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Healthcare Planning Section
Division of Health Service Regulation
NCDHHS
809 Ruggles Drive
Raleigh, NC 27603

Re: Atrium Health Wake Forest Baptist and Health Systems Management's Comments on behalf of Wake Forest University Health Sciences Dialysis Centers Comments Regarding Fresenius Medical Care Holdings, Inc., Petition to change the Assumptions of the Need Methodology in Chapter 9 of the 2024 State Medical Facilities Plan

Dear Acute Care Services Committee Members:

Atrium Health Wake Forest Baptist and Health Systems Management, Inc., ("HSM") on behalf of Wake Forest University Health Sciences ("WFUHS") offers comments regarding the Petition filed by Fresenius ("FMC"). The FMC Petition proposes changes to the assumptions of the need methodology found in Chapter 9 of the SMFP. At the heart of the proposed changes is a policy change that would provide a pathway by which home dialysis training facilities may add home hemodialysis training stations without having to transfer them from existing ICH facilities.
It is foreseeable that such a means would reduce the necessity to file two CON applications to allow home hemodialysis training at a home dialysis training facility.

- One CON to transfer the ICH stations to the home training facility permanently changing their use from ICH / HH training stations to solely HH training stations; and
- a follow-up CON to add ICH stations back to the host facility.

However, in allowing such a policy, necessary specifications related to existing policies must be made. We suggest the following:

1) Development of home dialysis training centers is allowed within the same service area (county) in which the applicant currently operates an ICH facility except in the case where no ICH facility exists (operational or CON-approved) within the service area (county.)
2) ICH backup for home hemodialysis patients followed by a home training facility may only be performed at a facility certified to provide ICH services.
3) A home dialysis training facility must have an ICH backup agreement with an ICH facility in the same service area (county) in which it operates or plans to operate except in the case where no ICH facility exists in the service area (county.) In such a case the home dialysis training facility must have an ICH backup agreement with an ICH facility in an adjacent county.
4) HH training stations at home dialysis training facilities may not be transferred to ICH facilities or converted to ICH stations.

Additionally, we believe after reviewing CON applications seeking to add home hemodialysis training stations, a disparity exists between the performance standard at 10A NCAC 14C .2203 (c) and how that standard is interpreted. The current performance standard for home hemodialysis training stations requires:

*"An applicant proposing to establish a new dialysis facility dedicated to home hemodialysis or peritoneal dialysis training shall document the need for the total number of home hemodialysis training stations in the facility based on **training** six home hemodialysis patients per station per year as of the end of the first full fiscal year of operation following certification of the facility."*

It seems that proponents of such applications routinely fail to provide the projected home hemodialysis training data and/or project analysts assume the difference in the facility's projected patient census (number of patients followed by the facility year over year) equates the number of patients the facility trained. This is evident in the findings of the two CON's recently filed by FMC requesting to add home hemodialysis training at each of its CON-approved home dialysis training facilities in Wilson and Chowan Counties, respectively. ***FMC aka BMA projected utilization for its Wilson County CON as indicated in the following excerpt from the findings for Project ID L-12269-22 on pages 6 and 7:***

Projected Utilization
In Section C, page 34, and Section Q, page 102, the applicant provides projected utilization, as illustrated in the following table.

Wilson Home Dialysis	**HH Patients**
Begin with six Wilson County patients expected to transfer and convert to HH when the station is certified on December 31, 2023.	6.0
Add the two Nash County patients expected to transfer to the facility when the station is certified on December 31, 2023. **This is the projected ending census for Interim Year One.**	6.0 + 2.0 =8.0
Project the Wilson County patient census forward for 12 months to December 31, 2024, using the Wilson County Five-Year AACR.	6.0 x 1.035 = 6.2
Add the two patients from other counties. This is the projected ending census for Operating Year One.	6.2 + 2.0 = 8.2
Project the Chowan County patient census forward for 12 months to December 31, 2025, using the Wilson County Five-Year AACR.	6.2 x 1.035 = 6.4
Add the two patients from other counties. **This is the projected ending census for Operating Year Two.**	6.4 + 2.0 = 8.4

The applicant projects to serve the following number of patients upon completion of this project and Project ID# L-11836-20.

	Operating Year 1	**Operating Year 2**
Home Hemodialysis	8.2	8.4
Peritoneal Dialysis	25.0	26.7

Source: Section C. page 34

Projected utilization is reasonable and adequately supported based on the following:

- *The applicant projects growth of HH patients using the Five-Year AACR for Wilson County, as published in the 2022 SMFP.*
- *The applicant projects utilization based on the growth of home therapy in Wilson County.*

However, the applicant never states how many patients it will "***train***" only the number of patients it will "***follow***." Patients performing their dialysis at home will not utilize a home hemodialysis training station in a home training facility unless they need to be **re-trained**. The analyst assumes that a ***"need"*** for a home hemodialysis training station is consistent with the number of home hemodialysis patients the applicant states it will ***"follow"***, but that is not an accurate assumption.
The same error in misconstruing the number of patients ***"followed"*** for a ***"need"*** for a home hemodialysis training station was made in the Chowan application filed by BMA. ***Below is an excerpt from those findings included in the FMC Petition related to Project ID R-12268-22 (findings pages 8 – 10):***

Projected Utilization
In Section C, page 35, and Section Q, page 102, the applicant provides projected utilization, as illustrated in the following table.

Chowan Home Dialysis	***HH Patients***
Begin with three Chowan County HH patients and two Chowan County PD patients expected convert to HH.	*5.0*
Add the two patients from other counties. This is the projected ending census for Interim Year One, December 31, 2023.	*5.0 + 2.0 = 7.0*
Project the Chowan County patient census forward for 12 months to December 31, 2024, increasing it by applying the Five-Year Chowan County AACR of 9.3%	*5.0 x 1.093 = 5.5*
Add the two patients from other counties. ***This is the projected ending census for Operating Year One.***	*5.5 + 2.0 =7.5*
Project the Chowan County patient census forward for 12 months to December 31, 2025,applying the Five-Year AACR for Chowan County.	*5.5 x 1.093 = 6.0*
Add the two patients from other counties. ***This is the projected ending census for Operating Year Two.***	*6.0 + 2.0 = 8.0*

The applicant projects to serve the following number of patients upon project completion.

	Operating Year 1	*Operating Year 2*
Home Hemodialysis	*7.5*	*8.0*
Peritoneal Dialysis	*13.0*	*14.1*

Source: Section C. page 36

Projected utilization is reasonable and adequately supported based on the following:

- *The applicant projects utilization based on the growth of home therapy in Chowan County and surrounding counties.*
- *Actual growth in home patients exceeds the applicant's original projections demonstrated in Project ID# R-11834-20.*

Again, the applicant and the analyst define the number of patients trained by the census of the patients projected to be followed by the home dialysis training facility, but those two patient groups are distinct from one another. **Patients followed ≠ Patients trained**.

To be clear, the number of patients "***followed***" by a home dialysis training facility is the facility's "***census***" of patients who perform their own dialysis at home or a location other than an ESRD treatment facility. Patients performing their own dialysis at home have no intrinsic ***"need"*** for home hemodialysis training stations in a home training facility, except if they require a re-train.

The number of patients the facility will **train** per home hemodialysis training station is the number of new patients the facility trained or projects to train *(whether they completed their training or not)* and the number of patients the facility re-trained or projects to re-train *(usually due to a change in equipment or partner to assist in performing their dialysis at home.)*

The ***only*** patients who ***"need"*** home hemodialysis training stations are the patients who will receive training on them. A training facility may train patients to perform their own dialysis at home and never follow the patient or the facility may follow patients trained elsewhere who transfer their support care to the home dialysis training facility. In order to clarify the difference between those two distinct patient groups, we suggest the following:

1) Home hemodialysis patients **trained** is the number of patients the facility projects to train for an OY based upon experience providing home dialysis training services and supported by physician referral patterns. This number is inclusive of new patients trained and existing patients re-trained and is not subject to growth based upon the county's growth rate nor the difference in the number of home hemodialysis patients the facility projects to follow year over year.
2) The number of patients **followed** by a home dialysis training facility year over year is the facility's census, not their number of patients trained. The home training facility's census (number of patients followed year over year) is not applicable when calculating need for new home hemodialysis training stations.
3) When requesting home hemodialysis training stations, applicants should provide their projected number of new patients trained, the average number of home hemodialysis training days per new patient trained, their projected number of re-trains, and the average number of home hemodialysis re-training days per patient trained.
4) Revenue for home dialysis patient **training** should be reported on the pro forma as a separate line item from revenue related to following patients who perform their dialysis at home just as ICH revenue, PD revenue, HH revenue, and drug administration revenue are all separate line items.

It is our belief that these clarifications will allow for the development of home hemodialysis training stations at home dialysis training facilities without resulting in duplication of services nor requiring two CON applications to accomplish the addition of home hemodialysis training services at a home dialysis training facility. To that end we support a policy that would allow home dialysis training facilities to add home hemodialysis training services without the necessity to transfer an ICH station from an ICH facility, provided the methodology for calculating compliance with the performance standards for home hemodialysis training stations is clarified as suggested.

Respectfully,

Marshia S. Coe, RN, BSN, MSHA
Chief Operating Officer
Health Systems Management, Inc.