



January 2, 2018

Ms. Martha Frisone, Chief
Ms. Celia Inman, Project Analyst
Healthcare Planning and Certificate of Need Section
Division of Health Service Regulation
809 Ruggles Drive
Raleigh, North Carolina 27603



Re: Public Written Comments,
CON Project ID # G-11439-17, Guilford County Dialysis

Dear Ms. Frisone:

Bio-Medical Applications of North Carolina, Inc. offers the following comments on the above referenced Certificate of Need application filed by Total Renal Care of North Carolina, LLC.

Total Renal Care of North Carolina (TRC) has filed an application to relocate a total of 10 dialysis stations from two existing dialysis facilities to develop a new 10-station dialysis facility in Guilford County. The applicant has filed an application which must be denied for myriad reasons.

- The application by TRC quite simply can not be approved. TRC's application fails to comply with ESRD-2.

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.

BMA has filed CON applications seeking to add four stations at Northwest Greensboro Kidney Center (CON Project ID # G-11398-17), and seeking to add four stations at FMC East Greensboro (CON Project ID # G-11395-17). Both of these applications were filed on September 15, 2017, and were included in the CON review commencing October 1, 2017. Approval of either of these applications will reduce the Guilford County deficit below 10 stations. Thus, approval of either of the BMA applications necessarily means the DaVita application must be disapproved because the deficit of stations will be less than 10 stations. BMA was informed of the approval of both applications on December 18, 2017. Consequently, the 10 station deficit does not exist.

The approval of BMA applications for the Northwest Greensboro facility and the FMC East Greensboro facility have reduced the Guilford County deficit by a total of eight stations. Approval of the TRC application would result in a station surplus in Guilford County. Pursuant to Policy ESRD-2, the application can not be approved.

Moreover, the January 2018 SDR indicates that the Guilford County dialysis station deficit is only one station.

- The letters of support are recycled from an earlier application.

In large measure, this application is a simply a re-play of the application filed by TRC in September, 2017 (CON Project ID # G-11412-17). The overwhelming majority of the patient letters are the exact same letters as used in the September application. The physician support letters are the exact same letters as used in the September application. The letter from the Medical Director is the exact same letter. To say that these are the same letters is not to say that the applicant updated the information and asked the same persons to sign again. Far from being updated, these letters are indeed the exact letters which were included in the September application. The letters have the same dates. The letters which were faxed to the applicant bear the exact same date/time stamps. The signatures appear to be the same.

To the extent that these letters are the same, then there is nothing in the letters to suggest that the signers of the letter have any real knowledge of the proposed project. Those who signed letters were offering support for a project in September, not November. Those who signed letters of support were offering support for a project which involved relocation of 10 stations from Rockingham County, not a combined package of stations from Rockingham and Alamance Counties.

The Agency has traditionally relied upon letters of support to provide an indication that the signer understood what the project involved. In this case, there is no evidence that

the signers of the letters have any knowledge of the change in scope of this proposed project, as opposed to the application which was filed in September.

- ❖ Changes include a change in source of dialysis stations to be relocated.
- ❖ Changes include the absence of the home hemodialysis training and support program in the proposed facility.

BMA does acknowledge that there are five letters from in-center dialysis patients, and one letter from a PD patient, all of which were signed in November 2017. BMA suggests that the balance of the letters of support should not be accepted as evidence of support. These are merely recycled letters from an application which was withdrawn.

TRC's Application Should be Denied for Other Failures and Inconsistencies:

1. The applicant offers a lengthy explanation of the reasoning behind relocating 10 stations from its facilities in Rockingham and Alamance Counties. This appears inconsistent with recent representations made by DaVita. Specifically, TRC states that it is proposing to serve *"patients who signed letters indicating an interest in possibly transferring their care to the proposed Guilford County dialysis..."* while those same patients *"receive their dialysis services at DaVita owned facilities in Alamance County."*¹ However, DaVita recently filed public written comments opposing a CON application in Johnston County, wherein Mr. Hyland suggest that *"the patients are being served at other nearby [sic] BMA locations..."*²

The inconsistent approach by DaVita must cause the CON Project Analyst to question the validity of the CON application in this case.

2. The applicant has included patient letters of support from patients who have signed letters of support for other, recent CON applications by DaVita. Any support letters from patients who also supported other DaVita projects in Alamance County should be discounted, since the approval of those applications will presumably result in those patients transferring to another facility in Alamance County, and not to a facility in Greensboro. A copy of the duplicate letters is at Attachment 1.
3. The application fails to conform to Review Criterion 3 and should be denied. Specifically, TRC has not adequately identified the need that the projected patient population has for the services at the proposed location.

The applicant proposes to relocate 10 dialysis stations from its facilities in Rockingham County and Alamance County to Greensboro. However, the applicant has proposed that less than half of its projected patient population would be residents of Guilford County. Despite providing 38 in-center patient letters of support, the applicant has not provided any description of the *"need that that the population to be served has for the proposed project..."*

¹ The TRC Application, response to Section A, Question 6, page 3.

² Public Written Comments filed by Mr. Hyland re: CON Project ID # J-11372-17, FKC Selma.

The applicant has not explained why patients residing in Alamance, Rockingham or Stokes Counties might need to have dialysis care and treatment at a facility in Greensboro. The location of the proposed facility is not proximate to the patients proposed to be served. In fact, most of the patients reside closer to another DaVita dialysis facility. It is not reasonable to suggest that a facility in Greensboro will truly be a shorter commute for dialysis, as is suggested by the patient letters of support.

Review Criterion 3 requires the applicant to identify the population to be served and to demonstrate the need that this population has for the services proposed. The applicant identified 38 in-center patients by letter of support. These are patients currently dialyzing at DaVita owned facilities. While BMA certainly doesn't agree with the identification of the projected population to be served, it is also important to note that the applicant has not provided any information about why these patients need to transfer to another facility in Greensboro, which in most cases is going to be a further travel distance than their current dialysis facility.

The location is, for practical discussion purposes, at the center of Greensboro and Guilford County. The following map identifies the primary location of the proposed facility.



The patient support letters do not state the patient's county of residence. However, the letter does state the patient's zip code and the applicant has included a table on page 16 of the application identifying the patient residence zip code. Of the 38 letters provided, only 15 of the patients actually reside within Guilford County. Thus, 23 of the patients, or 60.53% reside in counties other than Guilford.

The map depicts the location of the facility. The following table identifies the direct mileage from the facility to the nearest county boundary. This is straight-line distance and is not based on roadways. Travel by roadway would actually be further distance.

Distance to County Line	
Randolph County	8.4 miles south
Alamance County	14.4 miles east
Rockingham County	14.9 miles north

Based on the information provided by the applicant the following zip codes are within, or primarily within, the identified county:

County and Zip Code		# of Patient Letters of Support
Alamance County	27244	13
Alamance County	27349	5
Randolph County	27298	3
Stokes County	27046	2
Total		23

BMA has mapped the proposed facility, and existing DaVita facilities in Rockingham County and Alamance County. BMA has also mapped the zip code boundaries for each of the zip codes which are primarily located outside of Guilford County. The maps are included at Attachment 2 to these comments. The following table is developed based on these maps. The maps will demonstrate that 28 of the patients identified by letters of support actually reside closer to another DaVita dialysis facility. BMA obviously does not know the address of the patients signing letters of support. However, the applicant did include the patient's residence zip code.

Zip Code	Number of Projected Patients	Mileage Distance to proposed project	Closest DaVita Facility	Mileage Distance to Closest DaVita Facility
27046	2	32.0	DC Rockingham County	15.7
27349	5	16.6	DaVita Burlington	6.1
27298	3	12.5	DaVita Burlington	5.7
27244	13	14.9	DaVita Burlington	2.3
			DaVita Reidsville	10
27357	1	14.65	DaVita Reidsville	14.38

The applicant suggests on page 15 that “it is reasonable to assume that at least thirty-two (32) of the eight (38) in-center patients” would transfer their care to the new facility.

One must question why is this reasonable? Why would any patient actually travel further for dialysis than they currently do? Regardless of those patients’ willingness to sign support letters, these patients clearly do not *need* an additional dialysis facility further from their home than their current facility. Therefore the applicant does not demonstrate that its identified patient population needs the proposed facility.

Consider this change in travel distance and the patient letter of support. The patient letter says, *“I expect my travel time to this new facility to be shorter.”* Exactly how does DaVita propose to lengthen the commute and shorten the travel time?

BMA does not disagree that the 15 patients, who reside in Guilford County, might actually live closer to the proposed site of Guilford County Dialysis. However, the SMFP requires an application to demonstrate a need for 10 dialysis stations, based on a utilization rate of 80%. Utilization by 15 patients on 10 dialysis stations is only 37.5%, or 1.5 patient per station. The applicant has provided no explanation why another 17 patients need to travel further for their dialysis care than they do now.

It is not reasonable to expect patients to travel further for dialysis. Those patients who live in the area of Elon, within Alamance County are obviously closer to the DaVita Burlington facility, or the new, recently approved DaVita Glen Raven Dialysis (CON Project ID # G-11212-16, originally filed as Elon Dialysis).

In the Denial for CON Project ID # F-8073-08 (Attachment 3), a proposal by BMA to develop a 10 station facility at Huntersville, the Analyst noted on page 13 of the findings, *“[I]t is likewise not clear from the information presented by the applicant how it anticipates that 40 of its current patients will travel from existing BMA facilities to the proposed Huntersville location, when only 12 patients who reside*

*in the four Northern Mecklenburg County ZIP Codes ... **will actually see a reduction in travel.*** [Emphasis added].

The same must be true here. Of the patient letters of support provided by the Applicant, 23 patients reside in zip codes outside of Guilford County. It is not clear from the information presented how the applicant anticipates that at least 32 of its 38 current patients will transfer their care to the proposed new facility when only 15 of those 38 patients reside within Guilford County and possibly closer to the new facility location.

4. The applicant has proposed an unreasonable growth rate for its Peritoneal Dialysis patient population. The applicant suggests that number of PD patients will increase by 25% in the first year of operations, and by 20% in the second year of operations of the facility. However, the applicant has not provided any basis for growth rates of this nature.

The applicant suggested the home PD patients would transfer their care from the Burlington Dialysis facility.

- One of the patients resides in Alamance County. The Alamance County ESRD patient population is increasing at a rate of only 4.1%.
- One of the patients resides in Randolph County. The Randolph County ESRD patient population is increasing at a rate of only 1.2%.
- The applicant also proposes that two PD patient residing in Guilford County would transfer their care to the new facility. The Guilford County ESRD patient population is growing at a rate of only 4.7%.

The assertions of the applicant that the home PD patient population would increase by 25%, or 20% is simply inconsistent with the realities of the patient population of the three counties where the applicant's home PD patients currently reside.

As an additional consideration, consider the Required State Agency Findings for CON Project ID # P-8641-11 (Attachment 4), an application by Total Renal Care off North Carolina, LLC to add three stations to their Wallace Dialysis Center in Duplin County. On page 8 of the findings, the Project Analyst notes that the applicant "*provides no assumptions, methodology or projected utilization for home dialysis patients.*" The Agency expects the applicant to explain the basis for its projections of patients to be served. In this case, the applicant has failed to provide a basis for its projected patient population to be served, and the application should be denied.

5. The applicant has understated the effects of the proposed relocation of stations with regard to Criterion 3a, and should be found non-conforming.

Within the discussion about the Reidsville Dialysis facility, the applicant indicates that *“Reidsville Dialysis has grown by five in-center patients over the past three years.”* The applicant’s proposed facility is projected to be certified as of June 30, 2019, a period of 21 months from the beginning of the review period.

If the applicant patient census increased by five patients in 36 months, isn’t it then reasonable to conclude that the patient population would increase at a proportionate rate over the next 21 months?

The applicant bases this assertion on the July 2017 SDR and reported growth rate for Rockingham County. However, in addition to residents of Rockingham County, the facility has served patients from Alamance, Caswell, and Guilford Counties as well as patients from Virginia.

Consider the Rockingham County Five Year Average Annual Change Rate for the past several years.

- The July 2017 SDR reports the Rockingham County Five Year Average Change Annual Change Rate as -.002, or a negative 2/10 of one percent.
- The July 2016 SDR reports the Rockingham County Five Year Average Change Annual Change Rate as .010, or one percent.
- The July 2015 SDR reports the Rockingham County Five Year Average Change Annual Change Rate as -.008, or a negative 8/10 of one percent.
- The July 2014 SDR reports the Rockingham County Five Year Average Change Annual Change Rate as .015, or 1.5 percent.

While these are low growth rates, by the applicant’s own record, the census of the facility increased by five patients throughout the period of these low growth rates.

The next table includes information from the SDR beginning with the July 2014 SDR, through the current SDR:

DaVita Utilization		Reidsville Dialysis 34-2640	
SDR	Census Date	Cert Stations	# of Pts
July 2014	12/31/2013	19	67
January 2015	6/30/2014	27	69
July 2015	12/31/2014	27	67
January 2016	6/30/2015	27	69
July 2016	12/31/2015	27	72
January 2017	6/30/2016	27	73
July 2017	12/31/2016	27	72

6. Within its discussion of Criterion 4, on page 29, the applicant incorrectly states that Fresenius Medical Care is the sole dialysis provider in the greater Greensboro area. The State Medical Facilities Plan, in Chapter 14, defines the dialysis station service area as *"the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the remaining 94 counties is a separate dialysis station planning area."* Thus, the High Point Kidney Center and Triad Dialysis Center also serve Greensboro.
7. The applicant's statement on page 29 that the new facility will provide better geographic access is totally without merit. As discussed within these comments the applicant has not provided any evidence that the proposed facility would enhance geographic access for the patients identified by way of patient letters of support.
8. On page 47 of the application the applicant indicates that the floor plan included in Exhibit K-1(a) may not be correct. How is the CON Project Analyst to determine if the floor plan is adequate for development as a dialysis facility? How can the CON Project Analyst determine if sufficient square footage has been provided for the dialysis treatment area? It isn't possible. The applicant should be found non-conforming to CON Review Criterion 12.

Assuming that the information provided in response to Question 2 of Section K, page 48, BMA suggests that the applicant is over developing space for a 10 station dialysis facility. The applicant proposes to have 4,112 square feet available for the 10 stations. The Facility Guidelines Institute, FGI, 2010 edition of Guidelines for Design and Construction of Health Care Facilities has established that dialysis facilities *"shall contain at least 80 square feet."*³

The plan provided by the applicant includes approximately 457 square feet per station. This assumes one station is set aside for isolation/separation; thus the in-center treatment floor would have a total of nine dialysis stations in 4,112 square feet.

Furthermore, the applicant proposes to develop 685 square feet for home training. This is 685 square feet dedicated to serving only six PD patients (of course this does not diminish BMA assertions that the applicant has not provided sufficient information to justify its home patient projections). Thus, the applicant proposes to develop this 685 square feet of home training space for only six patients to be served.

Taken as separate pieces, or as a whole, BMA suggests that the applicant is proposing to develop a space much larger than is necessary for the proposed dialysis facility. This excessive space leads to excessive costs of construction.

³ FGI, 2010 edition, Guidelines for Design and Construction of Health Care Facilities, paragraph 3.10-3.2.2 Space Requirements, page 283. See Attachment 4.

CON Review Criterion 12 requires the applicant to “demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative...” Developing space equivalent to more than 500% of the minimum space is not a reasonable alternative.

BMA suggests the applicant is unreasonably increasing the cost of the project by over developing treatment space. The application should be found non-conforming to CON Review Criterion 12 and denied

9. The applicant has failed to appropriately identify the projected payor mix for its proposed facility. The applicant states that it has relied upon the information from DaVita operated facilities in Alamance county during the last full operating year, and that because Alamance and Guilford Counties are contiguous it was reasonable to rely upon that information as it developed a projected payor mix.

The applicant clearly failed to consider the difference in the populations of the two counties. Publicly available information from the US Census Bureau points out the difference between the two counties.

The CON Agency has relied upon the US Census Bureau Data in multiple CON reviews, including the 2010 Randolph County⁴ competitive review and the 2011 Northampton County⁵ competitive review. In both cases the Project Analyst considered elements such as minority populations and poverty levels. The following table offers clear contrasts between Alamance and Guilford Counties.

	Guilford	Alamance
Persons 65 and over	14.40%	16.70%
African American	34.60%	20.00%
Persons in Poverty	15.70%	18.90%

Source: US Census Bureau Quick Facts⁶

The table indicates that Alamance County has a slightly older patient population with 16% more persons over the age of 65. In addition, Alamance County has a higher percentage of persons living in poverty, as opposed to Guilford County. Guilford County also has a far higher percentage of African American persons. According to the CON Project Analyst in the 2010 Randolph County review, “[I]t is widely held that race impacts the incidence of kidney disease.” Based on the differences between Guilford County and Alamance County, BMA believes, just as in the 2010 Randolph review, that it is not reasonable to assume that these two counties, although contiguous, are comparable in economic, or payor source status. Therefore, the applicant did not demonstrate that the projected payor mix is based upon reasonable and supported assumptions. Further, the applicant has

⁴ Attachment 6, page 34

⁵ Attachment 7, page 34

⁶ Attachment 8

not demonstrated that the facility will provide adequate access to medically underserved populations. The application should be found non-conforming to CON Review Criterion 13.

The applicant has provided an application which can not be approved. Therefore the application must be denied.

If you have any questions please contact me at 910-568-3041, or email jim.swann@fmc-na.com.

Sincerely,

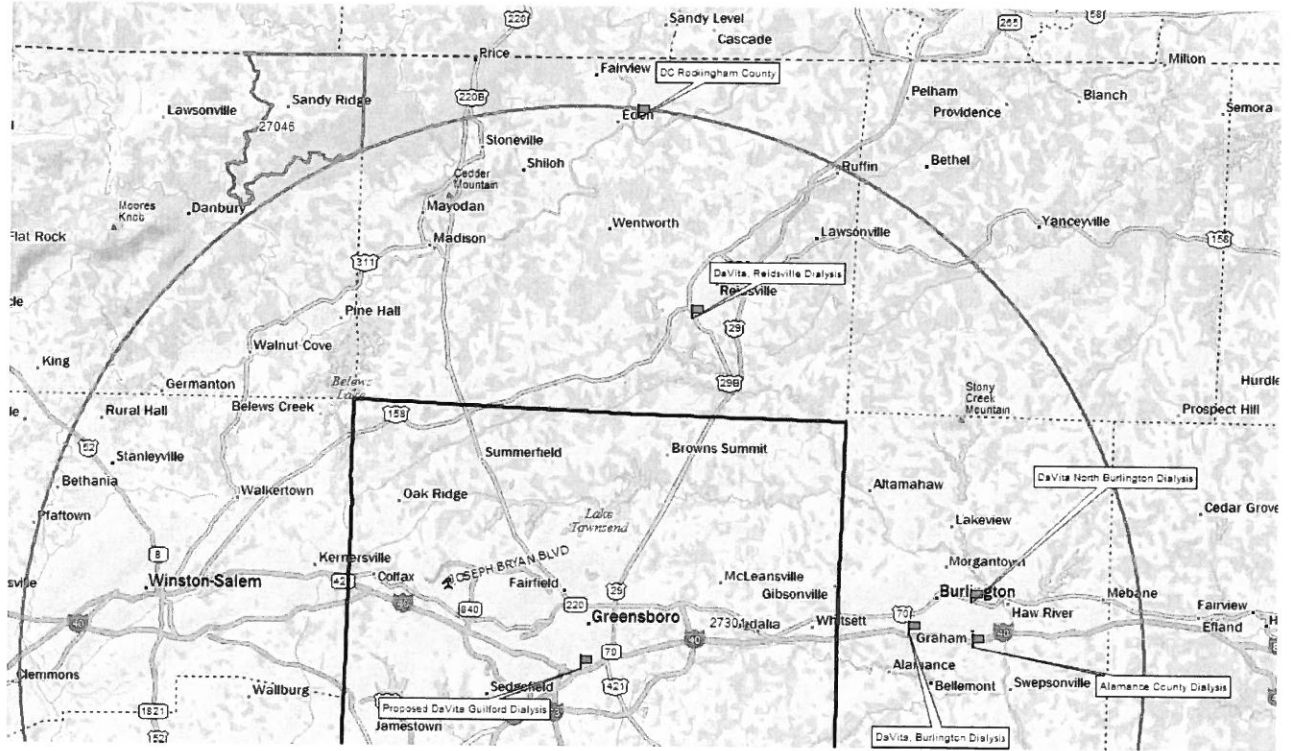
Jim Swann via email

Jim Swann
Director of Operations, Certificate of Need

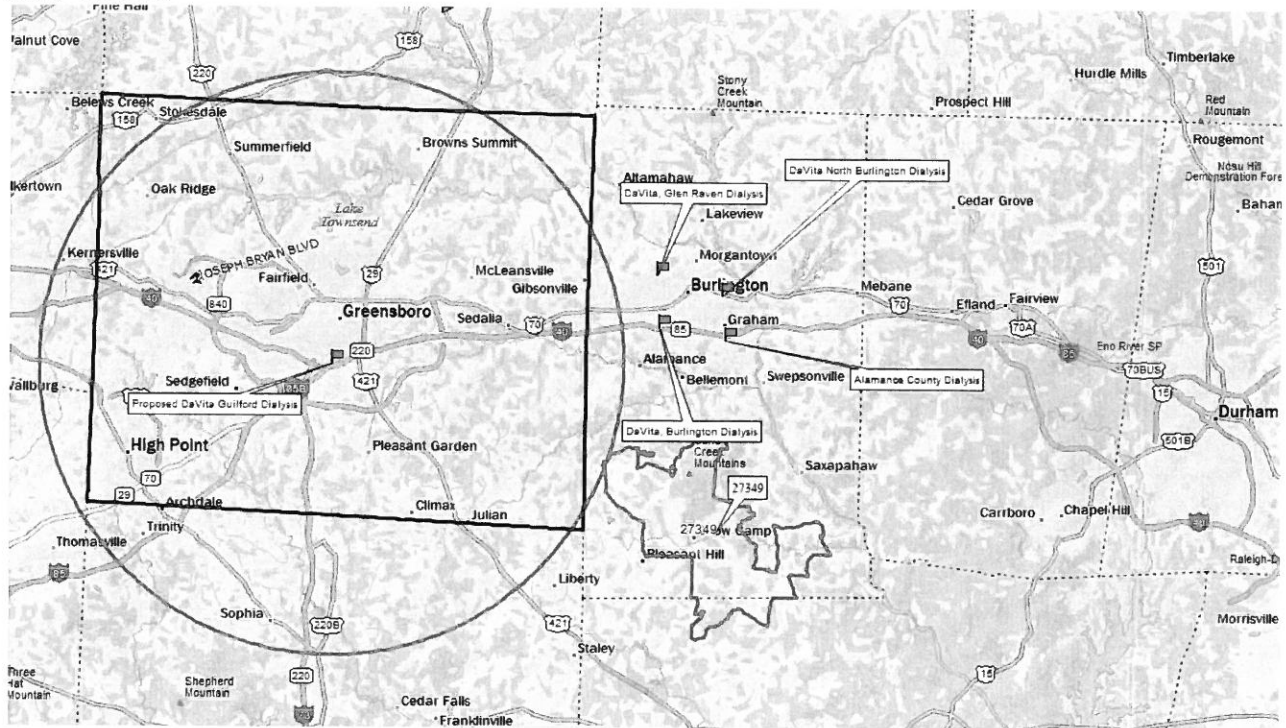
8 Attachments:

- 1) Duplicated patient letters
- 2) Zip Code maps
- 3) RSAF, CON Project ID # F-8073-08, FMC Huntersville
- 4) RSAF, CON Project ID # P-8641-11, TRC Wallace Dialysis Center
- 5) FGI, Guidelines For Design and Construction of Health Care Facilities, extract
- 6) RSAF, CON Project ID # G-8594-10, BMA Asheboro, page 34
- 7) RSAF, CON Project ID # L-8753-11, FMC East Northampton County, page 34
- 8) US Census Bureau Quick Facts, Guilford County, Alamance County

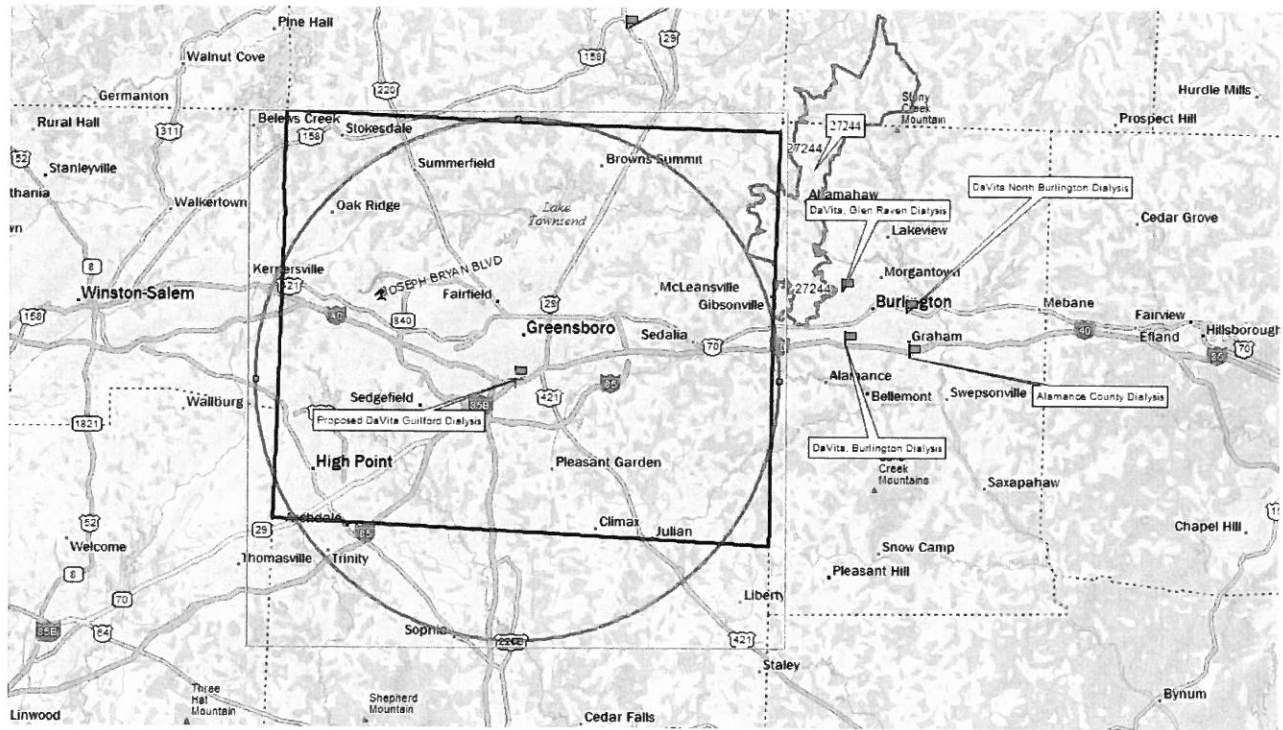
27046 – 32 miles



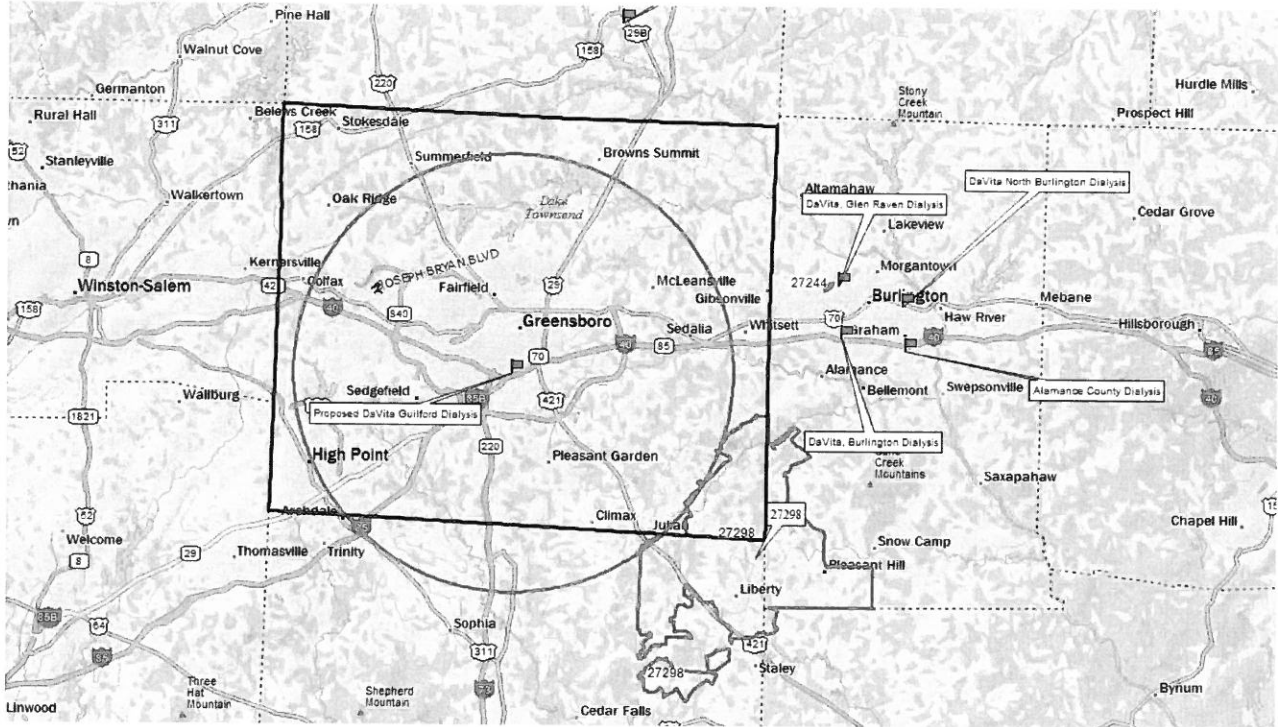
27349 – 16.6 miles



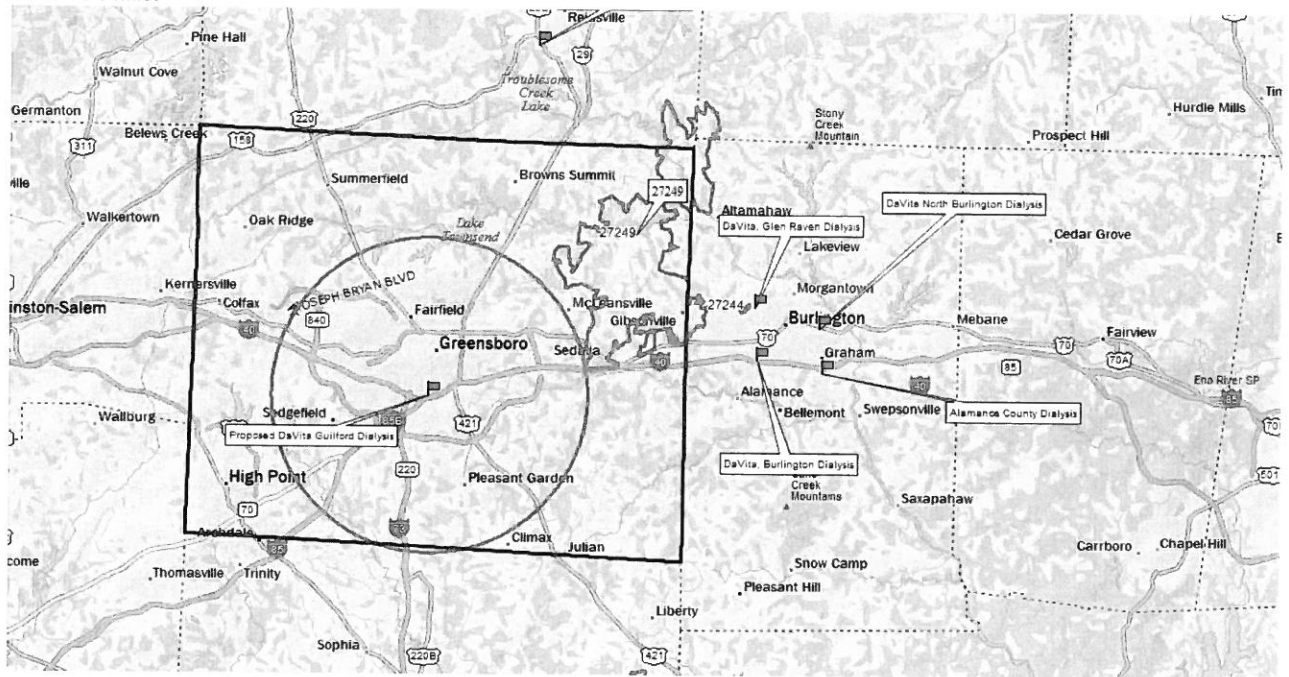
27244 - 14.9 miles



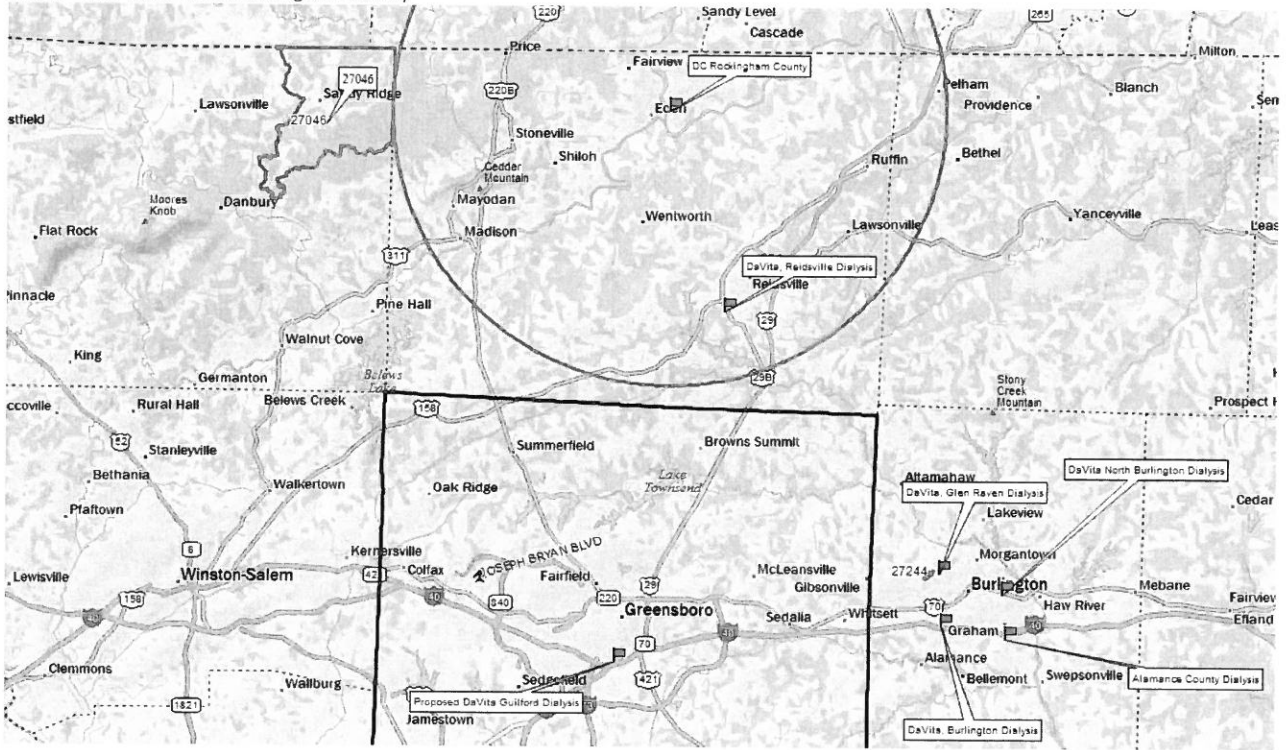
27298 – 12.5 miles



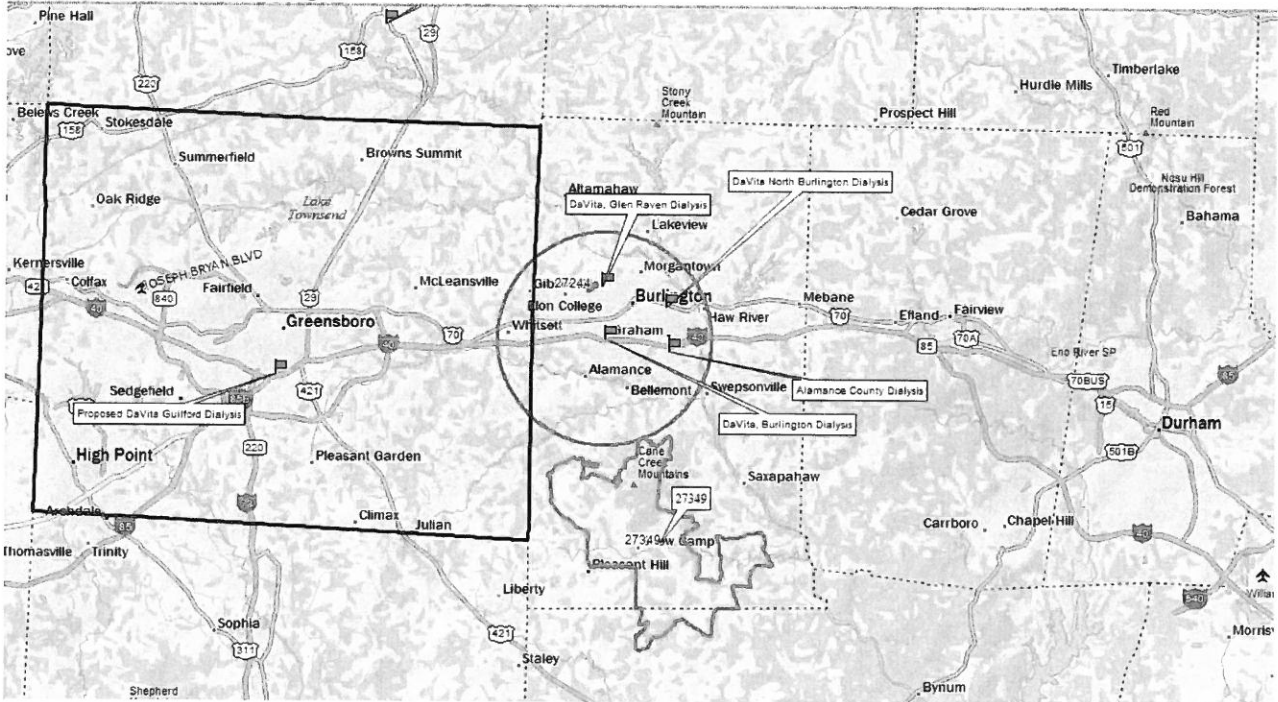
27249 – 9.0 miles



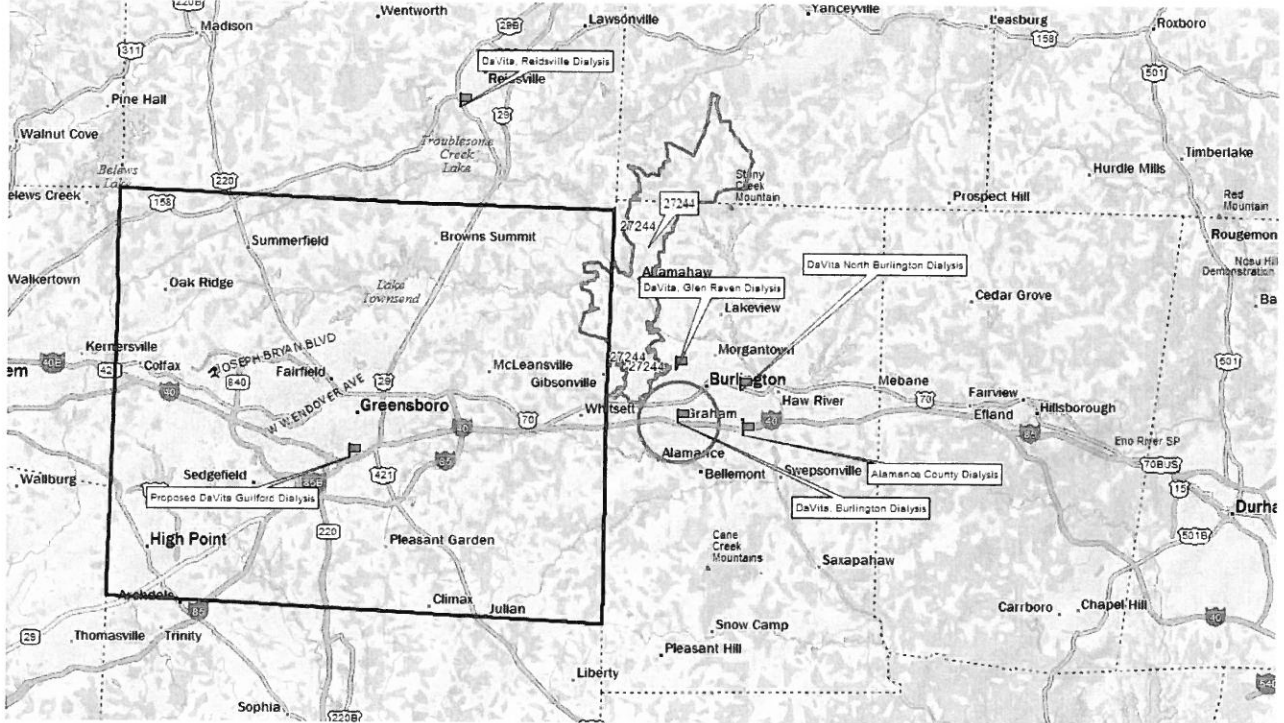
27046 – 15.7 miles to DC Rockingham County



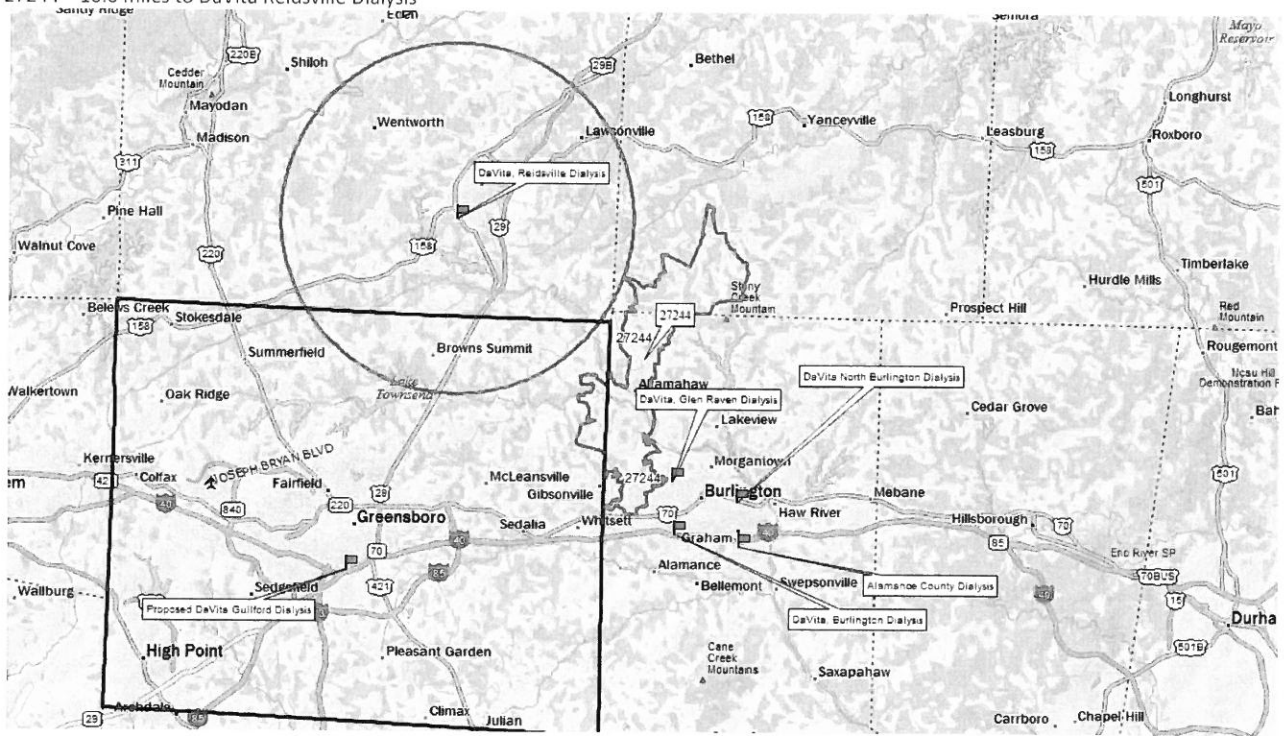
27349 – 6.1 miles to DaVita Burlington



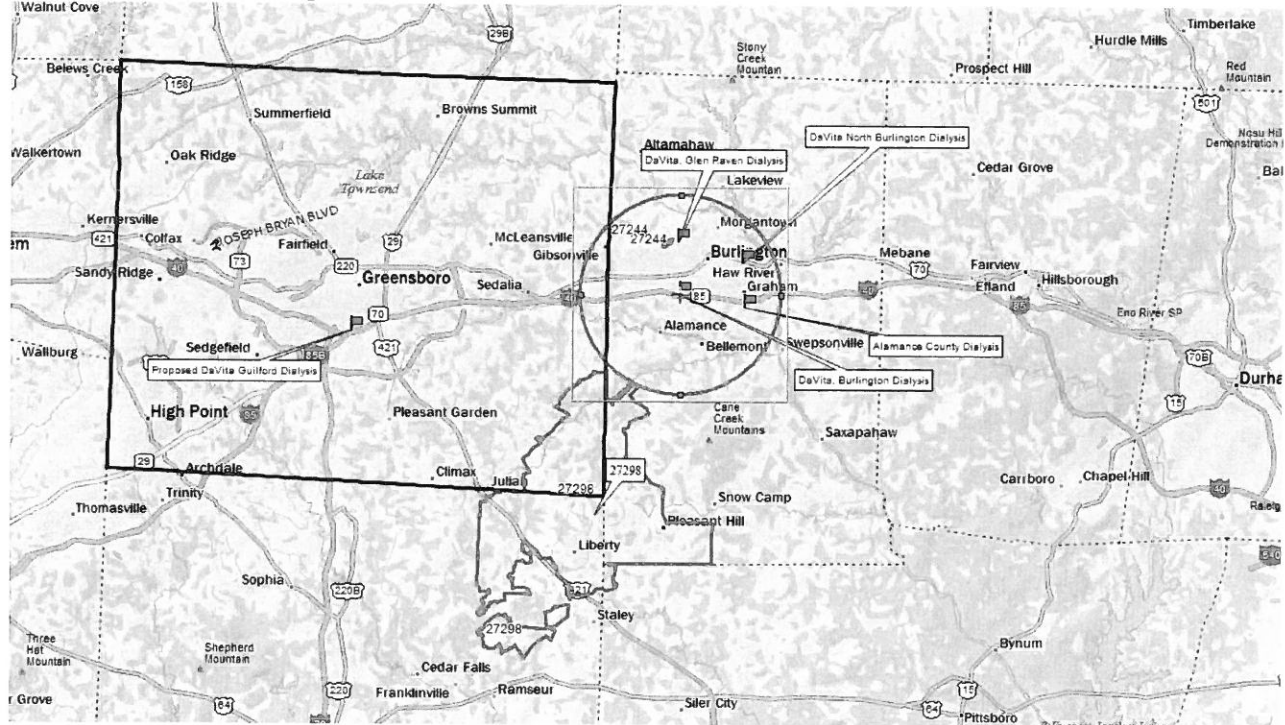
27244 – 2.3 miles to DaVita Burlington



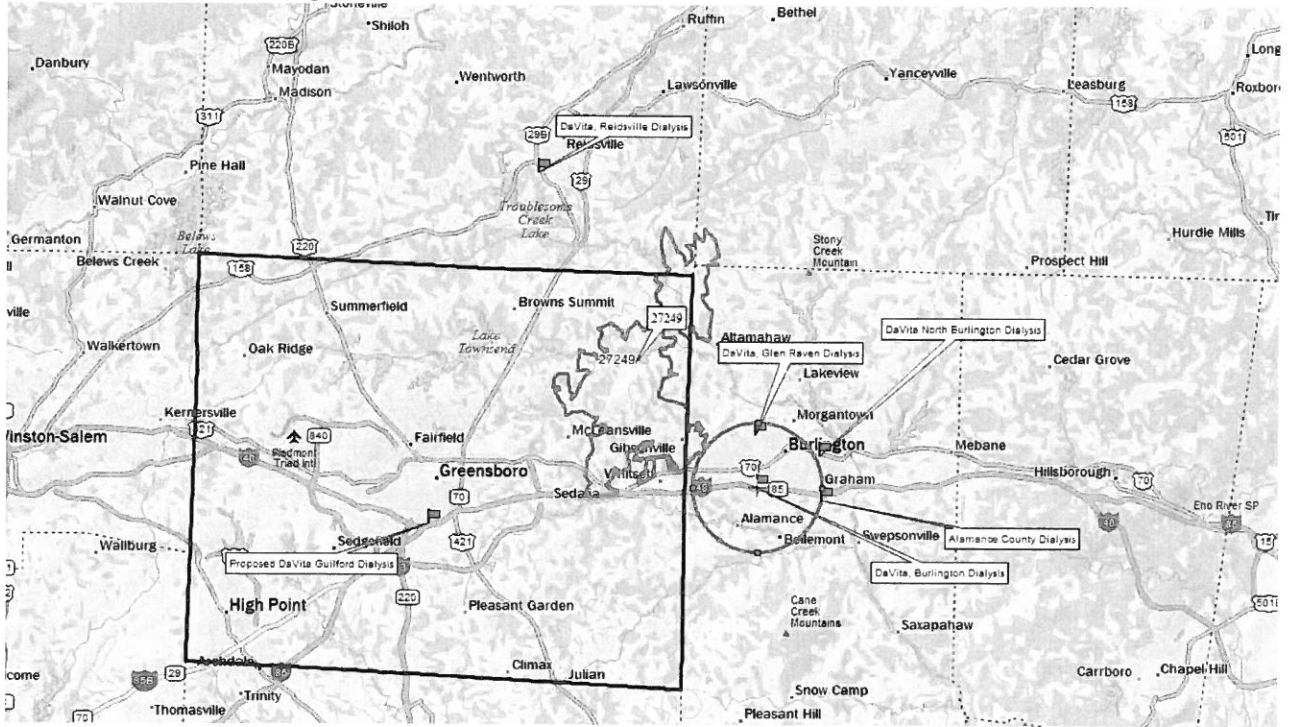
27244 – 10.0 miles to DaVita Reidsville Dialysis



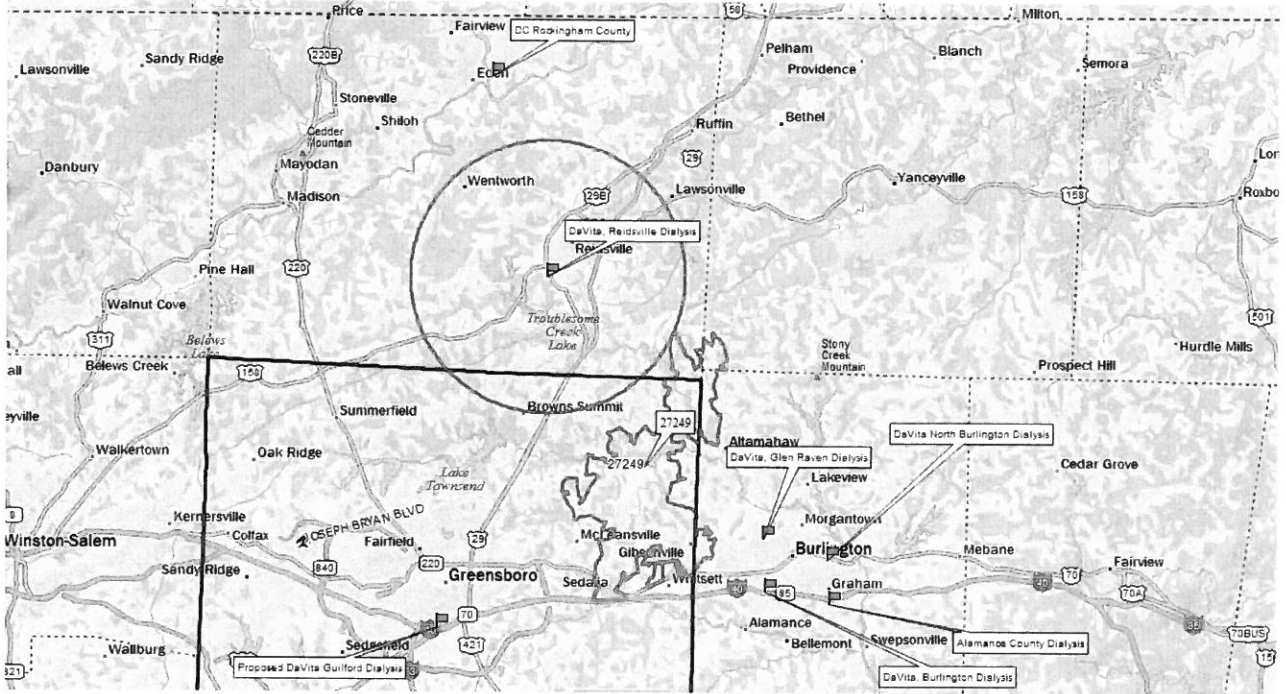
27298 – 5.7 miles to DaVita Burlington



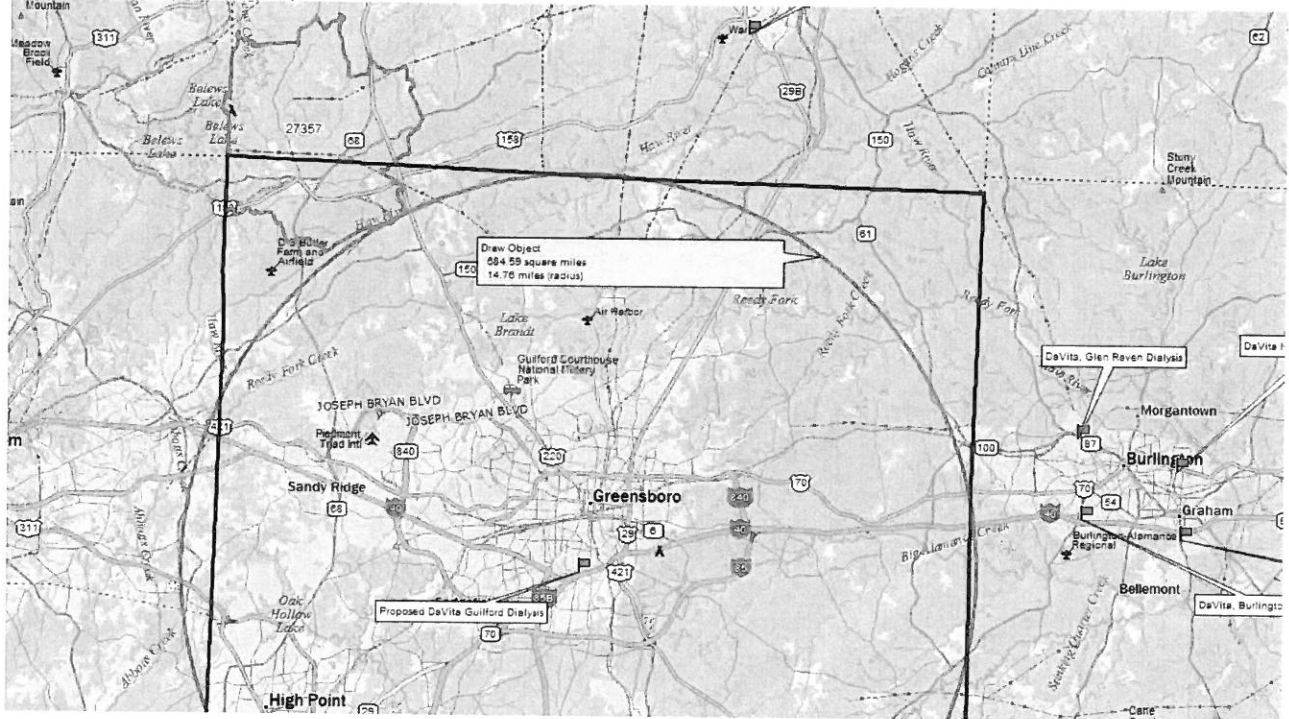
27249 – 3.7 miles to DaVita Burlington



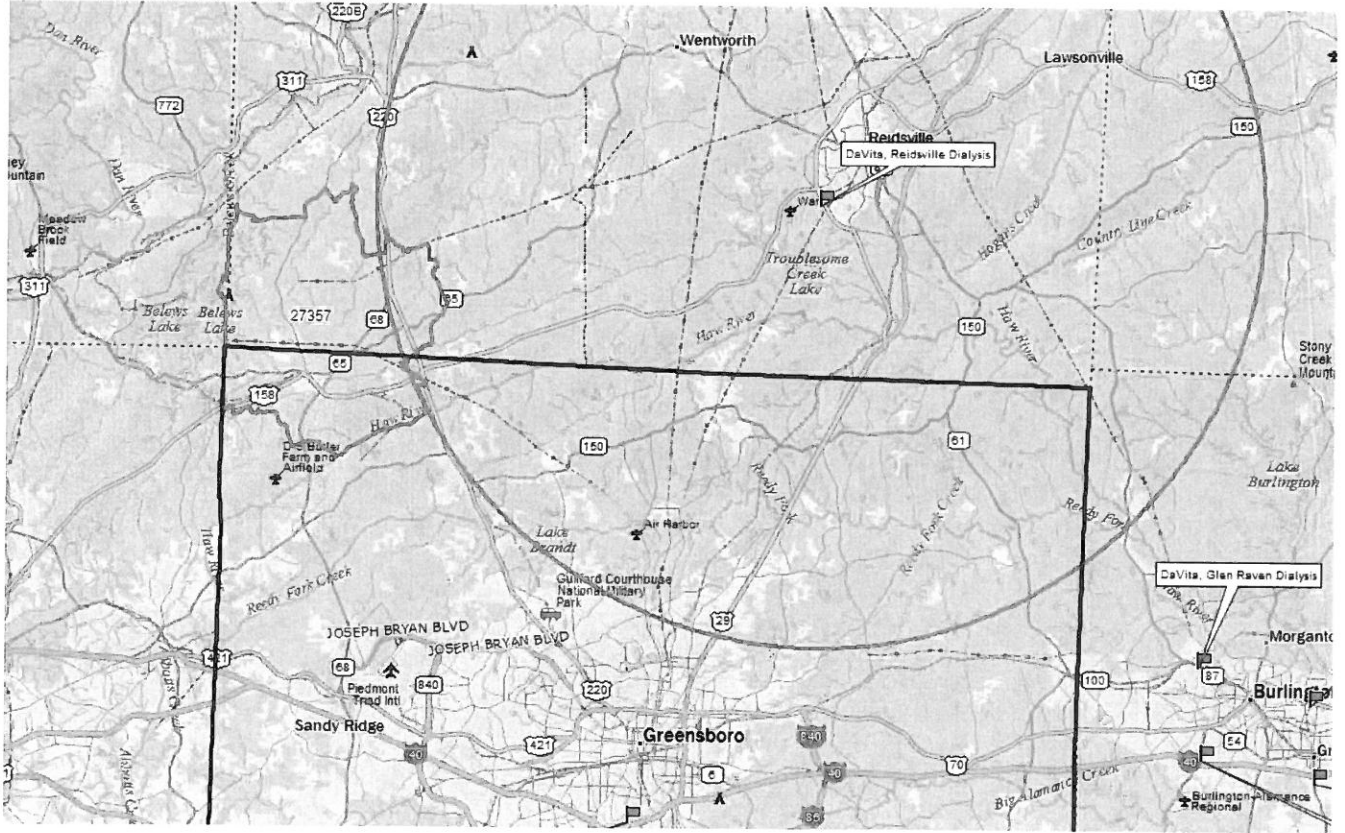
27249 – 7.8 miles to DaVita Reidsville Dialysis



27357 – 14.76 miles to propose location



27357 - 14.38 miles to DaVita Reidsville



Attachment 3

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: August 28, 2008
FINDINGS DATE: September 5, 2008

PROJECT ANALYST: Tanya S. Rupp
ASSISTANT CHIEF: Craig R. Smith

PROJECT I.D. NUMBER: F-8073-08 / Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Huntersville / Develop a new 12-station dialysis facility in Huntersville by relocating 12 existing certified dialysis stations from three BMA facilities in Mecklenburg County: BMA Beatties Ford, BMA North Charlotte, and BMA Charlotte / 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

Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Huntersville, proposes to establish a new dialysis facility to be located at 9801 W. Kincey Avenue in Huntersville, by relocating the following numbers of stations from existing dialysis facilities: four dialysis stations from the BMA Beatties Ford facility; four stations from the BMA North Charlotte facility, and four dialysis stations from the BMA Charlotte facility. The applicant does not propose to add dialysis stations to an existing facility or to establish new dialysis stations. Therefore, neither of the two need methodologies in the *2008 State Medical Facilities Plan* (SMFP) is applicable to the review. However, SMFP Policy ESRD-2 is applicable to this review. Policy ESRD-2, found on page 26 states:

Distance from Proposed BMA Huntersville to Patient Residence ZIP

PT. RESIDENCE ZIP	NUMBER OF PTS.	DISTANCE TO 28078
28031	5	6 miles
28036	1	9 miles
28070	1	0.5 miles
28078	5	< 2 miles
28205	1	18 miles
28216	19	11.5 miles
28262	2	15.5 miles
28269	17	10 miles
28278	1	30 miles

*Source: Mapquest search, zip codes from application

Based on the information in the above table, if the proposed facility were built in Huntersville, then 12 patients will travel less than 10 miles for dialysis treatment; 36 patients will travel from 10 to 15 miles for dialysis treatment; and 4 patients will travel more than 15 miles for dialysis treatment. Thus, the number of patients travelling over 15 miles decreases, but the number travelling less than 10 miles also decreases. Moreover, the number travelling 10 to 15 miles increases threefold. Thus, it is not clear from the information in the application and this analysis that the majority of patients who signed a letter indicating a willingness to transfer to the proposed BMA Huntersville facility would in fact travel a shorter time or distance for dialysis care, as represented by the applicant. Moreover, many of these patients would still have to travel the I-77 corridor, which the applicant states on page 18 is a current concern for existing patients. Furthermore, 38 of the identified patients live in three North Charlotte ZIP codes [28216, 28262 and 28269] where three dialysis facilities are located and that are 10 or more miles from Huntersville. Additionally, portions of these three ZIP codes are closer to the BMA-North Charlotte facility located on Tryon Road between Sugar Creek Road and the Eastway, as is the patient who lives in 28205.

It is likewise not clear from the information presented by the applicant how it anticipates that 40 of its current patients will travel from existing BMA facilities to the proposed Huntersville location, when only 12 patients who reside in the four Northern Mecklenburg County ZIP codes (28031, 28036, 28070, and 28078) will actually see a reduction in travel. Additionally, if we assume that only these 12 patients will transfer to the proposed facility, that is not enough patients to utilize a 12-station dialysis facility [12 patients / 12 stations = 1 patient per station]. Further if we allow for growth based on the January 2008 Semi-Annual Dialysis Report (January 2008 SDR) indicates a 5% Five Year Average Annual Change Rate (AACR) for Mecklenburg County. Twelve patients increased by 5% becomes 14 patients at the end of project year three [12 x 1.05 = 12.6 at PY 1 end. 12.6 x 1.05 = 13.23 at PY 2 end. 13.23 x 1.05 = 13.89 at PY 3 end]. Fourteen patients dialyzing on 12 stations is 1.167 patients per station, or a 29% utilization rate [14 / 12 = 1.167; 1.167 / 4 = 0.2916]. Therefore, the applicant has not provided sufficient information to adequately demonstrate the facility will meet the required

performance standards codified at 10A NCAC 14C .2300, which requires utilization of 3.2 patients per station per week at the end of the first operating year.

The applicant also states, on pages 21 and 22, that patient convenience is a factor which cannot be ignored in this application. The applicant states the fact that patients have signed letters indicating a Huntersville facility would be more convenient to them for dialysis treatments proves the need for a facility in Huntersville [ZIP code 28078]. However, as the above analysis shows only those 12 patients residing in the four Northern Mecklenburg ZIP codes who signed letters will be markedly closer to the proposed facility than their current facility. Thus, the applicant has not reasonably demonstrated that the proposal will be more convenient for a sufficient number of patients to justify the development of a new 12 station facility.

In this application, the applicant seeks to establish a 12-station dialysis facility by relocating existing stations and transferring 36 patients. However, the applicant has failed to reasonably demonstrate that the population it proposes will transfer to Huntersville is reasonable for the development of a new 12-station dialysis facility. In summary, the applicant failed to adequately demonstrate the need to establish a 12-station dialysis facility in Huntersville. Consequently, the application is not 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.

NC

Upon completion of the proposed project (July 31, 2009), BMA would have the following patients in the affected facilities:

JULY 31, 2009 PROJECTED PATIENT CENSUS AT CURRENT BMA FACILITIES

FACILITY	# PATIENTS	# STATIONS	PTS. PER STATION	UTILIZATION
BMA Beatties Ford	82	28	2.93	73.21%
BMA North Charlotte	73	23	3.17	84.78%
BMA Charlotte	134	42	3.19	78.57%

The applicant provided 52 signed letters from current patients stating they would consider transferring to the proposed facility. Exhibit 22 of the application contains patient letters of support for the proposed project, which state

"I am a dialysis patient receiving my dialysis treatments at [several different BMA facilities in Mecklenburg County]. My residence ZIP code

Attachment 4

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: July 8, 2011
PROJECT ANALYST: Jane Rhoe-Jones
TEAM LEADER: Angie Matthes

PROJECT I.D. NUMBER: P-8641-11 / Total Renal Care of North Carolina, LLC d/b/a Wallace Dialysis Center / Add three stations for a total of 15 stations upon project completion / Duplin 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

Total Renal Care (TRC) of North Carolina, LLC d/b/a Wallace Dialysis Center, operates a 12-station dialysis facility at 5650 S. North Carolina Highway 41, Wallace, North Carolina. The applicant proposes to add three dialysis stations for a total of 15 stations at Wallace Dialysis Center upon completion of this project.

The 2011 State Medical Facilities Plan (2011 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the revised January 2011 Semiannual Dialysis Report (SDR), the county need methodology shows there is no need for an additional facility in Duplin County. However, the applicant is eligible to apply for additional stations in its existing facility based on the facility need methodology, because the utilization rate reported for Wallace Dialysis Center in the January 2011 SDR is 3.92 patients per station. This utilization rate was calculated based on 47 in-center dialysis patients and 12 certified dialysis stations as of June 30, 2010 (47 patients / 12 stations = 3.92 patients per station). Therefore, application of the facility need methodology indicates additional stations are needed for this facility, as illustrated in the following table.

The average number of patients per station per week will exceed 3.2 patients per station per week as required by 10A NCAC 14C .2203(b). The number of in-center patients that the applicant projects to be served is based on reasonable and supported assumptions regarding future growth. However, the floor plan provided in Exhibit 18 shows additional space, two stations for “PD/HHD Training.”

The applicant states in Section II, page 15: “*The Wallace Dialysis Center provides in-center hemodialysis treatments to chronic End Stage Renal Disease Patients who require outpatient dialysis. The facility has an isolation area to provide dialysis treatments to patients who require isolation. The facility provides full support for patients receiving hemodialysis services. This support includes social services, dietary services, patient education, emergency care, diagnostic services and transplant evaluation.*”

Home training services are provided by Southeastern Dialysis Center-Wilmington. See Exhibit 8. [Emphasis in original.]

In Section IV.3, page 22, the applicant states, “*SEDC-Wilmington provides home training for patients living in Duplin County under an agreement with Wallace Dialysis Center.*” Also in Section V.2(d), page 25 regarding accessible follow-up for patients dialyzing at home, the applicant states, “*SEDC-Wilmington provides protocols and routines for patient follow-up.*”

The applicant provides no assumptions, methodology or projected utilization for home dialysis patients. The applicant does not provide any discussion regarding the need to add space for home dialysis training. Moreover, in Section V, page 24, the applicant states that home dialysis training will be provided by SEDC-Wilmington. The applicant does not demonstrate why additional space for home dialysis training is needed.

In summary, the applicant adequately identifies the population to be served and demonstrates the need for the three additional stations based on the population it proposes to serve. However, the applicant does not adequately demonstrate the need to add two home dialysis training stations. Therefore, the application is not conforming with 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.

NA

The applicant is not proposing to reduce or eliminate a service.

- (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.

Attachment 5

Guidelines

FOR DESIGN AND CONSTRUCTION OF
Health Care Facilities

The Facility Guidelines Institute

2010 edition



Includes ANSI/ASHRAE/ASHE
Standard 170-2008,
Ventilation of
Health Care Facilities



With assistance from
the U.S. Department of
Health and Human Services



3.10 Specific Requirements for Renal Dialysis Centers

Appendix material, shown in shaded boxes at the bottom of the page, is advisory only.

3.10-1 General

3.10-1.1 Application

This chapter applies to renal dialysis centers that treat patients for both acute and chronic conditions.

3.10-1.2 Functional Program

3.10-1.2.1 Size

3.10-1.2.1.1 The number of dialysis stations shall be based upon the functional program and may include several work shifts per day.

3.10-1.2.1.2 Space and equipment shall be provided as necessary to accommodate the functional program, which may include outpatient dialysis, home treatment support, and dialyzer reuse services.

3.10-1.3 Site

The location shall offer convenient access for outpatients. Accessibility to the renal dialysis center from parking and public transportation shall be a consideration.

3.10-2 Reserved

3.10-3 Diagnostic and Treatment Locations

3.10-3.1 Examination Room

At least one examination room shall be provided.

3.10-3.1.1 The examination room shall have a minimum clear floor area of 100 square feet (9.29 square meters).

3.10-3.1.2 The examination room shall have the following:

3.10-3.1.2.1 Hand-washing station

3.10-3.1.2.2 A counter or shelf space for writing or electronic documentation

3.10-3.2 Dialysis Treatment Area

3.10-3.2.1 General

3.10-3.2.1.1 Layout

- (1) The treatment area shall be separate from administrative and waiting areas.
- (2) The treatment area shall be permitted to be an open area.
- (3) Open treatment areas shall be designed to provide privacy for each patient.

3.10-3.2.2 Space Requirements

3.10-3.2.2.1 Individual patient treatment areas shall contain at least 80 square feet (7.44 square meters).

3.10-3.2.2.2 There shall be a clear dimension of at least 4 feet (1.22 meters) between beds and/or lounge chairs.

3.10-3.2.3 Reserved

3.10-3.2.4 Reserved

3.10-3.2.5 Hand-Washing Station

Hand-washing stations shall be provided following the requirements of 3.1-3.6.5.

3.10-3.2.6 Reserved

3.10-3.2.7 Reserved

3.10-3.2.8 Nurse Station

Nurse station(s) shall be located within the dialysis treatment area and designed to provide visual observation of all patient stations.

Attachment 6

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

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NA = Not Applicable

DECISION DATE: February 25, 2011
FINDINGS DATE: March 4, 2011
PROJECT ANALYST: Jane Rhoe-Jones
TEAM LEADER: Angie Matthes

PROJECT I.D. NUMBER: G-8583-10/ Total Renal Care of North Carolina, LLC (TRC) d/b/a Randolph County Dialysis/ Develop a new 10-station dialysis facility / Randolph County

G-8594-10/ Bio-Medical Applications of North Carolina, Inc. (BMA) d/b/a BMA Asheboro/ Relocate existing 27-station dialysis facility and add 10 dialysis stations, for a total of 46 stations upon project completion and completion of Project I.D. #G-8420-09 (add 7 stations) and Project I.D. #G-8489-10 (relocate 2 stations) / Randolph 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 – TRC
C – BMA

The 2010 State Medical Facilities Plan (SMFP) and the July 2010 Semiannual Dialysis Report (SDR) provide a county need methodology for determining the need for additional dialysis stations. According to the county need methodology, found on page 333 of the 2010 SMFP, *“If a county’s December 31, 2010 projected station deficit is 10 or greater and the July SDR shows that utilization of each dialysis facility in the county is 80 percent or greater, the December 31, 2010 county station need determination is the same as the December 31, 2010 projected station deficit. If a county’s December 31, 2010*

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

The following table illustrates the projected payor mix, as provided by the applicant in Section VI.1, page 42:

Payor Source	
Medicare/Medicaid	40.7%
Medicare/ Commercial	24.1%
Medicare	22.2%
Commercial Insurance	5.6%
Medicaid	3.7%
VA	3.7%
Total	100.0%

On page 42, the applicant states:

“These are average percentages of patients who are currently dialyzing at the Dialysis Care of Montgomery County facility. Montgomery County is contiguous to Randolph County and located to the south of Randolph County. ...”

The applicant is correct that Montgomery County is contiguous to Randolph County, however, the applicant fails to demonstrate that the economic status of residents in Montgomery County is comparable to Randolph County and that the payor mix is comparable, as well. US Census Bureau data show substantial differences in the economic status of the two counties. The poverty level in Montgomery County is 40% higher than in Randolph County. The families living below the poverty level is 37.7% higher in Montgomery County than in Randolph County. The per capita income is 21.2% higher in Randolph County than in Montgomery County. Further, the population in Randolph County is 138,134 and in Montgomery County the population is 26,723. Of that population, the black or African American population in Randolph County is 6%; while in Montgomery County it is 19.5%. It is widely held that race impacts the incidence of kidney disease. These indicators impact the eligibility for Medicaid (source: US Census Bureau, 2005-2009 Survey). The applicant fails to provide any documentation which supports its assertion that the payor mix in Randolph County will duplicate that of Montgomery County. Thus it is not reasonable to assume that these two counties, although contiguous, are comparable in economic status.

The applicant did not demonstrate that the projected payor mix is based upon reasonable and supported assumptions. Therefore, the applicant did not demonstrate

Attachment 7

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: February 27, 2012

FINDINGS DATE: March 2, 2012

PROJECT ANALYST: Gregory F. Yakaboski

ASSISTANT CHIEF: Martha J. Frisone

PROJECT I.D. NUMBER: L-8750-11 / DVA Healthcare Renal Care, Inc. d/b/a Northampton Dialysis/ Develop a new ten-station dialysis facility in Garysburg/ Northampton County

L-8753-11 / Bio-Medical Applications of North Carolina, Inc. d/b/a FMC East Northampton/ Add three dialysis stations to the existing facility in Conway for a total of 19 stations / Northampton 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-Northampton Dialysis

C-FMC East Northampton

The 2011 State Medical Facilities Plan (2011 SMFP) and the July 2011 Semiannual Dialysis Report (SDR) provide a county need methodology for determining the need for new dialysis stations. According to Section 2(E) of the dialysis station county need methodology, found on page 350 of the 2011 SMFP, "If a county's December 31, 2011 projected station deficit is ten or greater and the July SDR shows that utilization of each dialysis facility in the county is 80% or greater, the December 31, 2011 county station need determination is the same as the December 31, 2011 projected station deficit. ..." The county need methodology for 2011 results in a need determination for 10 dialysis stations in Northampton County. In the July 2011 SDR Table B: ESRD Dialysis Station Need Determinations by Planning Area, a total of 83.4 in-center dialysis patients and 9.5 home patients are projected in Northampton County as of December 31, 2011. Two applications were received by the Certificate of Need Section for

**Northampton Dialysis
Utilization by Payor Source**

PAYOR SOURCE	PERCENT UTILIZATION BY PAYOR SOURCE
Medicare	23.0%
Medicaid	2.4%
Medicare/Medicaid	36.1%
Commercial Insurance	8.4%
VA	2.4%
Medicare/Commercial	27.7%
TOTAL	100.0%

In Section VI.1(c), page 51, the applicant states:

"These are average percentages of patients who are currently dialyzing at the Ahoskie Dialysis Center facility. Hertford County is contiguous to Northampton County and located to the east of Northampton County. ..."

The applicant is correct that Hertford County is contiguous to Northampton County. US Census Bureau data shows substantial similarities in the economic status of the two counties. The poverty level in Northampton County is the same as in Hertford County. The families living below the poverty level is 32.0% in Northampton County and 31.9% in Hertford County. The per capita income is \$30,694 in Northampton County and \$26,985 in Hertford County. Further, as of July 2011, the population of Northampton County was 22,150 and 25,016 in Hertford County. As of July 2009, the total Medicaid eligible population in Northampton County was 6,111 and was 6,310 in Hertford County. Thus it is reasonable to assume that these two contiguous counties are comparable in economic status.



The applicant demonstrated that medically underserved populations will have adequate access to the proposed services. Therefore, the application is conforming to this criterion.

FMC East Northampton. In Section VI.1(c), page 50, the applicant provides the projected payor mix for in-center dialysis patients.

Payor	In-Center Patients
Commercial Insurance	3.3%
Medicare	90.4%
Medicaid	4.5%
VA	1.3%
Other [Specify] Self/Indigent	0.6%
Total	100.0%

**QuickFacts****Alamance County, North Carolina; Guilford County, North Carolina; North Carolina**QuickFacts provides statistics for all states and counties, and for cities and towns with a *population of 5,000 or more*.**Table**

ALL TOPICS	Alamance County, North Carolina	Guilford County, North Carolina	North Carolina
Population estimates, July 1, 2016, (V2016)	159,688	521,330	10,146,788
PEOPLE			
Population			
Population estimates, July 1, 2016, (V2016)	159,688	521,330	10,146,788
Population estimates base, April 1, 2010, (V2016)	151,144	488,464	9,535,688
Population, percent change - April 1, 2010 (estimates base) to July 1, 2016, (V2016)	5.7%	6.7%	6.4%
Population, Census, April 1, 2010	151,131	488,406	9,535,483
Age and Sex			
Persons under 5 years, percent, July 1, 2016, (V2016)	5.8%	6.0%	6.0%
Persons under 5 years, percent, April 1, 2010	6.3%	6.3%	6.6%
Persons under 18 years, percent, July 1, 2016, (V2016)	22.6%	22.6%	22.7%
Persons under 18 years, percent, April 1, 2010	23.5%	23.4%	23.9%
Persons 65 years and over, percent, July 1, 2016, (V2016)	16.7%	14.4%	15.5%
Persons 65 years and over, percent, April 1, 2010	14.6%	12.3%	12.9%
Female persons, percent, July 1, 2016, (V2016)	52.5%	52.6%	51.4%
Female persons, percent, April 1, 2010	52.4%	52.4%	51.3%
Race and Hispanic Origin			
White alone, percent, July 1, 2016, (V2016) (a)	74.8%	57.4%	71.0%
Black or African American alone, percent, July 1, 2016, (V2016) (a)	20.0%	34.6%	22.2%
American Indian and Alaska Native alone, percent, July 1, 2016, (V2016) (a)	1.4%	0.8%	1.6%
Asian alone, percent, July 1, 2016, (V2016) (a)	1.6%	4.9%	2.9%
Native Hawaiian and Other Pacific Islander alone, percent, July 1, 2016, (V2016) (a)	0.1%	0.1%	0.1%
Two or More Races, percent, July 1, 2016, (V2016)	2.1%	2.3%	2.2%
Hispanic or Latino, percent, July 1, 2016, (V2016) (b)	12.6%	7.9%	9.2%
White alone, not Hispanic or Latino, percent, July 1, 2016, (V2016)	64.6%	51.2%	63.5%
Population Characteristics			
Veterans, 2012-2016	9,934	28,499	683,221
Foreign born persons, percent, 2012-2016	8.1%	10.2%	7.7%
Housing			
Housing units, July 1, 2016, (V2016)	69,159	226,711	4,540,498
Housing units, April 1, 2010	66,576	218,017	4,327,528
Owner-occupied housing unit rate, 2012-2016	64.9%	58.8%	64.8%
Median value of owner-occupied housing units, 2012-2016	\$143,500	\$157,300	\$157,100
Median selected monthly owner costs -with a mortgage, 2012-2016	\$1,162	\$1,246	\$1,243
Median selected monthly owner costs -without a mortgage, 2012-2016	\$351	\$405	\$376
Median gross rent, 2012-2016	\$757	\$789	\$816
Building permits, 2016	1,353	2,204	60,550
Families & Living Arrangements			
Households, 2012-2016	62,053	200,298	3,815,392
Persons per household, 2012-2016	2.45	2.47	2.54
Living in same house 1 year ago, percent of persons age 1 year+, 2012-2016	85.7%	85.9%	84.7%
Language other than English spoken at home, percent of persons age 5 years+, 2012-2016	12.6%	13.0%	11.3%

Education			
High school graduate or higher, percent of persons age 25 years+, 2012-2016	84.7%	88.4%	86.3%
Bachelor's degree or higher, percent of persons age 25 years+, 2012-2016	22.1%	34.5%	29.0%
Health			
With a disability, under age 65 years, percent, 2012-2016	10.3%	7.3%	9.7%
Persons without health insurance, under age 65 years, percent	▲ 14.1%	▲ 13.2%	▲ 12.2%
Economy			
In civilian labor force, total, percent of population age 16 years+, 2012-2016	62.4%	63.6%	61.5%
In civilian labor force, female, percent of population age 16 years+, 2012-2016	57.8%	58.5%	57.4%
Total accommodation and food services sales, 2012 (\$1,000) (c)	254,425	1,158,488	18,622,258
Total health care and social assistance receipts/revenue, 2012 (\$1,000) (c)	801,896	3,512,781	55,227,505
Total manufacturers shipments, 2012 (\$1,000) (c)	3,138,351	26,932,176	202,344,646
Total merchant wholesaler sales, 2012 (\$1,000) (c)	627,214	14,111,449	105,275,586
Total retail sales, 2012 (\$1,000) (c)	2,108,413	6,979,731	120,691,007
Total retail sales per capita, 2012 (c)	\$13,698	\$13,935	\$12,376
Transportation			
Mean travel time to work (minutes), workers age 16 years+, 2012-2016	23.5	21.3	24.1
Income & Poverty			
Median household income (in 2016 dollars), 2012-2016	\$43,209	\$46,896	\$48,256
Per capita income in past 12 months (in 2016 dollars), 2012-2016	\$23,989	\$27,531	\$26,779
Persons in poverty, percent	▲ 16.1%	▲ 18.3%	▲ 15.4%
 BUSINESSES			
Businesses			
Total employer establishments, 2015	3,153	13,246	223,209 ¹
Total employment, 2015	56,328	258,166	3,670,284 ¹
Total annual payroll, 2015 (\$1,000)	2,166,786	11,472,846	164,936,258 ¹
Total employment, percent change, 2014-2015	10.2%	1.4%	3.1% ¹
Total nonemployer establishments, 2015	9,727	39,823	722,639
All firms, 2012	10,990	45,746	805,985
Men-owned firms, 2012	5,939	22,594	435,677
Women-owned firms, 2012	3,804	17,884	287,058
Minority-owned firms, 2012	2,283	14,168	183,380
Nonminority-owned firms, 2012	8,295	29,574	603,182
Veteran-owned firms, 2012	1,203	4,438	86,571
Nonveteran-owned firms, 2012	9,138	38,576	684,743
 GEOGRAPHY			
Geography			
Population per square mile, 2010	356.5	756.4	196.1
Land area in square miles, 2010	423.94	645.70	48,617.91
FIPS Code	37001	37081	37

Value Notes

1. Includes data not distributed by county.

▲ This geographic level of poverty and health estimates is 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. Click the QI left of each row in TABLE view to learn about sampling error.

The vintage year (e.g., V2016) refers to the final year of the series (2010 thru 2016). *Different vintage years of estimates are not comparable.*

Fact Notes

- (a) Includes persons reporting only one race
- (b) Hispanics may be of any race, so also are included in applicable race categories
- (c) Economic Census - Puerto Rico data are not comparable to U.S. Economic Census data

Value Flags

- Either no or too few sample observations were available to compute an estimate, or a ratio of medians cannot be calculated because one or both of the median estimates falls in the interval of an open ended distribution.
- D Suppressed to avoid disclosure of confidential information
- F Fewer than 25 firms
- FN Footnote on this item in place of data
- NA Not available
- S Suppressed; does not meet publication standards
- X Not applicable
- Z Value greater than zero but less than half unit of measure shown

QuickFacts data are derived from: Population Estimates, American Community Survey, Census of Population and Housing, Current Population Survey, Small Area Health Insurance Estimates, Small Area Poverty Estimates, State and County Housing Unit Estimates, County Business Patterns, Nonemployer Statistics, Economic Census, Survey of Business Owners, Building Permits.

Inman, Celia C

From: Jim Swann <Jim.Swann@fmc-na.com>
Sent: Tuesday, January 02, 2018 5:28 PM
To: Inman, Celia C
Subject: [External] Public Written Comments, G-11439-17
Attachments: Attachment 1, pg 14 - 20.pdf

CAUTION: External email. Do not click links or open attachments unless verified. Send all suspicious email as an attachment to report.spam@nc.gov.

Celia, I am not able to get the remaining attachments to transmit via email. I will say that there were a total of 13 patients with duplicate letters, meaning the patient support two project.



Jim Swann
Director, Certificate of Need
Fresenius Kidney Care
3390 Dunn Road
Eastover, NC 28312
Office: 910-568-3041 Fax: 910-568-3609
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Thrive On

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