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

January 2, 2018

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-011439-17

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") in Guilford County. The DaVita Guilford application seeks to develop a new 10-station End Stage Renal Disease ("ESRD") facility in Greensboro, Guilford County, by relocating 7 dialysis stations from Reidsville Dialysis in Rockingham County and 3 dialysis stations from Burlington Dialysis in Alamance 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

Initially, it is important to note that this CON application replaces an application DaVita filed on September 15, 2017, seeking to develop a 10-station Guilford County ESRD facility using 5 stations from Dialysis Care of Rockingham County and 5 stations from Reidsville Dialysis (Project I.D. No. G-011412-17). Both WFUHS and Bio-Medical Applications of North Carolina, Inc. ("BMA") filed comments on October 31, 2017 opposing the application.³ Shortly before the public hearing scheduled for November 17, 2017, DaVita withdrew the application and filed this new application. However, little has changed from the first application. Two items are of particular note:

1. As set forth in both the WFUHS and BMA's prior comments, the September DaVita application failed to comply with SMFP Policy ESRD-2 and Criterion 1, because Dialysis Care of Rockingham County did not serve any Guilford County residents. This time, the included comments clearly show that <u>Reidsville Dialysis Center</u> does not currently serve

¹ The proposed DaVita Guilford 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.

³ A copy of WFUHS' prior October 21, 2017 written comments is attached as *Exhibit 1*.

Guilford County residents. Therefore, the new application <u>also</u> fails to comply with SMFP Policy ESRD-2 and Criterion 1.

- 2. As with the prior application, the patient letters of support do not support the projections in that application. In fact, they show quite the opposite:
 - o 36 of those 42 letters of support are the exact same letters used in the prior application. As with the prior application, several of those letters were from patients who previously wrote similar letters for another DaVita facility CON application in Alamance County, which for most of those patients would be more convenient than a facility located in Greensboro.
 - O <u>None</u> of the letters actually include the patient name other than on the signature line, which is often illegible. The letters also include no address, city or <u>county</u> of the patient. Instead, they include only a zip code (which in several cases, turned out to be wrong).
 - o In order to test whether the patients whose names <u>were</u> legible actually lived where DaVita claimed, WFUHS mapped the addresses of those patients. In doing so, WFUHS discovered that the vast majority of these patients live <u>further</u> from the proposed new facility than from their existing dialysis facilities. Indeed, at least 5 of the patients providing letters of support live more than 30 miles away from DaVita Guilford's proposed site. Three of those 5 patients live more than 40 miles away from DaVita Guilford. In addition, at least 7 of the patients live in <u>different</u> zip codes from those reported in the patient letters.

Based upon these deficiencies, DaVita's utilization projections are unreliable, and the application is non-conforming with Criteria 1, 3, 4, 6 and 18a, as well as the Performance Standards in the Agency's rules. DaVita's financial projections, which are based on those unreliable utilization projections, are also unreliable, 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, <u>if</u> the applicant can demonstrate that <u>all</u> 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 7 dialysis stations from Reidsville Dialysis in Rockingham County and 3 dialysis stations from Burlington Dialysis in Alamance County. Under paragraph 1 of Policy ESRD-2, in order to transfer stations from <u>both</u> Reidsville Dialysis and Burlington Dialysis, DaVita must demonstrate that <u>each facility</u> currently serves Guilford County residents. Based on patient letters of support, <u>which comprise the sole basis for DaVita's patient projections</u>, and the results found when mapping the home address of the two Reidsville Dialysis Center patients identified in the letters of support, it does not appear that either patient actually lives in Guilford County. Thus, DaVita cannot demonstrate this requirement is satisfied.

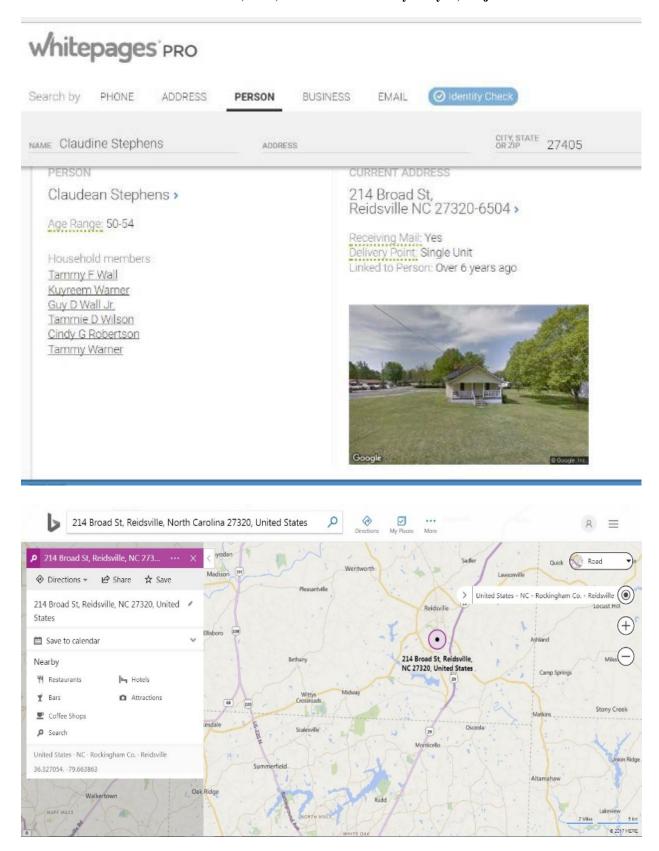
The following is an excerpt from Table A of the July 2017 SDR, providing December 2016 data for the ESRD facilities serving Guilford County residents:

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-011439-17

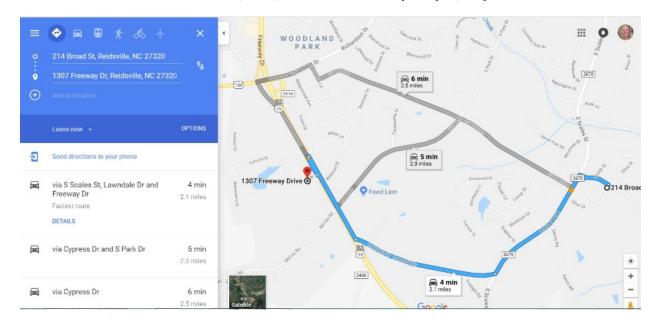
Provider Number	Facility Name	Facility County	Home Patients	In-Center Patients	County Total
Facilities ser	rving residents of Guilford County	•			
34-2504	BMA of Greensboro	Guilford	35	175	210
34-2537	BMA of South Greensboro	Guilford	0	173	173
34-2514	High Point Kidney Center	Guilford	28	117	145
34-2634	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

The SDR indicates that Reidsville Dialysis Center served two patients from Guilford County on December 31, 2016. SDR data is sent directly to the State Agency by providers who collect the data. The accuracy of that data (which is now 12 months old) is dependent upon the provider's ability to capture, verify, and maintain the data, so the July 2017 SDR alone is not sufficient to confirm that Reidsville Dialysis currently serves two Guilford County residents. Further, while 2 patients from Reidsville Dialysis Center provided patient support letters for DaVita Guilford, which identify zip codes that include Guilford County, *neither letter* includes or attests to the patient's actual home county. WFUHS' mapping evidences shows that both actually live in Rockingham County.

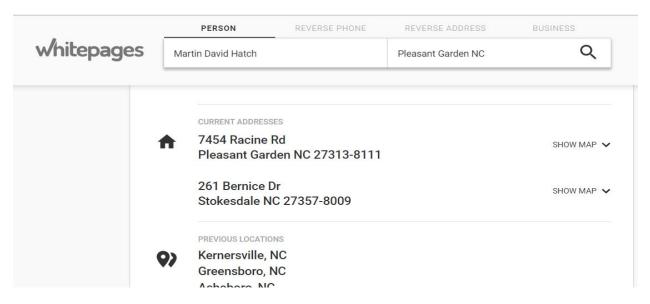
The first of those patients appears to be Claudene or Claudean Stephens, who signed a letter that stated her zip code is 27405 or 27406. However, using White Pages Pro at http://www.whitepages.com we could find no one by that name living in either zip code area. In fact within the state of North Carolina, we could only find two people with that name at all. One occurrence of the name Claudean or Claudene Stephens is a female living in the Statesville area of Iredell County. The Claudean Stephens we believe signed the patient support letter included in the DaVita Guilford application actually lives in zip code area 27320, Rockingham County, as demonstrated below.



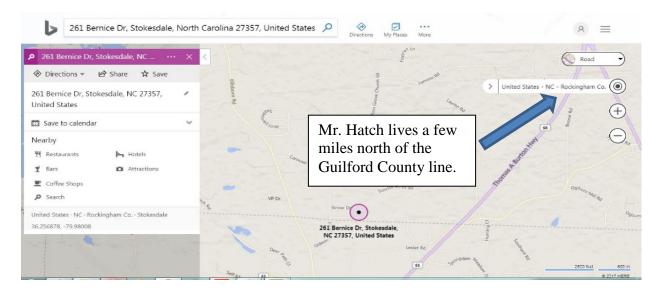
In fact, this Claudean or Claudene Stephens lives less than 3 miles from Reidsville Dialysis Center.



The other patient support letter from a Reidsville Dialysis Center patient was signed by David Hatch. The letter also does not indicate the patient's home county. However, it does include Mr. Hatch's zip code area of 27357, which lies in both Rockingham and Guilford Counties. White Pages Pro returned one result for David Hatch living in zip code area 27357. The other North Carolina address result for David Hatch is in Randolph County.



When we mapped Mr. Hatch's address, it shows that his address is just north of the Guilford County line in Rockingham County.



Because (1) <u>neither</u> of the letters of support from Reidsville Dialysis patients in Exhibit C-1 to the DaVita Guilford application attest to the patient's home county, (2) <u>neither</u> patient, when searched online and mapped, resides in Guilford County, and (3) there is no <u>other</u> documentation presented by DaVita to verify any patient's county residency, the DaVita Guilford application <u>fails</u> to provide adequate documentation of Reidsville <u>Dialysis Center's service to any Guilford County residents and therefore fails to conform to Policy ESRD-2.</u>

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 incenter 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*). Based on the Court of 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 Reidsville Dialysis appears to serve 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 Burlington Dialysis serves Guilford County residents, only 3 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 7 stations from Reidsville Dialysis in Rockingham County, DaVita Guilford cannot obtain a CON. Because the DaVita Guilford 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.

Of the 42 patient support letters submitted by DaVita Guilford, four are from PD patients, which may not be considered for dialysis station utilization. The remaining 38 ICH patient support letters originate from multiple DaVita facilities in Alamance County. *None of those letters attest to the patient's home county*.

On pages 14 and 15, DaVita describes from what facility its projected in-center patients will originate. Below is a spreadsheet illustrating the narrative on those pages:

County	Burlington	Reidsville	North Burlington	DC Rockingham	Alamance	Totals
Alamance	9		9			18
Guilford	13	2				15
Randolph	2				1	3
Stokes				2		2
Total	24	2	9	2	1	38

⁴ 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 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).

Page 15 also includes a chart with a patient breakdown by zip code and county. It includes 13 zip codes and four counties. This chart and the last paragraph on page 15 indicate that DaVita's patient projections are directly tied to the patients who signed support letters and those patients' willingness or unwillingness (32 of the 38 listed above) to transfer to the DaVita Guilford location. Page 15, thereby, defines the parameters by which DaVita has based its facility's projected census and pro forma.

However, the information contained in those letters of support is significantly flawed. Essentially, each of those letters includes a zip code. DaVita then assumes the county of residence of each patient. However, a number of those zip codes straddle county lines. None of the letters include the patient's address, city or county (many of them do not even include a legible name), and there is nothing else in the application to document the accuracy of these assumptions.

In order to test the veracity of DaVita's representations, WFUHS attempted to identify and map the physical location of each patient and determine drive times to their current facility, to DaVita Elon, and to DaVita Guilford. When drive distance and times appeared excessive we used the closest DaVita facility. If a patient's name was illegible, we mapped drive times from their zip code area to the same locations. Based on physical addresses for the patients we could find and zip code areas for the patients we could not find, we attempted to determine patient county residency and compare our findings with the information in Section C of the DaVita application. *Exhibits 4 and 5* provide those individual patient findings through a map ⁵ and a spreadsheet with drive times and distances.

Our findings based on patient mapping is condensed below for county residency by facility and modality:

,	Alamance		Alamance				Dialysis	Dialysis Care	North	North			
	County		County	Burlington		Burlington	Care of	of Rockingham	Burlington	Burlington	Reidsville	Reidsville	
	- Dialysis		Dialysis Total	Dialysis		Dialysis Total	Rockingham	County Total	Dialysis	Dialysis Total	Dialysis	Dialysis Total	Grand Total
Row Labels	ICH	PD		ICH	PD		ICH		ICH		ICH		
Alamance				10	I	11			3	3			14
Alamance, Caswell, Guilford				2		2			4	4			6
Alamance, Guilford, Randolph	I		1		l	1							2
Caswell									I	1			1
Guilford		1	1	12		12							13
Guilford, Rockingham		I	. 1										1
Rockingham									1	1	2	2	3
Stokes							2	2					2
Grand Total	1	2	3	24	2	26	2	2	9	9	2	2	42

These findings show the following:

• There are 9 patients who reside in zip code areas that lie in multiple counties and for whom we could not determine a name by which to search for an address to verify patient county

⁵ The map in <u>Exhibit 4</u> shows the locations of DaVita's existing facilities in Rockingham and Alamance Counties, the locations of WFUHS and BMA facilities in the area, DaVita's proposed facility site in Guilford County, and the current location of DaVita Guilford's projected patients. DaVita's proposed Guilford County site is identified by a green pushpin immediately under the word "Guilford."

residency. Thus, it is impossible to determine what need, if any, those patients would have for a new DaVita location in Guilford County.

- No more than 12 ICH and 1 PD patient who signed support letters actually reside in Guilford County, which is 3 patients less than DaVita indicates in Section C.
- There are 7 ICH patients whose actual zip code is different from the zip code reported in their letter.
- 1 patient resides in Caswell County and 3 patients reside in Rockingham County, neither of which was included in DaVita's service area projections for DaVita Guilford.

Comparing the drive times of patients we were able to identify to their current drive times and distances, we found the following:

- Drive times to DaVita Guilford versus their current facility will <u>increase</u> for 76% of the patients who provided support letters for DaVita Guilford, contrary to the expectations of greater convenience and shorter travel times included in the patient letters.
- Drive distances to DaVita Guilford versus their current facility will <u>increase</u> for 83% of the patients who provided support letters for DaVita Guilford, contrary to the expectations of greater convenience and shorter travel times included in the patient letter.
- Of the 42 patient letters submitted, at least 5 patients live more than 30 miles from DaVita Guilford, which is contrary to DaVita's assertion on page 19, which indicates 0% will travel more than 30 miles.
- 10 patients who signed letters of support for DaVita Guilford also signed letters of support for DaVita Elon, which has been CON approved, but not certified. See *Exhibits 5 and 6*. Of those patients, only 4 live closer to the proposed DaVita Guilford than DaVita Elon or their current facility.
- 2 patients who signed letters of support for DaVita Guilford live closer to another DaVita unit than the one they attend or DaVita Guilford.
- 27 patients who signed letters of support for DaVita Guilford live +/- 3 minutes as close to or closer to DaVita Elon than their current facility, which demonstrates that DaVita Elon is an effective alternative to DaVita Guilford in terms of convenience to patients.
- Only 12 patients out of all 42 who signed letters of support for DaVita Guilford will
 experience a travel convenience or benefit from its location. Of those 12 patients, only 8
 reside in Guilford County.

The DaVita Guilford application does not demonstrate that the Guilford County dialysis population has a need for the proposed service. As set forth on page 14 of the application, DaVita projects the following patient population in the first two years of operation:

Total Projected Patients by County of Residence

		OY 1			OY 2	County Patients as a Percent of Total		
County	In-center Patients	Home Hemo Patients	Peritoneal Patients	In-center Patients	Home Hemo Patients	Peritoneal Patients	OY 1	OY 2
Alamance	12	0	1	12	0	1	36.1%	34.2%
Guilford	15	0	2	16	0	3	47.2%	50.0%
Randolph	3	0	1	3	0	1	11.1%	10.5%
Stokes	2	0	0	2	0	0	5.6%	5.3%
Total *	32	0	4	33	0	5	100%	100%

Based on the table, above, DaVita projects to serve 15 of the 32 Guilford County patients projected to need the 10 deficit stations reported in the July 2017 SDR. This equates to about 5 stations' worth of patients of the 10 stations or about 50% of the Guilford County deficit.

$$15 \div 3.2 = 4.68$$
 stations' worth of patients

However, based on our patient mapping efforts utilizing the patient support letters, we were only able to verify the county residency of 12 ICH patients who reside in Guilford County.

$$12 \div 3.2 = 3.75$$
 stations' worth of patients

This equates to about 4 stations' worth of patients of the 10 stations or about 40% of the Guilford County deficit.

Of those 12 confirmed Guilford County residents, only 8 will experience greater convenience or shortened travel times by attending DaVita Guilford versus their current facility.

$$8 \div 2.5 = 3.2$$
 stations' worth of patients

This equates to about 3 stations' worth of patients of the 10 stations proposed, or about 30% of the Guilford County deficit.

The other 5 to 7 stations will serve primarily patients from Alamance County, where there is a 27-station surplus; Stokes County, where there is neither a surplus nor a deficit; Randolph County, where there is a 5-station surplus; and Rockingham County, where there is a 16-station surplus. Thus, after DaVita's project is operational, the patients of Guilford County will continue to be underserved by 5 to 7 dialysis stations since those stations are projected to be utilized by patients who have no need to attend a dialysis center outside of their home county.

Further, the facts do not support a need to serve even these few Guilford County residents. WFUHS has mapped the patient address for patients who had legible signatures and the current zip code areas of those patients who had illegible signatures or could not otherwise be found. The findings for those patients is included in *Exhibit 5* attached hereto. WFUHS was able to find address information for 27 of the 42 patients who submitted support letters for DaVita Guilford.

The other 15 patient letters contained either illegible signatures or contained names that could not be found at <u>whitepages.com</u> or other search locations. Given that 15 of the 42 (or 35.7%) of patient letters contained no defining information as to the identity, geographic proximity, nor home county of the patients who signed them, serious questions must be raised as to whether or not those letters may actually be relied upon to support DaVita's contentions. Failure to adequately document representations in an application are grounds for disapproval.

Even if the CON Section were to conclude the letters in Exhibit C-1 of the application are reliable, <u>Exhibit 5</u> attached hereto demonstrates that the majority of those patients (76%-83%) would face additional travel times and distances should they transfer their care to DaVita Guilford versus their current facility. <u>This is contradictory to the expectations expressed in the support letters the patients signed and on which DaVita bases all of its facility census and utilization projections.</u>

This lack of geographic support for a new Guilford County ESRD facility is even more troubling when coupled with the fact that DaVita <u>by its own admission</u> 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 of some of the same Alamance County residents it projects to serve in DaVita Guilford, as outlined below:

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 DaVita Guilford application, p. 3 (emphasis added).

Essentially, the DaVita Guilford 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 after the application has been filed. 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.
- <u>Mebane Dialysis</u> / 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.
- 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.

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

Name	City ⁶	County	Zip
James Wilson	McLeansville	Guilford	27301
Willette D. Mitchell	Greensboro	Guilford	27406
Tammy E. Moore	Greensboro	Guilford	27409
Louis Walker	Gibsonville	Guilford	27249
Anthony Martin	Greensboro	Guilford	27405
Mary Beale	Elon	Alamance	27244
Pauline H. Tate	Elon	Alamance	27244
Illegible		Unknown	27244
X		Unknown	27244
John S. Ingram	Burlington	Caswell	27217 ⁷

Copies of those duplicate letters from the Elon Dialysis and DaVita Guilford applications are attached hereto as <u>Exhibit 6</u> and are separately identified in <u>Exhibit 5</u>. 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

⁶ The city listed is based on the zip code given in each letter and name/address searches on <u>whitepages.com</u> as set forth in <u>Exhibit 5</u>. The zip code corresponds with the actual address found for the patient or in the case of "Illegible and X," it corresponds with the zip code on the letter. That exhibit also includes a column which identifies the Guilford support letters that are duplicates of support letters provided for the Elon application.

⁷ WFUHS mapping indicates that Mr. Ingram actually lives in zip code 27244. See *Exhibits 4 and 5*.

Criterion 3. See Elon Dialysis Required State Agency Findings, pp. 4-5, *Exhibit* 7 hereto. Because the 10 duplicate letters of support were material to the CON Section's approval of the Elon Dialysis application, they cannot be used to support the DaVita Guilford application. Without those letters, the DaVita Guilford application does not demonstrate the need for at least 3.2 patients per station 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.

As a practical matter, based on the zip codes and mapping data of the 10 patients listed above, as well as other patients from Stokes, Guilford and Alamance Counties, it is unrealistic to assume that the proposed DaVita Guilford facility will be more convenient than the patients' existing facilities. As shown in *Exhibits 4 and 5*, most of these patients live closer to their current facility or to the Elon Dialysis site than the proposed DaVita Guilford facility. Therefore, DaVita has failed to demonstrate the need that this population has for the services proposed.

The Agency has previously disapproved ESRD applications where the applicant failed to adequately demonstrate support for their projection that their proposed new site would be more convenient for existing patients. For instance, in 2008, the Agency disapproved DaVita's application to develop and operate a new 10-station dialysis facility in the town of Leland in Brunswick County and approved BMA's competing application to develop and operate a new dialysis facility in the town of Supply, also in Brunswick County. DaVita filed a petition for contested case hearing challenging that decision, which was upheld by the ALJ's Recommended Decision and the Final Agency Decision. The Court of Appeals affirmed, in part, because it concluded that DaVita had failed to demonstrate a need for its project, given the fact that there were insufficient patient letters of support to document DaVita's utilization projections of 31 patients upon opening of the facility. Total Renal Care of North Carolina, LLC v. North Carolina Dept. of Health and Human Services, 206 N.C. App. 674, 698 S.E.2d 446, 453 (2010) (copy attached as *Exhibit 8*).

Similarly, the DaVita Guilford application fails to demonstrate that it is reasonable to assume that 32 existing Alamance, Guilford, Randolph and Stokes County residents will transfer their care from their current facilities in Rockingham and Alamance Counties to the proposed DaVita facility in central Guilford County. For that reason alone, the application is non-conforming with Criterion 3 and unapprovable.

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 Guilford 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 DaVita Guilford 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 <u>only</u> because Alamance County, where DaVita already has 3 existing and 2 approved ESRD facilities, is east of Greensboro. As the chart in <u>Exhibit 5</u> and the map in <u>Exhibit 4</u> show, 76% of all patients who signed letters of support for DaVita Guilford would experience an <u>increase</u> in travel time to DaVita Guilford versus their current facility. Given Alamance County's 27-station surplus, DaVita's existing and approved Alamance County stations can adequately serve the needs of DaVita's existing Alamance County patients. If the locations of these patients justify more stations in Guilford County, the obvious conclusion is that they more likely are needed in eastern Guilford County near the Alamance/Guilford County line, 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.

Thus, serving DaVita's current patient population (which primarily consists of non-Guilford County residents) with its existing and approved Alamance and Rockingham County stations clearly is a more effective alternative than developing a new facility in Guilford County.

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

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, DaVita Guilford'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.

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 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 DaVita Guilford 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 by Dialysis Care of Rockingham County, the two Rockingham County residents currently served by Reidsville Dialysis, and the two Randolph County residents served in DaVita's Alamance County facilities. 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 DaVita Guilford proposal will not have a positive impact on the cost effectiveness, quality, and access to the services proposed. This is due in part to DaVita's proposal to serve non-Guilford County residents at a site in central Guilford County by moving stations from the neighboring counties where these patients reside. DaVita has failed to demonstrate a need for its proposal, and will not improve access to residents of Guilford (or any other) 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 DaVita Guilford 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 7 stations from Reidsville Dialysis in Rockingham County to the new facility, because Reidsville Dialysis 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, DaVita Guilford 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. Other than its own clearly incorrect assumptions, DaVita's application contains no supporting documentation as to the county residency of its projected patients. The applicant's patient letters contain zip codes which straddle multiple counties, and at least seven of those reported zip codes are incorrect. The patient support letters fail to validate the assumptions and methodology included in the application. DaVita offers no additional support such as patient maps, etc., which would validate the accuracy of the information it provided in its application. Therefore, the DaVita Guilford application is nonconforming with this rule.

CONCLUSION

In conclusion, the DaVita Guilford 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 that the CON Section deny the DaVita Guilford application

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. Written Comments filed October 31, 2017 by WFUHS regarding DaVita Guilford CON Application, Project I.D. No. G-011412-17
- 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, 638 S.E.2d 219 (2006)
- 4. Map showing the locations of DaVita's existing facilities in Rockingham and Alamance Counties, the locations of WFUHS and BMA facilities in the area, DaVita's proposed facility site in Guilford County, and the current location of DaVita Guilford's projected patients.
- 5. Patient mapping data based on whitepages.com research (a) showing patient county residency; (b) identifying travel times to the patients' current facilities, DaVita Elon, DaVita Guilford, and additional nearby DaVita locations, and comparing those relative travel times and distances; and (c) identifying those patients who would and would not experience a benefit from transferring their care to DaVita Guilford.
- 6. Duplicate letters from the Elon Dialysis and DaVita Guilford CON applications
- 7. 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
- 8. <u>Total Renal Care of North Carolina, LLC v. North Carolina Dept. of Health and Human Services</u>, 206 N.C. App. 674, 698 S.E.2d 446 (2010)

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.

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, <u>if</u> the applicant can demonstrate that <u>all</u> 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

of which are in Rockingham County. Under paragraph 1 of Policy ESRD-2, in order to transfer stations from <u>both</u> Reidsville Dialysis and Dialysis Care of Rockingham County, DaVita must demonstrate that <u>each facility</u> 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:

Facilities servin 34-2504 34-2537 34-2514 34-2634 34-2600 34-2613 34-2599 34-2505 34-2533	ng residents of Guilford County		Patients	Patients	Total
34-2537 34-2514 34-2634 34-2600 34-2613 34-2599 34-2505					
34-2514 34-2634 34-2600 34-2613 34-2599 34-2505	BMA of Greensboro	Guilford	35	175	210
34-2634 34-2600 34-2613 34-2599 34-2505	BMA of South Greensboro	Guilford	0	173	173
34-2600 34-2613 34-2599 34-2505	High Point Kidney Center	Guilford	28	117	145
34-2613 34-2599 34-2505	FMC of East Greensboro	Guilford	0	128	128
34-2599 34-2505	BMA of Southwest Greensboro	Guilford	0	105	105
34-2505	Northwest Greensboro Kidney Center	Guilford	0	96	96
	Triad Dialysis Center	Guilford	0	77	77
34-2533	Piedmont Dialysis Center	Forsyth	12	3	15
	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

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.

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 <u>Stokes</u> 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 incenter 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*). Based on the Court of

⁵ See map attached as <u>Exhibit 1</u> 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

Appeals' holding and the clear language of Policy ESRD-2, unless an applicant can demonstrate that <u>each</u> 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:

	OY 1				OY 2	County Patients as a Percent of Total		
	Home			Home				
	In-center	Hemo	Peritoneal	In-center	Hemo	Peritoneal		
County	Patients	Patients	Patients	Patients	Patients	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%

Total Projected Patients by County of Residence

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.

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

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

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.

<i>a</i> :	Dialysis Care Rockingham	Reidsville	Alamance County	Burlington	North Burlington	Total	
Zip	County	Dialysis	Dialysis	Dialysis	Dialysis	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.

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:

- <u>Elon Dialysis</u> / 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.
- <u>Mebane Dialysis</u> / 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.

• 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	City ⁷	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 <u>Guilford</u> County. This fact is particularly egregious in the case of the Burlington Dialysis CON application (Project I.D. No. G-011409-17) filed <u>the same day</u> 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 <u>whitepages.com</u> as set forth in <u>Exhibit 4</u>. That exhibit also includes a column which indicates the Guilford support letters that are duplicates of support letters provided for the Elon application.

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 <u>only</u> because Alamance County, where DaVita already has 3 existing and 2 approved ESRD facilities, is east of Greensboro. As the chart in <u>Exhibit 4</u> and the map in <u>Exhibit 1</u> 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, 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 nonconforming 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,

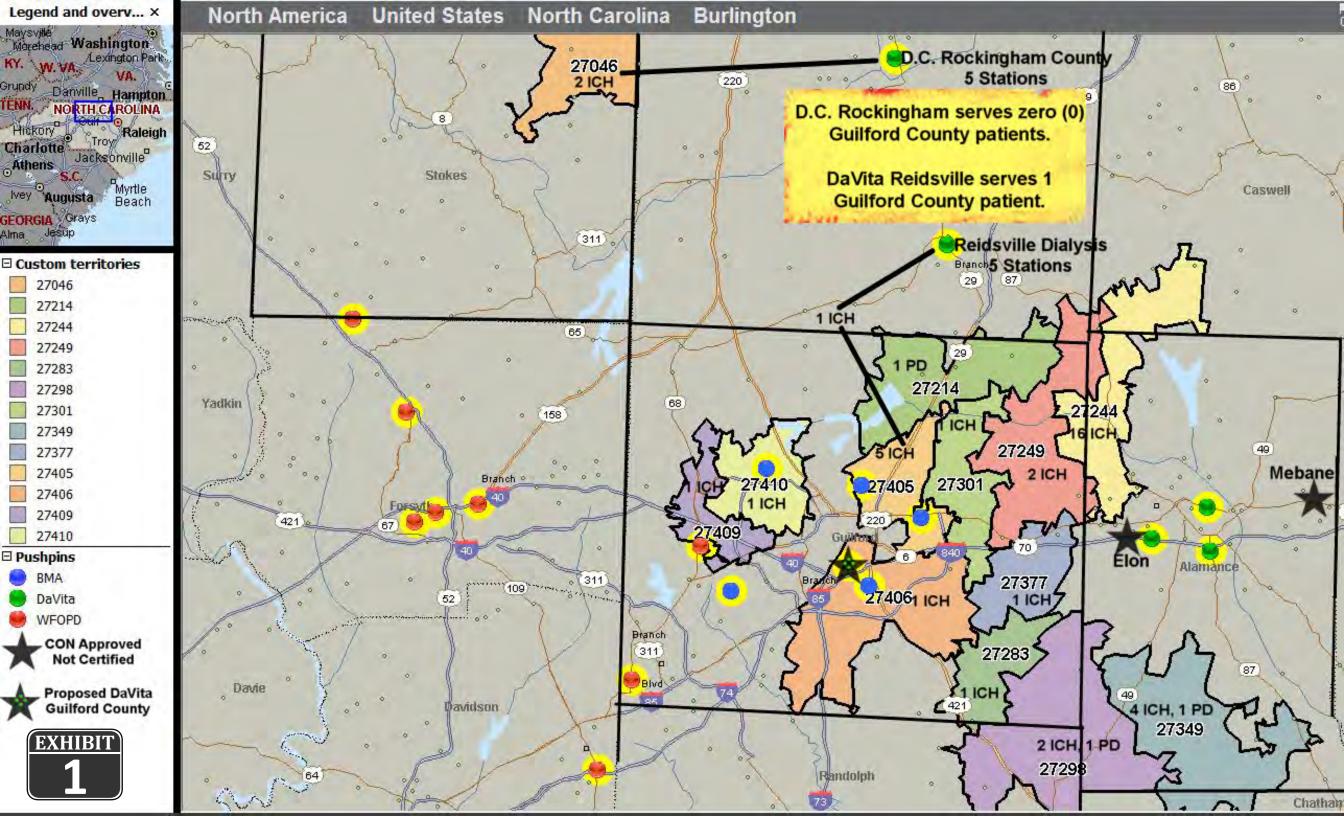
Russell Howerton, M.D.

Rewell fourter MD

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



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 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.





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

Unpublished Disposition

(Cite as: 2006 WL 3359688 (N.C.App.))

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 <u>S. Todd Hemphill</u>, Dana Evans Ricketts and <u>Matthew A. Fisher</u>, for petitioner-appellant.

Attorney General Roy Cooper, by Assistant Attorney

General <u>Thomas M. Woodward</u>, for respondent-appellee.

Wyrick Robbins Yates & Ponton, LLP, by <u>K.</u> <u>Edward Greene</u>, <u>Lee M. Whitman</u> 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.



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Unpublished Disposition

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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.

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Unpublished Disposition

(Cite as: 2006 WL 3359688 (N.C.App.))

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. <u>Burgess v. Your House of Raleigh</u>, 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 homecenter 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 incenter 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 <u>Carawan v. Tate</u>, 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 N	C	27046	ICH	Dialysis Care of Rockingham County
38 L Plevens (Illegible)				27214	PD	Alamance County Dialysis
39 Lorraine Russell	8638 NC 49	Snow Camp N	C	27349	PD	Burlington Dialysis
40 Kenny Reeter (Illegible)				27298	PD	Burlington Dialysis

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

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

Witness

6/21/2014

Date

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 (PIII) 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.

iness Signature and Title

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 mc, my diagnosis or treatment will be released as a part of this application.

Patient

Witness

Date

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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
Debbur Hamelet AA	8-28-17
Witness Signature and Title	Date Signed

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.

Patient

Vitnoss

Date

Dota

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

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.

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. 1 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 Beald
Debbie HAMLEH
Witness
Date
Date

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
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 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.

Pettent Signature or Mark

Date Signed

Date Signed

Date Signed

Date Signed

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.

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

Witness

Date

Date

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
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 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

100

Date Signed

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.

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 Tate

Patient

Asselve Claros Man

Witness

Date

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:

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- 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.

| Author | S-28-17 |
| Patient Signature or Mark | Date Signed

| Date Signature and Title | Date Signed

To Whom It May Concern:

l 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-Atlautic, 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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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.

Anthy b. Wanter	6/17/16
Patient 0	Date
Devoie HAMlett	6/17/16
Witness	Date

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.

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:

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- 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 North 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

Witness Signature and Title

Date Signed

Date Signed

☑002/036

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.

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

.____

Witness

41111b

10/10/

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.

 \mathbf{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 contigous [sic] county is currently serving residents of that contigous [sic] county; and
- 2. Demonstrate that the proposal shall not result in a deficit, or increase an existing deficit in the number of dialysis stations in the county that would be losing stations as a result of the proposed project, as reflected in the most recent North Carolina Semiannual Dialysis Report, and
- 3. Demonstrate that the proposal shall not result in a surplus, or increase an existing surplus of dialysis stations in the county that would gain stations as a result of the proposed project, as reflected in the most recent North Carolina Semiannual Dialysis Report."

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

Conclusion

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

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

 \mathbf{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:

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

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

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

The applicant adequately identifies the population to be served.

Analysis of Need

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

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

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

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

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

	Burlington Dialysis	North Burlington Dialysis	
Patients Transferring	31	2	

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

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

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

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

<u>Projected Utilization</u>

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

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

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

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

Elon Dialysis Project ID #J-11212-16 Page 6

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.

 \mathbf{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

		OY 1			OY 2	County Patients as a Percent of Total		
	In-center	Home Hemo	Peritoneal	In-center	Home Hemo	Peritoneal		
County	Patients	Patients	Patients	Patients	Patients	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.

<u>-</u>		
	# of	Growth
	pts	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 chan	ge 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

	Beginning service	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)	area (SA) census SA: Alamance County											
(b)	Interim Period			X		=		+		=		
(c)	Current Year	1/1/2017	79	х	1.05	=	82.95	+	17	=	99.239	12/31/2017
(d)	Interim Period	1/1/2018	82 - 24 = 58	X	1.05	Ш	60.9	+	17 - 7 = 10	=	102.6108	12/31/2018
(e)	Census OY 1	1/1/2019	60 - 16 = 44	X	1.05	Ш	46.2	+	10 - 1 = 9	=	55.845	12/31/2019
(f)	Census OY 2	1/1/2020	46.2	X	1.05	Ш	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.

This application does not call for any changes to home hemo or PD services at Burlington Dialysis.

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
	Beginning service area (SA) census						
(a)	SA:						
(b)	Census calculation interim period (specify period between beginning date and OY 1 start date) and calculate census, adding rows as needed			v		=	
				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	Growth
	pts	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 chan	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

	Beginning service	Start Date	# of SA Patients	X	Growth Rate	П	SA Year End Census	+	# out-of-SA existing patients	=	Total Year End Census	Year End Date
	area (SA)											
	census		i									
	SA:											
	Alamance											
(a)	County											
(b)	Interim Period			x		=		+		П		
(c)	Current Year	1/1/2017	79	X	1.05	11	82.95	+	17	Ш	99.95	12/31/2017
	Interim		82 - 24 =						17 - 7 =			
(d)	Period	1/1/2018	58	X	1.05	=	60.9	+	10	=	70.9	12/31/2018
(e)	Census OY 1	1/1/2019	60 - 16 = 44	X	1.05	II	46.2	+	10 - 1 = 9	Ш	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

Diary Sis Tutterius as of 12/01/2010							
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%

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 12/31/216

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:
 - (a) Describe in detail the necessity for relocation of stations, such as, physical inadequacy of existing facility or geographic accessibility of services;

Not Applicable.

(b) 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.

(c) 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		



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 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.



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

(Cite as: 2006 WL 3359688 (N.C.App.))

Unpublished Disposition



Briefs and Other Related Documents

Only the Westlaw citation is currently available.

NOTE: THIS OPINION WILL NOT 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

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 respondentappellee.

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 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.

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Unpublished Disposition

(Cite as: 2006 WL 3359688 (N.C.App.))

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.

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Unpublished Disposition

(Cite as: 2006 WL 3359688 (N.C.App.))

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. <u>Burgess v. Your House of Raleigh</u>, 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 homecenter 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 incenter 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 <u>Carawan v. Tate</u>, 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.

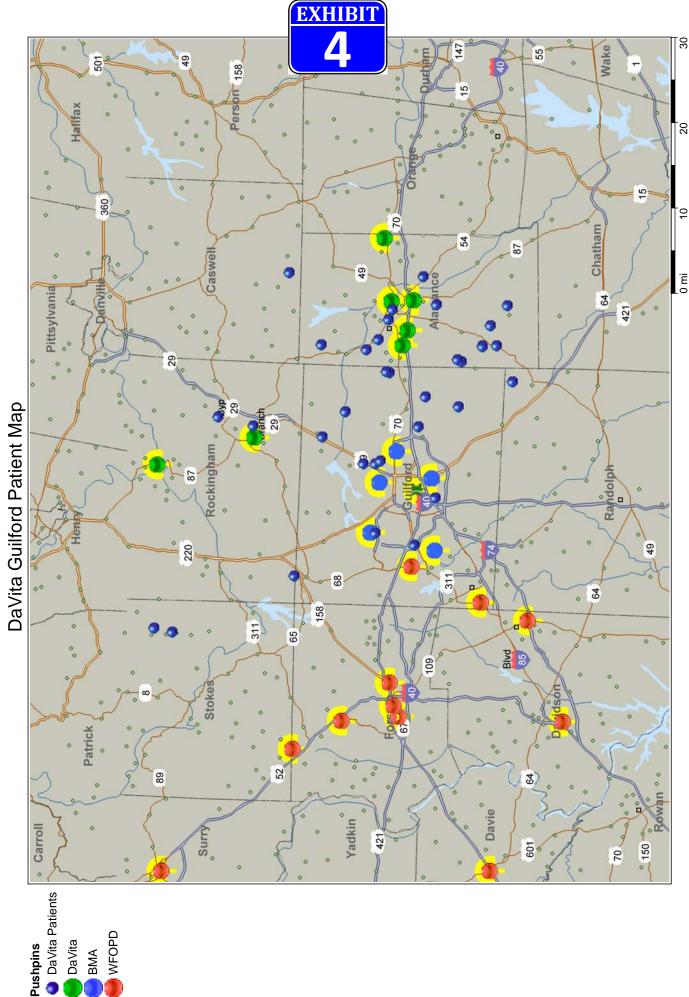
Report per Rule 30(e).

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Briefs and Other Related Documents (Back to top)

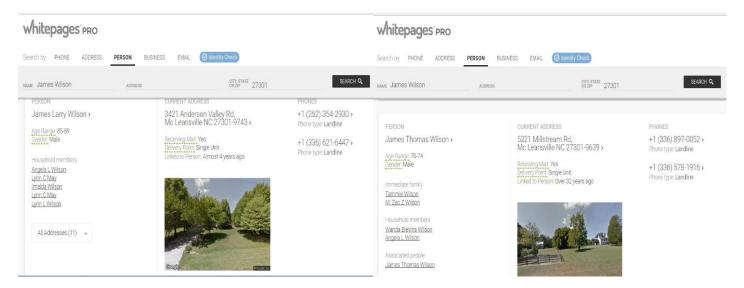
- 2006 WL 2150865 (Appellate Brief) Reply Brief of Petitioner-Appellants Wake Forest University Health Sciences and Huntersville Dialysis Center of Wake Forest University d/b/a Huntersville Dialysis Center (Rule 28(h) (2), N.C.R. App. P.) (Jul. 18, 2006)
- 2006 WL 1745721 (Appellate Brief) Brief of Respondent-Intervenor-Appellees,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

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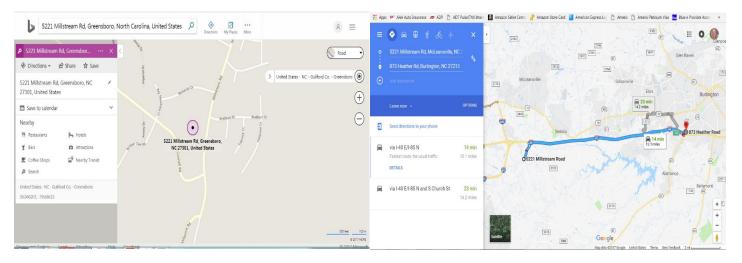
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01 James Wilson – We found two people named James Wilson residing in zip code 27301. Given the information provided in the patient letter, there is no way to tell which one is correct. We chose the younger of the two and mapped him. James Wilson provided letters of support for both DaVita Elon and DaVita Guilford.



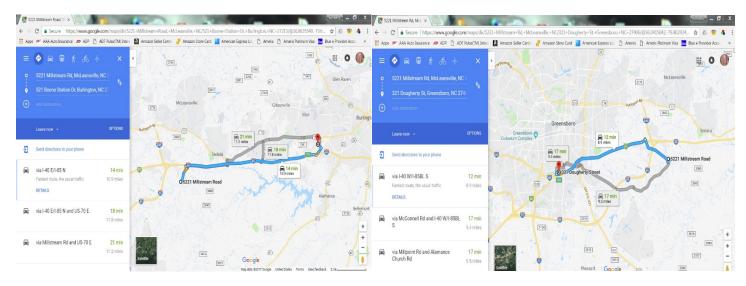
Verification of county residency based on address.

Drive time to current facility, DaVita Burlington – 14-23min.



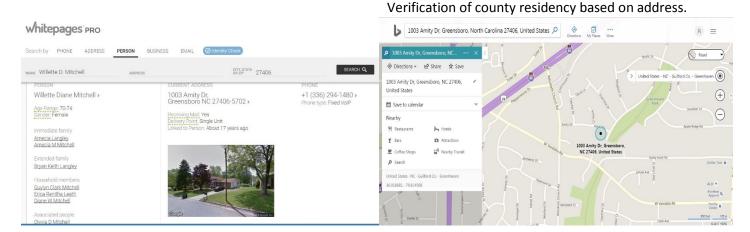
Drive time to DaVita Elon – 14-21 min.

Drive time to DaVita Guilford – 12-17 min.



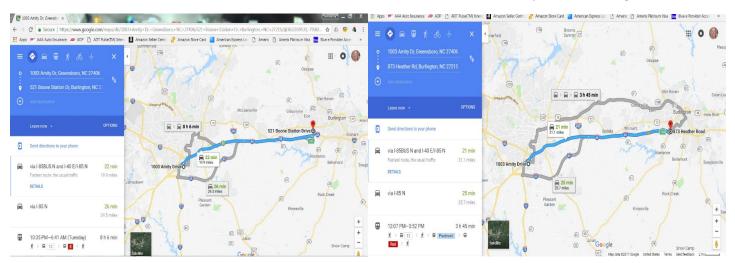
DaVita Guilford is not significantly more convenient for this patient.

02 Willette D. Mitchell – We found one person named Willette Mitchell living in zip code area 27406. Willette D. Mitchell provided letters of support for both DaVita Elon and DaVita Guilford.

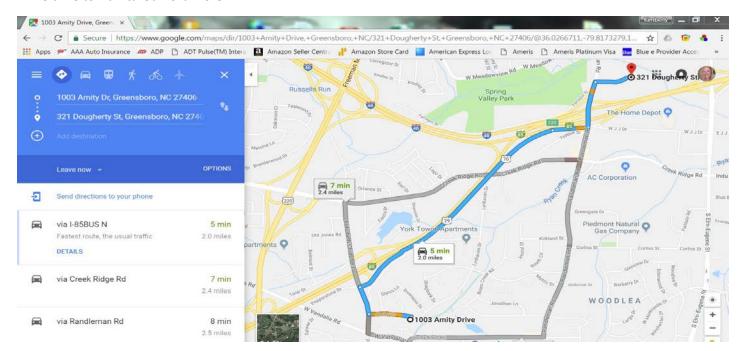


Drive time to Elon - 22-26 min.

Drive time to current facility, DaVita Burlington – 21-25 min.



Drive time to DaVita Guilford - 5-8 min.



DaVita Guilford would be closer for this patient.

03 Tammy E. Moore – We found one person named Tammy Moore living in zip code area 27409. Tammy Moore provided letters of support for both DaVita Elon and DaVita Guilford.

Search by PHONE ADDRESS PERSON BUSINESS EMAIL COMMENCIONS

NAME Tommy Moore Adoress PERSON BUSINESS EMAIL COMMENCIONS

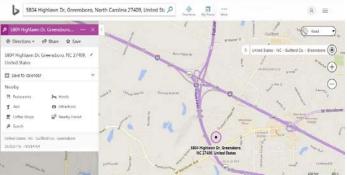
PERSON

Tammy E Moore > CURRENT ADDRESS

S804 Highlawn Dr. Greenboox
United States

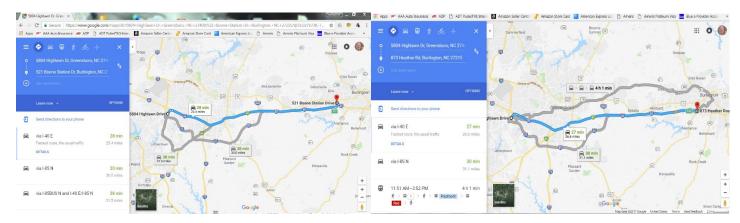
S804 Fighlawn Dr. Greenboox
United St

Verification of County residency based on address.

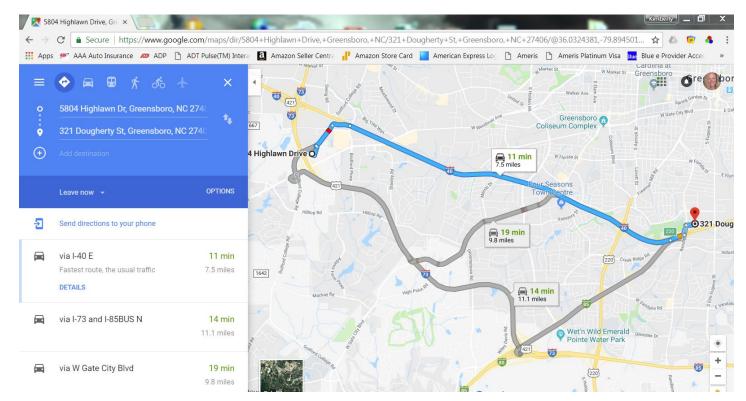


Drive time to Elon – 28-38 min.

Drive time to current facility, DaVita Burlington 27-30 min.

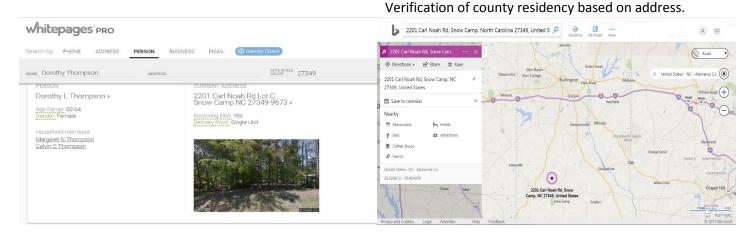


Drive time to DaVita Guilford - 11-19 min.



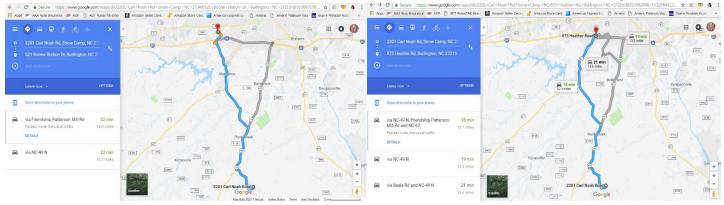
DaVita Guilford is closer for this patient.

04 Dorothy L. Thompson – We found one person named Dorothy Thompson living in zip code area 27349. Dorothy Thompson signed letters of support for both DaVita Elon and DaVita Guilford.

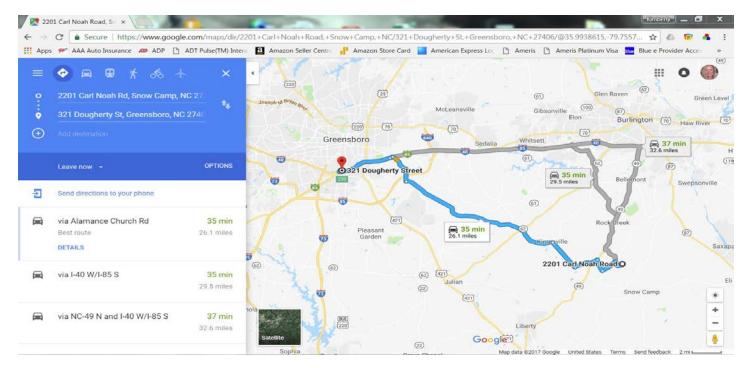


Drive time to Elon - 22 min.

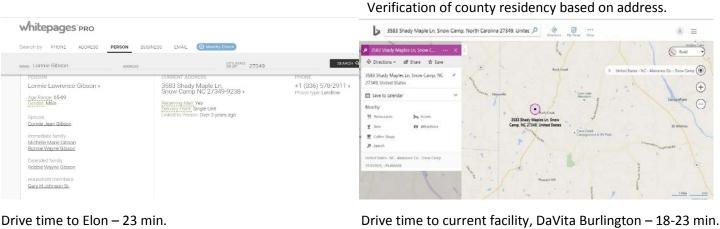
Drive time to current facility, DaVita Burlington – 18-21 min.

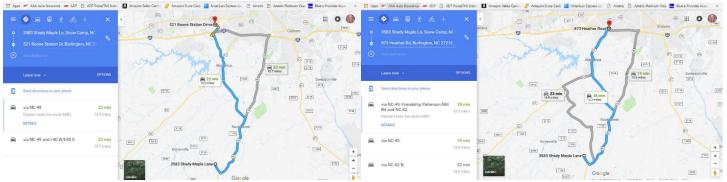


Drive time to DaVita Guilford - 35-27 min.

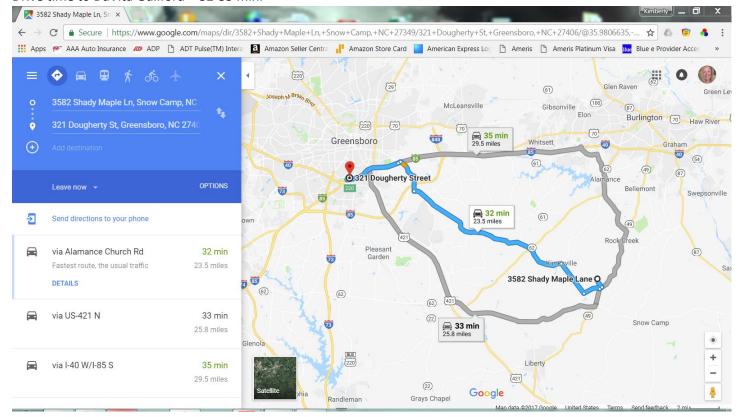


05 Lonnie Gibson – We found one person named Lonnie Gibson living in zip code area 27349.

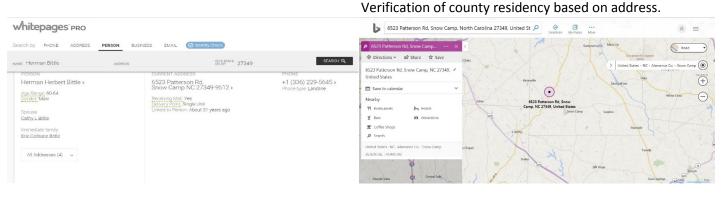




Drive time to DaVita Guilford - 32-35 min.

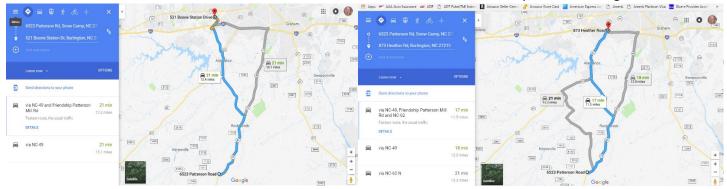


06 Herman Bittle – We found one person named Herman Bittle living in zip code area 27349.

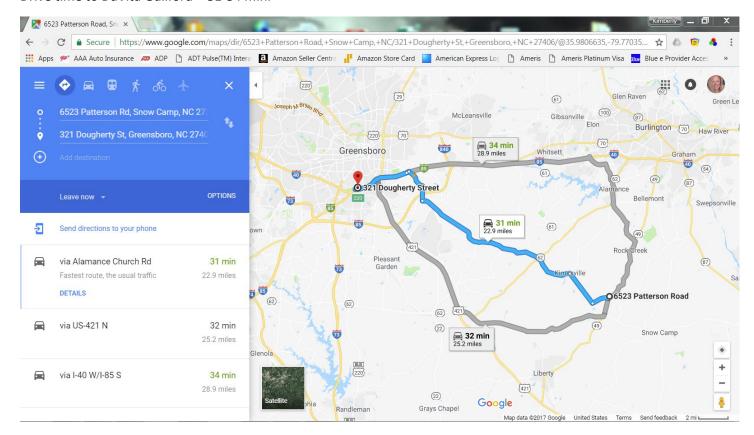


Drive time to Elon – 21 min.

Drive time to current facility, DaVita Burlington 17-21 min.



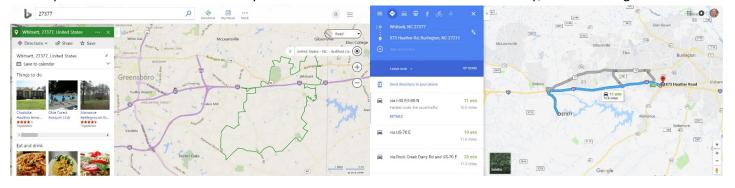
Drive time to DaVita Guilford - 31-34 min.



07 D. Jolus – Unable to either read this patient's signature or find him or her based on the assumption that the patient's last name is Jolus or variations, thereof. Given the information in the patient letter, we mapped the distance from zip code 27377 to nearby DaVita locations and DaVita Guilford.

All of zip code 27377 is in Guilford County.

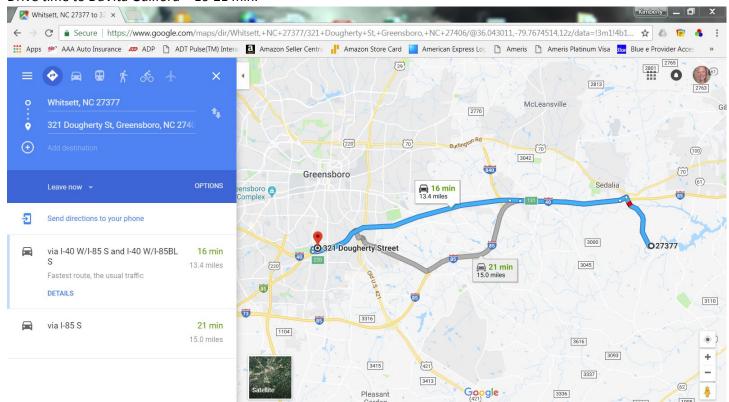
Drive time to current facility, DaVita Burlington 11-23 min.



Drive time to Elon – 13-17 min.

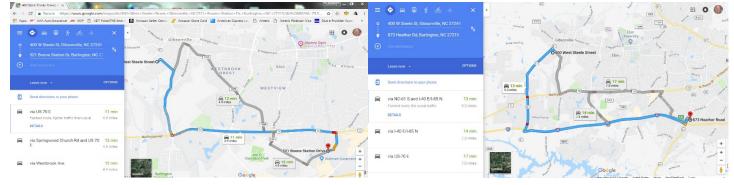


Drive time to DaVita Guilford - 16-21 min.

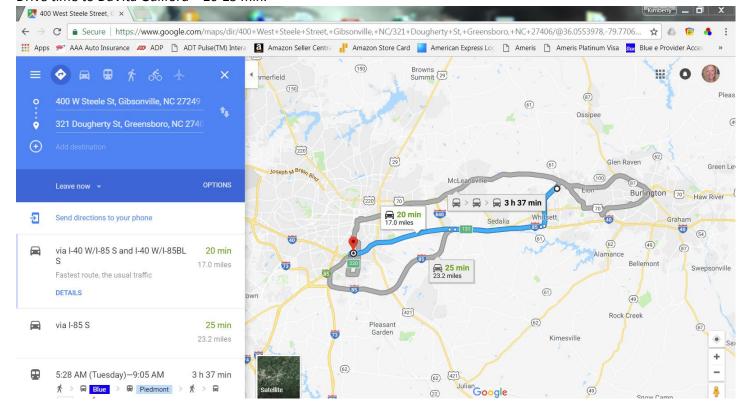


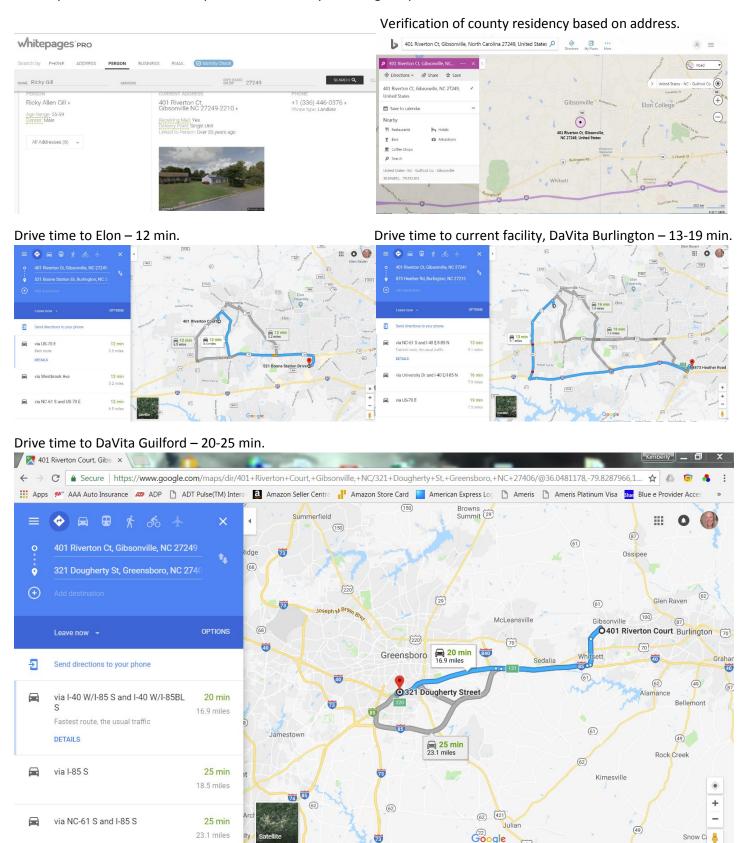
08 Louis Walker – We found one person named Louis Walker living in zip code area 27249. Louis Walker signed letters of support for DaVita Elon and DaVita Guilford.





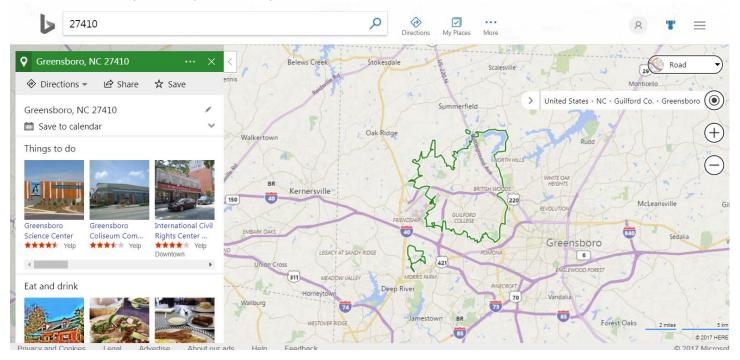
Drive time to DaVita Guilford - 20-25 min.





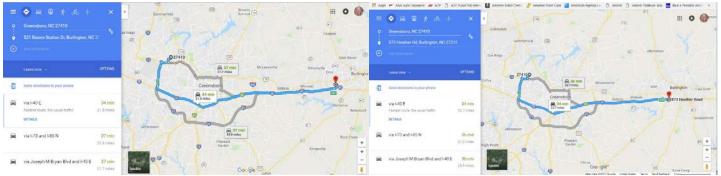
10 Jeffrey (Illegible) – Given the information provided in the application, we could not determine the patient's last name. We mapped the patient's zip code area from the letter to nearby DaVita locations in Alamance County as well as DaVita Guilford.

Verification of county residency based on zip code area.

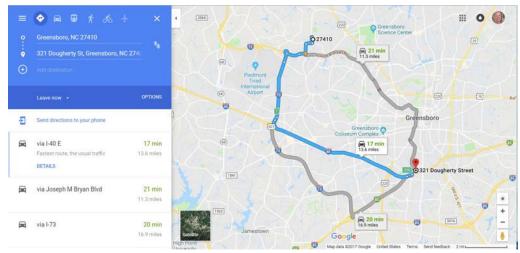


Drive time to Elon – 34-37 min.

Drive time to current facility, DaVita Burlington – 34-36 min.



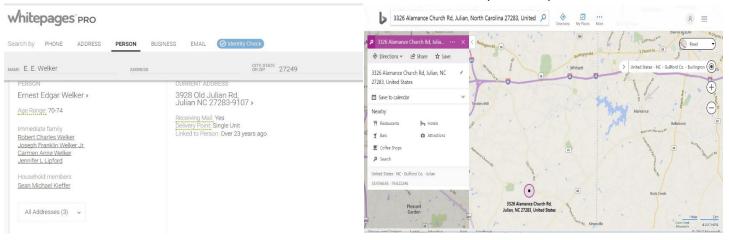
Drive time to DaVita Guilford – 17-21 min.



DaVita Guilford would be possibly more convenient for this patient.

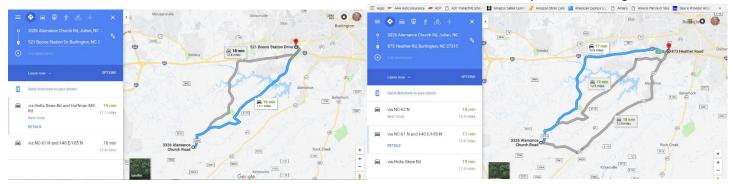
11 Ernest E. Welker – We found one person named Ernest E. Welker living in zip code area 27283.

Verification of county residency based on address.

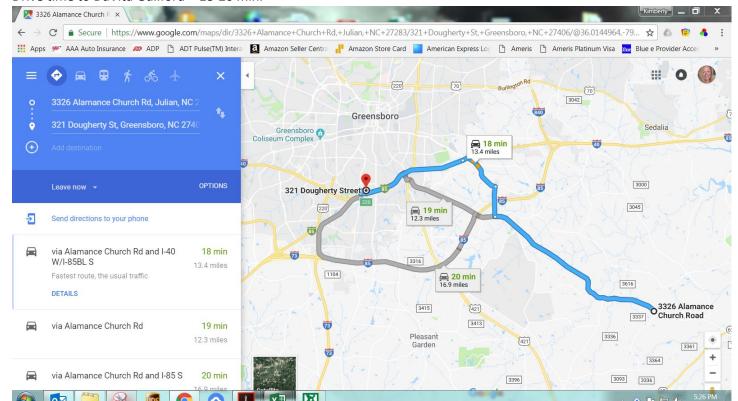


Drive time to Elon – 18-19 min.

Drive time to current facility, DaVita Burlington – 17-19 min.

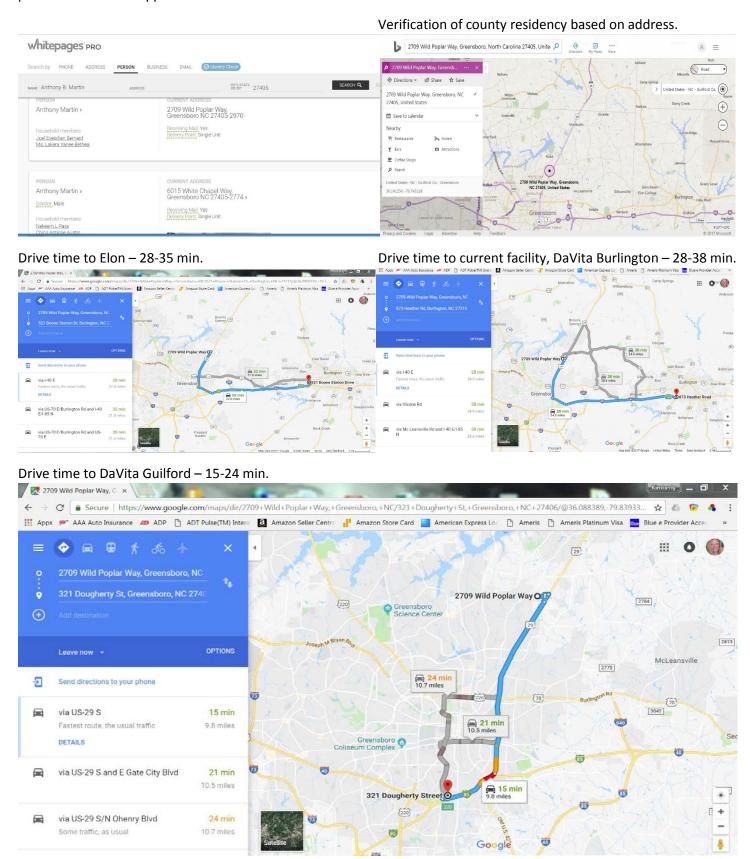


Drive time to DaVita Guilford - 18-20 min.



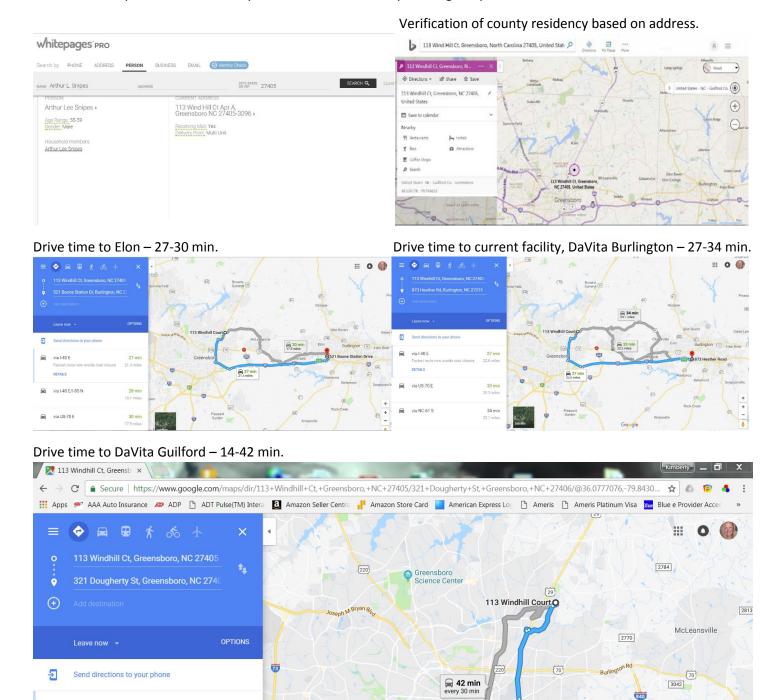
DaVita Guilford is no more convenient for this patient that his current facility or DaVita Elon. Drive time is not shorter.

12 Anthony Martin – We found one person named Anthony Martin living in zip code area 27405. Anthony Martin provided letters of support for both DaVita Elon and DaVita Guilford.



DaVita Guilford is potentially no more convenient for this patient that his current facility or DaVita Elon depending on traffic conditions.

13 Arthur L. Snipes – We found one person named Arthur Snipes living in zip code area 27405.



DaVita Guilford is likely no more convenient for this patient that his current facility or DaVita Elon given traffic and public transportation.

19 min 9.1 miles

321 Dougherty Street (

1104

Google

Map data @2017 Google

40

via N Ohenry Blvd

5:39 PM-6:21 PM

* > = 6 > *

DETAILS

Blvd

Fastest route, despite the usual traffic

via N Ohenry Blvd and E Gate City

14 min

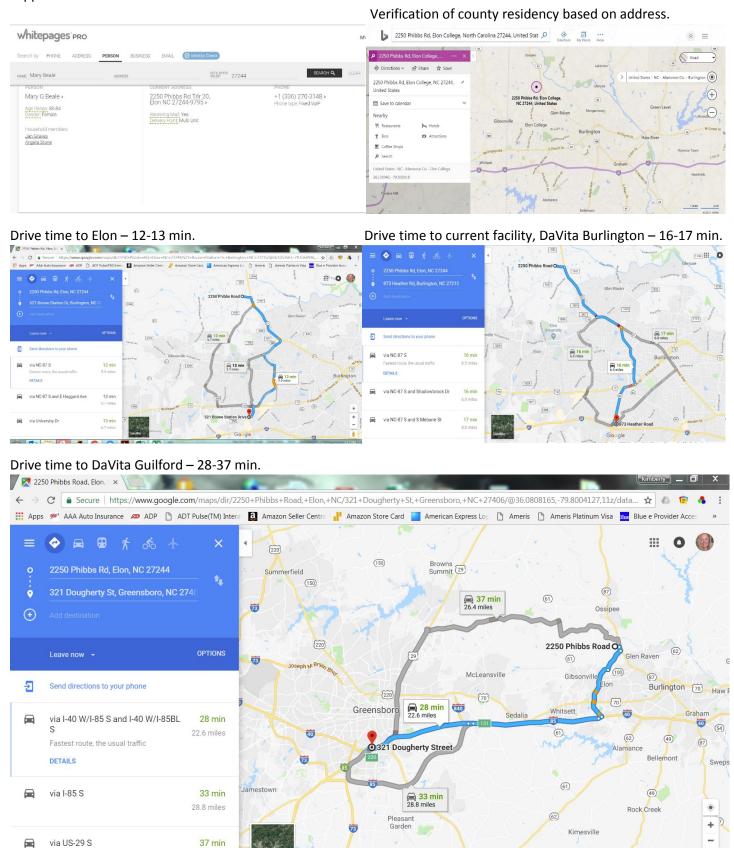
19 min

42 min

9.1 miles

8.4 miles

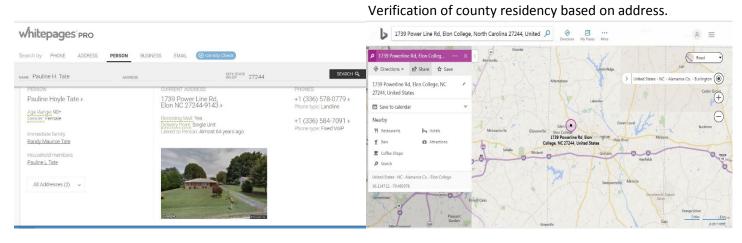
14 Mary Beale – We found one person named Mary Beale living in zip code area 27244. Mary Beale provided letters of support for both DaVita Elon and DaVita Guilford.



DaVita Guilford is NOT more convenient for this patient. Travel time to the new facility will NOT be shorter.

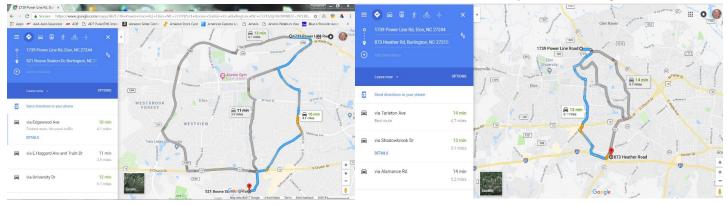
26.4 miles

15 Pauline H. Tate – We found one person named Pauline Tate living in zip code area 27244. Pauline Tate signed letters of support for both DaVita Elon and DaVita Guilford.

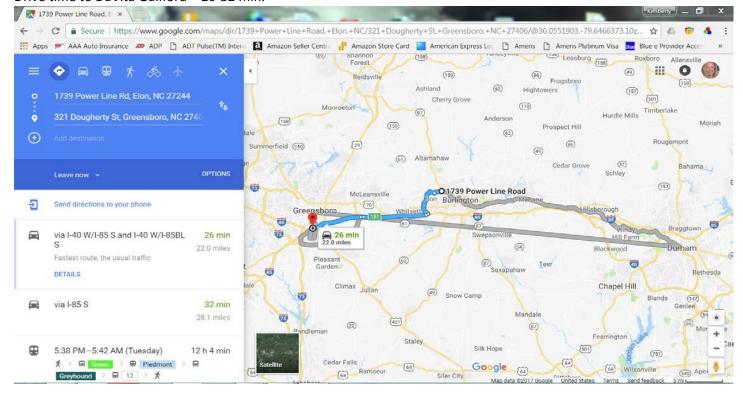


Drive time to Elon - 10-12 min.

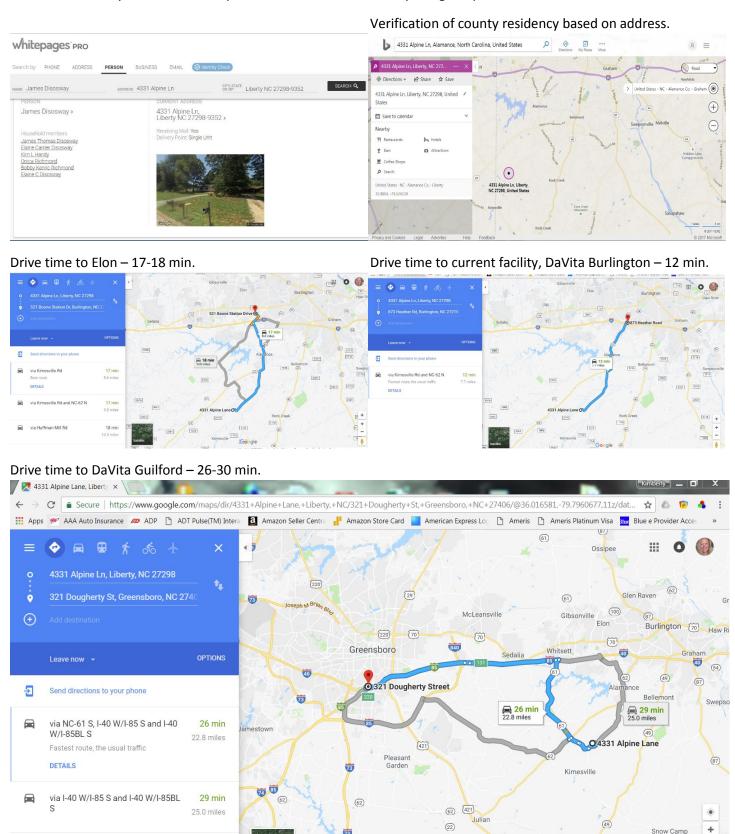
Drive time to current facility, DaVita Burlington – 13-14 min.



Drive time to DaVita Guilford - 26-32 min.



16 James Disosway – We found one person named James Disosway living in zip code area 27298.



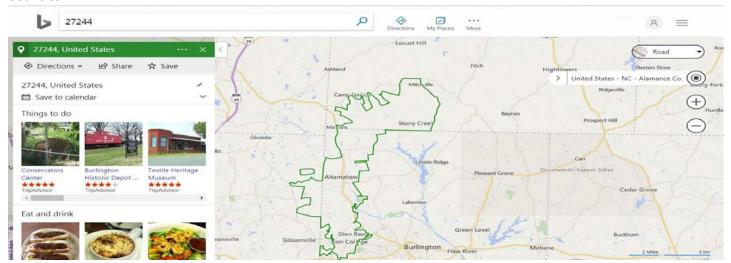
DaVita Guilford is NOT more convenient for this patient. Travel time to the new facility will NOT be shorter.

via Alamance Church Rd

30 min

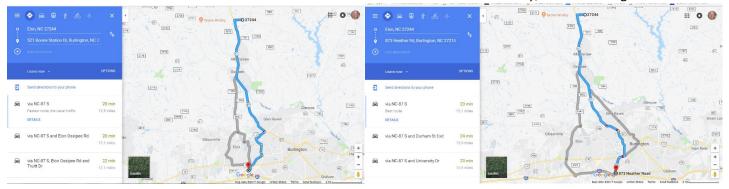
17 and 18 either marked with an X or their signature was completely illegible. Given the only information presented in their letter is the zip code area where they live, we mapped the distance from their zip code area to nearby DaVita locations and the proposed DaVita Guilford. Patients 17 and 18 both signed letters of support for both DaVita Elon and DaVita Guilford.

Verification of county residency is impossible to determine. The zip code area is in Alamance, Caswell, and Guilford Counties.

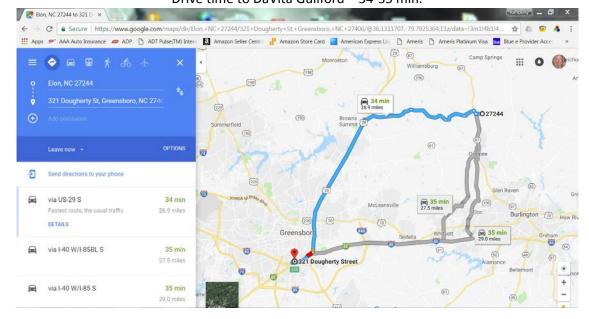


Drive time to Elon – 20-22 min.

Drive time to current facility, DaVita Burlington – 23-24 min.

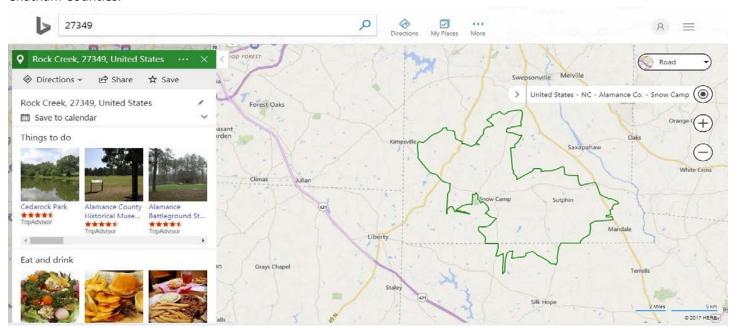


Drive time to DaVita Guilford – 34-35 min.



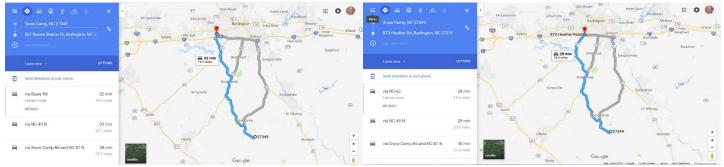
19 contained a signature that was completely illegible. Given the only information presented in their letter is the zip code area where they live, we mapped the distance from their zip code area to nearby DaVita locations and the proposed DaVita Guilford.

Verification of county residency is impossible to determine since zip code area 27349 is located in both Alamance and Chatham Counties.

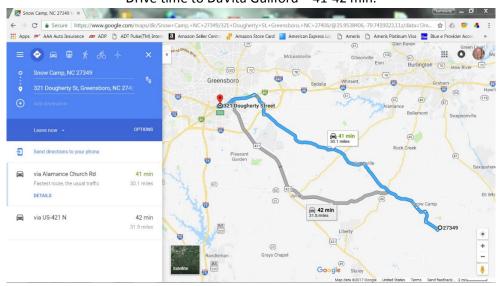


Drive time to Elon – 32-34 min.

Drive time to current facility, DaVita Burlington – 28-30 min.

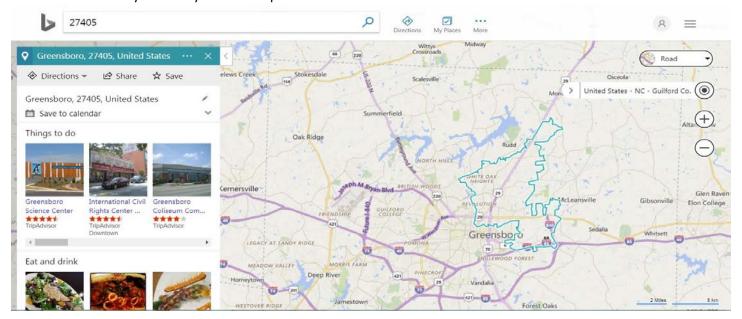


Drive time to DaVita Guilford – 41-42 min.



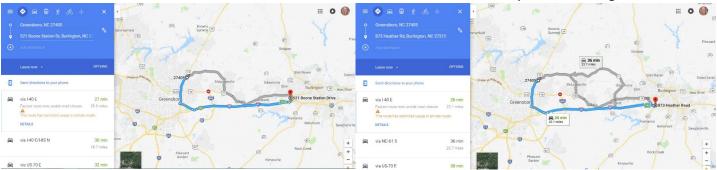
20 M. Stenunos - We were unable to identify anyone with the last name Stenunos nor variations thereof. Given the only information presented in their letter that can be found is the zip code area where they live, we mapped the distance from their zip code area to nearby DaVita locations and the proposed DaVita Guilford.

Verification of county residency based on zip code.

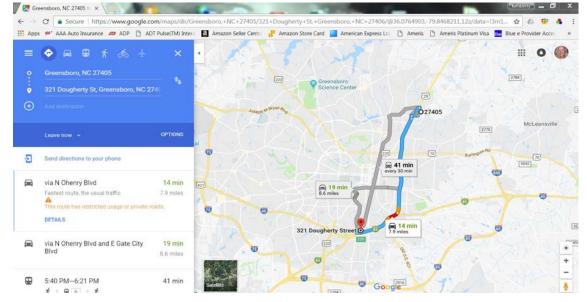


Drive time to Elon – 27-32 min.

Drive time to current facility, DaVita Burlington – 26-38 min.



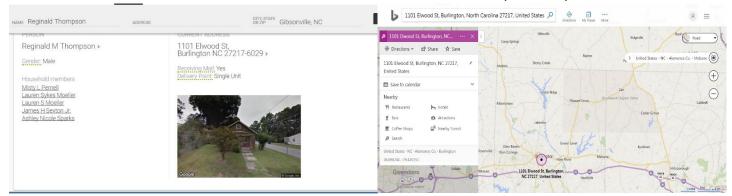
Drive time to DaVita Guilford – 14-41 min.



DaVita Guilford may be more convenient for this patient.

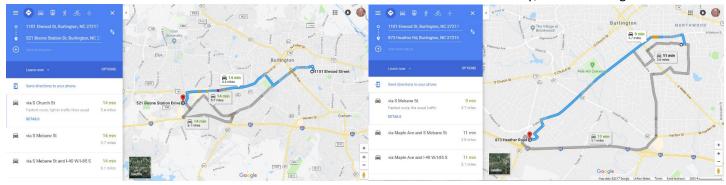
21 Reginald Thompson – We were unable to identify any person named Reginald Thompson living in zip code area 27249. However, we did find one person named Reginald Thompson living near Burlington in zip code area 27217.

Verification of county residency based on address.

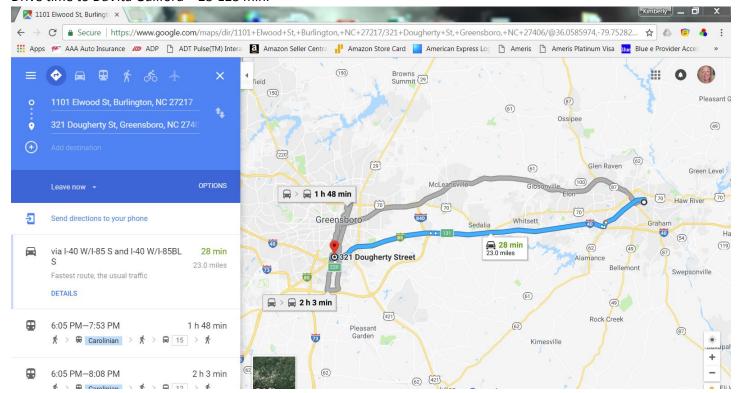


Drive time to Elon – 14 min.

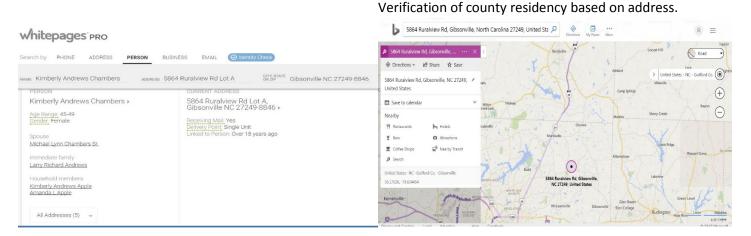
Drive time to current facility, DaVita Burlington – 9-11 min.



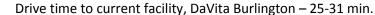
Drive time to DaVita Guilford - 28-123 min.

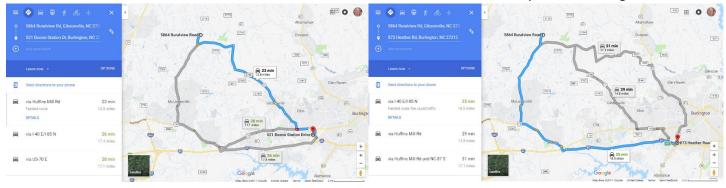


22. K. Chambers – We found one person with the last name Chambers and first initial K living in zip code area 27249.

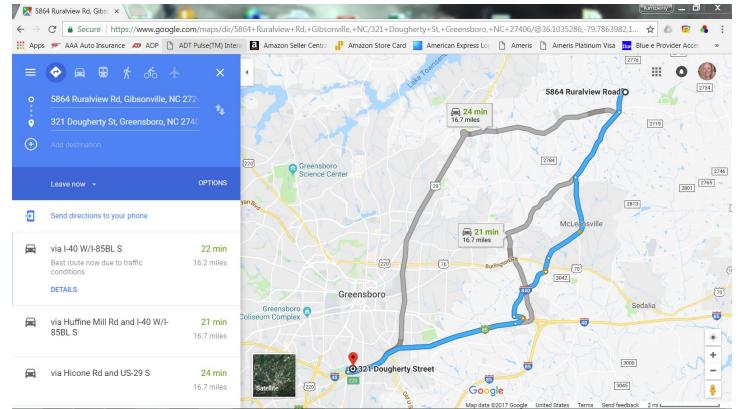


Drive time to Elon – 23-28 min.



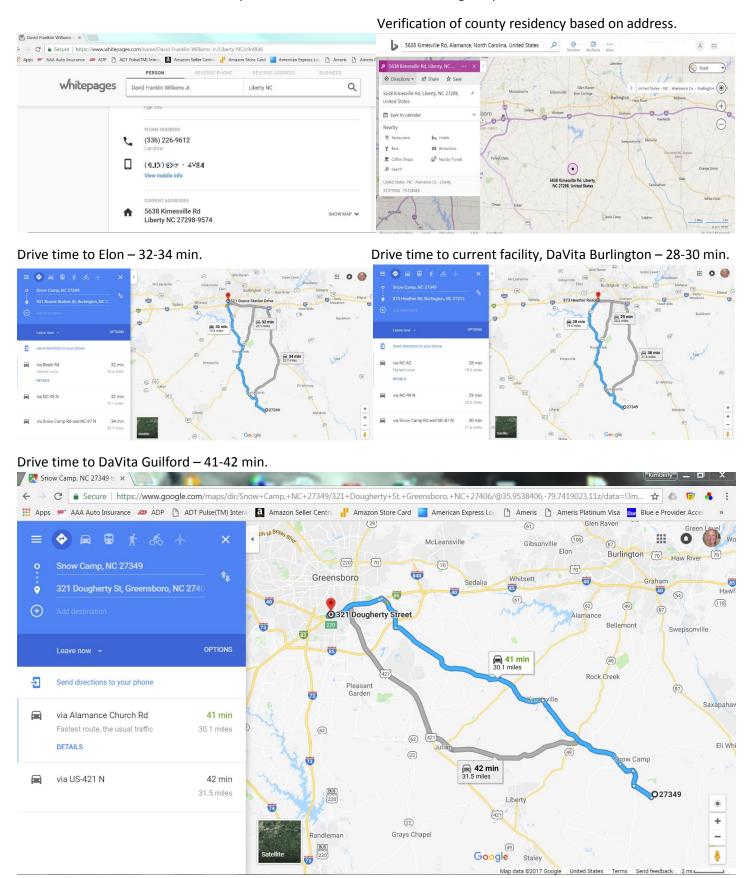


Drive time to DaVita Guilford – 21-24 min.



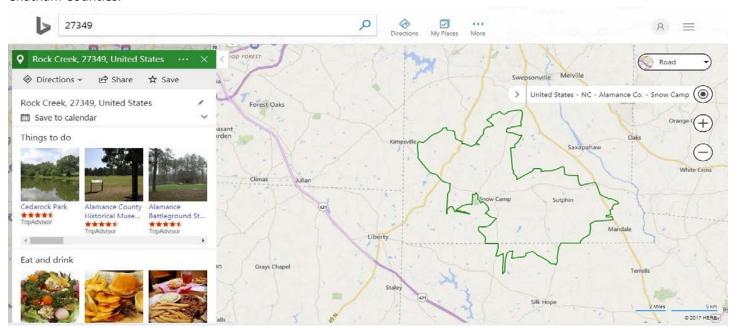
DaVita Guilford is likely NOT more convenient for this patient. Travel time is comparatively equal and NOT shorter.

23 David F. Williams – We found one person named David F. Williams living in zip code area 27298.



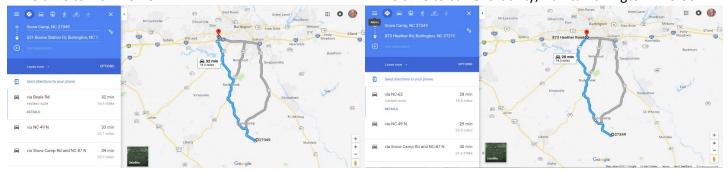
24 contained a signature that was completely illegible. Given the only information presented in their letter is the zip code area where they live, we mapped the distance from their zip code area to nearby DaVita locations and the proposed DaVita Guilford.

Verification of county residency is impossible to determine since zip code area 27349 is located in both Alamance and Chatham Counties.

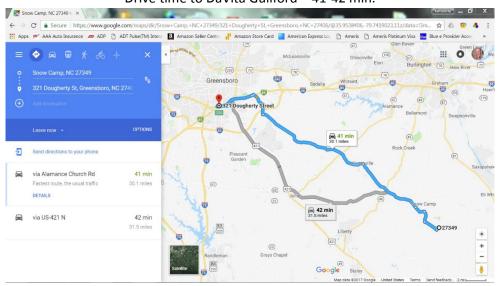


Drive time to Elon – 32-34 min.

Drive time to current facility, DaVita Burlington – 28-30 min.

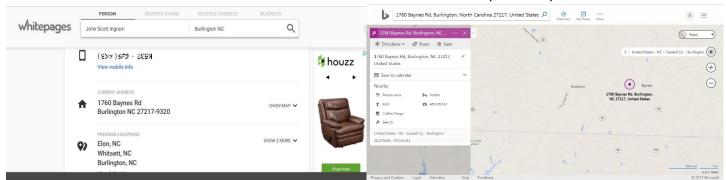


Drive time to DaVita Guilford – 41-42 min.



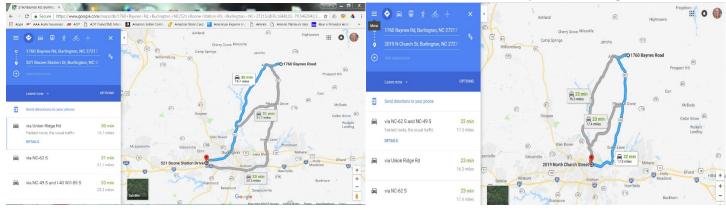
25 John S. Ingram – We found no person named J. Ingram or any derivative thereof living in zip code area 27244. However, we did find a John S. Ingram living near Burlington in zip code area 27217. J. Ingram signed letters of support for both DaVita Elon and DaVita Guilford.

Verification of county residency based on address.

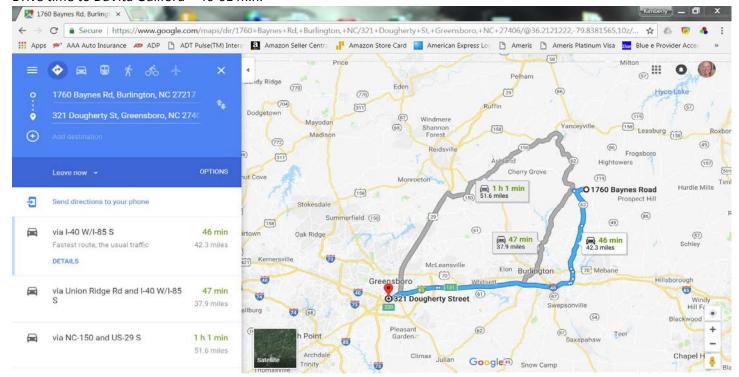


Drive time to Elon – 30-33 min.

Drive time to current facility, North Burlington – 22-23 min.

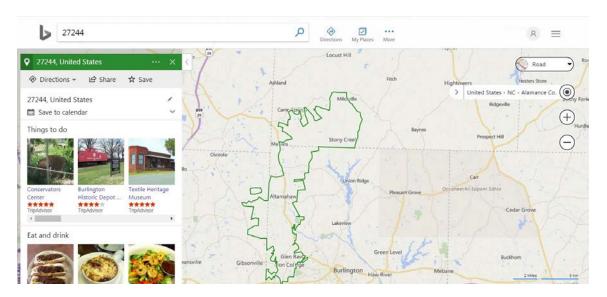


Drive time to DaVita Guilford - 46-61 min.

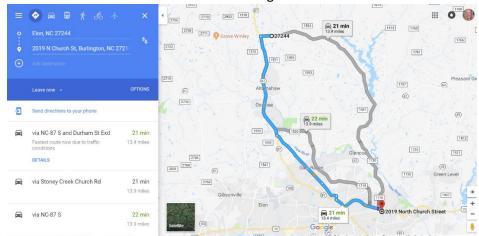


26, 27, 29 & 30 are identified as living in zip code area 27244. Signatures are illegible. Using the zip code area, we mapped the distance to the patients' current facility DaVita North Burlington and to the proposed location for DaVita Guilford.

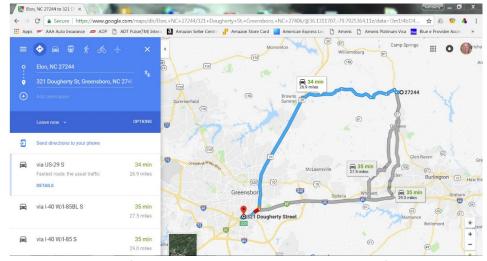
Verification of county residency is impossible to determine since zip code area 27244 lies in Alamance, Caswell, and Guilford Counties.



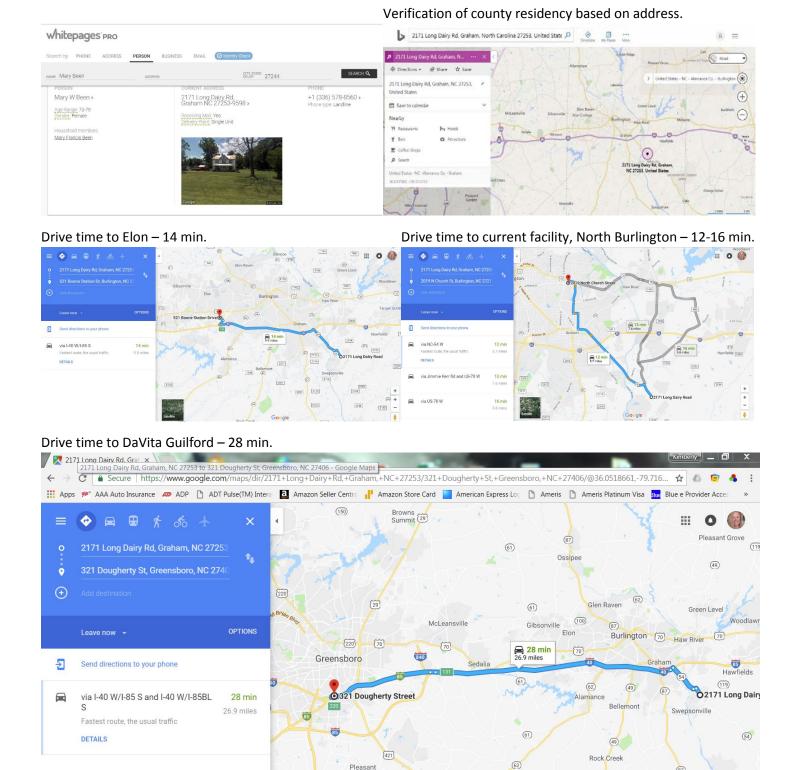
Drive time to North Burlington – 21-22 min.



Drive time to DaVita Guilford - 34-35 min.



28 Mary Been – We found no one named Mary Been living in zip code area 27244. However, we did find one Mary Been living in Alamance County, in zip code area 27253.



DaVita Guilford is NOT more convenient for this patient. Travel time to the new facility will NOT be shorter.

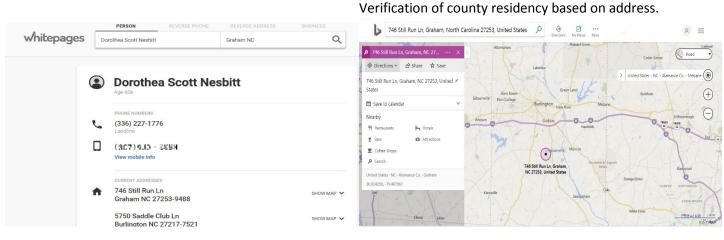
62 421

Kimesville

Google

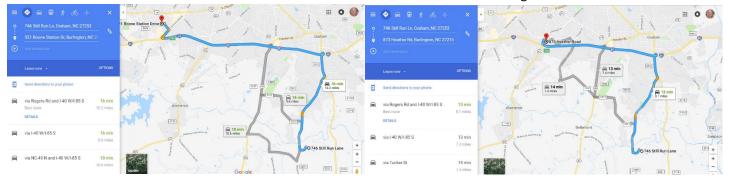
Eli W

31 Dorothea Nesbitt – We found no one named Dorothea Nesbitt living in zip code area 27244. However, we did find one person named Dorothea Nesbitt living in Alamance County. 746 Still Run Ln. is the most current address for this person.



Drive time to Elon - 16-18 min.

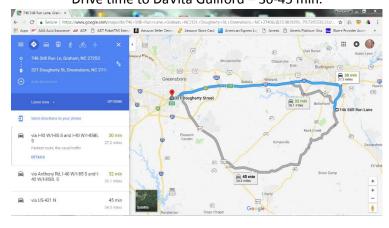
Drive time to DaVita Burlington – 13-14 min.



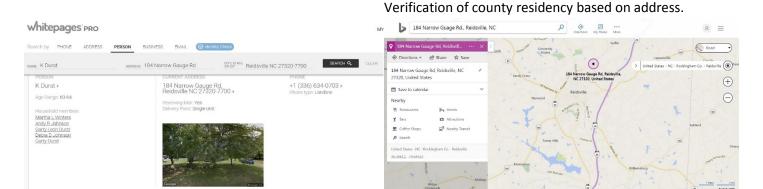
Drive time to current facility, North Burlington – 16-18 min.



Drive time to DaVita Guilford – 30-45 min.

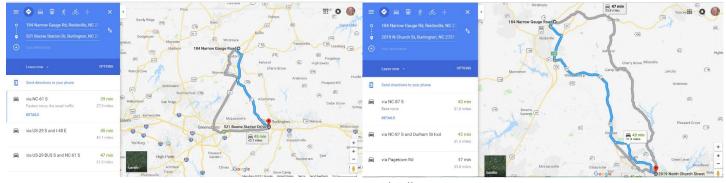


32 K. Durst – We found no one with the last name Durst or any variation thereof living in zip code area 27244. However, we did find K. Durst living near Alamance County in Rockingham County in zip code area 27320.

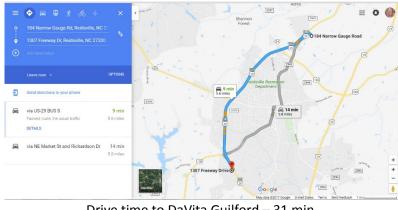


Drive time to Elon - 39-47 min.

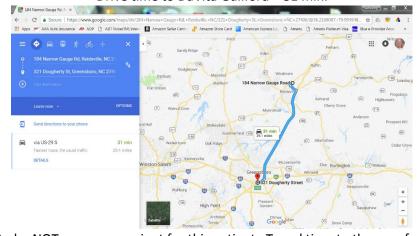
Drive time to current facility, North Burlington – 43-47 min.



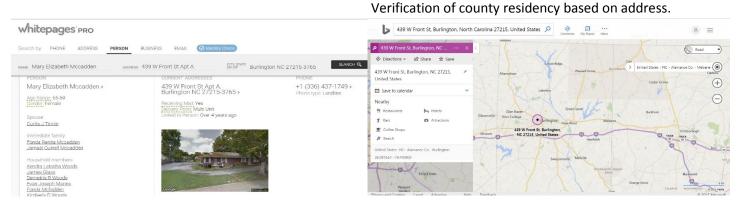
Drive time to DaVita Reidsville - 9-14 min.



Drive time to DaVita Guilford - 31 min.

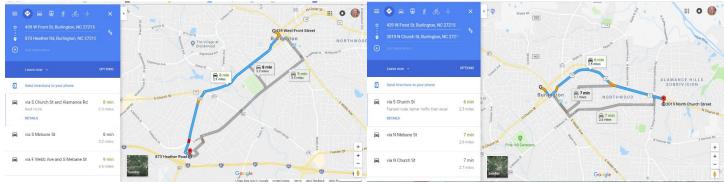


33 Mary McCadden – We found no person by the name Mary McCadden living in zip code area 27244. However, we did find one person named Mary McCadden living near Burlington in zip code area 27215.

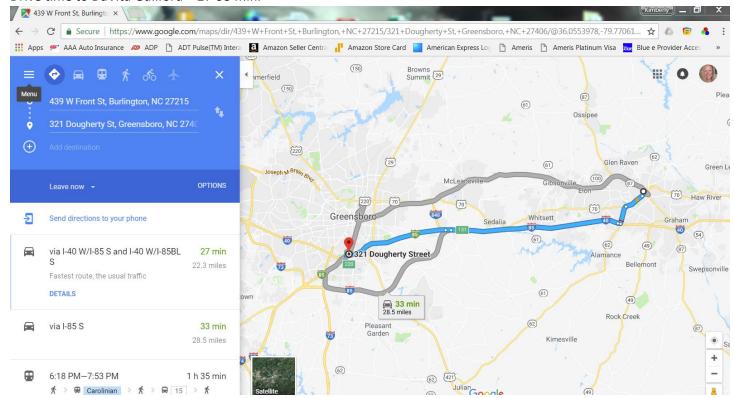


Drive time to DaVita Burlington – 8-9 min.

Drive time to current facility, North Burlington – 6-7 min.



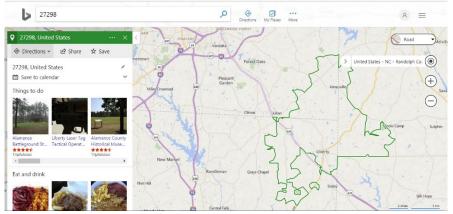
Drive time to DaVita Guilford – 27-95 min.



DaVita Guilford is NOT more convenient for this patient. Travel time to the new facility will NOT be shorter.

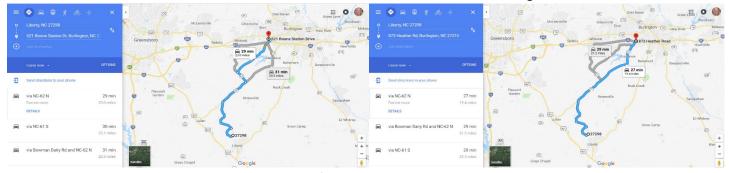
34 Earl (Illegible) is identified as living in zip code area 27298. The signature is completely illegible making verification of the patient's address impossible. Using the zip code area, we mapped the distance to nearby DaVita facilities and DaVita Guilford.

Verification of county residency is impossible. Zip code area 27298 lies in Alamance, Guilford, and Randolph Counties.

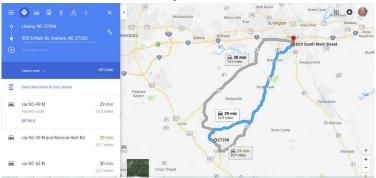


Drive time to Elon – 29-31 min.

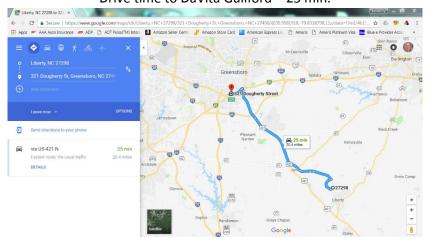
Drive time to DaVita Burlington – 27-29 min.



Drive time to current facility, DaVita Alamance – 29-30 min.



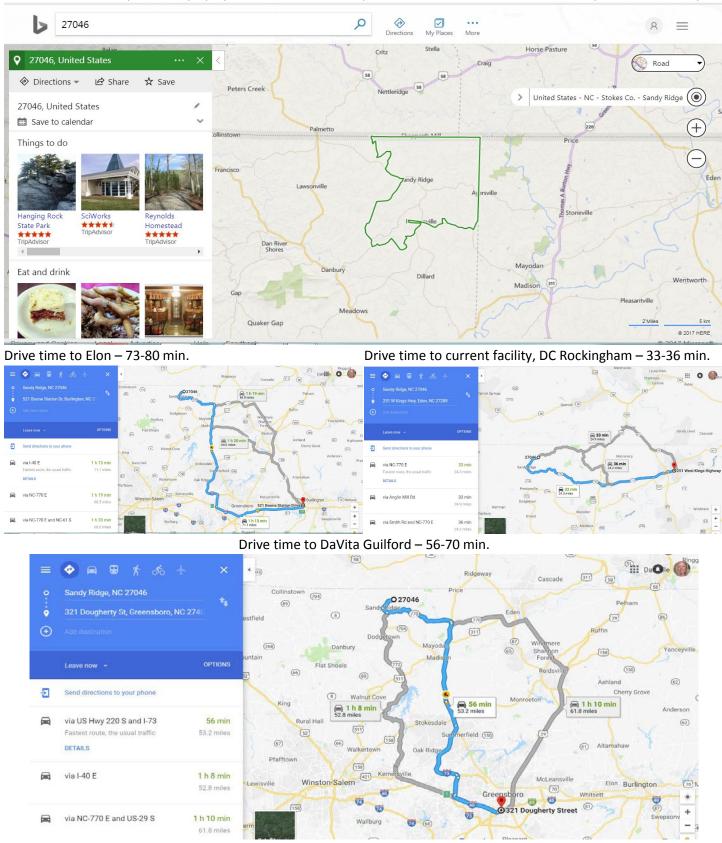
Drive time to DaVita Guilford – 25 min.



DaVita Guilford is no more convenient for the patient than other DaVita facilities. Drive time is roughly the same.

35 Robert (Illegible) is identified as living in zip code area 27046. The signature is completely illegible making verification of the patient's address impossible. Using the zip code area we mapped the distance to nearby DaVita facilities and DaVita Guilford.

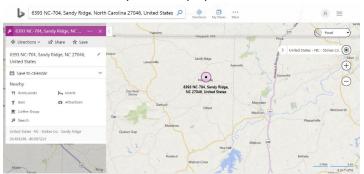
Verification of county residency by zip code area indicates zip code area 27046 is located exclusively in Stokes County.



DaVita Guilford is NOT more convenient for this patient. Travel time to the new facility will NOT be shorter.

36 Eunice Goins – We found one person named Eunice Goins living in zip code area 27046.

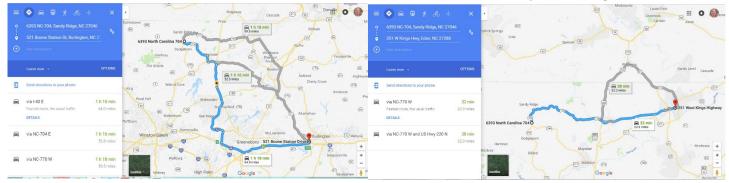
Verification of county residency by address.



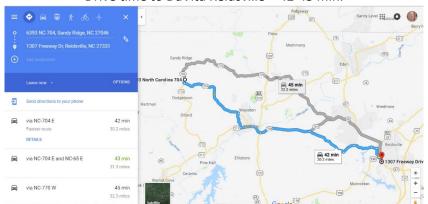
View Free Profile. Relatives: James E **Goins, Eunice** H **Goins**. Addresses: 6393 **Nc** 704 Hwy E, **Sandy Ridge, NC**; Rr 1 Box 157, **Sandy Ridge, NC**; Rr 1 Box 155, Sandy ...

Drive time to Elon – 70-78 min.

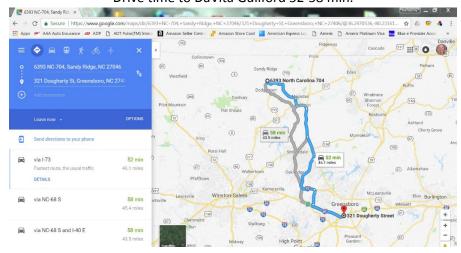
Drive time to current facility, DC Rockingham – 32-38 min.



Drive time to DaVita Reidsville - 42-45 min.

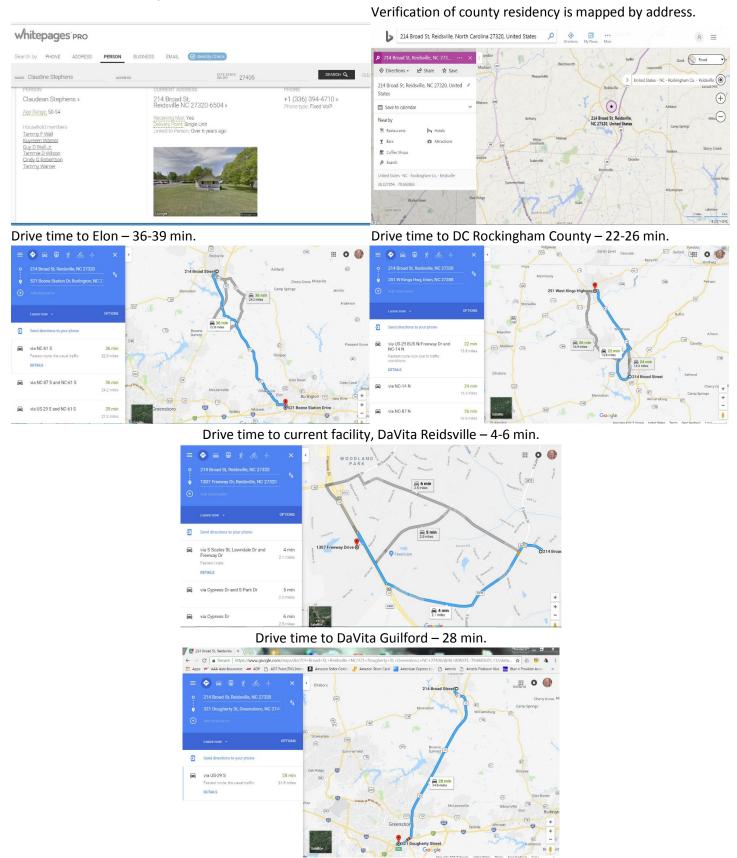


Drive time to DaVita Guilford 52-58 min.



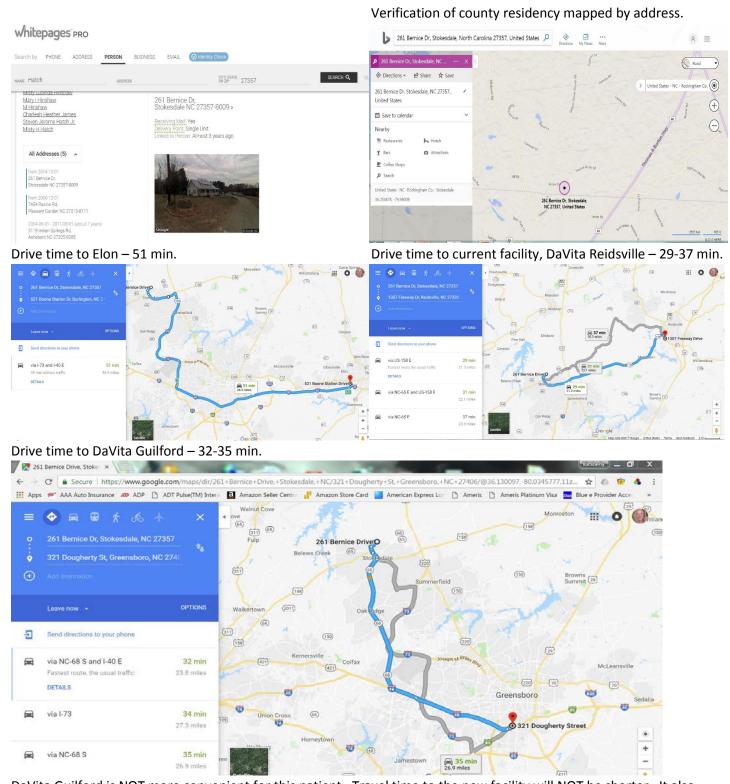
DaVita Guilford is NOT more convenient for this patient. Travel time to the new facility will NOT be shorter.

37 Claudean Stephens – We found no one named Claudean Stephens living in zip code area 27406. However, we did find a Claudean Stephens living near Reidsville, NC in zip code area 27320. Ms. Stephens is 1 of 2 patients projected to transfer from host facility DaVita Reidsville.



DaVita Guilford is NOT more convenient for this patient. Travel time to the new facility will NOT be shorter.

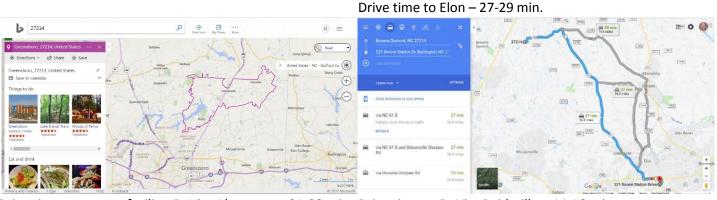
38 David Hatch – We found one person named David Hatch living in zip code area 27357. Mr. Hatch is 2 of 2 patients projected to transfer from the host facility, DaVita Reidsville. Zip code 27357 lies in both Rockingham and Guilford Counties.



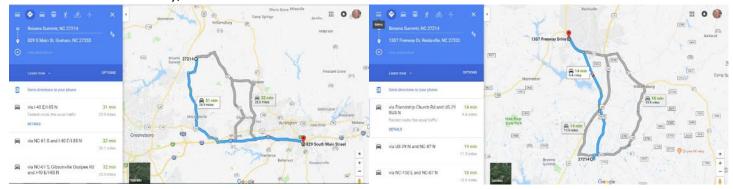
DaVita Guilford is NOT more convenient for this patient. Travel time to the new facility will NOT be shorter. It also appears this patient is a resident of Rockingham County not Guilford County, which raises an issue of compliance with ESRD-2, given the difficulties in mapping the other patient from that facility, Claudean Stephens, who also appears to reside in Rockingham County.

39 L. Plevens (Illegible) – Home Patient – is identified as living in zip code area 27214. The patient's signature is illegible making it impossible to map. Using zip code area 27214, we mapped the distance to the patient's current facility, nearby DaVita facilities, and DaVita Guilford.

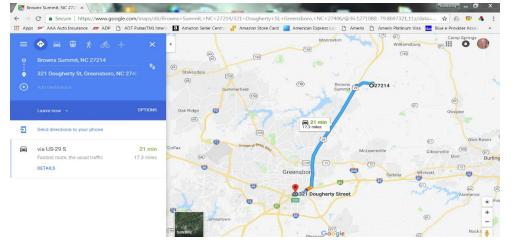
Verification of county residency by zip code area is impossible. Zip code area 27214 lies in both Guilford and Rockingham Counties.



Drive time to current facility, DaVita Alamance - 31-32 min. Drive time to DaVita Reidsville - 14-18 min.

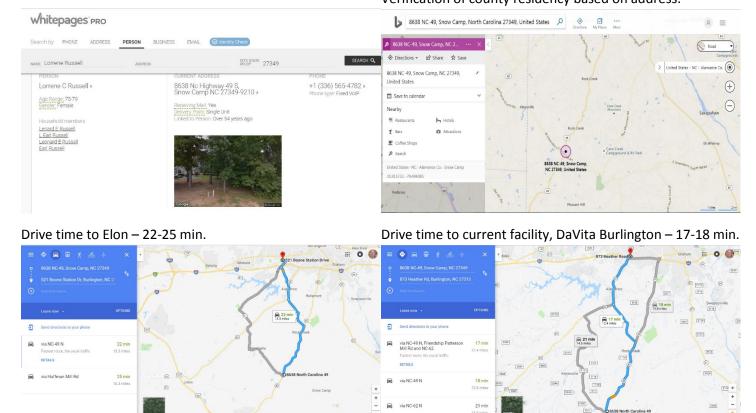


Drive time to DaVita Guilford – 21 min.

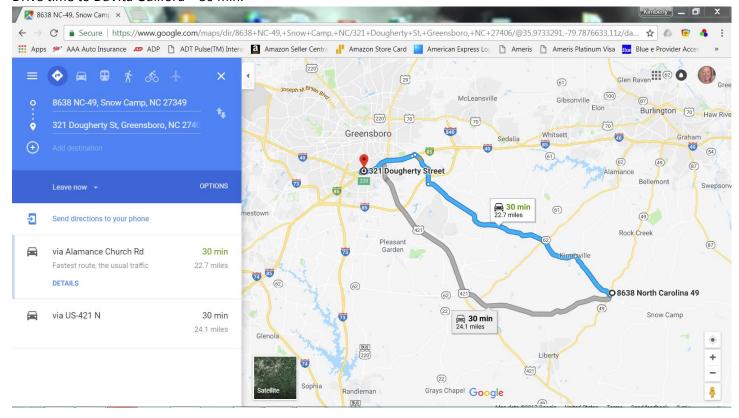


DaVita Guilford is NOT more convenient for this patient. Travel time to the new facility will NOT be shorter. DaVita Reidsville is the closes facility to this patient's mapped zip code area. Home patients are not considered when applying for new dialysis stations or facilities.

40 Lorrene C. Russell – Home Patient – We found one person named Lorrene Russell living in zip code area 27349. Verification of county residency based on address.



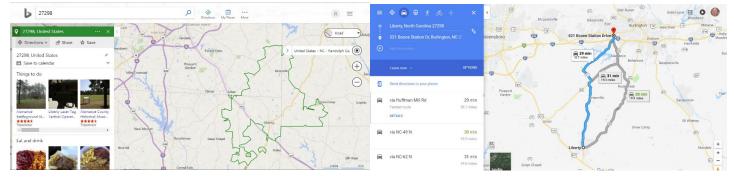
Drive time to DaVita Guilford - 30 min.



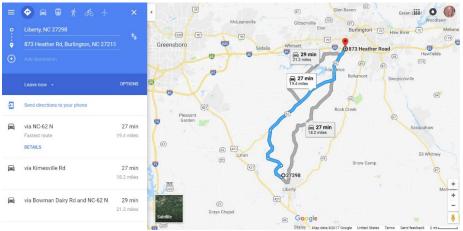
DaVita Guilford is NOT more convenient for this patient. Travel time to the new facility will NOT be shorter. Home patients are not considered when applying for new dialysis stations or facilities.

41 Kenny Reeter (27298) – We were unable to find anyone named Kenny Reeter, which may indicate the last name is incorrect (illegible.) Using zip code area 27298 we mapped drive times to the nearby DaVita locations, the patient's current facility, and DaVita Guilford. Zip code area 27298 lies in Alamance, Randolph, and Guilford Counties.

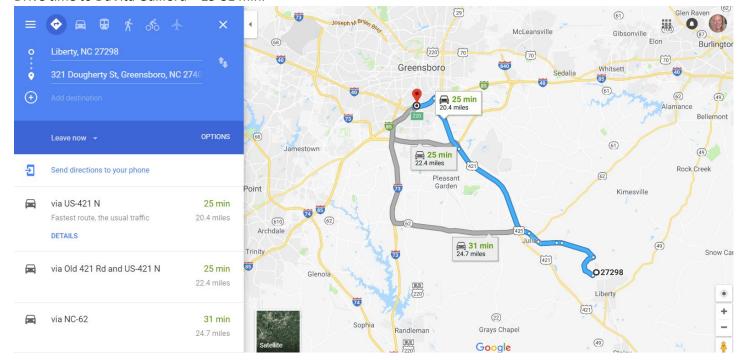
Verification of county residency is impossible. Drive time to Elon – 29-31 min.



Drive time to current facility, DaVita Burlington – 27-29 min.



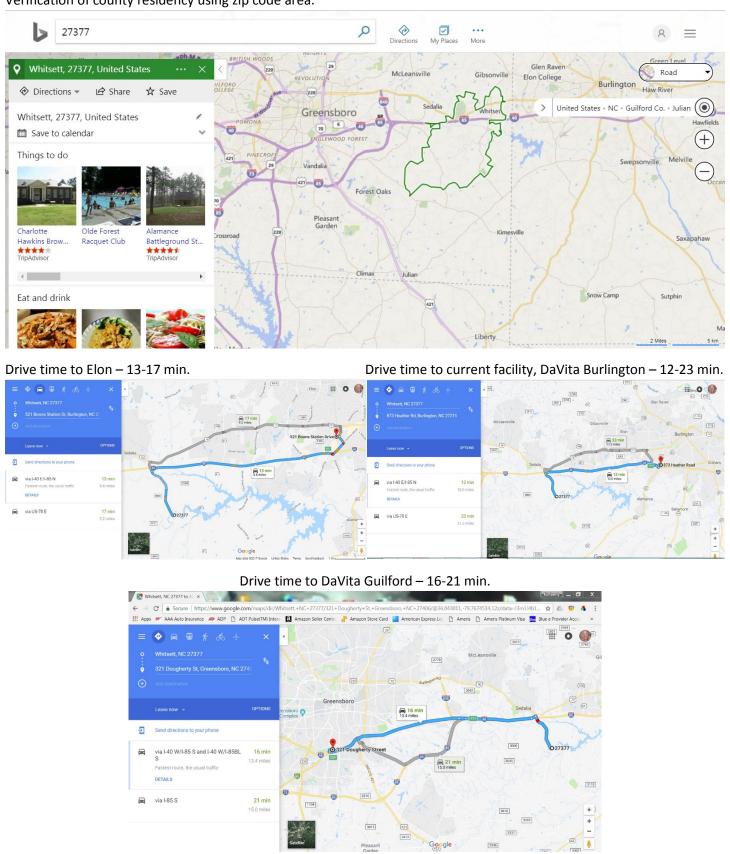
Drive time to DaVita Guilford - 25-31 min.



DaVita Guilford is likely NOT more convenient for this patient. Travel time to the new facility likely will NOT be shorter. Home patients are not considered when applying for new dialysis stations or facilities.

42 T. Siernny (27377) – Home Patient – We were unable to find anyone with the last name Siernny, which indicates the last name may be incorrect (illegible.) Using the zip code area we mapped travel times to the patient's current facility, nearby DaVita locations, and DaVita Guilford.

Verification of county residency using zip code area.



DaVita Guilford is likely NOT more convenient for this patient. Travel time to the new facility likely will NOT be shorter. Home patients are not considered when applying for new dialysis stations or facilities.

EXHIBIT

												,						,	Time &	Time & Distance VS. Curr		llity
																					·	
						Was													Drive Time	Travel	1	
						Zip Patier	ıt		Duplicate		Fastest	Shortest			Fastest Drive		Fastest		(Minutes)	Distance	% Change	
						Code Found	1		Support		Drive Time	Miles to	Fastest		Time DaVita	Shortest Miles	Drive	Shortest	Improved (+)	Improvem	in Drive	% Change
						on in Zi	Date of	Home County Based on	Letters for		to Current	Current	Drive Time	Shortest	Guilford	DaVita Guilford	Time To	Miles to	or	ent or	Time	in Drive
Order	Modality	Name	Street	City State	Zip		Letter	Mapping Data	Elon?	Current Facility	Facility	Facility	to Elon	Miles to Elon	County	County	Reidsville	Reidsville	Worsened (-)	Deficit	(Minutes)	Distance
1	ICH	James Wilson	5221 Millstream Rd	McLeansville NC			8/28/2017	Guilford	Duplicate	Burlington	14.00	12.10	14.00	10.90	12.00	8.90			2.00	3.20	14%	26%
2	ICH	Willette D. Mitchell	1003 Amity Dr			6 27406 Y	8/28/2017	Guilford	Duplicate	Burlington	21.00	21.10	22.00	19.90	5.00	2.00			16.00	19.10	76%	91%
2			5804 Highlawn Dr.					Guilford		_	27.00		28.00	25.40		7.50					59%	72%
3	ICH	Tammy E. Moore	<u> </u>			9 27409 Y	8/28/2017		Duplicate	Burlington		26.60			11.00				16.00	19.10		
4	ICH	Dorothy Thompson	2201 Carl Noah Rd	Snow Camp NC		27349 Y	8/28/2017	Alamance		Burlington	18.00	12.10	22.00	13.00	35.00	26.10			-17.00	-14.00	-94%	-116%
5	ICH	Lonnie Gibson	3583 Shady Maple Ln	Snow Camp NC	-	9 27349 Y	8/28/2017	Alamance		Burlington	18.00	12.20	23.00	13.00	32.00	23.50			-14.00	-11.30	-78%	-93%
6	ICH	Herman Bittle	6523 Patterson Rd	Snow Camp NC		9 27349 Y	9/13/2017	Alamance		Burlington	17.00	11.50	21.00	12.40	31.00	22.90			-14.00	-11.40	-82%	-99%
7	ICH	D. Jolus			27377	7 27377 Y	8/30/2017	Guilford		Burlington	11.00	10.00	13.00	8.80	16.00	13.40			-5.00	-3.40	-45%	-34%
8	ICH	Louis Walker	400 Steele St	Gibsonville NC	27249	9 27249 Y	8/28/2017	Guilford	Duplicate	Burlington	13.00	9.30	11.00	4.90	20.00	17.00			-7.00	-7.70	-54%	-83%
9	ICH	Ricky A. Gill	401 Riverton Ct	Gibsonville NC	27249	9 27249 Y	8/29/2017	Guilford		Burlington	13.00	9.10	12.00	5.20	20.00	16.90			-7.00	-7.80	-54%	-86%
10	ICH	Jeffrey (Illegible)			27410	27410 Y	8/29/2017	Guilford		Burlington	34.00	32.70	34.00	31.50	17.00	13.60			17.00	19.10	50%	58%
11	ICH	Ernest E. Welker	3326 Alamance Church Ro	d Julian NC	27283	3 27283 Y	8/29/2017	Guilford		Burlington	17.00	13.60	19.00	11.70	18.00	13.40			-1.00	0.20	-6%	1%
12	ICH	Anthony Martin	2709 Wild Poplar Way	Greensboro NC	2740	5 27405 Y	8/28/2017	Guilford	Duplicate	Burlington	28.00	24.00	28.00	22.80	15.00	9.80			13.00	14.20	46%	59%
13	ICH	Arthur L. Snipes	113 Wind Hill Ct	Greensboro NC	2740	5 27405 Y	8/29/2017	Guilford	_	Burlington	27.00	22.60	27.00	21.40	14.00	8.40			13.00	14.20	48%	63%
14	ICH	Mary Beale	2250 Phibbs Rd	Elon NC			8/28/2017	Alamance	Duplicate	Burlington	16.00	6.50	12.00	5.90	28.00	22.60			-12.00	-16.10	-75%	-248%
15	ICH	Pauline H. Tate	1739 Power Line Rd			1 27244 Y	8/29/2017	Alamance	Duplicate	Burlington	13.00	5.10	10.00	4.10	26.00	22.00			-13.00	-16.90	-100%	-331%
16	ICH	James T. Disosway	4331 Alpine Ln	Liberty NC		3 27298 Y	8/28/2017	Alamance	Duplicate	Burlington	12.00	7.70	17.00	8.60	26.00	22.80			-14.00	-15.10	-117%	-196%
10		·	4551 Alpine Lii	Liberty INC	_				Develiante	_												
17	ICH	Illegible				1 27244 Y	8/25/2017	Alamance, Caswell, Guilford	Duplicate	Burlington	23.00	13.10	20.00	12.50	34.00	26.90			-11.00	-13.80	-48%	-105%
18	ICH	X				1 27244 Y		Alamance, Caswell, Guilford	Duplicate	Burlington	23.00	13.10	20.00	12.50	34.00	26.90			-11.00	-13.80	-48%	-105%
19	ICH	Illegible			27349	9 27349 Y	9/13/2017	Alamance		Burlington	28.00	18.60	32.00	19.40	41.00	30.10			-13.00	-11.50	-46%	-62%
20	ICH	M. Stenunos			27405	5 27405 Y	9/12/2017	Guilford		Burlington	26.00	22.10	27.00	20.90	14.00	7.90			12.00	14.20	46%	64%
21	ICH	Reginald Thompson	1101 Elwood St	Burlington NC	2721	7 27249 N	11/11/2017	Alamance		Burlington	9.00	3.70	14.00	5.40	28.00	23.00			-19.00	-19.30	-211%	-522%
22	ICH	K. Chambers	5864 Ruralview Rd	Gibsonville NC	27249	9 27249 Y	11/10/2017	Guilford		Burlington	25.00	18.50	23.00	12.80	21.00	16.70			4.00	1.80	16%	10%
23	ICH	David F. Williams	5638 Kimesville Rd	Liberty NC	27298	3 27298 Y	11/10/2017	Alamance		Burlington	12.00	8.10	17.00	9.00	24.00	22.00			-12.00	-13.90	-100%	-172%
24	ICH	Illegible			27349	9 27349 Y	11/14/2017	Alamance		Burlington	28.00	18.60	32.00	19.40	41.00	30.10			-13.00	-11.50	-46%	-62%
25			1700 Parria P4	Burlington NC			8/25/2017		Duplicate	_	22.00	17.30	30.00	19.70	46.00	42.30			-24.00		-109%	-145%
25	ICH	John S. Ingram	1760 Baynes Rd.	Burlington NC		7 27244 N	Research Control of the Control of t	Caswell	Duplicate	N. Burlington				19.70						-25.00		
26		(Illegible)			2724		9/14/2017	Alamance, Caswell, Guilford		N. Burlington	21.00	13.40	20.00		34.00	26.90			-13.00	-13.50	-62%	-101%
27		(Illegible)				4 27244 Y		Alamance, Caswell, Guilford		N. Burlington	21.00	13.40	20.00		34.00	26.90			-13.00	-13.50	-62%	-101%
28	ICH	Mary Been	2171 Long Dairy Rd	Graham NC		3 27244 N	9/14/2017	Alamance		N. Burlington	12.00	5.70	14.00	9.90	28.00	26.90			-16.00	-21.20	-133%	-372%
29	ICH	Jeffrey M (Illegible)			2724	4 27244 Y	9/14/2017	Alamance, Caswell, Guilford		N. Burlington	21.00	13.40	20.00		34.00	26.90			-13.00	-13.50	-62%	-101%
30	ICH	Saie A (Illegible)			27244	1 27244 Y	9/14/2017	Alamance, Caswell, Guilford		N. Burlington	21.00	13.40	20.00		34.00	26.90			-13.00	-13.50	-62%	-101%
31	ICH	Dorothea Nesbitt	746 Still Run Ln	Graham NC	27253	3 27244 N	9/14/2017	Alamance		N. Burlington	16.00	6.50	16.00	10.20	30.00	27.20			-14.00	-20.70	-88%	-318%
32	ICH	Katrina Durst	184 Narrow Guage Rd	Reidsville NC	27320	27244 N	9/14/2017	Rockingham		N. Burlington	43.00	31.80	39.00	27.90	31.00	29.10	9.00	5.60	12.00	2.70	28%	8%
33	ICH	Mary McCadden	439 W Front St	Burlington NC	27215	5 27244 N	9/14/2017	Alamance		N. Burlington	6.00	2.50	8.00	2.90	27.00	22.30			-21.00	-19.80	-350%	-792%
34	ICH	Earl Murphy (Illegible)				3 27298 Y		Mamance, Guilford, Randolph		Alamance Co.	29.00	20.30	29.00	20.00	25.00	20.40			4.00	-0.10	14%	0%
35	ICH	Robert Selke (Illegible)		1		6 27046 Y	8/31/2017	Stokes		D.C. Rockingham	33.00	24.30	73.00	71.10	56.00	53.20			-23.00	-28.90	-70%	-119%
20		` '	C202 NC 704	Candy Did.													40.00	00.00				
36	ICH	Eunice Goins	6393 NC 704	Sandy Ridge NC		2.610	8/31/2017	Stokes		D.C. Rockingham	32.00	23.30	70.00	64.00	52.00	46.10	42.00	30.20	-20.00	-22.80	-63%	-98%
37	ICH	Claudean Stephens	214 Broad St	Reidsville NC		27406 N	9/11/2017	Rockingham		Reidsville	4.00	2.10	36.00	22.80	28.00	24.80	4.00	2.10	-24.00	-22.70	-600%	-1081%
38	ICH	David Hatch	261 Bernice Dr.	Stokesdale NC		7 27357 Y	11/10/2017	Rockingham		Reidsville	29.00	21.30	51.00	46.90	32.00	23.80			-3.00	-2.50	-10%	-12%
39	PD	L Plevens (Illegible)			27214	4 27214 Y	9/14/2017	Guilford, Rockingham		Alamance Co.	31.00	25.90	27.00	16.90	21.00	17.30	14.00	9.40	10.00	8.60	32%	33%
40	PD	Lorrene C. Russell	8638 NC 49	Snow Camp NC	27349	9 27349 Y	9/13/2017	Alamance		Burlington	17.00	12.40	22.00	13.30	30.00	22.70			-13.00	-10.30	-76%	-83%
41	PD	Kenny Reeter (Illegible)			27298	3 27298 Y	9/13/2017	Alamance, Guilford, Randolph		Burlington	27.00	18.20	29.00	18.70	25.00	20.40			2.00	-2.20	7%	-12%
42	PD	T. Siernny			2737	7 27377 Y	11/10/2017	Guilford		Alamance Co.	12.00	10.00	13.00	8.80	16.00	13.40			-4.00	-3.40	-33%	-34%
N	umber	of Patients NOT Fo	und in the Zin Code	Area On Their P	atient	Letter 7				Niim	iber of Patie	ents Farthe	r than 30 !	Miles from D	aVita Guilford	5						
								01 01 1 4110							4							
	Number of New Patient Letters for This Application 6								N	iumber of	t Patients C	ioser to Reids	sville Dialysis	4	4							
	_	Num	ber of Patients for W	hom County Res	sidenc	y Cannot B	e Identified	9		Number	of Patients	For Whon	1 DaVita G	uilford is <u>NC</u>	T More Conve	enient or Drive	Γime is <mark>N</mark> C	T Shorter	32	35	32	35
			Numh	er of Patients W	ho 11	so Provided	Letters of Si	pport for DaVita Elon	10	Percentage	of Patiente	For Whon	1 DaVita C	uilford is NC	T More Conve	enient or Drive	Fime is N C	YT Shorter	76%	83%	76%	83%
			Nullib	ci oi i aticitio VV	но ли	30 I I OVIUCU	1211213 01 31	ipport for Davita Lion	10	rerecinage	or rancinis	TOT WITH	ı Davna G	milora is MC	INIOIC COIIVE	mem of Dilve	1111C 10 11C	JI SHOTICI	10/0	00/0	10/0	0070

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.

EXHIBIT 6

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

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

Witness

Date 6 21 2014

Date

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.

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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

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.

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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.

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.

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- A new facility in Guilford County will be more convenient for me and my transportation
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 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.

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

Patient Signature or Mark

Date Signed

Debbur Hamelet. At 828-17

itness Signature and Title Date Signed

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.

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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

Vitnaca

Date

Date '

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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

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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 Beald
Debbie HAMLEH
Witness
Date
Date

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Patient Pauline Tate

April (1/10/10)

April (1/10/10)

Witness Date

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.

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Patient Debte HAmlett Date

Witness Date

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J. INGRAN ...

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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Patient Signature or Mark

Witness Signature and Title

Date Signed

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s. Ingram

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Patient

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ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS C = Conforming CA = Conditional

NC = Nonconforming

NA = Not Applicable

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

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

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

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

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

and 2 stations from North Burlington Dialysis

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

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

Need Determination

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

Policies

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

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

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

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

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

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

Conclusion

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

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

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

Population to be Served

On page 369, the 2016 SMFP defines the service area for dialysis stations as "the planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area." Thus, the service area is Alamance County. Facilities may serve residents of counties not included in their service area.

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

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

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

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

The applicant adequately identifies the population to be served.

Analysis of Need

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

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

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

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

- 1. DaVita is the parent company of Burlington Dialysis and North Burlington Dialysis in Alamance County.
- 2. Twenty-six in-center dialysis patients who reside in Alamance County and currently receive dialysis treatments at DaVita operated facilities in Alamance County have signed letters stating they would consider transferring their dialysis care to the proposed facility.
- 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.

<u>Projected Utilization</u>

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

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

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

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

Elon Dialysis Project ID #J-11212-16 Page 6

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.

 \mathbf{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.

Elon Dialysis Project ID #J-11212-16 Page 7

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

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

Elon Dialysis Project ID #J-11212-16 Page 8

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Burlington Dialysis and North Burlington Dialysis by policy, will continue to make dialysis services available to all residents in its service area without qualifications. We serve patients without regard to race, color, national origin, gender, sexual orientation, age, religion, or disability."

Conclusion

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

Therefore, the application is conforming to this criterion.

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

CA

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

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

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

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

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

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

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

feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

 \mathbf{C}

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

Capital and Working Capital Costs

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

Projected Capital Costs

110jected Cupital Costs			
Site Costs	\$ 48,000		
Construction	\$1,125,000		
Machines	\$ 152,400		
RO Equipment	\$ 134,675		
Other Equipment/Furniture	\$ 246,895		
Architect/Engineering Fees	\$ 90,000		
Total Capital Costs	\$1,796,970		

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

Availability of Funds

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

DaVita Accumulated Reserves / Owner's Equity

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

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

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

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

Financial Feasibility

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

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

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

Conclusion

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

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

 \mathbf{C}

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

On page 369, the 2016 SMFP defines the service area for dialysis stations as "the planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham

Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area." Thus, the service area is Alamance County. Facilities may serve residents of counties not included in their service area.

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

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

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

Source: July 2016 SDR

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

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

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

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

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

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

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

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

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

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

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

NA

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

NA

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

 \mathbf{C}

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

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

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:
 - (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

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

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

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

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

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

Totals may not sum due to rounding.

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

	Percent of Population					
County	County % 65+ % Female % Racial and Ethnic Minority* % Persons in Poverty** With a Disability Insurance**					
2014 Estimate	2014 Estimate	2014 Estimate	2014 Estimate	2010-2014	2010-2014	2014 Estimate
Alamance	16%	52%	34%	18%	10%	20%
Statewide	15%	51%	36%	17%	10%	15%

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

**"This geographic level of poverty and health estimates are not comparable to other geographic levels of these estimates

Some estimates presented here come from sample data, and thus have sampling errors that may render some apparent differences
between geographies statistically indistinguishable...The vintage year (e.g., V2015) refers to the final year of the series (2010 thru
2015). Different vintage years of estimates are not comparable."

However, a direct comparison to the applicant's current payor mix would be of little value. The population data by age, race or gender does not include information on the number of elderly, minorities, women or handicapped persons utilizing health services.

The Southeastern Kidney Council Network 6 Inc. 2014 Annual Report¹ provides prevalence data on North Carolina dialysis patients by age, race, and gender on page 59, summarized as follows:

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

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

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

The applicant demonstrates that it currently provides adequate access to medically underserved populations. Therefore, the application is conforming to this criterion.

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

 \mathbf{C}

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

In Section L.6, page 52, the applicant states that there have been no civil rights access complaints filed within the past five years. Therefore, the application is conforming to this criterion.

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

C

In Section R, the applicant projects that over 79% of the in-center patients who will receive treatments at Elon Dialysis will have some or all of their services paid for by Medicare or Medicaid. The table below shows the projected payment source for Elon Dialysis in-center patients for operating years one and two:

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

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

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

 \mathbf{C}

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

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

 \mathbf{C}

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

the proposed facility as a clinical training site. The information provided is reasonable and adequately supports a determination that the application is conforming to this criterion.

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

 \mathbf{C}

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

On page 369, the 2016 SMFP defines the service area for dialysis stations as "the planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area." Thus, the service area is Alamance County. Facilities may serve residents of counties not included in their service area.

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

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

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

Source: July 2016 SDR

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

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

"The proposed facility will not have an adverse effect on competition with any dialysis facilities located in Alamance County or in counties contiguous to it since the patients already being served by DaVita will be transferring their care from one DaVita facility to another DaVita facility, which will be more convenient for the patients who have indicated this in the letters they signed.

The bottom line is Elon Dialysis will enhance accessibility to dialysis for our patients, and by reducing the economic and physical burdens on our patients, this project will enhance the quality and cost effectiveness of our services because it will make it easier for patients, family members and other involved in the dialysis process to receive services. Patient selection is the determining factor, as the patient will select the provider that gives them the highest quality service and best meets their needs."

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

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

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

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

Therefore, the application is conforming to this criterion.

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

 \mathbf{C}

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

- (21) Repealed effective July 1, 1987.
- (b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C

The application is conforming with all applicable Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200. The specific criteria are discussed below:

10 NCAC 14C .2203 PERFORMANCE STANDARDS

- .2203(a) An applicant proposing to establish a new End Stage Renal Disease facility shall document the need for at least 10 stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the facility, with the exception that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.
- -C- In Section C, the applicant adequately demonstrates the need to establish the proposed 10-station Elon Dialysis facility by relocating 10 existing Alamance County dialysis stations to the proposed facility. At the end of the first operating year, CY2018, the applicant projects Elon Dialysis will serve 33 patients for a utilization of 3.3 patients per station per week. The discussion regarding analysis of need, including projected utilization, found in Criterion (3) is incorporated herein by reference.
- .2203(b) An applicant proposing to increase the number of dialysis stations in an existing End Stage Renal Disease facility or one that was not operational prior to the beginning of the review period but which had been issued a certificate of need shall document the need for the additional stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the additional stations.
- -NAThe applicant is not proposing to increase the number of dialysis stations in an existing End Stage Renal Disease facility or one that was not operational prior to the beginning of the review period but which had been issued a certificate of need. The applicant is seeking to develop a new 10-station dialysis facility in Alamance County by relocating existing Alamance county dialysis stations.
- .2203(c) An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.
- -C- In Section C.1, pages 13-15, the applicant provides the assumptions and methodology used to project utilization for the proposed facility. The discussion regarding analysis of need, including projected utilization, found in Criterion (3) is incorporated herein by reference.



698 S.E.2d 446 Court of Appeals of North Carolina.

TOTAL RENAL CARE OF NORTH CAROLINA, LLC d/b/a TRC-Leland, Petitioner, v.

NORTH CAROLINA DEPARTMENT OF HEALTH AND HUMAN SERVICES, DIVISION OF HEALTH SERVICE REGULATION, CERTIFICATE OF NEED SECTION, Respondent, and

Bio-Medical Applications of North Carolina, Inc., d/b/a Fresenius Medical Care of Brunswick County, Respondent-Intervenor.

No. COA09-879. Sept. 7, 2010.

Synopsis

Background: Applicant for certificate of need (CON) for a new dialysis facility sought review of order of Department of Health and Human Services (DHHS) granting a competitor's application, but denying its application.

Holdings: The Court of Appeals, Stroud, J., held that:

- 1 DHHS properly allowed competitor's application, and
- 2 disapproved applicant's application.

Affirmed.

*448 Appeal by petitioner from Final Agency Decision entered on or about 19 March 2009 by the North Carolina Department of Health and Human Services. Heard in the Court of Appeals 13 January 2010.

Attorneys and Law Firms

Poyner Spruill LLP, Raleigh, by William R. Shenton, for petitioner-appellant.

Attorney General Roy A. Cooper, III, by Scott Stroud, for respondent-appellee.

Wyrick Robbins Yates & Ponton LLP, Raleigh, by K. Edward Greene, Lee M. Whitman, and Tobias S. Hampson, for respondent-intervenor-appellee.

Opinion

STROUD, Judge.

Total Renal Care of North Carolina, LLC d/b/a TRC-Leland appealed the final agency decision affirming the decision of the North Carolina Department of Health and Human Services, Division of Health Service Regulation, Certificate of Need Section to approve the application of Bio-Medical Applications of North Carolina, Inc. d/b/a Fresenius Medical Care of Brunswick County for a new dialysis facility. For the following reasons, we affirm.

I. Background

On 28 March 2008, Total Renal Care of North Carolina, LLC d/b/a TRC-Leland ("TRC") filed a petition for a contested case hearing regarding the North Carolina Department of Health and Human Services, Division of Health Service Regulation, Certificate of Need Section's ("the CON Section") *449 decisions denying "TRC's application to develop and operate a new ten-station dialysis facility in the town of Leland in Brunswick County" and approving Bio-Medical Applications of North Carolina, Inc. d/b/a Fresenius Medical Care of Brunswick County's ("BMA") application "to develop and operate a new dialysis facility in the town of Supply, also in Brunswick County[.]" Both applications were submitted after a need was recognized "for 13 additional dialysis stations in Brunswick County, North Carolina." TRC requested that both decisions be reversed and that it be awarded a certificate of need ("CON") for a new dialysis facility in Leland. On or about 17 April 2008, BMA filed a motion to intervene in the case. On 1 May 2008, BMA's motion was granted.

On or about 23 December 2008, Joe L. Webster, administrative law judge, recommended that BMA and TRC be granted "a new review of the applications utilizing reviewers not involved in the initial review, and in the alternative, reverse the CON Section's decision to grant BMA's application for a certificate of need and to affirm the CON Section's decision to deny TRC's applications for a certificate of need." On or about 5 March 2009, TRC submitted its exceptions to the recommended decision and a proposed final agency decision. Also on or about 5 March 2009, the CON Section and BMA submitted their exceptions to the recommended decision and their proposed final agency decision. On or about 19 March 2009, the North Carolina Department of Health and Human Services Division of Health

Service Regulation ("DHHS") affirmed the CON Section's decision to award BMA a CON. TRC appealed.

II. Standard of Review

- 1 The standard of review of an administrative agency's final decision is dictated by the substantive nature of each assignment of error.
- 2 3 Where the appellant asserts an error of law in the final agency decision, this Court conducts de novo review. When the issue on appeal is whether a state agency erred in interpreting a statutory term, an appellate court may freely substitute its judgment for that of the agency.
- 4 Fact-intensive issues, such as sufficiency of the evidence or allegations that a decision is arbitrary or capricious, are reviewed under the whole record test.
- 5 A court applying the whole record test may not substitute its judgment for the agency's as between two conflicting views, even though it could reasonably have reached a different result had it reviewed the matter de novo. Rather, a court must examine all the record evidence-that which detracts from the agency's findings and conclusions as well as that which tends to support them-to determine whether there is substantial evidence to justify the agency's decision.

Substantial evidence means relevant evidence a reasonable mind might accept as adequate to support a conclusion. However, the whole record test is not a tool of judicial intrusion; instead, it merely gives a reviewing court the capability to determine whether an administrative decision has a rational basis in the evidence.

In *Britthaven* and *Total Renal Care*, this Court applied a standard of deference first described by the United States Supreme Court in *Skidmore v. Swift & Company*, 323 U.S. 134, 65 S.Ct. 161, 89 L.Ed. 124 (1944), regarding agency interpretations of enabling statutes.

6 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.

In *Total Renal Care*, this Court added: If appropriate, some deference to the Agency's interpretation is warranted when we are operating under the traditional standards of review.

Good Hope Health Sys., L.L.C. v. N.C. Dep't of Health and Human Servs., 189 N.C.App. 534, 543-44, 659 S.E.2d 456, 462-63 (citations, *450 quotation marks, ellipses, brackets, and headings omitted), aff'd per curium, 362 N.C. 504, 666 S.E.2d 749 (2008).

III. Legal Standards

7 TRC first contends that "the final agency decision failed to apply the correct legal standards." (Original in all caps). TRC argues DHHS cited the wrong standard for reviewing a recommended decision, "mischaracterized the standard for finding harmless error[,]" and misstated "principles applicable to reviewing applicants for conformity with review criteria and determining whether an applicant may receive a certificate of need." In its first argument, TRC does not specify how any of the alleged general failures "to apply the correct legal standards" changed the outcome of the case in any way, and therefore we will not address this argument further. See Responsible Citizens v. City of Asheville, 308 N.C. 255, 271, 302 S.E. 2d 204, 214 (1983) ("The burden is on the appellant not only to show error, but to show prejudicial error, i.e., that a different result would have likely ensued had the error not occurred." (emphasis in original) (citations omitted)). However, we will address DHHS's application of standards of review in regard to each substantive issue argued by TRC.

IV. BMA Application

8 N.C. Gen.Stat. § 131E-183 sets forth the criteria for issuing a CON. See N.C. Gen.Stat. § 131E-183 (2007). N.C. Gen.Stat. § 131E-183(a) provides that "[t]he 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." N.C. Gen.Stat. § 131E-183(a). N.C. Gen.Stat. § 131E-183(a)(3) ("Criterion 3") provides that

[t]he 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.

N.C. Gen.Stat. § 131E-183(a)(3). Furthermore, "[a]n 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[,]" 10A N.C. Admin. Code 14C.2203(a) (2008); this rule is under the "Performance Standards [.]" "[T]here is no specific methodology that must be used in determining patient origin, under CON regulations, patient origin must be projected and all assumptions, including the specific methodology by which patient origin is projected, must be clearly stated." *Retirement Villages, Inc. v. N.C. Dept. of Human Res.*, 124 N.C.App. 495, 500, 477 S.E.2d 697, 700 (1996) (citation, quotation marks, and brackets omitted).

TRC argues that DHHS erroneously determined that BMA complied with Criterion 3 and the Performance Standards Rule because "[t]he record shows that the CON Section simply did not consider whether BMA's fundamental assumption-that all Brunswick County patients who had been going to a facility outside the county would choose to dialyze at its Supply facility-was reasonable." (Emphasis added.) TRC contends that

[t]he crux of this appeal involves the CON Section's failure to consider pertinent information contained in the BMA and TRC Applications, presented in written comments and at the public hearing, and gathered by the CON Section Project Analyst herself. That information was directly pertinent to the fundamental assumption in BMA's Application. The Final Agency Decision upholds the CON Section's erroneous determinations.

Thus, TRC asserts that letters in support of its application, information presented at the public hearing, and information regarding travel distances reveal the flaw in "BMA's fundamental assumption-that all Brunswick County patients who had been going to a facility outside the county would choose to *451 dialyze at its Supply facility[.]" TRC further contends that the CON Section departed from its

normal standards in reviewing TRC and BMA's competing applications, thus leading to DHHS's erroneous conclusion.

A. Letters

9 TRC claims that "there were 35 letters of support in the TRC Application but only six letters of support in the BMA Application." In the final agency decision DHHS found as fact that

TRC's application was accompanied by a significant number of letters of support. Patient letters of support are not as relevant in a county need review because the patients typically know only one of the providers.... It would thus not be appropriate for the CON Section to have given great weight to these letters in determining whether BMA's need methodology was reasonable.... If patient support was the only deciding factor, there would be no need for publication of county need in an SDR or review of CON applications.

TRC fails to cite any law suggesting that patient letters should be "given great weight" during the CON process. Furthermore, TRC concedes that there were also letters in support of BMA's application.

As long as both applications are reasonable and supported by substantial evidence, this Court will not overturn the decision of DHHS through the use of contrary evidence. See Craven Reg'l Med. Auth. v. N.C. Dep't of Health and Human Servs., 176 N.C.App. 46, 59, 625 S.E.2d 837, 845 (2006) ("There were reasons to support both applications and deference must be given to the agency's decision where it chooses between two reasonable alternatives. It would be improper for this Court to substitute its judgment for the Agency's decision where there is substantial evidence in the record to support its findings. This argument is without merit." (citation omitted)); see also Good Hope Health Sys., L.L.C., 189 N.C.App. at 544, 659 S.E.2d at 462 ("Substantial evidence means relevant evidence a reasonable mind might accept as adequate to support a conclusion." (citations and quotation marks omitted)). Thus, we cannot substitute our judgment for that of DHHS in its consideration of the letters submitted on behalf of TRC or BMA.

B. Public Hearing

TRC also argues that

[w]hile the CON Section held a public hearing as required, neither the Project Analyst nor the supervisor assigned to this review attended the hearing, listened to, or reviewed a transcript of, the oral comments presented at the hearing by patients and family members before the decision on the applications.

However, Ms. Tanya Rupp, the project analyst who reviewed the TRC and BMA applications, testified that after she reviewed the applications she "read through the public hearing materials." These materials included a sign-in sheet which indicated in whose favor each individual spoke and "written summaries of the comments made at the public hearing[.]" Thus, there was substantial evidence that Ms. Rupp was aware of the comments at the public hearing and that she considered the public hearing in her decision. *See Good Hope Health Sys., L.L.C.* at 544, 659 S.E.2d at 462. As long as the public hearing is in compliance with the applicable statutes and regulations, we cannot impose a requirement that the project analyst be personally present for the entire public hearing.

11 Furthermore, though the CON Section was required to conduct a public hearing, *see* N.C. Gen.Stat. § 131E-185(a1) (2) (2007), TRC has failed to direct our attention to any law regarding what specifically must be done with the information gathered at the public hearing. While a failure to consider information from the public hearing at all would render N.C. Gen.Stat. § 131E-185(a1)(2) meaningless, we also do not read the statute to require the stringent application that TRC advocates. The CON Section conducted the hearing in accordance with N.C. Gen.Stat. § 131E-185(a1)(2); the CON Section employees who attended noted individuals who attended the meeting and their comments; and the public comments were summarized and reviewed by the project analyst. We conclude the CON Section did *452 enough to comply with N.C. Gen.Stat. § 131E-185(a1)(2).

C. Travel Distances and Dialysis Patient Population Growth

12 TRC also argues that Ms. Rupp "gathered information on travel distances between the available and proposed dialysis facilities[,]" but failed to use this information properly, along with other information that "demonstrated an increase in the Leland dialysis patient population and a decrease in the Supply dialysis patient population." TRC contends that Ms. Rupp knew that

[t]he distance between the proposed site of the TRC-Leland Facility and the TRC-Wilmington Facility was 8.81 miles or 14 minutes of travel time....

The distance between Supply, where BMA proposed its facility and the Leland area was 23.65 miles or 33 minutes of travel time....

The distance between the existing TRC-Shallotte Facility and Supply was 7.86 miles or 11 minutes of travel time....

Defendant contends "[t]his data established that the TRC-Wilmington facility was much closer to northern Brunswick County than the site of the BMA Supply facility[,]" thus "for patients leaving northern Brunswick County to get treatment at TRC's Wilmington facility, that facility still would be closer[.]"

However, TRC itself is making a fundamental assumption, which is that patients will automatically choose the closest facility, no matter the county. TRC ignores other relevant information presented before the CON Section and DHHS regarding the heavy traffic in Wilmington, the lack of public transportation options across county lines, and the Wave county van system that provides transportation for qualified dialysis patients within Brunswick County. As DHHS had substantial evidence before it as to why a patient might choose dialysis in his or her own county rather than to travel to Wilmington in New Hanover County, we again will not find error based upon conflicting evidence. See Good Hope Health Sys., L.L.C. at 544, 659 S.E.2d at 462.

13 TRC also contends that "[t]he data showed that BMA had proposed a facility in a zip code with a shrinking population of dialysis patients who would need hemodialysis treatments, and that the Leland zip code, where TRC had proposed to locate its facility, was experiencing significant patient growth." However, TRC failed to challenge the findings of fact which state that BMA based its projected patient population on "the Five Year Annual Change Rate published within the July 2007" Semiannual Dialysis Report by DHHS. "The Five Year Annual Change Rate represents the average annual growth rate over a five (5) year period so as to capture the dynamics of the population and account for all upswings and downturns in the population." TRC, on the other hand, based its projected patient population "on the Brunswick County growth rate over a six (6) month period, the Shallotte facility growth rate over an eight (8) month period and over a five (5) year period, and the North Carolina growth rate for all patients in the state over a five (5) year period."

Based on this information, we conclude DHHS did not err in determining that it was reasonable for BMA to base its projected population growth on five years' worth of data, rather than relying upon six month's worth of data which allegedly indicated a decrease. *See id.*

D. Prior Practice

TRC also argues that

[t]he CON Section's approach in this review directly conflicts with its analysis of a similar situation [regarding Anson County. In the Anson County application,] the ... Project Analyst concluded that one applicant had overstated the number of patients who would transfer to its Anson County facility by relying on the unreasonable assumption that a number of patients who lived in Anson County but were choosing to dialyze at a facility in Union County would transfer to the proposed Anson County facility. On that basis, the Project Analyst concluded that the applicant failed to conform to Review Criterion 3 or to meet the Performance Standard Rule.... In the instant case, BMA likewise overstated its projected patient population, but *453 the Project Analyst failed to analyze and reject this overstatement, and this oversight was not addressed in the Final Agency Decision.

DHHS found that the Anson County case was "substantively and materially different" from this case. DHHS ultimately concluded that the Anson County case was "not determinative of the ultimate decision reached in this case." We agree from our review that the facts of the Anson County case are markedly different from the present one.

With regard to Anson County, BMA included in its patient population 14 patients who lived in Anson County but stated "they wanted to go to the [proposed] Marshville facility [in Union County]." The Marshville facility was eventually approved and BMA's Anson County facility was not, in part because BMA's patient origin methodology did not take into account the 14 patients who wanted to dialyze in the Marshville facility. The Anson County situation is entirely different from the situation here; TRC has not identified specific patients who want to use its facility which were also included in BMA's calculation of its projected patient population. DHHS's finding of fact that the two cases are distinguishable on this point is supported by the record.

E. Criterion 3 and Performance Standards Rule

As to Criterion 3 and the Performance Standards Rule, TRC only contests BMA's assumption that Brunswick County patients would want to receive dialysis in Brunswick County. TRC does not challenge any other portion of compliance with Criterion 3 or the Performance Standard Rule. Therefore, as we have concluded that DHHS could properly decide, based upon the substantial evidence before it, that it was reasonable for BMA to assume that Brunswick County patients would want to receive dialysis in Brunswick County, we also conclude that DHHS properly concluded that BMA's application was in compliance with Criterion 3 and the Performance Standards Rule, as the "fundamental assumption" was the only challenge TRC brought as to these two requirements. These arguments are overruled.

V. TRC Application

TRC argues that DHHS erred in finding its application nonconforming to Criterion 3, N.C. Gen.Stat. § 131E-183(a) (14), in findings of fact 116 and 141, and 10A N.C. Admin. Code 14C.2202(b)(2). We disagree.

A. Criterion 3

14 TRC directs our attention to DHHS's determination that TRC did not did not comply with Criterion 3.

Again, Criterion 3 provides,

[t]he 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.

N.C. Gen.Stat. § 131E-183(a)(3).

As to Criterion 3, DHHS concluded that TRC's application did not conform due to TRC's methodology in projecting patient population. In its application, TRC projected that 29 of its existing patients would transfer to the new facility due to proximity to their homes and because they could continue seeing their current doctors. However, TRC projected it

would open its facility with 31 patients. TRC did not explain where the two other patients came from, as it had specifically identified only 29. Furthermore, in predicting its annual growth rate, TRC began its calculations from January 1, 2007. However, TRC did not submit its application until September of 2007 and did not project opening the facility until 2009. Therefore, we agree with DHHS's determination that TRC's methodology did not conform with Criterion 3 as TRC's population projections were "unreasonable and unsupported by the evidence."

B. Criterion 14

TRC next contends that DHHS erred in determining it did not comply with N.C. Gen.Stat. § 131E-183(a) (14) ("Criterion *454 14") which provides that "[t]he applicant shall demonstrate that the proposed health services accommodate the clinical needs of health professional training programs in the area, as applicable." N.C. Gen.Stat. § 131E-183(a)(14). TRC argues that the CON Section and DHHS should have taken note of a letter it submitted regarding "the President of Brunswick Community College indicating the College's appreciation of its long-standing relationship with TRC and the use of the Shallotte facility as training site for its nursing students." Assuming arguendo, as TRC argues, that the CON Section should have even considered this letter which was part of an entirely separate application not at issue, the letter still in no way establishes TRC conformed with Criterion 14. While TRC may have allowed Brunswick Community College use of its Shallotte facility, it cites to no evidence which showed it would allow the Brunswick Community College to use its Leland facility. As this is the only evidence TRC directs us to that it conformed with Criterion 14, DHHS properly concluded that TRC did not conform.

C. Findings of Fact 116 and 141

TRC next directs our attention to findings of fact 116 and 141 which provide:

116. The TRC application was nonconforming to Criterion 3.

141. ... If TRC's application had been found comparatively superior to BMA's application, the CON Section would have conditionally approved TRC's application and disapproved BMA's application.

TRC argues that these two findings are inconsistent. However, we find this argument meritless as finding of fact 141 is clearly conditioned by the word "[i]f." Certainly, if

TRC's application were found to be comparatively superior to BMA's application, it would have been appropriate for it to have been conditionally approved. However, TRC's application was not found to be comparatively superior; BMA's was. This argument is meritless.

D. Transplantation Standard Rule

16 TRC also argues that the CON Section erred in determining TRC had not complied with 10A N.C. Admin. Code 14C.2202(b)(2) ("Transplantation Standard Rule"), while concluding BMA had conformed. The Transplantation Standard Rule requires that

a letter of intent to sign a written agreement or a written agreement with a transplantation center describing the relationship with the dialysis facility and the specific services that the transplantation center will provide to patients of the dialysis facility.

10A N.C. Admin. Code 14C.2202(b)(2) (2008). While TRC alleges DHHS erred in concluding BMA had conformed with the Transplantation Standard Rule, the final agency decision provides a list of TRC's issues, which does not include this contention. Furthermore, TRC did not challenge this list by claiming it had further issues. Therefore, we will not review this issue regarding BMA. However, TRC has assigned error to the finding that it did not comply with the Transplantation Standard Rule, and we will review this contention.

TRC directs our attention to "a letter from Duke University Medical Center and an unsigned agreement between TRC-Leland and Carolinas Medical Center pertaining to provisions of transplant services." The letter from Duke University Medical Center was from Stephen R. Smith, M.D., an Associate Professor of Medicine in the Division of Nephrology at Duke University Medical Center. The letter stated that "Dr. McCabe and [sic] will continue to provide transplant services to the new unit DaVita Leland." Furthermore, although the record contains a document noted as a "Transplant Agreement[,]" the only signature on this agreement is on behalf of Davita Dialysis of Leland and the signature space on behalf of Carolinas Medical Center is blank. These two documents are neither "a letter of intent to sign a written agreement or a written agreement with a transplantation center[.]" While Dr. Smith indicated he and a colleague will provide services at TRC's new facility, he in no way indicated that Duke University's transplantation center will be doing the same. Furthermore, while TRC does have a written document purporting to be an agreement with

Carolinas Medical Center, this document is not an agreement until actually signed by an authorized representative of *455 Carolinas Medical Center. We therefore conclude that DHHS did not err in concluding TRC did not conform with the Transplantation Standard Rule.

VI. Comparative Review

Lastly, TRC contends DHHS should not have engaged in a comparative review of the applications, and even if it did, it should have found TRC's to be the superior application. TRC's contention that there should not have been a comparative review is based upon the argument that BMA did not conform to Criterion 3. However, we have already concluded that DHHS did not err in concluding BMA conformed to Criterion 3, and therefore this argument is meritless. TRC also points to various other errors in

DHHS's consideration, but we have already concluded that DHHS did not err as to its determinations regarding TRC's previous contentions of BMA's application and that TRC failed to comply with Criterion 3 and 14 and the Transplantation Standard Rule; these findings alone establish that TRC's application could not have been superior to BMA's application. This argument is also meritless.

VII. Conclusion

We conclude that DHHS properly allowed BMA's application and disapproved TRC's application. We affirm.

AFFIRMED.

Judges BRYANT and ELMORE concur.

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