

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: May 23, 2014
PROJECT ANALYST: Celia C. Inman
INTERIM CHIEF: Martha J. Frisone

PROJECT I.D. NUMBER: G-10265-14 / Renal Treatment Centers Mid-Atlantic, Inc. d/b/a Graham Dialysis / Develop 10 station dialysis facility by relocating 8 dialysis stations from Burlington Dialysis Center and 2 stations from North Burlington Dialysis Center / Alamance County

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

CA

Renal Treatment Centers Mid-Atlantic, Inc. d/b/a Graham Dialysis proposes to establish a new 10-station Kidney Disease Treatment Center which will be certified as an end-stage renal disease (ESRD) facility to provide in-center hemodialysis and home training for peritoneal dialysis and home hemodialysis. The proposed facility will be located in Graham, Alamance County. The applicant proposes to relocate eight existing dialysis stations from Burlington Dialysis Center and two existing dialysis stations from North Burlington Dialysis Center to establish the new facility. Both existing facilities are also located in Alamance County.

This application proposes to relocate dialysis stations from existing in-county dialysis facilities to a new Alamance County ESRD facility. Therefore, neither the county need nor the facility need methodologies in the 2014 SMFP are applicable to this review. Additionally, Policy GEN-3: BASIC PRINCIPLES is not applicable because neither need methodology is applicable to the review.

However, Policy GEN-4: ENERGY EFFICIENCY AND SUSTAINABILITY FOR HEALTH SERVICE FACILITIES is applicable because the applicant is proposing a capital expenditure greater than \$2 million. On page 38 of the 2014 State Medical Facilities Plan (SMFP), Policy GEN-4 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, the Certificate of Need Section 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 are required to submit a plan of 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.”

In Section I.14, page 9 of the application, the applicant states, “Response to Policy Gen-4: Not Applicable” In Section XI. 6(d), page 62, the applicant states:

“The facility will be constructed with energy-efficient glass, mechanically operated patient access doors and energy-efficient cooling and heating.”

On page 63, the applicant states:

“The facility will be located in an area that is supplied by potable city water. Exhibit 21 of the application contains documentation of availability of water and sewer services and the policies and procedures that will be in place so that the facility will comply with 42 C.F.R. Section 405 .2100. The facility will modify the existing water by providing for dechlorinization, softening, reverse osmosis water systems combined with pyrogen filters for bacteria removal.”

As stated above, Policy GEN-4, specifically the first paragraph of the policy, is applicable to this project. The few mentions in the application of energy-efficiency and

water consumption, as shown above, are not sufficient to be considered “*the project’s plan to assure improved energy efficiency and water conservation.*” Therefore, the application is not consistent with this policy.

Additionally, Policy ESRD-2: RELOCATION OF DIALYSIS STATIONS 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 currently served by the facility. Certificate of Need applicants proposing to relocate dialysis stations shall:

- (A) Demonstrate that the proposal shall not result in a 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 Dialysis Report, and*
- (B) Demonstrate that the proposal shall not result in a surplus of dialysis stations in the county that would gain stations as a result of the proposed project, as reflected in the most recent Dialysis Report.”*

In this application, the applicant proposes to relocate 10 certified dialysis stations within Alamance County, creating a new ESRD facility. The applicant states the project will enhance geographical accessibility of dialysis service for Alamance County patients. The project is scheduled for completion in December 2015. The applicant proposes to relocate dialysis stations between facilities within the same county. Consequently, there is no change in dialysis station inventory in Alamance County. The application is consistent with Policy ESRD-2 in the 2014 SMFP.

In summary, the application is consistent with Policy ESRD-2 but does not demonstrate consistency with Policy GEN-4. Therefore the application is conforming to this criterion, subject to the following condition:

Prior to issuance of the certificate of need, Renal Treatment Centers Mid-Atlantic, Inc. d/b/a Graham Dialysis shall provide the CON Section with the project’s plan to assure improved energy efficiency and water conservation.

- (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

The applicant, Renal Treatment Centers Mid-Atlantic, Inc. d/b/a Graham Dialysis proposes to relocate 10 existing Alamance County dialysis stations to develop Graham Dialysis, a new dialysis facility in Alamance County. The applicant proposes to relocate eight certified dialysis stations from Burlington Dialysis Center and two certified stations from North Burlington Dialysis Center.

Burlington Dialysis Center received conditional approval in December 2013 to add six certified dialysis stations for a total of 26 certified stations upon project completion. The stations received certification on March 14, 2014. The January 2014 SDR shows the stations pending and a June 30, 2013 utilization rate of 96.25% on its 20 operational stations.

The July 2013 SDR shows the North Burlington Dialysis Center with 10 certified stations and two pending certification in June 2013. The two pending stations were certified prior to the January 2014 SDR for a total of 12 certified stations. The North Burlington facility was conditionally approved in December 2013 to add one certified dialysis station for a total of 13 certified stations upon project completion. The additional station received certification on March 14, 2014. The January 2014 SDR shows the station pending and a June 30, 2013 utilization rate of 115.00% on the 10 certified stations.

In Section I, pages 2-3, the applicant states the proposed project will require the up-fit of a building shell, hiring and training of teammates and the purchase of equipment needed to operate an ESRD facility. The project also includes the relocation of the home peritoneal training and support program that is currently housed in the North Burlington Dialysis Center. The proposed project does not impact Alamance County's total inventory of dialysis stations.

Population to be Served

In Section 111.7, page 26, the applicant identifies the patient population it proposes to serve for the first two years of operation following project completion, as illustrated in the table below:

Projected Dialysis Patient Origin

COUNTY	OPERATING YEAR 1 2016		OPERATING YEAR 2 2017		COUNTY PATIENTS AS A PERCENT OF TOTAL	
	IN-CENTER	HOME	IN-CENTER	HOME	YEAR 1	YEAR 2
Alamance	32	26	34	28	100.0%	100.0%
Total	32	26	34	28	100.0%	100.0%

In Section III, page 26, the applicant states:

“Thirty-one patients who currently receive their dialysis treatments at the Burlington and North Burlington facilities in Alamance County have signed letters of support for the proposed Graham Dialysis facility. All of the patients have indicated in their letters that they live closer to the proposed Graham facility and that the facility will be more convenient for them.

Based on these letters, Graham Dialysis will have at least 31 in-center ESRD patients dialyzing in the facility January 1, 2016, which is projected to be the beginning of the first year of operation. These 31 patients are projected to transfer from the Burlington and North Burlington facilities. The facility is projected to have 32 in-center patients by the end of operating year one based on the current Average Annual Change Rate for the Past Five Years that is cited in the January 2014 Semiannual Dialysis Report in Table B: ESRD Dialysis Station Need Determination by Planning Area. This meets the requirement that at the end of the first operating year the facility shall have at least 32 patients or 3.2 patients per station, which documents the need for at least 10 stations.”

Exhibit 24 contains letters from 50 Burlington and North Burlington dialysis facility patients indicating a willingness to transfer to Graham Dialysis for their dialysis treatments. The following table shows the breakdown of letters by type of dialysis and facility in which the patient is currently dialyzing.

Total Number Support Letters Indicating a Willingness to Transfer to Graham Dialysis

Current Facility	In-center Hemodialysis	Home Training
North Burlington Dialysis Center	12	9
Burlington Dialysis Center	20	9
Total	32	18

The applicant appears to have made a typographical error in the support/transfer form letter used by the home training patients that indicated that they received their home training and support services at Burlington Dialysis Center. Obviously, because Burlington Dialysis Center does not provide home training services, those patients did not receive home training services at Burlington Dialysis Center. However, the point of the letters is still pertinent and credible. The patients are Alamance County patients who are willing to receive their home training services at the proposed Graham Dialysis facility.

The applicant adequately identified the population it proposes to serve.

Demonstration of Need

Graham Dialysis proposes to relocate 10 existing dialysis stations within Alamance County, eight from Burlington Dialysis Center and two from North Burlington Dialysis Center, to Graham Dialysis, a new dialysis facility. The January 2014 SDR shows four certified dialysis facilities operating in Alamance County. Three of the existing facilities are located in Burlington with one located in Mebane. The applicant is proposing to establish the new facility in Graham. Graham and Burlington are contiguous and located roughly in the center of the county.

In Section III, page 22, the applicant states that Renal Treatment Centers has analyzed the patient data and determined that there are at least 31 in-center patients in the Graham, Mebane, Haw River and Swepsonville areas of Alamance County that live closer to the proposed Graham facility. The applicant further states it analyzed the county population to determine other areas with a significant patient population and found none, other than Burlington and those listed above. In Section III, pages 20 and 26, the applicant states that 31 patients receiving dialysis treatments at the Burlington and North Burlington facilities have signed letters of support for the proposed dialysis facility in Graham. The support letters acknowledged the patients live closer to the Graham facility and indicate a willingness to consider transferring to the Graham facility.

In several areas of the application, including Section III, page 20, the applicant projects that the 10 stations to be relocated to Graham Dialysis Center will be utilized at 81.5% of capacity by December 31, 2016, the end of the first year of operation following the relocation of the 10 stations ($32.58 \text{ patients} / (4 \times 10) = 81.5\%$).

In Section III.3, pages 19-22, the applicant provides the assumptions and methodology it used to project the proposed in-center patient utilization of the proposed Graham Dialysis facility, and the existing Burlington and North Burlington facilities, before and after the proposed relocation of the 10 dialysis stations. They are summarized below.

- The Burlington Dialysis Center has 26 certified stations and 77 ESRD in-center patients per the January 2014 SDR.
- There are currently 17 in-center dialysis patients dialyzing at Burlington Dialysis Center *“who live in Graham (13), Mebane (3) and Swepsonville (1). A new facility in Graham will offer these patients the opportunity to receive their dialysis services closer to home and be more convenient.”*
- The applicant proposes to relocate eight stations and transfer 17 in-center patients to Graham Dialysis from Burlington Dialysis Center.
- The North Burlington Dialysis Center, a relatively new facility, currently has 13 certified dialysis stations with 46 ESRD in-center dialysis patients per the January 2014 SDR.
- There are currently 15 in-center dialysis patients dialyzing at North Burlington *“who live in Graham (7), Mebane (6) and Haw River (2) who live closer to the proposed site of Graham Dialysis.”*

- The applicant proposes to relocate two stations and transfer 14 in-center patients to Graham Dialysis from North Burlington Dialysis Center.
- The January 2014 SDR shows the Alamance County ESRD patient five-year average annual change rate of 0.051 (5.1% per year).
- The applicant states the home training center located at the North Burlington Dialysis Center does not provide enough space for the growing home-trained patient population.
- The applicant proposes to relocate the home training program and support from the North Burlington Dialysis Center to Graham Dialysis Center.
- January 1, 2016 – December 31, 2016 is the first operating year.
- January 1, 2017 – December 31, 2017 is the second operating year.

On page 21, regarding the existing Burlington Dialysis Center, the applicant states:

“With 17 in-center patients and eight dialysis stations transferring from the Burlington Dialysis Center to Graham Dialysis, this will leave 60 in-center patients and 18 dialysis stations at the Burlington Dialysis Center if we do not take into consideration any patient growth between June 30, 2013 and when Graham Dialysis is projected to be certified (January 1, 2016).”

However, we want to be conservative and project the maximum growth that the population of the Burlington Dialysis Center will experience because by doing this we will account for all of the potential growth of that population over the entire period from the data presented in the most recent Semiannual Dialysis Report through the point when the station transfer will occur and Graham Dialysis opens. We have projected the growth of the entire current patient population at the Burlington Dialysis Center by projecting the growth from the date of the most recent data, which is June 30, 2013. Taking into consideration that the Burlington Dialysis Center had 77 in-center patients as of June 30, 2013 and that Alamance County had an Average Annual Change Rate for the Past Five Years of 5.1%, we have projected the growth in the patient population from July 1, 2013 to the date Graham Dialysis is projected to be certified.”

On page 22, regarding the North Burlington Dialysis Center, the applicant states:

“With 14 in-center patients and two dialysis stations transferring from the North Burlington Dialysis Center to Graham Dialysis, this will leave 32 in-center patients and 11 dialysis stations at the North Burlington Dialysis Center if we do not take into consideration any patient growth between June 30, 2013 and when Graham Dialysis is projected to be certified (January 1, 2016).”

However, we want to be conservative and project the maximum growth that the population of the North Burlington Dialysis Center will experience because by doing this we will account for all of the potential growth of that population over the entire period from the data presented in the most recent Semiannual Dialysis Report through the point when the station transfer will occur and

Graham Dialysis opens. We have projected the growth of the entire current patient population at the North Burlington Dialysis Center by projecting the growth from the date of the most recent data, which is June 30, 2013. Taking into consideration that the North Burlington Dialysis Center had 46 in-center patients as of June 30, 2013 and that Alamance County had an Average Annual Change Rate for the Past Five Years of 5.1%, we have projected the growth in the patient population from July 1, 2013 to the date Graham Dialysis is projected to be certified.”

Applying the methodology and assumptions outlined by the applicant above results in the following table which projects in-center patients from July 1, 2013 through December 31, 2017 for the existing facilities and the proposed facility:

	Burlington Dialysis Center (Existing)	North Burlington Dialysis Center (Existing)	Graham Dialysis (Proposed)
Number of Stations Before Relocation	26	13	0
Number of Stations to Be Relocated	(8)	(2)	10
Number of Stations After Relocation	18	11	10
Number of Patients June 30, 2013	77	46	0
Number of Patients Projected Forward to December 31, 2013, using the January 2014 SDR Alamance County Average Annual Change Rate (AAGR) of .051 / 2 for the 6-month period	$(77 \times (.051/2)) + 77 = 78.96$	$(46 \times (.051/2)) + 46 = 47.17$	0
Number of Patients Projected Forward to December 31, 2014 using the AAGR of .051	$(78.96 \times .051) + 78.96 = 82.99$	$(47.17 \times .051) + 47.17 = 49.58$	0
Number of Patients Projected Forward to December 31, 2015 using the AAGR of .051	$(82.99 \times .051) + 82.99 = 87.22$	$(49.58 \times .051) + 49.58 = 52.11$	0
Number of Patients to be Transferred	(17)	(14)	31
Number of Patients After Transfer	70	38	31
Number of Patients Projected Forward to December 31, 2016. using the AAGR of .051	$(70 \times .051) + 70 = 73.57$	$(38 \times .051) + 38 = 39.94$	$(31 \times .051) + 31 = 32.58$
Number of Patients Projected Forward to December 31, 2017. using the AAGR of .051	$(73.57 \times .051) + 73.57 = 77.32$	$(39.94 \times .051) + 39.94 = 41.97$	$(32.58 \times .051) + 32.58 = 34.24$

Note: the 2016 and 2017 census for Burlington and North Burlington assumes no increase in stations following the transfer of stations to Graham Dialysis, even though the applicant expresses intent to apply to increase the number of stations as quickly as facility need dictates.

The applicant applies the same methodology to project utilization of the home training and support program which will be relocated from North Burlington Dialysis Center in its entirety to Graham Dialysis. On page 27, the applicant states:

“There is limited space at both the Burlington Dialysis Center and North Burlington Dialysis Center to adequately provide home training services to the growing number of patients who are being trained for one of the home modalities.

...

The North Burlington Dialysis Center had 23 home-trained patients as of December 31, 2013. It is assumed that the 23 home-trained patients that were being trained or followed by the North Burlington Dialysis Center as of December 31, 2013 will continue to grow at a rate of at least 5.1%, which is the Alamance County five-year average annual change rate.”

The applicant projects home training patients as shown in the following table:

Number of home training patients as of December 31, 2013	23
North Burlington home training patients projected forward for 12 months to December 31, 2014, using the county AAGR of .051.	$(23 \times .051) + 23 = 24.17$
North Burlington home training patients projected forward for 12 months to December 31, 2015, using the county AAGR of .051.	$(24.17 \times .051) + 24.17 = 25.40$
January 1, 2016 – The applicant relocates the home training program to Graham Dialysis and projects forward for 12 months to December 31, 2016, using the county AAGR of .051	$(25.40 \times .051) + 25.4 = 26.70$
Graham Dialysis home training patients projected forward for 12 months to December 31, 201, using the county AAGR of .051	$(26.70 \times .051) + 26.70 = 28.06$

The applicant is proposing to relocate stations and transfer patients from the Burlington and North Burlington Dialysis Centers to Graham Dialysis. In Section IV, page 30, the applicant provides tables that indicate all patients at Burlington Dialysis Center and North Burlington Dialysis Center originate from Alamance County. That, however, is not the case. The June 30, 2013 patient origin information compiled by the Medical Facilities Planning Section shows that 66 of Burlington Dialysis Center’s patients are Alamance County patients and 11 are from various surrounding counties. The same report shows that 45 of 46 North Burlington Dialysis Center’s in-center patients and 21 of 23 home dialysis patients originate from Alamance County. The applicant proposes to transfer a portion of the Alamance County patients to the Graham facility.

Applying the applicant’s methodology above using the correct counties of origin and the applicable AAGR for each county results in no difference in the projected

utilization at Graham Dialysis and a negligible difference in the projected utilization at Burlington and North Burlington Dialysis Centers, with both centers maintaining an in-center patient utilization rate far above 80%.

As previously stated, the applicant is not proposing to add stations based on county or facility need, but rather to create a new facility through the in-county relocation of existing stations from existing facilities.

The applicant adequately demonstrates the need the population proposed to be served has for the relocation of the eight dialysis stations from Burlington Dialysis Center and the two dialysis stations from North Burlington Dialysis Center, along with their home training program to Graham Dialysis.

Access to Services

In Section VI, page 38, the applicant states,

“Graham Dialysis, by policy, will make dialysis services available to all residents in its service area without qualifications. We will serve patients without regard to race, sex, age, or handicap. We will serve patients regardless of ethnic and socioeconomic situation.

...

Graham Dialysis will not require payment upon admission to its services; therefore, services are available to all patients including low-income persons, racial and ethnic minorities, women, handicapped persons, elderly and other under-served persons.”

The applicant projects that 57.4% of its patients will be covered by Medicare or Medicaid and another 24.2% will be covered by Medicare/Commercial. The applicant adequately demonstrates 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. See Criteria (3a) and (13) for further discussion on access which is incorporated hereby as if set forth fully herein.

In summary, the applicant adequately identifies the population to be served, demonstrates the need that population has for the proposed project and the extent to which all residents of the area are likely to have access to the services proposed. 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.

C

The applicant proposes to relocate 10 dialysis stations, eight from Burlington Dialysis Center and two from North Burlington Dialysis Center, to establish a new 10-station ESRD facility in Graham to provide in-center dialysis and home training for peritoneal and home hemodialysis. All three facilities are located in Alamance County. After the relocation of stations, Burlington Dialysis will have 18 ($26 - 8 = 18$) certified dialysis stations remaining and North Burlington Dialysis will have 11 ($13 - 2 = 11$).

Once the relocation of stations and transfer of patients takes place, the applicant projects that the Burlington Dialysis Center utilization rate will be 97% (87 patients – 17 transferred to Graham Dialysis = 70 patients / 18 stations = $3.88 / 4 = 97.2$). The applicant projects the North Burlington Dialysis Center utilization rate will be 86% (52 patients – 14 transferred to Graham Dialysis = 38 patients / 11 stations = $3.45 / 4 = 86.3$). Throughout Section III, the applicant states plans to increase the number of stations at both Burlington centers as the increased facility utilization dictates.

In Section III.3, page 24, the applicant discusses its intent to apply for stations at the existing facilities, stating:

“However, Renal Treatment Centers Mid-Atlantic, Inc. d/b/a Burlington will be applying for additional in-center stations as the patient census grows during the development of Graham Dialysis. ... Therefore, based on the plan to apply for additional stations once the Burlington Dialysis Center reaches or exceeds 80% utilization during the development of the Graham facility, the needs of the patients remaining at the Burlington Dialysis Center will be adequately met. Additional Certificate of Need application(s) will be submitted based on facility need at the Burlington Dialysis Center until the facility reaches full capacity of stations.”

The applicant makes the same statement as above relative to the North Burlington Dialysis Center on page 25.

The applicant states it is also proposing to relocate the home training program currently located at North Burlington to Graham. On page 27, the applicant states:

“There is limited space at both the Burlington Dialysis Center and North Burlington Dialysis Center to adequately provide home training services to the growing number of patients who are being trained for one of the home modalities.”

The proposed Graham Dialysis facility will be located in central Alamance County. There are patients currently dialyzing at the Burlington and North Burlington Dialysis

Centers who live in the Graham, Mebane, Haw River and Swepsonville areas who will find the proposed Graham facility closer and more convenient as documented in the patient support letters found in Exhibit 24 of the application. However, the Burlington, North Burlington and Graham facilities are all fairly central to Alamance County. Because of the facilities' locations, the home training services at the proposed Graham facility will continue to be accessible to the Burlington and North Burlington patients and other Alamance County dialysis patients.

The applicant demonstrates that the needs of the population presently served at the Burlington Dialysis Center and North Burlington Dialysis Center will continue to be adequately met following the proposed relocation of dialysis stations and the home training program to Graham Dialysis. See discussion in Criterion (13) with regard to access by medically underserved groups which is incorporated hereby as if set forth fully herein. 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 III.9, page 28, the applicant discusses how it determined that proposing to relocate stations and transfer patients from Burlington Dialysis Center and North Burlington Dialysis Center to a new facility in Graham was the most effective and least costly alternative for meeting the needs of its Alamance County dialysis patients. The applicant states:

“We have analyzed the other areas of Alamance County and have determined that the area in and around Graham has more need for a dialysis center than any other area of the county at this time (31 patients living in that and traveling to the Burlington Dialysis Center and North Burlington Dialysis Center have signed letters of support for the development of a facility in Graham). We also analyzed where all of the other patients dialyzing at the Burlington Dialysis Center and North Burlington Dialysis Center in Alamance County live by mapping their addresses on Google Maps. Most of the other patients live a few minutes from the Burlington facilities. Therefore, those patients living in the Graham area would be better served with a facility located in Graham.

Renal Treatment Centers Mid-Atlantic studied appropriate alternatives to this application and concluded that developing a new facility in the Graham area is the best option.”

On page 28, the applicant lists cost-effective approaches proposed for Graham Dialysis, including the use of DaVita Corporate centralized purchasing and a national contract

for pricing, electronic patient charting, preventative maintenance by the facility bio-medical technician, and inventory control planning.

The applicant adequately demonstrates that the proposed alternative is the most effective or least costly alternative based on the following:

- Thirty-one current Burlington and North Burlington Dialysis Center patients have indicated they live closer to the proposed Graham facility and would consider transferring to that facility for their dialysis treatments.
- The facility will be a modern, state-of-the-art dialysis facility that will serve the needs of the ESRD dialysis patients living in the identified service area.
- Patients will not have to travel an unreasonable distance to dialyze.

Furthermore, the application is conforming or conditionally 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 and the conditions in Criteria (1) and 10A NCAC 14C .2202 (b)(5).

- 1. Renal Treatment Centers Mid-Atlantic, Inc. d/b/a Graham Dialysis shall materially comply with all representations made in the certificate of need application.**
- 2. Renal Treatment Centers Mid-Atlantic, Inc. d/b/a Graham Dialysis shall relocate and operate no more than a total of ten (10) certified dialysis stations which shall include any home hemodialysis training stations or isolation stations.**
- 3. After the certification of the ten (10) relocated dialysis stations at Graham Dialysis, Renal Treatment Centers Mid-Atlantic, Inc. d/b/a Burlington Dialysis Center shall take steps to decertify eight (8) dialysis stations for a total of no more than eighteen (18) certified stations at Burlington Dialysis Center and Renal Treatment Centers Mid-Atlantic, Inc. d/b/a North Burlington Dialysis Center shall take steps to decertify two (2) dialysis stations for a total of no more than eleven (11) certified stations at North Burlington Dialysis Center.**
- 4. Renal Treatment Centers Mid-Atlantic, Inc. d/b/a Graham Dialysis shall install plumbing and electrical wiring through the walls for no more than ten (10) dialysis stations which shall include any home training or isolation stations.**

5. Renal Treatment Centers Mid-Atlantic, Inc. d/b/a Graham Dialysis shall acknowledge acceptance of and agree to comply with all conditions stated herein to the 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.

C

In Section VIII, page 46, the applicant states, “*The cost of establishing the dialysis center is estimated to be \$2,172,477.*” In the table in Section VIII, page 47, the applicant shows the capital cost of the project includes \$1,466,500 in construction costs and \$705,977 for architect/engineering fees, dialysis machines, water treatment equipment, dialysis chairs, a television system, patient computer system and other equipment and furniture.

In Section IX.3, page 50, the applicant projects that there will be start-up expenses of \$145,610 and estimated initial operating expenses of \$1,178,709 for a total working capital of \$1,324,319 associated with the proposed project.

Exhibit 17 contains a letter from the Chief Accounting Officer of DaVita Healthcare Partners Inc. confirming DaVita’s commitment of cash reserves in the sum of \$3,496,796 for the capital and working capital needs of the project. DaVita’s Form 10-K in Exhibit 18 confirms the availability of said cash reserves on the consolidated balance sheet, page F-6.

Based on information provided by the applicant in Section X.1, page 52, the dialysis facility’s projected allowable charges per treatment for each payment source are as follows:

SOURCE OF PAYMENT	ALLOWABLE CHARGE PER TREATMENT
Medicare	\$240.00
Medicaid	\$143.00
Medicare/Medicaid	\$240.00
Commercial Insurance	\$1,175.00
VA	\$193.00
Medicare/Commercial	\$240.00

Based on the calculations presented in Section X.3, page 54, the facility reimbursement is as follows:

SOURCE OF PAYMENT	REIMBURSEMENT PER TREATMENT
Medicare	\$192.00
Medicaid	\$143.00
Medicare/Medicaid	\$240.00
Commercial Insurance	\$1,175.00
VA	\$193.00
Medicare/Commercial	\$240.00

The rates shown above are consistent with the standard Medicare/Medicaid rates established by the Centers for Medicare and Medicaid Services.¹ In Sections X.2-X.4, pages 53-57, the applicant reported projected revenues and expenses as follows:

	OPERATING YEAR 1	OPERATING YEAR 2
Total Net Revenue	\$ 2,846,890	\$ 2,997,388
Total Operating Costs	\$2,357,417	\$2,460,393
Net Profit	\$489,473	\$536,995

The applicant projects that revenues will exceed operating expenses in each of the first two operating years. The assumptions used in preparation of the pro formas, including the number of projected treatments, are reasonable. See Section X.3, page 55 of the application for the applicant's assumptions on number of treatments (3 days/week, 52 weeks/year with 5% missed treatments). On page 27, the applicant states,

“Note: The numbers of hemodialysis patients for operating year 1 and 2 will be used to determine the number of treatments, operating revenue and operating expenses. With a starting patient population of 31 and ending patient population of 32 in year 1, we used an average of 31.5 patients over the course of the year to determine the number of treatments and the associated operating revenue and expenses. Likewise, with a starting patient population of 32 in operating year 2 and ending patient population of 341, we used an average of 33 patients over the course of the year to determine the number of treatments and the associated operating revenue and expenses.” [Emphasis in original]

The total number of patients includes the number of patients in the in-center and home training and support modalities.

The applicant's projections of treatments and revenues are reasonable based on the number of in-center and home patients projected for the first two operating years. In Section VII.1, page 43 and Section X.5, page 58, the applicant provides projected staffing and salaries. The applicant states compliance with all staffing requirements in 42 C.F.R.

¹ http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/End-Stage_Renal_Disease_Pro prospective_Payment_System_ICN905143.pdf

Section 494 (formerly 405.2100). Staffing by shift is provided on page 45. The applicant provides adequate staffing to provide dialysis treatments for the number of patients projected.

In summary, the applicant adequately demonstrates the availability of sufficient funds for the capital and working capital needs of the project. The applicant also adequately demonstrates that the financial feasibility of the proposal is based on reasonable projections of revenues and operating costs. 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.

C

Renal Treatment Centers Mid-Atlantic, Inc. d/b/a Graham Dialysis proposes to relocate 10 in-center dialysis stations, eight from Burlington Dialysis Center and two from North Burlington Dialysis Center, to create a new 10 station dialysis facility in Graham, in central Alamance County. Burlington Dialysis Center and North Burlington Dialysis Center are certified for 26 and 13 dialysis stations, respectively, as of March 14, 2014. The applicant also proposes to relocate the North Burlington home-training program to the Graham Dialysis facility. The project will not change the total number of dialysis stations in Alamance County, but it will increase the number of facilities. The project results in the relocation of existing home training services but not the development of new services.

The applicant discusses projections for the in-center and home-training patient population in Section III, pages 19-22 of the application. At the end of Operating Year One, with 10 dialysis stations and 32.58 dialysis patients, the applicant projects Graham Dialysis utilization will be 3.25 in-center patients per station ($32.58 \text{ patients} / 10 \text{ dialysis stations} = 3.25$). The applicant projects 26 patients in the home training program at Graham Dialysis by the end of year one.

Once the relocation of stations and transfer of patients takes place, the applicant projects that the Burlington Dialysis Center utilization rate will be 97% ($87 \text{ patients} - 17 \text{ transferred to Graham Dialysis} = 70 \text{ patients} / 18 \text{ stations} = 3.88 / 4 = 97.2$). The applicant projects the North Burlington Dialysis Center utilization rate will be 86% ($52 \text{ patients} - 14 \text{ transferred to Graham Dialysis} = 38 \text{ patients} / 11 \text{ stations} = 3.45 / 4 = 86.3$). Throughout Section III, the applicant states plans to increase the number of stations at both Burlington centers as the utilization increases.

In Section III.3, page 24, the applicant discusses its intent to apply for stations at Burlington Dialysis Center, stating:

“However, Renal Treatment Centers Mid-Atlantic, Inc. d/b/a Burlington will be applying for additional in-center stations as the patient census grows during the

development of Graham Dialysis. ... Therefore, based on the plan to apply for additional stations once the Burlington Dialysis Center reaches or exceeds 80% utilization during the development of the Graham facility, the needs of the patients remaining at the Burlington Dialysis Center will be adequately met. Additional Certificate of Need application(s) will be submitted based on facility need at the Burlington Dialysis Center until the facility reaches full capacity of stations.”

The applicant makes the same statement as above relative to the North Burlington Dialysis Center on page 25.

According to the January 2014 SDR, Alamance County has four dialysis centers, as shown in the table below.

ALAMANCE COUNTY DIALYSIS CENTERS		
FACILITY	LOCATION	UTILIZATION
BMA Burlington	Burlington	64.44%
Burlington Dialysis	Burlington	96.25%
FMC Mebane (Carolina Dialysis – Mebane)	Mebane	85.00%
North Burlington Dialysis	Burlington	115.00%

The table above shows that both Burlington Dialysis and North Burlington Dialysis are operating at above 95% utilization.

The applicant adequately demonstrates the need to relocate 10 dialysis stations to create Graham Dialysis based on the projected number of in-center patients willing to transfer from Burlington Dialysis Center and North Burlington Dialysis Center to the proposed Graham facility, closer to their homes. The total number of dialysis stations in Alamance County will not change as a result of this project. The applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of existing or approved dialysis facilities or stations in Alamance County. Consequently, 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.

C

The following table illustrates the projected staffing for Graham Dialysis, as provided by the applicant in Section VII.1, page 43.

Position	Total FTE Positions
RN	1.5
HTRN	1.0
PCT	4.5
Bio-Med Tech	0.3
MD	0.0
Admin	1.0
Dietician	0.5
Social Worker	0.5
Unit Secretary	1.0
Total	10.3

As shown in the above table, the applicant proposes to employ a total of 10.3 full-time equivalent (FTE) positions to staff the Graham Dialysis facility upon completion of the proposed project. The Medical Director is a contract position. In Section VII.1, pages 43-44, the applicant states,

“The Regional Operations Director is responsible for the overall operation of the facility and serves as liaison to the governing body. She is also responsible for ensuring compliance with 42 C.F.R. and budgetary compliance.

...

The UA is responsible for the quality dialysis care for all patients in the facility on a daily basis through planning and staff scheduling. The UA ensures that patients are properly assessed through physician rounds, patient monitoring and charting. The UA also ensures that direct patient care is provided. The UA also supervises orientation and training of new staff and ensures that staff members adhere to facility policies and procedures”

The following table shows the projected number of direct care staff for each shift offered in the Graham Dialysis facility after the relocation of the 18 stations.

	Shift Times	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
Morning	6am to 11am	3	3	3	3	3	3
Afternoon	11am to 4pm	3	3	3	3	3	3
Evening	N/A	0	0	0	0	0	0

In Section V.4, page 35, the applicant states that Dr. Munsoor Lateef of Central Carolina Kidney Associates, P.A. will serve as Medical Director of the proposed facility. Exhibit 12 contains a letter signed by Dr. Lateef expressing support for the dialysis station and home training program relocation project and agreeing to be the Medical Director for the new facility.

The applicant documents the availability of adequate health manpower and management personnel, including the medical director, for the provision of dialysis 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.

C

In Section V.1, page 33, the applicant provides a list of providers of the necessary ancillary and support services. Acute dialysis in an acute care setting, emergency care, diagnostic evaluation services, X-ray services, blood bank and vascular surgery will be provided by Alamance Regional Medical Center. Exhibit 9 contains a letter from the Alamance Regional Medical Center Director of Nursing and Patient Services agreeing to enter into a transfer agreement to provide Graham Dialysis patients with the above services. Carolinas HealthCare System wrote a letter provided in Exhibit 10 in which it agrees to enter into a Transplant Agreement with Graham Dialysis. Exhibit 12 contains a letter from Central Carolina Kidney Associate Munsoor Lateef, MD, expressing support for the proposed project. Exhibit 24 contains letters of support from Alamance County ESRD patients. 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 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

NA

- (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.

C

The applicant proposes to lease a 10,800 square foot dialysis facility, with 274 square feet per dialysis station, to be developed by Hill/Gray Seven, LLC. In Section VIII.1, page 47, the applicant provides a cost breakdown showing construction costs of \$1,466,500 and \$115,000 in architect and engineering fees. In Section XI.6 (d), page 62, the applicant states the facility will be constructed with energy-efficient glass, mechanically operated patient access doors and energy-efficient cooling and heating.

The applicant adequately demonstrates that the cost, design and means of construction represent the most reasonable alternative, and that the construction cost will not unduly increase costs and charges for health services. See Criterion (5) for discussion of costs and charges which is incorporated hereby as if set forth fully herein. 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;

C

In Section VI.1(a), page 38, the applicant states Graham Dialysis, by policy, will make dialysis services available to all residents in its service area without qualifications.

In Section VI.1(b), page 38, the applicant reports that 78.6% and 86.4% of the patients who received treatments at Burlington Dialysis Center and North Burlington Dialysis Center, respectively, had some or all of their services paid for by Medicare or Medicaid in the past year. The table below illustrates the historical payment source for the existing facilities:

BURLINGTON DIALYSIS CENTER PAYOR MIX	
SOURCE OF PAYMENT	PERCENTAGE
Medicare	31.70%
Medicaid	3.10%
Medicare/Medicaid	17.30%
Commercial Insurance	15.30%
VA	6.10%
Medicare/Commercial	26.50%
Total	100.0%

NORTH BURLINGTON DIALYSIS CENTER PAYOR MIX	
SOURCE OF PAYMENT	PERCENTAGE
Medicare	25.40%
Medicaid	8.50%
Medicare/Medicaid	32.20%
Commercial Insurance	8.50%
VA	5.10%
Medicare/Commercial	20.30%
Total	100.0%

The Division of Medical Assistance (DMA) maintains a website which offers information regarding the number of persons eligible for Medicaid assistance and estimates of the percentage of uninsured for each county in North Carolina. The following table illustrates those percentages for Alamance County and statewide.

	2010 Total # of Medicaid Eligibles as % of Total Population *	2010 Total # of Medicaid Eligibles Age 21 and older as % of Total Population *	2009 % Uninsured (Estimate by Cecil G. Sheps Center) *
Alamance County	16%	6.2%	21.0%
Statewide	17%	6.71%	19.7%

*More current data, particularly with regard to the estimated uninsured percentages, was not available.

The majority of Medicaid eligibles are children under the age of 21. This age group does not utilize the same health services at the same rate as older segments of the population, particularly the dialysis services offered by Graham Dialysis. In fact, in 2012 only 6.5% of all newly-diagnosed ESRD patients in North Carolina's Network 6 were under the age of 35 (*ESRD Network 6 2012 Annual Report/Data Table 1: ESRD Incidence – One Year Statistics as of 01/01/2012 – 12/21/2012*, page 74).

The Office of State Budget & Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina. In addition, data is available by age, race or gender. 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 or women utilizing health services. Furthermore, OSBM's website does not include information on the number of handicapped persons.

Additionally, The United States Renal Data System, in its *2013 USRDS Annual Data Report*, pages 216-223, provides the following national statistics for FY 2011:

*“The December 31, 2011 prevalent population included 430,273 patients on dialysis ...”*² (p. 216)

The report also provided the incidence of dialysis patients in 2011, adjusted by age, gender and race, which showed that 65.4% were White, 28.0% were African American, 15.0% were Hispanic, 4.7% were Asian, and 1.2% were Native American (p. 218). Moreover, the prevalence of ESRD for the 65-74 year old population grew by 31% since 2000 and by 48% for those aged 75 and older (p. 216). The report further states:

“In the 2011 prevalent population, 84 percent of hemodialysis patients and 81 percent of those on peritoneal dialysis had some type of primary Medicare coverage, compared to just 53 percent of those with a transplant.”(p. 216)

The report states that the overall Medicare expenditures for chronic kidney disease for 2011 were \$49.2 billion, including Medicare Part D (p. 118). The 2013 USRDS Annual Data Report provides 2011 ESRD spending by payor, as follows:

² www.usrds.org/adr.aspx

ESRD SPENDING BY PAYOR*		
PAYOR	SPENDING IN BILLIONS	% OF TOTAL SPENDING
Medicare Paid	\$30.7	62.4%
Medicare Patient Obligation	\$4.7	9.6%
Medicare HMO	\$3.6	7.3%
Non-Medicare	\$10.2	20.7%
TOTAL	\$49.2	100.0%

*Source: 2013 United States Renal Data System (USRDS) Annual Data Report, page 327.

The Southeastern Kidney Council (SKC) Network 6 2012 Annual Report provides prevalence data on North Carolina ESRD patients by age, race and gender on page 76, summarized as follows:

Number and Percent of Dialysis Patients by Age, Race and Gender 2012		
	# of ESRD Patients	% of Dialysis Population
Ages		
0-19	73	0.5%
20-34	751	5.0%
35-44	1,442	9.7%
45-54	2,644	17.7%
55-64	4,013	26.9%
65+	5,995	40.2%
Gender		
Female	6,692	44.9%
Male	8,226	55.1%
Race		
African American	9,346	62.7%
White/Caucasian	5,191	34.8%
Other	380	2.6%

Source: Southeastern Kidney Council (SKC) Network 6.
 Table includes North Carolina statistics only.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;

³ www.esrdnetwork6.org/publications/reports.html

C

In Section VI.1(f), page 40, the applicant states,

“Graham Dialysis will have 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. Graham Dialysis will have no obligation under the Hill Burton Act.”

In Section VI.6 (a), page 42, the applicant states, *“There have been no civil rights access complaints filed within the last five years.”*

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 VI.1(c), page 39, the applicant provides the projected payor mix for the proposed services at the new facility as follows:

GRAHAM DIALYSIS PROJECTED PAYOR MIX	
SOURCE OF PAYMENT	PERCENTAGE
Medicare	29.40%
Medicaid	5.10%
Medicare/Medicaid	22.90%
Commercial Insurance	12.70%
VA	5.70%
Medicare/Commercial	24.20%
Total	100.00%

The applicant projects Graham Dialysis payor mix by consolidating the payor mixes of the in-center patient population of the existing Renal Treatment Centers Mid-Atlantic facilities located in Alamance County.

In Section VI.1(a), page 38, the applicant states,

“Graham Dialysis will not require payment upon admission to its services; therefore, services are available to all patients including low

income persons, racial and ethnic minorities, women, handicapped persons, elderly and other under-served persons.”

The applicant demonstrates that medically underserved populations will have adequate access to the proposed services. 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.

C

In Section VI.5, page 41, the applicant states:

*“Patients with End Stage Renal Disease have access to dialysis services upon referral by a Nephrologist with privileges at Graham Dialysis. Graham Dialysis will grant privileges to all qualified nephrologists. Referrals to nephrologists most commonly come from primary care physicians or specialty physicians in Alamance and surrounding counties or transfer referrals from other Nephrologists outside of the immediate area. Patients, families and friends can obtain access by contacting a Nephrologist with privileges at the facility. Should a patient contact the facility directly or indirectly, the patient will be referred to a qualified Nephrologist for evaluation and subsequent admission if found to be medically necessary. Patients from outside the facility catchment area requesting transfer to this facility will be processed in accordance with the facility transfer and transient policies which comprise **Exhibit 13**. [Emphasis in original.] The patient, again, will be referred to a qualified Nephrologist for final evaluation and then admission based on a doctor’s orders.”*

The applicant adequately demonstrates that it provides a range of means by which a person can access the proposed 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.

C

In Section V.3, page 35, the applicant states,

“Graham Dialysis will be offered as a clinical learning site for nursing students at the local community colleges and nursing programs. ... Graham Dialysis will be open to developing relationships with any program that offers clinical training programs.”

The applicant further states that Exhibit 11 contains a letter from the DaVita Director of Healthcare Planning indicating Graham Dialysis’ interest in establishing a relationship with Alamance Community College. 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

The applicant proposes to develop a new 10-station dialysis facility in Graham, Alamance County by relocating eight existing dialysis stations from Burlington Dialysis Center and two existing dialysis stations from North Burlington Dialysis Center to Graham Dialysis. According to the January 2014 SDR, Alamance County has four dialysis centers, as shown below:

ALAMANCE COUNTY DIALYSIS CENTERS		
FACILITY	LOCATION	UTILIZATION
BMA Burlington	Burlington	64.44%
Burlington Dialysis	Burlington	96.25%
FMC Mebane (Carolina Dialysis - Mebane)	Mebane	85.00%
North Burlington Dialysis	Burlington	115.00%

In Section V.7, pages 36-37, the applicant discusses how any enhanced competition in the service area will promote cost-effectiveness, quality and access to the proposed services. The applicant states:

“The development of Renal Treatment Centers Mid-Atlantic d/b/a Graham Dialysis will have no effect on any dialysis facilities located in Alamance County or in counties contiguous to Alamance County. Fresenius Medical Care operates two facilities in Alamance County. One facility is located in Burlington and the other in Mebane. Each provider has their own source of referrals from Nephrologists. The Nephrologists associated with the Renal Treatment Centers Mid-Atlantic Burlington Dialysis Center and the North Burlington Dialysis Center refer patients to the two facilities. These Nephrologists maintain their practice offices in Alamance County.

The Nephrologists associated with the two Fresenius facilities in Alamance County make referrals to their facilities. Each provider has their own and different source of patient referrals.

The proposed Graham Dialysis will not have an adverse effect on competition since the patients already being served by Renal Treatment Centers Mid-Atlantic will be transferring their care from one RTC facility to another RTC facility, which will be more convenient for the patients who have indicated this in the letters they signed.

...

Bottom line, Graham 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.”

See also Sections II, III, V, VI and CII where the applicant discusses the impact of the project on cost-effectiveness, quality, and access.

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

- The applicant adequately demonstrates the need for the proposed project and that it is a cost-effective alternative;
- The applicant adequately demonstrates that it will continue to provide quality services; and
- The applicant demonstrates that it will continue to provide adequate access to medically underserved populations.

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.

C

Renal Treatment Centers Mid-Atlantic provides dialysis services at Burlington Dialysis Center and North Burlington Dialysis Center in Alamance County. According to the Acute and Home Care Licensure and Certification Section, Division of Health Service Regulation, both facilities operated in compliance with the Medicare Conditions of Participation within the 18 months immediately preceding the date of this decision. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.

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

CA

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

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

.2202 INFORMATION REQUIRED OF APPLICANT

(a) *An applicant that proposes to increase dialysis stations in an existing certified facility or relocate stations must provide the following information:*

(1) *Utilization rates;*

-C- In Section II.1, page 10, the applicant states the utilization rate is reported in the January 2014 SDR provided in Exhibit 7 and addressed in Section IV.1.

The January 2014 SDR Burlington Dialysis Center utilization rate of 96.25% was calculated based on 77 in-center dialysis patients and 20 certified dialysis stations as of June 30, 2013 (77 patients / 20 stations = 3.85 patients per station; 3.85 patients per station / 4.00 patients per station = 96.25%). Burlington Dialysis Center had six approved dialysis stations pending certification as of June 30, 2012. These dialysis stations have since been certified for a Burlington Dialysis Center total of 26 certified stations.

The January 2014 SDR North Burlington Dialysis Center utilization rate of 115% was calculated based on 46 in-center dialysis patients and 10 certified dialysis stations as of June 30, 2013 (46 patients / 10 stations = 4.6 patients per station; 4.6 patients per station / 4.00 patients per station = 115%). The North Burlington facility had two additional stations pending certification on June 30, 2013. Those two stations were shown as certified in the January 2014 SDR for a total of 12 certified stations as of December 31, 2013. The January 2014 SDR also shows one additional station pending certification. That station has since been certified for a North Burlington Dialysis Center total of 13 certified stations.

(2) *Mortality rates;*

- C- In Section IV.2, pages 30-31, the applicant reports the 2011, 2012 and 2013 Burlington Dialysis Center facility mortality rates as 9.1%, 14.6% and 12.4%, respectively. The applicant reports the 2012 and 2013 North Burlington Dialysis Center facility mortality rates as 11.1% and 10.8%, respectively. The North Burlington facility was not operational in 2011.

(3) *The number of patients that are home trained and the number of patients on home dialysis;*

- C- In Section IV.3, page 31, the applicant states:

“Burlington Dialysis Center has an agreement with the North Burlington Dialysis Center to provide home training services.

...

North Burlington Dialysis Center had 23 home-trained patients as of December 31, 2013.”

(4) *The number of transplants performed or referred;*

- C- In Section IV.4, page 31, the applicant states:

“Burlington Dialysis Center had two patients receive a transplant in 2013. Thirteen patients were referred for transplant evaluation in 2013.

...

North Burlington Dialysis Center had no patients receive a transplant in 2013. Eight patients were referred for transplant evaluation in 2013.”

(5) *The number of patients currently on the transplant waiting list;*

-C- In Section IV.5, page 31, the applicant states:

“Burlington Dialysis Center has seven patients on the transplant waiting list.

...

North Burlington Dialysis Center has six patients on the transplant waiting list.”

(6) *Hospital admission rates, by admission diagnosis, i.e., dialysis related versus non-dialysis related;*

-C- In Section IV.6, page 32, the applicant states that there were 136 hospital admissions in 2013 for Burlington Dialysis Center, 24 (17.6%) of which were dialysis related and 112 (82.4%) non-dialysis related. The applicant further states that North Burlington Dialysis Center had 64 hospital admissions in 2013, 11 (17.2%) of which were dialysis related and 53 (82.8%) non-dialysis related.

(7) *The number of patients with infectious disease, e.g., hepatitis, and the number converted to infectious status during last calendar year.*

-C- In Section IV.7, page 32, the applicant states that there were no patients dialyzing at Burlington or North Burlington Dialysis Centers with AIDS and no patients with Hepatitis B, as of December 31, 2013. The number of patients treated with infectious disease who have converted to infectious status within the last year is zero for both facilities.

(b) *An applicant that proposes to develop a new facility, increase the number of dialysis stations in an existing facility, establish a new dialysis station, or relocate existing dialysis stations shall provide the following information requested on the End Stage Renal Disease (ESRD) Treatment application form:*

(1) *For new facilities, a letter of intent to sign a written agreement or a signed written agreement with an acute care hospital that specifies the relationship with the dialysis facility and describes the services that the hospital will*

provide to patients of the dialysis facility. The agreement must comply with 42 C.F.R., Section 405.2100.

- C- Exhibit 9 contains a signed letter of intent from Alamance Regional Medical Center agreeing to enter into a Patient Transfer Agreement with Graham Dialysis and to provide the following services to patients receiving their dialysis treatments at Graham Dialysis:

- Acute Dialysis
- Emergency Room Care
- Diagnostic Evaluation Services
- X-ray Services
- Special, Immunological and Routine Laboratory Services
- Blood Banking Services
- Surgical Services including Vascular Surgery

- (2) *For new facilities, a letter of intent to sign a written agreement or a written agreement with a transplantation center describing the relationship with the dialysis facility and the specific services that the transplantation center will provide to patients of the dialysis facility. The agreements must include the following:*

- (A) *timeframe for initial assessment and evaluation of patients for transplantation,*
- (B) *composition of the assessment/evaluation team at the transplant center,*
- (C) *method for periodic re-evaluation,*
- (D) *criteria by which a patient will be evaluated and periodically re-evaluated for transplantation, and*
- (E) *signatures of the duly authorized persons representing the facilities and the agency providing the services.*

- C- Exhibit 10 contains a letter from Carolinas Healthcare System agreeing to enter into a Transplant Agreement for Graham Dialysis including the components identified above.

- (3) *For new or replacement facilities, documentation that power and water will be available at the proposed site.*

- C- Exhibit 8 provides company policies related to loss of power, back-up generators and alternate dialysis service sites. In Section XI.6 (e), page 63, the applicant states:

“The facility will be located in an area that is supplied by potable city water. Exhibit 21 of the application contains documentation of availability of water and sewer services....”

Exhibit 21 contains only company policies relative to water, no documentation from a power company. However, Exhibits 26 and 27 contain letters from appropriate officials documenting the availability of water, sewer and power for the primary and secondary sites proposed in the application.

(4) *Copies of written policies and procedures for back up for electrical service in the event of a power outage.*

-C- See Exhibit 8, in which the applicant provides copies of written policies and procedures for back up for electrical service in the event of a power outage.

(5) *For new facilities, the location of the site on which the services are to be operated. If such site is neither owned by nor under option to the applicant, the applicant must provide a written commitment to pursue acquiring the site if and when the approval is granted, must specify a secondary site on which the services could be operated should acquisition efforts relative to the primary site ultimately fail, and must demonstrate that the primary and secondary sites are available for acquisition.*

-CA- In Section I, page 2, the applicant identifies the primary site as 135 Auto Park Drive, Graham (Parcel #144064). However, in Section XI, pages 59-60, the applicant identifies the primary site as 412 South Main Street, Graham (Parcel #15759) and the secondary site as Parcel #144064. Exhibit 26 identifies Site 1 as Parcel #144064 and Site 2 as Parcel #145759. Neither site is owned or optioned.

A copy of the DaVita Minimum Base Building Improvements and the DaVita Standard Lease Agreement are located in Exhibit 25. The applicant provides written documentation of availability and commitment to pursue acquiring the proposed primary and/or secondary sites in Exhibits 26 and 27.

The application is conforming with this rule, subject to the following condition:

Prior to issuance of the certificate of need, Renal Treatment Centers Mid-Atlantic, Inc. d/b/a Graham Dialysis shall provide the Certificate of Need Section with written clarification on the primary site address.

(6) *Documentation that the services will be provided in conformity with applicable laws and regulations pertaining to staffing, fire safety equipment, physical environment, water supply, and other relevant health and safety requirements.*

-C- In Section XI.6(g), page 63, the applicant states, “*Graham Dialysis will operate within the applicable laws and regulations pertaining to staffing and fire safety equipment, physical environment, and other relevant health safety requirements.*”

The applicant states that Graham Dialysis will acquire and maintain Medicare Certification. See Exhibit 22 for excerpts from the Health and Safety Policy and Procedure Manual and Exhibit 23 for the In-Service Calendar with mandatory training classes.

(7) *The projected patient origin for the services. All assumptions, including the methodology by which patient origin is projected, must be stated.*

-C- The applicant provides the following projected patient origin on page 26 of the application, as shown below.

Projected Dialysis Patient Origin

COUNTY	OPERATING YEAR 1 2016		OPERATING YEAR 2 2017		COUNTY PATIENTS AS A PERCENT OF TOTAL	
	IN-CENTER	HOME	IN-CENTER	HOME	YEAR 1	YEAR 2
Alamance	32	26	34	28	100.0%	100.0%
Total	32	26	34	28	100.0%	100.0%

See Section III.7, pages 26-27 of the application and the discussion in Criterion (3) with regard to the methodology and assumptions the applicant uses to project patient origin which is incorporated hereby as if set forth fully herein.

(8) *For new facilities, documentation that at least 80 percent of the anticipated patient population resides within 30 miles of the proposed facility.*

-C- In Section III.8, page 28, the applicant states, “100% of the patients will travel less than 30 miles one way for dialysis treatments.”

(9) *A commitment that the applicant shall admit and provide dialysis services to patients who have no insurance or other source of payment, but for whom payment for dialysis services will be made by another healthcare provider in an amount equal to the Medicare reimbursement rate for such services.*

-C- In Section II. 1, page 12, the applicant states,

“Renal Treatment Centers Mid-Atlantic, Inc. d/b/a Graham Dialysis will admit and provide dialysis services to patients who have no insurance or other source of payment, if payment for dialysis services is made by another healthcare provider in an amount equal to the Medicare reimbursement rate for such services.”

.2203 PERFORMANCE STANDARDS

(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- The applicant proposes to establish Graham Dialysis, a new ESRD facility, with the relocation of 10 stations. In Section II, page 13, the applicant states that it anticipates 32 in-center patients and 3.2 patients per station per week at the end of operating year one, based on the methodology and assumptions found on pages 12-14 of the application. See Criterion (3) for further discussion of projected utilization which is incorporated hereby as if set forth fully herein.
- (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- Graham Dialysis is proposing to develop a new ESRD facility through the relocation of existing Alamance County dialysis stations.

.2204 SCOPE OF SERVICES

To be approved, the applicant must demonstrate that the following services will be available:

- (1) *diagnostic and evaluation services;*
 - C- The table in Section V.1, page 33, states patients will be referred to Alamance Regional Medical Center for diagnostic and evaluation services.
- (2) *maintenance dialysis;*
 - C- The table in Section V.1, page 33, states the applicant will provide in-center maintenance dialysis.
- (3) *accessible self-care training;*
 - C- The table in Section V.1, page 33, states the applicant will provide in-center hemodialysis self-care home training, CAPD and CCPD.
- (4) *accessible follow-up program for support of patients dialyzing at home;*
 - C- The applicant addresses accessible follow-up program for support of patients dialyzing at home in Section V, Question 2(d), page 34, stating:

“Graham Dialysis will provide protocols and routines for patient follow-up. The social workers and dieticians contact the home-trained patients monthly. The patients are supported by monthly visits to their Board Certified Nephrologist for examination. The Home Training Nursing teammates perform monthly medication reviews, nursing assessments and laboratory review of blood work in order to continuously monitor the well being of home patients. Patient’s blood chemistries are sent to a Medicare certified laboratory where they are analyzed. The results are reviewed by the teammates for adequacy and then reviewed by the dietitian and Nephrologist. Home trained patients are monitored by our Quality Management team.”

The home training program currently located at North Burlington Dialysis Center will be relocated to Graham Dialysis.

- (5) *x-ray services;*
 - C- The table in Section V.1, page 33, states patients will be referred to Alamance Regional Medical Center for x-ray services.
- (6) *laboratory services;*
 - C- The table in Section V.1, page 33, states patients will be referred to Dialysis Laboratories for routine and special laboratory services.
- (7) *blood bank services;*
 - C- The table in Section V.1, page 33, states patients will be referred to Alamance Regional Medical Center for blood bank services.
- (8) *emergency care;*
 - C- The table in Section V.1, page 33, states patients will be referred to Alamance Regional Medical Center for emergency care.
- (9) *acute dialysis in an acute care setting;*
 - C- The table in Section V.1, page 33, states patients will be referred to Alamance Regional Medical Center for acute dialysis in an acute care setting. See Exhibit 9 for a copy of the hospital’s letter of intent to enter into a patient transfer agreement with Graham Dialysis.
- (10) *vascular surgery for dialysis treatment patients;*

-C- The table in Section V.1, page 33, states dialysis patients will be referred to Alamance Regional Medical Center for vascular surgery.

(11) *transplantation services;*

-C- The table in Section V.1, page 30, states patients will be referred to UNC Hospitals for transplantation services. However, Exhibit 10 contains documentation from Carolinas HealthCare System of intent to enter into a Transplant agreement with Graham Dialysis. The application is conforming to this Rule.

(12) *vocational rehabilitation counseling and services; and*

-C- The table in Section V.1, page 33, states patients will be referred to the NC Division of Vocational Rehabilitation Services in Alamance County for vocational rehabilitation counseling and services.

(13) *transportation.*

-C- The table in Section V.1, page 33, states patients will be referred to Alamance County Transportation Service for transportation.

.2205 STAFFING AND STAFF TRAINING

(a) *To be approved, the state agency must determine that the proponent can meet all staffing requirements as stated in 42 C.F.R., Section 405.2100.*

-C- In Section VII.1, page 43, the applicant provides the proposed staffing for Graham Dialysis. Graham Dialysis plans for two dialysis shifts; direct care staffing of 3.0 FTE per shift on Monday through Saturday as noted in response to VII.10, page 45. See additional staffing details in Section 1.13 (c), pages 6-7. The application is conforming to the staffing requirement as stated in 42 C.F.R. Section 494 (formerly 42 C.F.R. Section 405.2100).

(b) *To be approved, the state agency must determine that the proponent will provide an ongoing program of training for nurses and technicians in dialysis techniques at the facility.*

-C- In Section VII.5, page 45, the applicant refers to Exhibit 16 for a copy of the training program. Exhibit 16 contains a copy of DaVita's Training Program for New Patient Care Provider. Exhibit 23 contains the Graham Dialysis Annual In-Service Calendar.