Agency: Department of Health

- Original Notice
- Supplemental Notice to WSR 18-01-084
- Continuance of WSR
- Preproposal Statement of Inquiry was filed as WSR 10-10-114; 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).

Title of rule and other identifying information: (describe subject) WAC 246-310-290 - Hospice Services - Standards and need forecasting method. The Department of Health (department) Certificate of Need (CoN) program is proposing revision of current criteria, standards and need methodology for hospice service agencies. This is a supplemental proposal to rules proposed as WSR 18-01-084 filed on December 15, 2017.

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<th>Hearing location(s):</th>
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<tr>
<td>Date:</td>
<td>Time:</td>
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<tr>
<td>July 17, 2018</td>
<td>10:30AM</td>
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</tbody>
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Date of intended adoption: 07/23/2018 (Note: This is NOT the effective date)

Submit written comments to:
Name: Katherine Hoffman
Address: P.O. Box 47852
Tumwater WA 98504-7852
Email: https://fortress.wa.gov/doh/policyreview
Fax: 360-236-2321

Assistance for persons with disabilities:
Contact Katherine Hoffman
Phone: 360-236-2979
Fax: 360-236-2321
TTY: (360) 833-6388 or 711
Email: katherine.hoffman@doh.wa.gov

Purpose of the proposal and its anticipated effects, including any changes in existing rules: The proposed changes update and modernize WAC 246-310-290. The revisions more clearly describe and clarify the methodology used for projecting future need for hospice services. These projections are used in the CoN hospice services application review process. The proposed changes establish consistent, timely and efficient decision making by the department, and will result in increased patient access to affordable, quality healthcare, consistent with the intent of chapter 70.38 RCW. The supplemental proposal makes substantive changes to the original proposal by retaining the average daily census (ADC) of 35 rather than 25 as previously proposed. It also makes one non-substantive revision to proposed WAC 246-310-290(12)(a)(iii) by changing the phrase "not being served" to "underserved."
Reasons supporting proposal: The proposed rule revisions are necessary to remain current and in alignment with national industry standards, guidelines, best practices, and statewide demographic shifts. The proposed rules will provide increased access to end of life care and support services to populations in need of such services, and support the statutory goals of chapter 70.38 RCW by making sure that patients have access to affordable, quality healthcare. The revisions in the supplemental proposal are necessary because the proposed substantive change retains the ADC of 35 rather than 25, which will support a sustainable level of hospice care, staffing and access to hospice care services. The proposed non-substantive revision to WAC 246-310-290(12)(a)(iii) is necessary because it changes the phrase “not being served” to “underserved” in a section of proposed rule that would allow the department to grant a CoN absent numeric need under specific circumstances. This change provides clarity and guidance to both applicants and the department when evaluating CoN hospice service applications.

Statutory authority for adoption: RCW 70.38.135

Statute being implemented: RCW 70.38.115

Is rule necessary because of a:

- Federal Law? ☐ Yes ☑ No
- Federal Court Decision? ☐ Yes ☑ No
- State Court Decision? ☐ Yes ☑ No

If yes, CITATION:

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

Name of proponent: (person or organization) Department of Health ☐ Private ☑ Public ☑ Governmental

Name of agency personnel responsible for:

<table>
<thead>
<tr>
<th>Name</th>
<th>Office Location</th>
<th>Phone</th>
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<tbody>
<tr>
<td>Drafting:</td>
<td>Katherine Hoffman</td>
<td>111 Israel Road SE, Tumater WA 98501</td>
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<td>Implementation:</td>
<td>Janis Sigman</td>
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<tr>
<td>Enforcement:</td>
<td>Janis Sigman</td>
<td>111 Israel Road SE, Tumwater WA 98501</td>
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Is a school district fiscal impact statement required under RCW 28A.305.135? ☐ Yes ☑ No

If yes, insert statement here:

The public may obtain a copy of the school district fiscal impact statement by contacting:

<table>
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<tr>
<th>Name:</th>
<th>Address:</th>
<th>Phone:</th>
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<tbody>
<tr>
<td></td>
<td>111 Israel Road SE, Tumwater WA 98501</td>
<td>360-236-2979</td>
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Is a cost-benefit analysis required under RCW 34.05.328?

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

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<th>Name:</th>
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<tbody>
<tr>
<td>Katherine Hoffman</td>
<td>111 Israel Road SE, P.O. Box 47852, Tumwater WA 98501</td>
<td>360-236-2979</td>
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<td>TTY: (360) 833-6388 or 711</td>
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</tbody>
</table>
Email: katherine.hoffman@doh.wa.gov
Other:

[ ] No: Please explain:
Regulatory Fairness Act Cost Considerations for a Small Business Economic Impact Statement:

This rule proposal, or portions of the proposal, may be exempt from requirements of the Regulatory Fairness Act (see chapter 19.85 RCW). Please check the box for any applicable exemption(s):

☐ This rule proposal, or portions of the proposal, is exempt under RCW 19.85.061 because this rule making is being adopted solely to conform and/or comply with federal statute or regulations. Please cite the specific federal statute or regulation this rule is being adopted to conform or comply with, and describe the consequences to the state if the rule is not adopted.

Citation and description:

☐ This rule proposal, or portions of the proposal, is exempt because the agency has completed the pilot rule process defined by RCW 34.05.313 before filing the notice of this proposed rule.

☐ This rule proposal, or portions of the proposal, is exempt under the provisions of RCW 15.65.570(2) because it was adopted by a referendum.

☐ This rule proposal, or portions of the proposal, is exempt under RCW 19.85.025(3). Check all that apply:

☐ RCW 34.05.310 (4)(b) (Internal government operations)
☐ RCW 34.05.310 (4)(c) (Incorporation by reference)
☐ RCW 34.05.310 (4)(d) (Correct or clarify language)
☐ RCW 34.05.310 (4)(e) (Dictated by statute)
☐ RCW 34.05.310 (4)(f) (Set or adjust fees)
☐ RCW 34.05.310 (4)(g) (i) Relating to agency hearings; or (ii) process requirements for applying to an agency for a license or permit

☐ This rule proposal, or portions of the proposal, is exempt under RCW .

Explanation of exemptions, if necessary:

COMPLETE THIS SECTION ONLY IF NO EXEMPTION APPLIES

If the proposed rule is not exempt, does it impose more-than-minor costs (as defined by RCW 19.85.020(2)) on businesses?

☐ No 

Briefly summarize the agency’s analysis showing how costs were calculated. There are nominal to no costs associated with the proposed rules. The proposed rules do not impose any regulatory burden on providers, nor do they change, modify, or otherwise alter the certificate of need application process. The supplemental proposal retains the existing ADC requirement. The supplemental proposal reverts back to the existing language and there is no change in the requirements. With respect to the addition of exception language, hospice service providers must meet all other existing criteria as part of the application process, including numeric need. The supplementary documentation and analysis that would accompany an exception request may result in additional but nominal administrative burden, including gathering publicly available data and other material. While this may require applicants to extend efforts beyond the usual and ordinary CN application process, applicants are aware of planning area access issues well before their letter of intent is submitted, and are appropriately prepared to put forth arguments to support exception requests. The nominal additional costs that may be voluntarily incurred by providers is far outweighed by the public benefit of increased access in areas where there is need for hospice services, even though that need may not be apparent through numeric measures.

☐ Yes 

Calculations show the rule proposal likely imposes more-than-minor cost to businesses, and a small business economic impact statement is required. Insert statement here:

The public may obtain a copy of the small business economic impact statement or the detailed cost calculations by contacting:

Name:
Address:
Phone:
Fax:
TTY:
Email:
Other:

Date: 05/31/2018

Name: John Wiesman, DrPH, MPH
Title: Secretary of Health

Signature: [Signature]
AMENDATORY SECTION (Amending WSR 03-07-096, filed 3/19/03, effective 4/19/03)

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

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

(a) "ADC" means average daily census and is calculated by:
   (i) Multiplying projected annual hospice agency admissions by the most recent average length of stay in Washington based on the most recent data reported to the Centers for Medicare and Medicaid Services (CMS) to derive the total annual days of care;
   (ii) Dividing the total calculated in (a)(i) of this subsection by three hundred sixty-five (days per year) to determine the ADC.

(b) "Current supply of hospice providers" means:
   (i) Services of all providers that are licensed and medicare certified as a provider of hospice services or that have a valid (unexpired) certificate of need but have not yet obtained a license, and
   (ii) Hospice services provided directly by health maintenance organizations who are exempt from the certificate of need program. Health maintenance organization services provided by an existing provider will be counted under (b)(i) of this subsection.

(c) "Current hospice capacity" means:
   (i) For hospice agencies that have operated (or been approved to operate) in the planning area for three years or more, the average number of admissions for the last three years of operation; and
   (ii) For hospice agencies that have operated (or been approved to operate) in the planning area for less than three years, an ADC of thirty-five and the most recent Washington average length of stay data will be used to calculate assumed annual admissions for the agency as a whole for the first three years.

(d) "Hospice agency" or "in-home services agency licensed to provide hospice services" means a person administering or providing hospice services directly or through a contract arrangement to individuals in places of temporary or permanent residence under the direction of an interdisciplinary team composed of at least a nurse, social worker, physician, spiritual counselor, and a volunteer and, for the purposes of certificate of need, is or has declared an intent to become medicaid eligible or certified as a provider of services in the medicare program.

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

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

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

(h) "Current supply of hospice providers" means all providers of hospice services that have received certificate of need approval to provide services within a planning area. State licensed only and vol-
(f) "Hospice services" means symptom and pain management provided to a terminally ill (individual) person, and emotional, spiritual and bereavement support for the (individual) terminally ill person and family in a place of temporary or permanent residence (and may include the provision of home health and home care services for the terminally ill individual.

(f) provided under the direction of an interdisciplinary team composed of at least a registered nurse, social worker, physician, spiritual counselor, and a volunteer.

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

(h) "Planning area" or "service area" means (each) an individual (county) geographic area designated by the department (as the smallest geographic area for which hospice services are projected) for which hospice need projections are calculated. For the purposes of (certificate of need, a planning or combination of) hospice services, planning area(e) may serve as the service area.

(g) "Service area" means, for the purposes of certificate of need, the geographic area for which a hospice agency is approved to provide medicare certified or medicaid eligible services and which consist of one or more planning areas)) and service area have the same meaning.

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

(2) The department ((shall)) will review a hospice application((8)) using the concurrent review cycle described in ((this)) subsection (3) of this section, except when the sole hospice provider in the service area ceases operation. Applications to meet this need may be accepted and reviewed in accordance with the regular review process described in WAC 246-310-110 (2)(c).

(3) Applications must be submitted and reviewed according to ((the following schedule and procedures)) Table A:

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

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

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

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

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

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

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

(ii) Testified or submitted evidence at a public hearing; and
(iii) Requested in writing to be informed of the department's decision, shall also be provided the opportunity to provide rebuttal statements to written or oral statements submitted during the first sixty-day period.

(g) The final review period shall be limited to sixty days, unless extended according to the provisions of WAC 246-310-120 (2)(d).

(4) Any letter of intent or certificate of need application submitted for review in advance of this schedule, or certificate of need application under review as of the effective date of this section, shall be held by the department for review according to the schedule in this section.

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

(6) Hospice agencies applying for a certificate of need must demonstrate that they can meet a minimum average daily census (ADC) of thirty-five patients by the third year of operation. An application projecting an ADC of under thirty-five patients may be approved if the applicant:

(a) Commits to maintain medicare certification;
(b) Commits to serve one or more counties that do not have any medicare certified providers; and
(c) Can document overall financial feasibility.

(7))

| Table A |
|---------------------------------|-----------------|-----------------|-----------------|
| **Application Submission Period** | **Department Action** | **Application Review Period** |
| **Concurrent Review Cycle** | **Letters of Intent Due** | **Receipt of Initial Application** | **End of Screening Period** | **Applicant Response** | **Beginning of Review** | **Public Comment** | **Rebuttal** | **Ex Parte Period** |
| **Cycle 1 (Chelan, Douglas, Clallam, Clark, Skamania, Cowlitz, Grant, Grays Harbor, Island, Jefferson, King, Kittitas, Klickitat, Okanogan, Pacific, San Juan, Skagit, Spokane, and Yakima)** | Last working day of November of each year. | Last working day of December of each year. | Last working day of January of each year. | Last working day of February of each year. | March 16 of each year or the first working day thereafter. | 45-Day public comment period (including public hearing). Begins March 17 or the first working day thereafter. | 30-Day rebuttal period. Applicant and affected person response to public comment. | 75-Day ex parte period. Department evaluation and decision. |

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

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

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

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

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

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

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

(d) For a hospice agency that has changed ownership, the department will use the historical three-year admissions to calculate the statewide use rates, and will use the admissions to calculate planning area capacity.

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

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

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

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

(iii) The predicted percentage of noncancer patients sixty-five and over who will use hospice services. This percentage is calculated by dividing the average number of hospice admissions over the last three years for patients age sixty-five and over with diagnoses other than cancer by the current statewide total of deaths over sixty-five with diagnoses other than cancer.

(iv) The predicted percentage of noncancer patients under sixty-five who will use hospice services. This percentage is calculated by dividing the average number of hospice admissions over the last three years for patients under the age of sixty-five with diagnoses other than cancer by the current statewide total of deaths under sixty-five with diagnoses other than cancer).
(b) Step 2. Calculate the average number of total resident deaths over the last three years for each planning area by age cohort.

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

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

(e) Step 5. ((Inflate the potential volume of hospice service by the one-year estimated population growth (using OFM data).) Combine the two age cohorts. Subtract the most recent three-year average hospice capacity in each planning area from the projected volumes calculated in Step 4 to determine the number of projected admissions beyond the planning area capacity.

(f) Step 6. ((Subtract the current hospice capacity in each planning area from the above projected volume of hospice services to determine unmet need.) Multiply the unmet need from Step 5 by the statewide average length of stay as determined by CMS to determine unmet need patient days in the projection years.

(g) ((Determine the number of hospice agencies in the proposed planning area which could support the unmet need with an ADC of thirty-five.)) Step 7. Divide the unmet patient days from Step 6 by 365 to determine the unmet need ADC.

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

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

(10) In addition to demonstrating numeric need under subsection (7) of this section, (hospice agencies) applicants must meet the following certificate of need requirements (including WAC 246-310-210-210):

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

(b) WAC 246-310-220 (e) Determination of financial feasibility under WAC 246-310-210;

(c) Criteria for structure and process of care under WAC 246-310-210; and

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

(49) If two or more hospice agencies are competing to meet the same forecasted net need, the department shall consider at least the following factors when determining which proposal best meets forecasted need:

(a) Improved service in geographic areas and to special populations;

(b) Most cost efficient and financially feasible service;

(c) Minimum impact on existing programs;

(d) Greatest breadth and depth of hospice services;

(e) Historical provision of services; and
(f) Plans to employ an experienced and credentialed clinical staff with expertise in pain and symptom management.

(10) (11) To conduct the superiority evaluation to determine which competing applications to approve, the department will use only the criteria and measures in this section to compare two or more applications to each other.

(a) The following measures must be used when comparing two or more applications to each other:
   (i) Improved service to the planning area;
   (ii) Specific populations including, but not limited to, pediatrics;
   (iii) Minimum impact on existing programs;
   (iv) Greatest breadth and depth of hospice services; and
   (v) Published and publicly available quality data.

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

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

(a) The department will consider if the applicant meets the following criteria:
   (i) All applicable review criteria and standards with the exception of numeric need have been met;
   (ii) The applicant commits to serving medicare and medicaid patients; and
   (iii) A specific population is underserved; or
   (iv) The population of the county is low enough that the methodology has not projected need in five years, and the population of the county is not sufficient to meet an ADC of thirty-five.

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

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

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

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