

Written Comments Filed by Wake Forest University Health Sciences, Triad Dialysis Center of Wake Forest University and High Point Kidney Center of Wake Forest University Concerning Total Renal Care of North Carolina, LLC, d/b/a Guilford County Dialysis, Project I.D. No.G-011412-17

Lisa Pitman, Team Leader
Celia Inman, Project Analyst
N.C. Department of Health and Human Services
Division of Health Service Regulation
Healthcare Planning and Certificate of Need Section
809 Ruggles Drive
Raleigh, North Carolina 27603

October 31, 2017

RE: Written Comments regarding CON application filed by Total Renal Care of North Carolina, LLC, d/b/a/ Guilford County Dialysis, HSA II – Project I.D. No.G-011412-17

Dear Ms. Pitman and Ms. Inman:

Wake Forest University Health Sciences (“WFUHS”), Triad Dialysis Center of Wake Forest University (“TDC”) and High Point Kidney Center of Wake Forest University (“HPKC”) submit the following written comments regarding the certificate of need (“CON”) application filed by Total Renal Care of North Carolina, LLC, d/b/a/ Guilford County Dialysis (hereinafter, “DaVita”)¹ in Guilford County. The Guilford County Dialysis application seeks to develop a new 10-station End Stage Renal Disease (“ESRD”) facility in Greensboro, Guilford County, by relocating 5 dialysis stations from Reidsville Dialysis and 5 dialysis stations from Dialysis Care of Rockingham County, both of which are in Rockingham County. WFUHS owns and TDC operates a 27-station ESRD facility in High Point, Guilford County, North Carolina. WFUHS owns and HPKC operates a 40-station ESRD facility in High Point, and has a certificate of need (“CON”) to add one additional station.²

SUMMARY OF COMMENTS

As discussed below, this proposal is, for many reasons not an effective solution to the 10-station deficit in Guilford County.

- Five of the 10 stations proposed to be relocated are currently at Dialysis Care of Rockingham County, which does not serve Guilford County resident patients. Therefore, the Guilford County Dialysis application fails to comply with SMFP Policy ESRD-2 and Criterion 1.
- The application is non-conforming with Criteria 3, 4, 6 and 18a because (1) Less than half of the proposed patients are Guilford County residents, leaving a continued and effective 6-station deficit in Guilford County; (2) patients from Alamance, Randolph and Stokes Counties, from which the rest of the facility’s patients are projected to come, have a total surplus of 32 stations available for their care and DaVita has shown no need for those

¹ The proposed Guilford County Dialysis facility and other related facilities in North Carolina are all owned by DaVita, Inc., so the applicant will be referred to hereinafter as DaVita.

² Unless otherwise noted, the three commenters hereafter will be referred to collectively as WFUHS.

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patients to travel to the proposed facility in central Guilford County; and (3) the application includes letters of support from patients who previously wrote similar letters for another DaVita facility CON application in Alamance County, which in fact would be more convenient for them than a facility located in Greensboro.

- Financial projections are based on unreliable utilization projections, and therefore, the application fails to demonstrate financial feasibility under Criterion 5.

Each of these issues is addressed below under the headings of the CON Section's CON application form.

ANALYSIS

SECTION B - "CRITERION (1)" - G.S. 131E-183(a)(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.

The July 2017 SDR identifies a deficit of 10 stations in Guilford County. There is no specific need determination in the SDR for a new 10-station facility under the county need methodology, because several BMA facilities in Guilford County are not at 80% utilization. However, where there is a deficit of 10 or more stations in a county, SMFP Policy ESRD-2 permits development of a new facility, through relocation of existing dialysis stations from a contiguous county, if the applicant can demonstrate that all of the following criteria are met.

Policy ESRD-2: Relocation of Dialysis Stations

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

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

As noted, DaVita proposes to develop a 10-station ESRD facility by relocating 5 dialysis stations from Reidsville Dialysis and 5 dialysis stations from Dialysis Care of Rockingham County, both

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of which are in Rockingham County. Under paragraph 1 of Policy ESRD-2, in order to transfer stations from *both* Reidsville Dialysis and Dialysis Care of Rockingham County, DaVita must demonstrate that *each facility* currently serves Guilford County residents.³ Based on both the data contained in the July 2017 SDR and its own application, DaVita cannot make demonstrate this requirement is satisfied.

The following is an excerpt from Table A of the July 2017 SDR, providing December 2016 data for the ESRD facilities serving Guilford County residents:

Provider Number	Facility Name	Facility County	Home Patients	In-Center Patients	County Total
Facilities serving residents of Guilford County					
34-2504	BMA of Greensboro	Guilford	35	175	210
34-2537	BMA of South Greensboro	Guilford	0	173	173
34-2514	High Point Kidney Center	Guilford	28	117	145
34-2634	FMC of East Greensboro	Guilford	0	128	128
34-2600	BMA of Southwest Greensboro	Guilford	0	105	105
34-2613	Northwest Greensboro Kidney Center	Guilford	0	96	96
34-2599	Triad Dialysis Center	Guilford	0	77	77
34-2505	Piedmont Dialysis Center	Forsyth	12	3	15
34-2533	BMA Burlington	Alamance	0	14	14
34-2567	Burlington Dialysis	Alamance	1	11	12
34-2553	Lexington Dialysis Center	Davidson	2	1	3
34-3504	Duke Hospital Dialysis	Durham	1	1	2
34-2640	Reidsville Dialysis	Rockingham	0	2	2
34-2616	Durham West Dialysis	Durham	2	0	2
34-2639	Thomasville Dialysis Center	Davidson	0	2	2
34-2691	Carolina Dialysis - Mebane	Alamance	1	1	2
34-2641	Rockingham Kidney Center	Rockingham	0	1	1
34-2667	Miller Street Dialysis Center	Forsyth	0	1	1
34-2524	BMA of Asheboro	Randolph	1	0	1
34-2512	BMA of Raleigh Dialysis	Wake	0	1	1
34-2569	Salem Kidney Center	Forsyth	0	1	1
34-2622	Carolina Dialysis Carrboro	Orange	1	0	1
Guilford Totals			84	910	994

As noted, of the two DaVita facilities from which 10 stations are proposed to be relocated, only Reidsville Dialysis currently serves any Guilford County residents. Based on the patient letters of support in Exhibit C-1 to the Guilford County Dialysis application, *only one* of those two patients (who resides in Guilford County zip code area 27405) supports the Guilford County Dialysis application.⁴ Thus, Reidsville Dialysis Center provides service to 2.564% of all the patients

³ Page 8 for the Guilford County Dialysis application cites a prior version of Policy ESRD-2. That Policy was amended in the 2016 SMFP to more clearly reflect this requirement. However, as discussed in the Court of Appeals case below, DaVita’s obligation under either the previous or current version of the Policy is the same.

⁴ This letter, which is contained on page 147 of the PDF version of the Guilford County Dialysis application, is difficult to make out in the original CON application, and enlarging it does not enhance readability. However, on line 1, it indicates the patient attends Reidsville Dialysis and on line 2, it indicates the patient lives in zip code 27405.

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projected by DaVita who may utilize its proposed new facility and Reidsville Dialysis' transfer of five stations may marginally conform to Policy ESRD-2.

However, Dialysis Care of Rockingham County currently serves **no** Guilford County residents. There are two letters of support in Exhibit C-1 from Dialysis Care of Rockingham County patients, but both patients state that they reside in zip code 27046, which is located in the northeast corner of Stokes County, and is nowhere near the Guilford County line.⁵ Section C, pp. 14-15 of the Guilford County application confirms the location of these patients, projecting that Guilford County Dialysis will serve two Stokes County residents. See also, projected patient origin chart on p. 6 below. Therefore, under the clear language of Policy ESRD-2, Dialysis Care of Rockingham County may not transfer stations to Guilford County.

The Agency already addressed this issue over 13 years ago, disapproving a CON application where the facility proposing to relocate stations across county lines was not providing in-center dialysis services to residents of the contiguous county at the time of the application. In 2004, Wake Forest University Health Sciences (Lessor) and Huntersville Dialysis Center of Wake Forest University d/b/a Huntersville Dialysis Center (Lessee) (collectively, "HDC") proposed to relocate 10 stations from Statesville Dialysis Center in Iredell County to a new facility in Huntersville, Mecklenburg County, Project I.D. No. F-7017-04. The CON Section found the application non-conforming with Policy ESRD-2 and Criterion 1, because while HDC proposed to serve 18 in-center dialysis patients from Mecklenburg County, which had been receiving their care at WFUHS' Mooresville facility (Lake Norman Dialysis Center) in Iredell County, HDC did not report serving any in-center dialysis patients from Mecklenburg County at Statesville Dialysis Center, from where stations would be relocated. See Required State Agency Findings, p. 2, Exhibit 2 hereto. HDC filed a Petition for Contested Case Hearing, contending that while Statesville Dialysis Center did not serve any *in-center* dialysis patients from Mecklenburg County, it did serve *home training* patients from that county, and therefore, the facility "currently served" Mecklenburg County residents within the meaning of Policy ESRD-2. However, the ALJ, the final Agency decision maker and the N.C. Court of Appeals all sided with the Agency, finding as a matter of law that the Agency's interpretation of Policy ESRD-2 was correct.

The Agency asserts and this Court agrees that it is implicit in the policies set forth, as well as in the action sought by Petitioners, i.e., the transfer of dialysis stations, that only in-center patients would be considered in determining whether the application complies with ESRD-2. ... Accordingly, we ... hold the Agency correctly determined that Petitioners' application for the transfer of ten dialysis stations failed to conform to the criteria set forth under ESRD-2.

Wake Forest Univ. Health Sciences v. N.C. HHS, Div. of Facility Servs., 180 N.C. App. 327, 331, 638 S.E.2d 219, 222 (2006) (copy attached as Exhibit 3).⁶ Based on the Court of

⁵ See map attached as Exhibit 1 hereto, which shows the locations of DaVita's existing facilities in Rockingham, and Alamance Counties, its proposed facility site in Guilford County, and the current location of Guilford County Dialysis's projected patients based on the zip codes provided in the letters of support.

⁶ As noted in the case caption of Exhibit 3, DaVita was a party in that appeal, supporting the Agency's interpretation of Policy ESRD-2 and its decision disapproving the application. Therefore, both the Agency and DaVita are bound by principles of res judicata and collateral estoppel from supporting a different interpretation of Policy ESRD-2, now. See Catawba Memorial Hosp. v. N.C. Dep't of Human Res., 112 N.C. App. 557, 436 S.E.2d 390 (1993), review denied

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Appeals’ holding and the clear language of Policy ESRD-2, unless an applicant can demonstrate that each facility transferring dialysis stations is currently serving in-center residents of the contiguous county, those stations cannot be moved under Policy ESRD-2.

DaVita cannot comply with this provision of ESRD-2 because Dialysis Care of Rockingham County serves no Guilford County in-center (or home) dialysis patients, so stations may not be relocated from that facility to a new facility in Guilford County. Further, even assuming that Reidsville Dialysis serves Guilford County residents, only 5 stations are proposed to be relocated from that facility, and under the SMFP and Agency rules, a new ESRD facility must have at least 10 stations to receive a CON. See 2017 SMFP, p. 373, Basic Principle No. 2; 10A N.C.A.C. 14C.2203(a). Without the 5 stations from Dialysis Care of Rockingham County, Guilford County Dialysis cannot obtain a CON. Because the Guilford County Dialysis application is non-conforming with Policy ESRD-2, Basic Principle No. 2 and Agency rules, it is non-conforming with Criterion 1 and must be denied.

SECTION C - “CRITERION (3)” - G.S. 131E-183(a)(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.

As set forth on page 14 of the Guilford County Dialysis application, DaVita projects the following patient population in the first two years of operation:

Total Projected Patients by County of Residence

County	OY 1			OY 2			County Patients as a Percent of Total	
	In-center Patients	Home Hemo Patients	Peritoneal Patients	In-center Patients	Home Hemo Patients	Peritoneal Patients	OY 1	OY 2
Alamance	15	0	1	15	0	1	44.4%	41.0%
Guilford	13	1	1	14	2	2	41.7%	46.2%
Randolph	2	0	1	2	0	1	8.3%	7.7%
Stokes	2	0	0	2	0	0	5.6%	5.1%
Total *	32	1	3	33	2	4	100%	100%

Based on the table, above, DaVita projects to serve 13 of the 32 Guilford County patients projected to need the 10 deficit stations reported in the July 2017 SDR. This equates to about 4 stations’ worth of patients of the 10 stations or about 40% of the Guilford County deficit.

$$13 \div 3.2 = 4.0625 \text{ stations' worth of patients}$$

336 N.C. 72, 445 S.E.2d 31 (1994); Thomas M. McInnis & Associates, Inc. v. Hall, 318 N.C. 421, 428, 349 S.E.2d 552, 556 (1986).

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The other 6 stations will serve primarily patients from Alamance County, where there is a 27-stations surplus; Stokes County, where there is neither a surplus nor a deficit; and Randolph County, where there is a 5-station surplus. Thus, after DaVita’s project is operational, the patients of Guilford County will continue to be underserved by about 6 dialysis stations.

Further, the facts do not support a need to serve even these few Guilford County residents. Below is a breakdown of patients by county, facility, and zip code area based on the letters included in Exhibit C-1 of DaVita’s CON application. WFUHS has mapped the current zip code locations of those patients in *Exhibit 1* hereto. However, WFUHS was unable to perform a complete *whitepages.com* search of the patients’ likely addresses, because most of the patient’s signatures in Exhibit C-1 were illegible. As shown in the chart attached as *Exhibit 4*, WFUHS was able to find addresses for only 13 of 40 (or 32.5%) patient letters. This raises a serious question as to the remaining letters may actually be relied upon to support DaVita’s contentions. Failure to adequately document representations in an application are grounds for disapproval.

Zip	Dialysis Care Rockingham County	Reidsville Dialysis	Alamance County Dialysis	Burlington Dialysis	North Burlington Dialysis	Total Pts.	Zip Location
27283				1		1	Guilford
27301				1		1	Guilford
27377				1		1	Guilford
27405		1		4		5	Guilford
27406				1		1	Guilford
27409				1		1	Guilford
27410				1		1	Guilford
27249				2		2	Guilford, Alamance, Caswell, Rockingham
27046	2					2	Stokes
27214			1			1	Guilford, Rockingham
27244				4	12	16	Guilford, Alamance, Caswell
27298			1	2		3	Guilford, Alamance, Randolph
27349				4		4	Alamance, Chatham
Facility Totals	2	1	2	22	12	39	

Even if the CON Section were to conclude the letters in Exhibit C-1 of the application are reliable, *Exhibits 1 and 4*, attached hereto, demonstrate the majority of those patients live as close or closer to existing or approved DaVita facilities located in Alamance and Rockingham Counties versus the proposed Guilford County facility.

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This lack of geographic support for a new Guilford County ESRD facility is even more troubling when coupled with the fact that DaVita by its own admission has separately applied and been approved several times in 2016 and 2017 to develop additional stations in its Alamance County facilities, based upon serving the needs some of the same Alamance County residents it projects to serve in Guilford County Dialysis, as outlined below (emphasis added):

Another issue is that some of the patients who receive dialysis services in Alamance County who signed letters of support for this project may have signed a letter of support for one of the other DaVita projects in Alamance County. All of these patients have indicated that this may be a once in a lifetime to receive services from a DaVita facility in their home county or at a location more convenient to them. Our Regional Operations Director has spoken to all of these patients. Other patients have been identified and have agreed to sign letters indicating their desire to consider transfer to the new facility being developed in Burlington. Mr. Hyland will meet with the Project Analyst who has responsibility for Alamance County and will offer to submit additional letters if needed.

See Guilford County Dialysis application, p. 3.

Essentially, the Guilford County Dialysis application admits to “**double-dipping,**” by using the same patients to support multiple CON applications for ESRD services. The application proposes to correct this duplication by submitting additional letters of support. However, that would be an impermissible amendment to the application under 10A N.C.A.C. 14C.0204. Further, since the Agency is not conducting an expedited review and has scheduled a public hearing on the DaVita application, the Agency cannot contact the applicant during the review “and request additional or clarifying information, amendments to, or substitutions for portions of the application.” N.C. Gen. Stat. §131E-185(a2).

The actual facts reveal that DaVita’s double dipping is not limited to this one instance. In 2015-2017, DaVita filed a number of CON applications proposing to relocate stations within Alamance County. According to the July 2017 SDR, the following approved projects are still under development:

- **Elon Dialysis** / Develop a new dialysis facility by relocating 8 stations from Burlington Dialysis and 2 stations from North Burlington Dialysis / Project I.D. No. G-11212-16 / Conditionally approved 10/4/16 – Not certified as of 6/9/2017.
- **Mebane Dialysis** / Develop a new 10-station dialysis facility in Alamance County by relocating 4 stations from Burlington Dialysis and 6 stations from North Burlington Dialysis / Project I.D. No. G-11289-17 / Conditionally approved 3/31/17 – Not certified as of 6/9/2017.
- **Burlington Dialysis** / Add four stations for a total of 16 dialysis stations upon completion of this project, Project I.D. No. G-11212-16 (relocate 8 stations) and Project I.D. No. G-11289-17 (relocate 4 stations) / Project I.D. No. G-11321-17 / Conditionally approved 5/9/17 – Not certified as of 6/9/2017.

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- **North Burlington Dialysis** / Add 2 dialysis stations for a total of 16 stations upon completion of this project, Project I.D. No. G-11089-15 (Add six dialysis stations), Project I.D. No. G-11212-16 (Relocate two stations from North Burlington Dialysis to Elon Dialysis), and Project I.D. No. G-11289-17 (Relocate six stations from North Burlington Dialysis to Mebane Dialysis) / Project I.D. No. G-11318-17 / Conditionally approved 6/12/17 – Not certified as of 6/9/2017.

In addition, on the same date the Guilford County Dialysis application was filed (September 15, 2017), Burlington Dialysis filed a CON application (Project I.D. No. G-011409-17) to add 1 dialysis station for a total of 17 upon completion of that project, Project ID #G-11321-17 (add 4 stations), Project ID #G-11212-16 (relocate 8 stations), and Project ID #G-11289-17 (relocate 4 stations).

An examination of the letters of support for the Elon Dialysis and Guilford County Dialysis applications reveals that at least eight patients signed letters of support for both facilities, as follows:

Name	City⁷	State	Zip
Pauline Tate	Elon	NC	27244
Louis Walker	Gibsonville	NC	27249
Anthony B. Martin	Greensboro	NC	27405
Willette D. Mitchell	Greensboro	NC	27406
Mary Beale	Elon	NC	27244
James Wilson	McLeansville	NC	27301
[illegible]	Elon	NC	27244
John [illegible]	Elon	NC	27244

Copies of those duplicate letters from the Elon Dialysis and Guilford County Dialysis applications are attached hereto as Exhibit 5. The Elon Dialysis application projected that the need for the facility was based upon the assumption that all 33 of the patients who signed letters of support for the application would transfer to the new facility. The Agency’s Findings accepted this assumption as reasonable and found the Application conforming to Criterion 3. See Elon Dialysis Required State Agency Findings, pp. 4-5, Exhibit 6 hereto. Because the 8 duplicate letters of support were material to the CON Section’s approval of the Elon Dialysis application, they cannot be used to support the Guilford County Dialysis application. Without those letters, the Guilford County Dialysis application does not demonstrate the need for at least 32 patients in the second year, and must be disapproved.

In addition, although the 2017 applications filed by Burlington Dialysis and North Burlington Dialysis took into account patients transferring to Elon Dialysis or Mebane Dialysis, neither application projected that patients would transfer to a new facility in Guilford County. This fact is particularly egregious in the case of the Burlington Dialysis CON application (Project I.D. No. G-011409-17) filed the same day as the Guilford County Dialysis application. That application

⁷ The city listed is based on the zip code given in each letter and name/address searches on whitepages.com as set forth in Exhibit 4. That exhibit also includes a column which indicates the Guilford support letters that are duplicates of support letters provided for the Elon application.

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includes no projection that any current patients would transfer to the Guilford County Dialysis facility, and in fact ***makes no mention of the Guilford County Dialysis application at all.*** See, e.g., Burlington Dialysis CON application (Project I.D. No. G-011409-17) pp. 13-15, *Exhibit 7* hereto. The two applications simply have inconsistent and incompatible projections.

As a practical matter, based on the zip codes of the 8 patients listed above, as well as other patients from Stokes, Guilford and Alamance Counties, it is unrealistic to assume that the proposed Guilford County Dialysis facility will be more convenient than the patients' existing facilities. As shown in *Exhibits 1 and 4*, most of these patients live closer to their current facility than the proposed Guilford County Dialysis facility. Therefore, DaVita has failed to demonstrate the need that this population has for the services proposed.

SECTION E - "CRITERION (4)" - G.S. 131E-183(a)(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.

On page 20 of the DaVita application, the applicant offers the following response when asked why the new facility is needed at the proposed site, as opposed to another area of the county:

The majority of the patients who signed letters indicating an interest in transferring their care to the proposed Guilford County Dialysis live in Greensboro or east of Greensboro. Most of the patients who live in Alamance County live on the western edge of the county in Elon. Even though Fresenius operates five facilities in the greater Greensboro area and has proposed to develop two additional facilities in Guilford County, the most practical placement for our dialysis facility is in Greensboro.

The first sentence above is true, but ***only*** because Alamance County, where DaVita already has 3 existing and 2 approved ESRD facilities, is east of Greensboro. As the chart in *Exhibit 4* and the map in *Exhibit 1* show, those facilities can more adequately serve the needs of DaVita's existing patients. If the location of these patients justify more stations in Guilford County, the obvious conclusion is that they likely are needed in eastern Guilford County near the Alamance/Guilford County line,⁸ much more than they are needed in the heart of Greensboro, which is thoroughly covered by BMA, TDC and HPKC.

It is also important to recognize that patients living outside of the metropolitan Greensboro area likely travel away from the city to avoid traffic patterns going into the city in the mornings and out of the city in the evenings. This is a conscious choice and indicative of travel patterns in metropolitan areas throughout North Carolina. Thus, the only way to possibly improve access for DaVita's Guilford County patients would be to develop a facility in eastern Guilford County.

Further, because Guilford County Dialysis has failed to demonstrate conformity with Criteria 1 and 3, it has not proposed an effective alternative and cannot be approved.

⁸ Based on the information contained in Table A of the July 2017 SDR, Table A (copied on page 3 above), 78% of Guilford County patients (25 of the 32 predicted to be underserved) going outside of Guilford County for their care travel to Alamance County, to BMA Burlington (14 patient) and DaVita's Burlington Dialysis (11 patients).

SECTION F - “CRITERION (5)” - G.S. 131E-183(a)(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.

As noted under the Criterion 3 discussion above, Guilford County Dialysis’s utilization projections are unreliable. The financial projections in the application are based on those unreliable utilization projections, and therefore, the application fails to demonstrate financial feasibility under Criterion 5.

SECTION G - “CRITERION (6)” - G.S. 131E-183(a)(6)

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

As discussed under Criterion 3 above, many of the dialysis patients projected to utilize the proposed Guilford County Dialysis facility reside in Alamance County and several have signed letters of support for CON projects in their home county. Due to the 27-station surplus in Alamance County, a provision of care for any Alamance County resident patient outside of Alamance County is by definition “*an unnecessary duplication of existing and/or approved health service capabilities or facilities.*” The same can be said for the two Stokes County residents currently served at Dialysis Care of Rockingham County. Thus, DaVita’s CON application is non-conforming with Criterion 6.

SECTION N - “CRITERION (18a)” - G.S. 131E-183(a)(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.

As shown under Criteria 3, 4, 5 and 6, the Guilford County Dialysis proposal will not have a positive impact on the cost effectiveness, quality, and access to the services proposed. DaVita has failed to demonstrate a need for its proposal, and will not improve access to residents of Guilford County in need of dialysis services. Its revenue projections are overstated, and the project will not be cost effective. Therefore, the project is non-conforming with Criterion 18a.

SECTION P - “RULES” - G.S. 131E-183(b)

The Guilford County Dialysis application is non-conforming with the following applicable rules.

10A NCAC 14C .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.*

As discussed under Criterion 1 above, Policy ESRD-2 prohibits the relocation of 5 stations from Dialysis Care of Rockingham County to the new facility, because Dialysis Care of Rockingham County does not currently serve Guilford County residents. The applicant also fails to demonstrate a need for the project, as discussed under Criterion 3. As such, Guilford County Dialysis cannot document a need for 10 stations, and is nonconforming with this rule.

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

As discussed under Criterion 3 above, the application fails to provide all assumptions, including the methodology by which patient origin was projected. Therefore, the Guilford County Dialysis application is nonconforming with this rule.

CONCLUSION

In conclusion, the Guilford County Dialysis application contains numerous critical errors, which make its application non-conforming with required CON criterion that would allow its approval. For these reasons and more specifically the reasons indicated above in these public comments, WFUHS requests the CON section deny the Guilford County Dialysis application submitted by DaVita (Total Renal Care.)

Thank you, for the opportunity to provide these comments and your careful consideration of these important issues. Please contact William McDonald at (229) 387-3528 or Kimberly Clark at (229) 387-3527 with Health Systems Management, Inc., with any follow up regarding these comments. You may also contact me directly at (336) 716-1025.

Respectfully Submitted,



Russell Howerton, M.D.
Chief Medical Officer and VP Clinical Operations

INDEX OF EXHIBITS

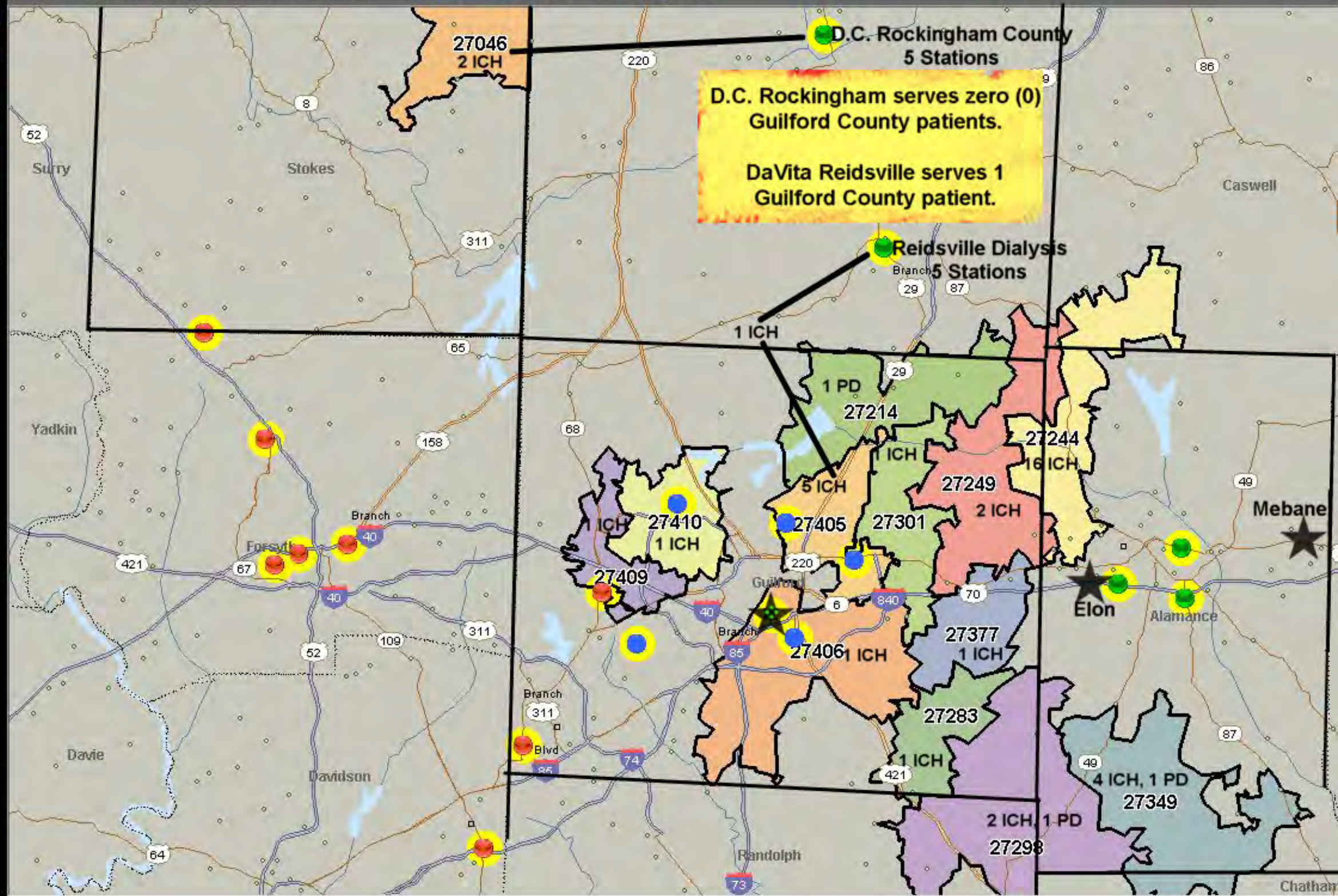
1. Map showing the locations of DaVita's existing facilities in Rockingham, and Alamance Counties, its proposed facility site in Guilford County, and the current location of Guilford County Dialysis's projected patients.
2. Required State Agency Findings / Project I.D. No. F-7017-04/Wake Forest University Health Sciences (Lessor) and Huntersville Dialysis Center of Wake Forest University d/b/a Huntersville Dialysis Center (Lessee) /Relocate ten stations from Statesville Dialysis Center in Iredell County to Huntersville in Mecklenburg County
3. Wake Forest Univ. Health Sciences v. N.C. HHS, Div. of Facility Servs., 180 N.C. App. 327, 331, 638 S.E.2d 219, 222 (2006)
4. Duplicate letters from the Elon Dialysis and Guilford County Dialysis CON applications
5. Chart showing current locations of those patients supporting Guilford County Dialysis CON application, based on letters of support and a Whitepages.com search
6. Required State Agency Findings / Project I.D. No. G-11212-16 / Renal Treatment Centers – Mid-Atlantic, Inc. d/b/a Elon Dialysis / Develop a new dialysis facility by relocating 8 stations from Burlington Dialysis and 2 stations from North Burlington Dialysis in Alamance County
7. Pertinent portions of Burlington Dialysis CON application (Project I.D. No. G--011409-17), filed September 15, 2017



- Custom territories**
- 27046
 - 27214
 - 27244
 - 27249
 - 27283
 - 27298
 - 27301
 - 27349
 - 27377
 - 27405
 - 27406
 - 27409
 - 27410

- Pushpins**
- BMA
 - DaVita
 - WFOPD
 - CON Approved
 - Not Certified
 - Proposed DaVita Guilford County

EXHIBIT
1



ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: July 28, 2004
PROJECT ANALYST: Mary Edwards
ASST. CHIEF CON: Craig R. Smith
PROJECT I.D. NUMBER: F-7017-04/Wake Forest University Health Sciences (Lessor) and Huntersville Dialysis Center of Wake Forest University d/b/a Huntersville Dialysis Center (Lessee) /Relocate ten stations from Statesville Dialysis Center in Iredell County to Huntersville in Mecklenburg County/Mecklenburg 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.

NC

Three applications for dialysis stations were received by the Certificate of Need Section in Mecklenburg County. The proposals submitted by Gambro Healthcare Renal Care, Inc. d/b/a Gambro Healthcare Charlotte, Project I.D. # F-6989-04 and Total Renal Care of North Carolina, LLC d/b/a Dialysis Care of Mecklenburg County, Project I.D. # F-7003-04 are under separate review. The proposal in this review is briefly described below.

Wake Forest University Health Sciences (Lessor) and Huntersville Dialysis Center of Wake Forest University d/b/a Huntersville Dialysis Center (Lessee) [Huntersville Dialysis] propose to relocate ten dialysis stations from Statesville Dialysis Center in Iredell County to Mecklenburg County, resulting in a new ten station dialysis facility in Huntersville.

The 2004 State Medical Facilities Plan (SMFP) and the January 2004 Semiannual Dialysis Report (SDR) provide a county need methodology for determining the need



for additional dialysis stations. According to the county need methodology, *“If a county’s June 30, 2004 projected station deficit is ten or greater and the January SDR shows that utilization of each dialysis facility in the county is 80% or greater, the June 30, 2004 county station need determination is the same as the June 30, 2004 projected station deficit.”* According to the January 2004 SDR, the result of the county need methodology was zero stations needed for Mecklenburg County.

Huntersville Dialysis Center proposes to relocate ten dialysis stations from Statesville Dialysis Center in Iredell County to Mecklenburg County, resulting in a new ten station dialysis facility in Huntersville. The applicant is applying to relocate dialysis stations across county lines, based on Policy ESRD-2: Relocation of Dialysis Stations. This policy states,

“Relocations of existing dialysis stations are allowed only within the host county and to contiguous counties currently served by the facility [emphasis added]. Certificate of need applicants proposing to relocate dialysis stations to contiguous counties 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.”*

Iredell County is contiguous with Mecklenburg County. As of the January 2004 SDR, the SDR in effect when the application was filed, Iredell County had a surplus of 15 dialysis stations, while Mecklenburg County had a deficit of ten dialysis stations. The applicants currently serve in-center dialysis patients from Mecklenburg County at its Mooresville facility (Lake Norman Dialysis Center) in Iredell County. However, the applicants do not report serving any in-center dialysis patients (those receiving hemodialysis at a dialysis station in the facility) from Mecklenburg County at the Statesville Dialysis Center, the location from where stations are being relocated. Therefore, the application does not conform with Policy ESRD-2 of the 2004 SMFP. Therefore, the applicants are not eligible to apply for stations, based on Policy ESRD-2 and, therefore, are not conforming with 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.

Briefs and Other Related Documents

Only the Westlaw citation is currently available.

NOTE: THIS OPINION WILL NOT BE PUBLISHED IN A PRINTED VOLUME. THE DISPOSITION WILL APPEAR IN A REPORTER TABLE.

An unpublished opinion of the North Carolina Court of Appeals does not constitute controlling legal authority. Citation is disfavored, but may be permitted in accordance with the provisions of Rule 30(e)(3) of the North Carolina Rules of Appellate Procedure.

Court of Appeals of North Carolina.
 WAKE FOREST UNIVERSITY HEALTH SCIENCES and Huntersville Dialysis Center of Wake Forest University d/b/a Huntersville Dialysis Center, Petitioner
 v.
 NORTH CAROLINA DEPARTMENT OF HEALTH AND HUMAN SERVICES Division of Facility Services North Carolina Department of Health and Human Services, Division of Facility Services, Respondent
 and
 Bio-Medical Applications of North Carolina, Inc. and Total Renal Care of North Carolina, LLC, Respondent-Intervenor.
No. COA05-1597.

Nov. 21, 2006.

*1 Appeal by Petitioners from a final agency decision entered 22 August 2005 by the North Carolina Department of Health and Human Services, Division of Facility Services. Heard in the Court of Appeals 10 October 2006.

Bode, Call & Stroupe, LLP, by [S. Todd Hemphill](#), Dana Evans Ricketts and [Matthew A. Fisher](#), for petitioner-appellant.

Attorney General [Roy Cooper](#), by Assistant Attorney

General [Thomas M. Woodward](#), for respondent-appellee.

Wyrick Robbins Yates & Ponton, LLP, by [K. Edward Greene](#), [Lee M. Whitman](#) and Sarah M. Johnson, for respondent-intervenor appellee, Bio-Medical Applications of North Carolina, Inc.

Poyner & Spruill, LLP, by William R. Sheraton, [Thomas R. West](#) and [Pamela A. Scott](#), for respondent-intervenor appellee, Total Renal Care of North Carolina, LLC.

[MARTIN](#), Chief Judge.

Wake Forest University Health Sciences and Huntersville Dialysis Center (hereinafter "Petitioners") appeal the final agency decision of the North Carolina Department of Health and Human Services, Division of Facility Services, granting summary judgment in favor of Respondents and upholding the decision of the Certificate of Need Section of the Facility Services Division to deny Petitioners' application for the transfer of ten dialysis stations.

Briefly summarized, this appeal comes before us on the following record: Petitioners filed a Certificate of Need ("CON") application with the North Carolina Department of Health and Human Services, Division of Facility Services, Certificate of Need Section (hereinafter "Agency") for the approval of the transfer of ten dialysis stations from Iredell County to Mecklenburg County. The application sought to relocate dialysis stations to a contiguous county based on the surplus of fifteen dialysis stations in Iredell County and the deficit of ten dialysis stations in Mecklenburg County.

Specifically, Petitioners' proposal would allow the transfer of eighteen in-center dialysis patients currently served by Petitioners' Lake Norman facility in Iredell County to the new Huntersville facility in Mecklenburg County along with the transfer of an existing home dialysis patient residing in Mecklenburg County from Petitioners' Statesville Dialysis Center to the new Huntersville facility. Petitioners sought to move dialysis stations from the Iredell County facility with the most underused capacity, Statesville Dialysis.

In general, there are two types of dialysis treatments available to end-stage renal disease (ESRD) patients which are provided by dialysis facilities: in-center hemodialysis and peritoneal dialysis or home dialysis. In-center hemodialysis involves the process of cycling a patient's blood through an external dialysis machine that replaces the function of the kidney. The external dialysis machines must be CON-approved and are known as dialysis stations. Patients participating in in-center hemodialysis treatment generally need treatment three times a week in intervals of two-to-four hours.

*2 The second method, home dialysis, involves the process of patients introducing a sterile premixed solution into their abdominal cavity. This method does not require the use of dialysis stations within a dialysis center; however, patients must be trained by the dialysis center for home dialysis over a period of several weeks and then re-visit the center for regularly scheduled check-ups.

On 28 July 2004 the Agency denied Petitioners' application based upon the Agency's finding that the application did not conform to the criterion set forth in Policy ESRD-2: Relocation of Dialysis Stations. Specifically, the Agency found that Petitioners' application failed to comply with the requirements under ESRD-2 that dialysis stations be relocated only to "contiguous counties *currently served* by the facility[.]" (Emphasis added). The Agency further found that Petitioners' application failed to conform with Criterion 1, 3, 4, 5, 6, 12, and 18(a) under [N.C. Gen.Stat. § 131E-183\(a\)](#).

Subsequent to the Agency's denial of the application for a CON, Petitioners filed a petition for a contested case hearing in the Office of Administrative Hearings (hereinafter "OAH"). Total Renal Care of North Carolina, LLC and Bio-Medical Applications of North Carolina, Inc. (hereinafter "Respondent-Intervenors") moved to intervene, and their motions were subsequently granted by OAH. Petitioners then filed a motion with OAH for partial summary judgment and Respondent-Intervenors subsequently filed cross-motions for summary judgment.

A recommended decision was issued by the Administrative Law Judge (hereinafter "ALJ") denying Petitioners' motion for partial summary judgment, granting Respondent-Intervenors' motions for summary judgment and recommending that the decision to deny the application for a CON be

upheld. The Agency adopted the recommended decision of the ALJ and issued a final agency decision in accordance therewith. Petitioners appeal, contending the Agency erred in concluding that their application failed to meet Criterion 1 under ESRD-2.

Petitioners assert that the Agency's determination that their application for a CON was non-conforming with Criterion 1 was erroneous as a matter of law. Specifically, [N.C. Gen.Stat. § 131E-183](#) states that all applications for a certificate of need must comply with the policies and need determinations set forth in the State Medical Facilities Plan ("SMFP"). [N.C. Gen.Stat. § 131E-183\(a\)\(1\) \(2005\)](#).

Where a party contends that an agency decision was based on an error of law, the appropriate standard of review is *de novo*. [Dialysis Care of N.C., LLC v. N.C. Dep't of Health and Human Servs.](#), 137 N.C.App. 638, 646, 529 S.E.2d 257, 261, *aff'd*, 353 N.C. 258, 538 S.E.2d 566 (2000).

The 2004 SMFP Policy ESRD-2 governs the relocation of dialysis stations and 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:

*3 (1) 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 semiannual Dialysis Report, and

(2) 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 semiannual Dialysis Report.

[10A N.C.A.C. 14B.0138 \(2006\)](#)(emphasis added).

The dispute in this case centers around the meaning of the words "currently served" as contained in the aforementioned policy. The final agency decision found the application for a certificate of need to be non-conforming with this section in that it did not report that any in-center dialysis patients from Mecklenburg County were currently being served by the Statesville Dialysis Center, the location from which the stations were being relocated. Specifically, the Agency concluded that in determining whether a contiguous county was currently served by the facility from which dialysis stations were being transferred, only in-center dialysis patients were to be considered and not home based patients.

In interpreting a statute, we first look to the plain meaning of its language. Where the language of a statute is clear, the courts must give the statute its plain meaning; however, where the statute is ambiguous or unclear as to its meaning, the courts must interpret the statute to give effect to the legislative intent. [Burgess v. Your House of Raleigh](#), 326 N.C. 205, 209, 388 S.E.2d 134, 136-37 (1990). Respondent correctly notes that the reviewing criteria are set forth in rules promulgated by the Agency and therefore the Agency's interpretation of the policies should be given some deference.

Although the interpretation of a statute by an agency created to administer that statute is traditionally accorded some deference by appellate courts, those interpretations are not binding. "The weight of such [an interpretation] in a particular case will depend upon the thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade, if lacking power to control." [Total Renal Care of N.C., LLC v. N.C. Dep't of Health and Human Servs.](#), 171 N.C.App. 734, 740, 615 S.E.2d 81, 85 (2005) (citations omitted).

With these principles of construction in mind we must determine the meaning of the words "currently served" as set forth in the SMFP guidelines for the relocation of dialysis stations. To "serve," as defined by *American Heritage College Dictionary*, means "to provide goods and services for." *American Heritage College Dictionary* 1246 (3rd ed.1997). Additionally, the Agency relied on Principle 5 enumerated in the 2004 SMFP which states that in projecting the need for new dialysis stations for end-stage renal disease dialysis facilities in North Carolina that, "[h]ome patients will *not* be included in the determination of need for new stations. Home patients include those that receive hemodialysis or peritoneal dialysis in their home." (Emphasis added).

*4 The Agency asserts and this Court agrees that it is implicit in the policies set forth, as well as in the action sought by Petitioners, i.e., the transfer of dialysis stations, that only in-center patients would be considered in determining whether the application complies with ESRD-2. The application seeks to transfer dialysis stations. These stations are only used by in center hemodialysis patients. While home-center patients would benefit from the ability to transfer to a center located within Mecklenburg

County, they are not the patients currently served by or sought to be served by the dialysis stations. Therefore, within the context of applying for a certificate of need contemplating the transfer of dialysis stations, the Agency correctly interpreted ESRD-2's terms "currently served" to include only in-center patients, those patients who now require the use of dialysis stations. Accordingly, we overrule Petitioners' corresponding assignment of error and hold the Agency correctly determined that Petitioners' application for the transfer of ten dialysis stations failed to conform to the criteria set forth under ESRD-2.

Because we affirm the Agency's final decision, we need not address Respondents' cross-assignment of error. [N.C.R.App. P 10\(d\) \(2006\)](#); see [Carawan v. Tate](#), 304 N.C. 696, 286 S.E.2d 99 (1982)(purpose of cross-assignment of error is to protect an appellee who has been deprived, by an action of the trial court, of an alternative legal basis upon which the judgment might be upheld).

Affirmed.

Judges [WYNN](#) and [MCGEE](#) concur.

Report per Rule 30(e).

Slip Copy, 2006 WL 3359688 (N.C.App.),
Unpublished Disposition

Briefs and Other Related Documents [\(Back to top\)](#)

- [2006 WL 2150865](#) (Appellate Brief) Reply Brief of Petitioner-Appellants Wake Forest University Health Sciences and Huntersville Dialysis Center of Wake Forest University d/b/a Huntersville Dialysis Center (Rule 28(h) (2), N.C.R. App. P.) (Jul. 18, 2006)
- [2006 WL 1745721](#) (Appellate Brief) Brief of Respondent-Intervenor-Appellees, Bio-Medical Applications of North Carolina, Inc. and Total Renal Care of North Carolina, LLC (Jun. 12, 2006)

END OF DOCUMENT

Order	Name	Street	City	State	Zip	Modality	Home Clinic	Duplicate Support Letters?
1	James Wilson	5221 Millstream Rd	McLeansville	NC	27301	ICH	Burlington Dialysis	Duplicate
2	Willette D. Mitchell	1003 Amity Dr	Greensboro	NC	27406	ICH	Burlington Dialysis	Duplicate
3	Tommy S. Moorey (Illegible)				27409	ICH	Burlington Dialysis	
4	Dorothy Thompson	2201 Carl Noah Rd	Snow Camp	NC	27349	ICH	Burlington Dialysis	
5	Lonnie Gibson	3583 Shady Maple Ln	Snow Camp	NC	27349	ICH	Burlington Dialysis	
6	Herman Bittle	6523 Patterson Rd	Snow Camp	NC	27349	ICH	Burlington Dialysis	
7	(Illegible)				27349	ICH	Burlington Dialysis	
8	X				27244	ICH	Burlington Dialysis	
9	D. Jolus				27377	ICH	Burlington Dialysis	
10	Louis Walker	400 Steele St	Gibsonville	NC	27249	ICH	Burlington Dialysis	Duplicate
11	Ricky A. Gill	401 Riverton Ct	Gibsonville	NC	27249	ICH	Burlington Dialysis	
12	Jeffrey J. Fle(illegible)				27410	ICH	Burlington Dialysis	
13	Ernest E. Walker	3326 Alamance Church Rd	Julian	NC	27283	ICH	Burlington Dialysis	
14	Archie O. Mcreele (illegible)				27405	ICH	Burlington Dialysis	
15	Anthony B. Mathis (illegible)				27405	ICH	Burlington Dialysis	Duplicate
16	Arthur L. Snipes	4717 Rudd Rd	Greensboro	NC	27405	ICH	Burlington Dialysis	
17	M. Stenunos (illegible)				27405	ICH	Burlington Dialysis	
18	Mary Beale	3009 Gwynn Rd	Elon	NC	27244	ICH	Burlington Dialysis	Duplicate
19	(Illegible)				27244	ICH	Burlington Dialysis	Duplicate
20	Pauline H. Tate	1739 Power Line Rd	Elon	NC	27244	ICH	Burlington Dialysis	Duplicate
21	James T. Disosusoy (illegible)				27298	ICH	Burlington Dialysis	
22	(Illegible)				27244	ICH	North Burlington Dialysis	
23	John V. S (illegible)				27244	ICH	North Burlington Dialysis	
24	(Illegible)				27244	ICH	North Burlington Dialysis	
25	Mary Been				27244	ICH	North Burlington Dialysis	
26	Reginald Thompson				27244	ICH	North Burlington Dialysis	
27	Jeffrey M (Illegible)				27244	ICH	North Burlington Dialysis	
28	Saie A (Illegible)				27244	ICH	North Burlington Dialysis	



29 Dorothea Nesbitt			27244	ICH	North Burlington Dialysis
30 Katrina Dunst (Illegible)			27244	ICH	North Burlington Dialysis
31 Mary McCadden			27244	ICH	North Burlington Dialysis
32 Ernest E. Welker			27244	ICH	North Burlington Dialysis
33 X			27244	ICH	North Burlington Dialysis
34 Earl Murphy (Illegible)			27298	ICH	Alamance County Dialysis
35 (Illegible)			27405	ICH	Reidsville Dialysis
36 Robert Selke (Illegible)			27046	ICH	Dialysis Care of Rockingham County
37 Eunice Goins	6393 NC 704	Sandy Ridge NC	27046	ICH	Dialysis Care of Rockingham County
38 L Plevens (Illegible)			27214	PD	Alamance County Dialysis
39 Lorraine Russell	8638 NC 49	Snow Camp NC	27349	PD	Burlington Dialysis
40 Kenny Reeter (Illegible)			27298	PD	Burlington Dialysis

DaVita - Guilford County

To Whom It May Concern:

I am an in-center dialysis patient receiving my dialysis treatments at Burlington Dialysis. I live in zip code 27301. I understand that DaVita Inc., operating as Total Renal Care of North Carolina, LLC d/b/a Guilford County Dialysis, is submitting a Certificate of Need application to the State of North Carolina for permission to develop a new ten-station dialysis facility in Greensboro in Guilford County. I enthusiastically support the efforts of DaVita and Total Renal Care of North Carolina and I want to strongly encourage the state to approve this Certificate of Need application to develop a new dialysis facility in Guilford County.

If the application to develop a new dialysis facility in Guilford County is approved, I definitely would consider transferring to the new facility because a DaVita dialysis center in Greensboro will certainly be beneficial to me and other patients who live in the area. There are two very important reasons to approve this application:

- A new facility in Guilford County will be more convenient for me and my transportation to and from dialysis. Patients like me who are have to deal with many hardships, especially arranging transportation three days a week. I expect my travel time to this new facility to be shorter.
- I understand that the new DaVita facility will be operated in the same manner as my current facility.

As a dialysis patient, I know this letter is not binding on me and that I have the right to choose where I receive my dialysis treatments at any time, but since Guilford County Dialysis would be so much more convenient for me and I will have access to the same services that have become so important to me at Burlington Dialysis, I would be willing to transfer my care to Guilford County Dialysis.

I understand that this letter will be a public record when Total Renal Care of North Carolina includes it in the certificate of need application for the new Guilford County Dialysis that will be submitted to the state. By my signature or mark below, I consent to having my letter included in the application. I further understand that no other Protected Health Information (PHI) regarding me, my diagnosis or treatment will be released as a part of this application.

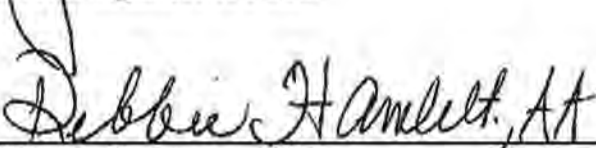
I wish DaVita and Total Renal Care of North Carolina every success in this effort.



 Patient Signature or Mark



 Date Signed



 Witness Signature and Title



 Date Signed



DaVita Elon Dialysis

To Whom It May Concern:

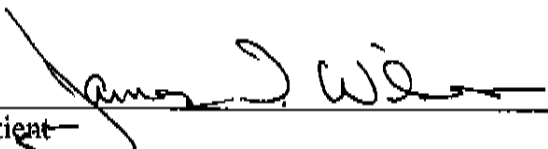
I am an in-center dialysis patient. I live in zip code 27301, which is located in McLeansville in Guilford County. I understand that Renal Treatment Centers Mid-Atlantic, Inc., which is owned by the same parent company that operates Burlington Dialysis where I receive treatment now, is proposing to start a new dialysis facility at a location in Alamance County to be known as Renal Treatment Centers Mid-Atlantic, Inc. d/b/a Elon Dialysis.

I fully support this new dialysis facility in to be built in Elon. Having my dialysis treatments at Elon Dialysis would be more convenient for me. I could travel between my home and that location more easily and quickly, which would save me time and money. Continuity of my care is very important to me. I understand that Elon Dialysis will be operated in the same manner as my current facility, so I would consider transferring to Elon Dialysis for my dialysis treatments.

I understand that this statement will in no way require me to transfer, and that decision to transfer is still up to me when the time comes. But I definitely would consider transferring because it would mean a shorter trip to dialysis that would make getting my treatments easier.

I have been informed that this letter will be included by Renal Treatment Centers Mid-Atlantic, Inc. in a certificate of need application proposing the Elon Dialysis facility that will be submitted to the Certificate of Need Section, Division of Health Service Regulation, in the N.C. Department of Health and Human Services, for review by that agency. I understand that the public will have access to the information in the Certificate of Need application and will have an opportunity to comment on the application. I agree to have this letter and the information about me as a patient that is contained in this letter included in the Elon Dialysis Certificate of Need application for that purpose.

By my signature or mark below, I consent to having my letter included in the application. I further understand that no other Protected Health Information (PHI) regarding me, my diagnosis or treatment will be released as a part of this application.



Patient

6/21/2016
Date

Debbie Hamlett

Witness

6/21/2016
Date

DaVita - Guilford County

To Whom It May Concern:

I am an in-center dialysis patient receiving my dialysis treatments at Burlington Dialysis. I live in zip code 27406. I understand that DaVita Inc., operating as Total Renal Care of North Carolina, LLC d/b/a Guilford County Dialysis, is submitting a Certificate of Need application to the State of North Carolina for permission to develop a new ten-station dialysis facility in Greensboro in Guilford County. I enthusiastically support the efforts of DaVita and Total Renal Care of North Carolina and I want to strongly encourage the state to approve this Certificate of Need application to develop a new dialysis facility in Guilford County.

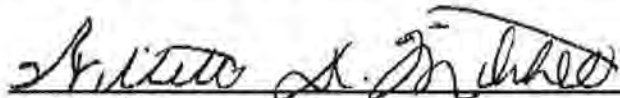
If the application to develop a new dialysis facility in Guilford County is approved, I definitely would consider transferring to the new facility because a DaVita dialysis center in Greensboro will certainly be beneficial to me and other patients who live in the area. There are two very important reasons to approve this application:

- A new facility in Guilford County will be more convenient for me and my transportation to and from dialysis. Patients like me who are have to deal with many hardships, especially arranging transportation three days a week. I expect my travel time to this new facility to be shorter.
- I understand that the new DaVita facility will be operated in the same manner as my current facility.


As a dialysis patient, I know this letter is not binding on me and that I have the right to choose where I receive my dialysis treatments at any time, but since Guilford County Dialysis would be so much more convenient for me and I will have access to the same services that have become so important to me at Burlington Dialysis, I would be willing to transfer my care to Guilford County Dialysis.

I understand that this letter will be a public record when Total Renal Care of North Carolina includes it in the certificate of need application for the new Guilford County Dialysis that will be submitted to the state. By my signature or mark below, I consent to having my letter included in the application. I further understand that no other Protected Health Information (PHI) regarding me, my diagnosis or treatment will be released as a part of this application.

I wish DaVita and Total Renal Care of North Carolina every success in this effort.


 Patient Signature or Mark

8.28.17
 Date Signed


 Witness Signature and Title

8.28.17
 Date Signed

DaVita Elon Dialysis

To Whom It May Concern:

I am an in-center dialysis patient. I live in zip code 27406, which is located in Greensboro in Guilford County. I understand that Renal Treatment Centers Mid-Atlantic, Inc., which is owned by the same parent company that operates Burlington Dialysis where I receive treatment now, is proposing to start a new dialysis facility at a location in Alamance County to be known as Renal Treatment Centers Mid-Atlantic, Inc. d/b/a Elon Dialysis.

I fully support this new dialysis facility in to be built in Elon. Having my dialysis treatments at Elon Dialysis would be more convenient for me. I could travel between my home and that location more easily and quickly, which would save me time and money. Continuity of my care is very important to me. I understand that Elon Dialysis will be operated in the same manner as my current facility, so I would consider transferring to Elon Dialysis for my dialysis treatments.

I understand that this statement will in no way require me to transfer, and that decision to transfer is still up to me when the time comes. But I definitely would consider transferring because it would mean a shorter trip to dialysis that would make getting my treatments easier.

I have been informed that this letter will be included by Renal Treatment Centers Mid-Atlantic, Inc. in a certificate of need application proposing the Elon Dialysis facility that will be submitted to the Certificate of Need Section, Division of Health Service Regulation, in the N.C. Department of Health and Human Services, for review by that agency. I understand that the public will have access to the information in the Certificate of Need application and will have an opportunity to comment on the application. I agree to have this letter and the information about me as a patient that is contained in this letter included in the Elon Dialysis Certificate of Need application for that purpose.

By my signature or mark below, I consent to having my letter included in the application. I further understand that no other Protected Health Information (PHI) regarding me, my diagnosis or treatment will be released as a part of this application.



Patient

6-17-16
Date



Witness

6/17/16
Date

DaVita - Guilford County

To Whom It May Concern:

I am an in-center dialysis patient receiving my dialysis treatments at Burlington Dialysis. I live in zip code 27249. I understand that DaVita Inc., operating as Total Renal Care of North Carolina, LLC d/b/a Guilford County Dialysis, is submitting a Certificate of Need application to the State of North Carolina for permission to develop a new ten-station dialysis facility in Greensboro in Guilford County. I enthusiastically support the efforts of DaVita and Total Renal Care of North Carolina and I want to strongly encourage the state to approve this Certificate of Need application to develop a new dialysis facility in Guilford County.

If the application to develop a new dialysis facility in Guilford County is approved, I definitely would consider transferring to the new facility because a DaVita dialysis center in Greensboro will certainly be beneficial to me and other patients who live in the area. There are two very important reasons to approve this application:

- A new facility in Guilford County will be more convenient for me and my transportation to and from dialysis. Patients like me who are have to deal with many hardships, especially arranging transportation three days a week. I expect my travel time to this new facility to be shorter.
- I understand that the new DaVita facility will be operated in the same manner as my current facility.

As a dialysis patient, I know this letter is not binding on me and that I have the right to choose where I receive my dialysis treatments at any time, but since Guilford County Dialysis would be so much more convenient for me and I will have access to the same services that have become so important to me at Burlington Dialysis, I would be willing to transfer my care to Guilford County Dialysis.

I understand that this letter will be a public record when Total Renal Care of North Carolina includes it in the certificate of need application for the new Guilford County Dialysis that will be submitted to the state. By my signature or mark below, I consent to having my letter included in the application. I further understand that no other Protected Health Information (PHI) regarding me, my diagnosis or treatment will be released as a part of this application.

I wish DaVita and Total Renal Care of North Carolina every success in this effort.

Louis Walker 8-28-17
 Patient Signature or Mark Date Signed

Debbie Hamlet, AA 8-28-17
 Witness Signature and Title Date Signed

DaVita Elon Dialysis

To Whom It May Concern:

I am an in-center dialysis patient. I live in zip code 27249, which is located in Gibsonville in Guilford County. I understand that Renal Treatment Centers Mid-Atlantic, Inc., which is owned by the same parent company that operates Burlington Dialysis where I receive treatment now, is proposing to start a new dialysis facility at a location in Alamance County to be known as Renal Treatment Centers Mid-Atlantic, Inc. d/b/a Elon Dialysis.

I fully support this new dialysis facility in to be built in Elon. Having my dialysis treatments at Elon Dialysis would be more convenient for me. I could travel between my home and that location more easily and quickly, which would save me time and money. Continuity of my care is very important to me. I understand that Elon Dialysis will be operated in the same manner as my current facility, so I would consider transferring to Elon Dialysis for my dialysis treatments.

I understand that this statement will in no way require me to transfer, and that decision to transfer is still up to me when the time comes. But I definitely would consider transferring because it would mean a shorter trip to dialysis that would make getting my treatments easier.

I have been informed that this letter will be included by Renal Treatment Centers Mid-Atlantic, Inc. in a certificate of need application proposing the Elon Dialysis facility that will be submitted to the Certificate of Need Section, Division of Health Service Regulation, in the N.C. Department of Health and Human Services, for review by that agency. I understand that the public will have access to the information in the Certificate of Need application and will have an opportunity to comment on the application. I agree to have this letter and the information about me as a patient that is contained in this letter included in the Elon Dialysis Certificate of Need application for that purpose.

By my signature or mark below, I consent to having my letter included in the application. I further understand that no other Protected Health Information (PHI) regarding me, my diagnosis or treatment will be released as a part of this application.

Laura Walker
Patient

6/17/16
Date

Debbie Hamlett
Witness

6/17/16
Date

DaVita - Guilford County

To Whom It May Concern:

I am an in-center dialysis patient receiving my dialysis treatments at Burlington Dialysis. I live in zip code 27244. I understand that DaVita Inc., operating as Total Renal Care of North Carolina, LLC d/b/a Guilford County Dialysis, is submitting a Certificate of Need application to the State of North Carolina for permission to develop a new ten-station dialysis facility in Greensboro in Guilford County. I enthusiastically support the efforts of DaVita and Total Renal Care of North Carolina and I want to strongly encourage the state to approve this Certificate of Need application to develop a new dialysis facility in Guilford County.


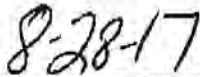
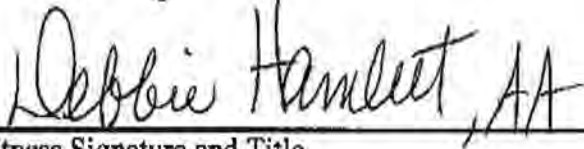
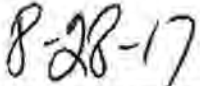
If the application to develop a new dialysis facility in Guilford County is approved, I definitely would consider transferring to the new facility because a DaVita dialysis center in Greensboro will certainly be beneficial to me and other patients who live in the area. There are two very important reasons to approve this application:

- A new facility in Guilford County will be more convenient for me and my transportation to and from dialysis. Patients like me who are have to deal with many hardships, especially arranging transportation three days a week. I expect my travel time to this new facility to be shorter.
- I understand that the new DaVita facility will be operated in the same manner as my current facility.

As a dialysis patient, I know this letter is not binding on me and that I have the right to choose where I receive my dialysis treatments at any time, but since Guilford County Dialysis would be so much more convenient for me and I will have access to the same services that have become so important to me at Burlington Dialysis, I would be willing to transfer my care to Guilford County Dialysis.

I understand that this letter will be a public record when Total Renal Care of North Carolina includes it in the certificate of need application for the new Guilford County Dialysis that will be submitted to the state. By my signature or mark below, I consent to having my letter included in the application. I further understand that no other Protected Health Information (PHI) regarding me, my diagnosis or treatment will be released as a part of this application.

I wish DaVita and Total Renal Care of North Carolina every success in this effort.

	
Patient Signature or Mark	Date Signed
	
Witness Signature and Title	Date Signed

DaVita Elon Dialysis

To Whom It May Concern:

I am an in-center dialysis patient. I live in zip code 27244, which is located in Elon in Alamance County. I understand that Renal Treatment Centers Mid-Atlantic, Inc., which is owned by the same parent company that operates Burlington Dialysis where I receive treatment now, is proposing to start a new dialysis facility at a location in Alamance County to be known as Renal Treatment Centers Mid-Atlantic, Inc. d/b/a Elon Dialysis.

I fully support this new dialysis facility in to be built in Elon. Having my dialysis treatments at Elon Dialysis would be more convenient for me. I could travel between my home and that location more easily and quickly, which would save me time and money. Continuity of my care is very important to me. I understand that Elon Dialysis will be operated in the same manner as my current facility, so I would consider transferring to Elon Dialysis for my dialysis treatments.

I understand that this statement will in no way require me to transfer, and that decision to transfer is still up to me when the time comes. But I definitely would consider transferring because it would mean a shorter trip to dialysis that would make getting my treatments easier.

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By my signature or mark below, I consent to having my letter included in the application. I further understand that no other Protected Health Information (PHI) regarding me, my diagnosis or treatment will be released as a part of this application.

Mary Beale
Patient

6/17/16
Date

Debbie Hamlett
Witness

6/17/16
Date

DaVita - Guilford County

To Whom It May Concern:

I am an in-center dialysis patient receiving my dialysis treatments at Burlington Dialysis. I live in zip code 27244. I understand that DaVita Inc., operating as Total Renal Care of North Carolina, LLC d/b/a Guilford County Dialysis, is submitting a Certificate of Need application to the State of North Carolina for permission to develop a new ten-station dialysis facility in Greensboro in Guilford County. I enthusiastically support the efforts of DaVita and Total Renal Care of North Carolina and I want to strongly encourage the state to approve this Certificate of Need application to develop a new dialysis facility in Guilford County.


If the application to develop a new dialysis facility in Guilford County is approved, I definitely would consider transferring to the new facility because a DaVita dialysis center in Greensboro will certainly be beneficial to me and other patients who live in the area. There are two very important reasons to approve this application:

- A new facility in Guilford County will be more convenient for me and my transportation to and from dialysis. Patients like me who are have to deal with many hardships, especially arranging transportation three days a week. I expect my travel time to this new facility to be shorter.
- I understand that the new DaVita facility will be operated in the same manner as my current facility.

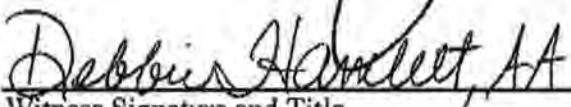
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I understand that this letter will be a public record when Total Renal Care of North Carolina includes it in the certificate of need application for the new Guilford County Dialysis that will be submitted to the state. By my signature or mark below, I consent to having my letter included in the application. I further understand that no other Protected Health Information (PHI) regarding me, my diagnosis or treatment will be released as a part of this application.

I wish DaVita and Total Renal Care of North Carolina every success in this effort.


Patient Signature or Mark


Date Signed


Witness Signature and Title


Date Signed

DaVita Elon Dialysis

To Whom It May Concern:

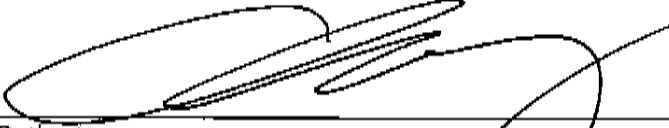
I am an in-center dialysis patient. I live in zip code 27244, which is located in Elon in Alamance County. I understand that Renal Treatment Centers Mid-Atlantic, Inc., which is owned by the same parent company that operates Burlington Dialysis where I receive treatment now, is proposing to start a new dialysis facility at a location in Alamance County to be known as Renal Treatment Centers Mid-Atlantic, Inc. d/b/a Elon Dialysis.

I fully support this new dialysis facility in to be built in Elon. Having my dialysis treatments at Elon Dialysis would be more convenient for me. I could travel between my home and that location more easily and quickly, which would save me time and money. Continuity of my care is very important to me. I understand that Elon Dialysis will be operated in the same manner as my current facility, so I would consider transferring to Elon Dialysis for my dialysis treatments.

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By my signature or mark below, I consent to having my letter included in the application. I further understand that no other Protected Health Information (PHI) regarding me, my diagnosis or treatment will be released as a part of this application.



Patient

6-20-16

Date

Jesse Williams

Witness

10/20/16

Date

DaVita - Guilford County

To Whom It May Concern:

I am an in-center dialysis patient receiving my dialysis treatments at Burlington Dialysis. I live in zip code 27244. I understand that DaVita Inc., operating as Total Renal Care of North Carolina, LLC d/b/a Guilford County Dialysis, is submitting a Certificate of Need application to the State of North Carolina for permission to develop a new ten-station dialysis facility in Greensboro in Guilford County. I enthusiastically support the efforts of DaVita and Total Renal Care of North Carolina and I want to strongly encourage the state to approve this Certificate of Need application to develop a new dialysis facility in Guilford County.

If the application to develop a new dialysis facility in Guilford County is approved, I definitely would consider transferring to the new facility because a DaVita dialysis center in Greensboro will certainly be beneficial to me and other patients who live in the area. There are two very important reasons to approve this application:

- A new facility in Guilford County will be more convenient for me and my transportation to and from dialysis. Patients like me who have to deal with many hardships, especially arranging transportation three days a week. I expect my travel time to this new facility to be shorter.
- I understand that the new DaVita facility will be operated in the same manner as my current facility.

As a dialysis patient, I know this letter is not binding on me and that I have the right to choose where I receive my dialysis treatments at any time, but since Guilford County Dialysis would be so much more convenient for me and I will have access to the same services that have become so important to me at Burlington Dialysis, I would be willing to transfer my care to Guilford County Dialysis.

I understand that this letter will be a public record when Total Renal Care of North Carolina includes it in the certificate of need application for the new Guilford County Dialysis that will be submitted to the state. By my signature or mark below, I consent to having my letter included in the application. I further understand that no other Protected Health Information (PHI) regarding me, my diagnosis or treatment will be released as a part of this application.

I wish DaVita and Total Renal Care of North Carolina every success in this effort.

Pauline H. Tate

8-29-17

Patient Signature or Mark

Date Signed

Debra Hamlet AA

8-29-17

Witness Signature and Title

Date Signed

DaVita Elon Dialysis

To Whom It May Concern:

I am an in-center dialysis patient. I live in zip code 27244, which is located in Elon in Alamance County. I understand that Renal Treatment Centers Mid-Atlantic, Inc., which is owned by the same parent company that operates Burlington Dialysis where I receive treatment now, is proposing to start a new dialysis facility at a location in Alamance County to be known as Renal Treatment Centers Mid-Atlantic, Inc. d/b/a Elon Dialysis.

I fully support this new dialysis facility in to be built in Elon. Having my dialysis treatments at Elon Dialysis would be more convenient for me. I could travel between my home and that location more easily and quickly, which would save me time and money. Continuity of my care is very important to me. I understand that Elon Dialysis will be operated in the same manner as my current facility, so I would consider transferring to Elon Dialysis for my dialysis treatments.

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By my signature or mark below, I consent to having my letter included in the application. I further understand that no other Protected Health Information (PHI) regarding me, my diagnosis or treatment will be released as a part of this application.

X Pauline Tate
Patient

6/16/16
Date

Ashe Williams MD
Witness

6/16/16
Date

DaVita - Guilford County

To Whom It May Concern:

I am an in-center dialysis patient receiving my dialysis treatments at Burlington Dialysis. I live in zip code 27405. I understand that DaVita Inc., operating as Total Renal Care of North Carolina, LLC d/b/a Guilford County Dialysis, is submitting a Certificate of Need application to the State of North Carolina for permission to develop a new ten-station dialysis facility in Greensboro in Guilford County. I enthusiastically support the efforts of DaVita and Total Renal Care of North Carolina and I want to strongly encourage the state to approve this Certificate of Need application to develop a new dialysis facility in Guilford County.

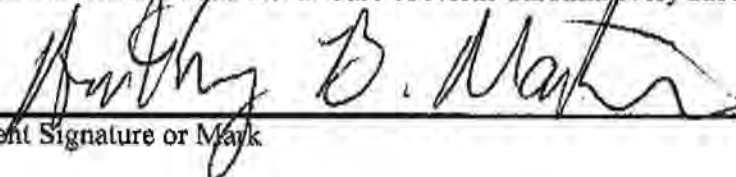
If the application to develop a new dialysis facility in Guilford County is approved, I definitely would consider transferring to the new facility because a DaVita dialysis center in Greensboro will certainly be beneficial to me and other patients who live in the area. There are two very important reasons to approve this application:

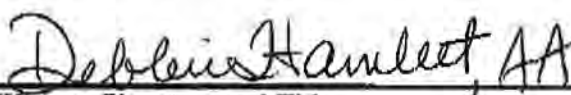
- A new facility in Guilford County will be more convenient for me and my transportation to and from dialysis. Patients like me who are have to deal with many hardships, especially arranging transportation three days a week. I expect my travel time to this new facility to be shorter.
- I understand that the new DaVita facility will be operated in the same manner as my current facility.

As a dialysis patient, I know this letter is not binding on me and that I have the right to choose where I receive my dialysis treatments at any time, but since Guilford County Dialysis would be so much more convenient for me and I will have access to the same services that have become so important to me at Burlington Dialysis, I would be willing to transfer my care to Guilford County Dialysis.

I understand that this letter will be a public record when Total Renal Care of North Carolina includes it in the certificate of need application for the new Guilford County Dialysis that will be submitted to the state. By my signature or mark below, I consent to having my letter included in the application. I further understand that no other Protected Health Information (PHI) regarding me, my diagnosis or treatment will be released as a part of this application.

I wish DaVita and Total Renal Care of North Carolina every success in this effort.


 Patient Signature or Mark 8-28-17
Date Signed


 Witness Signature and Title 8-28-17
Date Signed

DaVita Elon Dialysis

To Whom It May Concern:

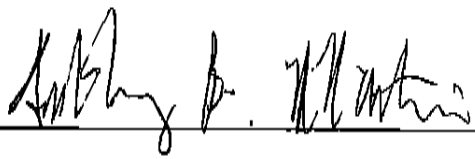
I am an in-center dialysis patient. I live in zip code 27405, which is located in Greensboro in Guilford County. I understand that Renal Treatment Centers Mid-Atlantic, Inc., which is owned by the same parent company that operates Burlington Dialysis where I receive treatment now, is proposing to start a new dialysis facility at a location in Alamance County to be known as Renal Treatment Centers Mid-Atlantic, Inc. d/b/a Elon Dialysis.

I fully support this new dialysis facility in to be built in Elon. Having my dialysis treatments at Elon Dialysis would be more convenient for me. I could travel between my home and that location more easily and quickly, which would save me time and money. Continuity of my care is very important to me. I understand that Elon Dialysis will be operated in the same manner as my current facility, so I would consider transferring to Elon Dialysis for my dialysis treatments.

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By my signature or mark below, I consent to having my letter included in the application. I further understand that no other Protected Health Information (PHI) regarding me, my diagnosis or treatment will be released as a part of this application.



Patient

6/17/14
Date

Debbie Hamlett

Witness

6/17/14
Date

DaVita - Guilford County

To Whom It May Concern:

I am an in-center dialysis patient receiving my dialysis treatments at North Burlington Dialysis. I live in zip code 27244. I understand that DaVita Inc., operating as Total Renal Care of North Carolina, LLC d/b/a Guilford County Dialysis, is submitting a Certificate of Need application to the State of North Carolina for permission to develop a new ten-station dialysis facility in Greensboro in Guilford County. I enthusiastically support the efforts of DaVita and Total Renal Care of North Carolina and I want to strongly encourage the state to approve this Certificate of Need application to develop a new dialysis facility in Guilford County.

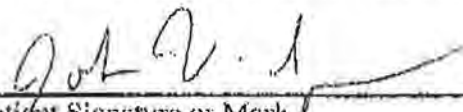
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As a dialysis patient, I know this letter is not binding on me and that I have the right to choose where I receive my dialysis treatments at any time, but since Guilford County Dialysis would be so much more convenient for me and I will have access to the same services that have become so important to me at North Burlington Dialysis, I would be willing to transfer my care to Guilford County Dialysis.

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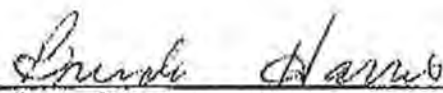
I wish DaVita and Total Renal Care of North Carolina every success in this effort.



 Patient Signature or Mark

8/25/17

 Date Signed



 Witness Signature and Title

8/25/17

 Date Signed

S. Ingram

DaVita Elon Dialysis

To Whom It May Concern:

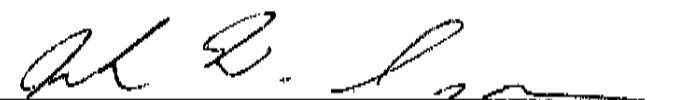
I am an in-center dialysis patient. I live in zip code 27244, which is located in Elon in Alamance County. I understand that Renal Treatment Centers Mid-Atlantic, Inc., which is owned by the same parent company that operates North Burlington Dialysis where I receive treatment now, is proposing to start a new dialysis facility at a location in Alamance County to be known as Renal Treatment Centers Mid-Atlantic, Inc. d/b/a Elon Dialysis.

I fully support this new dialysis facility in to be built in Elon. Having my dialysis treatments at Elon Dialysis would be more convenient for me. I could travel between my home and that location more easily and quickly, which would save me time and money. Continuity of my care is very important to me. I understand that Elon Dialysis will be operated in the same manner as my current facility, so I would consider transferring to Elon Dialysis for my dialysis treatments.

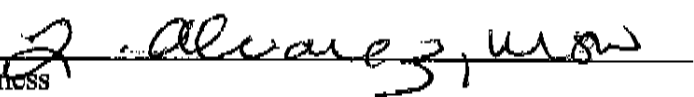
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By my signature or mark below, I consent to having my letter included in the application. I further understand that no other Protected Health Information (PHI) regarding me, my diagnosis or treatment will be released as a part of this application.


Patient

4/17/16
Date


Witness

4/17/16
Date

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.

C

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 contiguous [sic] county is currently serving residents of that contiguous [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.

C

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:

County	Operating Year (OY) 1			Operating Year (OY) 2			Percent of Total	
	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 – three 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.
3. 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.

Projected Utilization

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

Elon Dialysis	In-Center
The applicant begins the facility census with the in-center 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.	$(26.96 \times 0.037) + 26.96 = 27.96$
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 in-center 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.

C

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.

RENAL TREATMENT CENTERS-MID-ATLANTIC, INC.

D/B/A

BURLINGTON DIALYSIS

CERTIFICATE OF NEED APPLICATION

SEPTEMBER 15, 2017

FOR THE FACILITY LOCATED AT

**873 HEATHER ROAD
BURLINGTON, NORTH CAROLINA 27215**

ALAMANCE COUNTY



CERTIFICATION

The undersigned hereby assures and certifies that:

- (a) the work on the proposed project will be initiated in accordance with the timetable set forth on the certificate of need;
- (b) completion of the proposed project will be pursued with reasonable diligence;
- (c) the proposed project will be constructed, operated and maintained in full compliance with all applicable local, State and Federal laws, rules, regulations and ordinances;
- (d) the applicant will materially comply with the representations made in its application in the development of the project and the offering of the services pursuant to N.C.G.S. 131E-181(b); and,
- (e) that the information included in this application and all attachments is correct to the best of my knowledge and belief and that it is my intent to carry out the proposed project as described.

LEGAL NAME OF APPLICANT: Renal Treatment Centers Mid-Atlantic, Inc. d/b/a Burlington Dialysis

NAME OF RESPONSIBLE OFFICER: James K. Hilger

TITLE OF OFFICER: Chief Accounting Officer

ADDRESS: 2000 16th Street, Denver, CO 80202

SIGNATURE OF OFFICER: 

DATE: 9/12/2017

C

SECTION C - “CRITERION (3)” - G.S. 131E-183(a)(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.”

For All Applications (except Change of Scope and Cost Overruns)

1. Provide the county of residence for the patients who are projected to utilize the facility during the first two operating years using the format below. Provide all assumptions and data used to project the number of in-center, home hemo, and peritoneal (PD) patients by county of origin.

Total Projected Patients by County of Residence

County	OY 1			OY 2			County Patients as a Percent of Total	
	In-center Patients	Home Hemo Patients	Peritoneal Patients	In-center Patients	Home Hemo Patients	Peritoneal Patients	OY 1	OY 2
Alamance	46	0	14	48	0	15	85.7%	86.3%
Caswell	1	0	0	1	0	0	1.4%	1.4%
Guilford	4	0	1	4	0	1	7.1%	6.8%
Onslow	1	0	0	1	0	0	1.4%	1.4%
Person	1	0	0	1	0	0	1.4%	1.4%
Randolph	1	0	0	1	0	0	1.4%	1.4%
Other States	1	0	0	1	0	0	1.4%	1.4%
Total *	55	0	15	57	0	16	100%	100%

The following are the assumptions and data used for the projections to project the number of in-center, home hemo (HHD), and peritoneal (PD) patients by county of origin:

Burlington Dialysis had 96 in-center patients as of December 31, 2016 based on information included in Table A of the July 2017 Semiannual Dialysis Report (SDR). This is a station utilization rate of 100.00% based on the 24 certified stations. Of these 96 patients, 79 lived in the service area, Alamance County and 17 lived outside of the service area (Caswell, Guilford, Onslow, Orange, Person and Randolph Counties as well as Other States).

In Project ID # G-011212-16 Renal Treatment Centers-Mid-Atlantic, Inc. is approved to develop Elon Dialysis in Alamance County which will include the transfer of eight (8) stations from Burlington Dialysis, leaving the facility with 16 stations. Renal Treatment Centers-Mid-Atlantic, Inc. indicated in the application that 31 in-center patients would transfer their care from Burlington Dialysis to Elon Dialysis upon its projected certification date of January 1, 2018.

In Project ID # G-011289-17, Renal Treatment Centers-Mid-Atlantic, Inc. is approved to develop Mebane Dialysis in Alamance County which will include the transfer of four (4) stations from Burlington Dialysis, leaving the facility with 12 stations. Renal Treatment Centers-Mid-Atlantic,

Inc. indicated in the application that 17 in-center patients would transfer their care from Burlington Dialysis to Mebane Dialysis upon its projected certification date of January 1, 2019.

In Project ID # G-011321-17 Renal Treatment Centers-Mid-Atlantic, Inc. is approved to add four (4) stations to the existing facility, leaving the facility with 16 stations.

Operating Year One is projected to begin January 1, 2019 and end on December 31, 2019. Operating Year Two is projected to begin January 1, 2020 and end on December 31, 2020.

While the Average Annual Change Rate for the Past Five Years as indicated in Table D of the July 2017 SDR for Alamance County was 4.1%, Burlington Dialysis has experienced an average growth rate over the last five years of 6.2% (see table below). It is therefore reasonable to assume a growth rate of at least 5.0% for the facility, so as to be conservative.

	# of pts	Growth Rate
12/31/2012	76	
12/31/2013	85	11.8%
12/31/2014	90	5.9%
12/31/2015	101	12.2%
12/31/2016	96	-5.0%
5-year avg change rate		6.2%

The following are the in-center patient projections using the 5.0% Average Annual Change Rate for the Past Five Years for the 79 in-center patients living in Alamance County. The period of the growth begins January 1, 2017 and is calculated forward to December 31, 2020. No growth calculations were performed for the patients living outside of Alamance County.

It is projected that at least 31 current in-center patients from Burlington Dialysis will transfer to Elon Dialysis upon its certification. After the period of growth ending in 2017, there will be 99 in-center patients, 82 of them from Alamance County (see line (c) below). When we deduct the 24 Alamance County patients and 7 patients from outside of Alamance County projected to transfer to Elon Dialysis upon its certification, Burlington Dialysis will have 58 Alamance County patients at the beginning of 2018 (see line (d) below).

It is projected that at least 17 current in-center patients from Burlington Dialysis will transfer to Mebane Dialysis upon its certification. After the period of growth ending in 2018, there will be 70 in-center patients, 60 of them from Alamance County (see line (d) below). When we deduct the 16 Alamance County and 1 Orange County patients projected to transfer to Mebane Dialysis upon its certification, Burlington Dialysis will have 44 Alamance County patients at the beginning of 2019 (see line (e) below).

Based on the calculations below, Burlington Dialysis is projected to have at least 55 in-center patients by the end of operating year 1 for a utilization rate of 80.9% or 3.24 patients per station and at least 57 in-center patients by the end of operating year 2 for a utilization rate of 83.8% or 3.35 patients per station.

Patient Census Projections: In-Center

		Start Date	# of SA Patients	x	Growth Rate	=	SA Year End Census	+	# out-of-SA existing patients	=	Total Year End Census	Year End Date
(a)	Beginning service area (SA) census SA: Alamance County											
(b)	Interim Period			x		=		+		=		
(c)	Current Year	1/1/2017	79	x	1.05	=	82.95	+	17	=	99.239	12/31/2017
(d)	Interim Period	1/1/2018	82 - 24 = 58	x	1.05	=	60.9	+	17 - 7 = 10	=	102.6108	12/31/2018
(e)	Census OY 1	1/1/2019	60 - 16 = 44	x	1.05	=	46.2	+	10 - 1 = 9	=	55.845	12/31/2019
(f)	Census OY 2	1/1/2020	46.2	x	1.05	=	48.51	+	9	=	57.76565	12/31/2020

The table below summarizes the beginning and end of year census for each of the years in the period of growth and lists the average number of patients for each year. The numbers of patients shown below (beginning and end of year) were rounded down to the nearest whole number.

	Start Date	# of pts - begin of year	# of pts - end of year	Avg # of pts in year	pts per station	Utilization Rate
Current Year	1/1/2017	96	99	97.5		
Interim Period	1/1/2018	68	70	69		
Operating Year 1	1/1/2019	53	55	54	3.24	80.9%
Operating Year 2	1/1/2020	55	57	56	3.35	83.8%

Peritoneal Dialysis (PD):

Burlington Dialysis had 12 PD patients as of December 31, 2016 based on information included in Table C of the July 2017 SDR. Of these 12 patients, 11 lived in the service area, Alamance County and 1 lived outside of the service area (Guilford County).

Operating Year One is projected to begin January 1, 2019 and end on December 31, 2019. Operating Year Two is projected to begin January 1, 2020 and end on December 31, 2020.

The period of the growth begins January 1, 2017 and is calculated forward to December 31, 2020. It is reasonable to assume that the Burlington Dialysis home-training program will grow at a rate of at least one patient per year during the period of growth.

The table below summarizes the beginning and end of year census for each of the years in the period of growth and lists the average number of patients for each year. The numbers of patients shown below (beginning and end of year) were rounded down to the nearest whole number.

PD patient projections	Start Date	# of pts - begin of year	# of pts - end of year	Avg # of pts in year
Current Year	1/1/2017	12	13	12.5
Interim Period	1/1/2018	13	14	13.5
Operating Year 1	1/1/2019	14	15	14.5
Operating Year 2	1/1/2020	15	16	15.5

2. Describe the need that the population to be served has for the proposed project, including in-center, home hemo, and PD services. Provide supporting documentation.

Section B-2 clearly outlines the need that the population to served, the in-center patients of Burlington Dialysis, has for the one-station expansion proposed in this application.

3. Describe the extent to which all area residents, including low income persons, racial and ethnic minorities, women, handicapped persons, the elderly and other underserved groups, will have access to the proposed services.

By policy, the proposed services will be made available to all residents in its service area without qualifications. The facility will serve patients without regard to race, sex, age, or handicap. We will serve patients regardless of ethnic or socioeconomic situation.

We will make every reasonable effort to accommodate all patients, especially those with special needs such as the handicapped, patients attending school or patients who work. Dialysis services will be provided six days per week with two patient shifts per day to accommodate patient need.

Payment will not be required upon admission. Therefore, services are available to all patients including low income persons, racial and ethnic minorities, women, handicapped persons, elderly and other under-served persons.

For New Facility and Relocated Facility Applications (except Change of Scope and Cost Overruns)

4. Indicate the anticipated travel distance for patients from their homes to the applicant's proposed facility:

Not Applicable.

Travel Distance

	Percent of Patients
Percent that will travel 30 miles or less	
Percent that will travel more than 30 miles	
Total Percent	100%

5. Document that the new facility is needed at the proposed site as opposed to another area of the county.

Not Applicable.

For Existing Facilities (except Change of Scope and Cost Overruns)

6. Complete the following table (if it correctly reflects the methodology utilized to project the number of patients). For each row, provide all assumptions and data used to support the projection.

Not Applicable

		Date	# of Patients		Growth Rate	=	Year End Census
(a)	Beginning service area (SA) census SA:						
(b)	Census calculation interim period (specify period between beginning date and OY 1 start date) and calculate census, adding rows as needed			x		=	
(c)	Add out-of-SA existing patients			+		=	
(d)	Census calculation OY 1			x		=	
(e)	Add out-of-SA existing patients			+		=	
(f)	Census calculation OY 2			x		=	
(g)	Add out-of-SA existing patients			+		=	
(h)	Total Census (end of OY 2)						

7. If the above methodology was not used to project patient census, provide the methodology used along with all assumptions and data used to support the projections.

Burlington Dialysis had 96 in-center patients as of December 31, 2016 based on information included in Table A of the July 2017 Semiannual Dialysis Report (SDR). This is a station utilization rate of 100.00% based on the 24 certified stations. Of these 96 patients, 79 lived in the service area, Alamance County and 17 lived outside of the service area (Caswell, Guilford, Onslow, Orange, Person and Randolph Counties as well as Other States).

In Project ID # G-011212-16 Renal Treatment Centers-Mid-Atlantic, Inc. is approved to develop Elon Dialysis in Alamance County which will include the transfer of eight (8) stations from Burlington Dialysis, leaving the facility with 16 stations. Renal Treatment Centers-Mid-Atlantic,

Inc. indicated in the application that 31 in-center patients would transfer their care from Burlington Dialysis to Elon Dialysis upon its projected certification date of January 1, 2018.

In Project ID # G-011289-17, Renal Treatment Centers-Mid-Atlantic, Inc. is approved to develop Mebane Dialysis in Alamance County which will include the transfer of four (4) stations from Burlington Dialysis, leaving the facility with 12 stations. Renal Treatment Centers-Mid-Atlantic, Inc. indicated in the application that 17 in-center patients would transfer their care from Burlington Dialysis to Mebane Dialysis upon its projected certification date of January 1, 2019.

In Project ID # G-011321-17 Renal Treatment Centers-Mid-Atlantic, Inc. is approved to add four stations to the existing facility, leaving the facility with 16 stations.

Operating Year One is projected to begin January 1, 2019 and end on December 31, 2019. Operating Year Two is projected to begin January 1, 2020 and end on December 31, 2020.

While the Average Annual Change Rate for the Past Five Years as indicated in Table D of the July 2017 SDR for Alamance County was 4.1%, Burlington Dialysis has experienced an average growth rate over the last five years of 6.2% (see table below). It is therefore reasonable to assume a growth rate of at least 5.0% for the facility, so as to be conservative.

	# of pts	Growth Rate
12/31/2012	76	
12/31/2013	85	11.8%
12/31/2014	90	5.9%
12/31/2015	101	12.2%
12/31/2016	96	-5.0%
5-year avg change rate		6.2%

The following are the in-center patient projections using the 5.0% Average Annual Change Rate for the Past Five Years for the 79 in-center patients living in Alamance County. The period of the growth begins January 1, 2017 and is calculated forward to December 31, 2020. No growth calculations were performed for the patients living outside of Alamance County.

It is projected that at least 31 current in-center patients from Burlington Dialysis will transfer to Elon Dialysis upon its certification. After the period of growth ending in 2017, there will be 99 in-center patients, 82 of them from Alamance County (see line (c) below). When we deduct the 24 Alamance County patients and 7 patients from outside of Alamance County projected to transfer to Elon Dialysis upon its certification, Burlington Dialysis will have 58 Alamance County patients at the beginning of 2018 (see line (d) below).

It is projected that at least 17 current in-center patients from Burlington Dialysis will transfer to Mebane Dialysis upon its certification. After the period of growth ending in 2018, there will be 70 in-center patients, 60 of them from Alamance County (see line (d) below). When we deduct the 16 Alamance County and 1 Orange County patients projected to transfer to Mebane Dialysis upon its certification, Burlington Dialysis will have 44 Alamance County patients at the beginning of 2019 (see line (e) below).

Based on the calculations below, Burlington Dialysis is projected to have at least 55 in-center patients by the end of operating year 1 for a utilization rate of 80.9% or 3.24 patients per station and at least 57 in-center patients by the end of operating year 2 for a utilization rate of 83.8% or 3.35 patients per station.

Patient Census Projections: In-Center

		Start Date	# of SA Patients	x	Growth Rate	=	SA Year End Census	+	# out-of-SA existing patients	=	Total Year End Census	Year End Date
(a)	Beginning service area (SA) census SA: Alamance County											
(b)	Interim Period			x		=		+		=		
(c)	Current Year	1/1/2017	79	x	1.05	=	82.95	+	17	=	99.95	12/31/2017
(d)	Interim Period	1/1/2018	82 - 24 = 58	x	1.05	=	60.9	+	17 - 7 = 10	=	70.9	12/31/2018
(e)	Census OY 1	1/1/2019	60 - 16 = 44	x	1.05	=	46.2	+	10 - 1 = 9	=	55.2	12/31/2019
(f)	Census OY 2	1/1/2020	46.2	x	1.05	=	48.51	+	9	=	57.51	12/31/2020

The table below summarizes the beginning and end of year census for each of the years in the period of growth and lists the average number of patients for each year. The numbers of patients shown below (beginning and end of year) were rounded down to the nearest whole number.

	Start Date	# of pts - begin of year	# of pts - end of year	Avg # of pts in year	pts per station	Utilization Rate
Current Year	1/1/2017	96	99	97.5		
Interim Period	1/1/2018	68	70	69		
Operating Year 1	1/1/2019	53	55	54	3.24	80.9%
Operating Year 2	1/1/2020	55	57	56	3.35	83.8%

Peritoneal Dialysis (PD):

Burlington Dialysis had 12 PD patients as of December 31, 2016 based on information included in Table C of the July 2017 SDR. Of these 12 patients, 11 lived in the service area, Alamance County and 1 lived outside of the service area (Guilford County).

Operating Year One is projected to begin January 1, 2019 and end on December 31, 2019.
 Operating Year Two is projected to begin January 1, 2020 and end on December 31, 2020.

The period of the growth begins January 1, 2017 and is calculated forward to December 31, 2020. It is reasonable to assume that the Burlington Dialysis home-training program will grow at a rate of at least one patient per year during the period of growth.

The table below summarizes the beginning and end of year census for each of the years in the period of growth and lists the average number of patients for each year. The numbers of patients shown below (beginning and end of year) were rounded down to the nearest whole number.

PD patient projections	Start Date	# of pts - begin of year	# of pts - end of year	Avg # of pts in year
Current Year	1/1/2017	12	13	12.5
Interim Period	1/1/2018	13	14	13.5
Operating Year 1	1/1/2019	14	15	14.5
Operating Year 2	1/1/2020	15	16	15.5

8. Provide the following data on the existing facility's current dialysis patients and number of certified stations.

Dialysis Patients as of 12/31/2016

County of Residence	# of In-center Dialysis Patients	# of Home /Hemo Dialysis Patients	# of PD Dialysis Patients
Alamance	79	0	11
Caswell	1	0	0
Guilford	11	0	1
Onslow	1	0	0
Orange	1	0	0
Person	1	0	0
Randolph	1	0	0
Other States	1	0	0
Totals	96	0	12

Note: Add additional lines to the table as needed.

9. Complete the following chart for the last three operating years.

Patients Served by Facility

Year	(1) Beginning In-center and Home Patients	(2) Ending In-center and Home Patients	(3) Average (1)+(2) / 2	(4) Deaths	(5) Gross Mortality Rate (4) / (3)
2016	101	107	104	21	20.19%
2015	90	101	95.5	21	21.99%
2014	85	90	87.5	19	21.71%

10. Complete the following chart for the most recent operating year.

Patient Statistics	Number
Transplants performed or referred during 2016	16
Patients currently on transplant list as of 12/31/2016	7
Patients with infectious disease as of 12/31/2016	0
Patients converted to infectious status during 2016	0

11. Provide the facility's hospital admission rates by admission diagnosis (dialysis related vs. non-dialysis related) for the facility's last full operating year.

From 1/1/2016 To 12/31/2016

Hospital Admissions	Number	Rate
Dialysis related	71	42%
Non-dialysis related	100	58%
Total Admissions	171	100%

12. If an existing facility proposes to relocate some of its certified dialysis stations within the same county:
- Describe in detail the necessity for relocation of stations, such as, physical inadequacy of existing facility or geographic accessibility of services;

Not Applicable.
 - Document that the number of stations to be relocated are needed by the projected number of patients to be served at the new location; and

Not Applicable.
 - Document that the stations to be relocated are needed at the proposed site as opposed to another area of the county.

Not Applicable.

13. If an existing facility proposes to replace the facility within the same county by relocating all stations, document the need for replacing the facility. If the replacement facility will be located in another area of the county, document the need for a dialysis facility in the proposed new location.

Not Applicable.

For Change of Scope and Cost Overrun Applications

14. Describe in detail all of the differences between the scope of this proposal and the previously approved project:
- (a) Identify each change, including but not limited to;
 - (i) Number of stations,
 - (ii) Location,
 - (iii) Proposed service area,
 - (iv) Capital cost, and
 - (b) Document why each change is necessary.

Not Applicable.

15. Provide the number of patients who are projected to utilize the facility during the first two operating years using the format below. Provide all assumptions and data used to project the number of in-center and home dialysis patients.

Not Applicable.

**Change of Scope/Cost Overrun
Total Projected Patients**

	OY 1	OY 2
In-center patients		
Home hemodialysis patients		
Home peritoneal dialysis patients		
Total Patients		