PROPOSED RULE MAKING



CR-102 (October 2017) (Implements RCW 34.05.320)

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DATE: December 15, 2017

TIME: 12:40 PM

WSR 18-01-084

| Agency: Department of Health | | | | | | |
|--|---|---|--------------------------------------|------------------|--|--|
| ⊠Original Notice | | | | | | |
| Supplemental Notice to WSR | | | | | | |
| ☐ Continuance of WSR | | | | | | |
| ⊠Preproposal Statement of Inquiry was filed as WSR <u>10-10-114</u> ; or | | | | | | |
| ☐Expedited Rule Ma | kingProp | osed notice was filed as WSR | or | | | |
| ☐Proposal is exemp | □Proposal is exempt under RCW 34.05.310(4) or 34.05.330(1). | | | | | |
| ☐Proposal is exemp | t under RC | W . | | | | |
| | | g information: (describe subject | | | | |
| | | | ent) Certificate of Need (CoN) progr | ram is proposing | | |
| revision of current crite | eria, standar | ds and need methodology for ho | spice service agencies. | | | |
| | | | | | | |
| | | | | | | |
| Hearing location(s): | | | | | | |
| Date: | Time: | Location: (be specific) | Comment: | | | |
| 01/31/18 | 9:30AM | Department of Health | | | | |
| | | Town Center 2, Room 158 | | | | |
| | | 111 Israel Road SE | | | | |
| | 4: 00/0 | Tumwater WA 98501 | | | | |
| | | 3/2018 (Note: This is NOT the et | fective date) | | | |
| Submit written comm | | | | | | |
| Name: Katherine Hoffr | | | | | | |
| Address: P.O. Box | | 050 | | | | |
| Tumwater WA 98504-7852 | | | | | | |
| Email: https://fortress.wa.gov/doh/policyreview Fax: 360-236-2321 | | | | | | |
| Other: | | | | | | |
| By (date) <u>01/31/2018</u> | | | | | | |
| 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 | | | | | | |
| Other: | | | | | | |
| By (date) <u>01/24/2018</u> | | | | | | |
| | | anticipated effects, including | | The proposed | | |
| changes update and modernize WAC 246-210-290. 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 the intent of with chapter 70.38 RCW.

| Statute being implemented: RCW 70.38.115 Is rule necessary because of a: Federal Law? Federal Court Decision? State Court Decision? If yes, CITATION: Agency comments or recommendations, if any, as to statutory language, matters: N/A | modernization. The proposal: The current CoN hospice rules went into effect in March 2003, and require modernization. The proposed revisions are necessary to remain current and in alignment with national industry standards, guidelines, best practices, and statewide demographic shifts. The rules will provide increased access to end of life care and support services to populations in need of such services. The proposed rules support the statutory goals of chapter 70.38 RCW by making sure that patients have access to affordable, quality healthcare. | | | | | | | |
|--|---|----------|--|--|--|--|--|--|
| Is rule necessary because of a: Federal Law? Federal Court Decision? State Court Decision? If yes, CITATION: Agency comments or recommendations, if any, as to statutory language, | | | | | | | | |
| Federal Law? Federal Court Decision? State Court Decision? If yes, CITATION: Agency comments or recommendations, if any, as to statutory language, | | | | | | | | |
| Federal Court Decision? State Court Decision? If yes, CITATION: Agency comments or recommendations, if any, as to statutory language, | | | | | | | | |
| State Court Decision? If yes, CITATION: Agency comments or recommendations, if any, as to statutory language, | ☐ Yes ⊠ | No | | | | | | |
| If yes, CITATION: Agency comments or recommendations, if any, as to statutory language, | - - | No | | | | | | |
| Agency comments or recommendations, if any, as to statutory language, | ☐ Yes ⊠ | No | | | | | | |
| | implementation, enforcement, and f | iscal | | | | | | |
| Name of proponent: (person or organization) Department of Health | □Private □Public ⊠Governmer | ntal | | | | | | |
| Name of agency personnel responsible for: | | | | | | | | |
| Name Office Location | Phone | | | | | | | |
| Drafting: Katherine Hoffman 111 Israel Road SE, Tumw | vater WA 98501 360-236-2979 | <i>i</i> | | | | | | |
| Implementation: Janis Sigman 111 Israel Road SE, Tumw | vater WA 98501 360-236-2956 | i | | | | | | |
| Enforcement: Janis Sigman 111 Israel Road SE, Tumw | ater WA 98501 360-236-2956 | i | | | | | | |
| Is a school district fiscal impact statement required under RCW 28A.305.1 If yes, insert statement here: The public may obtain a copy of the school district fiscal impact statement by Name: Address: Phone: Fax: TTY: Email: Other: | | No | | | | | | |
| 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: 111 Israel Road SEP.O. Box 47852Tumwater WA 98501 Phone: 360-236-2979 Fax: 360-236-2321 TTY: (360) 833-6388 or 711 Email: katherine.hoffman@doh.wa.gov Other: ☐ No: Please explain: | j: | | | | | | | |

| Regulatory | Fairness Act Cost Considerations for a Small | Busine | ess Economic Impact Statement: | | | |
|---|---|--|--|--|--|--|
| | oposal, or portions of the proposal, may be exem 85 RCW). Please check the box for any applicable | | requirements of the Regulatory Fairness Act (see otion(s): | | | |
| adopted sol | e proposal, or portions of the proposal, is exempt lely to conform and/or comply with federal statute his rule is being adopted to conform or comply wit | or regul | | | | |
| Citation and | d description: | | | | | |
| defined by I | RCW 34.05.313 before filing the notice of this prop | posed ru | | | | |
| | e proposal, or portions of the proposal, is exempt a referendum. | under th | ne provisions of RCW 15.65.570(2) because it was | | | |
| | e proposal, or portions of the proposal, is exempt | under R | CW 19.85.025(3), Check all that apply: | | | |
| | RCW 34.05.310 (4)(b) | | RCW 34.05.310 (4)(e) | | | |
| Ш | (Internal government operations) | ш | (Dictated by statute) | | | |
| | RCW 34.05.310 (4)(c) | | RCW 34.05.310 (4)(f) | | | |
| | (Incorporation by reference) | _ | (Set or adjust fees) | | | |
| | RCW 34.05.310 (4)(d) | | RCW 34.05.310 (4)(g) | | | |
| | (Correct or clarify language) | | ((i) Relating to agency hearings; or (ii) process | | | |
| | | | requirements for applying to an agency for a license or permit) | | | |
| ☐ This rule | e proposal, or portions of the proposal, is exempt | under R | CW. | | | |
| Explanation | of exemptions, if necessary: | | | | | |
| | COMPLETE THIS SECTION O | NLY IF | NO EXEMPTION APPLIES | | | |
| If the propo | | | costs (as defined by RCW 19.85.020(2)) on businesses? | | | |
| alter the methodo step of the calculation makes it provider and a reacompa available application are approvoluntaring for hospectors. | The rule does not impose any regulatory burden certificate of need application process. With respology assumes that existing hospice agencies will he methodology has been lowered from 35 to 25. taff and to increase the number of patients they wons, this is a clear indication that the agency is not easier for new applicants to enter the Washingto. Additionally, reducing the ADC does not affect eduction in ADC allows new providers to serve the uses projected need in less populated areas to be spect to the addition of exception language, hospic application process, including numeric need. The stany an exception request may result in additional education and other material. While this may require a con process, applicants are aware of planning area copriately prepared to put forth arguments to supplify incurred by providers is far outweighed by the pice services, even though that need may not be a Calculations show the rule proposal likely imposic impact statement is required. Insert statement he | on provect to the maintain The depish to see the content of the co | n their current volumes. The ADC identified in the final partment does not restrict an existing hospice's ability to expect but if a need is present and demonstrated in the ag in line with population growth. Reducing the ADC are service market, benefiting both the consumer and providers since they already "hold steady" in the market, or patients who are not being served. Reducing the estrated earlier, thereby increasing access to services. The providers must meet all other existing criteria as part entary documentation and analysis that would inal administrative burden, including gathering publicly at the extend efforts beyond the usual and ordinary CN as issues well before their letter of intent is submitted, and potion requests. The nominal additional costs that may be expected in the providers of the provide | | | |
| conta | acting: | onomic | impact statement or the detailed cost calculations by | | | |
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|-------------------------------|------------|--|
| Date: 12/11/2017 | Signature: | |
| Name: John Wiesman, DrPH, MPH | John Wiss | |
| Title: Secretary of Health | | |

- 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 $((\cdot, \cdot))$ 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 <u>hospice</u> agency admissions by the most recent average length of stay in Washington ((+)), based on <u>the most recent data reported to the</u> Centers for Medicare and Medicaid Services (CMS) $((\frac{data}{}))$ to derive the total annual days of care; $((\frac{and}{}))$
- (ii) Dividing $((\frac{\text{this}}{}))$ the total <u>calculated in (a)(i) of this subsection</u> 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.
- (c) "Base year" means the most recent calendar year for which hospice survey data is available as of September 30th of each year.
 - (d) "CMS" means the Centers for Medicare and Medicaid Services.
- (e) "Current supply of hospice providers" means all providers of hospice services that have received certificate of need approval to provide services within a planning area. State licensed only and vol-

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unteer hospices are excluded from the current supply of hospice providers.

- $\underline{(f)}$ "Hospice services" means symptom and pain management provided to a terminally ill (($\underline{individual}$)) \underline{person} , and emotional, spiritual and bereavement support for the (($\underline{individual}$)) $\underline{terminally}$ ill \underline{person} and family in a place of temporary or permanent residence ((\underline{and} \underline{may} $\underline{include}$ \underline{the} $\underline{provision}$ \underline{of} \underline{home} \underline{health} \underline{and} \underline{home} \underline{care} $\underline{services}$ \underline{for} \underline{the} $\underline{terminally}$ \underline{ill} $\underline{individual}$.
- (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((s 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((s)) 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:
- ((\(\frac{a}\)) Letters of intent must be submitted between the first work-ing 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. | public comment period (including public hearing). Begins March 17 or the first working day thereafter. | 30-Day rebuttal period. Applicant and affected person response to public comment. | 75-Day ex parte period. Department evaluation and decision. |
| Cycle 2 (Adams, Asotin, Benton, Columbia, Ferry, Franklin, Garfield, Kitsap, Lewis, Lincoln, Mason, Pend Oreille, Pierce, Snohomish, Stevens, Thurston, Wahkiakum, Walla Walla, Whatcom, and Whitman). | Last working day of December of each year. | Last working day of January of each year. | Last working day of February of each year. | Last working day of March of each year. | April 16 of each year or the first working day thereafter. | public comment period (including public hearing). Begins April 17 or the first working day thereafter. | 30-Day rebuttal period. Applicant and affected person response to public comment. | 75-Day ex parte period. Department evaluation and decision. |

- (4) Pending certificate of need applications. A hospice service application submitted prior to the effective date of these rules will be reviewed and action taken based on the rules that were in effect on the date the application was received.
- (5) The department will notify applicants fifteen calendar days prior to the scheduled decision date if it is unable to meet the deci-

- <u>sion deadline on the application(s). In that event, the department</u> 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 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 twenty-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 twenty-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 ((four)) department of health (four) 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)).

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- (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.
- (8))) 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 twenty-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 <u>numeric</u> need under subsection (7) of this section, ((hospice agencies)) <u>applicants</u> must meet the ((other)) <u>following</u> certificate of need requirements ((including WAC 246-310-210-)):
 - (a) Determination of need((-)) under WAC 246-310-210;
- (b) WAC 246-310-220 ((-)) Determination of financial feasibility($(\frac{300}{3000} + \frac{310-230}{3000})$) under WAC 246-310-210;
- $\underline{\text{(c)}}$ Criteria for structure and process of care((, and WAC $\underline{246-310-240-}$)) $\underline{\text{under WAC } 246-310-230; \text{ and}}$
 - (d) Determination of cost containment under WAC 246-310-240.
- ((9) 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

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- (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 not being served; 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 twenty-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 ((in accordance with)) as approved in the certificate of need ((standards)) may be ((grounds)) a basis for revocation or suspension of ((an)) a hospice agency's certificate of need, or other appropriate action.