



**Certificate of Need – Kidney Dialysis Rules
Notes for Workshop # 2 – November 14, 2013**

Bart – I think we have general consensus that training stations should not be counted as a regular in-center HD station. Program has always viewed training stations as a type of a swing station – when you wanted to do training in it, you did training. When you wanted to do in-center HD, you did that. We never had a concept that training stations were restricted to only training.

On recent Certificate of Needs that we've issued, we've included a box that says, for example, you have a training station. This has caused some confusion. We were not indicating any kind of restrictive use. Our intent was to highlight that you do training because you said on your application that you do.

Palmer - I can tell you a problem we had with a surveyor recently. Our training stations are almost always physically segregated from our regular HD stations. In a separate room, maybe in a separate part of the facility. To make sure that we never exceed our license cap, if we have one or more training rooms in use, we make sure that we take down regular stations on the floor so that we never have more stations in use than we're licensed for at any one time. The surveyors struggled with this arrangement and I understand their struggle.

Bart – That's why we need to clarify this issue. We are leaning towards training stations not being counted as part of the station population for in-center HD. Now we need to figure out how to quantify how many training stations are a reasonable amount for a facility and include them in your C of N count. From our understanding, Medicare surveyors want to certify all of your stations. So if you have 6 training stations set up in your training unit and 12 stations designated for in-center HD, Medicare wants to certify you as an 18 station facility. We may have only issued a CoN for 12 stations. So that puts you in that weird mix.

Steve – We added a home therapies program 18 months ago. When Medicare came in and certified, the surveyors looked at what we did. Our intent was to add a PD and Home Hemo component. They were confused because of the CoN rules and they wanted to comply. They concluded that the Home Hemo station is counted as an in-center HD station but PD is not counted. They said we could train a PD patient and it does not impact the stations out on the floor. So we would have to reduce down the floor by one station in order to train a Home Hemo patient.

Bart – The reason we need to look at “adding on” is because of some of the issues around the amount of time that trainings take, how regularly training stations are used, the different types of equipment that may be used and how readily equipment can be moved in and out. The Medicare surveyor seemed to draw the line at PD. Now with PD, some PD requires equipment (Cycler) and some does not. So for PD that does require equipment, would that kind of PD be counted by Medicare as a station?

Steve – When we received our letter from Medicare, the letter stated that we were approved for Home Dialysis and down below it listed PD and Home Hemo, but it didn't list them as stations, just by modality.

It's a service versus a station. Now where you get confusion is the in-center PD station, where you actually are providing in-center Peritoneal Dialysis, that's where we're talking about a station. Not the home patient in training.

Bart – I looked at a Medicare form and at the bottom it listed in-center PD station. We looked at patient counts for this and there's very few. We've never added any of those patients as part of our projection methodology. If there are in-center PD patients, we need to somehow adjust our projection to capture these.

Unknown speaker? - This may be an issue of semantics – the term “in-center.” We do have the PD in the same building, we don't have off-site buildings. That could be where they refer to in-center PD? It's typically housed in the same building, but it's totally a different modality which uses completely different equipment. For home therapies, you don't plug into the central RO system that feeds the main facility because you're teaching them how to use the equipment in a home setting. Medicare may be referring to “in-center” because it is offered within the same building?

Katrina? - Now we have emerging technologies like “urgent start” PD where you're putting PD catheters in instead of vascular catheters. Patients need to lay flat while they're getting cycling dialysis.

Harold - When you're talking about “urgent start,” this should be considered a station. That patient will be there for 6 hours or more.

Bart – It feels like we're having some small population types of services that need to be provided in the centers. We learned that Medicare has restrictions on the isolation stations they require. We have always treated isolation stations as a regular station count. Our methodology doesn't account for the scenario of having one patient on your roles with Hep B; that station just became dedicated and it can't be used by anyone else.

Jody - When we calculate 80% occupancy, what would we include?

Bart - That's what we would need input on.

Jason - I suggest doing the calculation on all of the standard in-center HD stations, and then all the rare use stations are an add on.

Jeff – Someone submitted comments about station use and did a good job of articulating the various uses. If we went through this list and said as a group, this is a station and this is not, wouldn't that tell you what you need to know?

Bart – Yes. Part of our checks and balances is to say what kinds of stations get Medicare certification? We need to compare this with what we are approving in CoN. They need to be aligned. If Medicare comes through and certifies you for 16 stations, your CoN should say 16. If part of that 16 was because you had training and isolation stations then those stations would be used only for training and isolation; all the rest general. But you get the CoN for all of them.

Jason – Use the term “services” to distinguish from stations.

Ann - When we're talking about defining isolation, are we only talking about Hep B?

Harold – no, C-diff as well.

Ann - Well then we can include those that have the flu and then have a need for 2, 3, 4. We can always have someone in isolation from an infection control standpoint if it's beyond Hep B.

Bart – Where it runs a foul is the Medicare restriction on Hep B. Hep B patients are currently captured in the general projection model. You may have one or more Hep B patients on your roles all year long that is tying up your station(s). Instead of being able to get 5-6 patients associated with that station, you're stuck with one. That messes up our projection model. If you have a Hep B population that is large enough, that you need more than one isolation station because you're going to keep it busy, that's a capital investment that you need to make to provide that service.

Katrina – If you had a second isolation station to cover things like c-diff and other infectious conditions, and you don't use a station from the main floor, would that be appropriate? There are more and more medical conditions coming about where even though it's not in the regulations, it would be good medical practice to use an isolation station.

Bart – Do you have a terminal cleaning process that would allow that regular station to be cleaned and used by the general HD patients?

Harold – No, you really don't want to cross bugs like that.

Palmer – That's why we don't see a landslide of people wanting to do this kind of treatment because it's inefficient.

Bart – I think we may have general consensus regarding how to treat training and isolation stations. They should not be part of our general in-center HD. We shouldn't place any kind of limit on them and just call them services. Providers will decide how many of these stations to provide depending on their patient population.

Jody – Instead of getting into formulas and ratios, have providers attest to the fact that they will not use their stations for anything other than what the department approves.

Bart – That would be the bare minimum.

Unknown Speaker? - That's the same risk you run now when a surveyor walks into your facility and asks why is that person in your isolation room?

Jason – I might suggest that our isolation services are approved for anything where a physician orders isolation. That will include Hep B and may include random and rare stuff. If you offer isolation and a physician orders it, that's how you answer the Medicare surveyor question, the physician ordered

isolation for this patient. In regards to training, I would suggest we would avoid any sort of numerical methodology because it is very complicated. The state can approve doing training services and providers can do home training – some will do it in rooms, others on the floor, others in adjacent buildings. There's lots of variety out there. I worry if we try to do a percentage or a number of some sort that it will be unnecessarily complicated. I think you can just approve the service in general.

Gail – I think many physicians would say it would be better to take an immune compromised person and put them in an isolation room if you got one. There needs to be some strong boundaries around this. Otherwise you could be approved for 10 and build out as many isolation stations as you wanted to as long as you had physicians signing off. So in order to keep the playing field level you need to look at how those isolation stations are going to be used.

Katrina - Let's just talk about isolation for right now. If the requirement for new facilities is to have at least one isolation station, that's where the "plus one" comes in. Everybody ought to get a plus one for isolation. If you're going to be doing more than that, then it becomes a more complicated issue.

Jason – How about a plus two so you can serve a Hep B along with a c-diff patient

Palmer – We have facilities that run 3 or more isolation stations. That's where the problem with a number comes in. It's better if you say this service is exempt.

Bart – It's my understanding that there's not a lot of this demand out there?

Harold – But the demand is getting more and more and more.

Unknown speaker? - I was going to say, oh contrar. There is more and more. Especially when you look at MRSA and these resistive bacteria. It's becoming more and more prevalent in the hospital settings and now we're seeing it in the outpatient settings.

Bart – If that's the case, can we quantify it then? When something becomes the norm, that's what our projection models can deal with pretty easily. If we create a rule that says anytime I have a physician ordered isolation, it could mean that you have a whole lot of your population for a variety of medical reasons in isolation rooms.

Unknown speaker? - It doesn't make sense that a provider would build out say eight additional rooms for isolation just to game the system. It's so expensive that it's not going to happen. It doesn't make sense from a business standpoint.

Gail - We want to go forward with some strong boundaries. You can say no business would do such a thing but sometimes we can get very creative. We want to have some boxes here with some flexibility. A physician signature is not a strong boundary.

Bart - A solution for typical facilities out there is the plus one idea for isolation. Isolation would be defined as Hep B. Training may be a plus two.

Palmer – We started off with the idea of just exempting these, is that still on the table?

Bart – Yes, an exemption for isolation is one bookend. A plus one is the other bookend. I heard the concept of providing an attestation that stations won't be used for anything other than what was approved. Is there any way to validate the data the providers send to NWRN?

Lisa - We can look into this question and get back to the group.

Bart - We're not wanting to limit, we're wanting to say we know you have at least one, and we don't have a method to get utilization up. Now it becomes more of a business model, you got to decide when you add the next one, or do you aggregate them into a facility.

Bob - What about a plus two for isolation?

Katrina – If isolation is a service, we have to have at least one station to meet Medicare certification. If you have patients that have medical needs that are not Hep B and need isolation would we be prohibited from having a second isolation room? Would that patient be counted in our station utilization? So you still wouldn't have a plus two station, you have a plus one station for the Hep B but we could have a second isolation room to treat those patients.

Unknown Speaker? - Yes, absolutely. We do this now.

Bart - Medicare only has rules around Hep B. Can you efficiently terminal clean stations that have been used for say c-diff patients so that a regular HD patient can then use the machine?

Katrina - You can't turn a station over that quickly because you need to allow time for that terminal cleaning.

Harold – Terminal cleaning is an onerous process and that's why we don't do it. If we treat a patient with c-diff, we won't use that station for anyone else other than another c-diff patients.

Bart – So for isolation, we have three options for the department to consider: Exempt them. Plus one. Plus two.

Bart - Training stations. One bookend is treat training as a service with no stations associated with it. The reason for this is that the PD modality isn't considered a station by Medicare. The Home HD training is not considered a station by Medicare, you have to have a space or area, not necessarily a room.

Harold – The space, area or rooms used for training purposes are usually bigger than an in-center station, because the patient and their family members are typically all there learning how to use the machines.

Bart – So all training (HHD, PD) then can be considered a "service." Neither HHD or PD are counted as a numeric station by Medicare.

Natalie – This is a great opportunity to talk about what we want these rules to accomplish for home therapies.

Unknown speaker? - Well we don't want the rules to create any barriers to providing home therapies.

Bart – Right. That why we created the old Tiebreaker for home therapies because we wanted to encourage home training.

Natalie – So would an exemption for training be the next step for encouraging home training?

Bart – That's part of what we could do but we need to have a balance. We don't want to create a bunch of facility space out here that is tempting to use for in-center Home Dialysis purposes when it was intended to be for home training. We have a fundamental premise in CoN, trust but verify. We have great respect for and trust all the providers around the table. But we still try to go back and use data to verify, just to keep everybody fair with each other.

Natalie – I hear the providers saying that the equipment for Home Training is fundamentally different.

Bart – I accept that. If we say all of that is exempt, how do we validate? Is there a mechanism to validate those in-center pieces of training equipment that may be different or may not be that could potentially provide dialysis treatment when they shouldn't be?

Unknown speaker? - If you're training a person on Home Hemo, they're taking that machine home with them and we wouldn't be counting those machines. These are the "Next Day" machines. They are individualized machines. In most programs, the machine that a person trains on is the machine they take home with them.

Palmer – I think the question is how do we assure that the Home Training room does not get used for the normal population?

Bart – The only solution I'm hearing is to treat training as a service, they're not going to be counted as a station and the only method that we can rely on is the self-attestation and the goodwill of providers agreeing that they won't use training stations / rooms for in-center HD. You build a capacity based on your business model of what you think you need. The driving limiter of training would be the independent business model and you will give an attestation in your application. We would say on your CN as a reminder "don't use training stations for in-center HD." Once we decide on how to treat training in the future, we will need to figure out how to reconcile new station counts based on the application of the new rules with existing centers – so an administrative reconciliation process. It is unlikely that there would be a need for an administrative adjustment to currently issued CNs.

Harold – It sounds like there may be an unintended consequence that we're not thinking of yet? What about the scenario of someone wanting to build a facility that offers training services only right next to an existing Kidney center.

Bart - If we went with the proposal as described right now, someone could open a training only center without CN review / approval. That is an unintended consequence. There would be a gap unless we addressed it in the rules. We would need to write in the rules that services must be CN approved. Also, if you are an existing provider that is not providing training at present, if you decide to provide training you would need to submit a CoN application so we could approve it.

Gail – One of the reasons that we put a number on Home Training was to create some sort of boundary. We’re not sure how to verify that training stations are being used appropriately. An attestation is kind of a weak method for verifying. The department doesn’t go back and license Dialysis facilities so I don’t know where that regulatory ability is to truly verify. If you set a number and make it on the generous side then you have something fixed. Verification becomes less of an issue or at least easier. Otherwise you could have the entire universe and then struggle with verifying that.

Bart – This is a proposal that the group has put forward. We’ve done a fair amount of brainstorming already. So I ask that between now and our next meeting we think the proposal through and identify any unintended consequences.

Bart – We agreed that isolation should be a plus one concept.

Bart – I think we need to have conversation around capital costs. There was an unintentional consequence that came when we created the Tiebreaker associated with the per bed capital costs.

Harold – Better believe it!

Bart – I know we were trying to get an efficiency kind of measure. I’m not certain that it worked as we intended it too. Historically, the request to disclose capital costs has come from that fundamental perspective of “Can you afford to do this as an organization?” That’s why CoN has always asked this kind of question on all of its other applications. For those who don’t know how this works, We take the total disclosed capital costs, divide it by the total number of stations and whoever had the cheapest station gets a point. I suggest that is something we should rethink. Sounded good when we did it.

Harold – Amen! I would concur with that statement. I must have been asleep that day.

Jody – Jody explained Tri-State Dialysis situation in Clarkston, WA and Lewiston ID. Jody put together a background document which proposes an out of state modifying exemption. DOH received this document from Jody and emailed it to the Kidney Dialysis ListServ. Stakeholders were asked to provide feedback by 12/13/2013.

Natalie – Can we have people submit comments on the utilization level (4.8 / 3.2 proposal) so we can discuss this at our meeting?

Jason – Just to clarify, the core problem on the 4.8 was a release valve for facilities at capacity. There are different ways to solve that core problem – one of them is to change the 4.8. So the core problem should be on the agenda and we should discuss all the possible solutions.

Harold – And related to the release valve, there's got to be a percent that we all agree upon. What is that number? 100%? 105%?

Bart – Yes, the Clark County situation when you have providers that are at some level of capacity beyond the six, at what point would you now make an exception to let that provider expand, even if there is an existing provider that's under 4.8. Even if there is no projected need.