

## REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: February 27, 2024

Findings Date: February 27, 2024

Project Analyst: Gregory F. Yakaboski

Co-Signer: Micheala Mitchell

Project ID #: B-12428-23

Facility: Biltmore Home Training

FID #: 120484

County: Buncombe

Applicant: Total Renal Care of North Carolina, Inc.

Project: Relocate no more than four in-center dialysis stations from Asheville Kidney Center to be used exclusively for home hemodialysis and support

### REVIEW CRITERIA

G.S. 131E-183(a): The Department shall review all applications utilizing the criteria outlined in this subsection and shall determine that an application is either consistent with or not in conflict with these criteria before a certificate of need for the proposed project shall be issued.

- (1) The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service, health service facility, health service facility beds, dialysis stations, operating rooms, or home health offices that may be approved.

### NA

Total Renal Care of North Carolina, Inc. (hereinafter referred to as “the applicant” or TRC), proposes to relocate no more than four in-center dialysis stations from Asheville Kidney Center to the existing Biltmore Home Training (Biltmore HT) facility to be used exclusively for home hemodialysis (HHD) and support. The Biltmore HT facility exclusively provides training and support for peritoneal dialysis (PD). There are currently no certified dialysis stations at Biltmore HT. Upon project completion Biltmore HT would have four dialysis stations to be used for HHD and support.

The applicant does not propose to:

- develop any beds or services for which there is a need determination in the 2023 State Medical Facilities Plan (SMFP)

- acquire any medical equipment for which there is a need determination in the 2023 SMFP
- offer a new institutional health service for which there are any policies in the 2023 SMFP

Therefore, Criterion (1) is not applicable to this review.

- (2) Repealed effective July 1, 1987.
- (3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, ... persons [with disabilities], the elderly, and other underserved groups are likely to have access to the services proposed.

**C**

The applicant proposes to relocate no more than four in-center dialysis stations from Asheville Kidney Center to the existing Biltmore HT facility to be used exclusively for home hemodialysis and support. The Biltmore HT facility exclusively provides training and support for peritoneal dialysis. There are currently no certified dialysis stations at Biltmore HT. Upon project completion Biltmore HT would have four dialysis stations. The applicant does not propose to construct any new space or renovate any existing space as part of the proposed project.

The following table, summarized from data and statements on pages 27 and 38 of the application, shows the projected number of stations at Biltmore HT and Asheville Kidney Center upon project completion.

<b>Biltmore Home Training</b>		
<b>Stations</b>	<b>Description</b>	<b>Project ID #</b>
0	Total # of existing certified stations as reported in the most recent ESRD Data Collection Forms.	
+4	Stations to be added as part of this project.	B-12428-23
4	Total # of dialysis stations upon project completion. The dialysis stations will be used only for HHD training and support.	

<b>Asheville Kidney Center</b>		
<b>Stations</b>	<b>Description</b>	<b>Project ID #</b>
52	Total # of existing certified stations as reported in the most recent ESRD Data Collection Forms.	
-4	Stations to be relocated as part of this project (relocate 4 in-center dialysis stations to Biltmore Home Training).	B-12428-23
48	Total # of dialysis stations upon project completion.	

On page 113, the 2023 SMFP defines the service area for dialysis stations as, “... the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee, Clay and Graham counties and Avery, Mitchell, and Yancey counties.” Both Asheville Kidney Center and Biltmore HT are in Buncombe County. Thus, the service area for this application is Buncombe County. Facilities may serve residents of counties not included in their service area.

The following tables illustrate historical and projected patient origin.

<b>Biltmore HT Historical Patient Origin 01/01/2022-12/31/2022</b>						
<b>County</b>	<b>IC</b>		<b>HHD</b>		<b>PD</b>	
	<b># of Patients</b>	<b>% of Total</b>	<b># of Patients</b>	<b>% of Total</b>	<b># of Patients</b>	<b>% of Total</b>
Buncombe	0	0.00%	0	0.00%	48	67.61%
Haywood	0	0.00%	0	0.00%	3	4.23%
Henderson	0	0.00%	0	0.00%	7	9.86%
Madison	0	0.00%	0	0.00%	3	4.23%
McDowell	0	0.00%	0	0.00%	1	1.41%
Mitchell	0	0.00%	0	0.00%	1	1.41%
Yancey	0	0.00%	0	0.00%	8	11.27%
<b>Total</b>	<b>0</b>	<b>0.00%</b>	<b>0</b>	<b>0.00%</b>	<b>71</b>	<b>100.0%</b>

Source: Section C, page 23.

<b>Asheville Kidney Center Historical Patient Origin 01/01/2022-12/31/2022</b>						
<b>County</b>	<b>IC</b>		<b>HHD</b>		<b>PD</b>	
	<b># of Patients</b>	<b>% of Total</b>	<b># of Patients</b>	<b>% of Total</b>	<b># of Patients</b>	<b>% of Total</b>
Buncombe	122	94.6%	11	34.38%	0	0.00%
Caldwell			1	3.13%	0	0.00%
Cherokee			1	3.13%	0	0.00%
Georgia	1	0.8%	0	0.00%	0	0.00%
Haywood			6	18.75%	0	0.00%
Henderson	3	2.3%	1	3.13%	0	0.00%
Macon			1	3.13%	0	0.00%
McDowell			2	6.25%	0	0.00%
Mecklenburg	1	0.8%	0	0.00%	0	0.00%
Polk	1	0.8%	0	0.00%	0	0.00%
Swain			5	15.63%	0	0.00%
Transylvania	1	0.8%	2	6.25%	0	0.00%
Yancey			2	6.25%	0	0.00%
<b>Total</b>	<b>129</b>	<b>100.0%</b>	<b>32</b>	<b>100.0%</b>	<b>0</b>	<b>0.00%</b>

Source: Section C, page 24.

<b>Biltmore HT</b>
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Projected Patient Origin 01/01/2026-12/31/2026						
County	IC		HHD		PD	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Buncombe	0	0.00%	8	42.1%	52	69.33%
Caldwell	0	0.00%	1	5.3%	0	0.00%
Cherokee	0	0.00%	1	5.3%	0	0.00%
Henderson	0	0.00%	3	15.8%	3	4.00%
Macon	0	0.00%	1	5.3%	7	9.33%
Madison	0	0.00%	1	5.3%	0	0.00%
McDowell	0	0.00%	1	5.3%	3	4.00%
Mitchell	0	0.00%	0	0.0%	1	1.33%
Swain	0	0.00%	0	0.0%	1	1.33%
Haywood	0	0.00%	1	5.3%	0	0.00%
Transylvania	0	0.00%	1	5.3%	0	0.00%
Yancey	0	0.00%	1	5.3%	8	10.67%
<b>Total</b>	<b>0</b>	<b>0.00%</b>	<b>19</b>	<b>0.00%</b>	<b>75</b>	<b>100.0%</b>

Source: Section C, page 25.

In Section C, pages 25-27, the applicant provides the assumptions and methodology used to project its patient origin. The applicant’s patient origin projections are reasonable and adequately supported based on the following:

- The applicant begins its projections with the facility patient census as of December 31, 2022, as reported in the 2022 ESRD Data Collection Forms submitted to the Agency.
- Operating Year (OY) 1 is calendar year (CY) 2025 and OY2 is for CY2026.
- The applicant projects that half of the HHD patients at Asheville Kidney Center will transfer their care to Biltmore HT as of January 1, 2025 when the four stations of the proposed project are certified.
- The applicant projects that both the HHD and the PD home training programs at Biltmore HT will grow by one patient per year.
- All new home patients will be referred to Biltmore HTs HHD and PD programs upon project certification.

**Analysis of Need**

In Section C, pages 27-29, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. The applicant states:

*“This project proposed the addition of HHD services to Biltmore HT. Presently, this facility is dedicated to the training and support of PD patients only. In Buncombe County, one facility provides HHD services-AKC. The relocation of stations from AKC to Biltmore HT would allow for the addition of stations dedicated exclusively for HHD training and support.*”

...

*While AKC has capacity for an HHD program, moving the programs under one roof also has its advantages. As noted in the assumptions and methodology, relocating 4 stations to Biltmore HT will allow for the consolidation of care, with the aim of positively impacting staffing efficiencies as well as stimulating tighter coordination between caregivers and modalities. ... With both programs under one roof, the clinical and support staff can be more responsive to patients as their lives and medical status change, so they can extend the time that they reap the benefits of dialyzing at home via HHD, PD or both as they exercise options to shift from one modality to another, with greater ease, at different points in their journey.”*

The information is reasonable and adequately supported based on DaVita’s planned eventual consolidation of HHD and PD home training programs in Buncombe County in one facility to better serve patients.

Projected Utilization

In Section C, pages 25 and 27, and Section Q Form C, pages 87-89, the applicant provides the projected utilization, as summarized in the following table.

**Biltmore HT: Projected Stations and Utilization**

	<b>Stations</b>	<b>HHD Patients</b>	<b>PD Patients</b>
Patient Census at Biltmore HT as of January 1, 2023	0	0	71
Project patient census forward one year to December 31, 2023.	0	0	71 + 1 = 72
Project patient census forward one year to December 31, 2024.	0	0	72 + 1 = 73
The proposed project will be certified as of 1/1/2024. Half of the HHD patients at Asheville Kidney Center will transfer to Biltmore HT.	4	34 x .5 = 17	73
Project patient census forward one year to December 31, 2025. This is the ending patient census for <b>Operating Year 1 (CY 2025)</b> .	4	17 + 1 = <b>18</b>	73 + 1 = 74
Project patient census forward one year to December 31, 2026. This is the ending patient census for <b>Operating Year 2 (CY 2026)</b> .	4	18 + 1 = <b>19</b>	74 + 1 = 75

Source: Tables on pages 25 and 27 of the application.

In Section C, pages 2-27, and Section Q, Form C, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

- The applicant begins its projections with the facility patient census as of December 31, 2022, as reported in the 2022 ESRD Data Collection Forms submitted to the Agency.
- Operating Year (OY) 1 is calendar year (CY) 2025 and OY2 is for CY2026.

- The applicant projects that half of the HHD patients at Asheville Kidney Center will transfer their care to Biltmore HT as of January 1, 2025, when the four stations of the proposed project are certified.
- The applicant projects that both the HHD and the PD home training programs at Biltmore HT will grow by one patient per year.
- All new home patients will be referred to Biltmore HTs HHD and PD programs upon project certification.

Projected utilization, as set forth above, is reasonable and adequately supported based on the following:

- The applicant begins its projections with the facility patient census as of December 31, 2022, as reported in the 2022 ESRD Data Collection Forms submitted to the Agency.
- Operating Year (OY) 1 is calendar year (CY) 2025 and OY2 is for CY2026.
- The applicant projects that half of the HHD patients at Asheville Kidney Center will transfer their care to Biltmore HT as of January 1, 2025, when the four stations of the proposed project are certified.
- The applicant projects that both the HHD and the PD home training programs at Biltmore HT will grow by one patient per year.
- All new home patients will be referred to Biltmore HTs HHD and PD programs upon project certification.

Pursuant to the performance standards for ESRD services promulgated in 10A NCAC 14C .2203 (d) *“An applicant proposing to increase the number of home hemodialysis stations in a dialysis facility dedicated to home hemodialysis or peritoneal dialysis training shall document the need for the total number of home hemodialysis 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 additional stations.”*

As set forth above, the applicant projects 18 HHD patients at Biltmore HT as of the end of the first full fiscal year of operation (OY1-CY2025). Therefore, the applicant demonstrated the need for three (3) home hemodialysis stations at Biltmore HT [6 HHD patients per station per year x 3 stations = 18 HHD patients]. To demonstrate the need for four (4) home hemodialysis stations the applicant would have had to reasonably project at least 24 HHD patients [24 HHD patients / 6 HHD patients per station = 4 HHD stations].

The project analyst notes that in Section C.5, pages 30-31, and in Section C, pages 33-34, the applicant provides a projection of 25 HHD patients trained in the FFY1 (CY2025) and 27 HHD patients trained in second FFY (CY2026). However, there was no documentation or analysis supporting a projected utilization of 25 HHD patients training at Biltmore HT as of the end of the first full fiscal year (OY1-CY2025). The applicant projects that half of the HHD patients at Asheville Kidney Center ( $34 \times .50 = 17$  HHD patients) will transfer their care to Biltmore HT as of January 1, 2025 [See also Section D, page 39]. The applicant then projects that the HHD home training program at Biltmore HT will grow by one patient per year ( $17 + 1 = 18$  at the end of OY1-CY2025). Therefore, the projected utilization of 25 HHD patients trained at

Biltmore HT as of the end of the first full fiscal year operation following certification of the additional stations is not reasonable or adequately supported.

**Access to Medically Underserved Groups**

In Section C, page 31, the applicant states:

*“By policy, the proposed services will be made available to all residents in the service area without qualifications. The facility will serve patients without regard to race, color, national origin, gender, sexual orientation, age, religion, or disability and socioeconomic groups of patients in need of dialysis.”*

The applicant provides the estimated percentage during the second full fiscal year for each medically underserved group, as shown in the following table.

<b>Medically Underserved Groups</b>	<b>Percentage of Total Patients</b>
Low-income persons	87.5%
Racial and ethnic minorities	39.1%
Women	38.5%
Persons with Disabilities	100.0%
Persons 65 and Older	62.1%
Medicare beneficiaries	81.3%
Medicaid recipients	6.3%

Source: Section C, page 32 of the application.

The applicant adequately describes the extent to which all residents of the service area, including underserved groups, are likely to have access to the proposed services because it is based on historical data of the facility from which the stations are being relocated.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

- (3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, ... persons [with disabilities], and other underserved groups and the elderly to obtain needed health care.

**C**

The applicant proposes to relocate no more than four in-center dialysis stations from Asheville Kidney Center to the existing Biltmore HT facility to be used exclusively for home hemodialysis and support. The Biltmore HT facility exclusively provides training and support for peritoneal dialysis. There are currently no certified dialysis stations at Biltmore HT. Upon project completion Biltmore HT would have four dialysis stations. The applicant does not propose to construct any new space or renovate any existing space as part of the proposed project.

The following table, summarized from data and statements on pages 27 and 38 of the application, shows the projected number of stations at Biltmore HT and Asheville Kidney Center upon project completion.

<b>Biltmore Home Training</b>		
<b>Stations</b>	<b>Description</b>	<b>Project ID #</b>
0	Total # of existing certified stations as reported in the most recent ESRD Data Collection Forms.	
+4	Stations to be added as part of this project.	B-12428-23
4	Total # of dialysis stations upon project completion. The dialysis stations will be used only for HHD training and support.	

<b>Asheville Kidney Center</b>		
<b>Stations</b>	<b>Description</b>	<b>Project ID #</b>
52	Total # of existing certified stations as reported in the most recent ESRD Data Collection Forms.	
-4	Stations to be relocated as part of this project (relocate 4 in-center dialysis stations to Biltmore Home Training).	B-12428-23
48	Total # of dialysis stations upon project completion.	

In Section D, pages 38-39, the applicant explains why it believes the needs of the population presently utilizing the services to be relocated will be adequately met following completion of the project.

The applicant states that the proposal requests the relocation of 4 of Asheville Kidney Centers 52 certified dialysis stations to Biltmore HT. Both facilities are located in Buncombe County. The 4 stations being relocated to Biltmore HT will be dedicated to HHD patients.

***HHD Patients***

In Section D, page 38, the applicant states,

*“The AKC HHD program will eventually relocate entirely to Biltmore HT. However, it has been DaVita’s experience that when relocating home programs into new or different*

*existing facilities, issues with insurance agreements can arise for patients. So as to be in a position to mitigate any negative impact for our patients, AKC will continue to provide support to some existing patients during a period of transition.”*

**IC Patients**

In Section D, page 38, the applicant identifies the following assumptions and methodology regarding IC patients:

- Patient census as of December 31, 2022, was 129 IC patients per AKC’s December 2022 ESRD Data Collection Form.
- The applicant assumes a 0% growth rate, to be conservative, as AKC has experienced a declining patient census over the last few years following the pandemic.

**Asheville Kidney Center: Projected Stations and Utilization**

	<b>Stations</b>	<b>IC Patients</b>	<b>HHD Patients</b>
Patient Census at AKC as of December 31, 2022	52	129	32
Project patient census forward one year to December 31, 2023.	52	129	32+1 = 33
Project patient census forward one year to December 31, 2024.	52	129	33 +1 = 34
The proposed project will be certified as of 1/1/2024. Half of the HHD patients at Asheville Kidney Center will transfer to Biltmore HT.	52-4 = 48	129	34 x .5 = 17 patients relocate to Biltmore HT
Station Count and Patient Census as of 1/1/2025	48	129	17
Project patient census forward one year to December 31, 2025. This is the ending patient census for <b>Operating Year 1 (CY 2025)</b> .	48	129	
Project patient census forward one year to December 31, 2026. This is the ending patient census for <b>Operating Year 2 (CY 2026)</b> .	48	129	17

Source: Table on page 39 of the application.

As shown in the table above, the applicant projects AKC will serve 129 in-center patients by the end of the first full fiscal year of operation, for a utilization rate of 2.69 patients per station per week or 67.25% (129 patients / 48 stations = 2.69 patients per station per week / 4 = 0.6725 or 67.25%). By the end of OY2 (December 31, 2026), following the applicant’s methodology and assumptions, the facility will have also have 129 in-center patients dialyzing at the center with 48 stations so the utilization rate will the same as OY1.

The information is reasonable and adequately supported based on the following:

- The applicant will make every reasonable effort to accommodate all HHD patients.

- The applicant projects a utilization rate at AKC below 70% even after the relocation of four in-center stations which indicates more than sufficient capacity to provide service to all patients utilizing AKC.

### **Access to Medically Underserved Groups**

In Section D, page 39, the applicant states,

*“The relocation of stations from AKC will have not effect on the ability of low-income persons, racial and ethnic minorities, women, disabled persons, and other under-served group and the ability to obtain needed health care.*

*By policy, the facility will continue to make dialysis services available to all residents in its service area without qualifications. We serve patients without regard to race, color, national origin, gender, sexual orientation, age, religion or disability.*

The applicant adequately demonstrates that the needs of medically underserved groups that will continue to use dialysis services will be adequately met following completion of the project.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately demonstrates that the needs of the population currently using the services to be reduced, eliminated or relocated will be adequately met following project completion for all the reasons described above.
- The applicant adequately demonstrates that the project will not adversely impact the ability of underserved groups to access these services following project completion for all the reasons described above.

- (4) Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

### **CA**

The applicant proposes to relocate no more than four in-center dialysis stations from Asheville Kidney Center to the existing Biltmore HT facility to be used exclusively for home hemodialysis and support. The Biltmore HT facility exclusively provides training and support

for peritoneal dialysis. There are currently no certified dialysis stations at Biltmore HT. Upon project completion Biltmore HT would have four dialysis stations.

In Section E.2, page 42, the applicant describes the alternatives considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the identified need. The alternatives considered were:

- *Maintain the Status Quo* - The applicant states that maintaining the status quo is not an effective alternative because maintain the status quo would not allow consolidation of the home training will enhance coordination between caregivers across modalities, positively impact staffing efficiencies and address the preferences of physician partners in Buncombe County. Therefore, the applicant determined this is not the most effective alternative.
- *Relocate stations from another DaVita facility*- The other DaVita facility in Buncombe County, Weaverville Dialysis, does not currently have stations dedicated to home training and support. The four stations being relocated from Asheville Kidney Center to Biltmore Home Training are stations that are already set aside for HHD training and support. The applicant states that is less costly, more logical and less disruptive to patients, physicians and teammate scheduling to relocate stations from a facility already providing HHD training and support. Therefore, the applicant determined that it is less costly and more effective to transfer stations from Asheville Kidney Center as compared to transferring stations from Weaverville Dialysis.

The applicant adequately demonstrates that the alternative proposed in this application is the most effective alternative to meet the need for the following reasons:

- The application is conforming to all statutory and regulatory review criteria.
- The applicant provides credible information to explain why they believe the proposed project is the most effective alternative.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above. Therefore, the application is approved subject to the following conditions:

1. **Total Renal Care of North Carolina, Inc. (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**

- 2. The certificate holder shall relocate no more than three (3) in-center stations from Asheville Kidney Center to Biltmore Home Training to be used exclusively for home hemodialysis and support.**
  - 3. Upon completion of this project, the certificate holder shall take the necessary steps to decertify three stations at Asheville Kidney Center for a total of no more than forty-nine (49) in-center and home hemodialysis stations upon completion of the project.**
  - 4. Progress Reports:**
    - a. Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: <https://info.ncdhhs.gov/dhsr/coneed/progressreport.html>.**
    - b. The certificate holder shall complete all sections of the Progress Report form.**
    - c. The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.**
    - d. The first progress report shall be due on April 1, 2024.**
  - 5. The certificate holder shall install plumbing and electrical wiring through the walls for no more than three (3) home hemodialysis stations.**
  - 6. The certificate holder shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

**NA**

The applicant proposes to relocate no more than four in-center dialysis stations from Asheville Kidney Center to the existing Biltmore HT facility to be used exclusively for home hemodialysis and support. The Biltmore HT facility exclusively provides training and support for peritoneal dialysis. There are currently no certified dialysis stations at Biltmore HT. Upon project completion Biltmore HT would have four dialysis stations.

In Section F, page 44, the applicant states that the project will incur no capital costs. Furthermore, in Section F.3, pages 45-46, the project will have no working capital as Biltmore HT is an existing facility. Therefore, Criterion (5) is not applicable to this review.

- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

C

The applicant proposes to relocate no more than four in-center dialysis stations from Asheville Kidney Center to the existing Biltmore HT facility to be used exclusively for home hemodialysis and support. The Biltmore HT facility exclusively provides training and support for peritoneal dialysis. There are currently no certified dialysis stations at Biltmore HT. Upon project completion Biltmore HT would have four dialysis stations.

On page 113, the 2023 SMFP defines the service area for dialysis stations as, “... the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee, Clay and Graham counties and Avery, Mitchell, and Yancey counties.” Both Asheville Kidney Center and Biltmore HT are located in Buncombe County. Thus, the service area for this application is Buncombe County. Facilities may serve residents of counties not included in their service area.

According to Table 9A, page 119 of the 2023 SMFP, there are three existing or approved in-center dialysis facilities in Buncombe County, all of which are owned and operated by DaVita. Information on these dialysis facilities, from Table 9A of the 2023 SMFP, is provided below:

Dialysis Facility	In-Center Patients (12-31-21)	# of Certified Stations (12-31-21)	Utilization (12-31-21)
Arden Dialysis	29	14	51.79%
Asheville Kidney Center	138	52	66.35%
Weaverville Dialysis	46	20	57.50%

Source: 2023 SMFP, Table 9A.

According to Table 9E, page 138 of the 2023 SMFP, there is one existing dialysis home training facility in Buncombe County. That facility is the Biltmore HT facility which is also owned and operated by DaVita.

In Section G, page 51, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Buncombe County. The applicant states:

*“This project proposed the relocation of existing stations. These stations are currently at an in-center facility, AKC, and utilized for HHD training and support. The consolidation of home training and support services at Biltmore HT, including the relocation of stations to be dedicated exclusively to HHD training, services to meet the needs of the county’s current and projected home patients- patients referred by DaVita’s admitting nephrologists. The proposed project, therefore, serves to accommodate future growth and maximize efficiencies rather than duplicate any exiting or approved services in the service area.”*

The applicant adequately demonstrates that the proposal will not result in an unnecessary duplication of existing or approved services in the service area for the following reasons:

- The stations being relocated are currently located in the same county at another DaVita facility and are utilized for HHD training and support.
- The proposed project consolidates home training and support services at Biltmore HT maximizing efficiencies and does not duplicate any existing or approved service in the service area of Buncombe County.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

- (7) The applicant shall show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided.

### **C**

The applicant proposes to relocate no more than four in-center dialysis stations from Asheville Kidney Center to the existing Biltmore HT facility to be used exclusively for home hemodialysis and support. The Biltmore HT facility exclusively provides training and support for peritoneal dialysis. There are currently no certified dialysis stations at Biltmore HT. Upon project completion Biltmore HT would have four dialysis stations.

In Section Q, Form H, the applicant provides the current staffing and projected staffing in full-time equivalent (FTE) positions for the first and second full operating years of the proposed services, as summarized in the following table.

**Biltmore HT FTEs: Current and Projected**

<b>Position</b>	<b>Current Staff (8/31/2023)</b>	<b>Projected FTEs 1<sup>st</sup> FFY (CY2025)</b>	<b>Projected FTEs 2<sup>nd</sup> FFY (CY2026)</b>
Administrator	1.0	1.0	1.0
Home Training Nurse	2.0	3.0	3.0
PCT	0.0	0.5	0.5
Dietitian	1.0	1.0	1.0
Social Worker	1.0	1.0	1.0
Administrative/Business Office	1.0	1.0	1.0
Biomedical Tech	0.5	0.5	0.5
<b>Total</b>	<b>6.5</b>	<b>8.0</b>	<b>8.0</b>

The assumptions and methodology used to project staffing are provided in Section Q. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in the pro forma financials found in Section Q. In Section H.2 and H.3, pages 54-55, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services based on the following:

- The applicant reasonably accounts for the FTE staffing positions necessary to accommodate the proposed healthcare services at Biltmore HT.
- The costs are accounted for in the budgeted Operating Costs.
- The methods used to recruit or fill new positions and the existing training and continuing education programs are provided.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

- (8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

The applicant proposes to relocate no more than four in-center dialysis stations from Asheville Kidney Center to the existing Biltmore HT facility to be used exclusively for home hemodialysis and support. The Biltmore HT facility exclusively provides training and support for peritoneal dialysis. There are currently no certified dialysis stations at Biltmore HT. Upon project completion Biltmore HT would have four dialysis stations.

### **Ancillary and Support Services**

In Section I, page 57, the applicant identifies each ancillary and support service listed in the application as necessary for the proposed services. On pages 57-59, the applicant explains how each ancillary and support service is made available.

The applicant adequately demonstrates that the necessary ancillary and support services will be made available.

### **Coordination**

In Section I.2, page 60, the applicant describes its existing relationships with other local health care and social service providers.

The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

- (9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health service areas, shall document the special needs and circumstances that warrant service to these individuals.

**NA**

The applicant does not project to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which the services will be offered. Furthermore, the applicant does not project to provide the proposed services to a substantial number of persons residing in other states that are not adjacent to the North Carolina county in which the services will be offered. Therefore, Criterion (9) is not applicable to this review.

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:
- (i) would be available under a contract of at least 5 years duration;
  - (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
  - (iii) would cost no more than if the services were provided by the HMO; and
  - (iv) would be available in a manner which is administratively feasible to the HMO.

NA

The applicant is not an HMO. Therefore, Criterion (10) is not applicable to this review.

- (11) Repealed effective July 1, 1987.
- (12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

NA

The applicant proposed to relocate no more than four in-center dialysis stations from Asheville Kidney Center to the existing Biltmore Home Training facility to be used exclusively for home hemodialysis and support. The Biltmore Home Training facility exclusively provides training and support for peritoneal dialysis. There are currently no certified dialysis stations at Biltmore Home Training. Upon project completion Biltmore Home Training would have four dialysis stations. The applicant does not propose to construct any new space or renovate any existing space as part of the proposed project.

Therefore, Criterion (12) is not applicable to this review.

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and ... persons [with disabilities], which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:

- (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

**C**

In Section L, pages 69-70, the applicant provides the historical payor mix during CY2022 for both Biltmore HT and Asheville Kidney Center for the proposed services, as shown in the tables below.

<b>Biltmore HT Historical Payor Mix: Last FFY (1/01/2022-12/31/2022)</b>						
<b>Payor Source</b>	<b>IC</b>		<b>HHD</b>		<b>PD</b>	
	<b># of Patients</b>	<b>% of Total</b>	<b># of Patients</b>	<b>% of Total</b>	<b># of Patients</b>	<b>% of Total</b>
Self-Pay	0.0	0.00%	0.0	0.00%	1	1.4%
Insurance*	0.0	0.00%	0.0	0.00%	12	16.9%
Medicare*	0.0	0.00%	0.0	0.00%	52	73.2%
Medicaid*	0.0	0.00%	0.0	0.00%	3	4.2%
Other Misc. including VA	0.0	0.00%	0.0	0.00%	3	4.2%
<b>Total</b>	<b>0.0</b>	<b>0.00%</b>	<b>0.0</b>	<b>0.00%</b>	<b>71</b>	<b>100.0%</b>

\*Including any managed care plans.  
 Source: Table on page 69 of the application.

<b>Asheville Kidney Center Historical Payor Mix: Last FFY (1/01/2022-12/31/2022)</b>						
<b>Payor Source</b>	<b>IC</b>		<b>HHD</b>		<b>PD</b>	
	<b># of Patients</b>	<b>% of Total</b>	<b># of Patients</b>	<b>% of Total</b>	<b># of Patients</b>	<b>% of Total</b>
Self-Pay	2	1.6%	0	0.0%	0.0	0.00%
Insurance*	15	11.6%	4	12.5%	0.0	0.00%
Medicare*	94	72.9%	26	81.3%	0.0	0.00%
Medicaid*	9	7.0%	2	6.3%	0.0	0.00%
Other Misc. including VA	9	7.0%	0	0.0%	0.0	0.00%
<b>Total</b>	<b>129</b>	<b>100.0%</b>	<b>32</b>	<b>100.0%</b>	<b>0.0</b>	<b>0.00%</b>

\*Including any managed care plans.  
 Source: Table on page 70 of the application.

In Section L, pages 70-71, the applicant provides the following comparisons

**Biltmore HT**

	<b>Percentage of Total Patients Served by Biltmore HT during the Last Full FY (CY2022)</b>	<b>Percentage of the Population of the Service Area</b>
Female	42.3%	51.7%
Male	57.7%	48.3%
Unknown	0.0%	0.0%
64 and Younger	53.5%	82.7%
65 and Older	46.5%	17.3%
American Indian	1.4%	1.3%
Asian	2.8%	6.3%
Black or African American	21.1%	13.6%
Native Hawaiian or Pacific Islander	0.0%	0.3%
White or Caucasian	71.8%	75.5%
Other Race	2.8%	3.0%
Declined / Unavailable		

Source: Table on page 70 of the application.

**Asheville Kidney Center**

	<b>Percentage of Total Patients Served by Asheville Kidney Center during the Last Full FY (CY2022)</b>	<b>Percentage of the Population of the Service Area</b>
Female	38.5%	51.7%
Male	61.5%	48.3%
Unknown	0.0%	0.0%
64 and Younger	37.9%	82.7%
65 and Older	62.1%	17.3%
American Indian	0.0%	1.3%
Asian	1.2%	6.3%
Black or African American	35.4%	13.6%
Native Hawaiian or Pacific Islander	0.6%	0.3%
White or Caucasian	60.9%	75.5%
Other Race	1.9%	3.0%
Declined / Unavailable		

Source: Table on page 71 of the application.

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the applicant adequately documents the extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved. Therefore, the application is conforming to this criterion.

- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and persons with disabilities to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

### C

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 71, the applicant states that the facility is not obligated to provide uncompensated care or community service.

In Section L.2, page 71, the applicant states that there have been no civil rights access complaints filed against either Biltmore HT or Asheville Kidney Center within the last 18 months.

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

- (c) That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services; and

### C

In Section L, page 72, the applicant projects the following payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as shown in the table below.

<b>Biltmore HT Historical Payor Mix: Last FFY (1/01/2022-12/31/2022)</b>						
<b>Payor Source</b>	<b>IC</b>		<b>HHD</b>		<b>PD</b>	
	<b># of Patients</b>	<b>% of Total</b>	<b># of Patients</b>	<b>% of Total</b>	<b># of Patients</b>	<b>% of Total</b>
Self-Pay	0.0	0.00%	0.00	0.0%	1.06	1.4%
Insurance*	0.0	0.00%	2.38	12.5%	12.68	16.9%
Medicare*	0.0	0.00%	15.44	81.3%	54.93	73.2%
Medicaid*	0.0	0.00%	1.19	6.3%	3.17	4.2%
Other Misc. including VA	0.0	0.00%	0.00	0.0%	3.17	4.2%
<b>Total</b>	<b>0.0</b>	<b>0.00%</b>	<b>19.00</b>	<b>100.0%</b>	<b>71</b>	<b>100.0%</b>

\*Including any managed care plans.  
 Source: Table on page 72 of the application.

As shown in the table above, during the second full fiscal year of operation, 81.3% of HHD services will be provide to Medicare patients and 6.3% to Medicaid patients.

On page 72, the applicant provides the assumptions and methodology used to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported based on the following:

- The applicant calculates payor mix based upon treatment volumes as opposed to the number of patients. The applicant considers possible change in payor source during the fiscal year.
- Payor mix projections are based on recent facility performance where the patient’s received treatment during the last fiscal year.

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion based on the reasons stated above.

- (d) That the applicant offers a range of means by which a person will have access to its services. Examples of a range of means are outpatient services, admission by house staff, and admission by personal physicians.

**C**

In Section L.5, page 73, the applicant adequately describes the range of means by which patients will have access to the proposed services and provides supporting documentation in Exhibit L.5.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

- (14) The applicant shall demonstrate that the proposed health services accommodate the clinical needs of health professional training programs in the area, as applicable.

### **C**

The applicant proposes to relocate no more than four in-center dialysis stations from Asheville Kidney Center to the existing Biltmore HT facility to be used exclusively for home hemodialysis and support. The Biltmore HT facility exclusively provides training and support for peritoneal dialysis. There are currently no certified dialysis stations at Biltmore HT. Upon project completion Biltmore HT would have four dialysis stations.

In Section M, page 75, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M.1. The applicant adequately demonstrates that health professional training programs in the area have access to the facility for training purposes.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

- (15) Repealed effective July 1, 1987.  
(16) Repealed effective July 1, 1987.  
(17) Repealed effective July 1, 1987.  
(18) Repealed effective July 1, 1987.
- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall

demonstrate that its application is for a service on which competition will not have a favorable impact.

**C**

The applicant proposes to relocate no more than four in-center dialysis stations from Asheville Kidney Center to the existing Biltmore HT facility to be used exclusively for home hemodialysis and support. The Biltmore HT facility exclusively provides training and support for peritoneal dialysis. There are currently no certified dialysis stations at Biltmore HT. Upon project completion Biltmore HT would have four dialysis stations.

On page 113, the 2023 SMFP defines the service area for dialysis stations as, “... the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee, Clay and Graham counties and Avery, Mitchell, and Yancey counties.” Both Asheville Kidney Center and Biltmore HT are located in Buncombe County. Thus, the service area for this application is Buncombe County. Facilities may serve residents of counties not included in their service area.

According to Table 9A, page 119 of the 2023 SMFP, there are three existing or approved in-center dialysis facilities in Buncombe County, all of which are owned and operated by DaVita. Information on these dialysis facilities, from Table 9A of the 2023 SMFP, is provided below:

<b>Dialysis Facility</b>	<b>In-Center Patients (12-31-21)</b>	<b># of Certified Stations (12-31-21)</b>	<b>Utilization (12-31-21)</b>
Arden Dialysis	29	14	51.79%
Asheville Kidney Center	138	52	66.35%
Weaverville Dialysis	46	20	57.50%

Source: 2023 SMFP, Table 9A.

According to Table 9E, page 138 of the 2023 SMFP, there is one existing dialysis home training facility in Buncombe County. That facility is the Biltmore HT facility which is also owned and operated by DaVita.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 77, the applicant states:

*“The relocation of stations and addition of HHD services to Biltmore HT will not have an adverse effect on competition since the patients already being served by DaVita will be transferring their care from one DaVita facility to another.”*

Regarding the impact of the proposal on cost effectiveness and quality, in Section N, page 77, the applicant states:

*“This project will enhance the quality and cost effectiveness of our services because it will make it easier for patients, family members and others involved in the dialysis process to receive services.”*

See also Sections C, F, O and Q of the application and any exhibits.

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 77, the applicant states:

*“As discussed in Section C, Question 6, and documented in Exhibit L.5, the facility will serve patients without regard to race, color, national origin, gender, sexual orientation, age, religion, or disability and, by policy, works to make every reasonable effort to accommodate its patients.”*

See also Section L and C of the application and any exhibits.

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would have a positive impact on cost-effectiveness, quality, and access because the applicant adequately demonstrates that:

- 1) The proposal is cost effective because the applicant adequately demonstrated: a) the need the population to be served has for the proposal; b) that the proposal would not result in an unnecessary duplication of existing and approved health services; and c) that projected revenues and operating costs are reasonable.
- 2) Quality care would be provided based on the applicant’s representations about how it will ensure the quality of the proposed services and the applicant’s record of providing quality care in the past.
- 3) Medically underserved groups will have access to the proposed services based on the applicant’s representations about access by medically underserved groups and the projected payor mix.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion based on all the reasons described above.

- (19) Repealed effective July 1, 1987.
- (20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

In Section Q Form O Facilities, the applicant identifies the kidney disease treatment centers located in North Carolina owned, operated, or managed by the applicant or a related entity.

In Section O.5, page 82, the applicant states that, during the 18 months immediately preceding the submittal of the application, no incidents related to quality of care that resulted in a finding of “*Immediate Jeopardy*” occurred in any of these facilities. After reviewing and considering information provided by the applicant and publicly available data and considering the quality of care provided at all DaVita facilities, the applicant provides sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

(21) Repealed effective July 1, 1987.

G.S. 131E-183 (b): The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

## CA

The application is conforming with all applicable Criteria and Standards for End-Stage Renal Disease Services. The specific criteria are discussed below.

### **SECTION .2200 – CRITERIA AND STANDARDS FOR END-STAGE RENAL DISEASE SERVICES**

#### **10A NCAC 14C .2201 DEFINITIONS**

The following definitions shall apply to this Section:

- (1) “Dialysis” means the artificially aided process of transferring body wastes from a person's blood to a dialysis fluid to permit discharge of the wastes from the body.
- (2) “Dialysis facility” means a kidney disease treatment center as defined in G.S. 131E176(14e).
- (3) “Dialysis station” means the treatment area in a dialysis facility used to accommodate the equipment and supplies needed to perform hemodialysis on a single patient.
- (4) “Hemodialysis” means the form of dialysis in which the blood is circulated outside the body through equipment that permits transfer of waste through synthetic membranes.

(5) “Home hemodialysis” means hemodialysis performed in a location other than a dialysis facility by the patient after the patient is trained in a dialysis facility to perform the hemodialysis.

(6) “In-center hemodialysis” means hemodialysis performed in a dialysis facility.

(7) “Peritoneal dialysis” means the form of dialysis in which a dialysis fluid is introduced into the person's peritoneal cavity and is subsequently withdrawn. This form of dialysis is performed in a location other than a dialysis facility by the patient after the patient is trained in a dialysis facility to perform the peritoneal dialysis.

## **10A NCAC 14C .2203 PERFORMANCE STANDARDS**

(a) An applicant proposing to establish a new dialysis facility for in-center hemodialysis services shall document the need for at least 10 dialysis stations based on utilization of 2.8 in-center patients per station per week as of the end of the first full fiscal year of operation following certification of the facility. An applicant may document the need for fewer than 10 stations if the application is submitted in response to an adjusted need determination in the State Medical Facilities Plan for fewer than 10 stations.

**-NA-** The applicant is not proposing to establish a new dialysis facility for in-center hemodialysis.

(b) An applicant proposing to increase the number of in-center dialysis stations in:

(1) an existing dialysis facility; or

(2) a dialysis facility that is not operational as of the date the certificate of need application is submitted but has been issued a certificate of need shall document the need for the total number of dialysis stations in the facility based on 2.8 incenter patients per station per week as of the end of the first full fiscal year of operation following certification of the additional stations.

**-NA-** The applicant is not proposing to increase the number of in-center dialysis stations in any facility.

(c) 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 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.

**-NA-** The applicant is not proposing to establish a new dialysis facility dedicated to home hemodialysis or peritoneal dialysis.

(d) An applicant proposing to increase the number of home hemodialysis stations in a dialysis facility dedicated to home hemodialysis or peritoneal dialysis training shall document the need for the total number of home hemodialysis 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 additional stations.

- CA-** Biltmore HT is an existing dialysis facility dedicated to peritoneal dialysis training. The applicant proposes adding four HHD stations to the Biltmore HT facility by relocating four existing in-center stations from Asheville Kidney Center. Per this RULE the applicant must document training six HHD patients per station per year as of the end of the first full fiscal year of operation following certification of the additional stations. To comply with this RULE the applicant would need to document training 24 HHD patients by the end of OY1 (CY2025) [6 HHD patients x 4 HHD stations = 24 HHD patients]. However, the applicant only reasonably and adequately documents 18 HHD patients at the end of OY1 (CY2025) at Biltmore HT. The projected 18 HHD patients demonstrate the need for three, not four, HHD stations at Biltmore HT. Therefore, the application is conditionally approved for to relocate three (3) in-center stations from Asheville Kidney Center to be used exclusively for home hemodialysis and support. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference
- (e) The applicant shall provide the assumptions and methodology used for the projected utilization required by this Rule.
- C-** In Section C, pages 26-27, and Section Q, Form C, the applicant provides the assumptions and methodology used to project utilization for HHD stations. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.