



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 13-17-091 ; 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 246-310-010 and WAC 246-320-141. The proposed rule makes changes to Chapter 246-310 WAC - Certificate of Need, and Chapter 246-320 WAC - Hospital Licensing Regulations to implement the Directive of the Governor 13-12.

Hearing location(s): Department of Health
 310 Israel Road SE
 Point Plaza East
 Conference Rooms 152 & 153
 Tumwater WA 98501

Date: 11/26/2013

Time: 1:00 p.m.

Submit written comments to:

Name: Janis Sigman
 Address: Department of Health
 PO Box 47852
 Olympia WA 98502-7852
 e-mail: <http://www3.doh.wa.gov/policyreview/>
 fax 360.236.2321 by (date) 11/26/2013

Assistance for persons with disabilities: Contact

Janis Sigman by 11/18/2013

TTY (800) 833-6388 or () 711

Date of intended adoption: 12/10/2013

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

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

In response to the Governor Directive 13-12, the Department of Health (department) is amending Certificate of Need (CoN) rules to address health care facility affiliations, corporate restructuring, mergers and other arrangements. These types of transactions would require prior CoN review by the department. This would ensure the community will not lose access to services as a result to the new organizational structure. The department is also amending the hospital licensing rules to improve transparency for consumer information and the public's ease of access to hospital information.

Reasons supporting proposal:

The proposed rules respond to the Directive of the Governor 13-12 to initiate rulemaking to consider how arrangements between health care facilities result in outcomes similar to traditional methods of sales, purchasing and leasing of hospitals, when control of part or all of an existing hospital changes from one party to another. The department was also to consider ways to improve transparency to consumers of hospital services by requiring hospitals to provide online access to their policies of admissions, non-discrimination, end of life, and reproductive health care.

Statutory authority for adoption:

RCWs 70.38.135 and 70.41.030

Statute being implemented:

Chapters 70.38 and 70.41 RCW

Is rule necessary because of a:

- Federal Law? ☐ Yes ☒ No
 Federal Court Decision? ☐ Yes ☒ No
 State Court Decision? ☐ Yes ☒ No
 If yes, CITATION:

DATE 10/17/2013

NAME (type or print)

Jessica Todorovich for John Wiesman, DrPH, MPH

SIGNATURE

for John Wiesman, DrPH, MPH

TITLE

Deputy Secretary for Secretary of Health

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OFFICE OF THE CODE REVISER
 STATE OF WASHINGTON
 FILED

DATE: October 17, 2013

TIME: 11:54 AM

WSR 13-21-076

(COMPLETE REVERSE SIDE)

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

None

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

- ☐ Private
☐ Public
☒ Governmental

Name of agency personnel responsible for:

Name	Office Location	Phone
Drafting..... Janis Sigman	111 Israel Road SE, Tumwater, WA 98501	360.236.2956
Implementation....Janis Sigman	111 Israel Road SE, Tumwater, WA 98501	360.236.2956
Enforcement.....Janis Sigman	111 Israel Road SE, Tumwater, WA 98501	360.236.2956

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: Janis Sigman

Address: Department of Health

PO Box 47852

Olympia WA 98502-7852

phone 360.236.2956

fax 360.236.2321

e-mail Janis.Sigman@doh.wa.gov

☐ No. Explain why no statement was prepared.

Is a cost-benefit analysis required under RCW 34.05.328?

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

Name: Janis Sigman

Address: Department of Health

PO Box 47852

Olympia WA 98502-7852

phone 360.236.2956

fax 360.236.2321

e-mail Janis.Sigman@doh.wa.gov

☐ No: Please explain:

Small Business Economic Impact Analysis (SBEIS)

Proposed WAC 246-310-010 and WAC 246-320-141

Certificate of Need and Hospitals

October 1, 2013

Section 1. What is the scope of the rule?

Hospitals, licensed under chapter 70.41RCW, are subject to Certificate of Need (CoN) under chapter 70.38 RCW. The Washington State Department of Health (department) is proposing to change the CoN process through rulemaking. The proposed changes in WAC 246-310-010 will clarify the term “corporation” as used in the existing definition of “person.” A definition for “sale, purchase, or lease” of a hospital is also proposed. The proposed new definition will result in the requirement that when a hospital enters into an arrangement that effectively transfers “control” of the hospital from one person to another a CoN application must be submitted. This change improves transparency of significant hospital changes that have long lived impacts on the communities they serve.

The department is also proposing a new section of rules in WAC 246-320-141--Patient rights and organization ethics--that requires hospitals to submit their policies to the department on admission, non-discrimination, end of life care, and reproductive health care. Requiring hospitals to provide these policies improves transparency by the hospitals about consumer access to their services. This requirement will help consumers have access to important hospital information to help them make decisions on where to get their health care in advance of needing hospital services.

These proposed rules are in response to a directive from the Governor. Governor Jay Inslee issued Directive 13-12 on June 28, 2013, asking the Department of Health (department) to review its Certificate of Need (CoN) rules to consider “how the structure of affiliations, corporate restructuring, mergers and other arrangements among health care facilities results in outcomes similar to the traditional methods of sales, purchasing, and leasing of hospitals, particularly when control of part or all of an existing hospital changes from one party to another.” The directive also said the rule process must “consider ways to improve transparency for consumer education and ease of use, specifically the department shall ensure hospitals supply non-discrimination, end of life care, and reproductive health care policies,” and that consumers have access to those policies.

Section 2. Which businesses will be impacted? What are their minor cost thresholds?

General medical and surgical hospitals with North American Industrial Classification System (NAICS) industrial codes are the only business that will be affected by this proposed rule. We

used 2007 census data on NAICS to calculate the following two alternative industry thresholds based on industry annual sales (receipts) and also industry average annual payroll:

Hospital Industry threshold based on Annual sales (receipts)

Total industry annual sales:	\$13,703,434,000
Average industry annual sales:	\$135,677,000
Threshold (3/10 of 1% of total annual sales)	\$407,032

Industry threshold based on Annual payroll

Total industry annual payroll :	\$5,251,886,000
Average industry annual payroll:	\$51,999,000
Threshold (1% of total annual payroll)	\$519,989

Section 3. What are the average costs per business of the rule?

The department conducted a survey to estimate the compliance costs to hospitals. Most Washington State licensed hospitals were called. The purpose of this call was to contact key hospital leadership, explain the Governor’s directive, explain the proposed Hospital Licensing rule changes, and to request feedback through completion of the hospital survey. The department was unable to personally reach key leadership of some hospitals, despite multiple calls to top level positions. The Hospital Survey was emailed to 83 hospitals with a seven-day requested turnaround time. The department received 54 completed surveys.

The following two tables list the survey questions and hospital responses related to the proposed CoN and Hospital Licensing rules. It is important to note that survey responses came in such a wide range that it was not possible to summarize the results in terms of average costs or a reasonable range. For this reason, it was decided to report the survey responses as received.

A. WAC 246-310-010--CoN Definitions (amended)

The following table lists hospital responses to survey questions regarding the proposed changes to the CoN rules. The rules would be amended to provide a definition of “sale, purchase or lease” to include any transaction in which the control, direct or indirect, of any part of an existing hospital change to a different person (or entity).

Table 1. Survey Results for Costs to Complete a Certificate of Need Application

Hospital FTEs ¹	Potential to be an acquiring entity?	Estimated cost to create a CoN application?	Identify parts of estimated costs for CoN application?
66	No	n/a	n/a

¹ Hospital FTE information was obtained from department records.

Hospital FTEs¹	Potential to be an acquiring entity?	Estimated cost to create a CoN application?	Identify parts of estimated costs for CoN application?
85	No specific information provided	No specific information provided	No specific information provided
91	No	n/a	n/a
102	Unlikely	n/a	n/a
108	Confidential	n/a	n/a
135	No specific information provided	No specific information provided	No specific information provided
147	No	\$50,000	n/a
156	Cannot confirm	\$62,174 to \$93,262	Legal, consultants, staff, misc
178	No	n/a	n/a
188	Yes	Very substantial	Do not know
196	Cannot confirm	\$62,174 to \$93,262	Legal, consultants, staff, misc
199	No	\$40,000 plus	n/a
221	Cannot confirm	\$62,174 to \$93,262	Legal, consultants, staff, misc
228	Unlikely	\$50,000 to \$100,000	n/a
245	No	n/a	n/a
263	Yes	\$120,000	Consultation, staff, management, legal, communications, logistics
317	No	n/a	n/a
379	Prefer not to answer	\$70,000 to \$140,000	Consultants, legal, staff, misc
386	No	\$52,000	Staff, consultants, legal
443	Cannot confirm	\$62,174 to \$93,262	Legal, Consultants, staff, Misc
530	Could occur in the Future	\$45,000 to \$200,000	CN Consulting Administrative Leadership, Clinical Leadership, Legal Staff, Design Firm Consulting
546	No	n/a	n/a

Hospital FTEs¹	Potential to be an acquiring entity?	Estimated cost to create a CoN application?	Identify parts of estimated costs for CoN application?
563	Yes	\$120,000	Consultation, staff, management, legal, communications, logistics
576	Cannot confirm	\$62,174 to \$93,262	Legal, consultants, staff, misc
698	Could occur in the Future	\$45,000 to \$200,000	CN Consulting Administrative Leadership, Clinical Leadership, Legal Staff, Design Firm Consulting
849	Yes	\$120,000	Consultation, staff, management, legal, communications, logistics
879	Cannot confirm	\$62,174 to \$93,262	Legal, consultants, staff, misc
1,051	Yes	\$120,000	Consultation, staff, management, legal, communications, logistics
1,114	Cannot confirm	\$62,174 to \$93,262	Legal, Consultants, staff, Misc
1,157	Cannot confirm	\$62,174 to \$93,262	Legal, Consultants, staff, Misc
1,237	Yes	\$120,000	Consultation, staff, management, legal, communications, logistics
1,467	Yes	\$10,000 to \$50,000	Consultants, staff, legal
1,544	Yes	\$85,000 to \$125,000	Staff, medical, consultants, legal
1,700	Could occur in the Future	\$45,000 to \$200,000	CN Consulting Administrative Leadership, Clinical Leadership, Legal Staff, Design Firm Consulting

Hospital FTEs¹	Potential to be an acquiring entity?	Estimated cost to create a CoN application?	Identify parts of estimated costs for CoN application?
1,843	Cannot confirm	\$62,174 to \$93,262	Legal, consultants, staff, misc
1,868	No specific information provided	No specific information provided	No specific information provided
1,917	Yes	\$120,000	Consultation, staff, management, legal, communications, logistics
2,041	Yes	\$10,000 to \$50,000	Consultants, staff, legal
2,262	Could occur in the Future	\$45,000 to \$200,000	CN Consulting Administrative Leadership, Clinical Leadership, Legal Staff, Design Firm Consulting
2,535	Cannot confirm	\$62,174 to \$93,262	Legal, consultants, staff, misc
2,651	Yes	\$85,000 to \$125,000	Staff, medical, consultants, legal
2,987	Yes	\$10,000 to \$50,000	Consultants, staff, legal
3,212	Cannot confirm	\$62,174 to \$93,262	Legal, consultants, staff, misc
3,299	Yes	\$120,000	Consultation, staff, management, legal, communications, logistics
3,633	Unknown	\$65,000 to \$70,000	Staff hours, physician hours, legal, consultants
4,383	Yes	\$85,000 to \$125,000	Staff, medical, consultants, legal
4,683	Yes	\$85,000 to \$125,000	Staff, medical, consultants, legal
4,806	Unknown	Unable to estimate	n/a
5,002	Cannot confirm	\$62,174 to \$93,262	Legal, Consultants, staff, Misc
Not Available	Yes	\$120,000	Consultation, staff, management, legal, communications, logistics
Not Available	Yes	\$10,000 to \$50,000	Consultants, staff, legal

Hospital FTEs¹	Potential to be an acquiring entity?	Estimated cost to create a CoN application?	Identify parts of estimated costs for CoN application?
Not Available	Yes	\$10,000 to \$50,000	Consultants, staff, legal
Not Available	Cannot confirm	\$62,174 to \$93,262	Legal, Consultants, staff, Misc
Not open	Could occur in the Future	\$45,000 to \$200,000	CN Consulting Administrative Leadership, Clinical Leadership, Legal Staff, Design Firm Consulting

Note: 1. The above cost estimates do not include a \$40,700 CoN application fee.
2. One hospital included \$380,000 estimated costs associated with legal actions. The department did not include this cost as part of the cost of compliance with the proposed rule.

B. WAC 246-320-141—Hospital patient rights and organizational ethics (amended)

The following table lists hospital responses to survey questions regarding the proposed changes to the Hospital Licensing rules, specifically the requirement for hospitals to have a reproductive health care policy. The rules would be amended to require each hospital to send the department its policies on administration, non-discrimination, end of life and reproductive health care for posting to the department web site and require hospitals to provide the public easy access to these policies on the hospital's web site.²

Table 2. Survey Results for Costs to Complete Proposed Policy Work

Hospital FTEs³	Does Hospital have a Reproductive Health Care policy?	Estimated cost to develop a reproductive Health Care policy?	Identify parts of estimated costs for new policy?	Cost to send all policies to the department?	Cost to post all policies to Hospital webpage?
66	No	\$1,000	80% legal, 20% staff	<\$20	\$500
85	No	\$2,325 to \$3,000	\$550 staff time, \$250 legal, copying \$25, staff training \$1,700		
91	No	\$5,000 to \$10,000	20% staff, 80% legal	<\$100	<\$100
102	No	Uncertain	No specific information provided	Minimal	Minimal
108	No	No specific information	n/a	Nominal	\$3,050

² Under other statutes and rules, hospitals are required to have policies regarding admission, nondiscrimination, and end of life care.

³ Hospital FTE information was obtained from department records.

Hospital FTEs³	Does Hospital have a Reproductive Health Care policy?	Estimated cost to develop a reproductive Health Care policy?	Identify parts of estimated costs for new policy?	Cost to send all policies to the department?	Cost to post all policies to Hospital webpage?
		provided			
135	No	No specific information provided	No specific information provided	No specific information provided	No specific information provided
147	No	\$500 to \$1000	Legal, staff	\$25	Minimal
156	No	\$42,185 to \$63,278	Policy Research, Ethical Discernment, Written policy development, legal, leadership, board of directors, sponsors, Archbishop, implementation, communications	\$107.76	\$520 to \$780
178	No	\$700 to \$1,200	\$900 staff hours, \$300 legal	\$10	\$150
188	No	Unable to estimate	Unable to estimate	<\$100	Not exorbitant
196	No	\$42,185 to \$63,278	Policy Research, Ethical Discernment, Written policy development, legal, leadership, board of directors, sponsors, Archbishop, implementation, communications	\$107.76	\$520 to \$780
199	No	\$1,890	\$800 legal, \$1090 staff	Minimal	Minimal
221	No	\$42,185 to \$63,278	Policy Research, Ethical Discernment, Written policy development, legal, leadership, board of directors, sponsors, Archbishop, implementation, communications	\$107.76	\$520 to \$780
228	No	\$1,500	\$1,000 staff, \$500 legal	Depends on how they are	Minimal

Hospital FTEs³	Does Hospital have a Reproductive Health Care policy?	Estimated cost to develop a reproductive Health Care policy?	Identify parts of estimated costs for new policy?	Cost to send all policies to the department?	Cost to post all policies to Hospital webpage?
				sent?	
245	No	\$100 to \$400	Staff, legal	Copying costs \$5, staff time \$31, Postal rate \$9	\$50
263	No	\$25,000 to \$50,000	Consultation, staff, management, legal, communications, logistics	\$1,000	\$5,000
317	No	\$20,000 to \$25,000	20% staff time, 80% legal expense	Minimal	Minimal
379	No	\$5,000 to \$10,000	Staff, legal, misc	\$5 to \$10	\$50 to \$100
386	No	\$5,350	Staff hours, legal hours	\$100	\$260
443	No	\$25,690 to \$38,535	Policy research, Assessment, written policy development, legal, leadership, board, Implementation, Communications	\$67.35	\$325 to \$488
530	Some	\$5,000	Admin/Leadership Clinical Leadership Medical Staff Legal/Risk/Insurance	\$50	<\$100
546	No	\$10,500	\$4,500 legal, \$2,000 physician, \$4,000 staff	\$10	\$200 to \$400
563	No	\$25,000 to \$50,000	Consultation, staff, management, legal, communications, logistics	\$1,000	\$5,000
576	No	\$42,185 to \$63,278	Policy Research, Ethical Discernment, Written policy development, legal, leadership, board of directors, sponsors,	\$107.76	\$520 to \$780

Hospital FTEs³	Does Hospital have a Reproductive Health Care policy?	Estimated cost to develop a reproductive Health Care policy?	Identify parts of estimated costs for new policy?	Cost to send all policies to the department?	Cost to post all policies to Hospital webpage?
			Archbishop, implementation, communications		
698	Some	\$5,000	Admin/Leadership Clinical Leadership Medical Staff Legal/Risk/Insurance	\$50	<\$100
849	No	\$25,000 to \$50,000	Consultation, staff, management, legal, communications, logistics	\$1,000	\$5,000
879	No	\$42,185 to \$63,278	Policy Research, Ethical Discernment, Written policy development, legal, leadership, board of directors, sponsors, Archbishop, implementation, communications	\$107.76	\$520 to \$780
1,051	No	\$25,000 to \$50,000	Consultation, staff, management, legal, communications, logistics	\$1,000	\$5,000
1,114	No	\$25,690 to \$38,535	Policy research, Assessment, written policy development, legal, leadership, board, Implementation, Communications	\$67.35	\$325 to \$488
1,157	No	\$25,690 to \$38,535	Policy research, Assessment, written policy development, legal, leadership, board, Implementation, Communications	\$67.35	\$325 to \$488

Hospital FTEs³	Does Hospital have a Reproductive Health Care policy?	Estimated cost to develop a reproductive Health Care policy?	Identify parts of estimated costs for new policy?	Cost to send all policies to the department?	Cost to post all policies to Hospital webpage?
1,237	No	\$25,000 to \$50,000	Consultation, staff, management, legal, communications, logistics	\$1,000	\$5,000
1,467	No	No specific information provided	n/a	Minimal	Minimal
1,544	No	\$70,000 to \$100,000	Medical, administrative, staff, governing bodies, legal	Cost of admin prep time and postage	Cost of admin time which is unknown?
1,700	Some	\$5,000	Admin/Leadership Clinical Leadership Medical Staff Legal/Risk/Insurance	\$50	<\$100
1,843	No	\$42,185 to \$63,278	Policy Research, Ethical Discernment, Written policy development, legal, leadership, board of directors, sponsors, Archbishop, implementation, communications	\$107.76	\$520 to \$780
1,868	No specific information provided	No specific information provided	No specific information provided	No specific information provided	No specific information provided
1,917	No	\$25,000 to \$50,000	Consultation, staff, management, legal, communications, logistics	\$1,000	\$5,000
2,041	No	No specific information provided	n/a	Minimal	Minimal
2,262	Some	\$5,000	Admin/Leadership Clinical Leadership Medical Staff Legal/Risk/Insurance	\$50	<\$100
2,535	No	\$42,185 to \$63,278	Policy Research, Ethical Discernment,	\$107.76	\$520 to \$780

Hospital FTEs³	Does Hospital have a Reproductive Health Care policy?	Estimated cost to develop a reproductive Health Care policy?	Identify parts of estimated costs for new policy?	Cost to send all policies to the department?	Cost to post all policies to Hospital webpage?
			Written policy development, legal, leadership, board of directors, sponsors, Archbishop, implementation, communications		
2,651	No	\$70,000 to \$100,000	Medical, administrative, staff, governing bodies, legal	Cost of admin prep time and postage	Cost of admin time which is unknown?
2,987	No	No specific information provided	n/a	Minimal	Minimal
3,212	No	\$42,185 to \$63,278	Policy Research, Ethical Discernment, Written policy development, legal, leadership, board of directors, sponsors, Archbishop, implementation, communications	\$107.76	\$520 to \$780
3,299	No	\$25,000 to \$50,000	Consultation, staff, management, legal, communications, logistics	\$1,000	\$5,000
3,633	Uncertain	\$16,000 to \$20,000	Staff hours, physician hours, legal	\$50	\$2,500
4,383	No	\$70,000 to \$100,000	Medical, administrative, staff, governing bodies, legal	Cost of admin prep time and postage	Cost of admin time which is unknown?
4,683	No	\$70,000 to \$100,000	Medical, administrative, staff, governing bodies, legal	Cost of admin prep time and postage	Cost of admin time which is unknown?
4,806	No	\$5,000	Legal, regulatory, compliance, clinic operations	Very low	Uncertain

Hospital FTEs³	Does Hospital have a Reproductive Health Care policy?	Estimated cost to develop a reproductive Health Care policy?	Identify parts of estimated costs for new policy?	Cost to send all policies to the department?	Cost to post all policies to Hospital webpage?
5,002	No	\$25,690 to \$38,535	Policy research, Assessment, written policy development, legal, leadership, board, Implementation, Communications	\$67.35	\$325 to \$488
Not Available	No	\$25,000 to \$50,000	Consultation, staff, management, legal, communications, logistics	\$1,000	\$5,000
Not Available	No	No specific information provided	n/a	Minimal	Minimal
Not Available	No	No specific information provided	n/a	Minimal	Minimal
Not Available	No	\$25,690 to \$38,535	Policy research, Assessment, written policy development, legal, leadership, board, Implementation, Communications	\$67.35	\$325 to \$488
Not open	Some	\$5,000	Admin/Leadership Clinical Leadership Medical Staff Legal/Risk/Insurance	\$50	<\$100

Section 4. Does the rule impose more than minor costs on impacted businesses?

According to survey responses in Table 1, the compliance costs per business associated with the proposed CoN rules do not exceed either of the two, estimated minor cost threshold based on sales or receipts (\$407,032) or based on payroll (\$519,989). According to survey responses in Table (2), the compliance costs per business associated with the proposed Hospital Licensing rules do not exceed either of the two estimated minor cost thresholds.

Section 5. Does the rule have a disproportionate on small businesses?

The 54 hospitals that responded to our survey have more than 50 FTEs and are not considered small businesses based on the definition. In addition, all hospitals that are subject to these proposed rules have more than 50 FTEs and therefore do not meet the definition of a “small business.”

Section 6. Did we make any effort to reduce the impact of the rule?

a) Reducing, modifying, or eliminating substantive regulatory requirements?

In regards to the proposed Hospital Licensing rules, the department made efforts to reduce the burden of the new requirements. The department circulated draft rules requiring hospitals to submit a list of services that was limited or not available because of the access to care policies. Concerns were raised by some stakeholders that the term “reproductive health care” was vague, and does not describe what the department is looking for in terms of specific services. The department decided to strike from the draft rules the requirement of a list of services that are limited or not available.

The purpose of these rules is not to specify what is required in a reproductive health policy but simply to require hospitals to submit policies that reflect current practices and make that information available and transparent to the public. The department determined the least burdensome approach to achieving the goals and objectives of the proposed rule would be to publish the submitted hospital policies on reproductive health services, admission, non-discrimination, and end of life care on the department’s web site.

b) Simplifying, reducing, or eliminating record keeping and reporting requirements?

A hospital only must provide the policies required in proposed amendments to WAC 246-320-141 one time, unless the hospital revises those policies. The draft rule circulated to stakeholders in July 2013 would have required hospitals to submit a list of services they do not provide. To reduce the burden on hospitals, this requirement was removed from the draft.

c) Reducing the frequency of inspections?

Not applicable.

d) Delaying compliance timetables?

The proposed rule requires hospitals to submit its policies within 60 days after the effective date of the rule, to give hospitals time to develop the policies.

e) Reducing or modifying fine schedules for noncompliance?

Not applicable.

f) Any other mitigation techniques?

Not applicable

7. How are small businesses involved in the development of this rule?

No “small businesses” are impacted by the proposed rules.

8. Will businesses have to hire or fire any employees because of this rule?

The department has determined that the proposed rule does not require a change in hospital staffing.

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

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

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

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

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

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

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

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

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

(6) "Applicant," means:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(a) Independent living units;

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

(c) Assistance with activities of daily living;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

cant or holder, or any person with an interest regarding issuance or withdrawal of a certificate of need.

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

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

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

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

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

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

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

(i) Offers services only to contractual residents;

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

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

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

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

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

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

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

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

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

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

(d) Provides physicians' services primarily:

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

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

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

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

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

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

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

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

(34) "Interested persons" means:

(a) The applicant;

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

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

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

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

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

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

(35) "Licensee" means an entity or individual licensed by the department of health or the department of social and health services. For the purposes of nursing home projects, licensee refers to the op-

erating entity and those persons specifically named in the license application as defined under chapter 388-97 WAC.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(b) Is calculated using demographic data obtained from:

(i) The office of financial management; and

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

(54) "Sale, purchase, or lease" means any transaction in which the control, either directly or indirectly, of part or all of any existing hospital changes to a different person including, but not limited to, by contract, affiliation, corporate membership restructuring, or any other transaction.

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

~~((+55+))~~ (56) "State Health Planning and Resources Development Act" means chapter 70.38 RCW.

~~((+56+))~~ (57) "Statewide current ratio" means a bed-to-population ratio computed from the most recent statewide nursing home bed supply and the most recent estimate of the statewide resident population.

((+57+)) (58) "Swing beds" means up to the first five hospital beds designated by an eligible rural hospital which are available to provide either acute care or nursing home services.

((+58+)) (59) "Tertiary health service" means a specialized service meeting complicated medical needs of people and requires sufficient patient volume to optimize provider effectiveness, quality of service, and improved outcomes of care.

((+59+)) (60) "Transition period" means the period of time, not exceeding five years, between the date a CCRC is inhabited by a member, and the date it fully meets the requirements of a CCRC.

((+60+)) (61) "Under the established ratio" means the bed-to-population ratio is less than the statewide current established ratio.

((+61+)) (62) "Undertaking" means any action subject to the provisions of chapter 246-310 WAC.

((+62+)) (63) "Working days" excludes Saturdays, Sundays, and legal holidays observed by the state of Washington. Working days are counted in the same way as calendar days.

WAC 246-320-141 Patient rights and organizational ethics. The purpose of this section is to improve patient care and outcomes by respecting every patient and maintaining ethical relationships with the public.

Hospitals must:

(1) Adopt and implement policies and procedures that define each patient's right to:

(a) Be treated and cared for with dignity and respect;

(b) Confidentiality, privacy, security, complaint resolution, spiritual care, and communication. If communication restrictions are necessary for patient care and safety, the hospital must document and explain the restrictions to the patient and family;

(c) Be protected from abuse and neglect;

(d) Access protective services;

(e) Complain about their care and treatment without fear of retribution or denial of care;

(f) Timely complaint resolution;

(g) Be involved in all aspects of their care including:

(i) Refusing care and treatment; and

(ii) Resolving problems with care decisions((+)).

(h) Be informed of unanticipated outcomes according to RCW 70.41.380;

(i) Be informed and agree to their care;

(j) Family input in care decisions;

(k) Have advance directives and for the hospital to respect and follow those directives;

(l) Request no resuscitation or life-sustaining treatment;

(m) End of life care;

(n) Donate organs and other tissues according to RCW 68.50.500 and 68.50.560 including:

(i) Medical staff input; and

(ii) Direction by family or surrogate decision makers((+)).

(2) Provide each patient a written statement of patient rights from subsection (1) of this section;

(3) Adopt and implement policies and procedures to identify patients who are potential organ and tissue donors;

(4) Adopt and implement policies and procedures to address research, investigation, and clinical trials including:

(a) How to authorize research;

(b) Require staff to follow informed consent laws; and

(c) Not hindering a patient's access to care if a patient refuses to participate.

(5) No later than sixty days following the effective date of this section, every hospital must submit to the department its policies related to access to care:

(a) Admission;

(b) Nondiscrimination;

(c) End of life care; and

(d) Reproductive health care.

(6) The department shall post a copy of the policies received under subsection (5) of this section on its web site.

(7) If a hospital makes changes or additions to any of the policies listed under subsection (5) of this section, it must submit a

copy of the changed or added policy to the department within thirty days after the hospital approves the changes or additions.

(8) Hospitals must post a copy of the policies provided under subsection (5) of this section to its own web site where it is readily accessible to the public, without requiring a login or other restriction.