

**Certificate of Need – Kidney Dialysis Rules
Notes for Workshop # 3 – December 19, 2013**

Bart – We have a general consensus that isolation stations should have at least one station approved per facility beyond what the need projection model would show. That station would not be included in the need projection calculation. It would be an approved station, identified on the CN. It would be a dedicated isolation station.

Gail – Just to go on the record, we would be comfortable with a plus two for isolation.

Bart – Yes there was a concept of hinging the number to the facility size.

Harold – Any facility greater than 18, we would say plus two for isolation. 18 is an arbitrary number.

Bart – There's some threshold thinking that when a facility gets to a certain size, more isolation stations may be needed. I think a large facility may indeed need more than one isolation station.

Natalie – Could we work on drafting this rule language now?

Bart – No. We're not ready to draft any language yet. We have been gathering your comments. When we're ready, we will draft up some language for the group to consider. I'd like to start drafting some of these pieces soon so it's not done all at once.

Bart – We have general consensus that training services should also not be counted in the need projection model. Training should be considered an approved service, not a station. We won't attach a number to training spaces or areas that a facility should have. It's more of a business need that the provider has for the number of training spaces that they think is appropriate. If you have a designated training area, it can only be used for training.

Harold – So if I have a facility that has 10 approved in center stations and I have a home training going, I can only run 9 in-center?

Group – No, you can run 10.

Harold – So I could run 10 plus a home training?

Bart – Yes.

Harold – Ok, I'm good with that! I like what you said earlier, the department isn't wanting to deny patient access.

Natalie – What if we treated isolation like a service? Do you provide isolation services?

Gail – We would prefer that there were boundaries around training, to have a certain percentage similar to isolation.

Bart – Yes, I think there are interests on both sides.

Harold – As we move forward in the future, patient training centers are starting to become popular. What about having home training patients serviced in a patient training center, separate from the in-center facility? The patients are not at stage 5, they don't have kidney failure yet but will in the near future. Before their kidneys fail, let's train them up. Just something to consider.

Bart – So you've talking about setting up some kind of a patient education center. What would prevent you from opening a center like this right now?

Palmer – The rules say Dialysis has to be done at a Kidney Dialysis Center.

Bart – But you said there's no dialysis taking place at this center?

Harold – If you're training them for home hemo then there would be. If blood is hitting the tubing, then you've doing dialysis.

Palmer – I think there's a line between dialysis education and actual dialysis. I don't know how you could go from CKB education, whether in a separate facility or not, and then transition into a dialysis modality.

Harold – Well maybe when a patient gets to the point of needing actual training we could move them in-center like we do now.

Bart – Or you offer those types of services through an existing dialysis facility?

Harold – There's nothing stopping us from doing this today. In fact, I'm going to build a chronic kidney disease patient training center where nutritionist and other professionals will work.

Bart – I'd like to remember this concept when we talk about tiebreakers. Is the concept of providing education services to patients with early diagnosed Kidney disease an important role that Dialysis providers should be fulfilling? Should all centers have some level of this activity? Should this activity be considered within our tiebreakers?

Bart – If possible, I'd like to draft some proposed language for isolation and training for our next workshop.

Bart – Release / Relief Valve concept – In our planning areas, when we have facilities that are not at the 4.8 minimum standard and we have other facilities already above 4.8, there becomes an interest in wanting to give those higher capacity facilities opportunities to expand. What do we do to provide relief to the facility that is already at 4.8 or exceeding capacity? Our rule currently says that we won't add any more stations in a planning area to anybody's facility until all facilities are at 4.8 utilization.

Bart – It looks like we have general consensus that something should be done when this scenario happens.

Marla - Franciscan's proposal: If a facility is operating for at least a ninety day period, at or above 5.5 patients per station, it should be allowed to add up to 20% of its existing capacity, and able to do this within their existing physical plant. No construction. Most of us build in future capacity, making it a quick turnaround. If construction is needed in order to expand, that's a CN application.

Unknown speaker - Plus "two" annually until there's no more space available.

Jason - Davita's proposal: automatic expansion for facilities that reach a certain threshold for a certain amount of time. The threshold should be under 100%, say 90% or 5.5 patients per station. Bigger issues to consider – utilization can be a planning area utilization, rather than each individual facility. Also, lower the utilization threshold. Propose a quick approval process for the automatic expansion. Also, no construction.

Palmer – This automatic expansion is only an option for facilities that are overbuilt.

Harold – PSKC proposal: a facility that is running 5 patients per station for greater than 6 consecutive months would be allowed to expand an additional 2 in-center or whatever number gets them under 4.8, regardless of what other provider are doing in the planning area. This should be an expedited, non-contestable CoN review / approval process. Also, no construction.

Natalie's proposal: lower the threshold to 3.2, or some amount lower than the current 4.8.

Bart - The current projection model looks out three years. What about looking out 4 years? Looking out an extra year has a similar affect to some of the other proposals.

Gail / Stan – Fresenius: We ran the different proposed utilization numbers. 3.2 produced too much additional capacity. Lowering the utilization number to say 4.0 would open up stations sooner than if we had to wait until 4.8 was reached. It just takes time to bring these new stations on-line. We are open to the concept of an automatic expansion when certain thresholds are reached. We're proposing this two-pronged approach. I'm not understanding what people are talking about when they say "no construction?" Does that mean we can't install a new sink?

Palmer – NWKC: a facility that has been operating above a 90% utilization for two consecutive quarters should be allowed to submit an application to expand. Also, all existing providers in the planning area should have had their CoN awarded longer than 4 years.

Bart – Changing the 4.8 standard to a lower utilization level (4.0? 3.2?) does not seem to be addressing this "Release / Relief Valve" concept. The same potential problem exists for a provider not being able to reach that new threshold of 4.0. I suppose if we lower the threshold far enough then this scenario wouldn't occur. This approach seems to just push the potential problem out.

Harold – I think there may be some unintended consequences if we lower the utilization level too far. If you do away with the planning area portion and it is facility specific, then it helps what you're trying to do in terms of increasing access. So facility specific for greater than 5 patients per station for 2

consecutive quarters, clean and clear, get authorization to add 2 stations or whatever number gets us back to 4.8. 5 patients per station doesn't leave much room for scheduling. The planning area is a completely different equation – and that's when CoN kicks in.

Bart – It doesn't seem that simply increasing the total number of stations in the state addresses our problem. I think we need to look at some of these other solutions that are focused on providing facility specific relief, at a point in time, given circumstances, for addressing the issue of access. We need more capacity in this facility for whatever the circumstances where one facility is full at 6, or perhaps we look at some number between 5 and 6 where scheduling becomes challenging, regardless of the status of other facilities in the planning area. This seems to be a simple direct fix for these kind of challenges. I'll share that I would like some kind of a two-pronged approach. I prefer not having a lot of patchwork, add 2, add 2, add 2. It would be nice if we had a system that says there's a time when adding 2 quickly comes into play. But also an opportunity for a CN application that would address the "10" that are projected as needed in the planning area.

Gail – How would you open up the CN process? Would you require all facilities in the planning area to be at 80%?

Bart – No, that's the barrier in the current rules that we need to revisit. We typically look at the planning area. Under certain circumstances, should we refocus and say what are individual facilities doing and how is it impacting patient access?

Harold – If in a given planning area, a provider is not able to reach 4.8, the facility that is greater than 5 patients per station for a certain amount of time (6 months?) should be authorized to expand.

Bart – I'm agreeing with you – how many times should we allow a plus two expansion?

Harold – It's self-limiting. People build kidney centers to a certain physical size. A provider could only expand until the space was used up – no construction. Facility specific until it becomes a self-limiting issue.

Bart – So when this facility has expanded to say 12 stations and there's no more space for future expansion, if another provider in the planning area is still below 4.8, what does that facility now do? That's when the second prong comes in – the CN application process is open for that planning area.

Bart – Over lunch I drew an illustration on the board of what I thought I heard people proposing. This is a facility centered approach which trumps planning area realities. See attached pictures.

Palmer – Any new provider wanting to break into a planning area should have to wait until the existing facilities have reached 80%. It's that the one successful facility in that planning area that should have access to immediate capacity relief.

Bart – That's something that we haven't talked about so far – let's remember this.

Bob – You shouldn't worry about construction costs. The need in the planning area should be driving decisions.

Harold – I fundamentally disagree with not worrying about construction. Some providers don't have deep pockets like others do. Some providers could continue to do new construction year after year. It should be limited to the maximum number of stations that a facility was originally designed to accommodate – adding two until the physical space is used up, then no more.

Jason – You said facility #3 is operating at 6.0; the consensus around the room was around 90% or 5.4.

Harold – I would propose 5.0. Patient scheduling becomes challenging at 5.0.

Unknown – I think 5.4 or 5.5 is a better number.

Bob – The data suggests that some scheduling problems begin to pop up at 5.0 or 5.1. We just need to pick a number between 4.8 and say 5.5 and agree on it.

Bart – Sounds like the number should be between 5.0 and 6. With 6 being universally seen as too high.

Unknown – If we have a larger facility, say 40 stations, adding two stations annually won't help that much in terms of patient scheduling. That's why we proposed using a percentage to add stations to get below the 4.8. We proposed adding up to 20%.

Bart – I'd really want to think about going with a percentage and would invite the group to submit comments about this. If you're talking about now adding 6 to 10 new stations, we've seen many applications for new facilities at that size. From the department's perspective, we like the smaller community based facilities. Some of our large population dense communities, these smaller facilities don't make as much sense. But once you get out of these population dense areas, to have facilities that are 10 to 20 stations really seems to improve access to people, rather than having to drive a longer distance to get to the 40 station facility. I don't think we want to write rules that are going to encourage that. There are certainly circumstances where larger facilities make really good sense. But to add under a discretionary plus up what we would consider to be enough stations where a whole facility could be built – I don't think we would favor that. I don't mind 20% with a cap.

Gail – What would you cap it at?

Bart – I don't know, maybe the group can help figure that out.

Harold – I originally thought getting it back below 4.8 made more sense. There are times when a larger facility would need 4, 5, 6 new stations to get them below 4.8. I now agree that we need to put a number on that. I don't want to go with a percentage; I've changed my mind completely.

Bart – Let's say we have a 40 station facility that currently operating at 6 patients per station. To get them back down to 4.8, what's the number of new stations needed? 240 divided by 4.8 equals 50

stations. So this 40 station facility would need 10 additional stations to get down to 4.8. That's a big number.

Unknown – That's the size of a whole new facility.

Palmer - That doesn't seem like an emergency relief valve any more.

Harold – That's a long term strategy, not a release!

Palmer – Right now, we're limiting this to facilities that have already built surplus capacity. That will be a self-limiter. You can do plus 2, plus 2, plus 2, but eventually everybody will be land-locked. Then there's a need model.

Bob – What about relocating a facility?

Bart – Yes, where going to have to talk about this and other issues like construction. So far we've said No Construction. Is that what we really want to do? Do we want to frame construction a little more liberally where there could be some construction build-out.

Harold – This is one of those really loaded questions. We should take some time to think this through and come back with comments. Right now, I fundamentally disagree with allowing construction because it puts the smaller provider at a disadvantage.

Jason – I didn't hear anyone suggest construction should be allowed.

Bart – No, but what was said was No Construction. We need to think about this. Can you think of any circumstances where minimal construction to accommodate these additional stations should be allowed?

Unknown – Or what's the definition of construction?

Bart – Ok, now we need to look at prong-two or the second step. Now let's look at the scenario where we have a 10 station need projected for the planning area. These exact providers are existing in the planning area – facilities #1, #2, and #3. Facility #3 is eligible for a plus 2 but there is also need for 10 stations in the planning area. Under our current rules, facilities #1 and #2 are barriers – CN applications cannot be submitted. Do we want to do something about this scenario? I think we've heard the answer is "Yes." Because we have a facility with a CN that is only 2 years old, we have said no CN applications can be submitted. We've agreed that new providers deserve at least 4 protected years to get their facility up and running. See attached illustration.

Bart – What about the scenario where we take away facility #1? We have a planning area with facility # 2 and #3. Facility #2 is a four year old provider – they've had their CN for four years – and they're at 4.5 patients per station. Facility #3 is a six year old provider and they're at 5.5. The projection model says there's a need for 10 additional stations. Do we let an application come in? See attached illustration.

Palmer – Yes, we allow applications for this scenario.

Bart – So anybody can apply at this point? A new provider could potentially apply for the 10 stations?

Palmer – Did I say that?

Bart – I think we would be hard pressed in writing the rule to discriminate against a new provider coming in.

Jason – What if we say for plus 2, facilities need to be at 5.0. If the facility wants to be able to apply for more stations, given the planning area demonstrates need, then it needs to be at a higher threshold – say 5.6, 5.7?

Stan – I like this conceptually. It's a two step approach. It truly is a pressure release for that one facility.

Bart – I'm not hearing that we want to make this the only threshold. Test #1 – all existing providers need to have a CN that is older than 4 years. If Yes, then we go to Test #2 (facility centered test) – Is there a provider that is above a certain threshold (5.5)? If Yes, then go to Test #3 – Does the need projection model demonstrate station need for the planning area? If Yes to all, then allow CN applications to be submitted.

Bart – Question? What is the minimum volume that an existing provider should be above in order to apply? If they are below then they can't apply? 4.5? We need to start getting precise about these different numbers.

Bart – Clarifying this is an adult projection model.

Marla – We have a pediatric population, albeit small. Would that be counted into the number of patients we are servicing? We've had as many as six pediatric, right now we have two. The children transplant rather quickly so we don't have them long.

Jason – I recommend you treat pediatric dialysis like home training - as a service that is outside of the methodology.

Bart – I'd want to make sure that we could identify the data through NWRN.

Palmer – I wonder if we're talking about different things here. I think the genesis of this was not pediatric in adult facilities but rather the dialysis stations that belonged to Children's Hospital in Seattle.

Unknown – Our pediatric data is included in NWRN but it is not identifiable as Peds.

Bart – Ok, we may revise the rules to say something like "This projection model is not intended to project pediatric dialysis station need."

Bart – Not in rule, but program should be proactively updating zip codes. We've reacted to applications and recognize we need to be proactive.

Bart – I would support reducing review cycles from four to two cycles.

Bart – Refund. 100% supportive if we go to 2 review cycles

Bart – Border planning area discussion. Specifically - Tri-State in Clarkston, WA. Summary of issue. We have a single provider that has two facilities. One facility in Lewiston, ID and one facility in Clarkston, WA. The two facilities are about 5 miles apart. The provider is talking about closing down it's ID facility. There's not enough capacity in their WA facility to accommodate the patients that would come from their closed ID facility. Our projection model will not support enough capacity for the WA facility to service all the patients. Question. Given that they are the only provider in that planning area, can we look at the total patient census of both facilities, co-locate them into one new facility in WA, and be able to accommodate all the patients? Our current rules won't allow this when we run the numbers. Tri-State wants 25 total and our rules only support about 18 stations.

Jason – I think the problem goes away if “someone” were to build a facility in ID. We would go into ID but we aren't legally able to go. Stan, is Fresenius interested in going into ID?

Stan – I look at this situation from a different angle – I don't think this is a CoN issue. I think this is an operations issue or a business decision for Tri-State.

Bart – Yes, this is the very first thing that came to a lot of our minds. But a new provider going into ID would take time. So the question becomes what do we do about existing patient that will no longer have adequate access to dialysis? Clearly there is an underlying business interest here that Tri-State needs to meet.

Harold – Isn't this a business decision because they are being forced out of a lease?

Bart – The cost of the ID facility is too high in comparison to what they could do in this new facility in WA. There would be efficiencies for Tri-State if they were able to consolidate and relocate into a new larger WA facility rather than operating two smaller facilities. All of you from a business perspective can probably say, I understand the business motive.

Natalie – Bart, do you have an idea of how to solve this?

Bart - Unfortunately, I can't think of a solution that is within the current rules that is immediate. There is clearly a multi-step longer solution that would work over time, but that would take time. We have the providers at the table. So if the department were to be able to come up with a creative solution for Tri-State, would that approach go unchallenged by the other providers? It's the notion of “No good deed goes unpunished.” Or is there a provider here that is willing to step up and operate a facility in ID? That's the tough question and it's not the solution that Tri-State is wanting.

Jody – Let me add some context. We interpret the rules differently, and we, along with DaVita, believes the latitude exists in the current rules to accommodate our request. The department has said “No” so we are seeking other means to do this. So we put forth a rule proposal with specific criteria to be met

that would allow border facilities, like Tri-State, to replace their existing non-Washington facility without triggering a Certificate of Need.

Natalie – Does anyone here object to this approach?

Gail – Yes, we already talked about this.

Stan – I think this is a business model decision. Tri-State knew that this ID building lease would expire. I would have to believe that the hospital had contingency plans of how to serve these patients. This is not a Certificate of Need question, it's a business decision of what to do with a lease that is expiring or a landlord that is not renewing.

Jody – I don't want anyone to think that we waited till the last minute. Tri-State has been in discussion with the department for the past year.

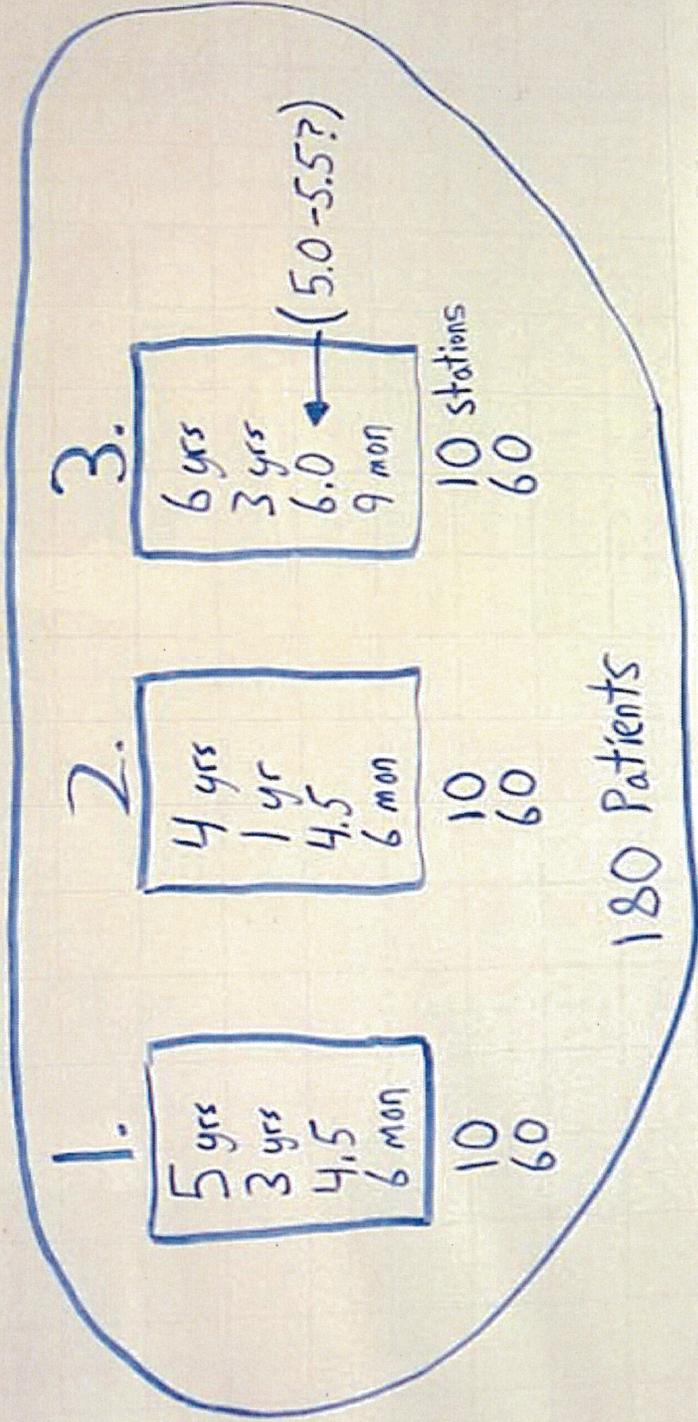
Natalie – The impression I'm getting is that this is not a conversation for here. Is that right?

Bart – I would say that it is a conversation to have in terms of how CoN should address various scenarios that bordering facilities face. It's just unfortunate that this has come up with a sense of urgency from Tri-State.

John – We're about out of time. Our next workshop is January 22, 2014. Please submit comments by January 15th. We will post all received comments by January 16th on the CoN webpage.

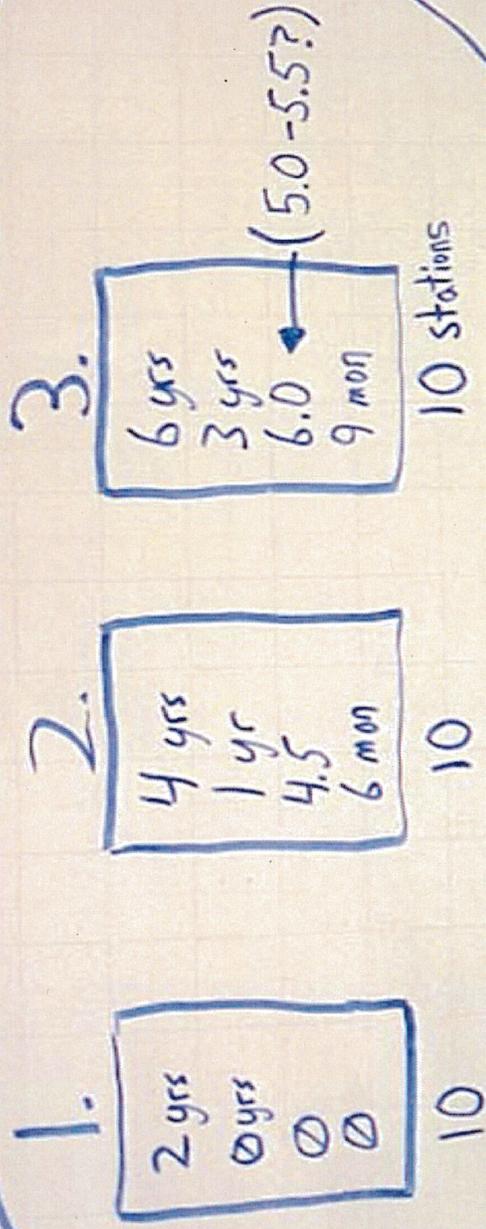
Bart – Comments also on Superiority Analysis and how it ties into Tie Breakers. In preparation for our next workshop, please re-read Certificate of Need section 240, and understand what the rules say and are supposed to do.

<u>CN issued</u>	<u>Operational</u>	<u>Utilization</u>	<u>Time</u>
1. 5 yrs ago	3 yrs	4.5	6 mon
2. 4 yrs ago	1 yr	4.5	6 mon
3. 6 yrs ago	3 yrs	6.0	9 mon



CN issued Operational Utilization Time

2 yrs ago	0 yrs	0	0
4 yrs ago	1 yr	4.5	6 mon
6 yrs ago	3 yrs	6.0	9 mon



Planning Area

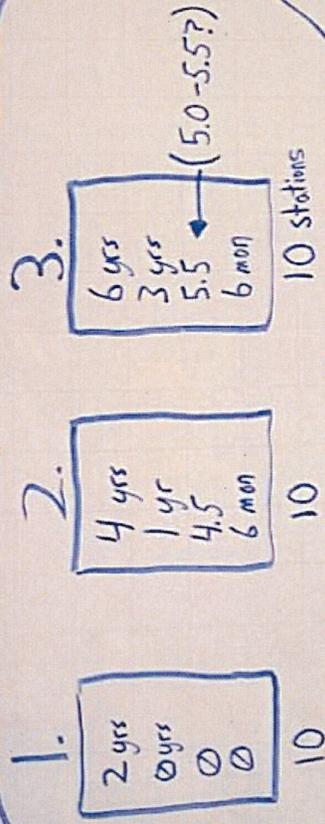
No need for additional stations

New Rule

If available, the rule should allow immediate relief to facility #3.

- Plus 2
- No Construction

<u>CN issued</u>	<u>Operational</u>	<u>Utilization</u>	<u>Time</u>
1. 2 yrs ago	0 yrs	0	0
2. 4 yrs ago	1 yr	4.5	6 mon
3. 6 yrs ago	3 yrs	5.5	6 mon



Planning Area

10 additional stations needed

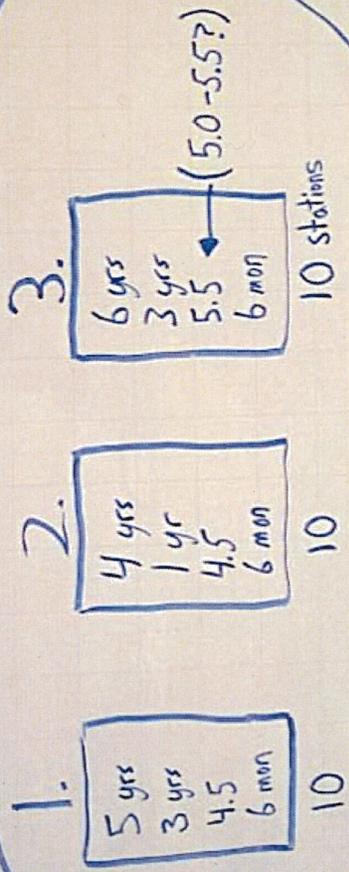
Current rules say facilities #1 and #2 are barriers to submitting CN applications for the 10 stations

We agreed that new providers deserve at least 4 years before new CN applications could be submitted.

Facility #1 is temporarily preventing CN applications from being submitted.

CN issued Operational Utilization Time

1. 5 yrs ago	3 yrs	4.5	6 mon
2. 4 yrs ago	1 yr	4.5	6 mon
3. 6 yrs ago	3 yrs	5.5	6 mon



Planning Area

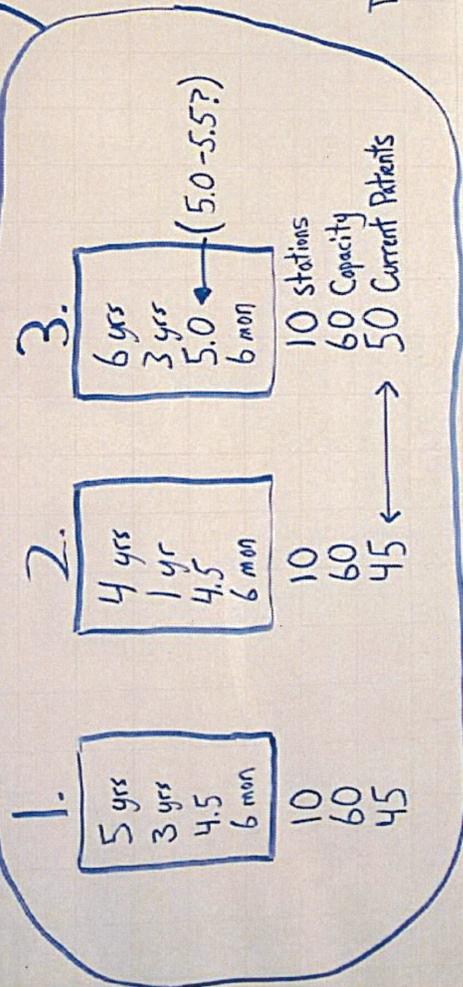
10 additional stations needed

Current rules say facilities #1 and #2 are barriers to submitting CN applications for the 10 stations

We have proposed that all new providers be given 4 years before allowing new CN applications.

In this scenario, we are proposing that facility #3 or a new provider be allowed to submit a CN application for the 10 stations

<u>CN issued</u>	<u>Operational</u>	<u>Utilization</u>	<u>Time</u>
1. 5 yrs ago	3 yrs	4.5	6 mon
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Planning Area

10 additional stations needed

Current rules say facilities #1 and #2 are barriers to submitting CN applications for the 10 stations

We have proposed that all new providers be given 4 years before allowing new CN applications.

In this scenario, we are proposing that facility #3 or a new provider be allowed to submit new CN applications.

Only 5 patients separate #3 from #1 and 2.

Do we want this gap to be wider?