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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 DaVita's Petition to amend the Assumptions of the Methodology found 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 DaVita. The DaVita Petition proposes changes to the assumptions of 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
- 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. **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

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