A meeting regarding the Certificate of Need (CoN) hospice services rules convened on January 10, 2017. The meeting was held at the Department of Health, 111 Israel Road SE, in Town Center 2, Conference Room 158, Tumwater, WA 98501.

PRESENT:
- Catherine Kozar, Providence
- Steve Pence, Providence
- Frank Fox, Providence
- Cristi Keith, Continuum Care Hospice
- Lori Ayoama, HFPD
- Mark Rake-Marona, Franciscan Hospice
- Candace Cheney, Assured/LHC
- Leslie Emerick, WSHPCO
- Chris McFaul, Horizon Hospice
- Barb Hansen, WSHPCO (by phone)
- Bart Eggen, DOH (by phone)
- Gina Drummond, Hospice of Spoke (by phone)
- Kathy Katzenberger, Evergreen Hospice (by phone)

STAFF PRESENT:
- Nancy Tyson, Executive Director
- Kathy Hoffman, Policy Analyst
- Beth Harlow, Analyst
- Jan Sigman, Program Manager

9:05 AM – Meeting opened with introductions, agenda overview,

1. **Presentation – Brief Overview of Rulemaking Process**

   - **Kathy** opened with rulemaking presentation. Please refer to PowerPoint presentation attached.
   - Discussed where the group was currently positioned in the rulemaking process, still in the developmental phase but moving toward CR 102 phase.
   - Explained statutory basis for rulemaking process, differences between phases and work associated with each phase. Described public hearing, formal comment period and statutory authority for each phase.

2. **Presentation and Discussion: Providence Issue Analysis: Steve, Frank, Catherine**

   - Four issues for consideration today; two technical, two other.
     - **Issue 1** – Planning Horizon: Recommend setting the planning horizon two years as opposed to three years Recommend that terms be defined, that base year be defined as the year in which
the hospice application is filed and project year be defined as the second year after the base year. Recommending that a standard set of definitions be used.

- **Issue 2** – Forecast Period: More complex, but rationale is that current methodology, capacity is defined as the most recent three years of actual data on admissions. Proposing that rather than holding hospice capacity constant as the rules currently dictate, allow the capacity to be defined based on the most recent three years of overall average annual growth in provider admissions across all counties. Recommending that rather than holding capacity constant as the methodology does currently, that capacity figure would be extrapolated forward at the rate of growth of the most prior three years of admissions. Asserts this is a better reflection of the market circumstances.

- **Issue 3** – Concurrent Review: Whether the department should maintain a concurrent review cycle for hospice applications. Low volume of hospice applications is not great, unlike other CoN reviews. Providence thinks no concurrent review cycle for hospice services would give more flexibility to someone who wants to enter the market to be able to file an application whenever they wish to. Asserts that concurrent review is not mandated in the statute or the CoN regulations for hospice applications, and concludes that given the small number of applications, concurrent review cycle is not needed.

- **Issue 4** – Update Applications: Good time to update application; separate process. Suggests interaction between department and providers reflective of current industry. Propose working collaboratively to develop a model hospice application. Does not have to occur during this rulemaking; could occur outside of it.

**Discussion (Issues 1 and 2):**

- Correct to say that for existing providers to adapt really is a matter of having staff and thinking of all the things that go into expanding capacity...staffing, staffing availability are the primary drivers.

- Much can and does happen in a three year period. A totally new provider (hire staff, develop marketing) would need that three years to establish themselves; two years would serve those of us that are already here, but may be hard for those who are brand new.

- Seems to be two separate questions: what does the hospice need methodology define as the projection year and what does the over financial feasibility analysis require. Talking about the projection year for hospice to determine whether there is need, but the department looks at, in the financial feasibility criteria, three years post-implementation, so there is a difference.

- Base year would be the most recent year of actuals (2015); application year would be 2016.

- If base year is last year data is available, but applications are submitted later, we have a concern about the lag time between when data is available and when the application is submitted. Works regardless of when the data is submitted. So, base year is the last year of actual data, and then the projection year is three years thereafter. Use an actual date example in rule – very helpful.

- Department indicates that holding existing capacity steady is appropriate because it allows for the potential for new providers to come in to provide services. Aim is not to create barriers. Understand staffing concerns, but want to encourage new providers. Most methodologies assume that new providers will take up the capacity that’s there, but won’t happen quickly. The only thing that CoN can do to improve penetration to hospice care is to add new providers.

- CoN does not control those other behaviors of providers, such as the level of outreach. CoN has no mechanisms to do that. The only thing CoN can do is approve another provider. But by holding the capacity of current providers steady while growing the need based on population you are saying that the providers should meet the future need now before it is even there – it is artificial.
Isn’t it artificial to inflate demand but not supply? Methodology does that. If inflating makes sense, then it’s presumed that there is always growth, unless projecting that there will be less (aggregate provider population is going down for some reason) safe to presume that last year can be used and it will be most reflective of what there is really is.

More comfortable with that than the average idea. Using statewide growth across all counties is something that we’d want to consider.

Philosophical discussion: What is capacity really telling us? Originally we said let’s average three years, the reason you had a decline is something other than a business motive. To look at capacity and say, what decisions have you made to reduce your capacity, even if the population remained at the current growth rate. The demand for hospice should not have changed, but there’s less provision of hospice services.

Want methodology to be reflective of how hospices actually work.

Need to test the methodology and see what we come up with. Concern that if test shows a reduction in need because appears in some counties, consistent with current rule, that you have a projection one year, but not others, appears there is a lock on the market. Not preferable.

Question is how to articulate this in the rule. Also agreed that using the last year of actuals at the county level for hospice admits can be extrapolated forward at the average annual growth of the most recent 3 years admits in that same county.

3. HFPD Presentation – Lori

- ADC of 25. HFPD has not been able to replicate ADC data and the way the methodology (first few steps) really increases need, at the same time, why would we reduce the threshold to gain entry – might be overstating net need.
- In an urban market does not seem viable, seems like it might be compromising, actually. Changing steps 1 – 4 in King County, just comparing the current methodology and proposed is about 750 more patients, just by growing age cohorts – huge difference.
- Maybe the current methodology understates need while the new methodology overstates need. Do we want to reduce the threshold, then, to get in without really understanding what the consequences are, particularly in urban markets where we already have choice? Describes examples in slides.
- Meaningful services are included in services, not just clinical staff – can do that if you are in a large provider. But small providers could be challenged to provide the same services. Might not have the same level of programming. In an urban market, want everyone to be able to provide these services. Maybe different thresholds between urban and rural. Providers indicate that ADC of 25 would be challenging – hard to be viable. Could not provide as many services. If you have choice, if ADC reduced to 25, what do people in planning area get by bringing in new providers.
- Department understands that group would like to go back to 35; can’t guarantee that we’re going to go back to that. The agency ultimately has the decision authority on this, but not sure that we’re going to agree to go back to 35. Again, for some of the same reasons that we discussed earlier, including the impact that had on the previous methodology. Department will take this into consideration.
- Providers discuss 25 vs 35. Resources, financial investments. Discussion of how 24 came about – find information that shows when agency is viable. Research didn’t show anything about the programs. 25 came about because of the analysis done. Through discourse in group, that number probably didn’t meet a lot of validity tests, holding on to 25 seems, in light of quality discussion, seems like we’re holding on the analysis of 25.
4. **Exception Language Follow Up – Lori**

- Believe it’s important for an applicant to have the opportunity to put forth an argument for exception. Burden on applicant to make argument for an exception. Exists in other CoN rules. Believes Jan mentioned exception language needs to be in rules. Dialysis exception language sets high bar, but exceptions need to be in rule. Before we discussed relying on 246-310-210, but we find that is not sufficient for the exception language, and we need to have exception language in the rule.
- In dialysis, bar is so high the department has never approved it.
- Department has approved exceptions dialysis before (Gig Harbor, Enumclaw) Jan describes circumstances related to granting of these two exceptions. Advantageous to have some hospice exception language. Needs to be high bar with some parameters around it.
- Discussed this at last meeting. Group voted (although this does not bind the department) it was not needed with the exception of one vote. Under the CoN need criteria regulations the question is does the population served or to be served have a need for the service, and are existing services available and accessible. Seems to us that with that language, someone can come in and make that argument that the existing services are not accessible for their, let me use the words, “special population” and that therefore, even though there might not be a numerical need, the department has the authority under those two criteria to approve their application. Are you saying that the department under those two criteria doesn’t have the authority to grant their application because there is no “numeric need” in that county?
- Department has learned from experience of adjudicative proceedings what are the parameters to have an exception when there is no numeric need. That’s the basis by which department is looking at potentially including some exception language. Don’t have to stay with current proposed language.
- In June, Nancy (F) Jody Corona were raising the issues that department is with respect to exceptions. Group asked both to propose language and neither did. Department used a hybrid of Florida exception language as a starting point. To date, no one in workgroup has proposed any other exception language.
- Lori agrees to provide revised exception language.
- Continued discussion of broad versus narrow approach to exceptions, use of terms “special populations” and “special circumstances.”

5. **ALOS Follow Up**

- Distributed full text of CMS email string to group for review. Group didn’t make any decisions last meeting on this issue; wanted to follow up in case there was additional discussion or comment. Beth had follow up.
- Tool on the CMS website does not allow pull of information. Need to contact CMS with a specific question to get that average length of stay. Issue is that we haven’t yet landed on our definition.
- Discussion of unduplicated deaths versus unduplicated admissions, average length of stay be episode. Should be unduplicated admissions, double counting and overhang balancing itself.
- Discussion of what CMS can provide to department, unduplicated admissions, unduplicated discharges.
- Discussion of counting unduplicated discharges instead of admissions, whether providers can give department three years of historical data.
- Previously from CMS in an annually produced, published table of average covered days of care per person, which is clearly different than what we are looking for here.
- If group wants to go to discharges, then department would have to ask the providers to do a three-year lookback and provide that. Time investment to do that is unknown. If group wants discharges from CMS, would want discharges from the providers as well.
- Frank and Beth will work up questions for CMS. Will bring questions to next meeting.
Concurrent Review Discussion (Conclusion of Agenda Item #2 - Providence Issue Analysis)

- Department and Providence has differing opinions of whether or not statute requires concurrent review cycles. Department updating rules to include concurrent review; Providence asserts that department has not had concurrent review schedules for several facility types.
- Discussion of timing for hospice services concurrent review. Pushing out a month or two just to accommodate vital statistics
- Discussion of differences between kidney dialysis and hospice cycles and methodology. In the interest of flexibility, multiple cycles would be better.

Roundtable

- General: Thanks for the productive meeting.
- Great discussion.

Conclusion

- Tasks/Assignments:
  - Frank and Beth will run the methodology based on the variables of 25 and 35, as well as ADC. Test the quantitative difference. If we’re going to be trending, might be a different picture. Work will go in to trending.
  - Lori will provide proposed language for exceptions.
  - Frank and Beth are going to work on questions for CMS.
  - Kathy will send out timeline regarding planning horizon/need projection for review after consulting with staff.

- Next meeting: Request for next meeting in mid to late March – group agrees that this works best with existing workload and additional tasks assigned at this meeting.
- Request that data be distributed a couple of weeks prior to meeting.

**END**
Brief Overview of Rulemaking Process

Kathy Hoffman, MPA
Department of Health/Certificate of Need
January 10, 2017
Basic Rulemaking Process

The standard rulemaking process is divided into three stages:

• Stage 1: Pre-proposal Statement of Inquiry (CR-101)
• Stage 2: Proposed Rule Making (CR-102)
• Stage 3: Rule-making Order (CR-103P)

Each stage consists of specific tasks and processes.
Basic Rule Making Flow Chart

Start

CR-101 Statement of Inquiry
Filed May 4, 2010
WSR #10-10-14

Stakeholder work

Rule Drafting, Analyses

We are here

CR-102 Proposal

Public Hearing/Comments

Respond to Comments

CR-103 Final Adoption

Finish
Statement of Inquiry (CR-101) – RCW 34.05.310

Purpose: Describes the issue(s) being addressed by rule

- The pre-proposal is filed with the Office of the Code Reviser and published in the Washington State Register. This is the formal document that identifies the purpose of rulemaking.
- The scope of rules created through this process is controlled by statutory authority and must be compatible with existing requirements.
- Most rulemaking work is done after the filing the pre-proposal statement of inquiry.
- The department works with stakeholders to develop draft rules.
- The department begins internal development of required analyses required by chapter 34.05 RCW, Administrative Procedures Act and chapter 19.85 RCW, Regulatory Fairness Act.
Proposal (CR-102) – RCW 34.05.320

Proposed rule language and impact analysis.

• The department creates the proposed rulemaking order, CR-102.
• This filing establishes the formal review and comment process, including the date, time and location of the public hearing.
• The public hearing is typically held at the end of the review period.
• At the hearing, public testimony is taken and written comments are submitted on the proposed rule(s).
Final Adoption (CR 103P ) Order – RCW 34.05.360

Final rules are adopted

- After the public hearing and review period ends, the department compiles all comments received and makes a decision whether the proposed rules should be changed or adopted as proposed.
- If the department makes substantive changes, a supplemental CR-102 must be filed and 2nd hearing held. This substantially extends the timeline of the process, and is uncommon in most rulemaking projects.
- If the department adopts the rules as proposed, the department files the rulemaking order, or CR-103, and the rules typically become effective 31 days later.
- All comments and the department’s responses are complied into a Concise Explanatory Statement and are provided to all commenters shortly after the adopted rules are filed.
Simple flow chart of the rule making process

1. Initiate rulemaking; file notice with the Office of the Code Reviser
2. Hold public workshop(s) to solicit input from interested persons/public
3. Draft rule language
4. Send draft rules out to the public for comments/input
5. Schedule formal rule hearing (can continue to accept comments)
6. Hold rule hearing; comments and/or testimony provided in person or in writing
7. Final rule adopted and filed with the Office of the Code Reviser, then sent to all interested persons
8. Department must address what comments were received, how the rule language was changed or not changed based on those comments
Why does rule making take so long?

Most HSQA rules take 12 to 18 months (and sometimes more) to develop and finalize.

• Waiting periods are set by law.
• Public involvement and deliberative dialogue take time.
• No two rule sets are exactly alike; some rules are very complex and/or controversial and require substantial time and work to develop.
• Data collection, research and economic analysis can, and often is, time consuming.
• DOH Internal review process is lengthy.
Resources

Washington State Office of the Code Reviser:
http://leg.wa.gov/CodeReviser/Pages/default.aspx

Department of Health Rule Making – General:
http://www.doh.wa.gov/AboutUs/RuleMaking

Department of Health Rule-Making Activity – Specific:
http://www.doh.wa.gov/AboutUs/RuleMaking/RuleMakingActivity

Department of Health – Certificate of Need Rule Making Activity:
http://www.doh.wa.gov/LicensesPermitsandCertificates/FacilitiesNewReneworUpdate/CertificateofNeed/RulemakingActivities

Washington State Administrative Procedure Act – Chapter 34.05 RCW – Part III Rule-Making Procedures:
http://apps.leg.wa.gov/RCW/default.aspx?cite=34.05