Certificate of Need – Kidney Dialysis Rules
Notes for Workshop # 1 – October 17, 2013

Bart- I like to treat these sessions as “workshop” sessions. I hope we can have a fairly casual environment where we are mutually respectful of one another in our points of views. We should brainstorm ideas and put everything on a list and then fully discuss what the ramifications are with each item. Ultimately we are looking for some kind of consensus on which ideas are seen as good ones. The ultimate outcome is to have rules that are predictable, we want people to understand how the decisions are reached, and have a sense that the process was fair and understood, whether or not it was the outcome that you would have liked to have seen. It’s absolutely predictable and doesn’t make a difference if the department reviews the application or if you had reviewed the application yourself, the conclusion, based on the rules, would be the same.

I think we were pretty successful in part of our rule development last time. It seems like, whether it’s a good projection model or not, everyone is able to use the station need projection model and predict the expected number of patient stations – everyone applies the model correctly.

Beyond this, I think we all recognize that we need to take the next step. At that time, we weren’t all on board on how we projected the station need. We spent a lot of time in that rules group working on the projection model. We did a little work around the topic of having equally approvable applications and how would we choose which application moved forward? Apparently we needed to do more work in this area? For the past several years we have agreed on what the station need is, but the rest of the process has been very difficult for us as a program. This is one of the primary reasons why we are coming back to revising the rules, to work on the other half of how we make decision for Kidney Dialysis.

We are a CoN state - statutory foundation is in chapter 70.38 RCW. Chapter 246-310 WAC implements the statute.

This workgroup will develop ideas and solutions for the Kidney Dialysis rules. The department will take the best ideas from the group and write new draft rules. This draft will be reviewed by the group for further feedback and refinement. Ultimately, the department will hold a formal public hearing to give all interested parties an opportunity to comment on the proposed new rules. It is our hope that at this public hearing, we will not hear any new comments from participants of this workgroup. We anticipate that we will already know all of your comments about the proposed rules as a result of our workshop discussions. We don’t know what the general public may say?

Jeff Lehman – One of the things we need to talk about is the way in which the department interprets some of these rules and a process for ensuring that department questions get answered by the applicant, so that the department isn’t making decisions in the end based on their interpretation of what somebody was going to do without having asked the question.
Bart – I agree. I hope we can write the rules in a way so that there is not a lot of interpretation necessary. We need to look at our process and see how it’s working.

Jeff Lehman – I don’t think we would codify this in a WAC. It’s more a matter of how you’re doing it internally. It’s a situation where a key question was misconstrued and that creates huge downstream effects.

Bart – Yes, we’ve seen that happen on more than one example. I don’t have any expectation that with competing applications, the person that is not approved is going to be thrilled about not getting an approval. I do hope that we can revise the rules so that providers understand how decisions are reached and the need for “interpretations” didn’t crop up that you weren’t expecting. Even if we go litigate the decision, maybe that’s what happens? Fundamental disagreements, I don’t think will ever get beyond that. We won’t make the rules bullet proof, but we can make them better.

Bob – There has been a change in the structure of the review process at the adjudicative level may have some bearing on how we would prepare specific rule changes to let’s say reduce the amount of time spent in adjudicative review. For example, in some cases the health law judges have indicated they wanted an interpretation of each of the four decision making activities and did not want to deal with the tiebreaker activities at all. In other cases, the judges went the other way. There may be a strategy on how we write the rules that may help projects get through the process and get a dialysis station open for a patient 6 or 12 months earlier than now. At some point, if we can get an overview of the changes in the adjudicative process and what impact that will have on Dialysis?

Palmer - You raised a good point, in the mutual interests statement, were the ALJ’s consulted on this and were they asked for any changes they’d like to see?

Bart – This has been at least a ten year frustration for some of us. You’re asking some very penetrating questions about how the legal adjudicative process works and expectations from health law judges. There have been some recent changes. Some of them haven’t even been tested yet. Within the next couple of months, we’re going to get some clarity on how those changes will impact CoN decisions. Those changes need to be part of this discussion. Bob is asking for the nitty gritty details and that’s what we don’t know yet. Legislation was passed that created a third review level of all agency actions with people that have appeal rights. Health law judges will no longer make a final decision on any adjudicative appeal. There’s a Reviewing Officer now that has been appointed. I am unclear about the nitty gritty of this Officer’s role. There are emergency rules in place that speak to the function of the Reviewing Officer. The concept is all program decision are agency decisions and are final unless appealed. If the decision is appealed, they take on the notion of a preliminary decision and the decision is made final by the health law judge. Now the Health law judge’s decision can be appealed and it falls to the Reviewing Officer to make a final review and decision. It has been very difficult to get any input from Health Law judges on needed changes to the rules due to their position as judges – giving such input is not seen as appropriate.
Natalie – I wonder if we could have as a goal an effort to clarify the rules so that final revision of the rules would contain less words than currently exists? Clarity equates less words.

Gail – I’im going to throw out a different perspective that says “you have as many words as you need.” Sometimes you need more words just to make sure it’s crystal clear. Sometimes this means you use less words. So the focus is on how many words do we really need.

Jan – Our mindset when we developed the rules was to break the rules into many sections so that in the future, when the rules needed to be changed, we could open up a specific section where the change was needed instead of having to open the entire rule set. That was our thought process at the time.

John – Based on the comments you submitted and our own issues, we developed this “Issues” list. We would like to use this workshop and subsequent workshop to discuss each “issue” and record your thoughts – support, no support and why.

Lori – Before we start going through this list, could we get an overview of each so we can better understand the issue?

Jason – I would also note that a lot of these are solutions to just a few core problems. So if we could identify what the core problems are and link the related issues, that may help us. Can we go over each issue, maybe hearing from the person who wrote the comment, so that we better understand what problem it is trying to solve?

Bart – A lot of the issues are connected, they are not mutually exclusive concepts. I can give you at least some background on each of the listed issues.

1. **Reduce station use from 4.8 to 3.2 for all stations:**

Bart - We created a two-tiered target for efficient utilization of stations. It was felt that having 4.8 patients per station was a good target for utilizing individual stations in larger developed communities. Providers and the department wanted to create an incentive to get providers to go into smaller rural communities that don’t project that same higher level of utilization – thus the 3.2.

Natalie – We ran into a situation where we hit the 4.8, the applications were filed and things proceeded as they should, but the process took longer than was expected. I suggested going with 3.2 as a buffer, it would give extra time as demand continues to grow and the process takes the time that it has to take, we would still have room to provide patient’s with appropriate station scheduling instead of pushing them onto night shifts. This change addresses lack of timeliness of new units relative to need.

Bart – So it adds a planning horizon concept that says waiting to reach 4.8 is too long to wait before getting new stations approved in a planning area.
2. Eliminate numeric need calculation:

Bart - Maybe numeric need is not a pivotal calculation that we should do? Less focus on numbers and more focus on quality of care and ensuring access.

3. Eliminate tiebreakers:

Natalie – In number 3, instead of picking one, once capacity is met, then open up the review process for any provider that wants to come in – don’t approve just one applicant. So if you have two qualified applicants, and they can demonstrate they will give excellent care, then they should be approved as a new resource for those patients needing care. Providers have an intrinsic sense of growth and an awareness of what the Dialysis need is in their areas so I wouldn’t expect a huge influx of Dialysis services for which there would be no patients. So numbers 2 and 3 are related.

Jason – So here’s an example of how this may work – So in a given planning area, there would no longer be a need calculation, only utilization, so once utilization was cleared everybody could apply, all applications from providers would be approved, and those facilities would be built, and in that area you would have a lot of capacity, enough to last for many years until utilization was cleared.

4. Approve all applications based on medical quality history:

Bart – so we would focus somewhere downstream on how well utilized is the existing capacity and what the decisions should be made about future expansions in that community. So this would say all applications would be approved. We can do quality of care checks and say, yep, there’s no history of bad care by this provider. It would be very difficult to try to calculate what is the financial viability of that proposed project? For example, everybody just hit an agreed utilization standard. We get applications from two applicants who say they both want to build 20 patient facilities. This proposed rule says we don’t have a need projection, only a quality assessment. Both applicants have good quality of care so if we want to approve both applications, how do we make any kind of decision about whether or not they’re financially going to be viable? Let alone approving one over the other. And we just leave it to the provider. One of the answers is to say, you’re a commercial business, if you want to build a facility and run the financial risk, then go ahead and do it, that’s your risk. The underpinning concept of CoN comes back to saying the legislature said that these types of facilities need to be reviewed and here’s the criteria they set up that we should look at. So 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. This ties to number 3 as well. Tiebreakers are not the way you should make decisions; the focus should be on quality providers who are willing to build facilities and improving patient access, that should be the paramount criteria period concept. This also ties to number 4 - Approve all applicants based on medical quality history. So issues 2 thru 4 are linked.

Unknown – There is a ton of data out there that is objective, that’s evaluated by a third party, that you can get your hands on to assist in determining quality. Outcome measures and intermediate process
measures. It may be good to consider using such data, whether it is part of the need process or part of the tiebreakers.

5. Develop a process for updating zip codes:

That’s self explanatory.

6. Reduce # of review cycles:

We currently have four review cycles per year; some have suggested that we go to two cycles.

Jan – 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.

7. Total refund for 2nd application if 1st application is approved:

Bart - 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. The current rule is structured around refunds assuming that program will complete reviews on time. How does litigation play into this?

8. Multiple applications by single provider in planning area exceeding total projected need:

To prevent “gaming” of the Tiebreakers.

9. Achievement of 4.8 / 3.2 within four years or auto reduction of approved stations:

This is trying to solve a problem whereby facilities that have been in a planning area for some period of time (4 years?) have not reached the 4.8 / 3.2 utilization standard and it looks like that planning area has projected need for additional capacity. Under our rules today, we can’t approve that additional capacity because of an existing operator’s under utilization. This is saying at some point in time, whatever the dynamics are in the planning area, we simply say we can’t prevent access to what would appear to be predicted additional station need because of underutilization. This is trying to solve an access problem.

Jason – If the problem is full facilities can’t grow because the unfull facilities are holding them back maybe the solution is to just allow the full facilities to grow rather than force the unfull facilities to have fewer stations.

10. Facility centered exception:

This is another access issue. A different way of looking at number nine.
11. Home training tiebreaker – within 35 miles regardless:

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?

12. Planning area revision (King 7 & 8):

It’s time to revisit the decisions that were made in 2005 and see if adjustments are needed.

13. Isolation stations:

Characterize this as “station use.” Compliance with Medicare conditions for coverage. Number of stations – plus one for isolation and plus one for training. Peritoneal patients – PD in center station 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 – this is a new expanding modality.

Gail - “Active station” – for example, you’re approved for 12 but build out 24. You never have more than 12 in use. You have your 12 active but you build out 24 you have less down time for cleaning. So you’re able to provide more access.

14. Training Stations:

Use of station issue. There’s a grave misunderstanding that you have a training station and somehow that means you’re only supposed to use that station for training. That’s not the intent. The intent is you told us you do training, so you should have at least one training station there. We don’t care if you use that training station for your general Dialysis population. We did find out that Medicare has strict expectations around isolation stations that caused a problem with our rules. We don’t have any restricted use stations in our methodology. We should have a robust discussion about how we use facilities and how that impacts projections.

15. Border planning areas:

In this context, the border is state borders. Not planning area borders. 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 department has dealt with these issues in a certain way and we need to discuss if our approach has been a good one.

16. Timing of NWRN Data:

This connect to # 6 (Review Cycles).
17. Data / information within the initial application:

There are fundamental elements of the application that applicants are asked to provide that should be disclosed at the time of submitting the initial application so that when we are screening the applications, we aren’t having to ask questions about these fundamental elements. For example, providers give the department some general information in their applications and have an expectation that the CoN analyst will eventually follow up and ask applicants questions about these known fundamental elements. There are known questions that CoN always asks, so provide answers to those questions up front in your initial applications. The problem to be solved is initial applications submitted to the department that are incomplete.

18. Adding stations to relocated facility before new facility opens:

When is the proper triggering time when we add capacity to previously approved projects?

19. Clarify Children’s – not in projection method:

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

20. Timeliness to address the need – what is no need met?

Unsure what this means and where it came from?

Jan – It may be dealing with facilities that have been approved but then do not move expeditiously towards completing construction and opening their center so that the projected need is being met?

Gail - Issue of commencement.

Natalie – From a patient’s standpoint, if the need exists, it’s a reasonable expectation to have a new unit up and running in the next six months. Decisions may take their required amount of time, litigation will take whatever time is needed, but from a sick patient’s perspective, that timeframe is not very relevant to them. There’s nothing in the current rules that is a “stop check” that looks at going beyond that reasonable amount of time. Some level of accountability to meeting that identified patient need.

Bart – 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 your application?

21. Multiple applications be single provider within same planning area – must rank projects:

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. This ties in with # 8.
22. History of applications – completing previous projects within timelines:

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?

Ann – Where does patient choice play into making such a decision?

Jason - Mutual exclusivity equals delay in litigation. Is it worthwhile brainstorming ideas for a process that is not mutually exclusive?

Bart – Yes, that’s what we are talking about here. But our current system is set up to create mutual exclusive decisions.

Bob – Consider moving some of the Settlement strategies into the CoN review process?

Bart – The concept is to develop a set of rules that would have avoided what happened in Clark County. Clark County was the perfect storm from a rules perspective that set up all of the things that we would have never anticipated happening. I would like to find some approaches that would have properly addressed this scenario in Clark County and would also be fair anywhere. We found ourselves very constrained and very litigious.

23. Application of tiebreakers:

Gail – We would like an analysis of superior alternatives under cost containment prior to tiebreakers. How are tiebreakers applied? How soon do you get to them?

Bart - Our perspective has always been that the tiebreakers fold back into any kind of a superiority analysis under WAC 246-310-210, 220, 230, 240. Tiebreakers are not independent. In litigation, some have used a sequential kind of an approach to the rules that we’ve never used. 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? Then we have to apply the art of saying, where do we want to write that rule within the existing rules?

Jeff Eustis – We need to have something in place so that when there is litigation going on, there’s some kind of “release valve” to service the community – that’s what half of these comments are about.
MEASUREMENTS

Question for providers to answer: How do you use your stations? Deadline for comments by Friday November 8th, 2013. Send to fslCoN mailbox. Post comments to CoN webpage.