FRESENIUS KIDNEY CARE

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 # J-11410-17, Clayton 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 in Wilson County, to develop a new 10-station dialysis facility in Johnston County. The applicant has filed an application which must be denied for myriad reasons.

BMA filed a CON application for FKC Selma, CON Project ID # J-11372-17 on July 17, 2017, two months prior to the TRC application. The FKC Selma application proposed to relocate four dialysis stations from FMC New Hope in Wake County as a part of a proposal to develop a 10 station dialysis facility in Selma, Johnston County. Approval of the FKC Selma CON application will reduce the Johnston County station deficit from 11 stations, as reported in the July 2017 SDR, to seven stations. As a consequence, TRC can not be approved to develop its proposed facility, since approval of the TRC application would result in a surplus of dialysis stations in Johnston County. Policy ESRD-2 requires an applicant for a Certificate of Need to *"demonstrate that the proposal shall not result in a surplus…of dialysis stations in the county that would gain stations…"*

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.

In this case, TRC was well aware of the BMA proposal to develop the FKC Selma project. DaVita Dialysis, parent organization to TRC, filed public written comments opposing the FKC Selma project, and also requested a public hearing on that project.

TRC is well aware that approval of the FKC Selma proposal necessarily reduces the Johnston County dialysis stations deficit to less than 10 stations. The 2017 SMFP, in Chapter 14, Basic Principle #2 requires that *"[N]ew facilities must have a projected need for at least 10 stations..."* Since the station deficit would be less than 10 stations, and since TRC could not develop a facility with less than 10 stations, the Agency must deny the TRC application for its facility in Clayton.

TRC's Application Should be denied for other failures and inconsistencies:

1. 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 Wilson County to Clayton. However, the applicant has proposed that only one third (11 of 32 patients) of its projected patient population would be residents of Johnston County. Despite providing 40 in-center patient letters of support[1], the applicant has not provided any description of the "*need that that the population to be served has for the proposed project...*"

   At least one of the patient letters of support does not include a zip code of residence. Further, that patient is not a dialysis patient, but is suffering with Chronic Kidney Disease (CKD) meaning the patient may eventually need dialysis. However, there is no indication from the patient, or a nephrologist, of how soon that need might arise. Absent more information, the Agency has no way of determining if that patient will need the facility, or if the patient would be well served by the proposed facility.

   At least one of the patient letters of support included in Exhibit C-1 is actually a letter for the DaVita proposal in Guilford County.

[1] The applicant includes more letters; not all are from in-center dialysis patients.

One of the patient signatures appears to be a duplicate of a patient who signed a letter of support for the DaVita application to develop its Nash County dialysis facility (an application filed in September 2013)[2]. This letter should be rejected since the applicant has already assumed this patient to transfer to another facility.

The applicant states on page 15 that the projected patient population would include patients who reside in Nash County (one patient), Wake County (13 patients), and Wilson County (seven patients). The applicant proposes to serve only 11 Johnston County patients. The applicant proposes to serve 21 patients residing in other counties.

The applicant has two operational dialysis facilities in Wilson County, and a third facility under development. The proposed location is at least 18.75 miles straight line distance to the nearest part of Wilson County. The applicant has included 16 letters of support from patients residing in Wilson County. Both of the applicant's existing facilities in Wilson County are in Wilson. It is a straight line distance of only 13.5 miles from Wilson Dialysis (the facility closest to the Wilson/Johnston boundary) to the same point where the two counties are contiguous, and closest to the proposed location for Clayton Dialysis. It is not reasonable to suggest that patients will travel further for dialysis.

The applicant has one operational facility in Wake County, and a second facility under development. The Wake County patients would travel further for dialysis, if going to the proposed facility. This is not consistent with the representations of the patient letter of support.

The applicant has a facility under development in Nash County. The patient from Nash County would travel further for dialysis, if going to the proposed facility. This is again, not consistent with the representations of the patient letter of support.

Review Criterion 3 requires the applicant to identify the population to be served and to demonstrate the need that this population has for the services proposed. 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 40 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 Clayton, which in most cases is going to be a further travel distance than their current dialysis facility.

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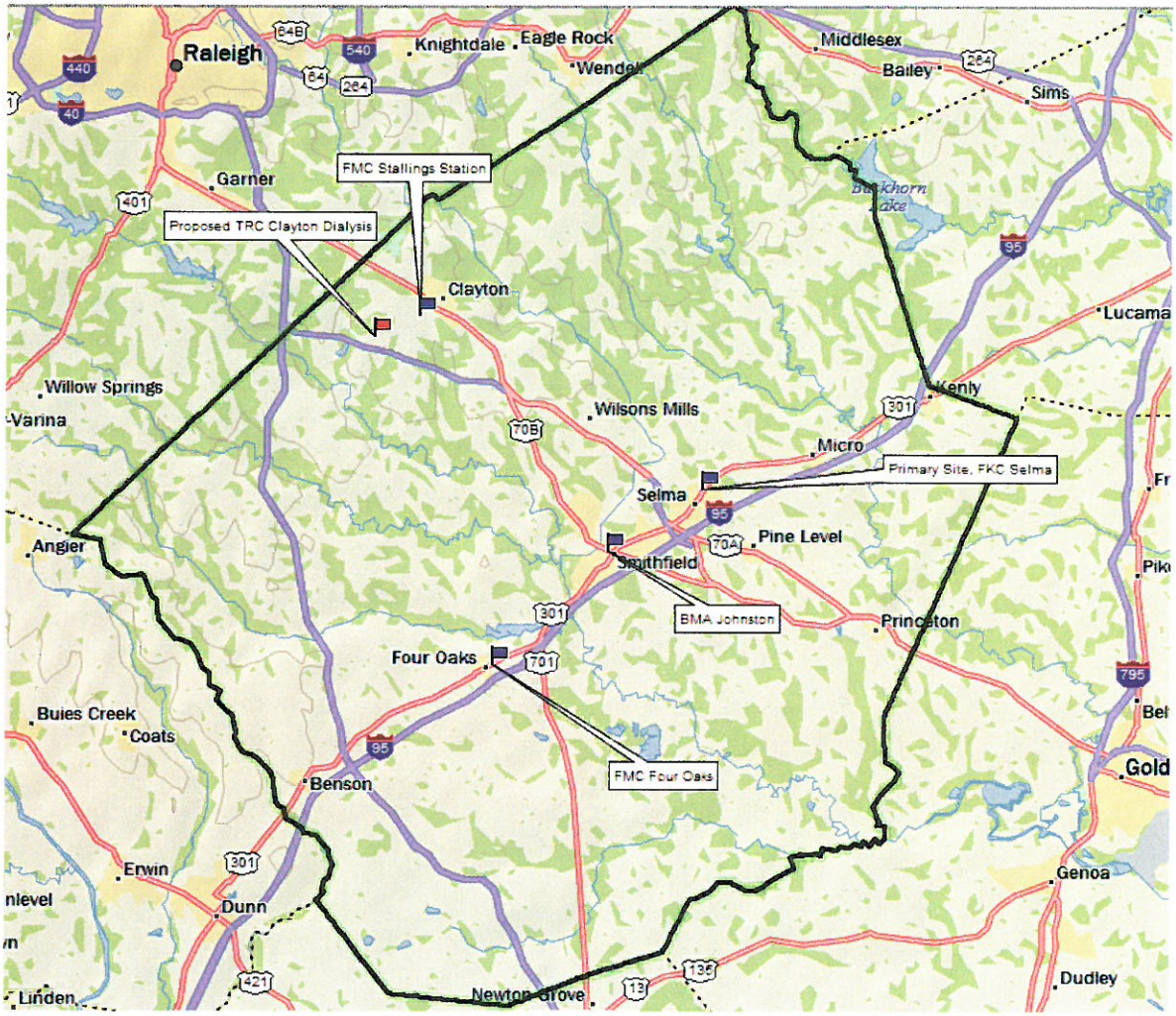
[2] See Attachment 1

Furthermore, the applicant has not adequately demonstrated the need that these patients have for dialysis services at the proposed location. The proposed location is simply not proximate to the patients residing in Nash, Wake and Wilson Counties. The following map identifies the primary location of the proposed facility.



The patient support letters do not state the patient's county of residence. However, the letter does state the patient's zip code and the applicant has included a table on page 15 of the application identifying the patient residence zip code and county of residence. Of the 40 in-center patient letters provided, only 10[3] of the patients actually reside within Johnston County. Thus, 30 of the patients, or 75% reside in counties other than Johnston.

[3] This is not an error. The applicant has apparently counted the one CKD patient as an in-center dialysis patient. Based upon the letter of support, at the time of the application that patient was not receiving dialysis.

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	
Wake County	2.4 miles west
Nash County	17.75 miles northeast
Wilson County	18.75 miles northeast

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
Wilson County	27880, 27893, 27896	16
Nash County	27807	4
Wake County	27513, 27519, 27526, 27545, 27597, 27604, 27610	10
Total		30

BMA has mapped the proposed facility, and existing DaVita facilities in Wilson County and Wake County. BMA has also mapped the zip code boundaries for each of the zip codes which are primarily located outside of Johnston County. The maps are included at Attachment 2 to these comments. The maps will demonstrate that at least 20 of the patients identified by letters of support actually reside closer to DaVita dialysis facilities in Wilson County. Those patients residing in zip codes 27807, 27880, 27893, and 27896 would have a significantly shorter commute to dialysis at either of the DaVita facilities in Wilson.

Zip codes 27513 and 27519 are in the Cary area of Wake County. These patients are much closer to the DaVita facilities in Raleigh, or even in Durham County as opposed to the proposed facility in Clayton.

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

One must question why is this reasonable? Why would 30 patients, 75% of those 40 in-center patients, actually travel further for dialysis than they currently do? 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?

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.

The applicant did include a single patient letter of support from a patient residing in zip code 27520, the same zip code as the proposed facility.

The applicant also included a single patient letter of support from zip code 27504, and one letter from a patient residing in 27577, and seven letters from patients residing in 27542. But this is only 10 Johnston County patients.

However, the SMFP requires an application to demonstrate a need for 10 dialysis stations, based on a utilization rate of 80%. Utilization by 10 patients on 10 dialysis stations is only 25.0%, or 1. patient per station. The applicant has provided no explanation why the remaining patients need to travel further for their dialysis care than they do now.

It is not reasonable to expect patients to travel further for dialysis. In the Denial for CON Project ID # F-8073-08 (Attachment 3), a proposal by BMA to develop a 10 station facility at Huntersville, the Analyst noted on page 13 of the findings, *"[I]t is likewise not clear from the information presented by the applicant how it anticipates that 40 of its current patients will travel from existing BMA facilities to the proposed Huntersville location, when only 12 patients who reside in the four Northern Mecklenburg County ZIP Codes ... will actually see a reduction in travel."*

The same must be true here. Of the patient letters of support provided by the Applicant, 30 patients reside in zip codes outside of Johnston County. It is not clear from the information presented how the applicant anticipates that at least 32 of its 40 current in-center patients will transfer their care to the proposed new facility when only 10 of those 40 patients reside within Johnston County and possibly closer to the new facility location.

2. The applicant has provided unfounded, unsupported and unreasonable projections of a home hemodialysis patient population to be served. Consider the Required State Agency Findings for CON Project ID# P-8641-11 (Attachment 4, an application by Total Renal Care off North Carolina, LLC to add three stations to their Wallace Dialysis Center in Duplin County. On page 8 of the findings, the Project Analyst notes that the applicant *"provides no assumptions, methodology or projected utilization for home dialysis patients."* It is incumbent upon the applicant to provide a reasonable and supportive 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.

3. 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 50% in the first year of operations, and by 33% in the second year of operations of the facility. However, the applicant has not provided any basis for growth rates of this nature.

   The information provided by the applicant is internally inconsistent. The applicant suggests that both of the PD patients proposed to transfer their care to the Clayton facility are currently receiving their care through the DaVita Wake Forest facility. However, only one of the patient letters of support is from a patient of the Wake Forest Facility.

   Further, the Johnston County ESRD patient population is increasing at a rate of only 6.3%, not the rates suggested by the application. It is not reasonable to expect the home patient population to increase at such rates. The applicant has not provided any supporting documentation from referring physicians to support such growth rates.

   The July 2017 SDR, Table A, Patient Origin Report, indicates that DaVita facilities were providing care for only seven of the 30 home patients residing in Johnston County. Absent any supporting documentation from the applicant, or the referring physicians, it is simply not reasonable to expect growth rates in the range of 50%, or even 33% when the applicant is serving such a small patient population.

4. The applicant states on page 19 of the application that, *"[B]ased on an analysis of the demographics of Johnston County* ***and the information available about our patient population*** *that lives in or near Johnston County, it was determined that Clayton would be the best location for the development of the proposed Clayton Dialysis."* (Emphasis added). It is most interesting that TRC has determined to develop in Clayton, while TRC serves a single patient residing in the Clayton zip code 27520.

5. The application should be found non-conforming to CON Review Criterion 6. BMA has proposed to relocate four dialysis stations from its FMC New Hope dialysis facility in Raleigh, Wake County, as a part of the proposal for FKC Selma. Approval of the FKC Selma application will necessarily reduce the Johnston County station deficit below 10. Approval of the TRC proposal would un-necessarily duplicate existing dialysis capability for Johnston County.

6. On page 48 of the application the applicant indicates that it proposes to lease 10,182 square feet of space for the project. This is an excessive amount of space for 10 station dialysis facility. Leasing and upfit for excessive space is an un-necessary capital expenditure. This is clearly not the best alternative for the project.

Assuming that the floor plan provided in Exhibit K-1 is accurate, BMA suggests that the applicant is over developing space for a 10 station dialysis facility. The applicant proposes to have 3,322 square feet available for the 10 stations. While the application says on page 47 that the Dialysis Stations would have only 1,154 square feet, the floor plan indicates nearly 300% more space for the dialysis 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."*[4]

The plan provided by the applicant includes approximately 369 square feet per station. This assumes one station is set aside for for isolation/separation; thus the in-center treatment floor would have a total of nine dialysis stations in 3,322 square feet. Further, the floor plan does not identify a space for the proposed home hemodialysis training.

Furthermore, the applicant proposes to develop 629 square feet for home training. This is 629 square feet dedicated to serving only four PD patients and three 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 seven 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

7. 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 Wilson County during the last full operating year, and that because Wilson and Johnston Counties are contiguous it was reasonable to rely upon that information as it developed a projected payor mix.

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[4] FGI, 2010 edition, Guidelines for Design and Construction of Health Care Facilities, paragraph 3.10-3.2.2 Space Requirements, page 283. See Attachment 5.

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[5] competitive review and the 2011 Northampton County[6] competitive review. In both cases the Project Analyst considered elements such as minority populations and poverty levels. The following table offers clear contrasts between Wilson and Johnston Counties.

	Johnston	Wilson
Persons 65 and over	12.9%	17.3%
African American	16.2%	40.6%
Persons in Poverty	13.0%	19.9%

Source: US Census Bureau Quick Facts[7]

The table indicates that Wilson County has an older patient population with a higher percentage of its population over the age of 65, a higher percentage of African Americans, and a higher percentage of persons living in poverty. 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 Johnston County and Wilson 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.

8. Exhibit A-9 does not include the referenced certification letters.

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

[5] Attachment 6, page 34
[6] Attachment 7, page 34
[7] Attachment 8

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

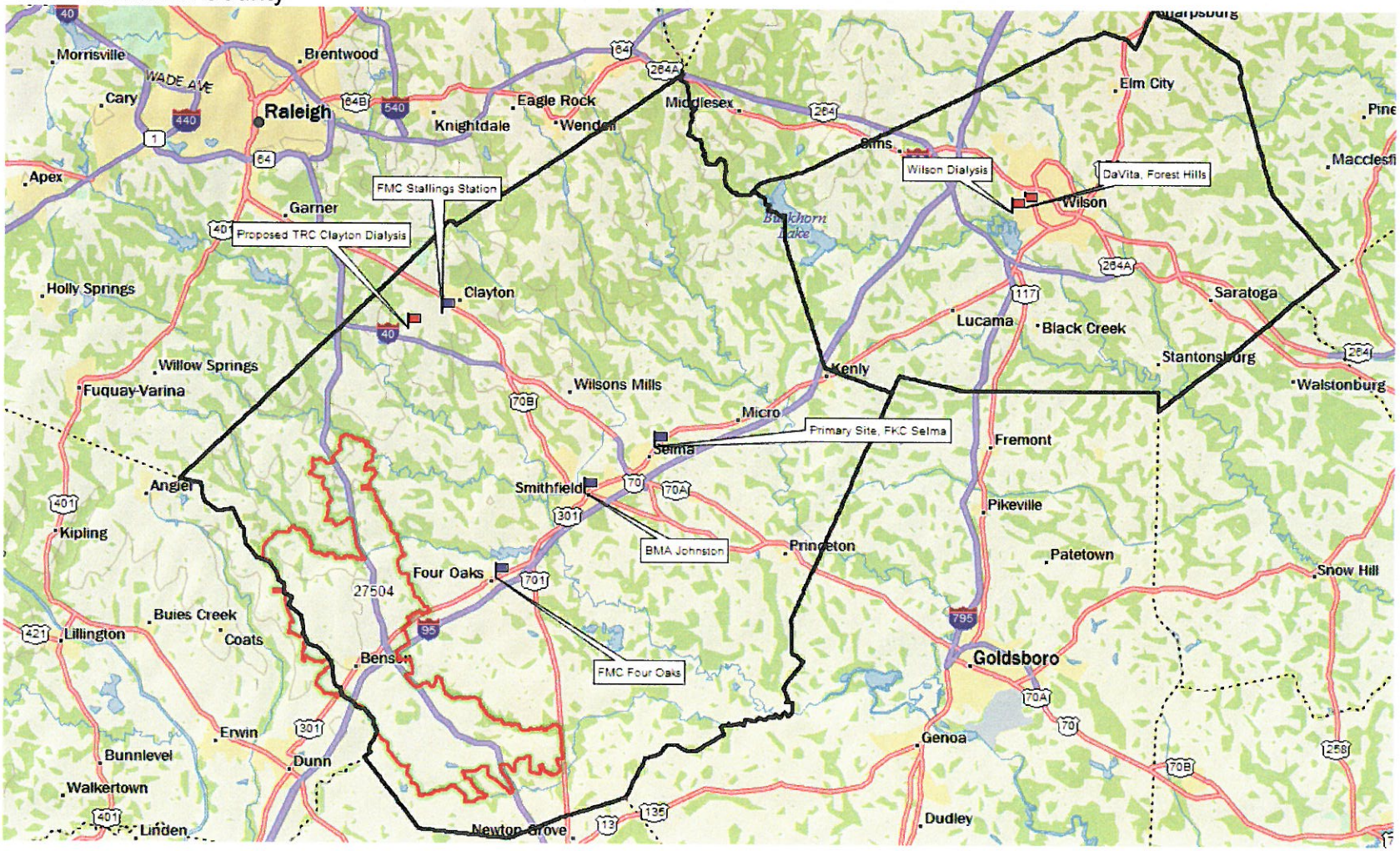
Sincerely,

Jim Swann
Director of Operations, Certificate of Need

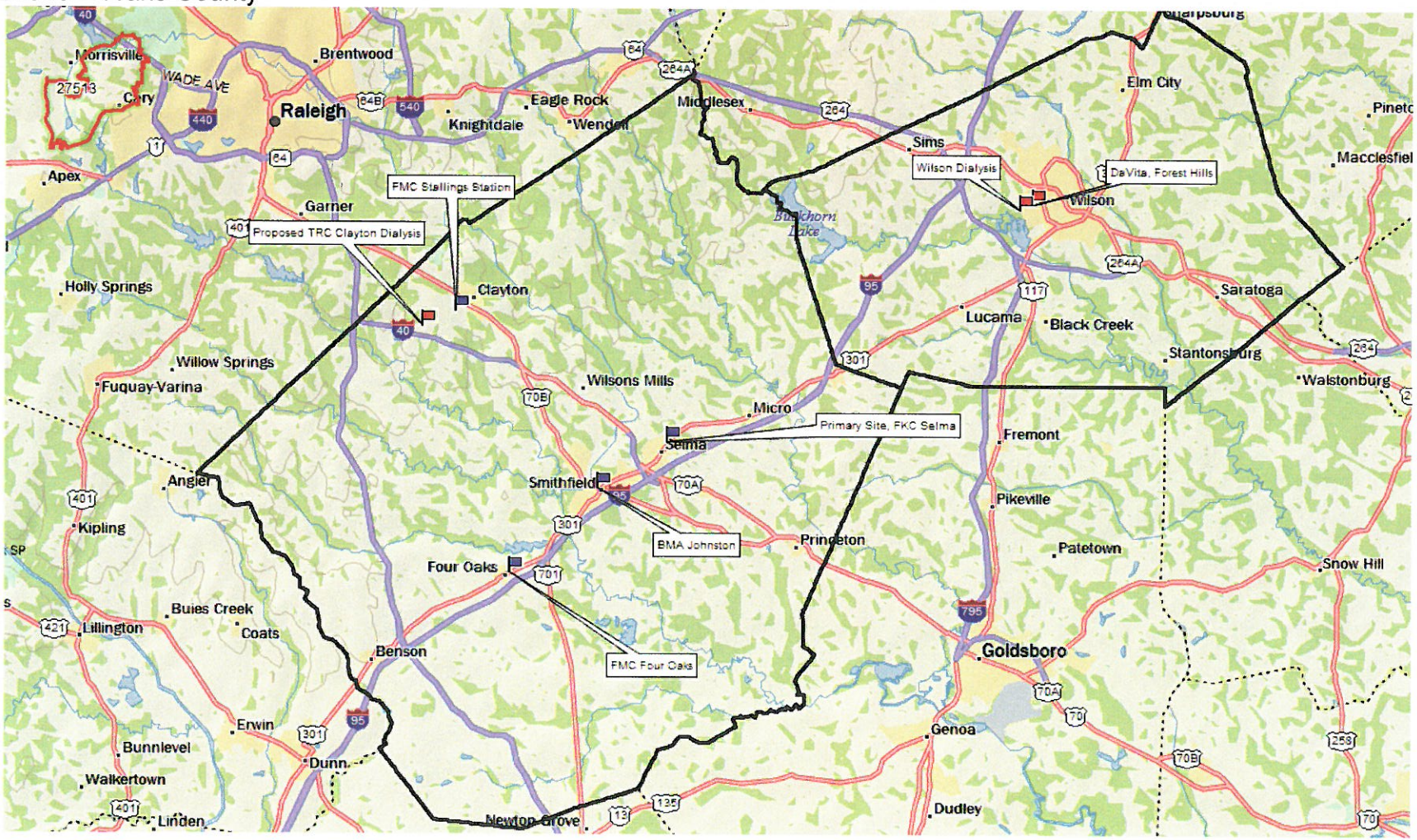
8 Attachments:

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

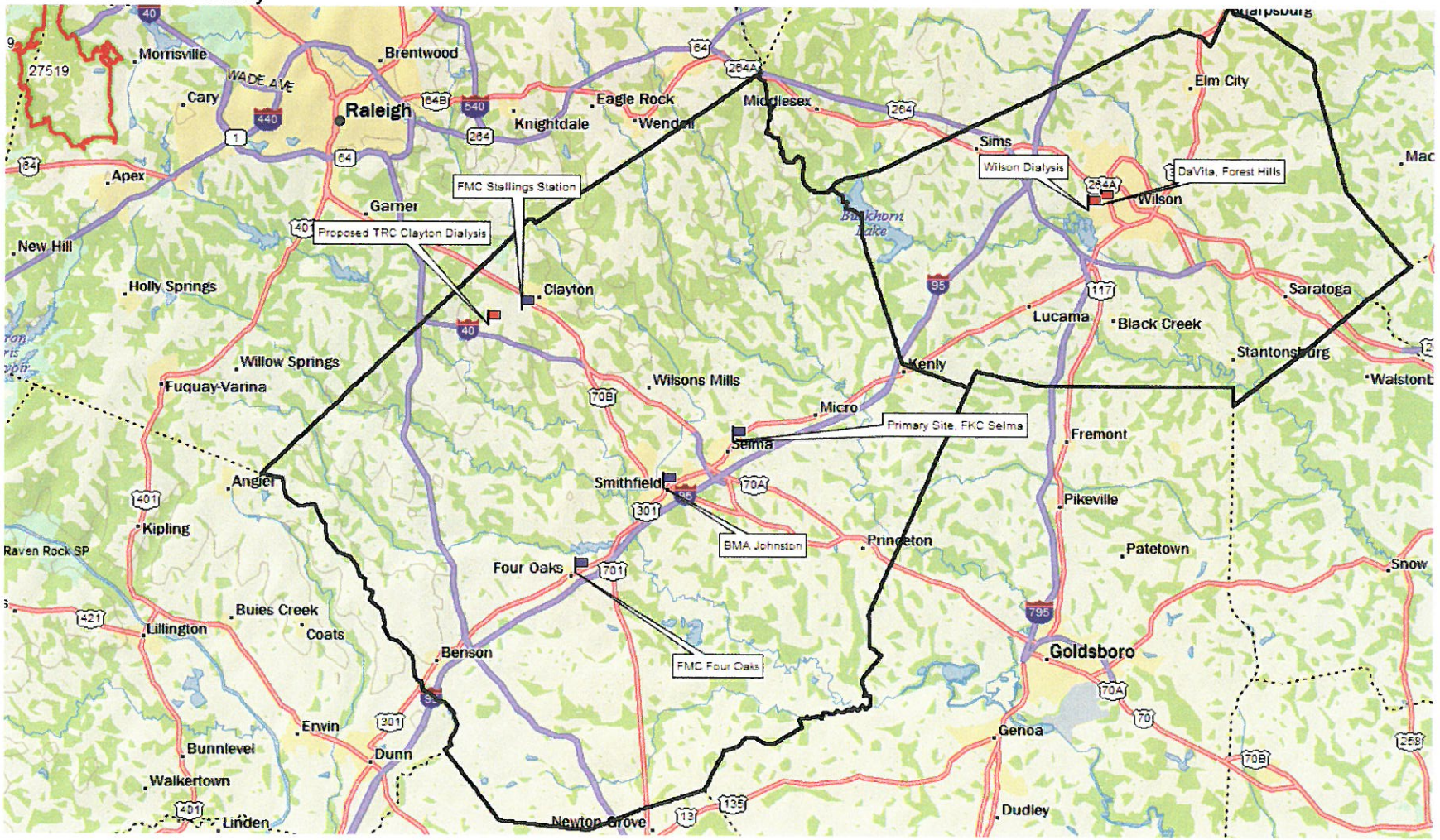
27504 – Johnston County



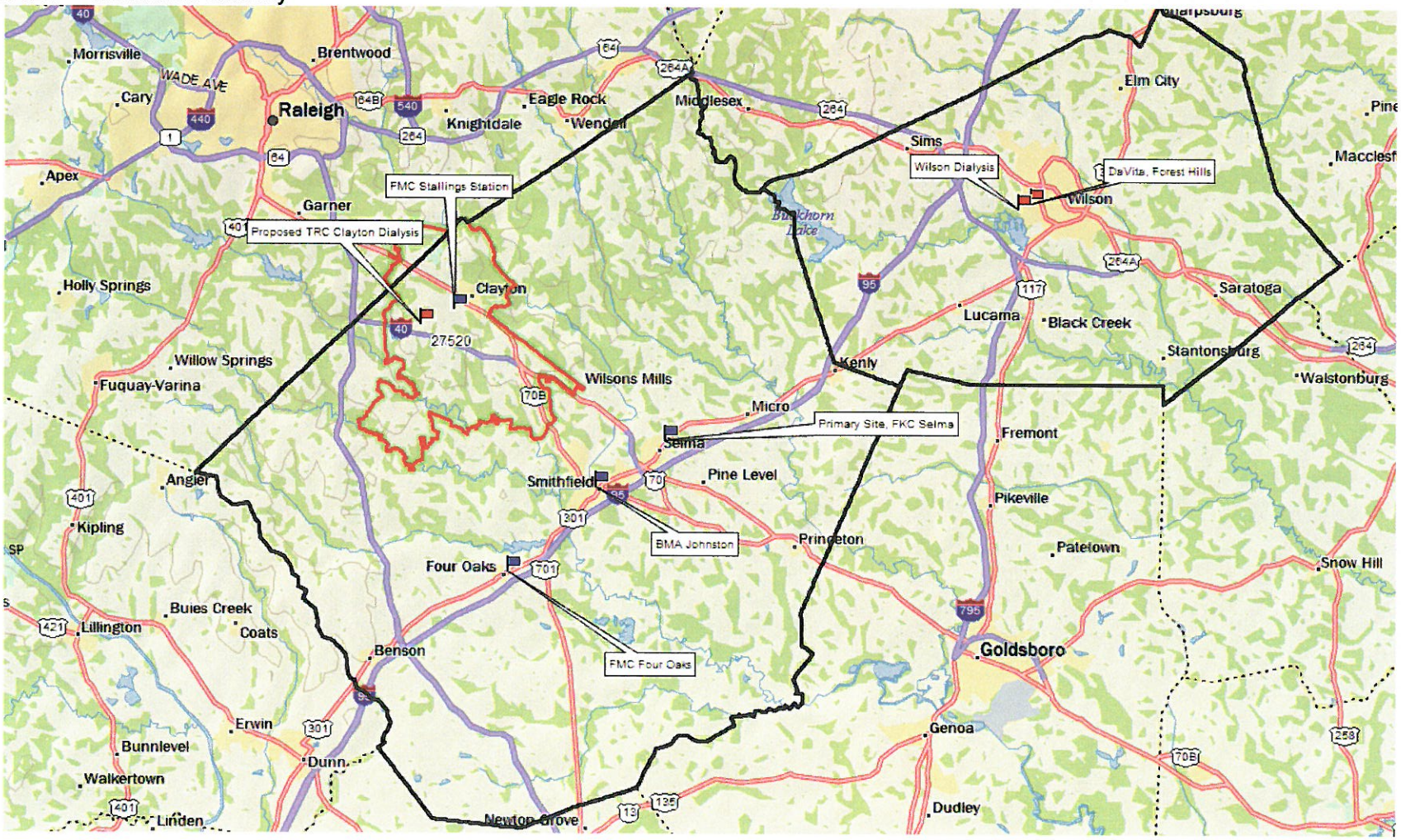
27513 – Wake County



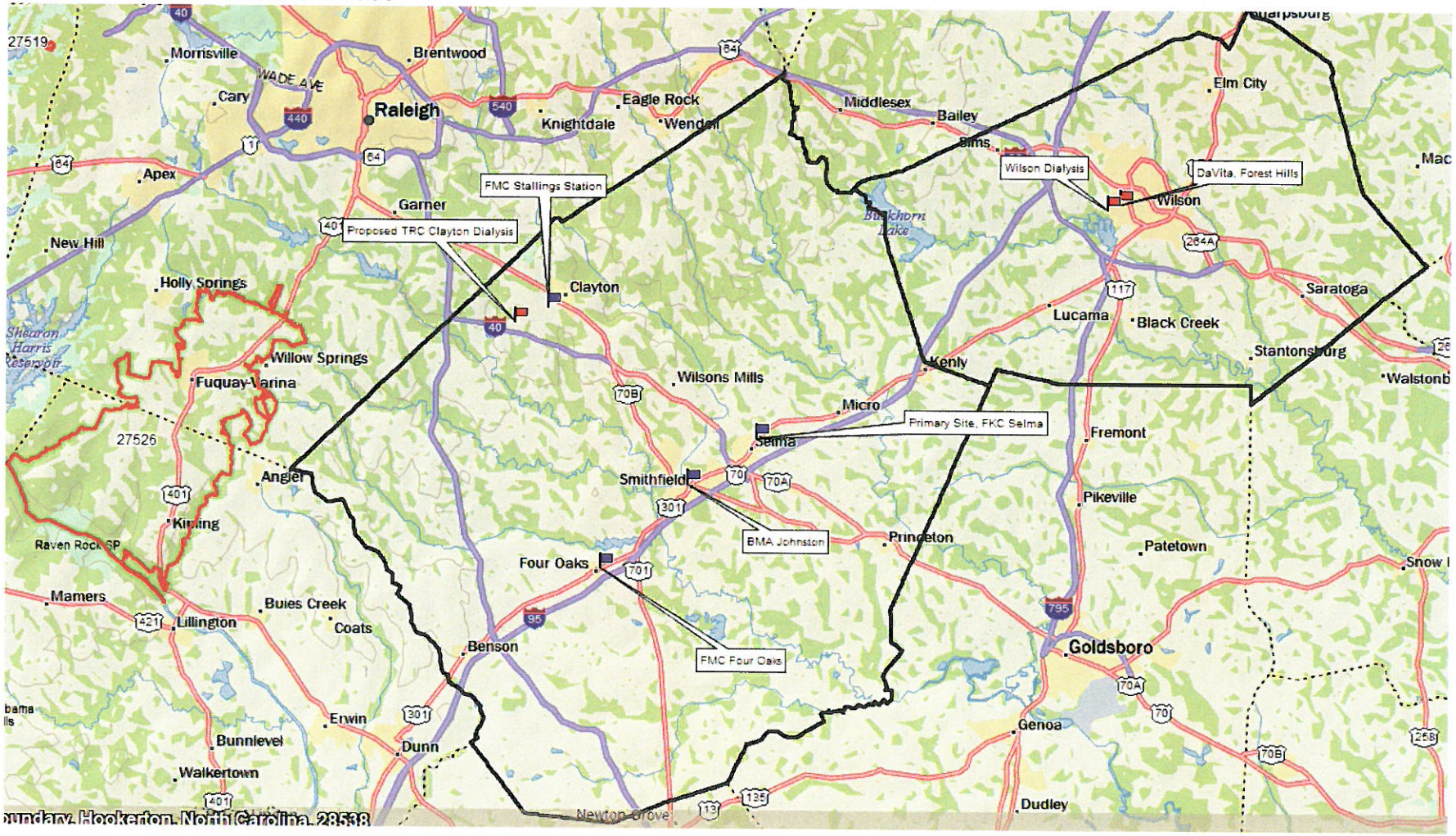
27519 – Wake County



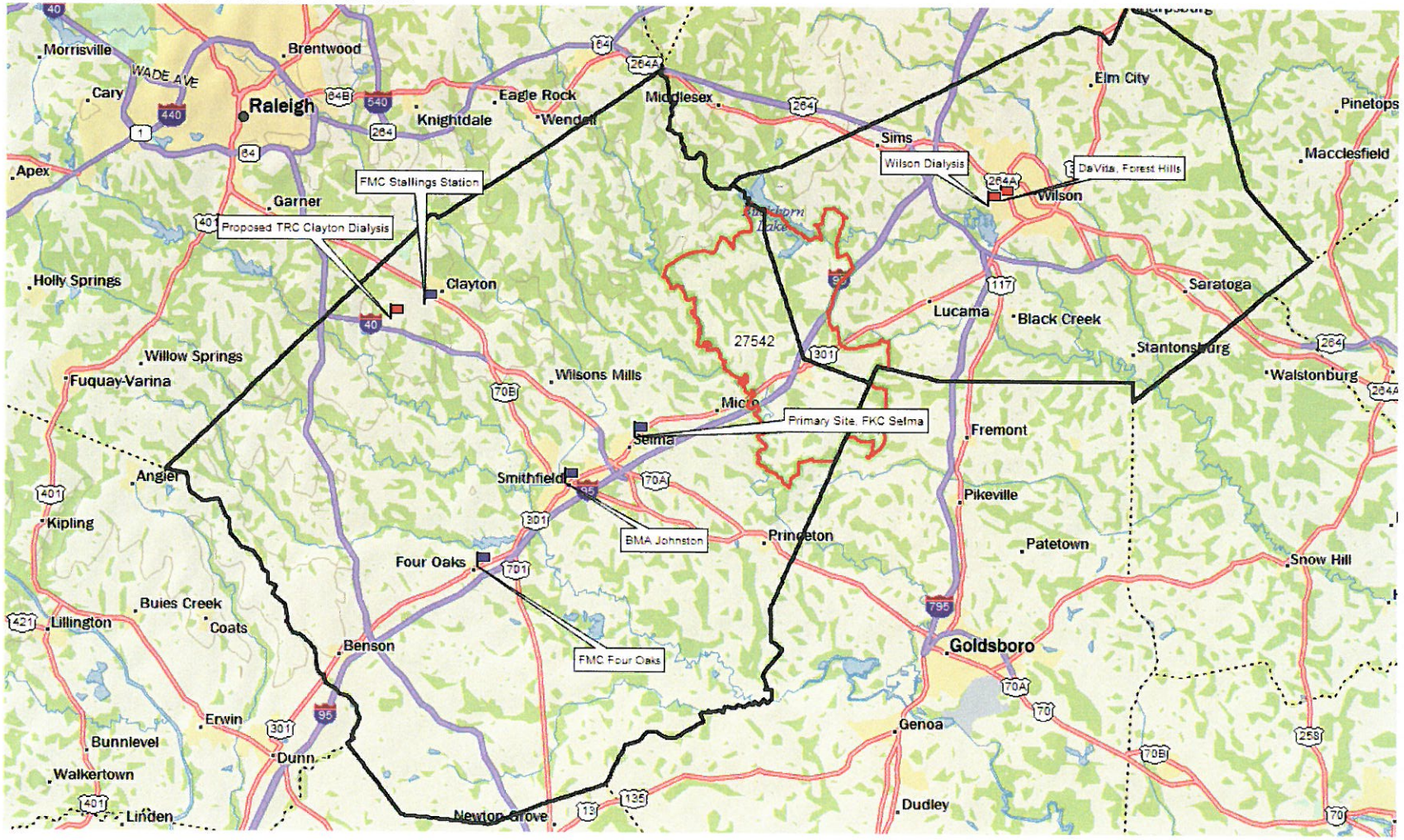
27520 – Johnston County



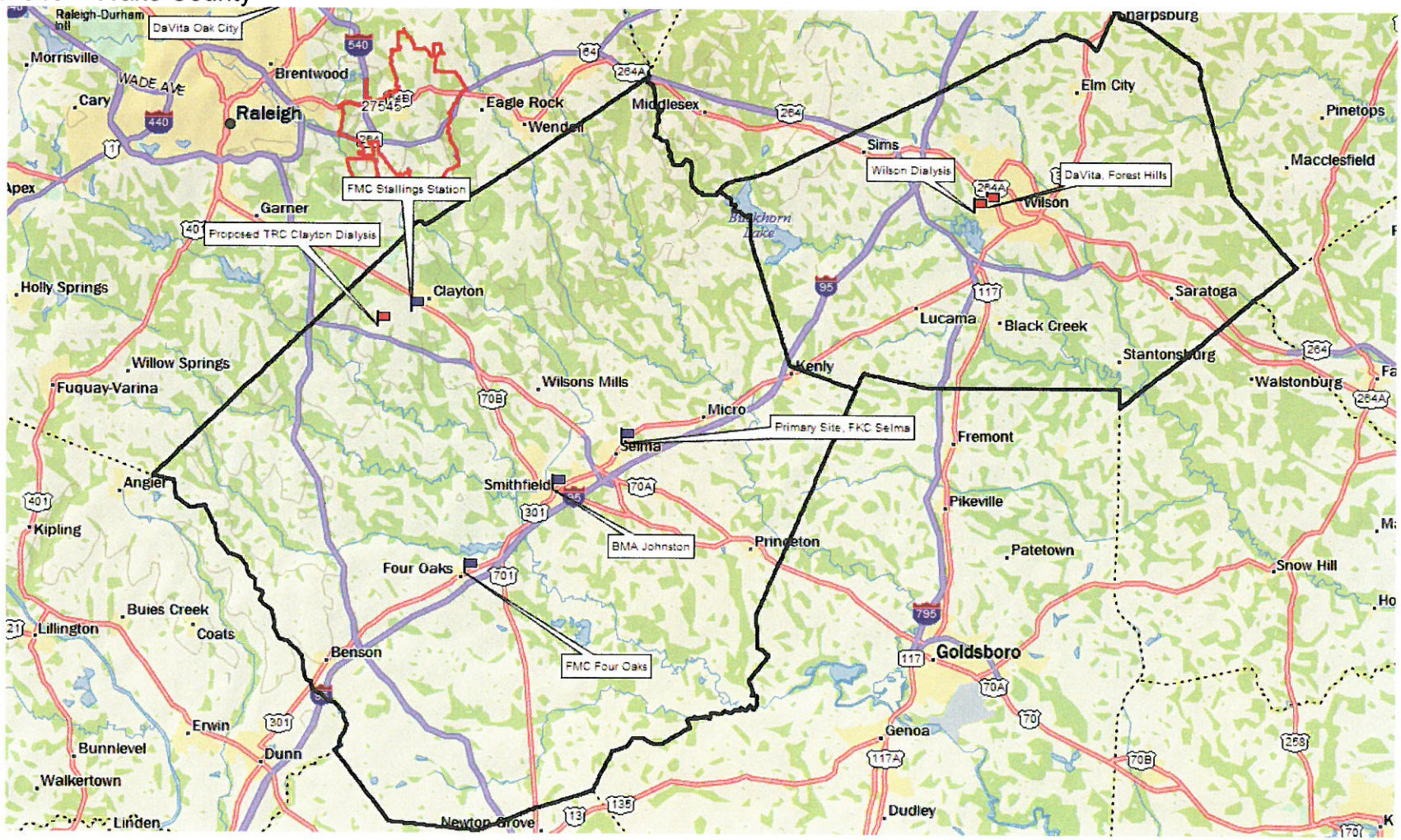
27526 – Wake / Harnett Counties



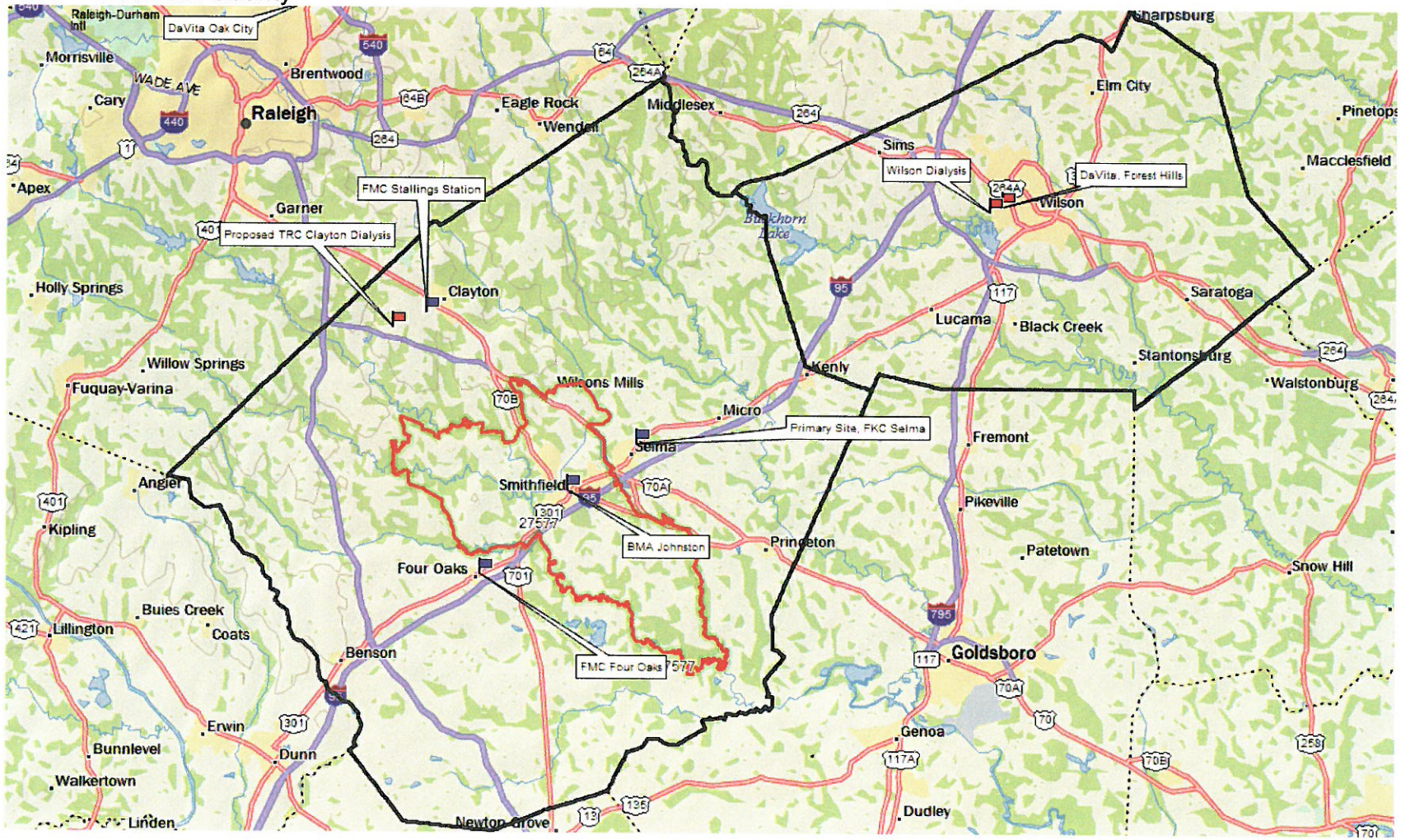
27542 – Johnston / Wilson Counties



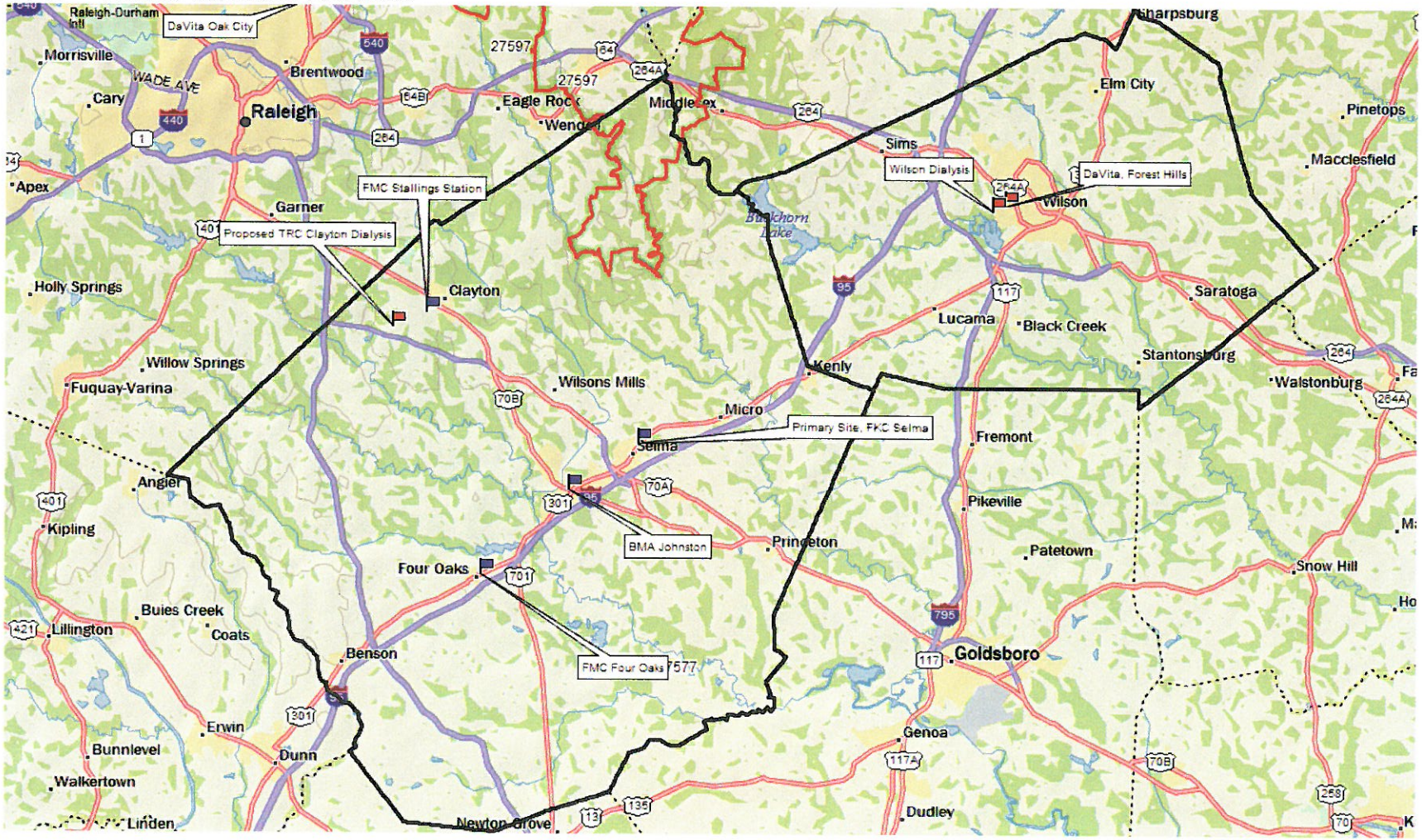
27545 – Wake County



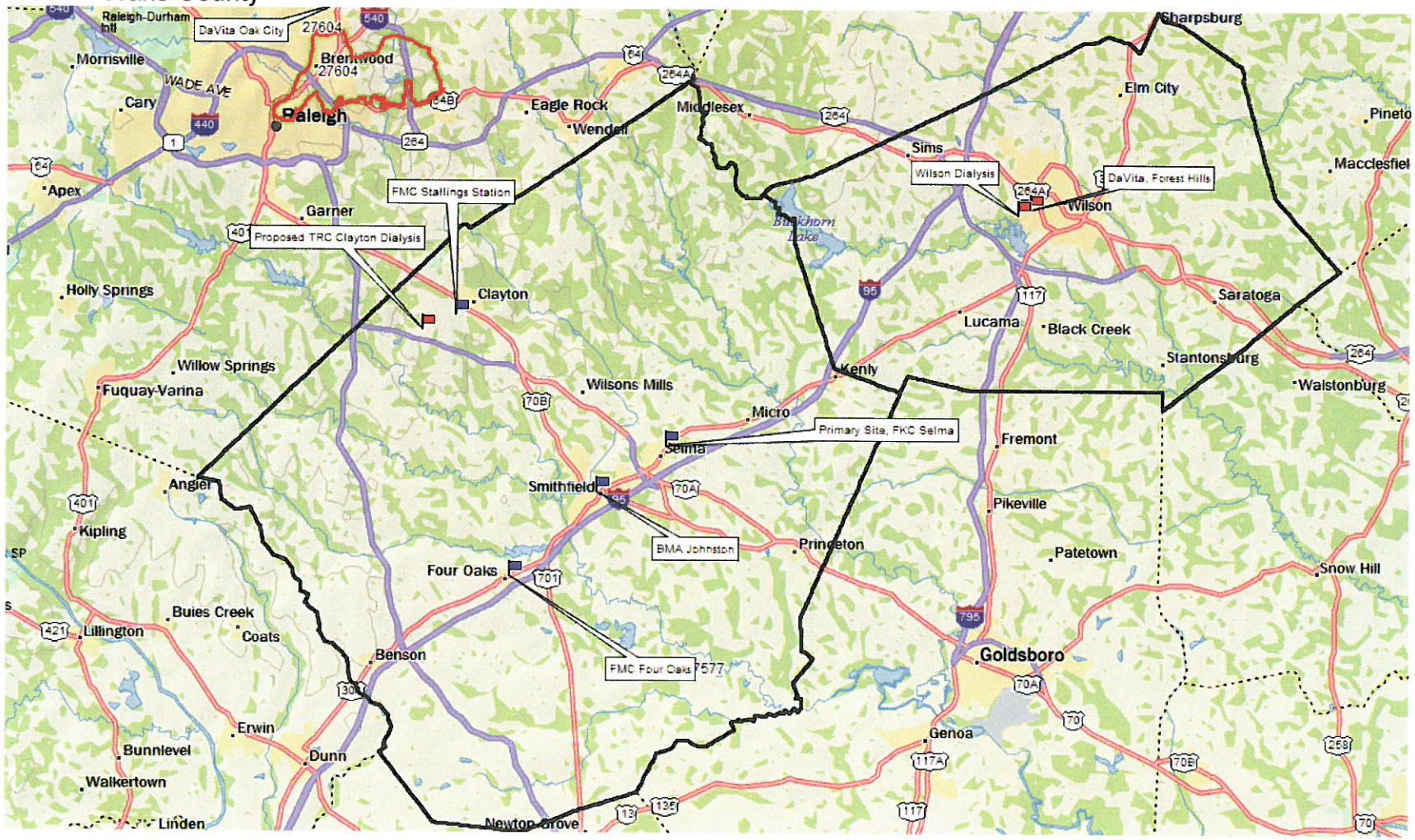
27577 – Johnston County



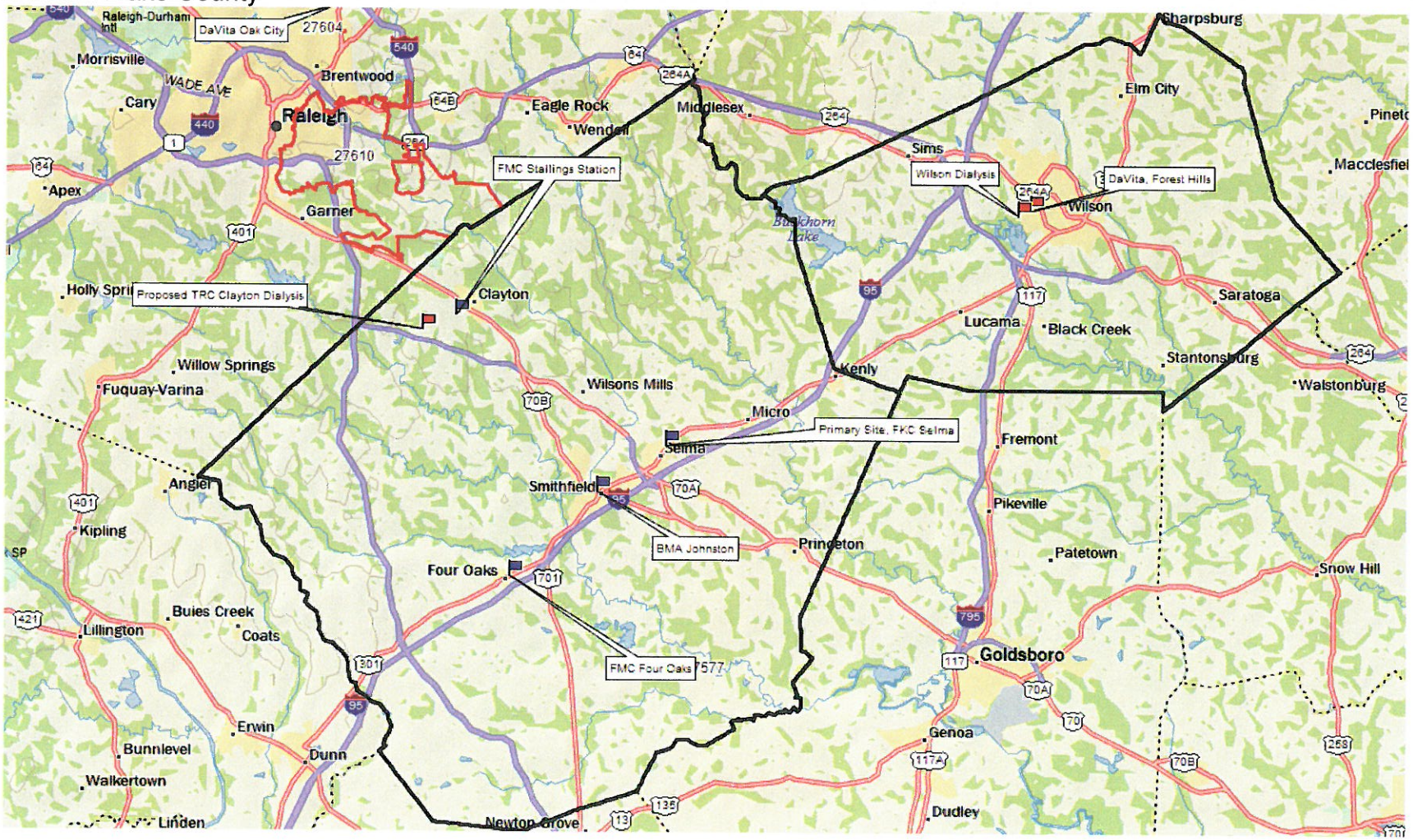
27597 – Wake / Johnston Counties



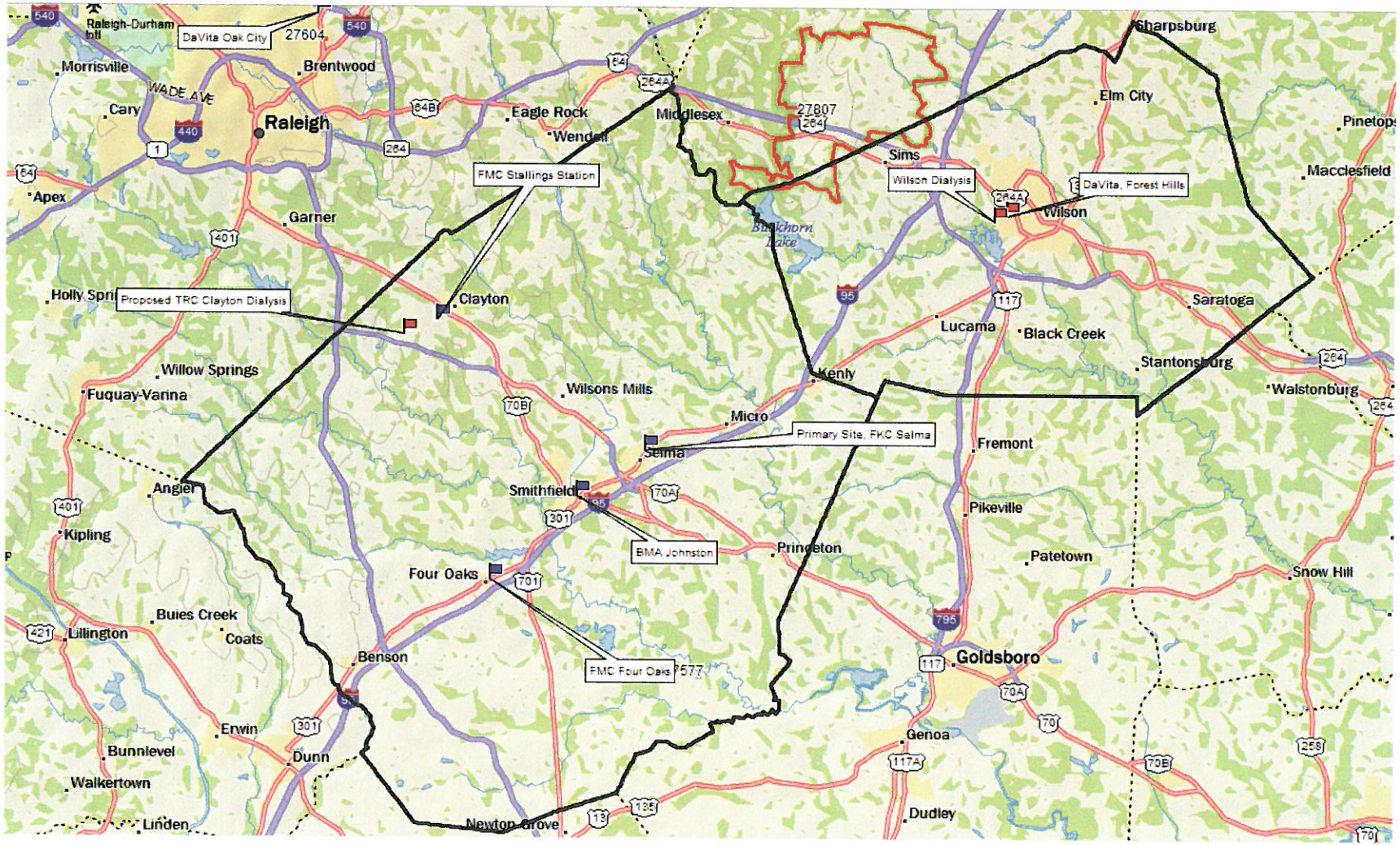
27604 – Wake County



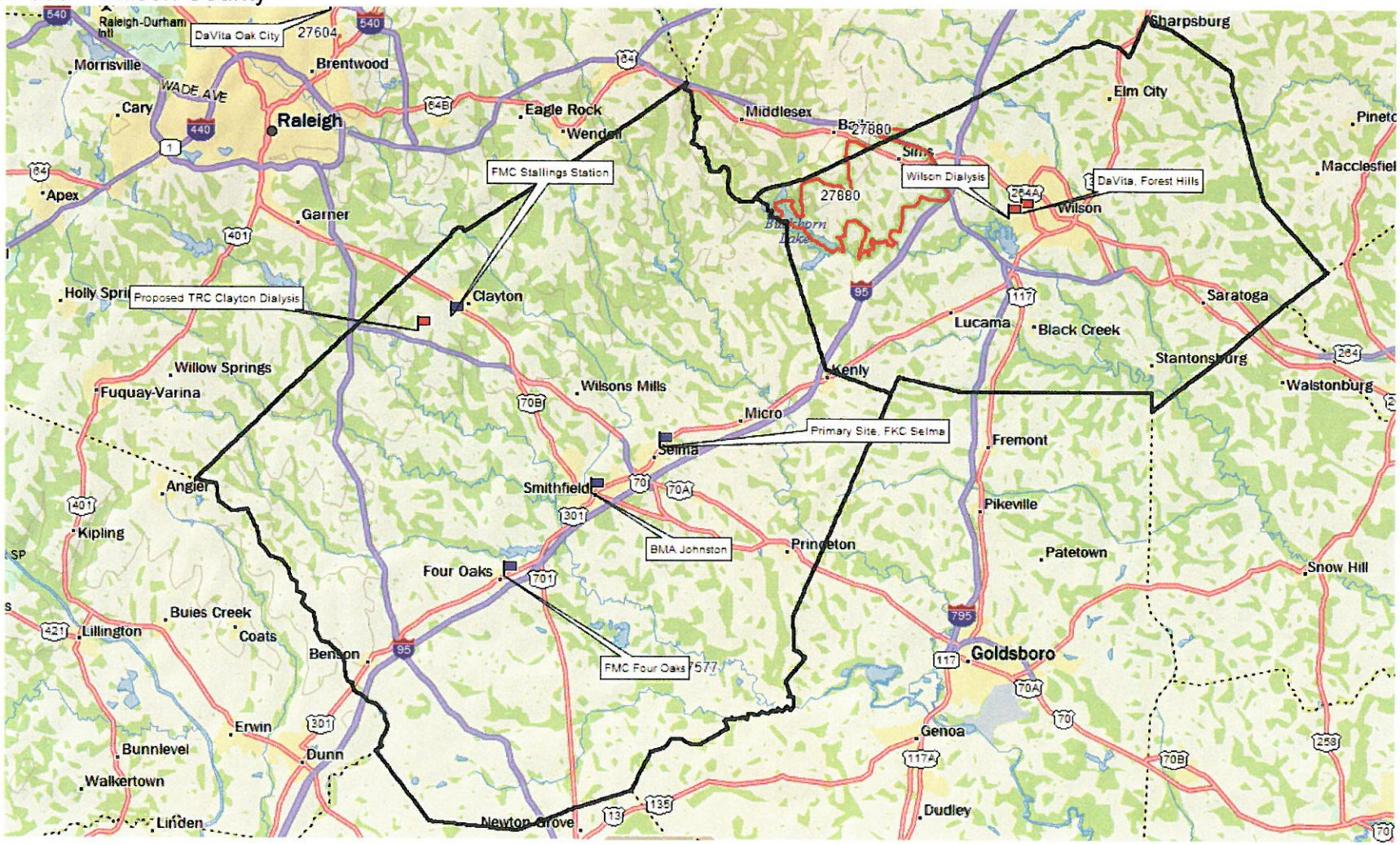
27610 – Wake County



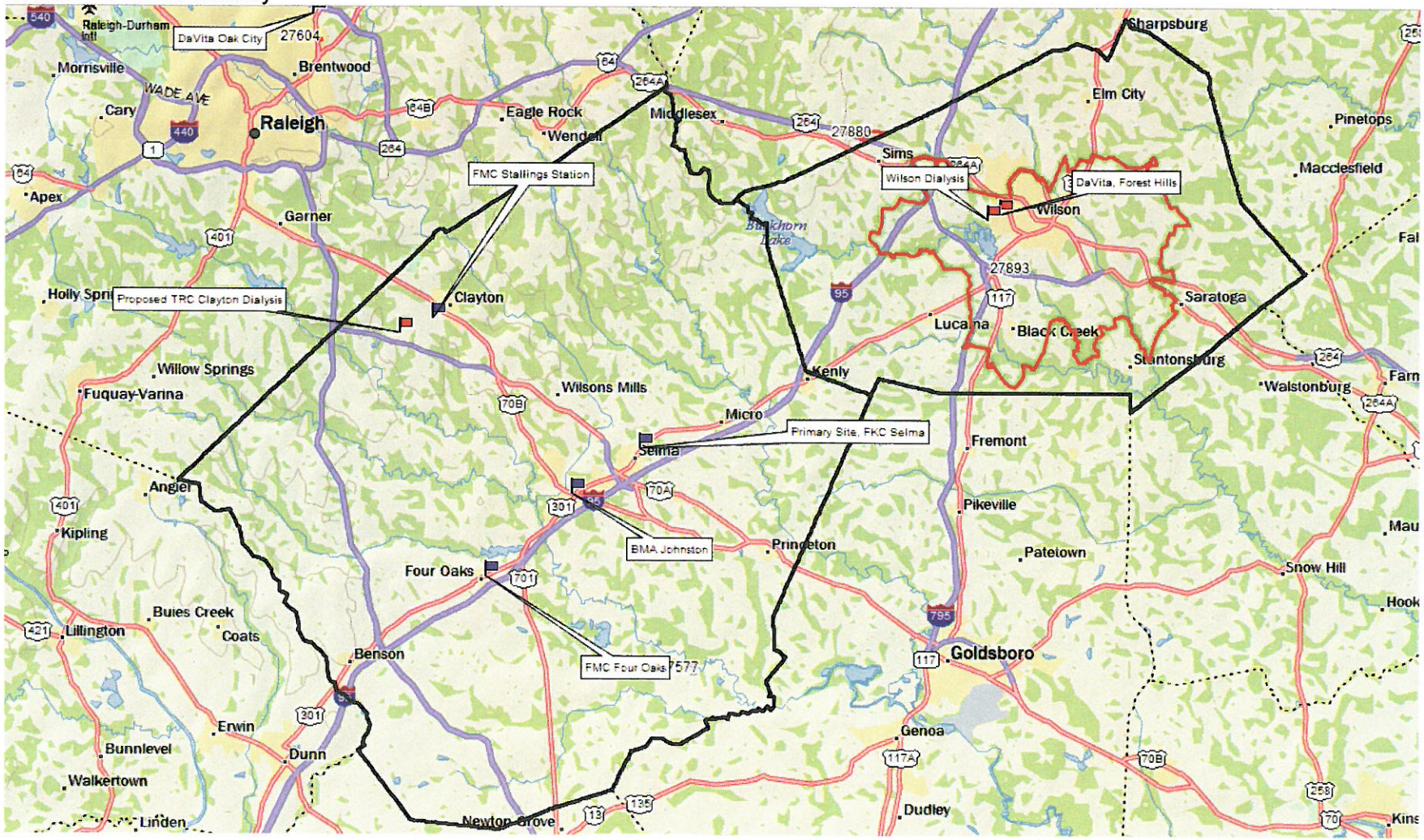
27807 – Nash / Wilson Counties



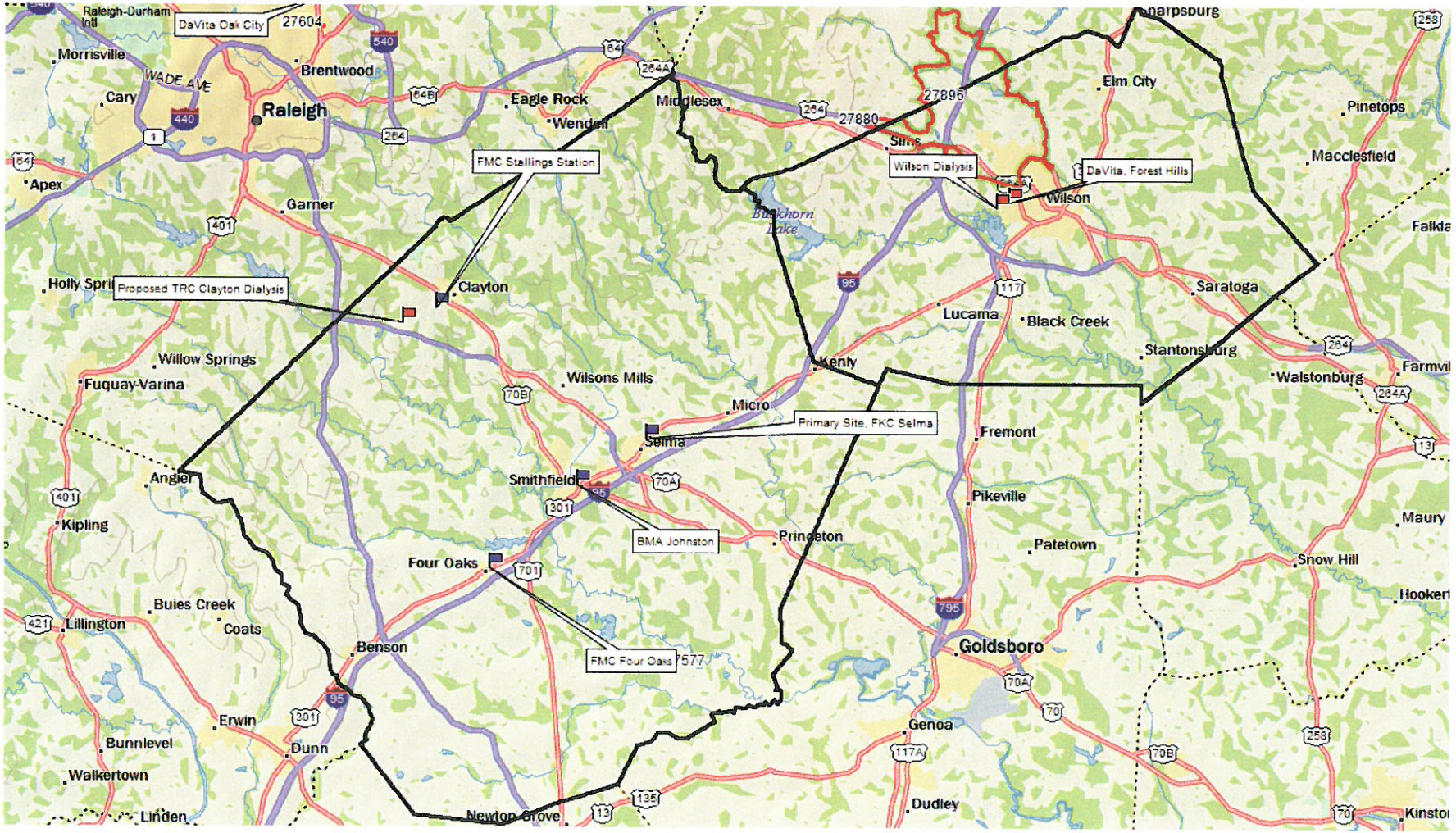
27880 – Wilson County



27893 – Wilson County



27896 – Wilson / Nash Counties



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

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS
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CA = Conditional
NC = Nonconforming
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DECISION DATE:	July 8, 2011
PROJECT ANALYST:	Jane Rhoe-Jones
TEAM LEADER:	Angie Matthes
PROJECT I.D. NUMBER:	P-8641-11 / Total Renal Care of North Carolina, LLC d/b/a Wallace Dialysis Center / Add three stations for a total of 15 stations upon project completion / Duplin County

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

NC

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

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

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

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

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

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

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

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

(3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

NA

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

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

Guidelines

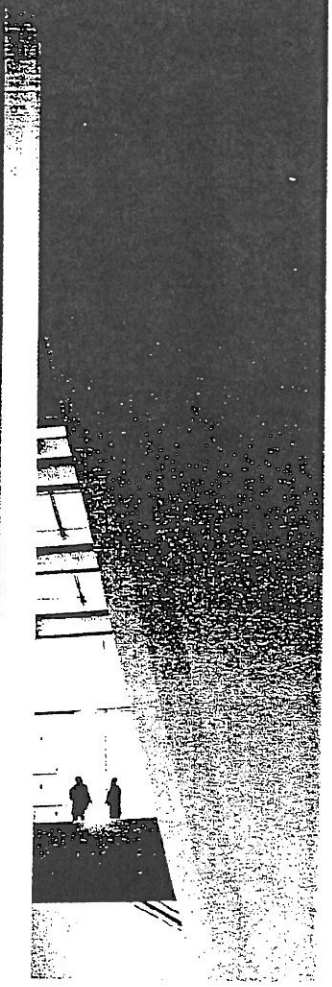
FOR DESIGN AND CONSTRUCTION OF

Health Care Facilities

The Facility Guidelines Institute

2010 edition

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



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

3.10 Specific Requirements for Renal Dialysis Centers

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

3.10-1 General

3.10-1.1 Application

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

3.10-1.2 Functional Program

3.10-1.2.1 Size

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

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

3.10-1.3 Site

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

3.10-2 Reserved

3.10-3 Diagnostic and Treatment Locations

3.10-3.1 Examination Room

At least one examination room shall be provided.

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

3.10-3.1.2 The examination room shall have the following:

3.10-3.1.2.1 Hand-washing station

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

3.10-3.2 Dialysis Treatment Area

3.10-3.2.1 General

3.10-3.2.1.1 Layout

(1) The treatment area shall be separate from administrative and waiting areas.

(2) The treatment area shall be permitted to be an open area.

(3) Open treatment areas shall be designed to provide privacy for each patient.

3.10-3.2.2 Space Requirements

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

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

3.10-3.2.3 Reserved

3.10-3.2.4 Reserved

3.10-3.2.5 Hand-Washing Station

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

3.10-3.2.6 Reserved

3.10-3.2.7 Reserved

3.10-3.2.8 Nurse Station

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

ATTACHMENT - 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 - REQUIRED STATE AGENCY FINDINGS

FINDINGS
C = Conforming
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NC = Nonconforming
NA = Not Applicable

DECISION DATE: February 27, 2012
FINDINGS DATE: March 2, 2012

PROJECT ANALYST: Gregory F. Yakaboski
ASSISTANT CHIEF: Martha J. Frisone

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

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

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

NC-Northampton Dialysis
C-FMC East Northampton

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

Northampton Dialysis
Utilization by Payor Source

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

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

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

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

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

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

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

United States Census Bureau

QuickFacts

selected: Wilson County, North Carolina; Johnston 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	Wilson County, North Carolina	Johnston County, North Carolina	North Carolina
Population estimates, July 1, 2016, (V2016)	**81,661**	**191,450**	**10,146,788**
PEOPLE			
Population			
Population estimates, July 1, 2016, (V2016)	**81,661**	**191,450**	**10,146,788**
Population estimates base, April 1, 2010, (V2016)	81,237	168,904	9,535,688
Population, percent change - April 1, 2010 (estimates base) to July 1, 2016, (V2016)	0.5%	13.3%	6.4%
Population, Census, April 1, 2010	81,234	168,878	9,535,483
Age and Sex			
Persons under 5 years, percent, July 1, 2016, (V2016)	5.8%	6.4%	6.0%
Persons under 5 years, percent, April 1, 2010	6.7%	7.6%	6.6%
Persons under 18 years, percent, July 1, 2016, (V2016)	23.4%	26.0%	22.7%
Persons under 18 years, percent, April 1, 2010	24.7%	27.8%	23.9%
Persons 65 years and over, percent, July 1, 2016, (V2016)	17.3%	12.9%	15.5%
Persons 65 years and over, percent, April 1, 2010	14.2%	10.2%	12.9%
Female persons, percent, July 1, 2016, (V2016)	52.6%	51.0%	51.4%
Female persons, percent, April 1, 2010	52.3%	50.8%	51.3%
Race and Hispanic Origin			
White alone, percent, July 1, 2016, (V2016) (a)	56.0%	80.0%	71.0%
Black or African American alone, percent, July 1, 2016, (V2016) (a)	40.6%	16.2%	22.2%
American Indian and Alaska Native alone, percent, July 1, 2016, (V2016) (a)	0.6%	0.9%	1.6%
Asian alone, percent, July 1, 2016, (V2016) (a)	1.1%	0.8%	2.9%
Native Hawaiian and Other Pacific Islander alone, percent, July 1, 2016, (V2016) (a)	0.2%	0.1%	0.1%
Two or More Races, percent, July 1, 2016, (V2016)	1.5%	2.0%	2.2%
Hispanic or Latino, percent, July 1, 2016, (V2016) (b)	10.0%	13.3%	9.2%
White alone, not Hispanic or Latino, percent, July 1, 2016, (V2016)	47.5%	68.6%	63.5%
Population Characteristics			
Veterans, 2011-2015	5,635	12,645	696,119
Foreign born persons, percent, 2011-2015	7.2%	7.5%	7.7%
Housing			
Housing units, July 1, 2016, (V2016)	35,882	72,404	4,540,498
Housing units, April 1, 2010	35,511	67,682	4,327,528
Owner-occupied housing unit rate, 2011-2015	60.0%	70.8%	65.1%
Median value of owner-occupied housing units, 2011-2015	$116,300	$145,500	$154,900
Median selected monthly owner costs -with a mortgage, 2011-2015	$1,182	$1,242	$1,248
Median selected monthly owner costs -without a mortgage, 2011-2015	$433	$366	$373
Median gross rent, 2011-2015	$715	$774	$797
Building permits, 2016	117	2,007	60,550
Families & Living Arrangements			
Households, 2011-2015	32,003	61,950	3,775,581
Persons per household, 2011-2015	2.50	2.85	2.54
Living in same house 1 year ago, percent of persons age 1 year+, 2011-2015	85.6%	89.3%	84.7%
Language other than English spoken at home, percent of persons age 5 years+, 2011-2015	10.7%	12.0%	11.2%

Education			
High school graduate or higher, percent of persons age 25 years+, 2011-2015	79.8%	84.0%	85.8%
Bachelor's degree or higher, percent of persons age 25 years+, 2011-2015	18.0%	20.3%	28.4%
Health			
With a disability, under age 65 years, percent, 2011-2015	10.5%	9.8%	9.6%
Persons without health insurance, under age 65 years, percent	▲ 15.0%	▲ 13.7%	▲ 12.2%
Economy			
In civilian labor force, total, percent of population age 16 years+, 2011-2015	60.1%	65.2%	61.8%
In civilian labor force, female, percent of population age 16 years+, 2011-2015	55.8%	60.5%	57.7%
Total accommodation and food services sales, 2012 ($1,000) (c)	139,263	243,001	18,622,258
Total health care and social assistance receipts/revenue, 2012 ($1,000) (c)	408,672	457,107	55,227,505
Total manufacturers shipments, 2012 ($1,000) (c)	13,159,851	3,712,563	202,344,646
Total merchant wholesaler sales, 2012 ($1,000) (c)	D	897,570	105,275,586
Total retail sales, 2012 ($1,000) (c)	992,692	2,134,227	120,691,007
Total retail sales per capita, 2012 (c)	$12,126	$12,200	$12,376
Transportation			
Mean travel time to work (minutes), workers age 16 years+, 2011-2015	20.4	29.1	23.9
Income & Poverty			
Median household income (in 2015 dollars), 2011-2015	$39,847	$50,512	$46,868
Per capita income in past 12 months (in 2015 dollars), 2011-2015	$21,486	$22,858	$25,920
Persons in poverty, percent	▲ 19.9%	▲ 13.0%	▲ 15.4%
BUSINESSES			
Businesses			
Total employer establishments, 2015	1,725	3,127	223,209[1]
Total employment, 2015	31,970	40,572	3,670,284[1]
Total annual payroll, 2015 ($1,000)	1,239,555	1,458,205	164,936,258[1]
Total employment, percent change, 2014-2015	1.2%	6.5%	3.1%[1]
Total nonemployer establishments, 2015	4,650	12,158	722,639
All firms, 2012	5,990	12,617	805,985
Men-owned firms, 2012	3,099	7,414	435,677
Women-owned firms, 2012	2,183	4,060	287,058
Minority-owned firms, 2012	1,834	2,581	183,380
Nonminority-owned firms, 2012	3,784	9,662	603,182
Veteran-owned firms, 2012	614	1,401	86,571
Nonveteran-owned firms, 2012	4,905	10,699	684,743
GEOGRAPHY			
Geography			
Population per square mile, 2010	220.6	213.4	196.1
Land area in square miles, 2010	368.17	791.30	48,617.91
FIPS Code	37195	37101	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 Q 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.