

Wake Forest Baptist Health – ESRD - Petition

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2. Petitioner requests the following changes to the 2021 SMFP:

- a. Establishment of a methodology by which need for new home hemodialysis training stations may be determined. See “**ESRD - HH Need Workbook**” attached as **Exhibit A, & Exhibit A Example**.
- b. Re-promulgation of 10A NCAC 14C .2203 to add performance standards specifically for the establishment and expansion of ESRD Treatment Facilities, which propose station(s) “**dedicated**” to providing **Home Hemodialysis Training Services**.

Methodology pertaining to the need for “dedicated” home hemodialysis training stations:

Condition 1: Pertains to “new” **dedicated** home hemodialysis training stations in ESRD Treatment Facilities, which do not currently offer nor are certified to provide home hemodialysis training and support.

- a. Existing ESRD providers in a service area (county) may request an initial – one (1) – **dedicated** Home Hemodialysis Training Station provided the existing ESRD provider can show it will train at least one (1) new home hemodialysis training patient as of the certification date of the proposed project.

An applicant currently providing home hemodialysis training and support in a service area (county) at one or more ESRD Treatment Facilities, may request additional home hemodialysis training stations to the extent Condition 2 is met, below:

Condition 2: Pertains to “new” **dedicated** home hemodialysis training stations in ESRD Treatment Facilities with one (1) or more existing **dedicated** certified home hemodialysis training station(s) in operation at the time of application for additional home hemodialysis training stations.

- a. Applicant provided home hemodialysis training and support at one or more dialysis treatment facilities in the service area (county) where the additional home hemodialysis training station(s) shall be located as reported in the current SMFP.
- b. If the utilization rate of the applicant’s existing home hemodialysis training station(s) in the service area (county) is equal to or greater than 50%, the applicant may apply to add up to the number of **dedicated** home hemodialysis training stations, calculated as follows:
 - i. Multiply **applicant’s** total number of patients trained to perform home hemodialysis during the last OY at **applicant’s** existing ESRD treatment facility(ies) in the service area (county) by the average number of home hemodialysis **training** days per home hemodialysis training patient. (*This is the **applicant’s** total home hemodialysis training days for the last OY in the service area (county).*)

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- ii. Multiply **applicant's** total number of patients re-trained for home hemodialysis during the last OY at the **applicant's** existing ESRD treatment facility(ies) in the service area (county) by the average number of home hemodialysis re-training days per home hemodialysis re-training patient. *(This is the **applicant's** total home hemodialysis re-training days for the last OY in the service area (county).)*
- iii. Sum Step i. and Step ii., above. *(This is the total home hemodialysis training days provided by the applicant in the service area (county) for the last full OY.)*
- iv. Multiply the applicant's total **dedicated** home hemodialysis training stations used during the last OY to provide home hemodialysis training in the service area (county) by 300 – (12 HH Training Patients Per Station x 25 Training Days Per Patient). If the applicant has no **dedicated** home hemodialysis training stations, enter "0." *(This is the applicant's maximum available home hemodialysis training days in the service area (county) for the last full OY.)*
- v. Divide the result of Step iii. by the result of Step iv. If the result of Step iv. is "0," divide the result of Step iii. by 300. *(This is the applicant's utilization rate of its existing home hemodialysis training stations in the service area (county) for the last full OY. If it is 0.50 or 50% or greater, proceed to Step vi.)*
- vi. If the result of Step v. is greater than or equal to 0.50 (50%), divide the result of Step iii., by 75. *(This is the maximum number of home hemodialysis training stations needed in the service area (county).)*
- vii. Subtract the applicant's total number of **dedicated** home hemodialysis training stations in the service area (county) reported in Step iv. from the result of Step vi. *(The applicant may apply for up to this number of **additional** home hemodialysis training stations.)*

Re-promulgation of the ESRD Performance Standards 10A NCAC 14C .2203, to include:

- (d) An applicant proposing to establish an initial **dedicated** home hemodialysis training station shall document need based on utilization by one (1) **new** home hemodialysis training patient as of certification of the home hemodialysis training station.
- (e) An applicant currently offering home hemodialysis training and support proposing to increase the number of home hemodialysis training stations in an existing ESRD Treatment Facility, shall document the need for the **total** number of **dedicated** home hemodialysis training stations based on 25% utilization (*75 Home Hemodialysis Training Days Per Station Per Year*) of all existing and proposed home hemodialysis training stations during Operating Year 1 and Operating Year 2 of the additional home hemodialysis training stations.
- (g) An applicant shall provide all assumptions, including the methodology (Condition 1 or Condition 2) by which patient utilization is projected. **Only** those **new** patients receiving home hemodialysis training or existing patients receiving home hemodialysis re-training shall be included in the utilization projections when calculating need for home hemodialysis training stations.

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3. Petitioner believes the proposed changes will serve the public interest, prevent unnecessary duplication of existing and approved healthcare services, promote safety, enhance quality of care, enhance geographic and demographic access to services by all persons, and reduce costs.

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a. Adverse Effects If Changes Are Not Made:

- i. **Duplication of Services** – the ESRD Performance Standards measure the “need” for new dialysis stations based upon past performance and future projection of patient growth. In-center hemodialysis providers offering home hemodialysis training may operate no more “dialysis stations” than the number of stations for which they are certified while home hemodialysis training is ongoing because the home hemodialysis training patient is effectively receiving a hemodialysis treatment during their training session. If the ICH provider has not dedicated “dialysis station(s)” to provide home hemodialysis training only, the provider must reduce the number of stations providing ICH in its treatment bays while offering home hemodialysis in its home dialysis training department. The lack of a performance standard for home hemodialysis training stations in home dialysis training facilities allows for the deliverance of hemodialysis services on dialysis stations for which no need has been established creating duplicative services and a double standard.
- ii. **Quality, Safety, and Access** – the lack of a methodology by which the need for home hemodialysis training services can be measured directly impacts the ability of the CON Section to measure quality, safety, and access specific to the service requested. There is currently no rule nor standard, which requires home dialysis training facilities offering home hemodialysis to report the number of patients trained by modality, the average number of training days per patient trained, the payor mix of patients trained, nor demographic data for patients trained to perform their dialysis treatments at home as part of the CON application. Past certificate of need applications involving requests by home dialysis training providers requesting dialysis stations to be used for home hemodialysis training failed to show any statistic for the actual patients who would be receiving the service, including but not limited to revenues and expenses associated with home dialysis training. Without providing vital information regarding the patients who will be trained, (not those already performing their dialysis at home), there is no way the CON Section may accurately determine if the basic principles of CON (Quality, Safety, and Access) will be nor have been observed.
- iii. **Costs** – When services are duplicated and there is no measure of Quality, Safety, and Access, the overall cost of providing the service and the cost of care for the patient(s) receiving the service is increased. The increase in costs can come in the form of unnecessary and duplicative services, which cost healthcare dollars to develop. The cost of development of duplicative services is passed along to the consumer via increased cost of care. Other providers suffer when their patient volume is reduced due to unnecessarily duplicative services and will be forced to increase their charges to meet operating costs. The increased cost of providing care is then reflected in higher service charges, which is passed on to the population at large via increased healthcare premiums.

b. Alternatives to the Proposed Change Considered and Found Unfeasible – The following alternatives to the proposed change were considered and found unfeasible:

- i. **Alternative 1 – Maintain the Status Quo** – Petitioner weighed continuance of the status quo with filing a petition for change. Maintaining the status quo would result in an unfair advantage for providers proposing home hemodialysis training in home-training-only facilities versus providers offering home hemodialysis training at in-center hemodialysis facilities. The status quo would promote unnecessary duplication of existing and approved healthcare services and could lead to discriminatory actions by providers in a service sector

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marked by an already high concentration of commercial insurance patients and a low concentration of Medicaid (low-income) patients. This is not a viable alternative.

- ii. **Alternative 2 – Require home hemodialysis training stations to meet in-center hemodialysis utilization requirements** – The rigors of home hemodialysis training are distinct from in-center dialysis. The average billable ICH treatment days per ICH patient per year is 150 ICH Treatment Days. Given, the HH Training Patient trains a maximum of 25 billable days before going home to perform their own dialysis treatments, it would take 6 HH Training Patients to utilize a HH Training Station in an ESRD Treatment Facility the same number of days (150 Days) an ICH station is utilized (on average) by a single ICH patient in the dialysis facility.

The table, below, provides a comparison of an ICH Station and a HH Training Station in an ESRD Treatment Facility:

<u>Comparative Factors</u>	<u>In-Center Hemodialysis Station</u>	<u>Home Hemodialysis Training Station</u>
What is a “Station?”	A designated space in a treatment bay with plumbing and wiring through the walls for hookup to a fixed dialysis machine, used by up to two (2) patients per day, four (4) patients per week.	A room or partitioned space in which a patient may be trained to perform their own dialysis on a portable hemodialysis machine that the patient will take home with them after their HH training is complete.
Equipment	Fixed – never leaves the dialysis facility	Portable – goes home with the HH patient who trained on it, when HH training is complete
Measurable Utilization of the Station is based upon	2 Treatment Shifts Per Station Per Day 3 Days Per Week Per Patient 156 Treatment Days Per Patient Per Year	1 Training Session Per Training Space Per Day 3 Days Per Week Per Patient for 8.3 Weeks 25 Training Days Per Patient, Lifetime Max
Maximum <u>Facility-Delivered</u> Treatments / Training Days Per Machine Per Year	600 - 624	25 <i>(HH Machine goes home with HH Patient)</i>
Patient to Station Ratio Maximum Capacity <u>Per Week</u>	4 : 1	2 : 1
How often does the dialysis patient require use of the station / training space <u>in the facility?</u>	156 Treatment Days Per Year, Perpetually	25 Training Days, Once in their Lifetime Limited re-training authorized or required

Given the differences in how the ICH station is utilized versus how the home hemodialysis training station is utilized, it is evident the two have differing utilization characteristics. Due to the differing utilization characteristics identified, above, it is clear that a home hemodialysis training station, if required, could never meet the utilization requirements of an ICH station. However, it is also clear that a performance standard for the home hemodialysis training station, (*a designated space in which home hemodialysis training is performed*), is needed to ensure duplication of services does not occur since ***both*** an ICH station and a Home Hemodialysis Training Station provide a hemodialysis treatment while in use in an ESRD

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Treatment Facility, and only ICH stations must currently meet a performance standard to demonstrate need.

4. Currently, there is no methodology nor Performance Standard by which the need for home hemodialysis training stations is measured. The only comparable service offering is the home hemodialysis training and support offered by ICH facilities in their home training departments. To comply with Medicare Conditions for Coverage, ICH facilities offering home hemodialysis training must “down” a certified in-center hemodialysis station in order to prevent offering hemodialysis services on more stations than for which it is certified on a given shift, if the ICH facility does not have “**dedicated**” home hemodialysis training stations. When the ICH facility reports its number of patients and stations to the State Planning Section, the facility must report its **total** number of certified ICH stations, including those used for home hemodialysis training, while excluding the number of home hemodialysis patients trained each year in its facility census used to determine facility utilization and ICH station need in the SMFP.

The establishment of a Performance Standard and Methodology to determine need for home hemodialysis training stations in any ESRD Treatment Facility would bring the need for those stations in line with their use and in line with the requirements placed upon ICH facilities which also offer home hemodialysis training services. The proposed Performance Standards and Methodology ensures the establishment of “**dedicated**” home hemodialysis training stations neither conflicts with nor duplicates the existing and approved health services in the service area, while allowing expansion of the service when and where it is needed. Without a performance standard requirement for “**dedicated**” home hemodialysis training stations, existing and approved ICH services in the service area are, in fact, duplicated during each home hemodialysis training session.

5. The requested change is consistent with the three Basic Principles governing the development of the North Carolina State Medical Facilities Plan to the extent:
 - a. **Safety and Quality** – The proposed Performance Standards and methodology will assist in the process of setting a standard of care by measuring past performance and expertise in service delivery with projected patient volumes and success rates. By requiring proponents of such services to document and demonstrate need by the persons for whom the services are requested (new home hemodialysis training patients) safety and quality become measurable standards that have been previously unrecognized. The limitation of services to only those needed also prevents the rapid rise in services that may be unsafe or of lesser quality.
 - b. **Access** – Prior CON applications requesting home hemodialysis training stations failed to report any number of patients who would actually receive home training. Revenue and Operating Costs were based solely upon patients already performing their dialysis at home, ignoring the patients for whom the home training service was requested – those who required “training.” The applicant(s) reported beginning and ending patient numbers, but failed to describe the patients who actually attempted training or received training during the year, the number of training days required per patient per modality, and the number of patients requiring re-training. Without a description of those who actually receive home hemodialysis training by group, it is impossible to determine if equal access to the service exists. However, when training stats are documented alongside a determination of need based upon training volume, access to the service by those who will actually utilize it becomes a reportable characteristic. Access is also improved by the

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CON process, which limits development of the service to where it is needed. This prevents the establishment of large underutilized facilities and enhances the overall geographic distribution of the service.

- c. **Value** – The cost to develop new institutional healthcare resources is staggering. When services are allowed to be developed that are not based on the need for the service, existing services are duplicated and treatment volume is diluted. The proposed Performance Standard and Methodology for home hemodialysis services requires those desiring to provide the service to demonstrate that the healthcare dollars expended for development represent a good value in terms of meeting the needs of those who will utilize the service. This in turn creates “value” for consumers of the service and other providers of similar services in the service area.

The current ESRD Performance Standards and methodology fail to include a means for determining the need for home hemodialysis training stations, which deliver an in-center hemodialysis treatment during training sessions. Yet, ICH stations delivering in-center hemodialysis and / or home hemodialysis training are subject to the ESRD Performance Standards requiring 3.0 patients per station or 75% utilization. Development of a new Performance Standard and Methodology for home hemodialysis training stations will maintain the integrity of the CON process for ESRD Services, and will all but assuredly expand the geographic availability of such services to all those who may require it without costly duplication of existing and approved healthcare services.