DATE 09/02/2016

NAME (type or print)

Kristin Peterson, JD for John Wiesman, DrPH, MPH

SIGNATURE

, JD for John Wiesman, DrPH, MPH

TITLE

Government Relations Director for Secretary of Health

CODE REVISER USE ONLY

**OFFICE OF THE CODE REVISER
 STATE OF WASHINGTON
 FILED**

DATE: September 02, 2016

TIME: 3:03 PM

WSR 16-18-070

(COMPLETE REVERSE SIDE)

Agency comments or recommendations, if any, as to statutory language, implementation, enforcement, and fiscal matters:

N/A

Name of proponent: (person or organization) Washington State Department of Health

- ☐ Private
☐ Public
☒ Governmental

Name of agency personnel responsible for:

Name	Office Location	Phone
Drafting..... Katherine Hoffman	111 Israel Road SE, Tumwater WA 98501	360-236-2979
Implementation....Katherine Hoffman	111 Israel Road SE, Tumwater WA 98601	360-236-2979
Enforcement.....Katherine Hoffman	111 Israel Road SE, Tumwater WA 98501	360-236-2979

Has a small business economic impact statement been prepared under chapter 19.85 RCW or has a school district fiscal impact statement been prepared under section 1, chapter 210, Laws of 2012?

☐ Yes. Attach copy of small business economic impact statement.

A copy of the statement may be obtained by contacting:

Name:

Address:

phone

fax

e-mail

☒ No. Explain why no statement was prepared.

A small business economic impact statement was not prepared. The proposed rule would not impose more than minor costs on businesses in an industry.

Is a cost-benefit analysis required under RCW 34.05.328?

☒ Yes A preliminary cost-benefit analysis may be obtained by contacting:

Name: Katherine Hoffman

Address: P.O. Box 47852

111 Israel Road SE

Tumwater, WA 98504-7852

phone 360-236-2979

fax 360-236-2321

e-mail katherine.hoffman@doh.wa.gov

☐ No: Please explain:

WAC 246-310-020 Applicability of chapter 246-310 WAC. (1) The ~~((following undertakings shall be subject to the provisions of chapter 246-310 WAC, with the exceptions provided for in this section.))~~ 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, or-

ganized, 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 transluminal 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.