

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: April 6, 2018

Findings Date: April 6, 2018

Project Analyst: Jane Rhoe-Jones

Assistant Chief: Lisa Pittman

Project ID #: L-11438-17

Facility: Kenly Dialysis

FID #: 170521

County: Wilson

Applicant(s): Renal Treatment Centers Mid-Atlantic, Inc.

Project: Develop a new 10-station dialysis facility in Wilson County by relocating five dialysis stations from Wilson Dialysis and five dialysis stations from Forest Hills Dialysis, and offer home peritoneal dialysis training and support

### REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

N.C. Gen. Stat. §131E-183(a) The Agency 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.

C

DaVita, Inc. is the parent company of Renal Treatment Centers Mid-Atlantic, Inc. Renal Treatment Centers Mid-Atlantic, Inc. (RTCMA) proposes to develop a new 10-station dialysis facility, Kenly Dialysis in Kenly, Wilson County by relocating five dialysis stations from Wilson Dialysis and five stations from Forest Hills Dialysis (both in Wilson County). The applicant does not propose to add dialysis stations to an existing facility or to establish new dialysis stations. Upon completion of this project, Kenly Dialysis will be certified for 10 dialysis stations and offer home peritoneal dialysis (PD) training and support. Upon completion of this project, Project L-11132-16 (add five stations), Project L-11139-17 (delete five stations), Project L-11319-17 (add five stations) and Project J-11410-17 (delete four stations), Forest Hills Dialysis will be certified for 27 dialysis stations. Upon completion of this project and Project L-11156-16 (add five stations), Project L-11132-16 (delete five

stations) and Project J-11410-17 (delete six stations), Wilson Dialysis will be certified for 29 dialysis stations.

### **Need Determination**

The applicant is proposing to relocate existing dialysis stations within Wilson County. Neither the county need nor the facility need methodology in the 2017 State Medical Facilities Plan (2017 SMFP) are applicable to this review. Additionally, Policy GEN-3: *Basic Principles* is not applicable because neither need methodology is applicable to the review.

### **Policies**

There are two policies in the 2017 SMFP that are applicable to this review: *Policy ESRD-2 Relocation of Dialysis Stations*, on page 27 and *Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities*, on page 33.

*POLICY ESRD-2: RELOCATION OF DIALYSIS STATIONS* states:

*“Relocations of existing dialysis stations are allowed only within the host county and to contiguous counties. Certificate of need applicants proposing to relocate dialysis stations to a contiguous county shall:*

- 1. Demonstrate that the facility losing dialysis stations or moving to a contiguous county is currently serving residents of that contiguous county; and*
- 2. Demonstrate that the proposal shall not result in a deficit, or increase an existing deficit in the number of dialysis stations in the county that would be losing stations as a result of the proposed project, as reflected in the most recent North Carolina Semiannual Dialysis Report, and*
- 3. Demonstrate that the proposal shall not result in a surplus, or increase an existing surplus of dialysis stations in the county that would gain stations as a result of the proposed project, as reflected in the most recent North Carolina Semiannual Dialysis Report.”*

DaVita is proposing to relocate existing dialysis stations within Wilson County, therefore the proposed project is in compliance with Policy ESRD-2- *Relocation of Dialysis Stations*.

*Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities* states:

*“Any person proposing a capital expenditure greater than \$2 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178 shall include in its certificate of need application a written statement describing the project’s plan to assure improved energy efficiency and water conservation.*

*In approving a certificate of need proposing an expenditure greater than \$5 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178, Certificate of Need shall impose a condition requiring the applicant to develop and*

*implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. The plan must be consistent with the applicant's representation in the written statement as described in paragraph one of Policy GEN-4.*

*Any person awarded a certificate of need for a project or an exemption from review pursuant to G.S. 131E-184 is required to submit a plan for energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation. The plan must be consistent with the applicant's representation in the written statement as described in paragraph one of Policy GEN-4. The plan shall not adversely affect patient or resident health, safety or infection control."*

The proposed capital expenditure is greater than \$2 million, but less than \$5 million. In Section B-5, pages 11-12, Section K-1, pages 45-46, and Exhibits B-5 and K-1(d), the applicant describes how it will assure improved energy efficiency and water conservation. Therefore, the application is conforming to Policy GEN-4.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- 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 the reasons stated above.

- (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, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C

RTCMA proposes to develop a new 10-station dialysis facility, Kenly Dialysis, by relocating five dialysis stations from Wilson Dialysis and five dialysis stations from Forest Hill Dialysis. The existing facilities are located and the proposed facility will be located in Wilson County. The applicant does not propose to add dialysis stations to an existing facility or to establish

new dialysis stations. Upon completion of this project, Kenly Dialysis will be certified for 10 dialysis stations and offer home PD training and support.

- Forest Hills Dialysis - Upon completion of this project, Project L-11132-16 (add five stations), Project L-11139-17 (delete five stations), Project 11319-17 (add five stations) and Project J-11410-17 (delete four stations), Forest Hills Dialysis will be certified for 27 dialysis stations.
- Wilson Dialysis - Upon completion of this project and Project L-11156-16 (add five stations), Project L-11132-16 (delete five stations) and Project J-11410-17 (delete six stations), Wilson Dialysis will be certified for 29 dialysis stations.

**Patient Origin**

On page 373, the 2017 SMFP defines the service area for dialysis services as the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area. Thus, the service area for this facility consists of Wilson County. Facilities may also serve residents of counties not included in their service area.

Kenly Dialysis will be a new facility in Wilson County and therefore has no existing patient origin.

In Section C, page 13, the applicant provides the projected patient origin for Kenly Dialysis for in-center (IC) and peritoneal dialysis (PD) patients for the first two years of operation following completion of the project as follows:

<b>KENLY DIALYSIS PROJECTED PATIENT ORIGIN</b>								
<b>COUNTY</b>	<b>OPERATING YEAR 1 CY2020</b>			<b>OPERATING YEAR 2 CY2021</b>			<b>COUNTY PATIENTS AS % OF TOTAL</b>	
	<b>IC</b>	<b>HH</b>	<b>PD</b>	<b>IC</b>	<b>HH</b>	<b>PD</b>	<b>OY 1</b>	<b>OY 2</b>
Wilson	32	0	3	34	0	4	94.6%	95.0%
Johnston	1	0	0	1	0	0	2.7%	2.5%
Pitt	1	0	0	1	0	0	2.7%	2.5%
<b>Total</b>	<b>34</b>	<b>0</b>	<b>3</b>	<b>36</b>	<b>0</b>	<b>4</b>	<b>100.0%</b>	<b>100.0%</b>

The applicant proposes to serve peritoneal dialysis patients but does not propose to serve home hemodialysis patients. The applicant states that projected IC patient origin is based on 33 existing IC patients; 31 Wilson County patients, one Johnston County patient and one Pitt County patient living in close proximity to the proposed facility and who signed letters stating their willingness to consider transferring their care to the proposed facility. The applicant states that projected PD patient origin is based on two existing PD patients who currently receive their support at Wilson Dialysis. Exhibit C-1 contains patient letters of support for Kenly Dialysis.

In Section C, pages 13-16, the applicant provides the assumptions and methodology used to project its patient origin. The applicant's assumptions are reasonable and adequately supported.

### **Analysis of Need**

In Section C.2, page 16, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services in the southwestern part of Wilson County. On page 16, the applicant states:

- 33 in-center patients currently receiving services at DaVita facilities in Wilson County live in or near the southwestern part of Wilson County.
- Two PD patients are currently served by one of its facilities and live in ZIP Codes “*in or near*” the southwestern part of Wilson County.
- There are three existing or approved dialysis facilities in Wilson County - Wilson Dialysis, Forest Hills Dialysis and an approved new site, Sharpsburg Dialysis. Based on the signed letters from patients currently dialyzing at Wilson Dialysis and Forest Hills Dialysis, the applicant concludes that the proposed new facility will be located closer to where a significant number of its patients reside. In Section C.2, page 16, the applicant states:

*“In order to make the travel to dialysis – three times a week for in-patients and monthly for PD patients -- more convenient, it was determined that Renal Treatment Centers – Mid-Atlantic, Inc. needs to provide a dialysis center nearer to their homes for better access to their dialysis services and support.”*

The information is reasonable and adequately supported for the following reasons:

- See Exhibit C-1 which contains 35 patient letters of support, 33 from IC patients and two from PD patients. The letters state:

*In-Center:*

*“I fully support this new dialysis facility ... to be built in Kenly. ... Having my dialysis treatments at Kenly Dialysis would be more convenient for me. I could travel between home and that location more easily and quickly, which would save me time and money.”*

*Peritoneal Dialysis:*

*“... Having support for my home training at Kenly Dialysis would be closer to my home and much more convenient for me. ...”*

### *Projected Utilization – In-center*

On pages 13-14, the applicant illustrates how in-center patient utilization was projected, which is summarized as follows:

- Operating Year One (OY1) is January 1, 2020 – December 31, 2020.
- Operating Year Two (OY2) is January 1, 2021 – December 31, 2021
- Thirty-one (31) Wilson County residents currently dialyzing at a DaVita facility in Wilson County have signed letters that they would consider transferring to Kenly Dialysis because the proposed facility would be located in the southwestern part of Wilson County and thus closer to where they reside. See also Exhibit C-1.
- One (1) in-center patient currently dialyzing at a DaVita facility in Wilson County and who lives in Johnston County has also signed a letter indicating that they would consider transferring to the proposed Kenly Dialysis based on the fact that it would be closer to where they currently live.
- One (1) in-center patient currently dialyzing at a DaVita facility in Wilson County and who lives in Pitt County has also signed a letter indicating that they would consider transferring to the proposed Kenly Dialysis based on the fact that it would be closer to where they currently live.
- Thus, there are thirty-three (33) patients who have signed letters that they would consider transferring to Kenly Dialysis. See also Exhibit C-1.
- The applicant projects no growth of the in-center patients who are not residents of Wilson County.
- In-center patient population of Wilson County residents is projected to grow at 5.2% (the Five-Year Average Annual Growth Rate (AAGR) for Wilson County) pursuant to Table D in the July 2017 Semi-Annual Dialysis Report (SDR).

The following table illustrates application of these assumptions and the methodology used.

RTCMA projects 31 in-center patients, all of whom reside in Wilson County as of January 1, 2020.	31
RTCMA projects this patient population forward one year to December 31, 2020, using the 5.2% AAGR.	$1.052 \times 31 = 32.612$
RTCMA then adds the two in-center patients who are not residents of Wilson County. This is the projected ending census for <b>Operating Year 1 (1/1/20 – 12/31/20)</b> .	$32.612 + 2 = 34.612$
RTCMA projects the Wilson County resident patient population forward one year to December 31, 2021 using the 5.2% AAGR.	$1.052 \times 32.612 = 34.30782$
RTCMA then adds the two in-center patients who are not residents of Wilson County. This is the projected ending census for <b>Operating Year 2 (1/1/21 – 12/31/21)</b> .	$34.30782 + 2 = 36.30782$

The applicant states on page 15 that the number of projected patients for OY1 and OY2 is rounded down to the nearest whole number. Therefore, at the end of both OY1 (CY 2019) and OY2 (CY2020) the facility is projected to serve 34 and 36 in-center patients, respectively.

The projected utilization rates for the first two operating years are as follows:

- OY1: 3.4 patients per station per week, or 85% (34 patients/10 stations =  $3.4/4 = 0.85$  or 85%).
- OY2: 3.6 patients per station per week, or 90% (36 patients/10 stations =  $3.6/4 = 0.9$  or 90%).

The projected utilization of 3.4 patients per station per week at the end of OY1 meets the minimum standard of 3.2 in-center patients per station per week required by 10A NCAC 14C .2203(b).

Projected in-center utilization is based on reasonable and adequately supported assumptions regarding projected growth at Kenly Dialysis.

*Projected Utilization-Home PD Patients*

The applicant provides projected utilization for its PD patients in Section C.1, page 15, as follows:

<b>Operating Year</b>	<b>Start Date</b>	<b>Beginning Census of PD Patients</b>	<b>Ending Census of PD Patients</b>
Operating Year 1	1/1/20	2	3
Operating Year 2	1/1/21	3	4

On page 15, the applicant provides the assumptions and methodology used to project utilization, which are summarized below.

- Exhibit C-1 contains two letters of support for the proposed facility from PD patients who currently receive their support at a DaVita facility indicating that they would

consider transferring their care to Kenly Dialysis, if approved, based on the fact that they either lived closer to the proposed new facility or it would be more convenient for them.

- RTCMA assumes the two patients who signed letters of support for the proposed facility will transfer their care to Kenly Dialysis upon certification.
- RTCMA assumes that the PD patients will increase one patient each year.

Projected PD utilization is based on reasonable and adequately supported assumptions regarding continued growth at Kenly Dialysis.

### Access

In Section C.3, page 16, the applicant states, “By policy, the proposed services will be made available to all residents in its service area without qualifications. The facility will serve patients without regard to race, sex, age, or handicap. We will serve patients regardless of ethnic or socioeconomic situation.”

In addition, the applicant projects, in Section L.1(b), page 52, that 88.4% of all its patients at Kenly Dialysis will have some or all their expenses paid by either Medicare or Medicaid. The applicant states that the projected payor mix for the proposed facility is based on sources of payment for DaVita operated facilities in Wilson County for the last full operating year. The applicant adequately demonstrates the extent to which all residents of the area, including the medically underserved, are likely to have access to the proposed services.

In Section L.1(b), page 52, the applicant projects the following payor mix during the second full fiscal year of operation following completion of the project, as illustrated in the following table.

<b>KENLY DIALYSIS</b>			
<b>Payor Source</b>	<b>Entire Facility</b>	<b>In-Center</b>	<b>PD</b>
Medicare	25.5%	26.3%	20.0%
Medicaid	7.0%	7.6%	2.9%
Medicare / Commercial	24.8%	23.9%	31.4%
Medicare / Medicaid	31.1%	32.7%	20.0%
Commercial Insurance	9.1%	6.8%	25.7%
VA	2.4%	2.8%	0.0%
<b>Total</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>

The projected payor mix is reasonable and adequately supported.

### Conclusion

The Agency reviewed the:

- Application
- Written comments

- Remarks made at the public hearing
- Responses to comments
- 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 the following reasons:

- The applicant adequately identifies the population to be served.
  - The applicant adequately explains why the population to be served needs the services proposed in this application.
  - Projected utilization is reasonable and adequately supported.
  - The applicant projects the extent to which all residents, including underserved groups, will have access to the proposed services (payor mix) and adequately supports its assumptions.
- (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, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

## C

The applicant proposes to develop a new 10-station dialysis facility, Kenly Dialysis, by relocating five dialysis stations from Wilson Dialysis and five dialysis stations from Forest Hills Dialysis, both in Wilson County. The existing facilities and the proposed facility will be located in Wilson County. The applicant does not propose to add dialysis stations to an existing facility or to establish new dialysis stations. The applicant also proposes to develop a PD home training and support program at Kenly Dialysis. Upon completion of this project, Kenly Dialysis will be certified for 10 dialysis stations. Wilson Dialysis - upon completion of this project and Project L-11156-16 (add five stations), Project L-11132-16 (delete five stations) and Project J-11410-17 (delete six stations), Wilson Dialysis will be certified for 29 dialysis stations. Forest Hills Dialysis - upon completion of this project, Project L-11132-16 (add five stations), Project L-11139-17 (delete five stations), Project L-11319-17 (add five stations) and Project J-11410-17 (delete four stations), Forest Hills Dialysis will be certified for 27 dialysis stations.

In Section D.1, pages 24-28, the applicant discusses how the needs of dialysis patients at Wilson Dialysis and Forest Hills Dialysis will continue to be met following the relocation of stations to Kenly Dialysis.

The applicant provides the following table in Section C.1, page 14 which depicts the ZIP code locations of patients projected to transfer their dialysis treatments to Kenly Dialysis.

<b>ZIP CODES of PATIENTS TRANSFERRING to KENLY DIALYSIS from WILSON DIALYSIS and FOREST HILLS DIALYSIS</b>					
Patient Zip Codes			Forest Hills	Wilson Dialysis	Total
27542	Kenly	Wilson	0	1	1
27542	Kenly	Johnston	0	1	1
27813	Black Creek	Wilson	1	0	1
27851	Lucama	Wilson	1	0	1
27880	Simms	Wilson	0	1	1
27893	Wilson	Wilson	12	5	17
27896	Wilson	Wilson	3	7	10
27828	Farmville	Pitt	1	0	1
<b>Total</b>			<b>18</b>	<b>15</b>	<b>33</b>

*Wilson Dialysis*

In Section D.1, page 26, the applicant states that as of December 31, 2016 (as reported in the July 2017 SDR), there were 138 in-center dialysis patients at Wilson Dialysis dialyzing on 40 dialysis stations, for a utilization rate of 86.25%. In addition, the applicant states that 115 of the 138 in-center patients lived in Wilson County and that 23 lived outside Wilson County.

In Section D.1, page 27, the applicant projects that 13 in-center patients currently receiving services at Wilson Dialysis and who also live in Wilson County will transfer to Kenly Dialysis. Additionally, the applicant projects that one in-center patient who is not a resident of Wilson County will transfer to Kenly Dialysis, and that three PD patients will choose to receive their care at Kenly Dialysis.

The applicant assumes that the number of in-center patients at Wilson Dialysis who live in Wilson County will increase at 5.2% per year based on the Five Year AACR for Wilson County, as reported in Table D of the July 2017 SDR. The applicant assumes that no growth will occur for the two in-center patients currently living outside Wilson County.

As shown in Section D.1, page 27, the applicant provides projected utilization as illustrated in the following table.

<b>WILSON DIALYSIS</b>	
RTCMA projects beginning service area patient census, all Wilson County residents as of December 31, 2016.	115
RTCMA projects an interim period of 1/1/2017 to 12/31/2017, using 5.2% AAGR and adding the 23 patients living outside Wilson County.	$115 \times 1.052 = 120.98 + 23 = 143.98$
RTCMA projects an interim period of 1/1/2018 to 12/31/2018, using 5.2% AAGR and subtracting 11 Wilson County patients projected to transfer to Sharpsburg Dialysis, plus 6 patients from the 23 patients living outside Wilson County, projected to transfer to Sharpsburg Dialysis	$120 - 11 = 109 \times 1.052 = 114.668 + 23 - 6 = 131.668$
RTCMA projects an interim period of 1/1/2019 to 12/31/2019, using 5.2% AAGR and subtracting 5 Wilson County patients and 3 patients outside Wilson County who are projected to transfer to Clayton Dialysis.	$114 - 5 = 109 \times 1.052 = 114.668 + 17 - 3 = 128.668$
RTCMA then subtracts the 13 Wilson County and 1 patient who is not a resident of Wilson County who are transferring to Kenly Dialysis. The projected ending census for <b>Operating Year 1 (1/1/20 – 12/31/20) is 119.</b>	$114 - 13 = 101 \times 1.052 = 106.252 + 14 - 1 = 119.252$
RTCMA then adds the two in-center patients who are not residents of Wilson County. The projected ending census for <b>Operating Year 2 (1/1/21 – 12/31/21) is 124.</b>	$106.252 \times 1.052 = 111.771 + 13 = 124.777$

The applicant states on page 15 that the number of projected patients for OY1 and OY2 is rounded down to the nearest whole number. Therefore, at the end of OY1 and OY2, Wilson Dialysis is projected to serve 119 and 124 in-center patients, respectively.

The projected utilization rates for the first two operating years are as follows:

- OY1: 4.10 patients per station per week, or 103% (119 patients / 29 stations = 4.10 / 4 = 1.025 or 103%).
- OY2: 4.27 patients per station per week, or 107% (124 patients / 29 stations = 4.27 / 4 = 1.068 or 107%).

Projected utilization for Wilson Dialysis is consistent with its historical utilization as reported in the most recent SDR (July 2017). The applicant states the following on page 27:

*“Given this projected growth of the in-center patient population, additional Certificate of Need application(s) will be submitted based on facility need as the facility approaches full capacity of stations to ensure that the needs of the facility’s patients will continue to be met.”*

The Kenly Dialysis home training program is proposed as a peritoneal dialysis training and support program. The applicant assumes that the two PD patients having signed letters of support for Kenly Dialysis will transfer their care from Wilson Dialysis to the new facility. (See Exhibit C-1.)

In Section D, page 27, the applicant states that Wilson Dialysis, by policy, will continue to make dialysis services available to all residents in the service area without qualifications.

*Forest Hills Dialysis*

In Section D.1, page 24, the applicant states that as of December 31, 2016 (as reported in the July 2017 SDR), there were 120 in-center dialysis patients at Forest Hills Dialysis dialyzing on 31 dialysis stations, for a utilization rate of 96.77%. In addition, the applicant states that 95 of the 120 in-center patients lived in Wilson County and that 25 lived outside Wilson County.

In Section D.1, page 25, the applicant projects that 18 in-center Wilson County patients currently receiving services at Forest Hills Dialysis will transfer to Kenly Dialysis, as well as one in-center patients who does not reside in Wilson County.

The applicant assumes that the number of in-center patients at Forest Hills Dialysis who live in Wilson County will increase at 5.2% per year based on the Five Year AACR for Wilson County, as reported in Table D of the July 2017 SDR. The applicant assumes that no growth will occur for the two in-center patients currently living outside Wilson County.

As shown in Section D.1, page 25, the following table illustrates the applicant’s assumptions and methodology.

<b>FOREST HILLS DIALYSIS</b>	
RTCMA projects beginning service area patient census, all Wilson County residents as of December 31, 2016.	95
RTCMA projects an interim period of 1/1/2017 to 12/31/2017, using 5.2% AAGR and adding the 25 patients living outside Wilson County.	$95 \times 1.052 = 99.94 + 25 = 124.94$
RTCMA projects an interim period of 1/1/2018 to 12/31/2018, using 5.2% AAGR and subtracting 4 Wilson County patients projected to transfer to Sharpsburg Dialysis, minus 5 patients from the 20 patients living outside Wilson County, projected to transfer to Sharpsburg Dialysis	$99 - 4 = 95 \times 1.052 = 99.94 + 25 - 5 = 20 = 119.94$
RTCMA projects an interim period of 1/1/2019 to 12/31/2019, using 5.2% AAGR and subtracting 2 Wilson County patients and 5 patients outside Wilson County who are projected to transfer to Clayton Dialysis.	$99 - 2 = 97 \times 1.052 = 102.044 + 20 - 5 = 15 = 117.044$
RTCMA then subtracts the 17 Wilson County and 1 patient who is not a resident of Wilson County who are transferring to Kenly Dialysis. RTCMA uses the 5.2% AAGR. The projected ending census for <b>Operating Year 1 (1/1/20 – 12/31/20) is 103.</b>	$102 - 17 = 85 \times 1.052 = 89.42 + 15 - 1 = 14 = 103.42$
RTCMA then adds the 14 patients who are not residents of Wilson County and 5.2% CAGR. The projected ending census for <b>Operating Year 2 (1/1/21 – 12/31/21) is 108.</b>	$*89.42 \times 1.052 = 94.06984 + 14 = 108.0698$
*The starting population for OY2 should be 89.42 vs.90.472 as indicated by the Applicant.	

The applicant states on page 15 that the number of projected patients for OY1 and OY2 is rounded down to the nearest whole number. Therefore, as stated on page 25, at the end of OY1 and OY2, Forest Hills Dialysis is projected to serve 103 and 108 in-center patients, respectively.

The projected utilization rates for the first two operating years are as follows:

- OY1: 3.81 patients per station per week, or 95% (103 patients / 27 stations = 3.81 / 4 = .9525 or 95%).
- OY2: 4.00 patients per station per week, or 100% (108 patients / 27 stations = 4.00 / 4 = 1.0 or 100%).

Historical utilization for Forest Hills Dialysis is over 96% as reported in the most recent SDR (July 2017). The applicant states the following on page 26:

*“Given this projected growth of the in-center patient population, additional Certificate of Need application(s) will be submitted based on facility need as the facility approaches full capacity of stations to ensure that the needs of the facility’s patients will continue to be met.”*

In Section D, page 27, the applicant states that Forest Hills Dialysis, by policy, will continue to make dialysis services available to all residents in the service area without qualifications.

### **Conclusion**

The Agency reviewed the:

- Application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that 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.
- The project will not adversely impact the ability of underserved groups to access these services following project completion.

- (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

Renal Treatment Centers Mid-Atlantic, Inc. d/b/a Kenly Dialysis proposes to develop a new 10-station dialysis facility (Kenly Dialysis) in Kenly, Wilson County by relocating five dialysis stations from Wilson Dialysis and five stations from Forest Hills Dialysis (both in Wilson County). The applicant also proposes to develop a PD home training and support program at Kenly Dialysis. The applicant does not propose to add dialysis stations to an existing facility or to establish new dialysis stations.

In Section E.1, page 29, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- Maintaining the status quo - the applicant concluded that maintaining the status quo did not meet the growing need for dialysis services in the western portion of Wilson County. Therefore, this is not an effective alternative.
- Locating the facility in another area of Wilson County - the applicant states that building the facility in another part of the county would not provide better geographic access to patients currently being served. Therefore, this is not an effective alternative.

On page 29, the applicant states that its proposal is the most effective alternative because Forest Hills Dialysis and Wilson Dialysis have grown significantly. Forest Hills is at station capacity while Wilson Dialysis has been approved to expand, because it continues to grow. Sharpsburg Dialysis will serve a different geographic area of the county. This project would provide all the Wilson County DaVita facilities space for growth. The applicant provides letters as supporting documentation in Exhibit C-1.

The applicant adequately demonstrates that the alternative proposed in this application is the most effective alternative to meet the need because it will better serve the identified patient population in southwestern in Wilson County.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- 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. Therefore, the application is approved subject to the following conditions:

- 1. Renal Treatment Centers Mid-Atlantic, Inc. d/b/a Kenly Dialysis shall materially comply with all representations made in the certificate of need application.**
- 2. Pursuant to Policy ESRD-2, Renal Treatment Centers Mid-Atlantic, Inc. shall develop a new kidney disease treatment center to be known as Kenly Dialysis by relocating no more than five dialysis stations from Wilson Dialysis and no more than five dialysis stations from Forest Hills Dialysis.**
- 3. Renal Treatment Centers Mid-Atlantic, Inc. d/b/a Kenly Dialysis shall develop a peritoneal dialysis training and support program at Kenly Dialysis.**

4. **Renal Treatment Centers Mid-Atlantic, Inc. d/b/a Kenly Dialysis shall install plumbing and electrical wiring through the walls for no more than 10 dialysis stations, which shall include any isolation stations.**
  5. **Renal Treatment Centers Mid-Atlantic, Inc. shall take the necessary steps to decertify five dialysis stations at Wilson Dialysis for a total of no more than 29 dialysis stations at Wilson Dialysis upon completion of this project, Project L-11156-16 (add five stations), Project L-11132-16 (delete five stations) and Project J-11410-17 (delete six stations).**
  6. **Renal Treatment Centers Mid-Atlantic, Inc. shall take the necessary steps to decertify five dialysis stations at Forest Hills Dialysis for a total of no more than 27 dialysis stations at Forest Hills Dialysis upon completion of this project, Project L-11132-16 (add five stations), Project L-11139-17 (delete five stations), Project L-11319-17 (add five stations), and Project J-11410-17 (delete four stations).**
  7. **Renal Treatment Centers Mid-Atlantic, Inc. d/b/a Kenly Dialysis 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.

C

Renal Treatment Centers Mid-Atlantic, Inc. proposes to develop a new 10-station dialysis facility, Kenly Dialysis in Kenly, Wilson County by relocating five dialysis stations from Wilson Dialysis and five stations from Forest Hills Dialysis (both in Wilson County). The applicant also proposes to develop a PD home training and support program at Kenly Dialysis. The applicant does not propose to add dialysis stations to an existing facility or to establish new dialysis stations.

**Capital and Working Capital Costs**

In Section F, page 30, the applicant projects the total capital cost of the project as shown in the table below.

<b>KENLY DIALYSIS</b>	
Site Costs	\$72,400
Construction Costs	\$1,449,000
Miscellaneous Costs	\$839,730
<b>Total</b>	<b>\$2,361,130</b>

In Section F.10 and F.11, pages 32-34, the applicant projects that start-up costs will be \$191,283 and initial operating expenses will be \$785,219 for a total working capital of \$976,502. In Section F, pages 32-34 and in the pro forma, Form B, the applicant provides the assumptions and methodology used to project the working capital needs of the project.

In Section F.2, page 31, the applicant states that the capital cost will be funded as shown below in the table.

<b>KENLY DIALYSIS Sources of Capital Cost Financing</b>		
Type	Renal Treatment Centers Mid-Atlantic, Inc.	Total
Loans	\$	\$
Accumulated reserves or OE *	\$2,361,130	\$2,361,130
Bonds	\$	\$
Other (Specify)	\$	\$
<b>Total Financing **</b>	<b>\$2,361,130</b>	<b>\$2,361,130</b>

\*OE = Owner's Equity

In Section F.13, page 34, the applicant states that the working capital needs of the project will be funded as shown below in the table.

<b>KENLY DIALYSIS Sources of Financing for Working Capital</b>		Amount
(a)	Loans	\$976,502
(b)	Cash Reserves	\$
(c)	Lines of credit	\$
(d)	Bonds	\$
(e)	<b>Total *</b>	<b>\$976,502</b>

### **Financial Feasibility**

The applicant provided pro forma financial statements for the first two full fiscal years of operation following completion of the project. In Form B, the applicant projects that revenues will exceed operating expenses in the first three operating years of the project, as shown below in the table.

<b>KENLY DIALYSIS Financial Feasibility</b>		
	<b>1<sup>st</sup> Full Fiscal Year</b>	<b>2<sup>nd</sup> Full Fiscal Year</b>
Total Treatments*	4,965	5,187
Total Gross Revenues (Charges)	\$1,643,812	\$1,782,131
Total Net Revenue	\$1,580,178	\$1,714,488
Average Net Revenue per Treatment	\$318.26	\$330.54
Total Operating Expenses (Costs)	\$1,570,437	\$1,656,227
Average Operating Expense per Treatment	\$316.30	\$319.30
<b>Net Income</b>	<b>\$9,741</b>	<b>\$58,262</b>

\*Total treatments adjusted for missed treatments

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section R of the application for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

## Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- 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 the following reasons:

- The applicant adequately demonstrates that the capital and working capital costs are based on reasonable and adequately supported assumptions.
  - The applicant adequately demonstrates availability of sufficient funds for the capital and working capital needs of the proposal.
  - The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.
- (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

Renal Treatment Centers Mid-Atlantic, Inc. proposes to develop a new 10-station dialysis facility, Kenly Dialysis in Kenly, Wilson County by relocating five dialysis stations from Wilson Dialysis and five stations from Forest Hills Dialysis (both in Wilson County). The applicant also proposes to develop a PD home training and support program at Kenly Dialysis. The applicant does not propose to add dialysis stations to an existing facility or to establish new dialysis stations.

On page 373, the 2017 SMFP defines the service area for dialysis services as the dialysis station planning area in which the dialysis station is located. Thus, the service area for this facility consists of Wilson County. Facilities may also serve residents of counties not included in their service area.

The existing and approved dialysis services in Wilson County are shown below in the table.

<b>WILSON COUNTY DIALYSIS FACILITIES Existing &amp; Approved/Certified Stations &amp; In-Center Utilization as of June 9, 2017</b>						
Dialysis Facilities	Owner	# of Patients	Location	# of Certified Stations	# of Approved Stations	Percent Utilization
Forest Hills Dialysis	DaVita	120	Wilson	31	NA	96.77%
Sharpsburg Dialysis	DaVita	0	Sharpsburg	0	10	00.00%
Wilson Dialysis	DaVita	138	Wilson	40	NA	86.25%

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In Section G.2, page 36, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Wilson County. The applicant states:

*“... This certificate of need application does not propose to increase the number of stations in Wilson County. Transferring ten stations from Forest Hills Dialysis and Wilson Dialysis will create a new facility at a different location to better serve patients living in the area of the new facility, but it will not result in duplication of existing services.”*

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

- The application conforms to *Policy ESRD-2 Relocation of Dialysis Stations*, in the 2017 SMFP for the proposed dialysis services.
- The proposal would not result in an increase in the number of dialysis stations in Wilson County.
- The applicant adequately demonstrates that the proposed new dialysis facility is needed in addition to the existing or approved dialysis facilities.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- 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

In Section H, pages 37 and 40, and in Section R, Form A, the applicant provides projected full-time equivalent (FTE) staffing for the proposed services as illustrated in the following table.

<b>KENLY DIALYSIS Staffing</b>		
<b>Position</b>	<b>Projected FTEs</b>	
	<b>1<sup>st</sup> Full Fiscal Year</b>	<b>2<sup>nd</sup> Full Fiscal Year</b>
RN	2.0	2.0
PCT Technician	4.0	4.0
Administrator	1.0	1.0
Dietician	0.5	0.5
Social Worker	0.5	0.5
Home Training RN	0.5	0.5
Administrative Assistant	1.0	1.0
Biomed Tech	0.3	0.3
<b>TOTAL</b>	<b>9.8</b>	<b>9.8</b>

The assumptions and methodology used to project staffing are provided in Section R – pro forma. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.A, which is found in Section R. In Section H.3 and H.4, pages 38-39, the applicant describes the methods to be used to recruit for or fill new positions and its existing training and continuing education programs. In Section H.2, page 38 and I.3, page 42, the applicant identifies the proposed medical director. In Exhibit I-3, the applicant provides a letter from the proposed medical director indicating an interest in serving as medical director for the proposed services. In Section H.3, pages 38-39, the applicant describes its physician recruitment plans. In Exhibit I-3, the applicant provides supporting documentation.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services.

**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.

C

In Section I, page 41, the applicant states that the following ancillary and support services are necessary for the proposed services, adequately explains how each ancillary and support services will be made available and provides supporting documentation in Exhibit I.

<b>KENLY DIALYSIS Ancillary and Support Services</b>	
In-center dialysis/maintenance	Kenly Dialysis
Self-care training (in-center)	Kenly Dialysis
Home training HH PD Accessible follow-up program	Wilson Dialysis
Psychological counseling	Kenly Dialysis
Isolation – hepatitis	Kenly Dialysis
Nutritional counseling	Kenly Dialysis
Social Work services	Kenly Dialysis
Acute dialysis in an acute care setting	Wilson Medical Center
Emergency care	Wilson Medical Center
Blood bank services	Wilson Medical Center
Diagnostic and evaluation services	Wilson Medical Center
X-ray services	Wilson Medical Center
Laboratory services	DaVita Laboratory Services
Pediatric nephrology	Wilson Medical Center
Vascular surgery	Wilson Medical Center
Transplantation services	Vidant Medical Center
Vocational rehabilitation & counseling	NC Division of Vocational Rehabilitation
Transportation	Medical Transport Service

In Section I, pages 42-43, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit I.

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.

- (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.

C

In Section K.2, page 46, the applicant states that the project involves upfitting 4,931 square feet of new space that will be leased. Line drawings are provided in Exhibit K-1(a).

On pages 45-48, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal and provides supporting documentation in Exhibit K.

On pages 45-46, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services and provides supporting documentation in Exhibit K.

On page 45, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans and provides supporting documentation in Exhibit K.

On pages 46-48 and Exhibit K, the applicant identifies the proposed site and provides information about the current owner, zoning and special use permits for the site, and the availability of water, sewer and waste disposal and power at the site.

### **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.

- (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 handicapped persons, 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, page 55, the applicant provides the historical payor mix during CY2016 for the current services at the existing dialysis facilities from which stations will be relocated - Forest Hills Dialysis and Wilson Dialysis, as shown below in the tables. In Project J-11410-17, the applicant's payor mix for the same facilities during the same timeframe (CY2016) differs slightly. The differences are immaterial.

<b>FOREST HILLS DIALYSIS</b>	
<b>Payor Category</b>	<b>Percent of Total Patients</b>
Medicare	26.9%
Medicaid	7.6%
Medicare / Medicaid	33.6%
Medicare / Commercial	21.0%
Commercial Insurance	7.6%
VA	3.4%
<b>Total</b>	<b>100.0%</b>
<b>WILSON DIALYSIS</b>	
<b>Payor Category</b>	<b>Percent of Total Patients</b>
Medicare	23.2%
Medicaid	6.8%
Medicare / Medicaid	28.9%
Medicare Commercial	29.5%
Commercial Insurance	9.5%
VA	2.1%
<b>Total</b>	<b>100.0%</b>

The United States Census Bureau provides demographic data for North Carolina and all counties in North Carolina. The following table contains relevant demographic statistics for the applicant's service area.

<b>Percent of Population</b>						
<b>County</b>	<b>% 65+</b>	<b>% Female</b>	<b>% Racial and Ethnic Minority*</b>	<b>% Persons in Poverty**</b>	<b>% &lt; Age 65 with a Disability</b>	<b>% &lt; Age 65 without Health Insurance**</b>
<b>2016 Estimate</b>	<b>2016 Estimate</b>	<b>2016 Estimate</b>	<b>2016 Estimate</b>	<b>2015 Estimate</b>	<b>2011-2015</b>	<b>2015 Estimate</b>
Wilson	17%	52%	53%	20%	11%	15%
Statewide	16%	51%	37%	16%	10%	13%

Source: <http://www.census.gov/quickfacts/table> Latest Data 7/1/16 as of 8/22/17

\*Excludes "White alone" who are "not Hispanic or Latino" \*\*\*This geographic level of poverty and health estimates are not comparable to other geographic levels of these estimates. Some estimates presented here come from sample data, and thus have sampling errors that may render some apparent differences between geographies statistically indistinguishable...The vintage year (e.g., V2016) refers to the final year of the series (2010 thru 2016). Different vintage years of estimates are not comparable."

The IPRO SA Network 6 provides prevalence data on dialysis patients by age, race, and gender in its 2015 annual report, pages 27-28<sup>1</sup>. In 2015, over 85% of dialysis patients in Network 6 were 45 years of age and older, over 67% were non-Caucasian and 45% were female. (IPRO SA Network 6). However, a direct comparison to the applicant's current payor mix would be of little value because the population data by age, race or gender does not include information on the number of elderly, minorities, women or handicapped persons utilizing health services.

The information in the application, including any exhibits, is reasonable and adequately supported because the applicant's historical payor mix is adequate documentation of the extent to which medically underserved populations utilize the applicant's existing services.

The application is conforming to this criterion based on a review of:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- 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 handicapped persons 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 the applicant states, in Section L.1, page 51,

*Kenly Dialysis, by policy, will 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."*

In Section L.6, page 54, the applicant states that during the last five years no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina.

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.

- (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 52, 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 below in the table.

<b>KENLY DIALYSIS</b>	
<b>Payor Category</b>	<b>Percent of Total Patients</b>
Private Pay	0.0%
Medicare	25.5%
Medicaid	7.0%
Medicare / Medicaid	31.1%
Medicare / Commercial	24.8%
Commercial Insurance	9.1%
VA	2.4%
<b>Total</b>	<b>100.0%</b>

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 50.3% of total services will be provided to Medicare patients, 7% to Medicaid patients and 31.1% to Medicare/Medicaid patients.

On pages 52-53, 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 for the following reasons:

- The projected payor mix is based on the payor mix at Forest Hills Dialysis and Wilson Dialysis (facilities housing the stations proposed to be relocated to Kenly Dialysis).
- The history of DaVita policy regarding the uninsured and underinsured.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- 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.

- (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.4, page 54, the applicant adequately describes the range of means by which patients will have access to the proposed services.

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.

- (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

In Section M, page 56, the applicant describes the extent to which health professional training programs in the area will have access to the facility for training purposes and provides supporting documentation in Exhibit M-2.

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the applicant adequately demonstrates that the proposed services will accommodate the clinical needs of area health professional training programs, and therefore, the application is conforming to this criterion.

- (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

Renal Treatment Centers Mid-Atlantic, Inc. proposes to develop a new 10-station dialysis facility, Kenly Dialysis, in Kenly, Wilson County by relocating five dialysis stations from Wilson Dialysis and five stations from Forest Hills Dialysis (both in Wilson County). The applicant also proposes to develop a PD home training and support program at Kenly Dialysis. The applicant does not propose to add dialysis stations to an existing facility or to establish new dialysis stations.

On page 373, the 2017 SMFP defines the service area for dialysis services as the dialysis station planning area in which the dialysis station is located. Thus, the service area for this facility consists of Wilson County. Facilities may also serve residents of counties not included in their service area.

The existing and approved dialysis services in Wilson County are shown below in the table.

<b>WILSON COUNTY DIALYSIS FACILITIES</b>						
<b>Existing &amp; Approved/Certified Stations &amp; In-Center Utilization as of June 9, 2017</b>						
<b>Dialysis Facilities</b>	<b>Owner</b>	<b># of Patients</b>	<b>Location</b>	<b># of Certified Stations</b>	<b># of Approved Stations</b>	<b>Percent Utilization</b>
Forest Hills Dialysis	DaVita	120	Wilson	31	NA	96.77%
Sharpsburg Dialysis	DaVita	0	Sharpsburg	0	10	00.00%
Wilson Dialysis	DaVita	138	Wilson	40	NA	86.25%

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In Section N, page 57, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services. On page 57, the applicant states,

*“The proposed facility 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 DaVita facility, which will be more convenient for the patients who have indicated this in the letters they signed. There are no other dialysis facilities in the proposed service area; therefore, there can be no effect on the competition.*

*The expansion of Kenly Dialysis will enhance accessibility to dialysis for our patients, and by reducing the economic and physical burdens on our patients, this project will enhance the quality and cost effectiveness of our services because it will make it easier*

*for patients, family members and other involved in the dialysis process to receive services.”*

Because the applicant is the only provider of dialysis services in Wilson County, there are no competing services in the service area. The applicant adequately demonstrates:

- The cost-effectiveness of the proposal (see Sections E, F and R of the application and any exhibits)
- Quality services will be provided (see Section O of the application and any exhibits)
- Access will be provided to underserved groups (see Section L of the application and any exhibits)

### **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 the above stated reasons.

- (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.

### C

In Section A, page 5, and Exhibit A-11 the applicant discusses and identifies the dialysis facilities located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of 75 dialysis facilities located in North Carolina.

In Section O, page 58, and Exhibit O-3, the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents related to quality of care occurred in one of these facilities. The applicant states that all the problems have been corrected and the applicant is awaiting re-inspection by the Acute and Home Care Licensure and Certification Section, DHHS to be scheduled. After reviewing and considering information provided by the applicant and considering the quality of care provided at all 75 facilities, the applicant provided 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.
- (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.

## C

The Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200 are applicable to this review. The application is conforming to all applicable criteria, as discussed below.

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

*.2203(a) An applicant proposing to establish a new End Stage Renal Disease facility shall document the need for at least 10 stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the facility, with the exception that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.*

-C- In Section C.1, pages 15, the applicant adequately demonstrates that Kenly Dialysis will serve at least 34 in-center patients on 10 stations at the end of OY1 (CY2020) for a utilization rate of 85% or 3.4 patients per station per week ( $34/10 = 3.4$ ;  $3.4/4 = 0.85$ ). The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

*.2203(b) An applicant proposing to increase the number of dialysis stations in an existing End Stage Renal Disease facility or one that was not operational prior to the beginning of the review period but which had been issued a certificate of need shall document the need for the additional stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the additional stations.*

-NA- The applicant is seeking to develop a new 10-station dialysis facility.

*.2203(c) An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*

-C- In Section C.1, pages 13-15, the applicant provides the assumptions and methodology used to project utilization of Kenly Dialysis. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.