Certificate of Need – Kidney Dialysis Rules
Workshop # 1 – October 17, 2013 - Comments Grouped and Summarized

Access Issues:

- Eliminate numeric need calculation, eliminate tiebreakers, and approve all applications based on a quality of care assessment. (This addresses comments from #2, #3, and #4)

  This proposal would eliminate having a need projection methodology. CoN would focus on a planning area's utilization of existing capacity. When a planning area's capacity is met, applications would be accepted and all applications from providers would be approved as long as they passed a quality of care assessment. Objective data is available to assist in determining quality. The approved applicants would build their facilities and that planning area would have a lot of capacity for many years.

  Washington State is a CoN state. The legislature said that Kidney Dialysis Centers need to be reviewed by CoN according to the criteria they established. In our current efforts to revise the rules, we can't get away from having to follow the guidance that the legislature established. There needs to be a rational determination for why you allow a facility to build. Tiebreakers are not the way decisions should be made. Decisions should focus on quality providers who are willing to build facilities to improve patient access.

- Station utilization standards. (This addresses comments from #1, #9, #10, and #18)

  This proposal would reduce station utilization from 4.8 to 3.2 for all stations (urban and rural). Waiting to reach 4.8 patients per station is too long before allowing new stations to be approved in a planning area. Lowering utilization to 3.2 would allow facilities to reach more quickly that benchmark, allowing additional stations to be approved sooner, and therefore ensuring patients have additional station scheduling available to them.

  This next proposal would allow CoN to approve additional projected stations for one or more facilities that have reached the agreed upon utilization standard, (4.8? 3.2? Other?) despite another facility within that same planning area not at or above the utilization standard. The time frame would have to be agreed upon – some have suggested 4 years? Whatever the dynamics are in a given planning area, CoN would say they can't prevent access to predicted additional station need because of underutilization.

  This second proposal has at least two options to deal with a facility's underutilization:

  Option #1 – After an agreed upon period of time (for example, 4 years?), a facility that has not reached the utilization standard would have a reduction of stations to the point that the utilization standard is achieved.

Option #2 - After an agreed upon period of time (for example, 4 years?), if a facility has not reached the utilization standard, the department would be able to approve additional capacity to other facilities within that planning area that were at or above the utilization standard.

- How are stations used? (This addresses comments from #13 and #14)
    - Discussion about "isolation" stations.
    - Discussion about "training" stations. There is a pervasive misunderstanding amongst providers that training stations are only to be used for training. The intent is you told CoN you do training, so you should have at least one training station at your facility. That training station can also be used for your general Dialysis population.
    - Discussion about emerging modalities. Peritoneal Dialysis (PD) patients. PD in-center stations to allow patients to come in three times a week for eight to ten hours. Patient is ready to start, they already have their PD cath in place and today's the day to start.
    - Discussion about the concept of "Active" stations. For example, a facility is approved for 12 stations but builds out 24. They would never have more than 12 stations in use. You have your 12 active stations but you build out 24 so you have less down time for cleaning – thus greater patient access.

Process Issues:

- Develop a process for updating zip codes. (This addresses comments from #5)
- King 7 & 8 planning areas were established in 2005. It's time to revisit the decisions that were made in 2005 and see if adjustments are needed. (This addresses comments from #12)
- Reduce # of review cycles. (This addresses comments from #6 and #16)

  We currently have four review cycles per year; some have suggested that we go to two cycles. This is addressing release of NWRN Data so that we can time the concurrent review with the year-end data and the most recent quarterly data. This may assist in getting decisions completed with less overlap occurring.

- Total refund for 2nd application submitted before a decision has been made on 1st application. (This addresses comments from #7)

  If DOH doesn't get their decision out on time, we run into the situation where a 2nd application is submitted in the next review cycle and ultimately is withdrawn when the first decision is finally made public. The 2nd application may never have been submitted if DOH had made its decision during the first review cycle. If this occurs, 2nd applicant should receive a total (not partial) refund.

- Border planning areas. (This addresses comments from #15)

  This deals with facilities that are operating near state borders, the unique dynamics that occur near borders and how we should look at projections and utilization. Patients can cross state borders freely. The current rules have dealt with these issues in a certain way and we need to discuss if this approach has been a good one.

- Data / information within the initial application. (This addresses comments from #17)

  The application asks fundamental questions. The intent is for applicants to provide detailed responses to these questions when submitting their initial application. If these key questions are not answered with the appropriate level of detail, CoN analysts will have to take additional time to contact the applicants to get the required information. The problem to be solved is initial applications submitted to the department that are incomplete.

- Clarify Children's – not in projection method. (This addresses comments from #19)

  Adding a simple clarifier in rule that our model is not projecting need for Pediatric Dialysis.

- Need a process for ensuring that department questions get answered by the applicant, so that the department isn't making decisions based on their interpretation of what somebody was going to do without having asked the question. It's a situation where an answer to a key question was misconstrued and that creates huge downstream effects.

Superiority Analysis / Tiebreaker Issues:

- Discussion about multiple applications by single provider in planning area exceeding total projected need. (This addresses comments from #8)

  To prevent "gaming" of the Tiebreakers.

- Home training tiebreaker – within 35 miles regardless. (This addresses comments from #11)

  Our rule currently says if you have a program within the same planning area that provides training services and you're proposing an expansion or new facility within that same planning area, if your other facility is within 35 miles you don't have to duplicate your training. What if my primary training facility is ten miles away but it crosses a zip code boundary, now do I have to duplicate training in this new facility that I'm proposing?

- Timeliness to address the need. (This addresses comments from #20)

  From a patient's standpoint, if the need exists, it's a reasonable expectation to have new units up and running in the next six months. There's nothing in the current rules that acts as a "stop check" that looks at going beyond that reasonable amount of time.

Some discussion about what's the value of projects that can come on-line earlier to provide access to patients compared to a project that will take longer. Whether we call this a "tiebreaker" or a standard for the "superiority analysis" I don't know. We would need an enforcement mechanism – if you tell me six months and it's been a year and a half, how does that impact the next time we look at an application from you?

- Multiple applications be single provider within same planning area – must rank projects. (This addresses comments from #21)

  When we get these multiple applications, we would want to know from the provider which of their applications they consider superior. We wouldn't necessarily pick the same application as superior that you would have picked – so tell us which one is the one you really want.

- History of applications – completing previous projects within timelines. (This addresses comments from #22)

  This is a test back concept – looking at the history of previous applicants. Did they do what they said they were going to do and within the stated timeframes? Should there be a follow up process that assesses what was supposed to have happened and having the results of that assessment impact future decisions? Not so much to say we are going to enforce what you said you were going to do in that project but from the context of how should it impact the decision for the future project? This would be either in the superiority analysis or tiebreaker area. Problem to solve - How do we decide whose application to approve when we have competing applications that are otherwise equal?

- Application of tiebreakers. (This addresses comments from #23)

  We would like an analysis of superior alternatives under cost containment prior to tiebreakers. We have this expectation of conducting a superiority analysis but we don't have any written guidelines or nationally accepted standards to evaluate. If we want to create those, tell the department how to evaluate that?