

Wake Forest Baptist Health
Response to Comments Submitted by BMA / Fresenius to Rules Review Committee on 25 August 2020
regarding the Healthcare Planning and Certificate of Need Section's Proposed Readoption of
Certificate of Need Regulations : 10A N.C.A.C. 14C

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1. NAME, ADDRESS, EMAIL ADDRESS, AND PHONE NUMBER OF COMMENTER

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2. 10A NCAC 14C .2201 (3) – “Dialysis station” means the treatment area used to accommodate the equipment and supplies needed to perform dialysis on a single patient.

There are multiple types of dialysis stations, which include, but are not limited to ICH stations, PD training stations, in-center PD stations, and HH training stations. Given the varied nature of dialysis station use, there is no reason to specifically exclude PD training stations from the definition of “dialysis station.” Rather, a broad definition of “dialysis station” is both logical and appropriate to encompass all the various modalities.

3. 10A NCAC 14C .2201 (5) – “Home hemodialysis” means hemodialysis performed in the patient’s home by the patient after the patient is trained in a dialysis facility to perform the hemodialysis.

Recently, the State has allowed the certification of dialysis stations dedicated to Home Hemodialysis (“HH”) training within stand-alone, dedicated, home-training dialysis facilities (facilities not CON-approved to provide ICH). In ICH facilities, ICH stations are used for HH training and ICH facilities may not operate more than the total number of stations for which they are certified during any treatment shift. In other words, ICH facilities must “down” an ICH station in the bay treatment area while providing HH training in their dialysis training department. Under CMS rules, the certification of a dialysis station does not limit the modality by which a dialysis station may be used. North Carolina CON rules, however, limit the use of a dialysis station to the extent that HH training stations in home-training-only facilities may not be used for in-center hemodialysis treatments.

It has been suggested that a change in the definition of Home Hemodialysis in .2201 (5) is warranted because patients may wish to perform their HH treatments at their office or vacation home. The wording suggested by BMA is something to the effect of:

“Home hemodialysis means dialysis performed by a patient trained to perform their own hemodialysis at a treatment location other than at an ICH facility.”

Yet, that proposed definition would leave open the possibility that such patients **could** perform their own HH treatments at home dialysis training facilities. This would, functionally, be the equivalent of an ICH treatment at a facility with CMS licensed dialysis—despite the lack of CON approval to provide ICH. Such a situation would provide such facilities a means by which to circumvent the CON requirements regulating the geographic distribution of ICH services. As it stands, the current definition found in .2201 (5) in no way limits the ability of a home hemodialysis patient to perform their own dialysis at their vacation home, office, or other personal area outside of a dialysis center.

4. **10A NCAC 14C .2203 (a) Performance Standards** – The performance standard at .2203 is the measure by which the CON Planning Section determines facility need. It is also the benchmark standard against which providers requesting additional dialysis stations under the facility need methodology demonstrate need for their proposed project. This standard was reduced from 3.2 patients to 2.8 patients per station due to an increase in the lag time between data reporting and data publication—which increased from six months (SDR) to one year (SMFP).

It has been suggested that 2.8 patients per station (70% utilization) is too low—generating too many dialysis station needs—and that 3.5 patients per station (87.5% utilization) is more appropriate. Yet, the reality is that an increased utilization requirement (paired with patient data that is over a year old at the time the SMFP is published) will eliminate published facility needs for innumerable facilities while placing an undue burden on providers by requiring them to project growth and plan to accommodate patient need far into the future.

In addition to defining “station need” the utilization standard also substantially impacts the ability of providers to react to growth in patient volumes—thereby complicating the ability of providers to calculate remaining facility capacity before 100% utilization is reached. In other words: a lower Performance Standard requirement provides greater time for a provider to react and plan for patient growth that may occur during the year between data submission to the Planning Section and facility need publication in the SMFP, while a higher Performance Standard provides far less reaction time to patient growth.

Availability of dialysis service to patients is a primary consideration in the CON process. The current utilization standard of 2.8 patients per station serves North Carolina dialysis patients well. A higher performance standard requirement could impede the ability of dialysis providers to offer services when and where they are needed, increase the costs of those services, and reduce quality of care. Additionally, any increase in the ICH Performance Standard would be particularly inappropriate at this time in light of the COVID-19 pandemic and social distancing measures protecting at-risk groups such as dialysis patients.

5. **10A NCAC 14C .2203 (d) Performance Standards** – Given the increase in interest in the provision of home dialysis training and the development of home training only dialysis facilities, the Planning Section has suggested a Performance Standard applicable to the development of home hemodialysis training stations in such facilities as follows:

*“(d) An applicant proposing to increase the number of home hemodialysis stations in a dialysis facility dedicated to home hemodialysis or peritoneal dialysis services shall document the need for the total number of home hemodialysis stations in the facility based on **six home hemodialysis patients per station per year** as of the end of the first full fiscal year of operation following certification of the additional stations.” **(Emphasis added)***

In prior comments Wake Forest suggested that the proposed Performance Standard be slightly re-worded such that **only those patients trained for home hemodialysis during an OY** be included in the count of patients applicable to the HH training station’s utilization measure for determining need. Patients already performing their dialysis at home would not be included in the number of patients **trained** under the Performance Standard. Assuming the requested edit is approved—given the purpose of the HH training station is to provide HH training and not backup hemodialysis services (ICH)—Wake Forest offers the additional following commentary.

It has been suggested that no such performance standard should exist given a facility may train less than four patients for home hemodialysis per year and that the presence of such a performance standard may limit the ability of home training facilities to provide HH training.

However, it is interesting to note that the **Medicare Benefit Policy Manual 30.2** provides,

“An ESRD facility may bill a maximum of 25 training sessions per patient for hemodialysis training—”

That measure is not per year, but is a **lifetime limit with few exceptions**. Realistically, facilities would not provide unreimbursed services (training days in excess, of 25 home hemodialysis training days per patient.)

30.2 A. Hemodialysis Training goes on to say,

“The average training time for hemodialysis patients is based upon 5-hour sessions given 3 times per week.”

Based upon the experience of Wake Forest, the industry standard is to offer HH training 5 days per week. Below, is an example of the **LEAST** number of patients one HH training station **could**

train, if all patients require the full 25 days of HH training before beginning to perform their own dialysis at home. It is reasonable to assume this is the **LEAST** number of patients that could be trained per year per station because—again, in Wake Forest’s experience—most patients require less than the full 25 days of HH training reimbursable under Medicare.

	Training Days Per Week	5
1 Patient Per Day	Training Sessions Per Year	5 X 52 Weeks = <u>260 Training Days Per Year</u>
	Lifetime Max Reimbursable Training Sessions Per Pt.	25
	If ALL HH Training Patients Required a Full 25 Sessions of Training, this is the 100% Utilization number of Patients Trained Per Year	260 Training Sessions / 25 Max Training Sessions Per Pt. = <u>10 Patients Per Year</u>
	6 HH Training Patients Per HH Training Station Represent a Utilization Rate of:	6 / 10 = 0.60 <u>60% Utilization</u>

Thus, if each station trains only one patient per day the maximum 25 training days, offering services 5 days per week, the suggested performance standard of **6 patients trained per OY** represents a utilization rate of **at most** 60%. **Since most patients do not require the full 25 days of home hemodialysis training, the potential to train more than the required 6 patients per year, per home hemodialysis training station is an ever-present reality.**

Despite the suggestions of some other providers, it is wholly reasonable to conclude that the proposed performance standard of 6 patients trained per dedicated home hemodialysis training station per operating year **will not** impede the ability of a home training only dialysis facility to offer home hemodialysis training. As demonstrated in the table, above, this 6 patient standard is wholly consistent with the Planning Section’s goals of preventing the unnecessary duplication of the service without excessively restricting the growth of the modality.