Certificate of Need
3390 Dunn Road, Eastover, NC 28312
Phone: 910 568 3041 Fax: 910 568 3609

October 31, 2017

Ms. Martha Frisone, Chief
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-11412-17, 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.

BMA has filed CON applications seeking to add four stations at Northwest Greensboro Kidney Center, and seeking to add four stations at FMC East Greensboro. Both of these applications were filed on September 15, 2017, and are 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.

TRC's application is fatally flawed, and fails to comply with ESRD-2.

This application is not consistent with Policy ESRD-2, is therefore fatally flawed and cannot be approved. Policy ESRD -2 requires that a facility proposing to relocate stations across county lines must be currently serving patients residing within the receiving county. Thus, Policy ESRD-2 would require that both Reidsville Dialysis and Dialysis Care of Rockingham County be serving patients residing in Guilford County.

- The July 2017 SDR, Table A reports that Dialysis Care of Rockingham County (Provider No. 34-2536) was serving no Guilford County patients. Table A indicates that Reidsville Dialysis was serving only two patients residing in Guilford County.

- BMA has obtained copies of the ESRD Data Collection Forms submitted by DaVita for both Reidsville Dialysis and Dialysis Care of Rockingham County, for the six months ending June 30, 2017[1]. As of that date, the number of Guilford County residents served at Reidsville Dialysis had fallen to only one patient, and the Dialysis Care of Rockingham County facility was still serving no Guilford County patients at all.

- Further, within the application, page 15, the applicant reports that Reidsville Dialysis was serving a single patient[2] who resides in Guilford County. There is o representation that Dialysis Care of Rockingham County serves any Guilford County patients.

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.

Since the applicant is not currently serving residents of Guilford County at its Dialysis Care of Rockingham County facility, the stations from that facility do not qualify under Policy ESRD-2 for relocation to Guilford County.

The State Medical Facilities Plan states in Chapter 14, Basic Principles, that new dialysis facilities must have a projected need for at least 10 stations to be cost effective and to assure quality of care. The applicant therefore cannot be approved to develop a five-station dialysis facility.

Because Dialysis Care of Rockingham County does not currently serve patients residing in Guilford County, the application for Guilford County Dialysis must be disapproved.

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[1] Copies attached

[2] The patient signed a letter of support for the project

The State Medical Facilities Plan states in Chapter 14, Basic Principles that new dialysis facilities must have a projected need for at least 10 stations to be cost effective and to assure quality of care. The applicant therefore cannot be approved to develop a five-station dialysis facility.

TRC's failure to demonstrate that the Reidsville Dialysis facility is currently serving patients residing in Guilford County, and/or applying to relocate 10 dialysis stations from Dialysis Care of Rockingham County, the application for Guilford County Dialysis must be disapproved.

See e.g.

- CON Project ID # M-8294-09, BMA Dunn (Attachment 4)

In this application BMA was denied in part based on Policy ESRD-2. The applicant failed to demonstrate that the facility losing stations was currently serving patients of the gaining county. See discussion on page 2 of the Required State Agency Findings.

- CON Project ID # K-10099-13, FMC Tar River (Attachment 5)

In this application the applicant was approved under Policy ESRD-2 to relocate stations from two dialysis facilities. See discussion on page 6 of the Required State Agency Findings; the analyst quoted the application which expressed that both facilities contributing stations to the project were serving patients of the gaining county.

- CON Project ID # N-10345-14, Dialysis Care of Hoke County (Attachment 6)

This application was denied in part based on Policy ESRD-2. The applicant failed to demonstrate that the facility losing stations was currently serving patients of the gaining county. See discussion on page 3 of the Required State Agency Findings

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

1. The certification page for the application is not dated. As the Responsible Officer certifying the content of the document, Mr. Hilger's signature should be dated. Absent a date, one cannot determine the authenticity of the certification page.

2. The applicant offers a lengthy explanation of the reasoning behind relocating 10 stations from its facilities in Rockingham County that 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."*[3] *However, DaVita recently filed public* written comments opposing a CON application Johnston County. Wherein Mr. Hyland suggest that "the patients are being served at other nearly [sic] BMA locations..."[4]

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

3. TRC's application is an improper and delinquent attempt to amend a CON application that this Agency has already considered and ruled upon. The applicant has clearly included letters from patients who have previously indicated an intention to transfer their care to another clinic. The applicant suggests that it is possible to offer replacement letters for those patients who have been counted in a previous application and now sign letters for this proposal.

   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.

4. The application fails to conform to Review Criterion 3 and should be denied. Specifically, TRC has not adequately identified the patient population to be served, or the need that the population has for the services at the proposed location.

   The applicant proposes to relocate 10 dialysis stations from its facilities in Rockingham 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 37 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..."*

   The applicant states on page 19 of the application that the development of the proposed facility will *"result in providing **future** dialysis patients a choice of providers..."* (emphasis added).

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

[4] Attachment 7, Public Written Comments CON Project ID # J-11372-17, page 4

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. While BMA certainly doesn't agree with the identification of the population to be served, it is also important to note that the applicant has not demonstrated the need this population has for the services proposed.

- The applicant identified 37 in-center patients by letter of support. These are patients currently dialyzing at DaVita owned facilities. 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.

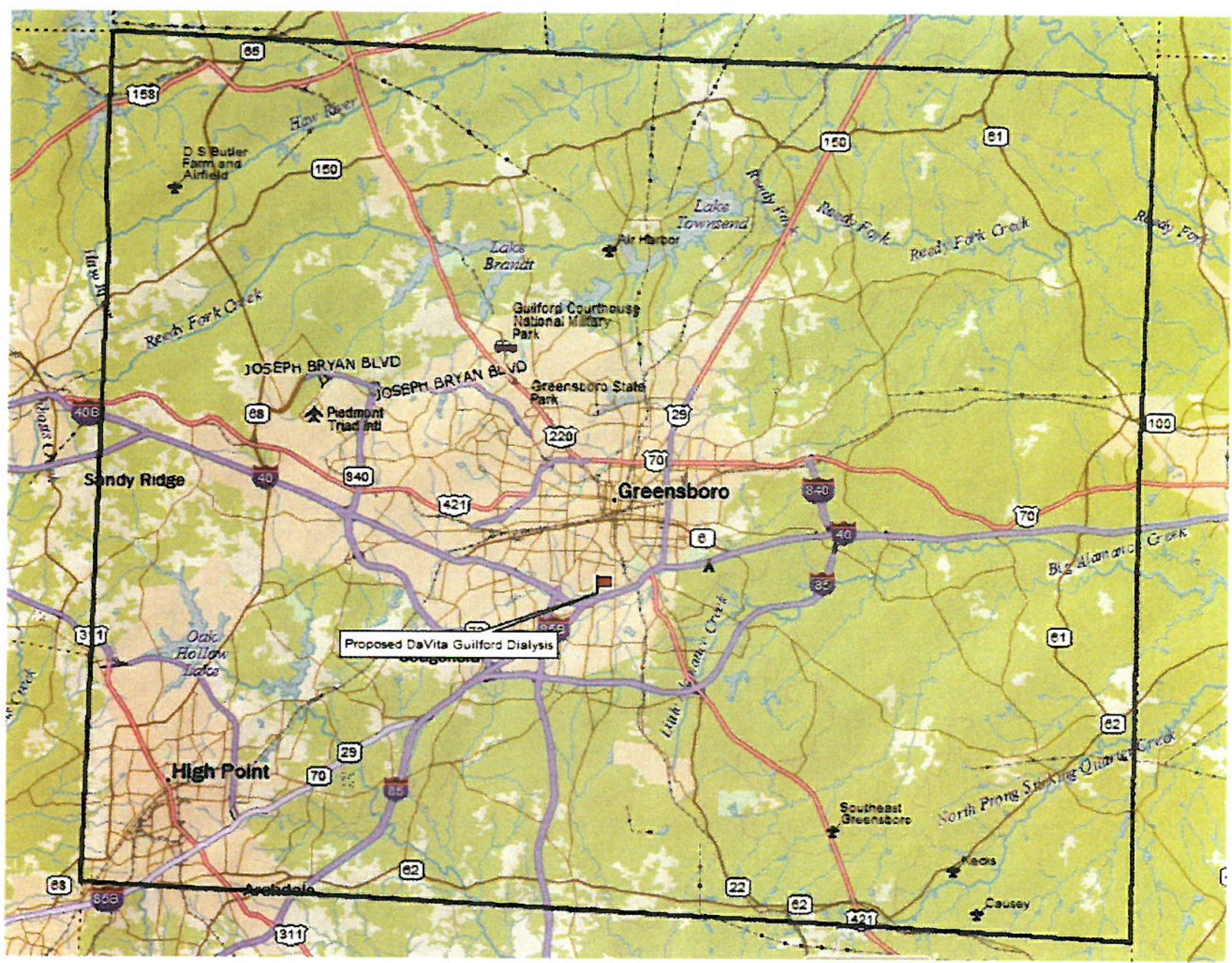
- Equally as important, the application seeks to address the needs of a future patient population. This is in stark contrast to the needs of the existing patient population, the very same patient population proposed to be served by the facility. The application totally fails to demonstrate that the 37 patients identified by letter of support need this facility in Greensboro.

In addition to the 37 in-center patient letters of support, the applicant provided three letters of support from Peritoneal Dialysis patients. The SMFP expressly excludes home dialysis patients when determining the need for dialysis stations. Chapter 14 of the SMFP includes 12 Basic Principles to be used for *"projection of need for additional dialysis stations"*. Basic Principle #5 reads as follows:

> *"Home patients will not be included in the determination of need for new stations."*

Thus, the applicant has correctly relied upon the 37 in-center patient letters of support for the new 10-station dialysis facility.

However, the applicant has not adequately demonstrated the need that these patients have for dialysis services at the proposed location. 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 secondary location is within close proximity to the primary site and is not identified on this map).



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 37 letters provided, only 13 of the patients actually reside within Guilford County. Thus, 24 of the patients, or 64.87% 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	16
Alamance County	27349	4
Randolph County	27298	2
Stokes County	27046	2
Total		24

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 8 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	16	14.9	DaVita Burlington	2.3
			DaVita Reidsville	10
27249	2	9.0	DaVita Burlington	3.7
			DaVita Reidsville	7.8

The applicant suggests on page 16 that "it is reasonable to assume that at least thirty-two (32) of the thirty-seven (37) in-center patients" would transfer their care to the new facility.

One must question why is this reasonable? Why would 28 patients, 75.68% of those 37 patients, 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 11 of the patients 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 11 patients on 10 dialysis stations is only 27.5%, or 1.1 patient per station. The applicant has provided no explanation why the other 28 patients need to travel further for their dialysis care than they do now.

It is unreasonable for the applicant to suggest on page 20 of the application that *"Most of the patients who live in Alamance county live on the western edge of the county in Elon."* 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 9), 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."*

The same must be true here. Of the patient letters of support provided by the Applicant, 24 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 37 current patients will transfer their care to the proposed new facility when only 11 of those 37 patients reside within Guilford County and possibly closer to the new facility location.

5. The applicant has provided unfounded, unsupported and unreasonable projections of a home hemodialysis patient population to be served. The applicant indicates that the nephrology physicians referring to their facilities in Rockingham and Alamance Counties do not currently refer for home hemodialysis.[5] Yet, the same physicians are projected to begin to referring home hemodialysis patients at the new facility in Guilford County.

   The applicant has not provided any indication of why patients would be referred for home hemodialysis.

[5] Application, page 17

The applicant has not provided any supporting documentation from the referring physicians which support such a change in referral patterns for home hemodialysis. The letter from the proposed Medical Director, Dr. Harmeet Singh, and the other nephrologists of Central Carolina Kidney Associates, P.A. do not, in any way, suggest a change in the referral patterns. The letters do not say that patients will be referred for home hemodialysis. (See application exhibit I-3).

Absent any direct indication of support for home hemodialysis, the assertion by the applicant that patients will be referred for home hemodialysis is not reasonable, not supported and most certainly is not credible, especially in light of the specific representation that the neither of the DaVita home programs in Rockingham and Alamance Counties are providing home hemodialysis.

Moreover, it is important that the CON Project Analyst not allow the applicant to amend the application through comments at the scheduled Public Hearing. Rule 10A NCAC 14C .0204 expressly says that an applicant may not amend an application. It would not be appropriate for the Applicant, the proposed Medical Director, or the proposed referring nephrologists to appear at the public hearing and say (after reading these public written comments) that they would be referring patients for home hemodialysis. Any such statements should be considered as an amendment to the application, and thereby result in denial of the application, or at the very minimum, such comments should not be considered by the Analyst during the conduct of the review.

As an additional consideration, consider the Required State Agency Findings for CON Project I D# P-8641-11 (Attachment 9), 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 is expects the applicant to explain the basis for its projections of patients to be served. In this case, the applicant has (once again) failed to provide a basis for its projected patient population to be served, and the application should be denied.

6. 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 33% in the first year of operations, and by 25% 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 third home PD patient resides in Guilford County. 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 33%, or 25% is simply inconsistent with the realities of the patient population of the three counties where the applicant's home PD patients currently reside.

7. 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.

Further, on page 26 of the application, the applicant suggests that the growth rate of the Dialysis Care of Rockingham County facility is stagnant, while that facility increased its census by *"four in-center patients over the past three years."* This too while the Rockingham County Five Year Average Change Annual Change Rate was very low.

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

DaVita Utilization		DC Rockingham 34-2536		Reidsville Dialysis 34-2640	
SDR	Census Date	Cert Stations	# of Pts	Cert Stations	# of Pts
July 2014	12/31/2013	23	73	19	67
January 2015	6/30/2014	23	71	27	69
July 2015	12/31/2014	23	77	27	67
January 2016	6/30/2015	23	79	27	69
July 2016	12/31/2015	23	80	27	72
January 2017	6/30/2016	23	80	27	73
July 2017	12/31/2016	23	77	27	72

During this time of low growth, the applicant applied to add two stations at the Rockingham Kidney Center (CON Project ID # G-10337-14, filed September 15, 2014). The applicant had some growth during this time, or it would not have qualified for application of the Facility Need Methodology.

8. 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.

9. 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.

10. 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."*[6]

    The plan provided by the applicant includes approximately 514 square feet per station. This assumes one station is set aside for home hemodialysis, and one station is set aside for isolation/separation; thus the in-center treatment floor would have a total of eight dialysis stations in 4,112 square feet. This does not include the nurses station.

    Furthermore, the applicant proposes to develop 685 square feet for home training. This is 685 square feet dedicated to serving only four PD patients and two home hemodialysis 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. 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

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[6] FGI, 2010 edition, Guidelines for Design and Construction of Health Care Facilities, paragraph 3.10-3.2.2 Space Requirements, page 283. See Attachment 11.

11. 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 County[7] competitive review and the 2011 Northampton County[8] 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 Facts[9]

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

[7] Attachment 12, page 34

[8] Attachment 13, page 34

[9] Attachment 14

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

Sincerely,

Jim Swann
Director of Operations, Certificate of Need

14 Attachments:

1) ESRD Data Collection Forms, 34-2640, Reidsville Dialysis
2) ESRD Data Collection Forms, 34-2536, Dialysis Care Rockingham County
3) Patient letter of support, Included in Application Exhibit C-1
4) RSAF, CON Project ID # M-8294-19, BMA Dunn
5) RSAF, CON Project ID # K-10099-13, FMC Tar River
6) RSAF, CON Project ID # N-10345-14, Dialysis Care of Hoke County
7) Public Written Comments by Mr. Hyland, CON Project ID # J-11372-17
8) Zip Code maps
9) RSAF, CON Project ID # F-8073-08, FMC Huntersville
10) RSAF, CON Project ID # P-8641-11, TRC Wallace Dialysis Center
11) FGI, Guidelines For Design and Construction of Health Care Facilities, extract
12) RSAF, CON Project ID # G-8594-10, BMA Asheboro, page 34
13) RSAF, CON Project ID # L-8753-11, FMC East Northampton County, page 34
14) US Census Bureau Quick Facts, Guilford County, Alamance County

Attachment
1

Data Collection Form
End-Stage Renal Disease Facilities
June 2017

Please Read Carefully

Instructions
This is a data form for dialysis providers who are certified to provide services for individuals with end-stage renal disease.

This information is needed to determine current utilization of in-center dialysis stations services and the percentage of patients receiving home dialysis in the state to project future need for new dialysis stations and facilities. **Documented need for such service is a requirement in order to expand the number of facilities or stations for any county in the state.**

There are seven sections in this data collection form on six pages. **Please answer all of the questions in the designated location on each page**.

Section A collects information regarding the particular dialysis facility. **DHSR Healthcare Planning staff will contact the Facility Administrator if the agency has any questions regarding this form.**

Sections B and C are related to the time period of this report and the number of certified stations in the facility.

Sections D, E, and F collect patient origin information on the facility's active patients on June 30, 2017.

Section G is for the electronic signature. Enter the name of the individual who is certifying the accuracy of the information in the Name box. **This Section must be completed and returned along with all other sections of the form to NC DHSR by the established deadline in order for the data submission to be considered complete.**

PLEASE NOTE: THE ONLY FILE NAMING CONVENTION THAT WILL BE ACCEPTED IS THE FOLLOWING: THE CAPITAL LETTERS ESRD COMBINED WITH THE FACILITY'S MEDICARE PROVIDER NUMBER. DO NOT USE A DASH NOR A BLANK SPACE BETWEEN THE LETTERS AND NUMBERS. FOR EXAMPLE: ESRD343815

Email the completed Excel workbook to **DHSR.SMFP.ESRD-Inventory@dhhs.nc.gov** by **August 25, 2017**. It is imperative that all forms are submitted by the deadline. **Any facility that does not submit this data collection form by August 25, 2017 will be shown as having zero patients on June 30, 2017 in the North Carolina Semiannual Dialysis Report January 2018.**

If you have questions, call Elizabeth Brown in Healthcare Planning at (919) 855-3865 or email DHSR.SMFP.ESRD-Inventory@dhhs.nc.gov.

Data Collection Form
End-Stage Renal Disease Facilities
June 2017

Section A: Contact Information

1. Facility Information

Facility Name (Do not use all caps)	Reidsville Dialysis
Medicare Provider Number (e.g. 34-1533)	34-2640

2. Facility Address

Street Address	1307 Freeway Drive
City	Reidsville
State (2 letter abbreviation)	NC
Zip Code	27320
Phone Number (use dashes)	336-348-6857

3. County where Facilty is Located

County (Name Only)	Rockingham

4. Chief Executive Officer or approved designee

Chief Executive Officer	Cheryl Evans
Street Address	1307 Freeway Drive
City	Reidsville
State (2 letter abbreviation)	NC
Zip Code	27320
Phone Number (use dashes)	336-348-6857
Email	cheryl.evans@davita.com

5. Facility Administrator

Name	Cheryl Evans
Title	Facility Administrator
Direct Line Phone Number (use dashes)	336-348-6857
Email	cheryl.evans@davita.com

Data Collection Form
End-Stage Renal Disease Facilities
June 2017

Section B: Time Period

1/1/2017 - 6/30/2017 (enter either Yes or No)	Yes
Other Time Period: Start Date	
End Date	

Section C: Certification Information

1. Is your facility certified for Medicare/Medicaid?	Yes
2. How many certified dialysis stations were at this location on June 30, 2017?	27
3. Was there a change to the certified station capacity between January 1, 2017 and June 30, 2017?	No
3a. Were certified stations added?	
3b. If yes in 3a, how many were added?	
3c. If yes in 3a, what was the effective date of change?	
3d. Were certified stations removed?	
3e. If yes in 3d, how many were removed?	
3f. If yes in 3d, what was the effective date of change?	

Data Collection Form
End-Stage Renal Disease Facilities
June 2017

Section D: In-Center Dialysis Population by County

By *county of residence*, report the total patients, including all transient patients, for whom dialysis services were provided on June 30, 2017 for **in-center dialysis patients.**

Note: County of Residence means the county where the patient lives

County	Number In-Center Patients
Alamance	1
Alexander	
Alleghany	
Anson	
Ashe	
Avery	
Beaufort	
Bertie	
Bladen	
Brunswick	
Buncombe	
Burke	
Cabarrus	
Caldwell	
Camden	
Carteret	
Caswell	10
Catawba	
Chatham	
Cherokee	
Chowan	
Clay	
Cleveland	
Columbus	
Craven	
Cumberland	
Currituck	
Dare	
Davidson	
Davie	
Duplin	
Durham	

Data Collection Form
End-Stage Renal Disease Facilities
June 2017

County	Number In-Center Patients
Edgecombe	
Forsyth	
Franklin	
Gaston	
Gates	
Graham	
Granville	
Greene	
Guilford	1
Halifax	
Harnett	
Haywood	
Henderson	
Hertford	
Hoke	
Hyde	
Iredell	
Jackson	
Johnston	
Jones	
Lee	
Lenoir	
Lincoln	
McDowell	
Macon	
Madison	
Martin	
Mecklenburg	
Mitchell	
Montgomery	
Moore	
Nash	
New Hanover	
Northampton	
Onslow	
Orange	
Pamlico	
Pasquotank	
Pender	
Perquimans	
Person	
Pitt	

Data Collection Form
End-Stage Renal Disease Facilities
June 2017

County	Number In-Center Patients
Polk	
Randolph	
Richmond	
Robeson	
Rockingham	65
Rowan	
Rutherford	
Sampson	
Scotland	
Stanly	
Stokes	
Surry	
Swain	
Transylvania	
Tyrrell	
Union	
Vance	
Wake	
Warren	
Washington	
Watauga	
Wayne	
Wilkes	
Wilson	
Yadkin	
Yancey	
Georgia	
South Carolina	
Tennessee	
Virginia	1
Other States	

Total In-Center Patients	78

Section E: Home Hemodialysis Population by County

By *county of residence,* report the total patients for whom dialysis services were provided on June 30, 2017 for **home hemodialysis patients.**

Note: County of Residence means the county where the patient lives.

County	Number Home Hemodialysis Patients
Alamance	
Alexander	
Alleghany	
Anson	
Ashe	
Avery	
Beaufort	
Bertie	
Bladen	
Brunswick	
Buncombe	
Burke	
Cabarrus	
Caldwell	
Camden	
Carteret	
Caswell	
Catawba	
Chatham	
Cherokee	
Chowan	
Clay	
Cleveland	
Columbus	
Craven	
Cumberland	
Currituck	
Dare	
Davidson	
Davie	
Duplin	
Durham	
Edgecombe	

Data Collection Form
End-Stage Renal Disease Facilities
June 2017

County	Number Home Hemodialysis Patients
Forsyth	
Franklin	
Gaston	
Gates	
Graham	
Granville	
Greene	
Guilford	
Halifax	
Harnett	
Haywood	
Henderson	
Hertford	
Hoke	
Hyde	
Iredell	
Jackson	
Johnston	
Jones	
Lee	
Lenoir	
Lincoln	
McDowell	
Macon	
Madison	
Martin	
Mecklenburg	
Mitchell	
Montgomery	
Moore	
Nash	
New Hanover	
Northampton	
Onslow	
Orange	
Pamlico	
Pasquotank	
Pender	
Perquimans	
Person	
Pitt	
Polk	

Data Collection Form
End-Stage Renal Disease Facilities
June 2017

County	Number Home Hemodialysis Patients
Randolph	
Richmond	
Robeson	
Rockingham	
Rowan	
Rutherford	
Sampson	
Scotland	
Stanly	
Stokes	
Surry	
Swain	
Transylvania	
Tyrrell	
Union	
Vance	
Wake	
Warren	
Washington	
Watauga	
Wayne	
Wilkes	
Wilson	
Yadkin	
Yancey	
Georgia	
South Carolina	
Tennessee	
Virginia	
Other States	

Total Home Patients	0

Data Collection Form
End-Stage Renal Disease Facilities
June 2017

Section F: Home Peritoneal Dialysis Population by County

By *county of residence,* report the total patients for whom dialysis services were provided on June 30, 2017 for **home peritoneal dialysis patients.**

Note: County of Residence means the county where the patient lives.

County	Number Home Peritoneal Patients
Alamance	
Alexander	
Alleghany	
Anson	
Ashe	
Avery	
Beaufort	
Bertie	
Bladen	
Brunswick	
Buncombe	
Burke	
Cabarrus	
Caldwell	
Camden	
Carteret	
Caswell	
Catawba	
Chatham	
Cherokee	
Chowan	
Clay	
Cleveland	
Columbus	
Craven	
Cumberland	
Currituck	
Dare	
Davidson	
Davie	
Duplin	
Durham	
Edgecombe	

Data Collection Form
End-Stage Renal Disease Facilities
June 2017

County	Number Home Peritoneal Patients
Forsyth	
Franklin	
Gaston	
Gates	
Graham	
Granville	
Greene	
Guilford	
Halifax	
Harnett	
Haywood	
Henderson	
Hertford	
Hoke	
Hyde	
Iredell	
Jackson	
Johnston	
Jones	
Lee	
Lenoir	
Lincoln	
McDowell	
Macon	
Madison	
Martin	
Mecklenburg	
Mitchell	
Montgomery	
Moore	
Nash	
New Hanover	
Northampton	
Onslow	
Orange	
Pamlico	
Pasquotank	
Pender	
Perquimans	
Person	
Pitt	
Polk	

Data Collection Form
End-Stage Renal Disease Facilities
June 2017

County	Number Home Peritoneal Patients
Randolph	
Richmond	
Robeson	
Rockingham	2
Rowan	
Rutherford	
Sampson	
Scotland	
Stanly	
Stokes	
Surry	
Swain	
Transylvania	
Tyrrell	
Union	
Vance	
Wake	
Warren	
Washington	
Watauga	
Wayne	
Wilkes	
Wilson	
Yadkin	
Yancey	
Georgia	
South Carolina	
Tennessee	
Virginia	
Other States	

Total Home Patients	2

Data Collection Form
End-Stage Renal Disease Facilities
June 2017

Section G: Certification and Signature

This section must be completed and returned along with all other sections of the form to NC DHSR by the established deadline in order for the data submission to be considered complete.

The undersigned Chief Executive Officer or approved designee certifies the accuracy of the information contained on all pages of this form.

Name	William L. Hyland
Title	Director of Healthcare Planning
Date Signed	8/24/2017

Email	bill.hyland@davita.com
Phone Number (use dashes)	704-577-2853

	Facility Patient Summary
Total Number In-Center Patients	78
Total Number Home Hemo Patients	0
Total Number Home Peritoneal Patients	2
Total Number of Patients	80

Attachment
2

Data Collection Form
End-Stage Renal Disease Facilities
June 2017

Please Read Carefully

Instructions
This is a data form for dialysis providers who are certified to provide services for individuals with end-stage renal disease.

This information is needed to determine current utilization of in-center dialysis stations services and the percentage of patients receiving home dialysis in the state to project future need for new dialysis stations and facilities. **Documented need for such service is a requirement in order to expand the number of facilities or stations for any county in the state.**

There are seven sections in this data collection form on six pages. **Please answer all of the questions in the designated location on each page**.

Section A collects information regarding the particular dialysis facility. **DHSR Healthcare Planning staff will contact the Facility Administrator if the agency has any questions regarding this form.**

Sections B and C are related to the time period of this report and the number of certified stations in the facility.

Sections D, E, and F collect patient origin information on the facility's active patients on June 30, 2017.

Section G is for the electronic signature. Enter the name of the individual who is certifying the accuracy of the information in the Name box. **This Section must be completed and returned along with all other sections of the form to NC DHSR by the established deadline in order for the data submission to be considered complete.**

PLEASE NOTE: THE ONLY FILE NAMING CONVENTION THAT WILL BE ACCEPTED IS THE FOLLOWING: THE CAPITAL LETTERS ESRD COMBINED WITH THE FACILITY'S MEDICARE PROVIDER NUMBER. DO NOT USE A DASH NOR A BLANK SPACE BETWEEN THE LETTERS AND NUMBERS. FOR EXAMPLE: ESRD343815

Email the completed Excel workbook to **DHSR.SMFP.ESRD-Inventory@dhhs.nc.gov** by **August 25, 2017**. It is imperative that all forms are submitted by the deadline. **Any facility that does not submit this data collection form by August 25, 2017 will be shown as having zero patients on June 30, 2017 in the North Carolina Semiannual Dialysis Report January 2018.**

If you have questions, call Elizabeth Brown in Healthcare Planning at (919) 855-3865 or email DHSR.SMFP.ESRD-Inventory@dhhs.nc.gov.

Data Collection Form

End-Stage Renal Disease Facilities
June 2017

Section A: Contact Information

1. Facility Information

Facility Name (Do not use all caps)	Dialysis Care of Rockingham County
Medicare Provider Number (e.g. 34-1533)	34-2536

2. Facility Address

Street Address	251 W Kings Highway
City	Eden
State (2 letter abbreviation)	NC
Zip Code	27288
Phone Number (use dashes)	336-623-7906

3. County where Facilty is Located

County (Name Only)	Rockingham

4. Chief Executive Officer or approved designee

Chief Executive Officer	Lisa Frankel
Street Address	251 W Kings Highway
City	Eden
State (2 letter abbreviation)	NC
Zip Code	27288
Phone Number (use dashes)	336-623-7906
Email	lisa.frankel@davita.com

5. Facility Administrator

Name	Lisa Frankel
Title	Facility Administrator
Direct Line Phone Number (use dashes)	336-623-7906
Email	lisa.frankel@davita.com

Data Collection Form
End-Stage Renal Disease Facilities
June 2017

Section B: Time Period

1/1/2017 - 6/30/2017 (enter either Yes or No)	Yes
Other Time Period: Start Date	
End Date	

Section C: Certification Information

1. Is your facility certified for Medicare/Medicaid?	Yes
2. How many certified dialysis stations were at this location on June 30, 2017?	25
3. Was there a change to the certified station capacity between January 1, 2017 and June 30, 2017?	Yes
3a. Were certified stations added?	Yes
3b. If yes in 3a, how many were added?	2
3c. If yes in 3a, what was the effective date of change?	2/3/2017
3d. Were certified stations removed?	
3e. If yes in 3d, how many were removed?	
3f. If yes in 3d, what was the effective date of change?	

Data Collection Form
End-Stage Renal Disease Facilities
June 2017

Section D: In-Center Dialysis Population by County

By *county of residence*, report the total patients, including all transient patients, for whom dialysis services were provided on June 30, 2017 for **in-center dialysis patients.**

Note: County of Residence means the county where the patient lives

County	Number In-Center Patients
Alamance	
Alexander	
Alleghany	
Anson	
Ashe	
Avery	
Beaufort	
Bertie	
Bladen	
Brunswick	
Buncombe	
Burke	
Cabarrus	
Caldwell	
Camden	
Carteret	
Caswell	1
Catawba	
Chatham	
Cherokee	
Chowan	
Clay	
Cleveland	
Columbus	
Craven	
Cumberland	
Currituck	
Dare	
Davidson	
Davie	
Duplin	
Durham	

Data Collection Form

End-Stage Renal Disease Facilities

June 2017

County	Number In-Center Patients
Edgecombe	
Forsyth	
Franklin	
Gaston	
Gates	
Graham	
Granville	
Greene	
Guilford	
Halifax	
Harnett	
Haywood	
Henderson	
Hertford	
Hoke	
Hyde	
Iredell	
Jackson	
Johnston	
Jones	
Lee	
Lenoir	
Lincoln	
McDowell	
Macon	
Madison	
Martin	
Mecklenburg	
Mitchell	
Montgomery	
Moore	
Nash	
New Hanover	
Northampton	
Onslow	
Orange	
Pamlico	
Pasquotank	
Pender	
Perquimans	
Person	
Pitt	

Data Collection Form
End-Stage Renal Disease Facilities
June 2017

County	Number In-Center Patients
Polk	
Randolph	
Richmond	
Robeson	
Rockingham	65
Rowan	
Rutherford	
Sampson	
Scotland	
Stanly	
Stokes	2
Surry	
Swain	
Transylvania	
Tyrrell	
Union	
Vance	
Wake	
Warren	
Washington	
Watauga	
Wayne	
Wilkes	
Wilson	
Yadkin	
Yancey	
Georgia	1
South Carolina	
Tennessee	
Virginia	11
Other States	

Total In-Center Patients	80

Data Collection Form
End-Stage Renal Disease Facilities
June 2017

Section E: Home Hemodialysis Population by County

By *county of residence,* report the total patients for whom dialysis services were provided on June 30, 2017 for **home hemodialysis patients.**

Note: County of Residence means the county where the patient lives.

County	Number Home Hemodialysis Patients
Alamance	
Alexander	
Alleghany	
Anson	
Ashe	
Avery	
Beaufort	
Bertie	
Bladen	
Brunswick	
Buncombe	
Burke	
Cabarrus	
Caldwell	
Camden	
Carteret	
Caswell	
Catawba	
Chatham	
Cherokee	
Chowan	
Clay	
Cleveland	
Columbus	
Craven	
Cumberland	
Currituck	
Dare	
Davidson	
Davie	
Duplin	
Durham	
Edgecombe	

Data Collection Form
End-Stage Renal Disease Facilities
June 2017

County	Number Home Hemodialysis Patients
Forsyth	
Franklin	
Gaston	
Gates	
Graham	
Granville	
Greene	
Guilford	
Halifax	
Harnett	
Haywood	
Henderson	
Hertford	
Hoke	
Hyde	
Iredell	
Jackson	
Johnston	
Jones	
Lee	
Lenoir	
Lincoln	
McDowell	
Macon	
Madison	
Martin	
Mecklenburg	
Mitchell	
Montgomery	
Moore	
Nash	
New Hanover	
Northampton	
Onslow	
Orange	
Pamlico	
Pasquotank	
Pender	
Perquimans	
Person	
Pitt	
Polk	

Data Collection Form
End-Stage Renal Disease Facilities
June 2017

County	Number Home Hemodialysis Patients
Randolph	
Richmond	
Robeson	
Rockingham	
Rowan	
Rutherford	
Sampson	
Scotland	
Stanly	
Stokes	
Surry	
Swain	
Transylvania	
Tyrrell	
Union	
Vance	
Wake	
Warren	
Washington	
Watauga	
Wayne	
Wilkes	
Wilson	
Yadkin	
Yancey	
Georgia	
South Carolina	
Tennessee	
Virginia	
Other States	

Total Home Patients	0

Data Collection Form
End-Stage Renal Disease Facilities
June 2017

Section F: Home Peritoneal Dialysis Population by County

By *county of residence,* report the total patients for whom dialysis services were provided on June 30, 2017 for **home peritoneal dialysis patients.**

Note: County of Residence means the county where the patient lives.

County	Number Home Peritoneal Patients
Alamance	
Alexander	
Alleghany	
Anson	
Ashe	
Avery	
Beaufort	
Bertie	
Bladen	
Brunswick	
Buncombe	
Burke	
Cabarrus	
Caldwell	
Camden	
Carteret	
Caswell	1
Catawba	
Chatham	
Cherokee	
Chowan	
Clay	
Cleveland	
Columbus	
Craven	
Cumberland	
Currituck	
Dare	
Davidson	
Davie	
Duplin	
Durham	
Edgecombe	

Data Collection Form
End-Stage Renal Disease Facilities
June 2017

County	Number Home Peritoneal Patients
Forsyth	
Franklin	
Gaston	
Gates	
Graham	
Granville	
Greene	
Guilford	
Halifax	
Harnett	
Haywood	
Henderson	
Hertford	
Hoke	
Hyde	
Iredell	
Jackson	
Johnston	
Jones	
Lee	
Lenoir	
Lincoln	
McDowell	
Macon	
Madison	
Martin	
Mecklenburg	
Mitchell	
Montgomery	
Moore	
Nash	
New Hanover	
Northampton	
Onslow	
Orange	
Pamlico	
Pasquotank	
Pender	
Perquimans	
Person	
Pitt	
Polk	

Data Collection Form
End-Stage Renal Disease Facilities
June 2017

County	Number Home Peritoneal Patients
Randolph	
Richmond	
Robeson	
Rockingham	2
Rowan	
Rutherford	
Sampson	
Scotland	
Stanly	
Stokes	
Surry	
Swain	
Transylvania	
Tyrrell	
Union	
Vance	
Wake	
Warren	
Washington	
Watauga	
Wayne	
Wilkes	
Wilson	
Yadkin	
Yancey	
Georgia	
South Carolina	
Tennessee	
Virginia	2
Other States	

Total Home Patients	5

Data Collection Form
End-Stage Renal Disease Facilities
June 2017

Section G: Certification and Signature

This section must be completed and returned along with all other sections of the form to NC DHSR by the established deadline in order for the data submission to be considered complete.

The undersigned Chief Executive Officer or approved designee certifies the accuracy of the information contained on all pages of this form.

Name	William L. Hyland
Title	Director of Healthcare Planning
Date Signed	8/24/2017

Email	bill.hyland@davita.com
Phone Number (use dashes)	704-577-2853

	Facility Patient Summary
Total Number In-Center Patients	80
Total Number Home Hemo Patients	0
Total Number Home Peritoneal Patients	5
Total Number of Patients	85

Attachment
3

To Whom It May Concern:

I am an in-center dialysis patient receiving my dialysis treatments at Reidsville 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 write 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 Reidsville 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

Attachment 4

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS
C = Conforming
CA = Conditional
NC = Nonconforming
NA = Not Applicable

DATE: August 21, 2009

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

PROJECT I.D. NUMBER: M-8294-09 / Bio-Medical Applications of North Carolina, Inc. d/b/a BMA Dunn / Relocate three existing dialysis stations from FMC South Ramsey in Cumberland County to BMA Dunn, for a facility total of 25 dialysis stations upon project completion / Harnett 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

The applicant, Bio-Medical Applications of North Carolina, Inc. (**"BMA"**) currently operates four dialysis centers in Cumberland County, and two dialysis centers in Harnett County. The applicant states on page 25 of the application that on May 9, 2008, three stations that were relocated from BMA Dunn to FMC Lillington were certified and thus operational, as shown in the following table, based on the January, 2009 Semi-Annual Dialysis Report (January 2009 SDR):

BMA Dialysis Station Inventory Cumberland and Harnett Counties

Facility	Location	# Certified Stations	Stations to be Deleted	Stations to be Added	Total End Stations
The Fayetteville Kidney Center, Inc.	Cumberland Co.	36	0	0	36
FMC West Fayetteville	Cumberland Co.	33	0	0	33
FMC North Ramsey	Cumberland Co.	40	0	0	40
FMC South Ramsey	Cumberland Co.	51	0	3	48
Dunn Kidney Center	Harnett Co.	22	3	0	25
FMC Lillington	Harnett Co.	13	0	0	13

*Source: January 2009 Semi Annual Dialysis Report

In this application, the applicant proposes to relocate three existing dialysis stations from FMC South Ramsey (**"FMC South Ramsey"**) in Cumberland County, to the Dunn Kidney Center (**"BMA Dunn"**) in Harnett County. The January, 2009 Semiannual Dialysis Report (January 2009 SDR), published by the North Carolina State Medical Facilities Planning Section, indicates a total of 51 certified stations at FMC South Ramsey, and 22 certified dialysis stations at BMA Dunn. The applicant does not propose to add dialysis stations to an existing facility or to establish new dialysis stations pursuant to a county need or facility need methodology. Therefore, neither of the two need methodologies in the *2009 State Medical Facilities Plan* (SMFP) is applicable to this review. However, SMFP Policy ESRD-2 is applicable to this review. Policy ESRD-2, found on page 32 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 applicant proposing to relocate dialysis stations shall:*
>
> *(A) demonstrate that the proposal shall not result in a deficit in the number of dialysis stations in the county that would be losing stations as a result of the proposed project, as reflected in the most recent Dialysis Report, and*
>
> *(B) demonstrate that the proposal shall not result in a surplus of dialysis stations in the county that would gain stations as a result of the proposed project, as reflected in the most recent Dialysis Report.*

The applicant proposes to relocate three existing, certified dialysis stations from a facility in Cumberland County to another facility in Harnett County. Cumberland and Harnett Counties share a common border. Therefore, the two counties are contiguous. The applicant proposing to relocate the existing dialysis stations must demonstrate that the relocation shall not result in a surplus of dialysis stations in Harnett County, nor a deficit of dialysis stations in Cumberland County. Further, the applicant must show that BMA South Ramsey currently serves Harnett County hemodialysis patients.

In Section II, page 11, the applicant states the January 2009 SDR indicates a surplus of 17 dialysis stations in Cumberland County and a deficit of 10 dialysis stations in Harnett County. Thus the proposed location will not result in a deficit of stations in Cumberland County nor a surplus of stations in Harnett County. However, the applicant fails to demonstrate that the BMA South Ramsey dialysis facility currently serves Harnett County hemodialysis patients (See Criterion 3).

Thus, the applicant has not shown that the proposed relocation of three existing dialysis stations from FMC South Ramsey in Cumberland County to BMA Dunn in Harnett County is conforming to Policy ESRD-2 in the 2009 SMFP. Consequently, the application is not conforming to this criterion.

Attachment
5

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS
C = Conforming
CA = Conditional
NC = Nonconforming
NA = Not Applicable

DECISION DATE: August 27, 2013

PROJECT ANALYST: Michael J. McKillip
ASSISTANT CHIEF: Martha J. Frisone

PROJECT I.D. NUMBER: K-10099-13 / Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Tar River / Develop a new 10-station dialysis facility in Louisburg by relocating 7 stations from BMA Zebulon and 3 stations from FMC Eastern Wake / Franklin 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.

C

Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Tar River filed a Category D application on March 15, 2013 for the review cycle beginning April 1, 2013. The applicant proposes to develop a new 10-station dialysis facility in Louisburg (Franklin County) by relocating 7 stations from BMA Zebulon and 3 stations from FMC Eastern Wake, both of which are located in Wake County. The applicant does not propose to add dialysis stations to an existing facility or to establish new dialysis stations. *Table B: ESRD Dialysis Station Need Determination by Planning Area* in the January, 2013 Semi-Annual Dialysis Report (SDR) projects a 10-station deficit in Franklin County. The January 2013 SDR is part of the 2013 State Medical Facilities Plan (SMFP) and is published by the State Health Coordinating Council and the Medical Facilities Planning Branch, Department of Health and Human Services. However, because the utilization of the dialysis stations in the only existing dialysis facility in Franklin County is less than 80%, the county need determination is zero. The county and facility need methodologies in the January 2013 SDR and the 2013 SMFP are not applicable to this review.

7. *BMA is suggesting that patients currently served by BMA and residing in Franklin County, or in Vance, Wake and Nash Counties, will transfer care to the facility.*

8. *The January 2013 SDR reports that the DaVita facility in Louisburg was underutilized on June 30, 2011 with a reported 79.35%* [sic] *utilization rate.*

9. *In his letter of support, Dr. Fred Jones, Medical Director for the proposed FMC Tar River facility, and President of the Capital Nephrology Associates, has indicated that he and his associates would extend their practice footprint into Franklin County by seeking admitting privileges at the Franklin Regional Medical Center in Louisburg. The significance of this is that Dr. Jones and his associates are already serving a significant portion of the Franklin County ESRD patient population.*

10. *This proposal by BMA is consistent with Policy ESRD 2. ESRD 2 says in part, 'Relocations of existing dialysis stations are allowed only within the host county and to contiguous counties* ***currently served*** *by the facility.' [Emphasis added] Both of the facilities contributing dialysis stations to this proposal are currently serving at least one patient from Franklin County.* [Emphasis in original]

    Further, the relocation of these stations will not create a surplus of stations in Franklin County, nor will the relocations create a deficit in the counties losing stations. See discussion specific to Policy ESRD 2.

11. *This project is scheduled for completion and certification of stations at December 31, 2014.*
    Operating Year 1 is January 1 through December 31, 2015
    Operating Year 2 is January 1 through December 31, 2015 [sic]. "

In Section III.7, page 73, the applicant projects that 31 in-center patients will initially transfer their treatment to the proposed Franklin County facility when it becomes operational in January 2015, including 25 Franklin County in-center dialysis patients and 6 in-center patients from other counties who have expressed their intention to transfer to the proposed facility. The applicant also projects that four home dialysis patients will transfer to the proposed Franklin County facility.

In Exhibit 22, the applicant provides 35 letters signed by current BMA patients as evidence of those patients' willingness to transfer their care to FMC Tar River when the facility is certified. Each letter includes the patient's signature, the name of the dialysis facility in which the patient currently receives treatment, and the county and ZIP code of the patient's residence. The project analyst prepared the following table to illustrate the information contained in the patient letters:

Attachment 6

ATTACHMENT – REQUIRED STATE AGENCY FINDINGS

FINDINGS
C = Conforming
CA – Conditional
NC – Nonconforming
NA = Not Applicable

Decision Date: February 25, 2015
Findings Date: February 25, 2015

Project Analyst: Tanya S. Rupp
Team Leader: Lisa Pittman

Project ID #: N-10345-14
Facility: Dialysis Care of Hoke County
FID #: 945165
County: Hoke
Applicant(s): Total Renal Care of North Carolina, LLC
Project: Relocate one existing dialysis station from Dialysis Care of Richmond County, for a facility total of 28 dialysis stations upon project completion

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 of North Carolina, LLC d/b/a Dialysis Care of Hoke County is currently certified for 27 in-center dialysis stations. In this application, the applicant proposes to add one dialysis station by relocating one station from Dialysis Care of Richmond County (DC Richmond County), for a total of 28 dialysis stations at Dialysis Care of Hoke County upon completion of this project.

Need Determination

The 2014 State Medical Facilities Plan (2014 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the July 2014 Semiannual Dialysis Report (SDR), the county need

Policy GEN-3, on page 38 of the 2014 SMFP is not applicable to this review, because the applicant is not proposing to develop a facility pursuant to a need determination in the 2014 SMFP. Policy GEN-4: ENERGY EFFICIENCY AND SUSTAINABILITY FOR HEALTH SERVICE FACILITIES is likewise not applicable to this review, because the applicant is not proposing a capital expenditure greater than $2 million.

However, Policy ESRD-2: RELOCATION OF DIALYSIS STATIONS, on page 32 of the 2014 SMFP, is applicable to this review, because the applicant proposes to relocate one dialysis station from DC Richmond County to DC Hoke County. The policy 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:*
>
> 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 North Carolina 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 North Carolina Semiannual Dialysis Report."*

DC Hoke County proposes in this application to relocate one existing dialysis station from DC Richmond County, for a total of 28 stations at DC Hoke County and 29 stations at DC Richmond County following completion of this project. Richmond County and Hoke County are contiguous; however, DC Richmond County, the county that will contribute dialysis stations to Hoke County, does not currently serve any patients from Hoke County. The policy states that relocations of existing stations are allowed *"within the host county and to contiguous counties currently served by the facility."* [emphasis added].

In Section III.7, page 25, the applicant provides projected patient origin for DC Hoke County which is based on its current patient origin:

COUNTY	OY 1 2016	OY 2 2017	COUNTY PATIENTS AS % OF TOTAL	
	IN-CTR.	IN-CTR.	OY 1	OY 2
Hoke	80	85	86.6%	87.6%
Cumberland	2	2	2.2%	2.1%
Moore	1	1	1.1%	1.0%
Robeson	9	9	9.8%	9.3%
Total	92	97	100.0%	100.0%

In addition, in Section III.3, page 22, the applicant states:

Attachment
7

TOPCATS Division
2321 West Morehead Street
Charlotte, NC 28208

August 31, 2017

Ms. Bernetta Thorne-Williams, Project Analyst
Healthcare Planning and Certificate of Need Section
Division of Health Service Regulation
North Carolina Department of Health and Human Services
809 Ruggles Drive
Raleigh, North Carolina 27603

RE: Project #J-11372-17/Bio-Medical Applications of North Carolina, Inc. d/b/a Fresenius Kidney Care Selma/Develop a new 10-station dialysis facility by relocating two dialysis stations from FMC Four Oaks, four from Johnston Dialysis Center and four from FMC New Hope Dialysis/Johnston County

Dear Ms. Thorne-Williams:

The July 2017 Semiannual Dialysis Report indicates in Table D that there is a projected station deficit of 11 stations in Johnston County. Bio-Medical Applications of North Carolina, Inc. submitted a Certificate of Need application on July 17, 2017 to establish a fourth dialysis facility in Johnston County via transfer of stations from three facilities. The purpose of this letter is to bring to your attention several deficiencies in the CON application. The FKC Selma application should be found non-conforming with multiple statutory review criteria, including: Criteria 3, 3a, 6, 18a, and 20.

Mr. Mark Fawcett, Senior Vice President and Treasurer of Bio-Medical Applications of North Carolina, Inc. d/b/a Fresenius Kidney Care Selma signed the Certification stating, "The undersigned applicant(s) hereby assures (assure) and certifies (certify) that the information included in this application and all attachments is correct to the best of my (their) knowledge and belief and that it is my (their) intent to develop and offer the proposed new institutional health service as described". Based on this statement the application presented must stand on its own and no other information should be requested or presented to add to or delete information to the application.

As an initial matter, there are multiple errors and misstatements in the FKC Selma application, which appear to be a result of BMA originally intending to submit an application for a new facility in Selma based only on relocating stations <u>within</u> Johnston County, from two of their existing facilities (FMC Four Oaks and Johnston Dialysis). It appears that the application was then changed to be both a relocation within Johnston County as well as a relocation from Wake County. However, many inconsistencies and errors remain. There are multiple references to only Johnston County, and instances where Wake County is not appropriately mentioned or taken into account (see pp. 11, 16, 17, 30, 37, 50, 74, 77, 80). There are incorrect statements that this application will not change the inventory of Johnston County (p. 16). BMA proposes to shift stations from Wake County, and thus the inventory of Johnston County is changing.

On page 30 of the application the applicant is asked to, "Describe in detail the necessity for relocation of stations, such as, physical inadequacy of existing facility or geographic accessibility of services". In response, the applicant states, "It is necessary to relocate the 10 stations to develop FKC Selma primarily for patient convenience. There are no physical plant deficiencies associated with either of the facilities contributing stations to this proposal. The patients who have signed letters of support for this project are indeed receiving dialysis care and treatment at an existing BMA dialysis facility."

In another part of the response to the request the applicant states, "The absence of a dialysis facility in this area of north, and eastern Selma forces patients to travel to other areas of Selma of Selma for dialysis. The closest facility is the FMC Four Oaks facility."

The applicant indicates in their response that there are no physical inadequacies. The applicant further states that the only reason for relocation of stations to develop the Selma facility is patient convenience. The statement that the Four Oaks facility is the closest facility to Selma is incorrect. Smithfield, where Fresenius operates Johnston Dialysis Center is 3.8 miles from Selma. Johnston Dialysis Center had 25 certified stations as of June 9, 2017 and a certificate of need for six additional stations that were not yet certified as of June 9th. Based on 31 in-center stations at Johnston Dialysis Center, the facility would have a utilization rate of 75.8% based on the 94 in-center patients as of 12/31/16. FMC Four Oaks had a utilization rate of 65.9% as of 12/31/16. Based on this information, there is significant room for new patients or for patients living in Selma who are receiving services at FMC Four Oaks to transfer their care to the closer Johnston County Dialysis.

The three dialysis centers in Johnston County, FMC Four Oaks, FMC Stallings Station and Johnston County Dialysis had a total of 71 certified stations with a certificate of need for an additional six stations for a total of 77 in-center stations as of 6/9/17. The three facilities had a total of 230 in-center patients as of 12/31/16. This equates to a utilization rate of 74.6% or 2.98 patients per station.

The applicant has provided 40 patient letters of support in the application. All of the patients live in Johnston County. However, only one of the patients is receiving their dialysis services outside of Johnston County. Table A of the July 2017 SDR indicates that as of December 31, 2016 there were 266 in-center ESRD patients living in Johnston County. As indicated above, the three dialysis facilities operated by Fresenius in Johnston County had a census of 230 in-center patients. Table A of the July 2017 SDR indicates that 222 of the 230 or 96.5% of the in-center patients live in Johnston County.

The other 44 Johnston County in-center patients (266 – 222 = 44) were receiving their dialysis services at six dialysis facilities operated by DaVita Inc. (15 in-center patients) and nine dialysis facilities operated by Fresenius (29 in-center patients). If all of the 29 Johnston County in-center patients receiving services outside of Johnston County were added to the December 31, 2016 census of 230 in-center patients, the overall utilization rate of the facilities in Johnston County would be 79.9%. Increasing the utilization rate by the Average Annual Change Rate for Past

Five Years of 6.3% for Johnston County, the combined facilities would have a utilization rate of 84.8% or 275 in-center patients (230 + 29 = 259 X 1.063 = 275).

The chart below contains a list of Fresenius facilities that are dialyzing in-center patients who live in Johnston County and the number of patients in each facility. There are a total of 29 in-center patients who are receiving their care at Fresenius facilities located in other counties. Based on the information above, there is no need for a new Fresenius facility in Johnston County. The proposed facility would only serve one of the twenty-nine Johnston County patients who receive services outside of the county. The applicant has failed to address any of the other twenty-eight Johnston County in-center patients.

Facility	County	# of Johnston County IC Patients
Wake Dialysis Clinic	Wake	3
BMA of Raleigh Dialysis	Wake	2
Dunn Kidney Center	Harnett	5
FMC New Hope Dialysis	Wake	5
Southwest Wake County Dialysis	Wake	5
BMA of Fuquay Varina Kidney Center	Wake	4
Zebulon Dialysis	Wake	3
New Bern Dialysis	Carteret	1
FMC Central Raleigh	Wake	1
Total # of In-Center Patients		**29**

The three existing in-center dialysis facilities located in Johnston County have had a combined average utilization rate of less than 75% in each of the past five years. See the chart below:

SDR	# of Johnston County Stations	# of IC Patients	Utilization %
July 2017 SDR	77	230	74.6%
July 2016 SDR	71	212	74.6%
July 2015 SDR	71	194	68.3%
July 2014 SDR	71	187	65.8%
July 2013 SDR	71	183	64.4%

The applicant indicates on page 15 and 16 of the application, "Development of the FKC Selma facility should be recognized in two ways. First, this is another effort by Fresenius Medical Care to promote community based delivery of dialysis care. And secondly, this facility will enhance access to care for patients residing in the north and east areas Selma within Johnston County, and nearby areas of Johnston County". The applicant is already providing community based care for the patients in and around Selma. The Smithfield community is located just 3.8 miles from Selma and has an underutilized facility with 31 in-center stations and a utilization rate of 75.8%.

The applicant indicates in the application that the Four Oaks facility is the closest dialysis facility to Selma, which is incorrect. Smithfield is located just 3.8 miles from Selma.

On page 50 the applicant states, "Approval of this application will not unnecessarily duplicate any existing health service. The July SDR reports an 11 station deficit in for Johnston County. With such a deficit it is not reasonable to suggest relocation of existing stations, to a location closer to the residence of the patients to be served, is duplicative. Approval of this application will not create additional stations in the county, but does enhance community based delivery of health care". The development of this facility will duplicate an existing healthcare service. There is already an underutilized facility available to serve the target patient population just 3.8 miles from the proposed location of the Selma facility. If the Selma facility was developed, there would be three Fresenius facilities within 12.5 miles of each other. Two of the facilities would continue to be underutilized. The applicant is incorrect in stating that the approval of the application will not create additional stations in the county. The applicant is proposing to transfer four stations from a facility in Wake County which would increase the station count to 81 stations. However, the applicant is proposing to serve only one additional Johnston County patient who receives their dialysis services outside of Johnston County. The application will not enhance community based delivery of health care. The services already exist and the facilities that provide the services are underutilized.

On page 74 of the application the applicant states, "The projected patient population for the FKC Selma facility begins with patients currently served by BMA at other nearby BMA locations…". The fact that the patients are being served at other nearly BMA locations is proof that the Selma facility is unnecessary. The identified patients are being served at nearby facilities that are already underutilized.

The applicant states on page 13 of the application, "In this application BMA has elected to relocate stations from FMC News Hope to the new facility in Johnston County. Of the seven BMA facilities serving Johnston County patients, FMC New Hope and Southwest Wake Dialysis were both serving five Johnston County residents….." "BMA has elected to relocate stations from one of its facilities serving the most number of Johnston County patients". The applicant proposes to transfer four stations from FMC New Hope, but only one Johnston County resident receiving their services outside of Johnston County. This is the only justification provided by the applicant for the movement of four stations across county lines.

Based on this information, the FKC Selma application should have been found non-conforming with Criterion 3 because the applicant did not demonstrate the need for its project. In addition, the project unnecessarily duplicates BMA's existing facilities in the area, which have sufficient capacity to treat patients, and thus the FKC Selma application should also be found non-conforming with Criterion 6.

Criterion 3a requires the applicant to demonstrate that patients served by existing services will not be harmed by the relocation of services. BMA fails to demonstrate that the patients currently served at FMC Four Oaks, Johnston Dialysis Center, and FMC New Hope will not be adversely impacted by this relocation. Specifically, the utilization at FMC Four Oaks is projected to be

95.31% after the shift. Utilization at FMC New Hope is proposed to be 96.09%. The application does not describe any future plans for adding new stations at these facilities, and it merely concludes (without any support) that there will not be any adverse impact on its patients.

Criterion 18a is intended to require applicants to address the impact that the application will have on competition. BMA is currently the sole provider of dialysis services in Johnston County, with a monopoly on dialysis stations there. Davita intends to submit an application on September 15, 2017 for a new dialysis facility to address the station deficit in Johnston County, which would provide patients with choice and would promote competition among providers. BMA did not provide any information about how the FKC Selma facility would have a positive impact on competition.

Finally, the application should be found nonconforming with Criterion 20. The FKC Selma application discloses information which demonstrates that the applicant has not provided quality of care in the past.

Criterion 20 states that: "An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past."

The FKC Selma application discloses in Section O of its application that in the 18 month look-back period, BMA had two "Immediate Jeopardy" citations at the following facilities:

- RAI West College – Warsaw, NC
- FMC Four Oaks – Four Oaks, NC

FMC Four Oaks is one of the facilities BMA proposes to transfer stations from to develop the FKC Selma facility.

BMA did not include the actual Immediate Jeopardy surveys to the Agency in the FKC Selma application. Based on the exhibits to the application, it appears that the Immediate Jeopardy citations occurred at RAI West College and BMA East Rocky Mount, instead of FMC Four Oaks. It is impossible to tell from the application whether FMC Four Oaks also had an Immediate Jeopardy citation, or whether BMA erroneously included the reference to FMC Four Oaks instead of BMA East Rocky Mount. In any event, the information provided to the Agency in the FKC Selma application regarding BMA's Immediate Jeopardy citations is not correct. The FMC Four Oaks facility did have a survey which identified standard level deficiencies, but the deficiencies did not result in an Immediate Jeopardy citation.

Davita has been able to obtain copies of the survey indicating the Immediate Jeopardy citation at BMA East Rocky Mount, attached as Exhibit A. The FMC Four Oaks survey is attached as Exhibit B.

<u>BMA East Rocky Mount</u>
One of the primary issues noted in the CMS survey for the BMA East Rocky Mount facility relates to Infection Control. The following information came directly from the CMS survey:

- "The facility failed to prevent staff members from providing care to (Hepatitis B Surface Antigen) **positive** patients and HBV (Hepatitis B) **susceptible** patients ***concurrently*** during hemodialysis treatment for 12 of 12 HBV susceptible patients receiving care in stations located across and/or diagonally from the facility's dedicated isolation room." (p. 1)

- Some of the general descriptions of the facility's deficiencies in infection control were that the staff:

    - **Failed to** perform hand hygiene and glove changes as necessary to prevent cross-contamination between clean and dirty processes. (p. 3)

    - **Failed to** ensure containers of clean cloth/wipes soaked with bleach solution were not stored in designated dirty areas. (p. 4)

    - **Failed to** ensure vascular access clamps and scissor clamps were fully submerged in bleach solution to ensure proper disinfection. (p. 4)

    - **Failed to** ensure all non-disposable equipment and contaminated surfaces were cleaned and disinfected in manner to prevent cross-contamination between patients. (p. 4)

    - **Failed to** ensure ALL patient care equipment and supplies used in the isolation room for Positive Hepatitis B antigen patients was labeled as dedicated "isolation" equipment and supplies to prevent potential transmission of HBV to HBV susceptible patients

    - **Failed to** use aseptic techniques when preparing medications syringes., (p. 5)

    - **Failed to** ensure a patient's PPE mask fully covered the mouth and nose to prevent potential cross-contamination during initiation of treatment via a central venous catheter (CVC). (p. 5)

Some details regarding BMA's infractions are as follows:

- "The PCT failed to remove their gloves, perform hand hygiene, and don clean gloves after removing the old dressings and before cleansing the area around the CVC exist site with an antiseptic." (p. 7)
- "The soaked white cloths/wipes used for cleaning and disinfection were being stored in a designated dirty area." (p. 10)
- "Observation revealed the PCT failed to first empty the PWC prior to cleaning and disinfecting the surfaces of the machine and failed to remove her contaminated gloves, perform hand hygiene, and don clean gloves after emptying the PWC and before cleaning and disinfecting the machine's surfaces." (p. 14)

- "PCT failed to clean and disinfect the counters around (behind the dialysis station)." (p. 14)
- "The staff do not clean the countertops after each patient treatment." (p. 15)

One of the most concerning issues noted was the lack of care taken with the possible transmission of Hepatitis B.

- "The facility's staff failed to ensure ALL patient care equipment and supplies used in the isolation room for Positive Hepatitis B Antigen (HBsAg+) patients was labeled as dedicated 'isolation' equipment and supplies; to prevent potential transmission to HBV susceptible patients and staff." (p. 15)
- A single RN was assigned to both the isolation room with a Hepatitis B patient and the right side bay, which included susceptible patients NOT immune to Hepatitis B. (p. 19)
- Multiple patients susceptible to Hepatitis B "were concurrently cared for by one or more of the same facility staff members who provided direct patient care" to a Hepatitis B positive patient, and BMA "failed to prevent potential Hepatitis B transmission." (p. 28)
- A nurse provided care to HBV susceptible patients after administering an IV medication to a Hepatitis B patient in the isolation room. (p. 30)

Aseptic techniques were also not followed, as evidenced by the following findings:

- "The PCT failed to clean and disinfect the injection port of the normal saline bag prior to each needle insertion." (p. 33)
- In using an open vial of Heparin, "the PCT failed to disinfect the rubber diaphragm of the medication vial prior to insertion of the needle." (p. 33)

In addition to Infection control the following other issues were noted as well:

- Staff failed to ensure patient vascular accesses and bloodline connections were visible during hemodialysis treatment. (p. 43)
- Facility's RN failed to perform a patient's pre-dialysis treatment assessment prior to starting treatment. In some cases, these assessments were documented after the patient had begun treatment. (p. 47)

Finally, BMA had violations related to managing the patient's volume status, evidencing a lack of attention to detail and a general lack of supervision and care provided to BMA's patients. The facility's patient care staff failed to monitor a patient at a minimum of every 30 minutes during hemodialysis treatments, as required.

Some patients endured dialysis for the following periods of time without being monitored by staff:

- 60 minutes
- 47 minutes
- 42 minutes
- 60 minutes
- 48 minutes

- 40 minutes
- 138 minutes
- 54 minutes

The result of all of these findings, as contained in the BMA East Rocky Mount survey, are that:

> **"The facility's staff failed to develop and implement an effective infection control program that demonstrated recognition of cross-contamination and potential transmission of bloodborne pathogens; as evidence by the facility's inability to ensure the provision of safe infection control practices for all 123 hemodialysis patients on census; resulting in an identification of immediate jeopardy (IJ) to the health and safety of the facility's patients."**

(p. 59) (emphasis added).

The FKC Selma CON application also misrepresents what is contained in the exhibits relating to this BMA East Rocky Mount survey.

Exhibit O-4b to the application is a letter dated January 30, 2017 from the state Agency recommending a 23 day termination from the Medicare Program. Instead of accurately describing this exhibit, the FKC Selma application states that exhibit O-4b is "Notice to BMA that the IJ has been recommended for abatement." This is not true.

In addition, Exhibit O-4a to the application is a letter dated March 2, 2017 from the state Agency recommending removal of the Immediate Jeopardy and recommending that the facility be back in compliance. Instead of accurately describing this exhibit, the BMA application states that exhibit O-4a is "notice that the facility is back in compliance." This is simply false, and there is no evidence in the FKC Selma application that BMA East Rocky Mount was back in compliance.

FMC Four Oaks

The survey for FMC Four Oaks, although not rising to the level of Immediate Jeopardy, also raised the issue of Infection Control, and some of the deficiencies are for 494.30, Infection Control. The issues noted in these surveys demonstrate that there is a pattern of substandard infection control that demonstrates that BMA has not provided adequate quality of care to its patients, and it should be found nonconforming with Criterion 20.

Specifically, the following violations in the FMC Four Oaks survey relate to infection control:

- "The facility's staff failed to wear cover gowns with long sleeves covering forearms and a face mask over the nose during a CVC initiation." (p. 1)
- "The PCT did not remove the prime waste bucket for cleaning and disinfecting that was attached to the dialysis machine. The observation revealed the CT wiped over the prime bucket with a disinfectant cloth but failed to clean and disinfect he prime waste bucket

according to facility policy and procedure by removing it from the machine to empty it before cleaning." (p. 4)

- A "machine's front casing covering above and below the blood flow pump was missing and the irregularity on the surface of the dialysis machine that may allow fluids or blood (and/or dirt or bacteria) to enter the machine, which would be difficult to remove during routine disinfection." (p. 7)

The building was also not maintained in a safe and clean manner, as evidenced by the following findings:

- The surveyor found a dead roach that was squashed and stained on the facility floor located directly beside a chair. (p. 5)
- Broken and cracked tiles were "potentially not able to be cleaned and disinfected as well as potential trip or fall hazards." (p. 6)

Finally, "the facility failed to develop, individualize and implement blood pressure alarm parameters for patient dialysis machines to alert staff for patient abnormal blood pressures for 8 of 8 observed patients." (p. 8). These machines had capabilities to provide this additional layer of safety, such that staff can be notified if a patient's blood pressure goes outside of certain parameters. There is no evidence in the survey that staff even knew about this capability, and staff "had never done anything with setting alarms for the dialysis machines blood pressure." Based on the interview, the machines were likely on their default, factory settings. (p. 9)

Although not rising to the level of an Immediate Jeopardy, this survey reveals serious issues relating to a pattern of infection control problems and provides further support that the FKC Selma application should be found nonconforming with Criterion 20.

<u>RAI West College</u>

The FKC Selma application also misrepresents what is contained in the exhibits relating to the RAI West College survey. It does accurately describe Exhibit O-3a as notice that the facility is back in compliance, but it provides a false and misleading description of Exhibit O-3b. Instead of accurately describing this exhibit, the FKC Selma application states that exhibit O-3b is "Notice to BMA that the IJ has been recommended for abatement." This is not true. In fact, the letter appearing at Exhibit O-3b is the letter from CMS, notifying BMA that "the facility no longer meets the requirements for participation in the Medicare program because of deficiencies that represent an immediate jeopardy to patient health and safety. . . . Accordingly, the Medicare provider/ supplier agreement between RAI Care Centers of North Carolina (West College Warsaw) and the Secretary of [DHHS] is being terminated **<u>effective April 17, 2016</u>**." (emphasis in original)

By reviewing p. 79 of the FKC Selma application alone, the reader is erroneously led to the believe the that supporting documents provided do nothing more than notify BMA that its facilities are back in compliance and that Immediate Jeopardy status has been recommended for

abatement. As described above, many of these statements are false and misleading, and the documents are not as described.

Even if these BMA facilities have been deemed to have returned to compliance with the Medicare Conditions of Participation by the date the application is submitted and a Plan of Correction has been accepted, the serious incidents giving rise to the Immediate Jeopardy status at BMA East Rocky Mount and RAI West College should be considered and taken into account by the Agency in evaluating Criterion 20. Additionally, the FMC Four Oaks survey indicates quality issues and a pattern of infection control problems at a facility which is proposing to transfer stations to develop the FKC Selma facility.

Criterion 20 does not ask whether a facility has been brought back into compliance as of the date a CON application is submitted or is back in compliance by the date the CON Section makes a decision. Instead, this statutory provision requires the Agency to evaluate whether an applicant already involved in the provision of health services has provided evidence that quality care has been provided in the past. Discussed herein and attached to these comments are surveys that demonstrate that BMA has not provided quality care in the past, and BMA should be found nonconforming with Criterion 20.

Conclusion

The applicant has presented a CON applications based on the July 2017 Semiannual Dialysis Report with the intent to keep a monopoly of dialysis services for the End Stage Renal Disease patients living in Johnston County.

DaVita Inc. reserves the right to provide additional documentation in opposition to the development of the Fresenius Kidney Care Selma. DaVita Inc. is requesting a Public Hearing on the above referenced certificate of need application. We respectfully request that the public hearing be held on or before September 19th.

Davita intends to submit an application on September 15, 2017 for a new dialysis facility to address the station deficit in Johnston County. Were the FKC Selma application to be approved, despite the numerous and significant non-conformities identified in these comments, Davita would be substantially harmed, prejudiced, and disadvantaged in its efforts to develop a Johnston County facility. This would also be a great disservice Johnston County's citizens.

Davita requests that the CON Section deny the FKC Selma application.

Sincerely,

William L. Hyland

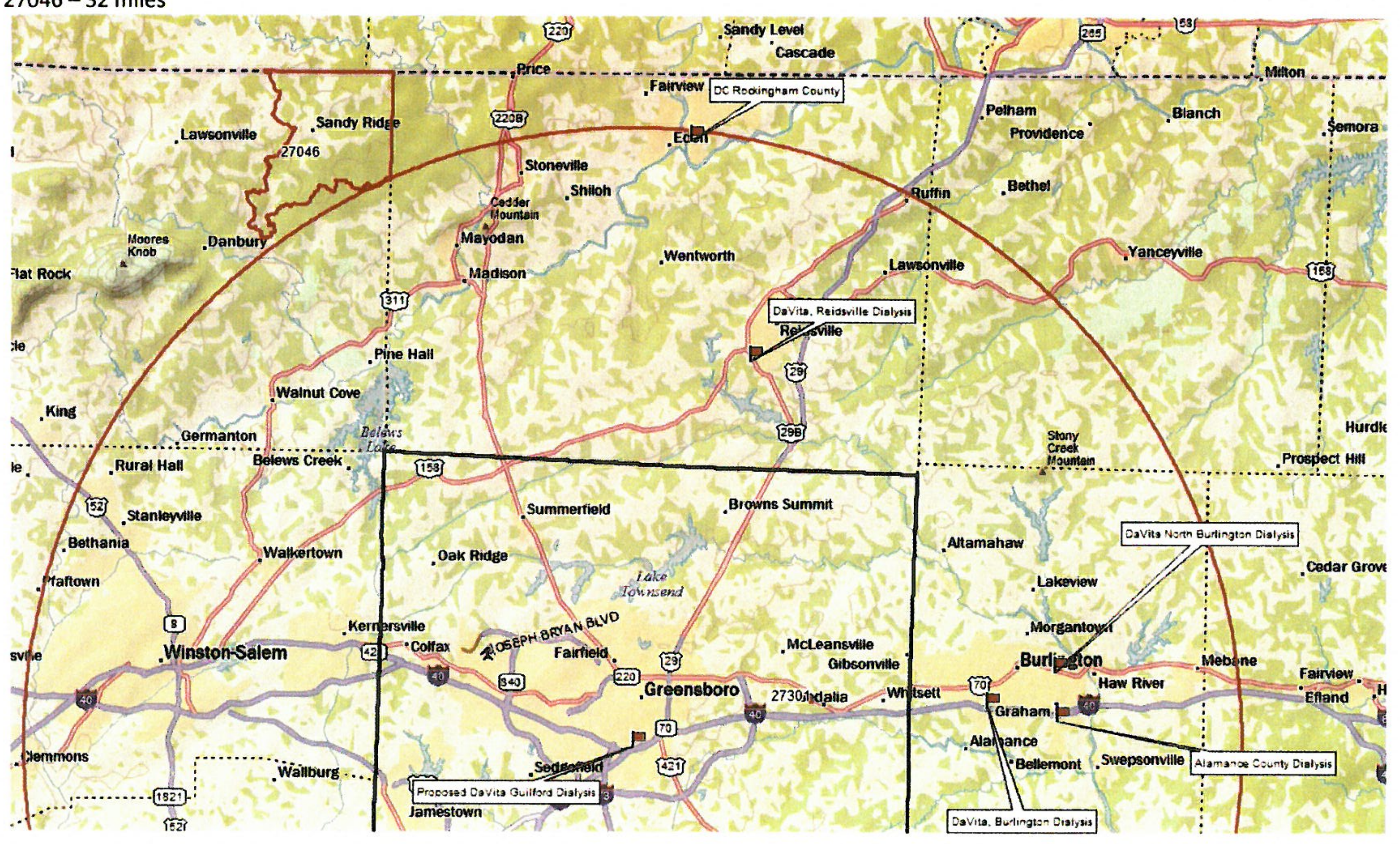
William L. Hyland
Director or Healthcare Planning

c: Martha Frisone, Chief
Lisa Pittman, Team Leader

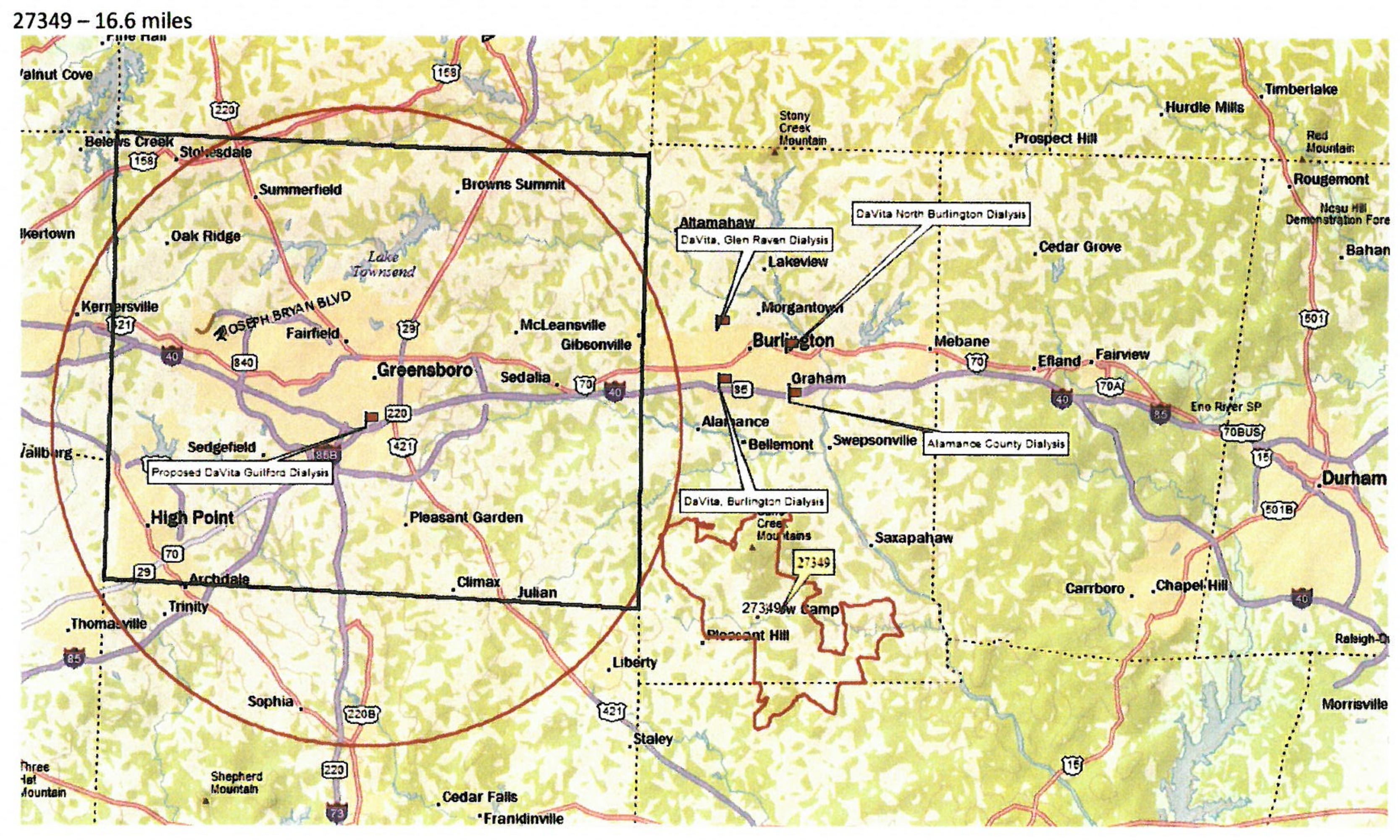
Exhibits

Attachment
8

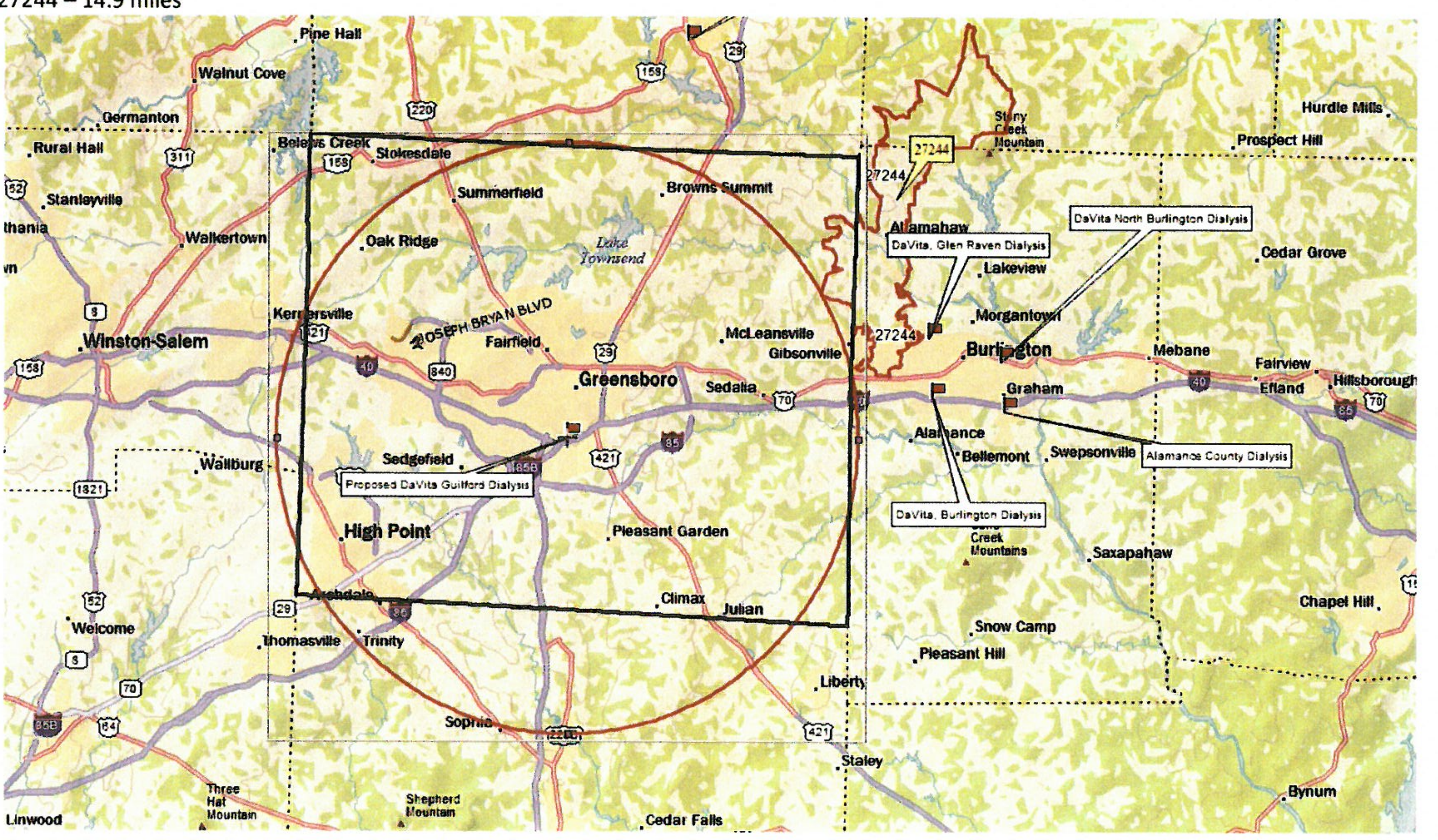
27046 – 32 miles



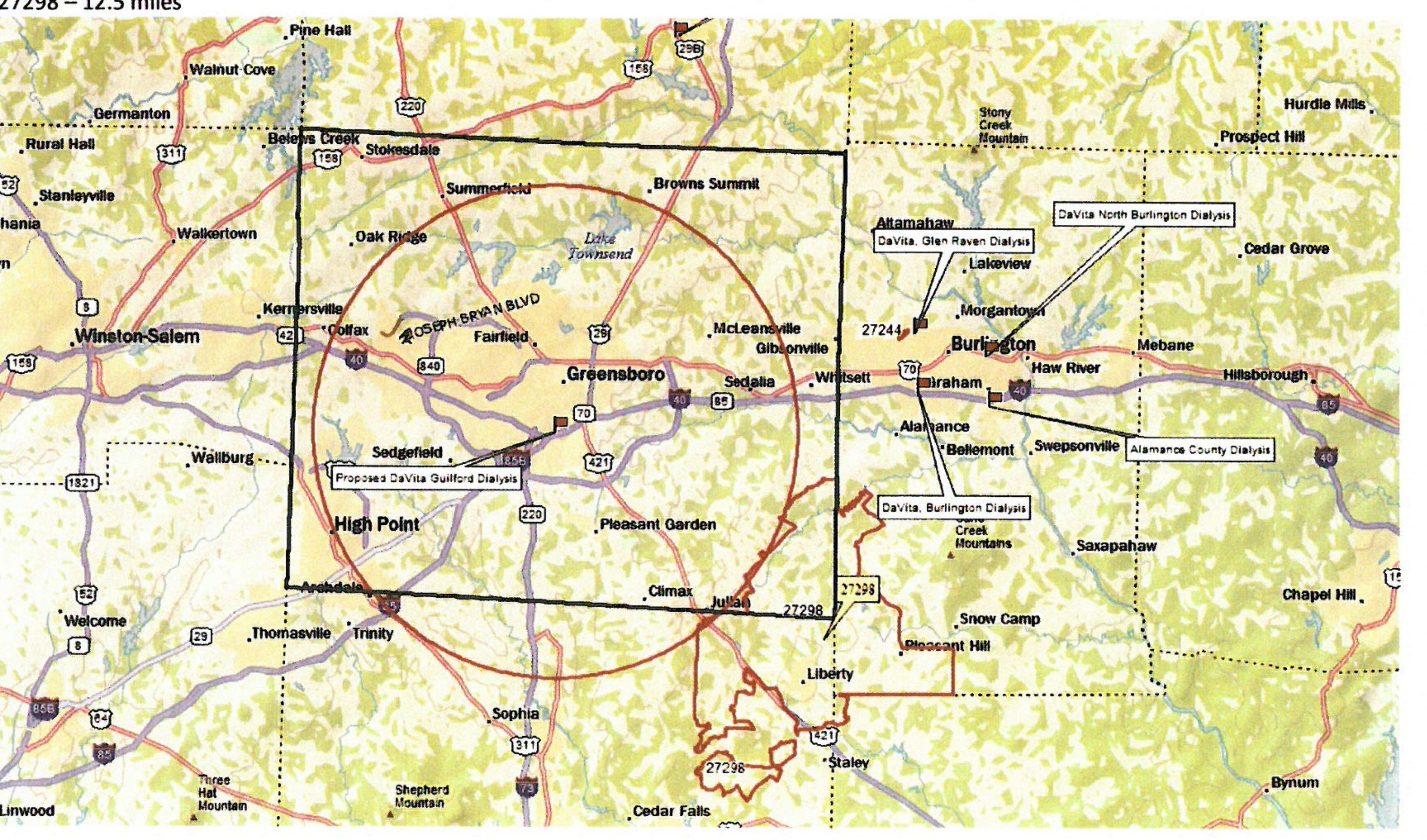
27349 – 16.6 miles



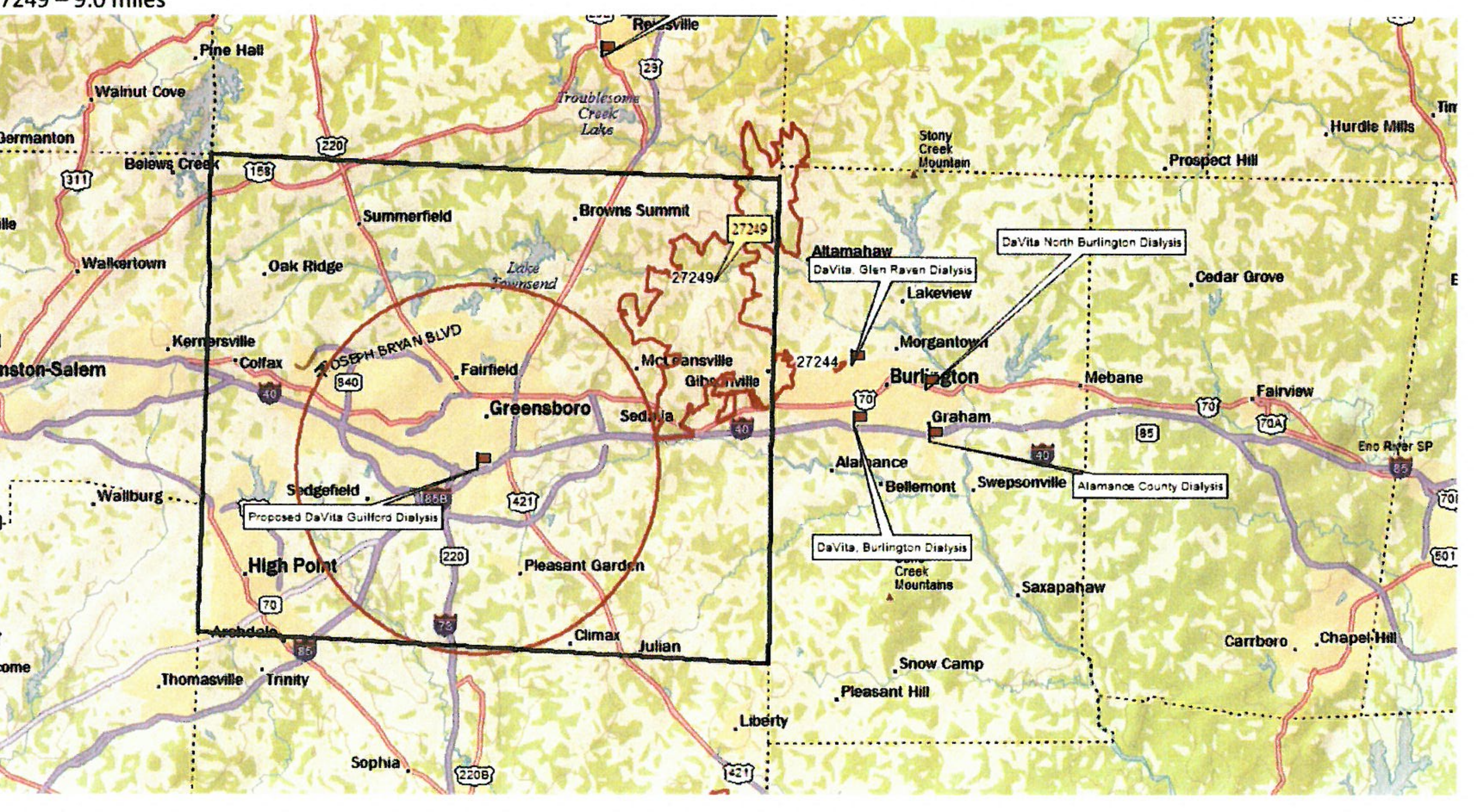
27244 – 14.9 miles



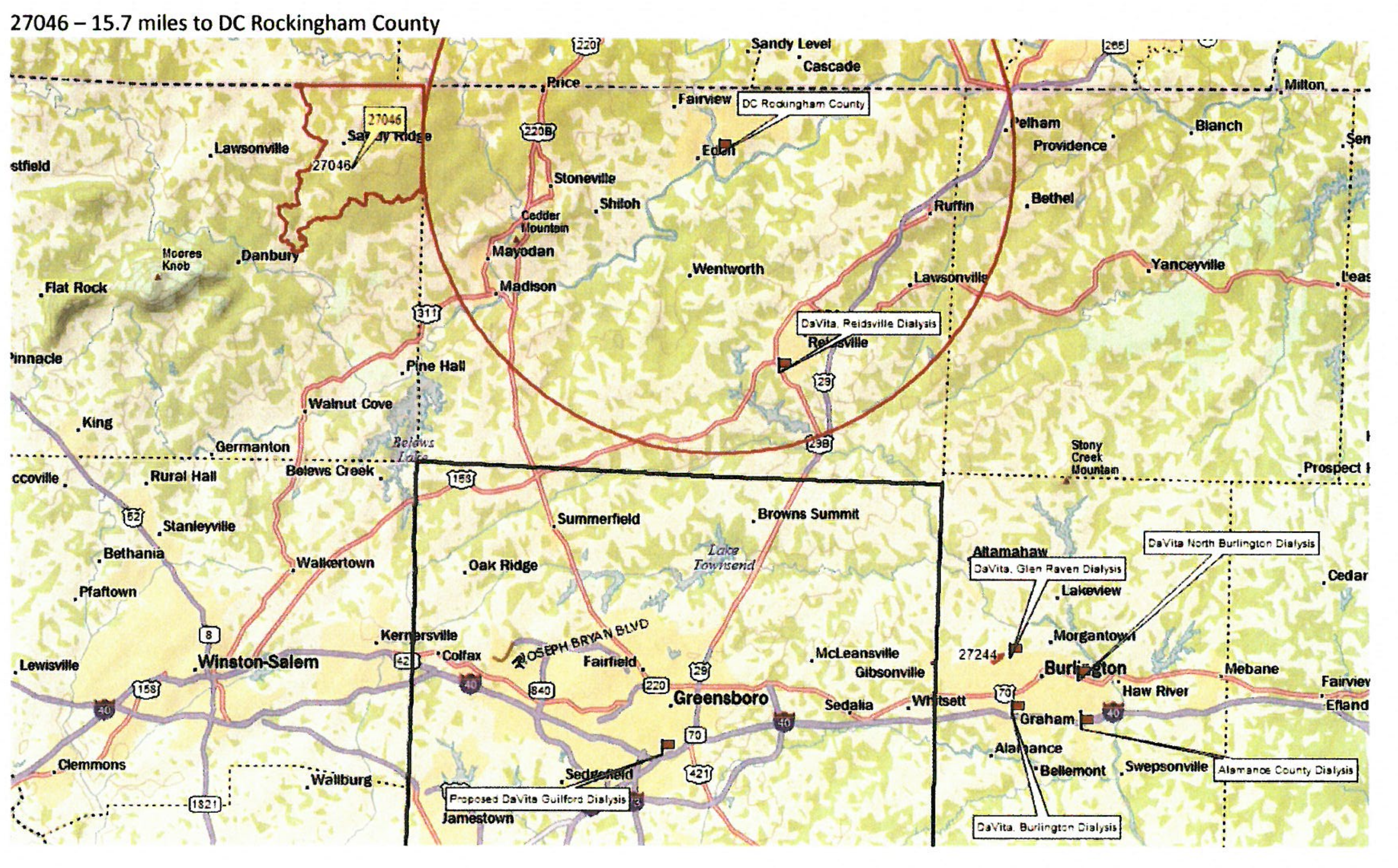
27298 – 12.5 miles



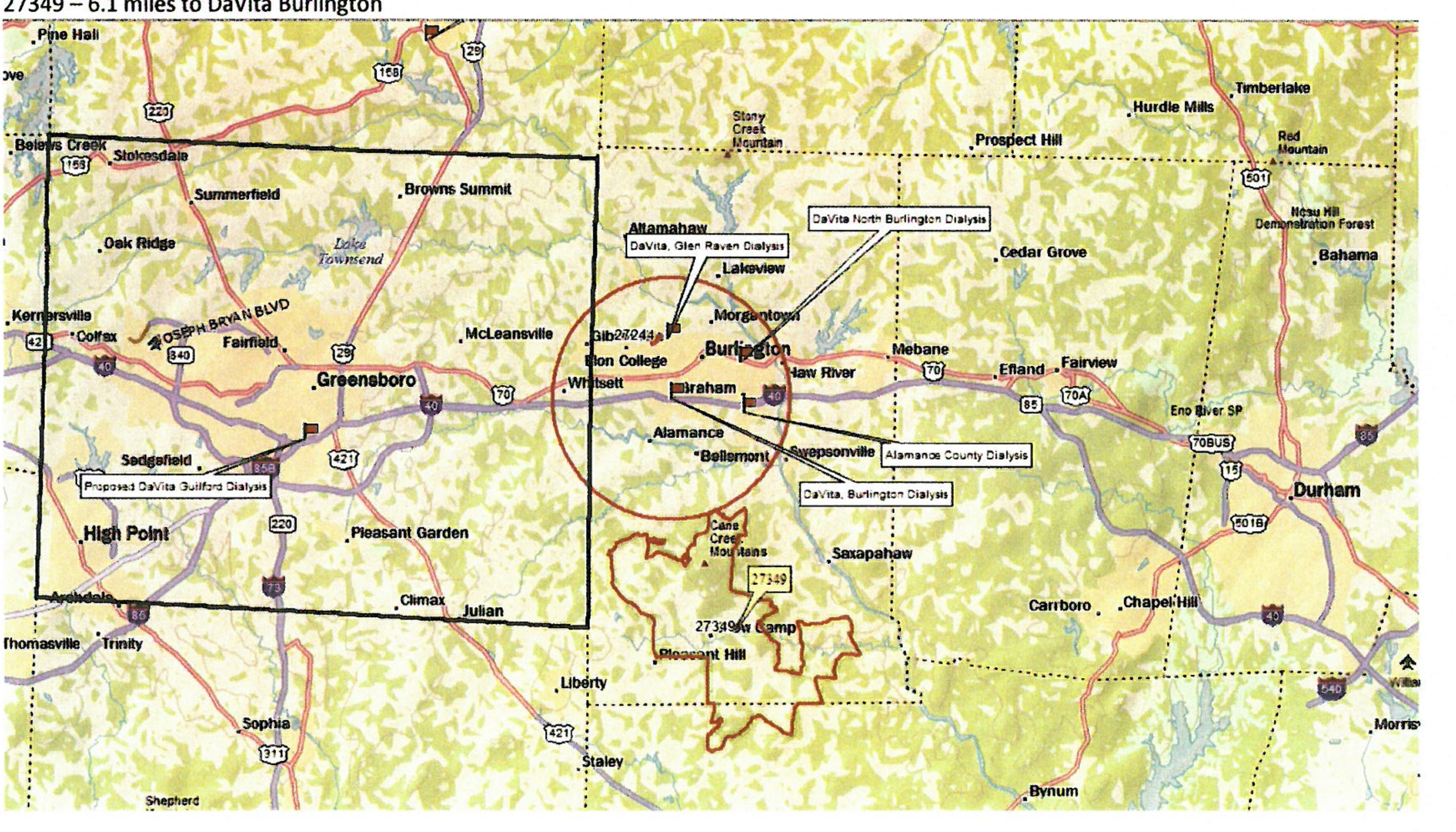
27249 – 9.0 miles



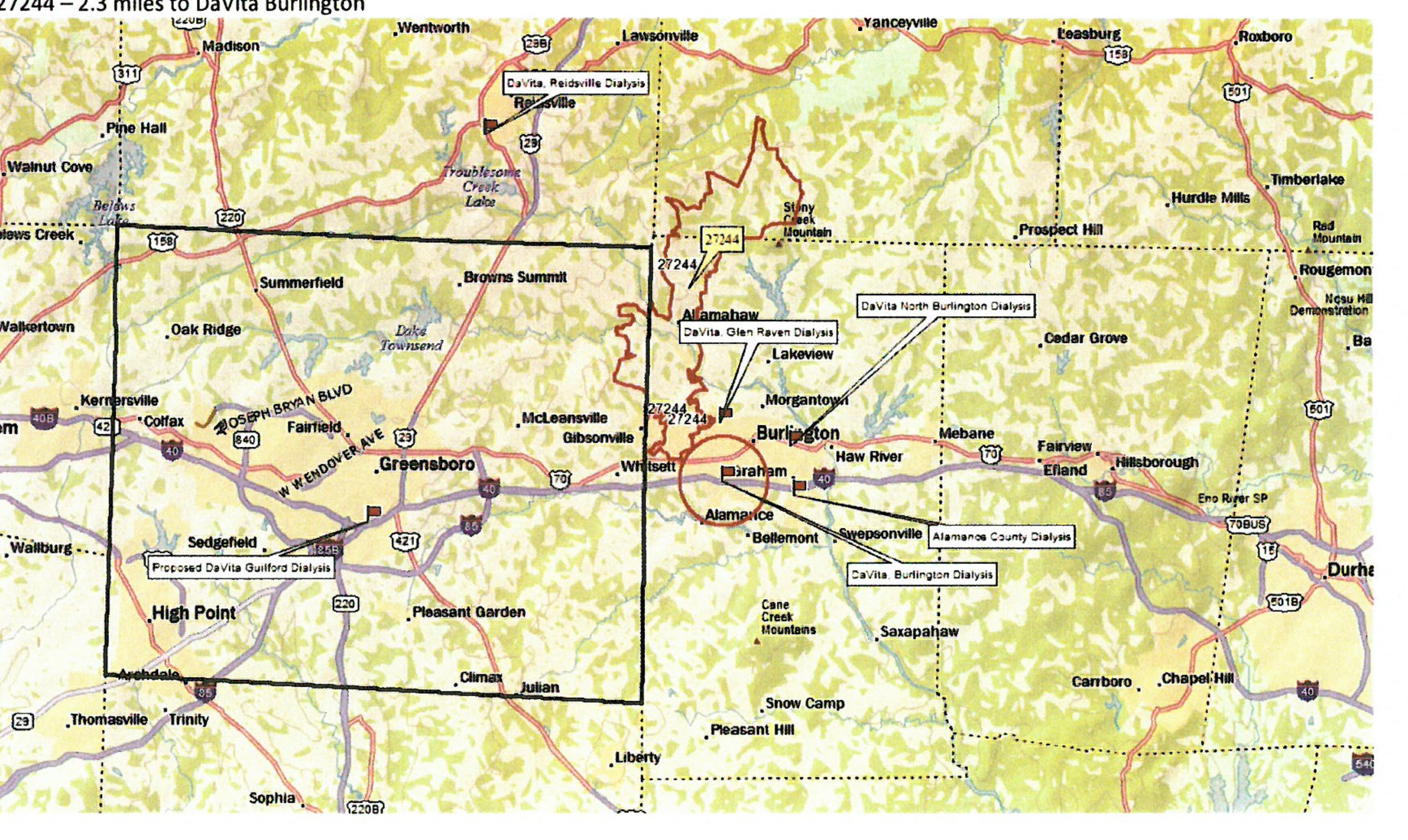
27046 – 15.7 miles to DC Rockingham County



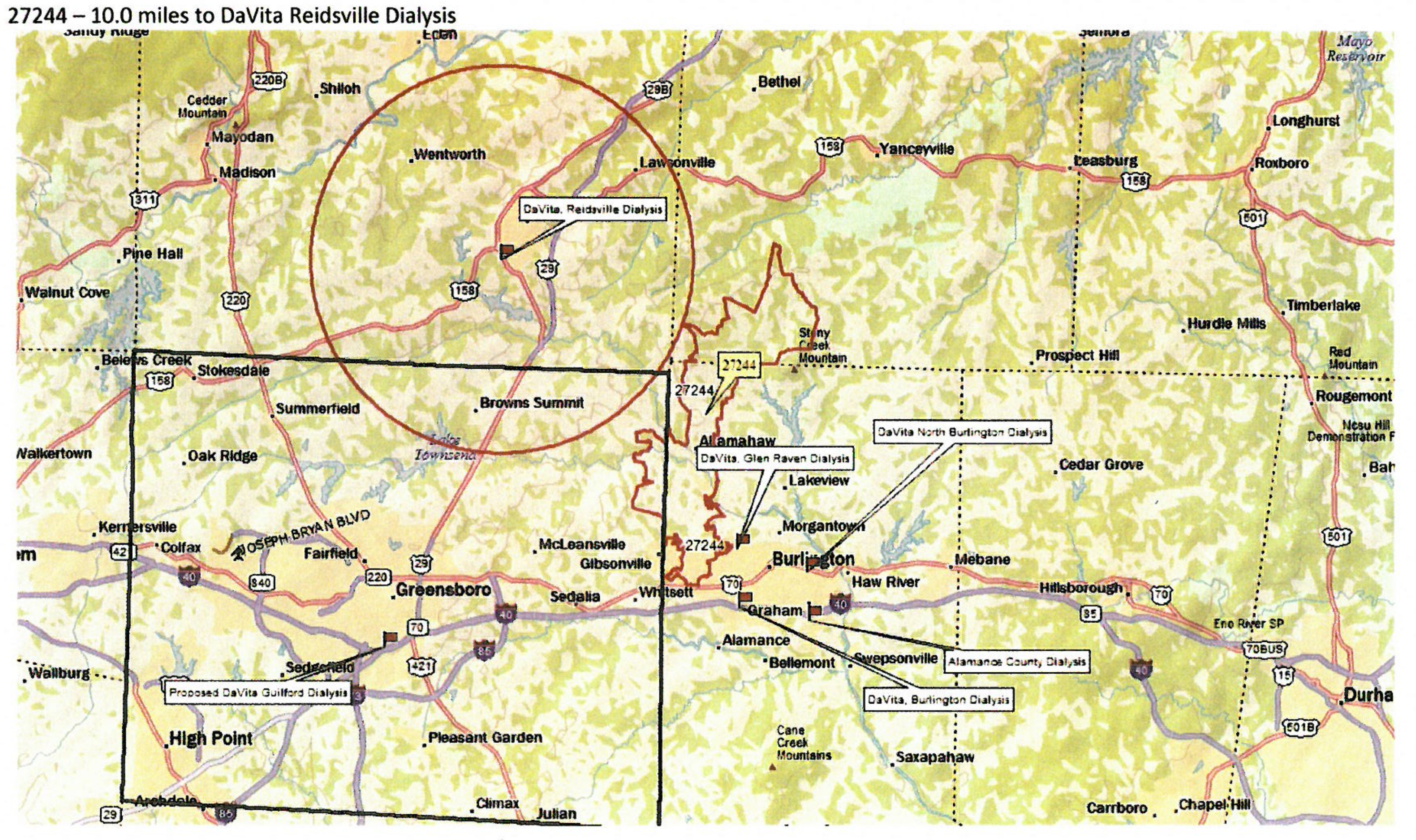
27349 – 6.1 miles to DaVita Burlington



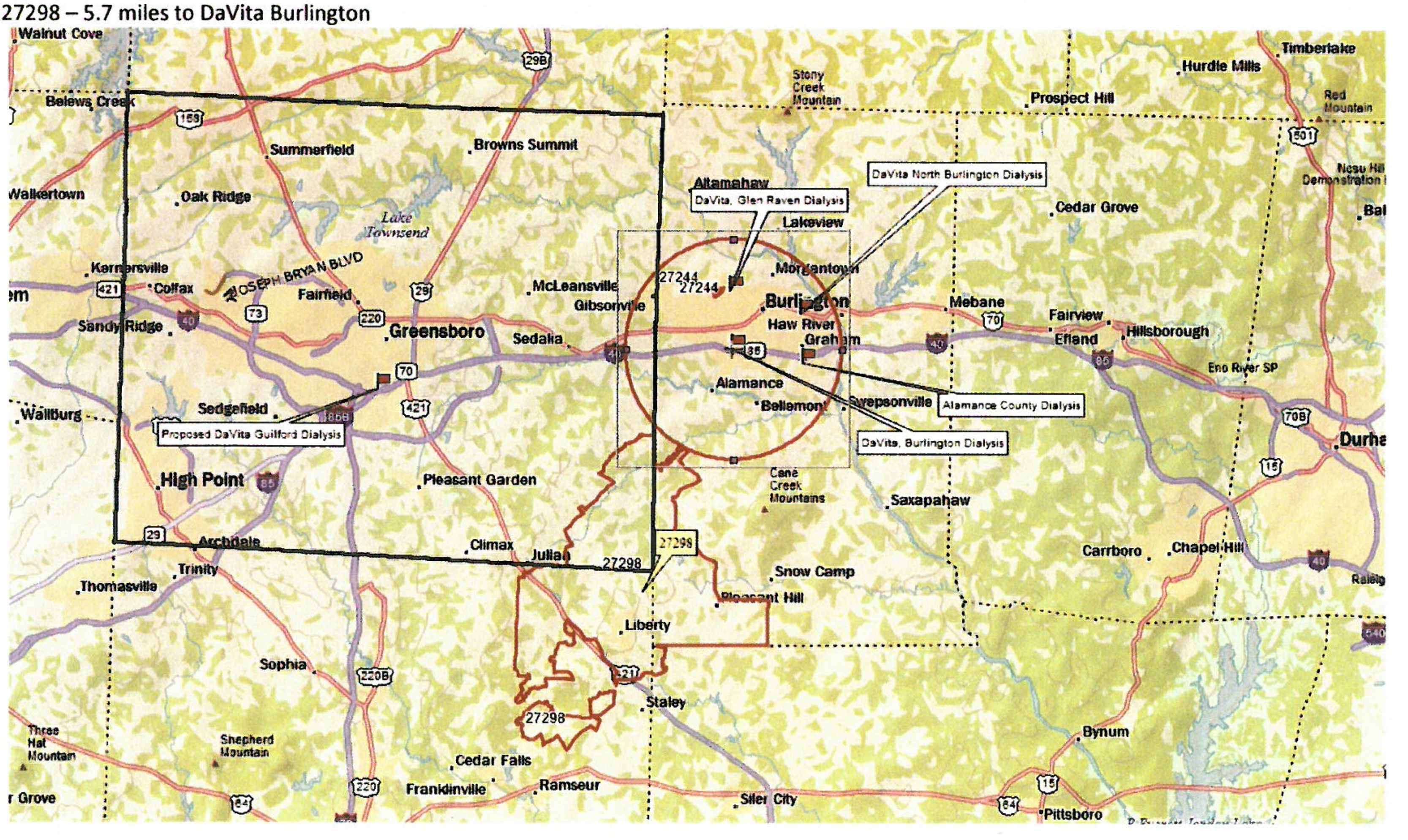
27244 – 2.3 miles to DaVita Burlington



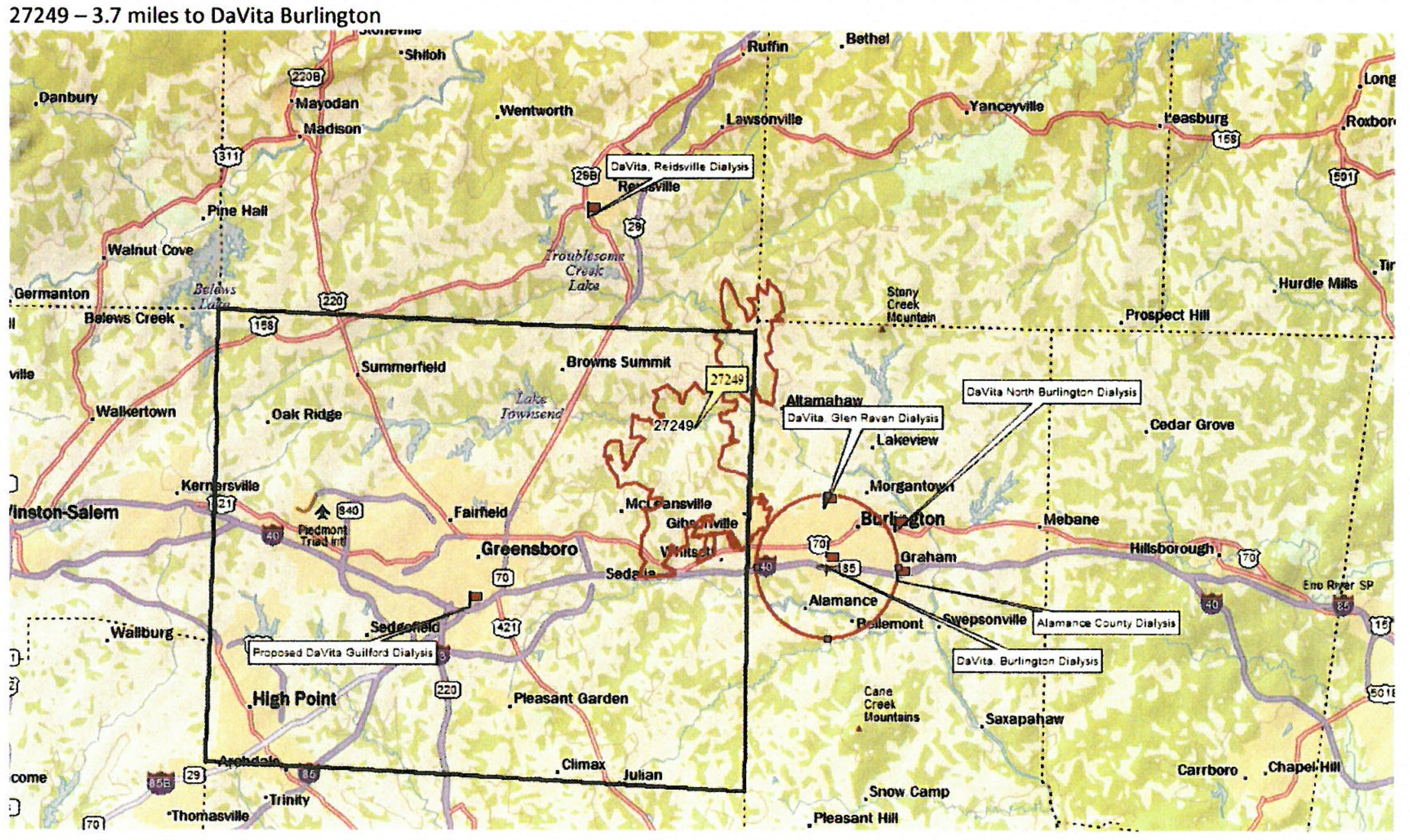
27244 – 10.0 miles to DaVita Reidsville Dialysis



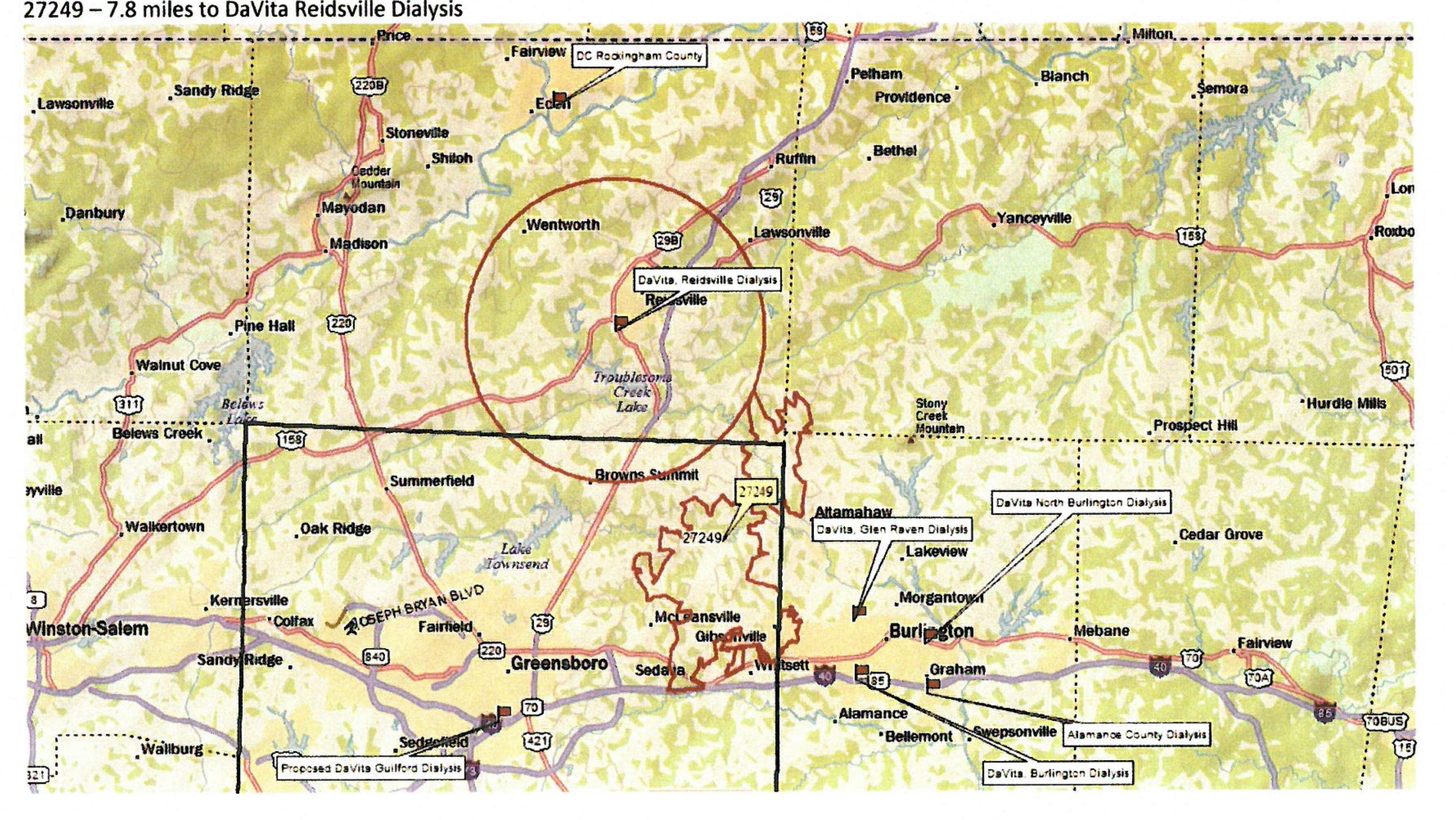
27298 – 5.7 miles to DaVita Burlington



27249 – 3.7 miles to DaVita Burlington



27249 – 7.8 miles to DaVita Reidsville Dialysis



Attachment
9

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
10

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.

stations, not three as indicated in the above quote by the applicant. Moreover, the applicant proposes space for home dialysis training for which they do not demonstrate a need. The application is consistent with the facility need determination for three dialysis stations.

Policy GEN-3 in the 2011 SMFP is applicable to this review. Policy GEN-3 states:

> *"A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project shall promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area."*

Promote Safety and Quality

In Section I.13(c), page 7, the applicant states:

> "*The DaVita multidisciplinary care team works closely* [sic] *our physicians to provide optimal care for our patients. In fact, DaVita has delivered patient outcomes well above national standards in terms of key dialysis metrics, URRs, Kt/Vs, hematocrits, and other clinical dialysis indicators. ...*
>
> *DaVita utilizes the 'DaVita Quality Index', a unified measure of clinical performance for dialysis facilities. Seven individual clinical parameters have been weighted and combined in to a unified clinical metric. This simplified clinical scoring system allows for clinical differentiation among dialysis facilities ... The intent is to evaluate overall clinical care and drive improvement to benefit dialysis patients.*"

The applicant provides additional information regarding quality of care in Exhibit 4. Therefore, the applicant adequately demonstrates it will promote safety and quality of care in the provision of the services proposed to be provided.

Promote Equitable Access

In Section VI.1 (a), page 29, the applicant states:

> *"Wallace Dialysis Center, by policy, has always made dialysis services available to all residents in its service area without qualifications. We have served and will continue to serve without regard to race, sex, age, handicap, or ethnic and socioeconomic groups of patients in need of dialysis regardless of their ability to pay.*

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.

In Exhibit 9, the applicant provides a copy of a March 1, 2011 letter from DaVita to James Sprunt Community College in Kenansville, offering Wallace Dialysis Center as a clinical training site for student nurses. Therefore, the application is conforming with 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.

NC

Total Renal Care of North Carolina, LLC d/b/a/ Wallace Dialysis Center, does not adequately demonstrate that the proposal would have a positive impact upon the cost effectiveness, quality and access to the services proposed for the reasons below. Cost effectiveness is addressed in Sections II (page 11), III (pages 20-21), and V (pages 27-28). Quality is addressed in Sections I (page 7), II (page 16), V (pages 27-8), VII (page 34) and Exhibit 4. Access is addressed in Sections V (pages 27-28) and VI (pages 29-32).

a) the applicant does not adequately demonstrate that the proposal is a cost effective alternative [See Criteria (1), (3) (5) and (12)].

Therefore, the application is not conforming with this criterion because the applicant does not adequately demonstrate that the proposal will have a positive impact upon cost effectiveness.

(19) Repealed effective July 1, 1987.

(20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C

The applicant adequately demonstrates that Wallace Dialysis provided quality care in the past. The files in the Acute and Home Care Licensure and Certification Section of the Division of Health Service Regulation show that the facility operated in compliance with the Medicare Conditions of Participation, and there were no incidents resulting in a determination of immediate jeopardy within the eighteen months immediately preceding the date of this decision. Therefore, the application is conforming with this criterion.

Attachment
11

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 12

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS
C = Conforming
CA = Conditional
NC = Nonconforming
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
13

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS
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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%**

Attachment
14

QuickFacts

selected: **Guilford County, North Carolina; Alamance 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	Guilford County, North Carolina	Alamance County, North Carolina	North Carolina
Population estimates, July 1, 2016, (V2016)	**521,330**	**159,688**	**10,146,788**
PEOPLE			
Population			
Population estimates, July 1, 2016, (V2016)	**521,330**	**159,688**	**10,146,788**
Population estimates base, April 1, 2010, (V2016)	488,464	151,144	9,535,688
Population, percent change - April 1, 2010 (estimates base) to July 1, 2016, (V2016)	6.7%	5.7%	6.4%
Population, Census, April 1, 2010	488,406	151,131	9,535,483
Age and Sex			
Persons under 5 years, percent, July 1, 2016, (V2016)	6.0%	5.8%	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	23.4%	23.5%	23.9%
Persons 65 years and over, percent, July 1, 2016, (V2016)	14.4%	16.7%	15.5%
Persons 65 years and over, percent, April 1, 2010	12.3%	14.6%	12.9%
Female persons, percent, July 1, 2016, (V2016)	52.6%	52.5%	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)	57.4%	74.8%	71.0%
Black or African American alone, percent, July 1, 2016, (V2016) (a)	34.6%	20.0%	22.2%
American Indian and Alaska Native alone, percent, July 1, 2016, (V2016) (a)	0.8%	1.4%	1.6%
Asian alone, percent, July 1, 2016, (V2016) (a)	4.9%	1.6%	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)	2.3%	2.1%	2.2%
Hispanic or Latino, percent, July 1, 2016, (V2016) (b)	7.9%	12.6%	9.2%
White alone, not Hispanic or Latino, percent, July 1, 2016, (V2016)	51.2%	64.6%	63.5%
Population Characteristics			
Veterans, 2011-2015	29,345	10,096	696,119
Foreign born persons, percent, 2011-2015	9.9%	7.8%	7.7%
Housing			
Housing units, July 1, 2016, (V2016)	226,711	69,159	4,540,498
Housing units, April 1, 2010	218,017	66,576	4,327,528
Owner-occupied housing unit rate, 2011-2015	59.6%	65.4%	65.1%
Median value of owner-occupied housing units, 2011-2015	$156,100	$138,100	$154,900
Median selected monthly owner costs -with a mortgage, 2011-2015	$1,264	$1,172	$1,248
Median selected monthly owner costs -without a mortgage, 2011-2015	$401	$347	$373
Median gross rent, 2011-2015	$771	$745	$797
Building permits, 2016	2,204	1,353	60,550
Families & Living Arrangements			
Households, 2011-2015	199,540	61,545	3,775,581
Persons per household, 2011-2015	2.46	2.45	2.54
Living in same house 1 year ago, percent of persons age 1 year+, 2011-2015	86.0%	85.4%	84.7%
Language other than English spoken at home, percent of persons age 5 years+, 2011-2015	12.7%	12.4%	11.2%

Education			
High school graduate or higher, percent of persons age 25 years+, 2011-2015	88.2%	83.2%	85.8%
Bachelor's degree or higher, percent of persons age 25 years+, 2011-2015	34.1%	21.6%	28.4%
Health			
With a disability, under age 65 years, percent, 2011-2015	7.1%	10.3%	9.6%
Persons without health insurance, under age 65 years, percent	▲ 13.2%	▲ 14.1%	▲ 12.2%
Economy			
In civilian labor force, total, percent of population age 16 years+, 2011-2015	64.0%	62.5%	61.8%
In civilian labor force, female, percent of population age 16 years+, 2011-2015	59.1%	58.2%	57.7%
Total accommodation and food services sales, 2012 ($1,000) (c)	1,158,488	254,425	18,622,258
Total health care and social assistance receipts/revenue, 2012 ($1,000) (c)	3,512,781	801,896	55,227,505
Total manufacturers shipments, 2012 ($1,000) (c)	26,932,176	3,138,351	202,344,646
Total merchant wholesaler sales, 2012 ($1,000) (c)	14,111,449	627,214	105,275,586
Total retail sales, 2012 ($1,000) (c)	6,979,731	2,108,413	120,691,007
Total retail sales per capita, 2012 (c)	$13,935	$13,698	$12,376
Transportation			
Mean travel time to work (minutes), workers age 16 years+, 2011-2015	21.3	23.7	23.9
Income & Poverty			
Median household income (in 2015 dollars), 2011-2015	$45,651	$41,814	$46,868
Per capita income in past 12 months (in 2015 dollars), 2011-2015	$26,762	$23,434	$25,920
Persons in poverty, percent	▲ 15.7%	▲ 18.9%	▲ 15.4%

BUSINESSES

Businesses			
Total employer establishments, 2015	13,246	3,153	223,209[1]
Total employment, 2015	258,166	56,328	3,670,284[1]
Total annual payroll, 2015 ($1,000)	11,472,846	2,166,786	164,936,258[1]
Total employment, percent change, 2014-2015	1.4%	10.2%	3.1%[1]
Total nonemployer establishments, 2015	39,823	9,727	722,639
All firms, 2012	45,746	10,990	805,985
Men-owned firms, 2012	22,594	5,939	435,677
Women-owned firms, 2012	17,884	3,804	287,058
Minority-owned firms, 2012	14,168	2,283	183,380
Nonminority-owned firms, 2012	29,574	8,295	603,182
Veteran-owned firms, 2012	4,438	1,203	86,571
Nonveteran-owned firms, 2012	38,576	9,138	684,743

GEOGRAPHY

Geography			
Population per square mile, 2010	756.4	356.5	196.1
Land area in square miles, 2010	645.70	423.94	48,617.91
FIPS Code	37081	37001	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 Qu 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 th 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, Sm Poverty Estimates, State and County Housing Unit Estimates, County Business Patterns, Nonemployer Statistics, Economic Census, Survey of Business Owners, Building Permits.