ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS
C = Conforming
CA = Conditional

NC = Nonconforming NA = Not Applicable

Decision Date: October 4, 2016 Findings Date: October 4, 2016

Project Analyst: Celia C. Inman Team Leader: Fatimah Wilson

Project ID #: G-11212-16
Facility: Elon Dialysis
FID #: 160341
County: Alamance

Applicant: Renal Treatment Centers – Mid-Atlantic, Inc.

Project: Develop a new dialysis facility by relocating 8 stations from Burlington Dialysis

and 2 stations from North Burlington Dialysis

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

G.S. 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.

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Renal Treatment Centers – Mid-Atlantic, Inc. (RTCMA or "the applicant") proposes to develop Elon Dialysis, a new Alamance County dialysis facility, by relocating eight existing certified stations from Burlington Dialysis and two existing certified stations from North Burlington Dialysis. All three facilities are DaVita HealthCare Partners, Inc. (DaVita) dialysis facilities in Alamance County. The applicant does not propose to add dialysis stations to an existing facility or to establish new dialysis stations.

Need Determination

The applicant proposes to relocate existing dialysis stations within Alamance County; therefore, there are no need methodologies in the 2016 State Medical Facilities Plan (SMFP) applicable to this review.

Policies

POLICY GEN-3: BASIC PRINCIPLES, on page 39 of the 2016 SMFP, is not applicable to this review because neither the county nor facility need methodology is applicable to this review.

POLICY GEN-4: ENERGY EFFICIENCY AND SUSTAINABILITY FOR HEALTH SERVICE FACILITIES, on page 39 of the 2016 SMFP, is not applicable to this review because the total capital expenditure is projected to be less than \$2 million.

POLICY ESRD-2: RELOCATION OF DIALYSIS STATIONS, on page 33 of the 2016 SMFP, is applicable to this review. *POLICY ESRD-2* 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 contiguous counties shall:

- 1. Demonstrate that the facility losing dialysis stations or moving to a contigous [sic] county is currently serving residents of that contigous [sic] 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."

The applicant proposes to develop a new 10-station dialysis facility, Elon Dialysis, in Alamance County, by relocating eight existing certified stations from Burlington Dialysis and two existing certified stations from North Burlington Dialysis. Because all three facilities are located in Alamance County, there is no change in the total dialysis station inventory in Alamance County. Therefore, the application is consistent with Policy ESRD-2.

Conclusion

In summary, the applicant adequately demonstrates that the application is consistent with Policy ESRD-2 in the 2016 SMFP. Therefore, the application is conforming to this criterion.

- (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.

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The applicant proposes to develop Elon Dialysis, a new 10-station Alamance County dialysis facility, by relocating 10 existing Alamance County certified dialysis stations: eight from Burlington Dialysis and two from North Burlington Dialysis.

Population to be Served

On page 369, the 2016 SMFP defines the service area for dialysis stations as "the 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 is Alamance County. Facilities may serve residents of counties not included in their service area.

In Section C.1, page 13, the applicant provides the projected patient origin for Elon Dialysis for in-center (IC), home hemodialysis (HH) and peritoneal (PD) patients for the first two years of operation following completion of the project, CY2018 and CY2019, as follows:

	Operating Year (OY) 1		Operating Year (OY) 2			Percent of Total		
County	IC	HH*	PD*	IC	HH*	PD*	OY1	OY2
Alamance	26	0	0	27	0	0	78.8%	79.4%
Guilford	7	0	0	7	0	0	21.2%	20.6%
Total	33	0	0	34	0	0	100.0%	100.0%

^{*}The facility does not propose to offer HH or PD services.

The applicant has identified 26 in-center Alamance County dialysis patients who have signed letters indicating interest in transferring their care to the proposed Elon facility. In addition, seven in-center patients originating from Guilford County and receiving dialysis treatments in Alamance County have signed letters indicating they would consider transferring their care to the proposed Elon facility. The applicant states that each of the patients is currently receiving dialysis care and treatment at another DaVita dialysis facility in Alamance County. Exhibit C contains copies of signed letters of support from these patients indicating that the proposed facility would be more convenient for them and they would consider transferring their care to the new facility upon certification. The letters also state the patients' county of residence and zip code.

The applicant adequately identifies the population to be served.

Analysis of Need

In Section C.2, page 15, the applicant discusses the need to relocate stations to the proposed western Alamance facility, stating:

"In doing an analysis of the patients that are served by Renal Treatment Centers Mid-Atlantic, Inc. in Alamance County, it was determined that DaVita is serving a total of 33 in-center patients who live in or near the western part of Alamance County.

In order to make the travel to dialysis – tree times a week for in-patients – more convenient, it was determined that DaVita needs to provide a dialysis center nearer to their homes for better access to their dialysis services and support."

On pages 13-15, the applicant provides the methodology and assumptions used to project need and utilization for DaVita's proposed Elon Dialysis as follows:

- 1. DaVita is the parent company of Burlington Dialysis and North Burlington Dialysis in Alamance County.
- 2. Twenty-six in-center dialysis patients who reside in Alamance County and currently receive dialysis treatments at DaVita operated facilities in Alamance County have signed letters stating they would consider transferring their dialysis care to the proposed facility.
- Seven in-center dialysis patients who reside in Guilford County and currently receive
 dialysis treatments at DaVita operated facilities in Alamance County have signed
 letters stating they would consider transferring their dialysis care to the proposed
 facility.
- 4. The 33 patient letters also state that the patient lives closer to the proposed facility and/or that the new facility will be more convenient for them. See Exhibit C. The following table summarizes the applicant's table on page 14, which shows the number of in-center patients willing to transfer, their resident zip codes, and the current dialysis facilities from which the in-center patients will transfer.

	Burlington Dialysis	North Burlington Dialysis	
Patients Transferring	31	2	

5. The project is scheduled for certification January 1, 2018.

Operating Year 1 is Calendar Year 2018, January 1 through December 31, 2018. Operating Year 2 is Calendar Year 2019, January 1 through December 31, 2019.

6. The applicant assumes the 26 Alamance County in-center dialysis patients transferring to the new Elon Dialysis facility will increase at the Alamance County Five Year Average Annual Change Rate of 3.7%, as published in the July 2016 Semiannual Dialysis Report (SDR). Guilford County patients are not projected to increase and are added to the census in a separate step.

The information provided by the applicant on the pages referenced above is reasonable and adequately supported.

<u>Projected Utilization</u>

The applicant's methodology is illustrated in the following table.

Elon Dialysis	In-Center
The applicant begins the facility census with the incenter Alamance County patient population projected to transfer care to the proposed facility upon certification on January 1, 2018.	26
Project growth of the Alamance County patients by the Alamance County Five Year Average Annual Change Rate (3.7%) for one year to December 31, 2018.	$(26 \times 0.037) + 26 = 26.96$
Add the Guilford County patients projected to transfer. This is the end of OY1, December 31, 2018.	26.96 + 7 = 33.96
Project growth of the Alamance County patients by the Alamance County Five Year Average Annual Change Rate for one year to December 31, 2019.	(26.96 X 0.037) + 26.96 = 27.96
Add the Guilford County patients. This is the end of OY2, December 31, 2019.	27.96 + 7 = 34.96

The applicant's methodology rounds down to the whole patient and projects to serve 33 incenter patients or 3.3 patients per station (33 / 10 = 3.3) by the end of Operating Year 1 and 34 in-center patients or 3.4 patients per station (34 / 10 = 3.4) by the end of Operating Year 2 for the proposed 10-station facility. This exceeds the minimum of 3.2 patients per station per week as of the end of the first operating year as required by 10A NCAC 14C .2203(b). The applicant does not propose to serve any home hemodialysis or peritoneal patients at the proposed facility. Exhibit I contains an agreement with Burlington Dialysis to provide home training in home hemodialysis and peritoneal dialysis for Elon Dialysis patients.

In this application, the applicant assumes a projected annual rate of growth of 3.7% for the Alamance County dialysis patient census, which is consistent with the Alamance County Five Year Average Annual Change Rate published in the July 2016 SDR. Projected utilization is based on reasonable and adequately supported assumptions regarding continued growth.

Access

In Section L.1(a), pages 49-50, the applicant states that Elon Dialysis, by policy, will make dialysis services available to all residents in its service area, including low-income, racial and ethnic minorities, women, handicapped, elderly, and other underserved persons, without regard to race, color, national origin, gender, sexually orientation, age, religion, or disability. Form C in Section R, shows the applicant projects over 79% of its in-center patients will have some or all of their services paid for by Medicare or Medicaid. The applicant adequately demonstrates the extent to which all residents, including underserved groups, will have access to the proposed services. In Section L, page 50, the applicant states:

"The projected payor mix is based on the sources of patient payment that have been received by DaVita operated facilities in Alamance County during the last full operating year."

Conclusion

In summary, the applicant adequately identifies the population to be served, adequately demonstrates the need that this population has for the proposed project, and adequately demonstrates the extent to which all residents, including underserved groups, are likely to have access to the proposed services. Therefore, the application is conforming to this criterion.

(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.

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The applicant proposes to develop Elon Dialysis, a new 10-station Alamance County dialysis facility, by relocating 10 existing Alamance County certified dialysis stations: eight from Burlington Dialysis and two from North Burlington Dialysis.

The development of the proposed facility results in the following changes to DaVita's existing and proposed Alamance County dialysis facilities, assuming the completion of this project and all previously approved projects.

Calculation of DaVita Existing, Approved and Proposed Dialysis Stations in Alamance County

	 	North			Stations in Alamance County
	Burlington Dialysis	Burlington Dialysis	Graham Dialysis	Elon Dialysis	Explanation
Certified Stations as of		-	-		-
3/14/14	26	13			
Project ID #G-10265-14, Issued 6/30/14, but not complete	-8	-2	10		Develop Graham Dialysis [Alamance County Dialysis], a 10- station dialysis facility by relocating 8 dialysis stations from Burlington Dialysis Center and 2 stations from North Burlington Dialysis Center
Certified Stations upon completion of Relocation and Certification G-10265- 14	18	11			Assumes project completion and certification of stations
Project ID #G-10347-14, Issued 2/24/15, Certified 6/21/16	6				Add six stations for a total of 24 upon completion of this project and Project ID #G-10265-14 (Relocate 8 stations from Burlington Dialysis)
Project ID #G-10352-14, Issued 2/24/15, Certified 6/25/14		3			Add three dialysis stations for a total of 14 dialysis stations upon completion of this project and Project ID G-10265-14 (relocate 2)
Project ID #G-11015-15, Issued 7/7/15, not Certified		2			Add no more than two dialysis stations for a total of no more than 16 stations upon completion of this project, Project ID #G-10352-14 (add 3 stations) and Project ID #G-10265-14 (relocate two from North Burlington to Graham)
Project ID #G-11089-15, Issued 3/22/16, not Certified		6			Add 6 dialysis stations for a total of 22 stations upon completion of this project and Project ID #G-10265-14 (relocate 2 stations) and Project ID #G-11015-15 (add 2 stations)
Stations prior to submission of current project G-11212-16	24	22	10	0	Assumes project completion and certification of stations
Proposed Project ID #G- 11212-16	-8	-2	0	10	Develop a new dialysis facility by relocating 8 stations from Burlington Dialysis and 2 stations from North Burlington Dialysis
Total Dialysis Stations after certification of all projects	16	20	10	10	Assumes the certification of all approved, under development and proposed stations

The July 2015 SDR shows the following number of certified stations and utilization for Burlington Dialysis and North Burlington Dialysis, as of December 31, 2015.

	Burlington Dialysis	North Burlington Dialysis
Total Certified Dialysis Stations per July 2016 SDR	26	16
Number of In-Center Patients, 12/31/15	101	69
Utilization Patients per Station	3.8846	4.3125
Utilization Rate by Percent	97.12%	107.81%

In Section D.1, on pages 24-26, the applicant discusses how the needs of dialysis patients at Burlington Dialysis and North Burlington Dialysis will continue to be met after the relocation of stations to the proposed Elon Dialysis facility. The applicant states the relocation of stations and transfer of patients is projected to occur on January 1, 2018.

On pages 24-25, the applicant discusses the Burlington facility, stating that of the 101 incenter patients, as of December 31, 2015, 88 were from Alamance County. On page 25, the applicant provides a table projecting the in-center patient census at Burlington Dialysis from December 31, 2015 through December 31, 2019. The assumptions for projecting Burlington Dialysis' utilization are summarized below:

- The July 2016 SDR reports Burlington Dialysis with 101 in-center patients on December 31, 2015, 26 dialysis stations and a utilization rate of 97.12%.
- 88 of the 101 patients were Alamance County residents; 13 patients lived outside of Alamance County.
- Upon the completion of Project ID #G-10265-14 (relocate 8 stations from Burlington Dialysis to Graham Dialysis [Alamance County Dialysis]) and Project ID #G-10347-14 (add 6 stations to Burlington Dialysis), Burlington Dialysis will have a total of 24 stations. It is assumed those stations will have been certified before the proposed relocation of 8 stations, which will leave the center with 16 certified dialysis stations.
- The Alamance County patient population is projected forward using the 3.7% Alamance County Five Year Average Annual Change Rate, as published in the July 2016 SDR.
- No growth rate is applied to the 13 patients who reside outside of Alamance County.
- The applicant expects at least 31 current in-center patients from Burlington Dialysis will transfer to Elon Dialysis upon its certification: 24 Alamance County residents and seven non-Alamance residents.

Based on the above assumptions, the Project Analyst calculates projected utilization at Burlington Dialysis as follows:

Burlington Dialysis	In-Center
The methodology begins the facility census with the in-center Alamance County patient population, as of December 31, 2015	88
Project growth of the Alamance County patient census by the Alamance County Five Year Average Annual Change Rate for 1 year to December 31, 2016.	$(88 \times 0.037) + 88$ = 91.26
Project growth of the census by the Alamance County Five Year Average Annual Change Rate for 1 year to December 31, 2017.	(91.26 x 0.037) + 91.26 = 94.63
The methodology deducts the 24 Alamance County residents who will transfer to Elon Dialysis on January 1, 2018.	94 - 24 = 70
Project growth of the Alamance County patients by the Alamance County Five Year Average Annual Change Rate for 1 year to December 31, 2018.	$(70 \times 0.037) + 70$ = 72.59
The methodology adds back 6 non-Alamance County patients (13 patients less the 7 patients that transfer) for the total Burlington Dialysis Center patients as of December 31, 2018.	72.59 + 6 = 78.59
Project growth of the Alamance County patients by the Alamance County Five Year Average Annual Change Rate for 1 year to December 31, 2019.	(72.59 x 0.037) + 72.59 = 75.28
The methodology adds back 6 non-Alamance County patients (13 patients less the 7 patients that transfer) for the total Burlington Dialysis Center patients as of December 31, 2019.	75.28 + 6 = 81.28

Thus, as of December 31, 2018, the end of the first full operating year following the relocation of eight stations and transfer of 24 Alamance County patients and 7 non-Alamance County patients, Burlington Dialysis is projected to have 78 patients (78.59 rounded down) and 16 stations, which is a utilization rate of 121.9% (78 patients / 16 stations = 4.88 / 4 = 1.219).

On pages 25-26, the applicant discusses the North Burlington facility, stating that of the 69 in-center patients, as of December 31, 2015, 67 were from Alamance County. On page 26, the applicant provides a table projecting the in-center patient census at North Burlington Dialysis from December 31, 2015 through December 31, 2019. The assumptions for projecting North Burlington Dialysis' utilization are summarized below:

• The July 2016 SDR reports Burlington Dialysis with 69 in-center patients on December 31, 2015, 16 dialysis stations and a utilization rate of 107.81%.

- 67 of the patients were Alamance County residents; 2 patients lived outside of Alamance County.
- Upon the completion of Project ID #G-10265-14 (relocate 2 stations from North Burlington Dialysis to Graham Dialysis [Alamance County Dialysis]) and Project ID #G-11015-15 (add 2 stations to North Burlington Dialysis), North Burlington Dialysis will have a total of 22 stations. It is assumed those stations will have been certified before the proposed relocation of 2 stations, which will leave the center with 20 certified dialysis stations.
- The Alamance County patient population is projected forward using the 3.7% Alamance County Five Year Average Annual Change Rate as published in the July 2016 SDR.
- No growth rate is applied to the 2 patients who reside outside of Alamance County.
- The applicant expects at least 2 current Alamance County in-center patients from North Burlington Dialysis will transfer to Elon Dialysis upon its certification.

Based on the above assumptions, the Project Analyst calculates projected utilization at North Burlington Dialysis as follows:

North Burlington Dialysis	In-Center
The methodology begins the facility census with the in-center Alamance County patient population, as of December 31, 2015.	67
Project growth of the Alamance County patient census by the Alamance County Five Year Average Annual Change Rate for 1 year to December 31, 2016.	(67 x 0.037) + 67 = 69.48
Project growth of the Alamance County patient census by the Alamance County Five Year Average Annual Change Rate for 1 year to December 31, 2017.	(69.48 x 0.037) + 69.48 = 72.05
The methodology deducts the two Alamance County patients transferring to Elon Dialysis on January 1, 2018	72.05 - 2 = 70
Project growth of the Alamance County patients by the Alamance County Five Year Average Annual Change Rate for 1 year to December 31, 2018.	$(70 \times 0.037) + 70$ = 72.59
The methodology adds back the 2 non-Alamance County patients for the total census at December 31, 2018, the end of OY1.	72.59 + 2 = 74.59
Project growth of the Alamance County patients by the Alamance County Five Year Average Annual Change Rate for 1 year to December 31, 2019.	(72.59 x 0.037) + 72.59 = 75.28
The methodology adds back the 2 non-Alamance County patients for the total census at December 31, 2019, the end of OY2.	75.28 + 2 = 77.28

Thus, as of December 31, 2018, the end of the first full operating year following the relocation of two stations and transfer of two Alamance County patients, North Burlington Dialysis is projected to have 77 patients (77.28 rounded down) and 20 stations, which is a utilization rate of 96.3% (77 patients / 20 stations = 3.85 / 4 = 0.963).

On pages 25 and 26, in reference to both Burlington Dialysis and North Burlington Dialysis, the applicant states:

"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 applicant demonstrates that the needs of the population presently served at Burlington Dialysis and North Burlington Dialysis will continue to be adequately met following the proposed relocation of dialysis stations to Elon Dialysis.

In Section D.2, page 26, the applicant states:

"The transfer of stations from Burlington Dialysis and North Burlington Dialysis will have no effect on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other under-served group [sic] and the elderly to obtain needed health care.

Burlington Dialysis and North Burlington Dialysis by policy, 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."

Conclusion

The applicant demonstrates that the needs of the population presently served at Burlington Dialysis and North Burlington Dialysis will continue to be adequately met following the proposed relocation of eight and two dialysis stations from Burlington Dialysis and North Burlington Dialysis, respectively, to Elon Dialysis and that access for medically underserved groups will not be negatively impacted.

Therefore, the application is conforming to this criterion.

(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

In Section E, page 28, the applicant describes the alternatives considered prior to submitting this application for the proposed project, which include:

- Maintain the status quo The applicant states that maintaining the status quo does not serve to meet the needs of a growing in-center patient population in the western region of the Alamance County service area.
- Locate a facility in another area of Alamance County The applicant states that the sites selected for the new facility were selected to allow better geographic access to the identified patient population, as reflected in the patient letters in Exhibit C. The applicant further states that a facility in another area of Alamance County would not address the needs of the identified patients. Therefore, this alternative was rejected.
- Develop the project as proposed Relocate eight Burlington Dialysis stations and two North Burlington Dialysis stations to develop Elon Dialysis in western Alamance County.

The applicant states that there has been significant growth at both Burlington Dialysis and North Burlington Dialysis, with Burlington Dialysis at station capcity and North Burlington being approved to expand, but still projected to experience growth. The applicant further states that Graham Dialysis [Alamance County Dialysis], Project ID #G-10265-14, will serve a different

geographic area of the county; therefore, the project represented in this application is the more effective alternative to better serve the patient population identified and documented in the patient letters in Exhibit C. The applicant further states, "This action will provide all of the DaVita facilities in Alamance County space for future growth."

Furthermore, the application is conforming to all other statutory and regulatory review criteria, and thus, is approvable. A project that cannot be approved cannot be an effective alternative.

In summary, the applicant adequately demonstrates that its proposal is the least costly or most effective alternative to meet the identified need. Therefore, the application is conforming to this criterion and approved subject to the following conditions.

- 1. Renal Treatment Centers Mid-Atlantic, Inc. d/b/a Elon Dialysis shall materially comply with all representations made in the certificate of need application.
- 2. Renal Treatment Centers Mid-Atlantic, Inc. d/b/a Elon Dialysis shall relocate no more than eight dialysis stations from Burlington Dialysis and two dialysis stations from North Burlington Dialysis.
- 3. Renal Treatment Centers Mid-Atlantic, Inc. d/b/a Elon Dialysis shall install plumbing and electrical wiring through the walls for no more than 10 dialysis stations, which shall include any isolation or home hemodialysis stations.
- 4. Renal Treatment Centers Mid-Atlantic, Inc. d/b/a Elon Dialysis shall take the necessary steps to decertify eight dialysis stations at Burlington Dialysis for a total of no more than 16 certified dialysis stations at Burlington Dialysis upon completion of this project, Project I.D. #G-10265-14 (relocate eight dialysis stations from Burlington Dialysis to Graham Dialysis) and Project I.D. #G-10347-14 (Add six stations for a total of 24).
- 5. Renal Treatment Centers Mid-Atlantic, Inc. d/b/a Elon Dialysis shall take the necessary steps to decertify two dialysis stations at North Burlington Dialysis for a total of 20 certified dialysis stations at North Burlington Dialysis upon completion of this project, Project I.D. #G-10265-14 (relocate two dialysis stations from North Burlington Dialysis to Graham Dialysis), Project I.D. #G-11015-15 (Add two stations for no more than 16) and Project I.D. #G-11089-15 (Add six dialysis stations for a total of 22).
- 6. Renal Treatment Centers Mid-Atlantic, Inc. d/b/a Elon Dialysis shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Healthcare Planning and Certificate of Need Section 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.

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The applicant proposes to develop Elon Dialysis, a new 10-station Alamance County dialysis facility, by relocating eight certified stations from Burlington Dialysis and two certified stations from North Burlington Dialysis.

Capital and Working Capital Costs

In Section F.1, page 29, the applicant projects \$1,796,970 in capital costs to develop this project, as itemized below.

Projected Capital Costs

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Site Costs	\$ 48,000
Construction	\$1,125,000
Machines	\$ 152,400
RO Equipment	\$ 134,675
Other Equipment/Furniture	\$ 246,895
Architect/Engineering Fees	\$ 90,000
Total Capital Costs	\$1,796,970

In Sections F.10-F.12, pages 31-32, the applicant states that start-up expenses and initial operating expenses incurred for this project will be \$182,779 and \$759,699, respectively, for a total estimated working capital of \$942,478.

Availability of Funds

In Section F.2, page 30, F.13, pages 32-33, and Exhibit F, the applicant states DaVita Inc., the applicant's parent company, will finance the capital costs and working capital costs with accumulated reserves / owner's equity, as shown below.

DaVita Accumulated Reserves / Owner's Equity

	Total
Capital Costs	\$ 1,796,970
Working Capital	\$ 942,478
Total	\$ 2,739,448

Exhibit F contains a letter dated July 14, 2016, from DaVita Chief Accounting Officer and signed by William Hyland, authorizing and committing \$2,739,448 in capital costs and working capital for the project. Exhibit F also contains a letter dated July 14, 2016, from William Hyland, stating authority to sign the above letter on behalf of DaVita's Chief Accounting Officer, who was made aware of the commitment but was unavailable to sign the letter. Exhibit F-7 contains the Securities and Exchange Commission Form 10-K for DaVita which indicates that it had \$1,499,116,000 in cash and cash equivalents, \$4,503,280,000 in

total current assets, and \$5,084,172,000 in net assets (total assets less total liabilities) as of December 31, 2015.

The applicant adequately demonstrates that sufficient funds will be available for the capital and working capital needs of the project.

Financial Feasibility

The applicant provides pro forma financial statements for the first two years of the project. In the pro forma financial statement (Form B), the applicant projects that revenues will exceed operating expenses in the first two operating years of the project, as shown in the table below.

	CY2018	CY2019
Total Gross Revenue	\$1,645,364	\$1,670,333
Deductions from Gross	\$68,841	\$69,900
Total Net Revenue	\$1,576,523	\$1,600,433
Total Operating Expenses	\$1,519,398	\$1,547,208
Net Income	\$57,126	\$53,224

The applicant provides the assumptions for its projections in Section R of the application. The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See the financial section of the application for the assumptions used regarding costs and charges. The discussion regarding utilization projections found in Criterion (3) is incorporated herein by reference. The applicant adequately demonstrates that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

Conclusion

In summary, the applicant adequately demonstrates that sufficient funds will be available for the capital and working capital needs of the project. Furthermore, the applicant adequately demonstrates that the financial feasibility of the proposal is based upon reasonable projections of costs and charges. Therefore, the application is conforming to this criterion.

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

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The applicant proposes to develop Elon Dialysis, a new 10-station Alamance County dialysis facility, by relocating eight stations from Burlington Dialysis and two stations from North Burlington Dialysis.

On page 369, the 2016 SMFP defines the service area for dialysis stations as "the 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 is Alamance County. Facilities may serve residents of counties not included in their service area.

As of December 31, 2015, DaVita was operating two existing dialysis centers in Alamance County and had been approved to establish a third, Graham Dialysis [Alamance County Dialysis], Project I.D. #G-10265-14. Bio-Medical Applications of North Carolina, Inc. (BMA) is the only other provider of dialysis services in Alamance County, and operates two dialysis centers, as shown in the table below.

Alamance County Dialysis Facilities
Certified Stations and Utilization as of December 31, 2015

Dialysis Facility	Certified Stations 12/31/15	# In-center Patients	Percent Utilization	Patients/ Station
BMA Burlington (BMA)	45	102	56.67%	2.27
Burlington Dialysis (DaVita)	26	101	97.12%	3.88
Carolina Dialysis – Mebane (BMA)	12	49	102.08%	4.08
Graham (Alamance County) Dialysis (DaVita)	0	0		
North Burlington Dialysis (DaVita)	16	69	107.81%	4.31

Source: July 2016 SDR

As shown in the table above, the DaVita Alamance County dialysis facilities are operating far above 80% utilization (3.2 patients per station), and one of the BMA facilities is operating above 100% utilization. Graham [Alamance County] Dialysis was approved in Project I.D. #G-10265-14, but not certified as of December 31, 2015.

The applicant proposes to relocate eight Burlington Dialysis stations and two North Burlington Dialysis stations to a new facility, Elon Dialysis. Burlington Dialysis was serving 101 patients on 26 stations, which is 3.88 patients per station, or 97.12% of capacity, as of December 31, 2015. North Burlington Dialysis was serving 69 patients on 16 stations or 4.31 patients per station at 107.81% of capacity. The applicant provides reasonable projections for the patient population it proposes to serve on pages 13-15 of the application. The growth projections are based on a projected 3.7% average annual growth rate in the number of Alamance County dialysis patients transferring their care to the proposed facility. The applicant states that the methodology rounds down to the whole patient and projects to serve 33 in-center patients or 3.3 patients per station, a utilization rate of 82.5% (33/10 = 3.3) /4 = .825) by the end of Operating Year 1 and 34 in-center patients or 3.4 patients per station, a utilization rate of 85.0% (34 / 10 = 3.4 / 4 = .850) by the end of Operating Year 2 for the proposed 10-station facility. This exceeds the minimum of 3.2 patients per station per week as of the end of the first operating year as required by 10A NCAC 14C .2203(b). The applicant does not propose to increase the number of certified stations in the service area. The applicant adequately demonstrates the need to develop a new 10-station dialysis center by relocating existing Alamance County DaVita dialysis stations.

The applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of existing or approved dialysis stations or facilities. Therefore, the application is conforming to this criterion.

(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.

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In Section H.1, page 36, the applicant provides the proposed staffing for the new facility, which includes 9.3 full-time equivalent (FTE) employee positions, as shown below.

Position	Projected # of FTE Positions
Medical Director*	
RN	2.0
Technician	4.0
Administrator	1.0
Dietitian	0.5
Social Worker	0.5
Administrative Assistant	1.0
Biomed Technician	0.3
Total FTE Positions	9.3

^{*}The Medical Director is a contract position, not an FTE of the facility.

In Section H.3, pages 37-38, the applicant describes its experience and process for recruiting and retaining staff. Exhibit H contains information on DaVita staffing, employee benefits and training. Exhibit I-3 contains a copy of a letter from Munsoor Lateef, M.D., expressing his interest in serving as the Medical Director for the facility. Exhibit I-3 also contains support letters from other area physicians stating their intent to seek admission privileges at the proposed facility. The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services. Therefore, the application is conforming to this criterion.

(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.

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In Section I.1, page 40, the applicant includes a list of providers of the necessary ancillary and support services. The applicant discusses coordination with the existing health care system on pages 41-42. Exhibit I contains documentation for home training, laboratory, vocational rehabilitation, transportation, vascular surgery and other acute care services, respectively. Exhibit I also contains a copy of an unsigned agreement for transplantation services by an un-named hospital. During the public comment period, the Agency received a letter from Wake Forest Baptist Health documenting its intention to enter into a Transplant Agreement with Elon Dialysis. Exhibit I-3 contains a letter from the proposed medical director for the facility expressing his support for and commitment to the proposed project. The Exhibit also contains other physician support letters. The applicant adequately demonstrates that the necessary ancillary and support services will be available and that the proposed services will be coordinated with the existing health care system. Therefore, 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

- (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

- (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.

 \mathbf{C}

The applicant proposes to develop Elon Dialysis, a new 10-station dialysis facility, in a 7,000 square foot building, per the line drawings, as provided by the applicant in Exhibit K-1(a). In Section K.2, page 45, the applicant states there are 3,078 square feet in treatment area in the building. In Section F.1, page 29, the applicant lists the project costs, including \$1,125,000 for construction and \$623,970 in miscellaneous costs including water treatment equipment, furniture, architect/engineering fees for a total project cost of \$1,796,970. In Section K.1, pages 44-45, the applicant describes its plans for energy-efficiency and water conservation. Costs and charges are described by the applicant in Section R of the application. The discussion regarding costs and charges found in Criterion (5) is incorporated herein by reference.

The applicant adequately demonstrates that the proposed cost, design and means of construction represent the most reasonable alternative, that energy saving features have been incorporated into the construction plans and that the construction cost will not unduly increase costs and charges for health services. Therefore, 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;

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In Section L.3(c), page 51, the applicant states:

"In short, it has been DaVita's practice in North Carolina to accept patients in need of dialysis treatment first, and assist them with insurance and billing issues later. Our goal is to serve the needs of our patient population in accordance with CMS regulations related to billing practices."

In Section L.7, page 53, the applicant provides the historical payor mix for Burlington Dialysis and North Burlington Dialysis patients, showing over 74% and 86%, respectively, of the in-center patients had some or all of their services paid for by Medicare or Medicaid, as shown below.

In-Center Patients 1/1/15 through 12/31/15

Payment Source	Burlington Dialysis	North Burlington Dialysis
Medicare	29.5%	31.9%
Medicaid	2.1%	5.6%
Commercial Insurance	13.7%	6.9%
Medicare/Commercial	25.3%	15.3%
Medicare/Medicaid	17.9%	33.3%
VA	11.6%	6.9%
Total	100.0%	100.0%

Totals may not sum due to rounding.

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.

Percent of Population						
County	% 65+	% Female	% Racial and Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance**
2014 Estimate	2014 Estimate	2014 Estimate	2014 Estimate	2010-2014	2010-2014	2014 Estimate
Alamance	16%	52%	34%	18%	10%	20%
Statewide	15%	51%	36%	17%	10%	15%

http://www.census.gov/quickfacts/table Latest Data as of 12/22/15

**"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., V2015) refers to the final year of the series (2010 thru
2015). Different vintage years of estimates are not comparable."

However, a direct comparison to the applicant's current payor mix would be of little value. 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 Southeastern Kidney Council Network 6 Inc. 2014 Annual Report¹ provides prevalence data on North Carolina dialysis patients by age, race, and gender on page 59, summarized as follows:

^{*}Excludes "White alone" who are "not Hispanic or Latino"

¹http://esrd.ipro.org/wp-content/uploads/2016/06/2014-Network-6-Annual-Report-web.pdf

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Number and Percent of Dialysis Patients by Age, Race, and Gender 2014				
	# of ESRD Patients	% of Dialysis Population		
Age				
0-19	52	0.3%		
20-34	770	4.8%		
35-44	1,547	9.7%		
45-54	2,853	17.8%		
55-64	4,175	26.1%		
65+	6,601	41.3%		
Gender				
Female	7,064	44.2%		
Male	8,934	55.8%		
Race				
African-American	9,855	61.6%		
White	5,778	36.1%		
Other, inc. not specified	365	2.3%		

The applicant demonstrates that it currently provides adequate access to medically underserved populations. 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;

 \mathbf{C}

In Section L.3, page 52, the applicant states that it has no obligation under any applicable federal regulation to provide uncompensated care, community service or access by minorities and handicapped persons except those obligations which are placed upon all medical facilities under Section 504 of the Rehabilitation Act of 1973 and its subsequent amendment in 1993.

In Section L.6, page 52, the applicant states that there have been no civil rights access complaints filed within the past five years. Therefore, 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 R, the applicant projects that over 79% of the in-center patients who will receive treatments at Elon Dialysis will have some or all of their services paid for by Medicare or Medicaid. The table below shows the projected payment source for Elon Dialysis in-center patients for operating years one and two:

Payment Source	In-Center Patients
Medicare	30.5%
Medicaid	3.5%
Commercial Insurance	10.8%
Medicare/Commercial	21.0%
Medicare/Medicaid	24.6%
VA	9.6%
Total	100.00%

In Section L.1(b), page 50, the applicant provides the assumptions used to project payor mix, stating that the payor mix is based on the sources of patient payment that have been received by DaVita operated facilities in Alamance County during the last full operating year. The applicant's projected payment sources in Section L are consistent with the facility's projected (CY2019) payment sources as reported by the applicant in Section R. The applicant demonstrates that medically underserved groups will have adequate access to the services offered at Elon Dialysis. Therefore, 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.

 \mathbf{C}

In Section L.4, page 52, the applicant describes the range of means by which a person will have access to the dialysis services at Elon Dialysis, stating that a patient must have a referral from a nephrologist with privileges at the facility. Exhibit I-3 contains support letters from area physicians stating their intent to refer patients to the proposed facility. The applicant adequately demonstrates that the facility will offer a range of means by which patients will have access to dialysis services. Therefore, 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.

 \mathbf{C}

In Section M.1, page 54, the applicant states that it has offered the proposed facility as a clinical learning site for nursing students from Alamance Community College. Exhibit M-1 contains a copy of correspondence from DaVita to Alamance Community College offering

the proposed facility as a clinical training site. The information provided is reasonable and adequately supports a determination that 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.

 \mathbf{C}

The applicant proposes to develop Elon Dialysis, a new 10-station Alamance County dialysis facility, by relocating eight certified dialysis stations from Burlington Dialysis and two certified dialysis stations from North Burlington Dialysis.

On page 369, the 2016 SMFP defines the service area for dialysis stations as "the 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 is Alamance County. Facilities may serve residents of counties not included in their service area.

The applicant operates two existing dialysis centers in Alamance County and, as of December 31, 2015, has been approved to establish a third, Graham Dialysis [Alamance County Dialysis], Project I.D. #G-10265-14. Bio-Medical Applications of North Carolina, Inc. (BMA) is the only other provider of dialysis services in Alamance County, and operates two dialysis centers, as shown in the table below.

Alamance County Dialysis Facilities Certified Stations and Utilization as of December 31, 2015

Dialysis Facility	Certified Stations 12/31/15	# In-center Patients	Percent Utilization	Patients/ Station
BMA Burlington (BMA)	45	102	56.67%	2.27
Burlington Dialysis (DaVita)	26	101	97.12%	3.88
Carolina Dialysis – Mebane (BMA)	12	49	102.08%	4.08
Graham [Alamance County] Dialysis (DaVita)	0	0		
North Burlington Dialysis (DaVita)	16	69	107.81%	4.31

Source: July 2016 SDR

As shown in the table above, the DaVita Alamance County dialysis facilities are operating far above 80% utilization (3.2 patients per station), and one of the BMA facilities is operating above 100% utilization. Graham [Alamance County] Dialysis was approved in Project I.D. #G-10265-14, but not certified as of December 31, 2015.

In Section N.1, page 55, the applicant discusses how any enhanced competition will have a positive impact on the cost-effectiveness, quality and access to the proposed services. The applicant states:

"The proposed facility will not have an adverse effect on competition with any dialysis facilities located in Alamance County or in counties contiguous to it 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.

The bottom line is Elon 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. Patient selection is the determining factor, as the patient will select the provider that gives them the highest quality service and best meets their needs."

See also Sections B, C, E, F, H, I, L, and N in the application, where the applicant discusses the impact of the project on cost-effectiveness, quality and access.

The information in the application is reasonable and adequately demonstrates that any enhanced competition in the service area includes a positive impact on the cost-effectiveness, quality and access to the proposed services. This determination is based on the information in the application and the following analysis:

• The applicant adequately demonstrates the need for the project and that it is a costeffective alternative. The discussions regarding the analysis of need, including projected utilization, and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.

- The applicant adequately demonstrates it will provide quality services. The discussion regarding quality found in Criterion (20) is incorporated herein by reference.
- The applicant demonstrates that it will provide adequate access to medically underserved populations. The discussions regarding access found in Criteria (3) and (13) are incorporated herein by reference.

Therefore, the application is conforming to this criterion.

- (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.

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In Exhibit O-3, the applicant identifies four kidney disease treatment centers (out of a total of 67) located in North Carolina, owned and operated by the applicant, that were cited in the past 18 months for deficiencies in compliance with 42 CFR Part 494, the Centers for Medicare and Medicaid (CMS) Conditions for Coverage of ESRD Facilities. In Section O.3(c), page 56, the applicant states, "Each facility is currently in compliance." Exhibit O-3 contains copies of letters documenting that the facilities were determined to be back in compliance by the Centers for Medicare and Medicaid Services and the Division of Health Service Regulation. Based on a review of the certificate of need application and publicly available data, the applicant adequately demonstrates that it has provided quality care during the 18 months immediately preceding the submittal of the application through the date of the decision. 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.

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The application is conforming with all applicable Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200. The specific criteria are 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, the applicant adequately demonstrates the need to establish the proposed 10-station Elon Dialysis facility by relocating 10 existing Alamance County dialysis stations to the proposed facility. At the end of the first operating year, CY2018, the applicant projects Elon Dialysis will serve 33 patients for a utilization of 3.3 patients per station per week. The discussion regarding analysis of need, including projected utilization, 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.
- -NAThe applicant is not 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. The applicant is seeking to develop a new 10-station dialysis facility in Alamance County by relocating existing Alamance county dialysis stations.
- .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 for the proposed facility. The discussion regarding analysis of need, including projected utilization, found in Criterion (3) is incorporated herein by reference.