

Received by
the CON Section
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Martha Frisone, Assistant Chief
Bernetta Thorne-Williams, Project Analyst
N.C. Department of Health and Human Services
Division of Facility Services
Certificate of Need Section
805 Ruggles Drive
Raleigh, North Carolina 27603-2008

October 1, 2015

RE: Written Comments regarding FMS ENA Home, LLC CON Application, HSA VI – Project
I.D. # L-11067-15

Dear Ms. Frisone and Ms. Thorne-Williams:

I am writing to provide comments from Wake Forest University Health Sciences (WFUHS) regarding the CON application filed by FMS ENA Home, LLC in Health Service Area VI. The FMS ENA application seeks to develop a new End Stage Renal Disease (ESRD) facility in Tarboro, Edgecombe County, which FMS states will develop a home dialysis training and support program exclusively for the provision of Home Peritoneal Dialysis training and support.

Wake Forest University Health Sciences (“WFUHS”) is a non-profit corporation, organized under the laws of the State of North Carolina, which owns 16 certified dialysis facilities in 8 North Carolina counties offering in-center and home training services, and has received approval pursuant to the Certificate of Need Law (“CON Law”) to develop and operate a 17th facility in Randolph County. Through its dialysis facilities, WFUHS provides both in-center hemodialysis and training and support for patients performing peritoneal dialysis or hemodialysis at home.

WFUHS does not provide dialysis services in Edgecombe County, and does not anticipate that the specific proposal at issue will directly impact services provided at WFUHS’ existing facilities. Nevertheless, WFUHS is deeply concerned about the model proposed by FMS ENA. In addition to failing to conform to the applicable review criteria and rules for ESRD services, FMS ENA’s proposal fails to comply with the entire purpose of the CON law, to ensure that only appropriate and needed institutional health services are made available in the area to be served. FMS ENA’s proposal likely would unnecessarily duplicate existing services by simply shifting the training of existing home peritoneal dialysis patients from other equally or more accessible locations. The model it has chosen to achieve this goal appears to be to offer referring physicians a percentage interest in the facility, thus providing them with a financial incentive to refer these patients to the facility, regardless of the convenience of those patients.¹ The FMS ENA application provides very little information about the proposed nature of this relationship. This proposal raises serious questions regarding the potential violation of federal and State anti-kickback and anti-self-referral laws. Without more information about FMS ENA’s intended relationship with the referring physicians, the Agency should be hesitant to approve this proposal.

¹ This inconvenience to the patients is borne out by the fact that most of the patients providing letters of support for the proposal actually live closer to their existing home training sites than to the FMS ENA’s proposed site in Tarboro.

SUMMARY OF COMMENTS

As discussed below, this proposal is, for many reasons not an effective alternative to provide home dialysis training.

- FMS ENA's patient projections are unfounded and false based upon mapping data for the patients who provided letters of support for the project.
- FMS ENA bases growth of the proposed facility on the statewide five-year Average Annual Change Rate ("AACR") for home and ICH patients, yet ignores the five-year AACR for home and ICH patients for Edgecombe County, the project's service area. The five-year AACR for home for Edgecombe County is -3.76%. The five-year AACR for ICH for Edgecombe County is 1.42%. Thus, in Edgecombe County, the home patient population is in decline.
- Had FMS ENA mapped the patients it projects to serve (those providing patient support letters for its project), it would have demonstrated that Tarboro *is not* the most appropriate location for those patients. Thus, it is not an effective alternative.
- The application projects to lease the space from a commercial developer who would purchase the property. However, there is no evidence in the application of a commercial developer willing to purchase the property, construct the building, or lease space to FMS ENA.
- FMS ENA's financial projections are based upon unreliable revenue data. For instance, FMS ENA's OY2 payor mix totals over 100% of the projected patient population.
- The calculated allowable rates for Medicare / Commercial and VA fail to include a contractual allowance for those payors. Correction of these financial errors leads to a loss in OY1 and OY2 of the project.
- FMS ENA does not provide an affiliation agreement with an in-county backup facility.
- FMS ENA does not propose adequate access to the medically underserved. FMS ENA does not project to serve Medicaid patients and requires all patients to have some form of medical coverage prior to admission.
- FMS ENA failed to provide evidence of an affiliation intent with a local health professional training facility.

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

ANALYSIS

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

“The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.”

FMS ENA projects the following patient population in the first two years of operation:

Total Projected Patients by County of Residence

County	OY 1			OY 2			County Patients as a Percent of Total	
	In-center Patients	Home Hemo Patients	Peritoneal Patients	In-center Patients	Home Hemo Patients	Peritoneal Patients	OY 1	OY 2
Edgecombe			6			6	100%	100%
Total *			6			6	100%	100%

Those patient projections are based upon the following erroneous assumptions:

1. Pages 19 and 23-25 of the application reference letters from eight patients who currently dialyze at BMA facilities in either Nash or Pitt Counties, but reside within Edgecombe County. Those letters are attached as exhibits to the application. The application goes on to say that the current facility locations for these patients is not as convenient for the patient; requires more time for travel to and from the dialysis facility; and involves more expense related to travel. FMS ENA concludes that the need that this population has for the proposed services *“is a function of the individual patient need for dialysis care and treatment, and the stated desires of the patients to have dialysis at the proposed FMS ENA Edgecombe County location.”*

None of these contentions is supported by the facts. The patient letters do not indicate a desire to transfer to FMS ENA but rather state that they would be willing to consider transferring their care to the proposed facility. The patient support letters also do not state that FMS ENA is more convenient for the particular patient, nor do they state that FMS ENA is closer to the patient’s home.

In fact, the proposed site for the project is within a few blocks of an existing ESRD facility which provides home PD training and support services. Without taking existing home patients living in and around Tarboro, which the FMS ENA application does not propose, it is unclear how FMS ENA’s new facility would benefit any of the patients the applicant says it will serve.

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Further, as shown below, based upon WFUHS’ analysis of the patients’ locations using <http://www.whitepages.com> and various web mapping sites, all but one of these patients live closer to their current facility than the proposed FMS ENA. See patient letters and supporting mapping documentation, **Exhibit 1** attached hereto. If it were more convenient for those patients to utilize a home dialysis training facility in Tarboro, they would already be using the existing one. Most of the ones who provided letters live within a few miles / minutes of their current backup facility and would be greatly inconvenienced if they had to transfer their care to a location in Tarboro.

Below is the list of the patients who provided letters of support, their address location according to the internet, and the time and distance from the patients’ homes to existing BMA facilities closest to their residence. Of the eight patients who provided letters for the application, seven could be identified and mapped. The address for one patient could not be found and is not included below.

Patient	Address	County	BMA East Rocky Mount	BMA Rocky Mount	FMS ENA
Harper	1703 W. Wilson St. Tarboro, 27886	Edgecombe	16.0 Miles 17 Minutes	19.7 Miles 19 Minutes	2.8 Miles 4 Minutes
Johnson	1224 Tarboro St. Rocky Mount, 27801	Edgecombe	0.7 Miles 2 Minutes	7.2 Miles 11 Minutes	14.4 Miles 19 Minutes
Lloyd	400 Kingston Ave. Rocky Mount, 27803	Nash	3.3 Miles 9 Minutes	7.4 Miles 9 Minutes	17.8 Miles 22 Minutes
Spruill	1708 Farmington Rd. Rocky Mount, 27801	Edgecombe	4.3 Miles 7 Minutes	7.5 Miles 9 Minutes	12.9 Miles 15 Minutes
Strother	1016 Blandwood Dr. Rocky Mount, 27801	Edgecombe	1.6 Miles 3 Minutes	7.5 Miles 13 Minutes	16.5 Miles 23 Minutes
Webb	1778 Faith Baptist Church Rd. Pinetops, 27864	Edgecombe	13.6 Miles 18 Minutes	21.1 Miles 26 Minutes	12.8 Miles 19 Minutes
Jenkins	303 E. Pitt St. Pinetops, NC 27864	Edgecombe	14.3 Miles 18 Minutes	24.7 Miles 25 Minutes	11.4 Miles 14 Minutes
Isles (sic)	Pinetops, 27864	Edgecombe	N/A	N/A	N/A

Only one of the seven identified patient lives closer to the proposed FMS ENA than their next closest facilities. That patient also lives equally as close to the existing DaVita unit in Tarboro that offers home dialysis training and support.

Four of the seven identifiable patients live twice as close to BMA Rocky Mount and BMA East Rocky Mount than they live to the proposed FMS ENA. It is highly unlikely that it would be more convenient for those patients to double their drive time to go to FMS ENA.

Two patients, Patients Webb and Jenkins, essentially live equally close to BMA East Rocky Mount and FMS ENA. BMA Rocky Mount is only minutes further away. Given the size and location of Pinetops, it is likely that Patient Isles’ experience would be the same.

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FMS ENA’s projection that six of those eight patients will transfer their care to the new facility is unsupported and unrealistic. It appears that only one of the seven FMS ENA patients actually lives significantly closer to the proposed new facility than other existing providers.

Because FMS ENA’s patient projections cannot be supported, it is also unlikely FMS ENA could reach the revenue projections identified in its pro forma statements, especially when coupled with other errors in those worksheets. See **Section R** below for further information on the pro forma errors.

2. Using July SDR data for the years 2011-2015, the applicant suggests on page 20 that the home patient population in North Carolina is growing at a faster rate than the ICH population statewide. However, FMS ENA is not proposing a statewide home training facility. It is proposing a facility to serve Edgecombe County patients. SDR data for Edgecombe County, the population that FMS ENA proposes to serve, paints a much different picture of the growth of home dialysis and other patients in Edgecombe County.² See table below with data pulled from the July SDR’s from the same time frame as in the application. Copies of the relevant pages from the July 2011-2015 SDRs are attached as **Exhibit 2**.

Home Dialysis Patient Data for Edgecombe County 12/31/2010 – 12/31/2014

Data Date	12/31/2010	12/31/2011	12/31/2012	12/31/2013	12/31/2014	Mean
July SDR	2011	2012	2013*	2014	2015	
Home Patients	25	24	23	19	21	22.40
Annual Change Rate		-4.00%	-4.17%	-17.39%	10.53%	-3.76%
5-Year AACR					-3.76%	-3.76%
Home Pts. As a % of						
All Pts.	12.60%	11.50%	10.13%	8.70%	10.40%	10.67%

**The July 2013 SDR contained multiple errors, one of which was the report that there were only 8 Edgecombe County home patients. Thus, for 12/31/2012 a 3-year average of home dialysis patients was used and the percentage of home dialysis patients was corrected from 3.90% to 10.13%. These errors were due in large part to new self-reporting of patient data that began with the July 2013 SDR.*

² Significantly, when projecting need for its in-center facility in the same building, BMA, FMS ENA’s parent company, projected need based upon the 5-Year AACR Edgecombe County patient growth in the January 2015 SDR. See CON application for Project I.D. No. L-11011-15, p. 43. The Agency found that methodology reasonable. See Required State Agency Findings issued August 28, 2015, pp. 5-6.

Edgecombe County Overall Dialysis Patient Data 12/31/2010 – 12/31/2014

Data Date	12/31/2010	12/31/2011	12/31/2012	12/31/2013	12/31/2014	Mean
July SDR	2011	2012	2013*	2014	2015	
All Patients	198	208	227	218	202	210.60
Annual Change Rate		5.05%	9.13%	-3.96%	-7.34%	
5-Year AACR					0.72%	

Edgecombe County ICH Patient Data 12/31/2010 – 12/31/2014

Data Date	12/31/2010	12/31/2011	12/31/2012	12/31/2013	12/31/2014	Mean
July SDR	2011	2012	2013*	2014	2015	
Home Pts. As a % of All Pts.	12.60%	11.50%	10.13%	8.70%	10.40%	10.67%
ICH Pts. As a % of All Pts.	87.40%	88.50%	89.87%	91.30%	89.60%	89.33%
Number of ICH Pts.	173	184	204	199	181	188.23
Annual Change Rate		6.37%	10.82%	-2.43%	-9.06%	1.42%
5-Year AACR					1.42%	

The 5-Year AACR for Home Dialysis Patients for Edgecombe County is -3.76%, while the 5-Year AACR for Edgecombe County ICH patients is 1.42%. Similarly, the data shows that the mean number home patients as a percentage of all patients has been decreasing, and is currently approximately 10%. Thus, it appears that the number of home dialysis patients in Edgecombe County declining, not growing.

FMS ENA's failure to consider the historical experience of Edgecombe County residents is surprising, given the fact that only two years ago, BMA relied upon SDR data showing a significantly higher growth of home patients in Bladen County, in obtaining approval to develop a new PD home training facility in Bladen County. See Required State Agency Findings, FMC Bladen Home Dialysis, Project I.D. # N-10153-13, p. 3, Exhibit 3 hereto. The person who prepared the FMS ENA application, Jim Swann, has prepared CON applications for BMA for many years. Clearly, Mr. Swann had available and could have used the same type of SDR data for Edgecombe County that BMA used for the Bladen County application to demonstrate need.

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3. The applicant suggests that Eastern Nephrology Associates (ENA) will increase the overall percentage of home patients in Edgecombe County as compared to the percentage of ICH patients because they have done so in Carteret, Craven and Jones Counties. In each instance, FMS ENA states that growth in the percentage of home dialysis patients to ICH patients “is primarily a function of the nephrology practice.”

Based upon the data provided by the applicant, there is no support for the assumption that FMS ENA’s patient projections will come to fruition. As shown on its web site, <http://easternnephrology.com/contact/office-locations/>, ENA has multiple offices and is affiliated with a number of dialysis facilities in eastern North Carolina. Without analyzing the experience of the dialysis facilities in all of those counties, there is no way to determine that the percentage of home patients in three isolated counties is indicative of ENA’s experience overall.

More important, a growth in the percentage of home dialysis patients definitely is not ENA’s experience in Edgecombe County. The practice already serves both in-center and home patients in Edgecombe County at the DaVita Dialysis Care of Edgecombe County facility, which is the only dialysis facility in Edgecombe County which serves home patients.³ The historical ESRD data for Edgecombe County shows the home dialysis patient population for Edgecombe County is in decline versus (very small) positive growth of the overall and ICH patient population. It is clear that what little patient growth there is in Edgecombe County is ICH patient growth and not home dialysis patient growth.

4. Using the Edgecombe County population 5-Year AACR, the applicant projects growth of the overall ESRD patient population, then calculates what the home patient population would be if the percentage of home patients increases from 10.4% of the overall patients to 15% of the overall patients. A chart with the following data can be found on page 21 of the FMS ENA application:

Date	Census	Growth Rate	Projected Year End Census	% of Home Pts.	Projected Home Pts.	Projected ICH Census
12/31/2014	202.00	1.007	203.41	10.40%	21.16	182.26
12/31/2015	203.41	1.007	204.84	11.90%	24.38	180.46
12/31/2016	204.84	1.007	206.27	13.40%	27.64	178.63
12/31/2017	206.27	1.007	207.72	14.90%	30.95	176.77
12/31/2018	207.72	1.007	209.17	15.00%	31.38	177.79
12/31/2019	209.17	1.007	210.63	15.00%	31.60	179.04
12/31/2020	210.63	1.007	212.11	15.00%	31.82	180.29

FMS ENA’s assumed growth of the percentage of home patients from 10.4% in 2014 to 15% in

³ So far, BMA of North Carolina, Inc., which owns FMS ENA, has declined to make home training services available to patients at its Edgecombe County ESRD facility.

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2020 has no valid basis. There is no historical data in the application to support this projection. As previously noted, the percentage of home patients to total patients in Edgecombe County had actually been decreasing annually until 2015. The Edgecombe County 5-Year AACR shows that the number of home patients has decreased, while the number of ICH patients has increased.

Further, as shown in the chart below, it appears FMS ENA projects an immediate 15.22% increase in the number of home dialysis patients in Edgecombe County, a percentage rate increase which has not occurred in any of the past five years. However, that rate of growth appears to decline to 11.97% during OY1 of FMS ENA and down to 1.38% growth during OY2 of FMS ENA. It is unclear why the applicant projects the annual growth of home patients to decline once its project becomes operational. This projection fails to support FMS ENA’s statement that a joint-venture with ENA would create sustained growth of home dialysis patients.

Date	Census	Growth Rate	Projected Year End Census	% of Home Pts.	Projected Home Pts.	Annual Change	5-Year AACR	Projected ICH Census	Annual Change	5-Year AACR
12/31/2014	202.00	1.007	203.41	10.40%	21.16			182.26		
12/31/2015	203.41	1.007	204.84	11.90%	24.38	15.22%		180.46	-0.99%	
12/31/2016	204.84	1.007	206.27	13.40%	27.64	13.39%		178.63	-1.01%	
12/31/2017	206.27	1.007	207.72	14.90%	30.95	11.97%		176.77	-1.04%	
12/31/2018	207.72	1.007	209.17	15.00%	31.38	1.38%	10.49%	177.79	0.58%	-0.62%
12/31/2019	209.17	1.007	210.63	15.00%	31.60	0.70%	6.86%	179.04	0.70%	-0.19%
12/31/2020	210.63	1.007	212.11	15.00%	31.82	0.70%	3.69%	180.29	0.70%	0.23%

Another interesting observation of the FMS ENA projections is a comparison of the beginning 12/31/2014 Edgecombe County patient census overall, home dialysis, and ICH with the ending 12/31/2020 Edgecombe County patient census for those same categories. While FMS ENA projects the overall patients of Edgecombe County will experience a net increase of 10.11 patients, FMS ENA projects greater than all of those patients will both be eligible to receive and choose home dialysis. Consequentially, FMS ENA projects the overall census of ICH patients in Edgecombe County will decline by -1.97 or -2.00 patients during the same time period. The historical experience of Edgecombe County, as shown in the 5-Year AACR for Edgecombe County do not support the assumption that all of the net new patients for the next five years will be home dialysis patients.

- On page 22 of the application, FMS ENA assumes one-half of the future PD patient population of Edgecombe County will choose to dialyze with the new center and “--*the initial patient population will be comprised of six Edgecombe County residents.*”

However, given the actual historical 5-Year AACR for home dialysis patients in Edgecombe County (-3.76%) and the applicant’s lack of objective support for its patient projection assumptions, it is unlikely FMS ENA will have the ability to generate even its projected starting

patient population of six Edgecombe County PD patients. This is further emphasized by FMS ENA's lack of ability to provide letters of support from at least six existing home dialysis patients for whom it would actually be more convenient to travel to FMS ENA versus their current dialysis facility.

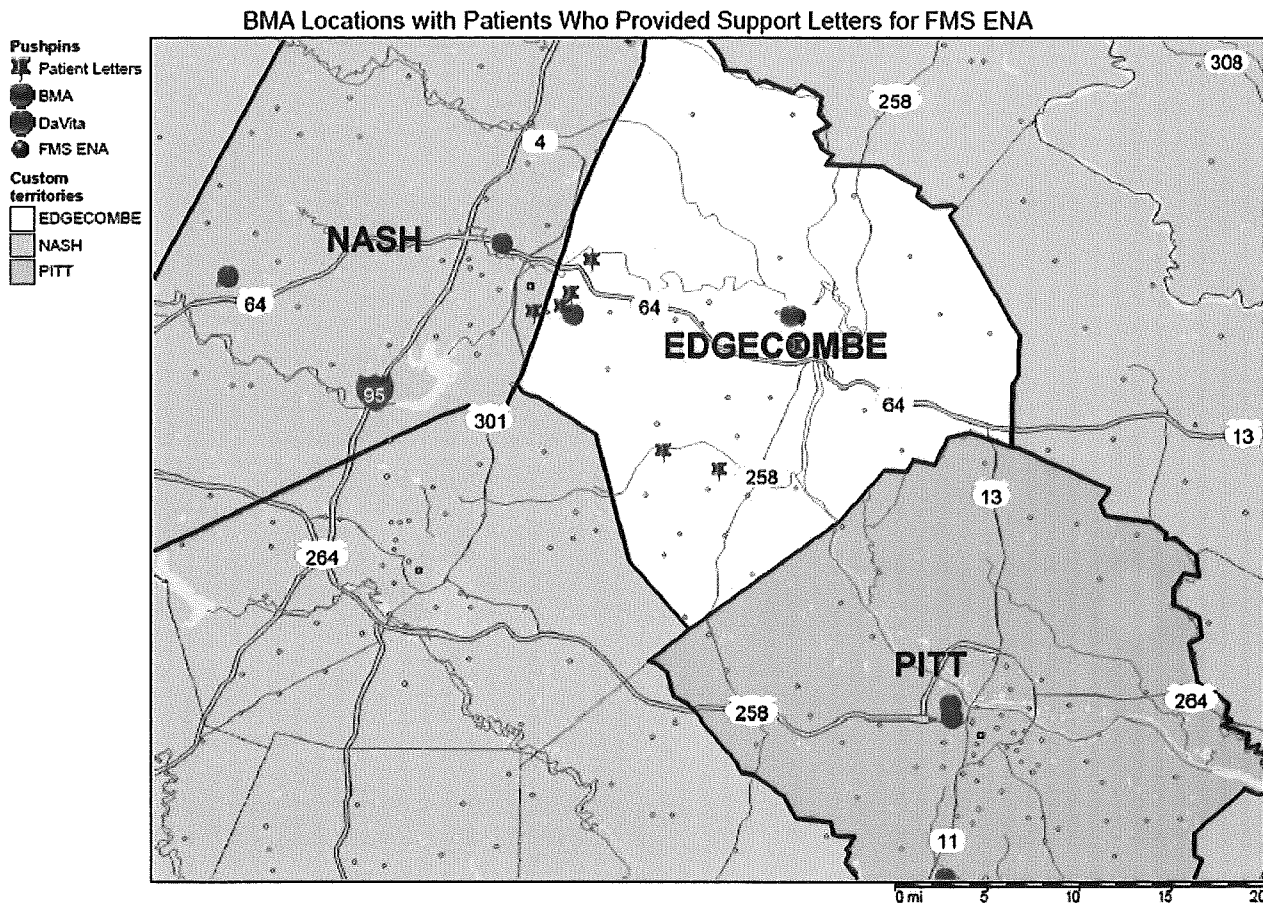
For all of these reasons, FMS ENA application is non-conforming with Criterion 3. The applicant has failed to identify an applicable population to be served, and has failed to show the need the proposed population has for the project.

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

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

FMS ENA states on page 35 of its application, ***"Given the residence location of the existing patients projected to be served at the FMS ENA Home facility, FMS ENA believes it is most appropriate to apply for this development in Tarboro, Edgecombe County."***

Based upon the mapped addresses below of seven of the eight BMA patients who provided support letters for the FMS ENA project, the proposed location in Tarboro does not appear to provide any geographical benefit to at least four of them. FMS ENA failed to provide documentation from ENA of potential future patients who reside in the Tarboro area, and there is an existing home dialysis training facility very near the proposed FMS ENA location. A more effective alternative might have been locating a home dialysis training location in Pinetops or near the BMA East Rocky Mount facility. However, FMS ENA did not consider either of those options.



Further, FMS ENA and its parent company, BMA, have failed to demonstrate that a separate home training facility owned by FMS ENA located in the same building as BMA’s approved in-center dialysis facility is the most effective alternative for patients needing home dialysis. Only six months ago, BMA filed its CON application for Project I.D. No. L-11011-15, arguing that home training effectively could be provided at BMA’s Greenville Dialysis facility home training program, or the BMA Rocky Mount home training program. See CON Application for Project I.D. No. L-11011-15, p. 68. No explanation is given in the FMS ENA application why that alternative suddenly has become unacceptable.

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

“Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.”

1. While the applicant’s parent organization has demonstrated its willingness and ability to fund the capital costs necessary to construct the space and acquire necessary equipment,

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there is no evidence of the existence of a developer willing to acquire the property and lease it to FMS ENA.

In this regard, the application states on page 64 that FMS ENA will not be the property owner but rather will lease space from a commercial property developer. However, nowhere in the application is there any indication of the willingness of a third-party developer to acquire the property, which is listed as costing in excess of \$100,000 per acre. Further, there is no indication that the developer would be willing to lease the space to FMS ENA at the proposed rental rate identified in the pro forma. In fact, no potential developer is even identified in the application.

While the applicant's parent organization has demonstrated its willingness and ability to construct the space necessary for the site, it has not identified a willingness to purchase the property needed to develop the site. Further, no land cost is included in the application. Thus, there is nothing in the application demonstrating the availability of funds for capital and operating needs.

This failure to identify a developer willing and able to acquire and develop a proposed site or lease space to the applicant is a fundamental flaw in the application, making it unapprovable. Our Court of Appeals has held that where a CON project is to be funded in part by parties other than by the applicant, the application must contain evidence of a commitment to provide the funds by each funding entity. Without such a commitment, an applicant cannot adequately demonstrate availability of funds or the requisite financial feasibility. Retirement Villages, Inc. v. N.C.D.H.R., 124 N.C. App. 495, 477 S.E.2d 697 (1996). Without evidence of a developer willing and able to acquire the property and lease it to FMS ENA, the application is non-conforming with Criterion 5 and must be disapproved.

2. On Page 42, FMS ENA states, "*FMS ENA expects that it could take as much as eight months for cash in-flow to exceed cash out-flow.*" However, as discussed under Criterion 3, the patient projections put forth by FMS ENA are not supported by the geographical reality of the patients who have provided project support letters and who FMS ENA project to serve. If FMS ENA cannot achieve its patient projections of even the initial six proposed patients, it is very unlikely FMS ENA can reach its financial projections.
3. The revenue assumptions in Pro Forma Form C contained in Section R, p. 97 of the application include several errors that greatly impact overall revenue and performance, as noted below:
 - a. The application states that the allowable charge is \$3,988 for all payors. While it is clear after reading the assumptions that this is meant to be the **billable** charge, it nevertheless is extremely high. When you convert it from the hemo-equivalent rate shown to a per treatment home rate, it is still very high for industry standards:

$$(\$3988 \times 3) / 7 = \$1709.14 \text{ Per Treatment}$$

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The dialysis centers of WFUHS provide home dialysis services in multiple counties throughout the state of North Carolina. The home dialysis **billable rate** average for the WFUHS facilities was \$641.10 for the last full operating year and is \$761.57 for the current and next two operating years.

- b. The payor mix percentages for OY2 add up to be 132.76%. When you multiply the 100% payor mix percentage shown for OY2 for Medicare by the ***“Total Tx Adjusted for Missed Tx”*** and by the ***“Allowable Charge,”*** OY2 gross revenue for Medicare alone is projected to be \$3,445,632.

If FMS ENA had properly projected its OY2 Medicare payor mix at 67.24% of total revenue, as it should be, Medicare revenue would be \$2,316,962, just as it was in OY1. Thus, revenue for OY2 is overstated by the difference between Medicare revenue for OY1 and Medicare revenue for OY2 or:

$$\$3,445,632 - \$2,316,962 = \$1,128,670$$

- c. The applicant fails to state its “allowable” charge per treatment on Form C. However, using data from Forms B and C of the FMS ENA application, the hemo-equivalent allowable amount per payor source can be calculated, as demonstrated below:

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	OY1 (From FMS ENA Form B)	Contractual Allowances (From FMS ENA Form B)	OY1 # of Tx (From FMS ENA Form C)	OY1 Net Contractual Adjustments (A - B)	OY1 Allowable Per Tx (A-B) / C	OY2 (From FMS ENA Form B)	Contractual Allowances (From FMS ENA Form B)	OY2 # of Tx (From FMS ENA Form C)	OY2 Net Contractual Adjustments (A - B)	OY2 Allowable Per Tx (A-B) / C
	A	B	C	(A - B)	(A-B) / C	A	B	C	(A - B)	(A-B) / C
Self Pay / Indigent Charity	81,509	(52,384)	20	29,125	1,456.25	81,509	(52,384)	20	29,125	1,456
Medicare	2,316,962	(2,178,095)	581	138,867	239.01	3,445,632	(3,239,119)	864	206,513	239
Medicaid	28,387	(27,388)	7	999	142.71	28,387	(27,388)	7	999	143
Commercial	884,056	(568,163)	222	315,893	1,422.94	884,056	(568,163)	222	315,893	1,423
Medicare / Commercial	98,953	-	25	98,953	3,958.12	98,953	-	25	98,953	3,958
Medicare / Medicaid				-				0	-	
VA	35,765	-	9	35,765	3,973.89	35,765	-	9	35,765	3,974
Other										
Total	3,445,632	(2,826,030)	864	619,602		4,574,302	(3,887,054)	1147	687,248	
Charity Care										
Bad Debt		(37,176)					(41,235)			
Total Deductions from Patient Revenue		(2,863,206)					(3,928,289)			
Net Patient Revenue					582,426					646,013
Expenses (From Form A)										
Routine Services					(184,366)					(186,457)
General and Administrative					(203,579)					(229,908)
Property, Ownership, and Use					(173,755)					(176,706)
Total Operating Expenses					(561,700)					(593,071)
Net Income					20,726					52,942

What is significant about this data is that there is no contractual allowance amount for Medicare / Commercial or VA payors. On page 48 of the application FMS ENA states, “FMS ENA assumptions follow the Form B.” However, there are no such assumptions to explain the lack of a contractual allowance deduction for Medicare / Commercial or VA.

- d. In order to achieve the revenue projected for each of those payors, FMS ENA would have to project the allowable amounts for those payors in excess of \$3,900 per treatment. Typically, Medicare / Commercial has an allowable equal to 105% of the Medicare allowable rate. The VA allowable amount is typically slightly higher than Medicare. Thus, the revenue for both Medicare / Commercial and VA is grossly overstated for both operating years.
- e. Form B states that Net Income for OY1 is \$20,726 and for OY2 is \$52,941. However, due to a lack of contractual allowance for Medicare / Commercial and VA paired with an overstatement of revenue for Medicare for OY2, it is impossible for the applicant to have a positive net income. In fact, by correcting Medicare / Commercial and VA contractual allowance amounts to those reported on page 92 of the FMC Tarboro CON application, Project ID # L-11011-15, and those allowable amounts are reduced from **\$3,958.12 to \$239.02** for Medicare / Commercial and

**Written Comments Filed by Wake Forest University Health Sciences
Concerning FMS ENA Home, LLC CON Application, HSA VI – #L-11067-15**

from \$3,973.89 to \$231.12 for VA. As shown below, this would result in a net loss of \$68,760 for OY1 and \$32,485 for OY2.

	OY1 (From FMS ENA Form B) A	Contractual Allowances (From FMS ENA Form B) B	Tx (From FMS ENA Form C) C	OY1 Net Contractual Adjustments (A - B)	OY1 Allowable Per Tx (A-B) / C	OY2 (From FMS ENA Form B) A	Contractual Allowances (From FMS ENA Form B) B	OY2 # of Tx (From FMS ENA Form C) C	OY2 Net Contractual Adjustments (A - B)	OY2 Allowable Per Tx (A-B) / C
Self Pay / Indigent Charity	81,509	(52,384)	20	29,125	1,456.25	81,509	(52,384)	20	29,125	1,456
Medicare	2,316,962	(2,178,095)	581	138,867	239.01	3,445,632	(3,239,119)	864	206,513	239
Medicaid	28,387	(27,388)	7	999	142.71	28,387	(27,388)	7	999	143
Commercial	884,056	(568,163)	222	315,893	1,422.94	884,056	(568,163)	222	315,893	1,423
Medicare / Commercial	98,953	(92,978)	25	5,975	239.02	98,953	(92,978)	25	5,975	239.02
Medicare / Medicaid				-				0	-	
VA	35,765	(33,685)	9	2,080	231.12	35,765	(33,685)	9	2,080	231.12
Other										
Total	3,445,632	(2,952,692)	864	492,940		4,574,302	(4,013,716)	1147	560,586	
Charity Care										
Bad Debt					(37,176)					(41,235)
Total Deductions from Patient Revenue					(2,952,692)					(4,013,716)
Net Patient Revenue					492,940					560,586
Expenses (From Form A)										
Routine Services					(184,366)					(186,457)
General and Administrative					(203,579)					(229,908)
Property, Ownership, and Use					(173,755)					(176,706)
Total Operating Expenses					(561,700)					(593,071)
Net Income					(68,760)					(32,485)

Based upon the information contained in the application, the project does not demonstrate immediate nor long-term financial feasibility. Thus, the application is non-conforming with Criterion 5.

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

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

Due to FMS ENA's non-conformity with Criterion 3 (failure to identify the population to be served by the proposed project and failure to demonstrate the need that population has for the service), approval of FMS ENA's proposed home dialysis training certified facility would result in the unnecessary duplication of services in the proposed service area. Thus, FMS ENA is non-conforming with Criterion 6.

SECTION I - “CRITERION (8)” - G.S. 131E-183(a)(8)

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

The applicant indicates on page 56 of its application that patients requiring in-center dialysis / maintenance would be referred to FMC Edgecombe County, BMA East Rocky Mount, BMA Rocky Mount, or Greenville Dialysis Center. However, there are only two home dialysis affiliation agreements in Exhibit I-1 to the application. One is with BMA South Rocky Mount. The other is with Greenville Dialysis Center. The applicant does not provide a backup agreement with a BMA location in Edgecombe County for the home dialysis patients who would utilize FMS ENA.

SECTION K - “CRITERION (12)” - G.S. 131E-183(a)(12)

“Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.”

For the reasons discussed under Criterion 5, the applicant is also non-conforming with Criterion 12. Without a developer willing to purchase the property and lease the building to FMS ENA at the rate stated in the pro forma, there is no way for FMS ENA to demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative.

SECTION L - "CRITERION (13)" - G.S. 131E-183(a)(13)

"The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:

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

The application projects on p. 70 to serve no Medicaid patients. However, on page 71 the applicant provides the following payor mix for the two closest BMA facilities, which provide ICH as well as home dialysis services:

**BMA Home Dialysis Historical Payor Mix
As of June 30, 2015
Based upon Treatment Volumes**

	BMA Rocky Mount	Greenville Dialysis
MEDICARE	67.2%	73.0%
COMMERCIAL	29.4%	21.9%
MEDICAID	1.1%	0.5%
MISC INS	0.0%	2.1%
SELF PAY	2.2%	2.5%
TOTAL	100.0%	100.0%

No explanation is given for the discrepancy between FMS ENA's proposed payor mix and these facilities' historical payor mix. Refusal to provide service to Medicaid patients does not demonstrate access to the medically underserved.

On page 72, the applicant states that the admission policy included at Exhibit L-1 indicates that patients are required to have some type of insurance prior to admission for treatment. Exceptions are provided only when the Regional Vice President elects to override the policy. By requiring some type of insurance prior to admission for treatment, FMS ENA is in fact limiting services to a medically underserved group – the uninsured.

SECTION M - “CRITERION (14)” - G.S. 131E-183(a)(14)

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

The applicant provided a letter “to” but did not provide any correspondence from or evidence of an affiliation intent with a local health professional training facility.

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

“The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.”

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

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

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

The FMS ENA application is non-conforming with the following applicable rules.

10A NCAC 14C .2202 INFORMATION REQUIRED OF APPLICANT

(b) An applicant that proposes to develop a new facility, increase the number of dialysis stations in an existing facility, establish a new dialysis station, or relocate existing dialysis stations shall provide the following information requested on the End Stage Renal Disease (ESRD) Treatment application form:

-
- (5) For new facilities, the location of the site on which the services are to be operated. If such site is neither owned by nor under option to the applicant, the applicant must provide a written commitment to pursue acquiring the site if and when the approval is granted, must specify a secondary site on which the services could be operated should acquisition efforts relative to the primary site ultimately fail, and must demonstrate that the primary and secondary sites are available for acquisition.*
 - (6) Documentation that the services will be provided in conformity with applicable laws and regulations pertaining to staffing, fire safety equipment, physical environment, water supply, and other relevant health and safety requirements.*

Neither FMS ENA nor its parent companies have obtained an option or provided a commitment to acquire a site. Rather, the application states that some unidentified developer will do so, and lease the property to FMS ENA at a specified rate. Without the identification of a developer willing to acquire the property and lease the facility to FMS ENA, the applicant cannot demonstrate conformity with either of the above rules.

- (7) The projected patient origin for the services. All assumptions, including the methodology by which patient origin is projected, must be stated.*

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

10A NCAC 14C .2203 PERFORMANCE STANDARDS

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

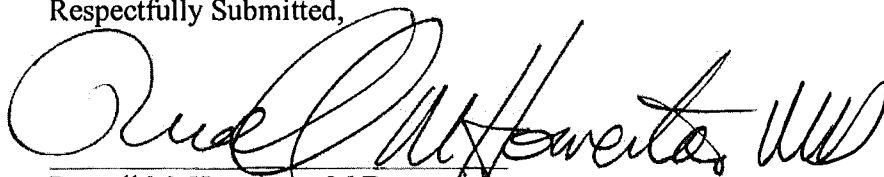
As discussed under Criterion 3 above, the application fails to provide all assumptions, including the methodology by which patient origin was projected. Therefore, the FMS ENA application is nonconforming with this rule.

CONCLUSION

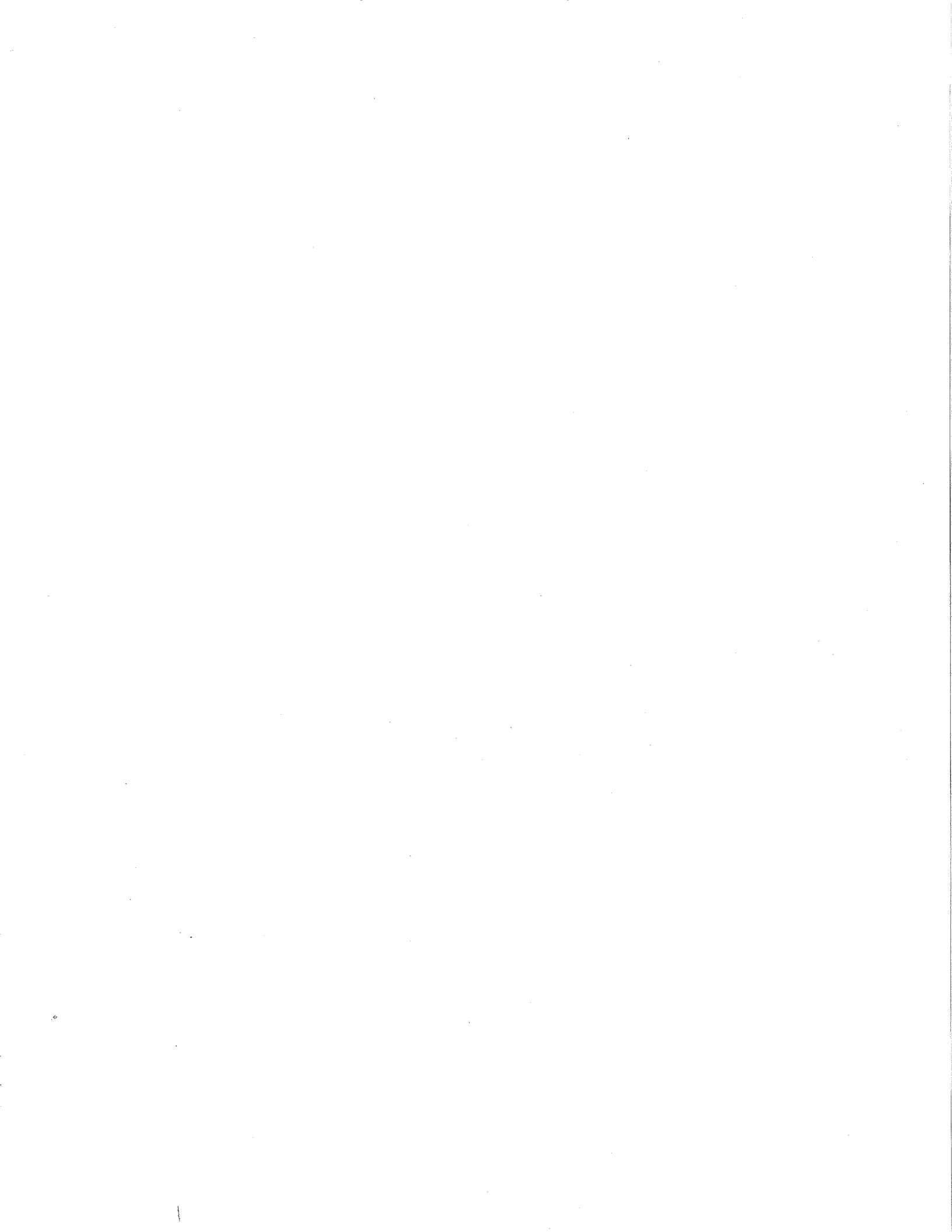
In conclusion, the FMS ENA application contains a number of crucial errors, which make its application non-approvable. For these reasons, WFUHS recommends disapproval of FMS ENA's project.

Thank you for the opportunity to provide these comments and your careful consideration of these important issues. Please do not hesitate to contact me at (336) 716-1025.

Respectfully Submitted,



Russell M. Howerton, M.D.
Chief Medical Officer
Professor of Surgery



DATE: 7/29/2015

Ms. Martha Frisone, Chief
Certificate of Need Section
Division of Health Service Regulation
809 Ruggles Drive
Raleigh, North Carolina 27603

Dear Ms. Frisone:

I am a home dialysis patient. My residence zip code is 27886. My residence is in Edgecombe County.

I understand that Bio-Medical Applications of North Carolina and Eastern Nephrology Associates, PLLC will be submitting an application for a Certificate of Need to develop a new dialysis facility focused exclusively on home peritoneal dialysis. I understand the new home dialysis facility will be located in Tarboro, very near the hospital. I enthusiastically support development of the new Fresenius Medical Care ENA Home, LLC dialysis facility.

I am pleased to learn that Fresenius Medical Care and the nephrologists of Eastern Nephrology Associates, PLLC will be developing a dialysis facility with a focus on peritoneal dialysis patients. I think it is important to have staff dedicated to home dialysis patients and their needs. I will be able to have my monthly clinic visit at this facility.

The location of the proposed new facility, in Tarboro is very convenient. Having the facility near the hospital will allow me to schedule other doctor office visits for the same day as my clinic visit. Combining my doctor visits into a single day each month is very convenient and would mean less time involved in transportation and more time for me, and my needs.

I also understand that Eastern Nephrology Associates will have a nephrology trained clinician on site at all times when a patient is training to perform home peritoneal dialysis. Having the clinician on site will be very beneficial to the patient while training to perform home peritoneal dialysis. I would be willing to consider transferring my care to the Fresenius Medical Care ENA Home, LLC dialysis facility.

I am aware that this letter will be used as support for the Bio-Medical Applications of North Carolina application for Certificate of Need. By my signature below, I consent to my name being associated with this application. I further understand that no other Protected Health Information, PHI, regarding me, my diagnosis or treatment is released as a part of this application. I wish Bio-Medical Applications of North Carolina every success in this effort.

Roger Harper (Wife) Elizabeth Harper
(Patient Signature)

EXHIBIT 1

PEOPLE

BUSINESS

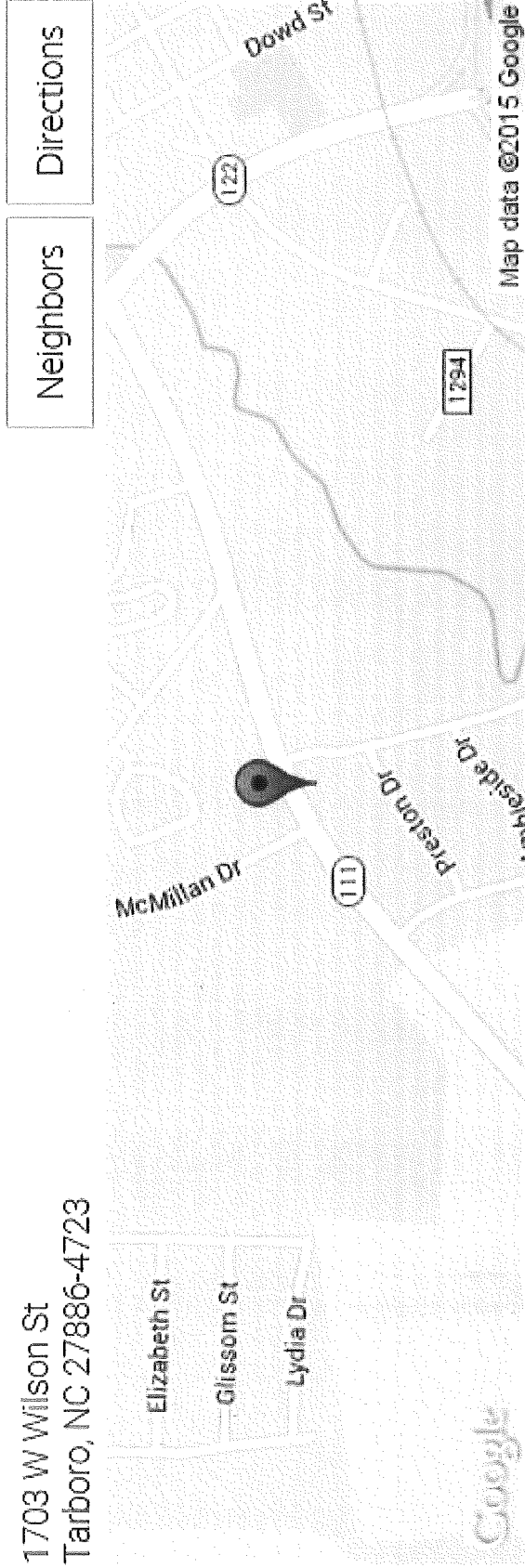
PHONE

Roger T Harper	Where Tarboro NC
----------------	-------------------------

[View Roger's Social Profiles from BeenVerified.com](#)

Address

1703 W Wilson St
Tarboro, NC 27886-4723



People Roger may know

Elizabeth R Harper	▶
--------------------	---

Route planner x

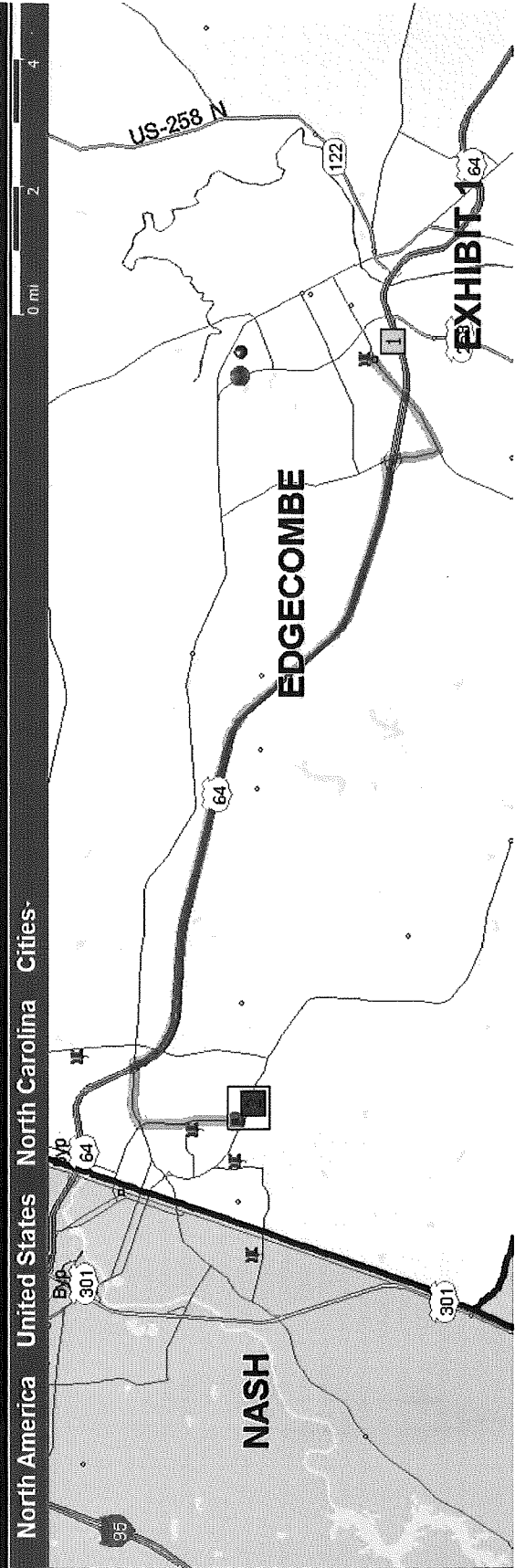
Type place or address

Add to route

Get directions Reverse route

Harper - 1703 W Wilson St, Tar...
BMA of East Rocky Mount

Time	Mile	Instruction	For	Toward
Summary: 16.0 miles (17 minutes)				
Construction information for your route is out of date. Click this line to update.				
9:00 AM	0.0	1 Depart Harper - 1703 W Wilson St, Tarbot 1.8 mi		
9:02 AM	1.8	Turn RIGHT (North) onto NC-122 [McNair Rd]	0.9 mi	
9:03 AM	2.6	Take Ramp (LEFT) onto US-64	10.5 mi	US-64 W
9:12 AM	13.2	At exit 472, keep RIGHT onto Ramp	0.3 mi	NC-43 S / US-64-ALT / US-64-BR / Rt
9:12 AM	13.5	Turn LEFT (West) onto US-64 ALT [US-64 Brand 0.2 mi		
9:12 AM	13.6	Road name changes to US-64 Branch [NC-43]	0.9 mi	
9:14 AM	14.5	Turn LEFT (South) onto NC-43 Branch [N Fairvie 1.0 mi		
9:16 AM	15.5	Keep STRAIGHT onto NC-43 Branch [S Fairview 0.5 mi		
9:17 AM	16.0	Turn RIGHT (West) onto Local road(s)	43 yds	
9:17 AM	16.0	Arrive BMA of East Rocky Mount		



North America United States North Carolina Cities

Optimize stops
More options

Route planner

Type place or address

Add to route

Get directions

Reverse route

Harper - 1703 W Wilson St, Tar...

BMA of Rocky Mount Inc

Optimize stops

More options...

Time Mile Instruction For Toward

Summary: 19.7 miles (19 minutes)

Construction information for your route is out of date. Click this line to update.

9:00 AM	0.0	1	Depart Harper - 1703 W Wilson St, Tarbc 1.8 mi		
9:02 AM	1.8		Turn RIGHT (North) onto NC-122 [McNair Rd]	0.9 mi	
9:03 AM	2.6		Take Ramp (LEFT) onto US-64	10.5 mi	US-64 W
9:12 AM	13.2		At exit 472, road name changes to US-64 Byp	6.1 mi	
9:17 AM	19.3		At exit 466, keep RIGHT onto Ramp	0.2 mi	Winstead Avenue
9:18 AM	19.5		Keep LEFT to stay on Ramp	65 yds	
9:18 AM	19.5		Turn LEFT (North-East) onto N Winstead Ave	0.1 mi	
9:18 AM	19.7		Turn RIGHT (South-East) onto English Rd	153 yds	
9:19 AM	19.7	■	Arrive BMA of Rocky Mount Inc [750 Eng		

North America United States North Carolina Cities-

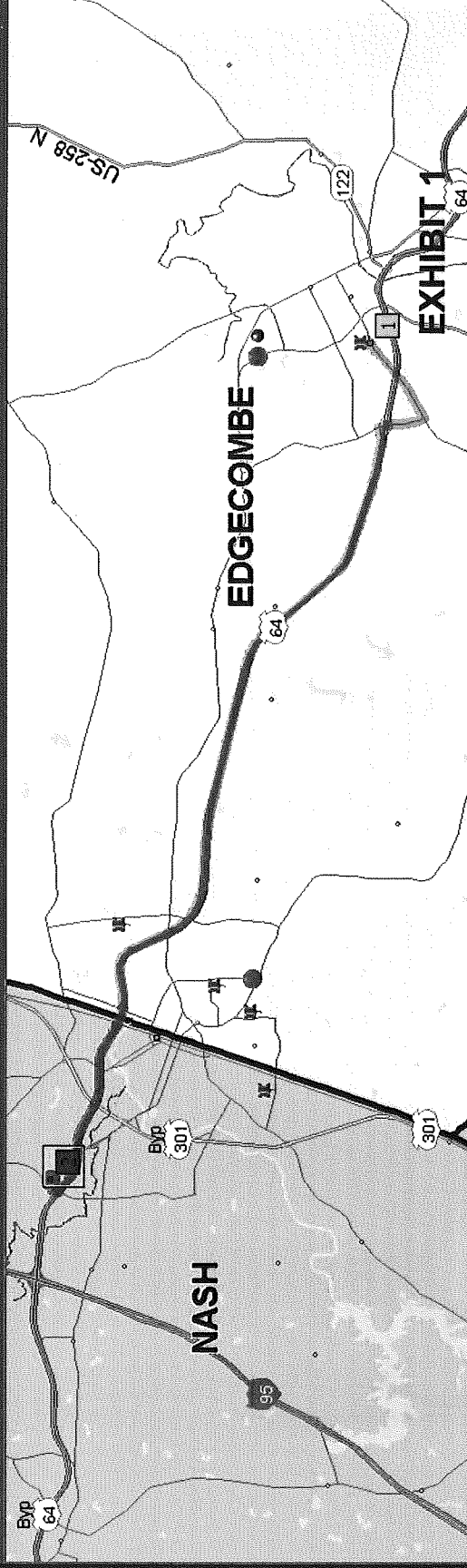


EXHIBIT 1

Route planner ▾

Type place or address

Add to route

Get directions

Reverse route
Harper - 1703 W Wilson St, Tar...
123 Hospital Dr, Tarboro, NC 2...

Time

Mile

Instruction

For

Toward

Summary: 2.8 miles (4 minutes)

Construction information for your route is out of date. Click this line to update.

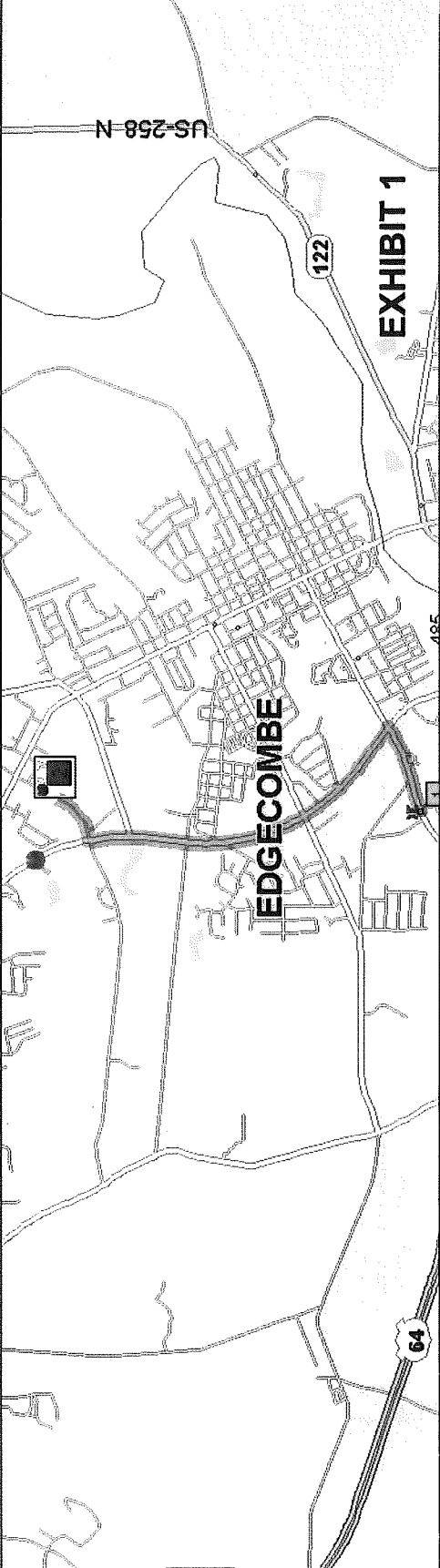
- 9:00 AM 0.0 **1** Depart Harper - 1703 W Wilson St, Tarboro 0.5 mi
- 9:00 AM 0.5 Turn LEFT (North-West) onto US-64 ALT [NC-12 0.7 mi
- 9:01 AM 1.2 Keep STRAIGHT onto US-64 ALT [Western Blvd] 1.2 mi
- 9:03 AM 2.4 Turn RIGHT (East) onto Hospital Dr 0.4 mi
- 9:04 AM 2.8 **2** Arrive 123 Hospital Dr, Tarboro, NC 2784

SUMMARY

Driving distance: 2.8 miles

Trip duration: 4 minutes

North America United States North Carolina Cities



Optimize stops

DATE: 7-31-15

Ms. Martha Frisone, Chief
Certificate of Need Section
Division of Health Service Regulation
809 Ruggles Drive
Raleigh, North Carolina 27603

Dear Ms. Frisone:

I am a home dialysis patient. My residence zip code is 27864. My residence is in Edgecomb County.

I understand that Bio-Medical Applications of North Carolina and Eastern Nephrology Associates, PLLC will be submitting an application for a Certificate of Need to develop a new dialysis facility focused exclusively on home peritoneal dialysis. I understand the new home dialysis facility will be located in Tarboro, very near the hospital. I enthusiastically support development of the new Fresenius Medical Care ENA Home, LLC dialysis facility.

I am pleased to learn that Fresenius Medical Care and the nephrologists of Eastern Nephrology Associates, PLLC will be developing a dialysis facility with a focus on peritoneal dialysis patients. I think it is important to have staff dedicated to home dialysis patients and their needs. I will be able to have my monthly clinic visit at this facility.

The location of the proposed new facility, in Tarboro is very convenient. Having the facility near the hospital will allow me to schedule other doctor office visits for the same day as my clinic visit. Combining my doctor visits into a single day each month is very convenient and would mean less time involved in transportation and more time for me, and my needs.

I also understand that Eastern Nephrology Associates will have a nephrology trained clinician on site at all times when a patient is training to perform home peritoneal dialysis. Having the clinician on site will be very beneficial to the patient while training to perform home peritoneal dialysis. I would be willing to consider transferring my care to the Fresenius Medical Care ENA Home, LLC dialysis facility.

I am aware that this letter will be used as support for the Bio-Medical Applications of North Carolina application for Certificate of Need. By my signature below, I consent to my name being associated with this application. I further understand that no other Protected Health Information, PHI, regarding me, my diagnosis or treatment is released as a part of this application. I wish Bio-Medical Applications of North Carolina every success in this effort.

Lena H. Jenkins
(Patient Signature)

EXHIBIT 1

PEOPLE

BUSINESS

PHONE

Lena Jenkins

Where Pinetops NC



Print



Download



Text Me



Send them flowers
1-800-Flowers.com

Phone number

252-827-0415

CenturyLink Landline

[View Lena's Social Profiles from BeenVerified.com](#)

Address

303 E Pitt St

Pinetops, NC 27864-8804

Neighbors

Directions

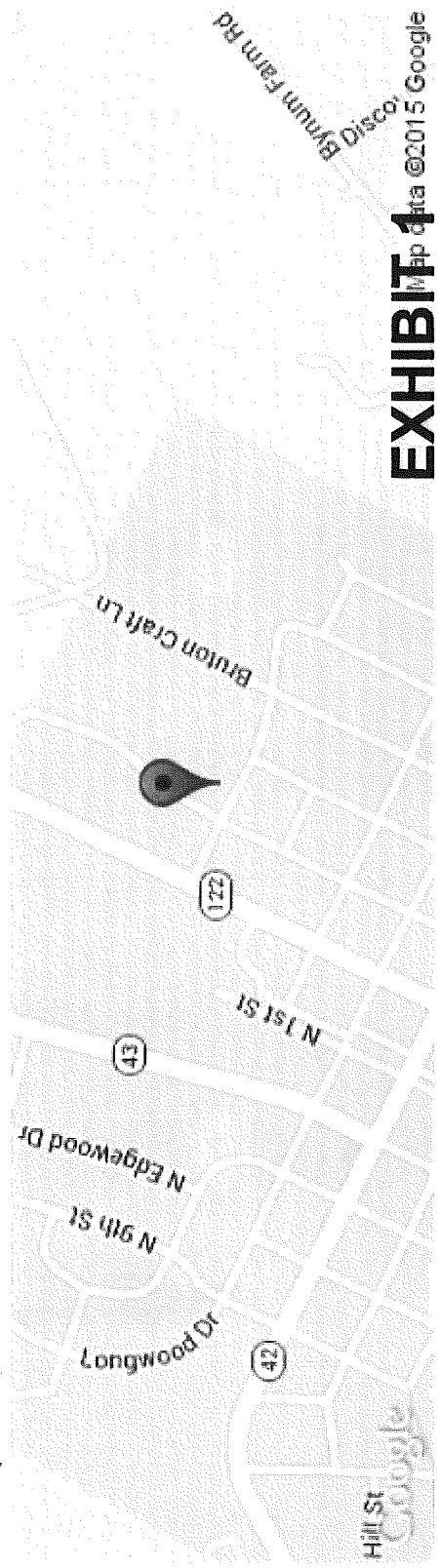


EXHIBIT 4

Route planner

Type place or address

BMA of East Rocky Mount

Add to route

Get directions

Reverse route

1 Jenkins

BMA of East Rocky Mount

Time Mile Instruction

For Toward

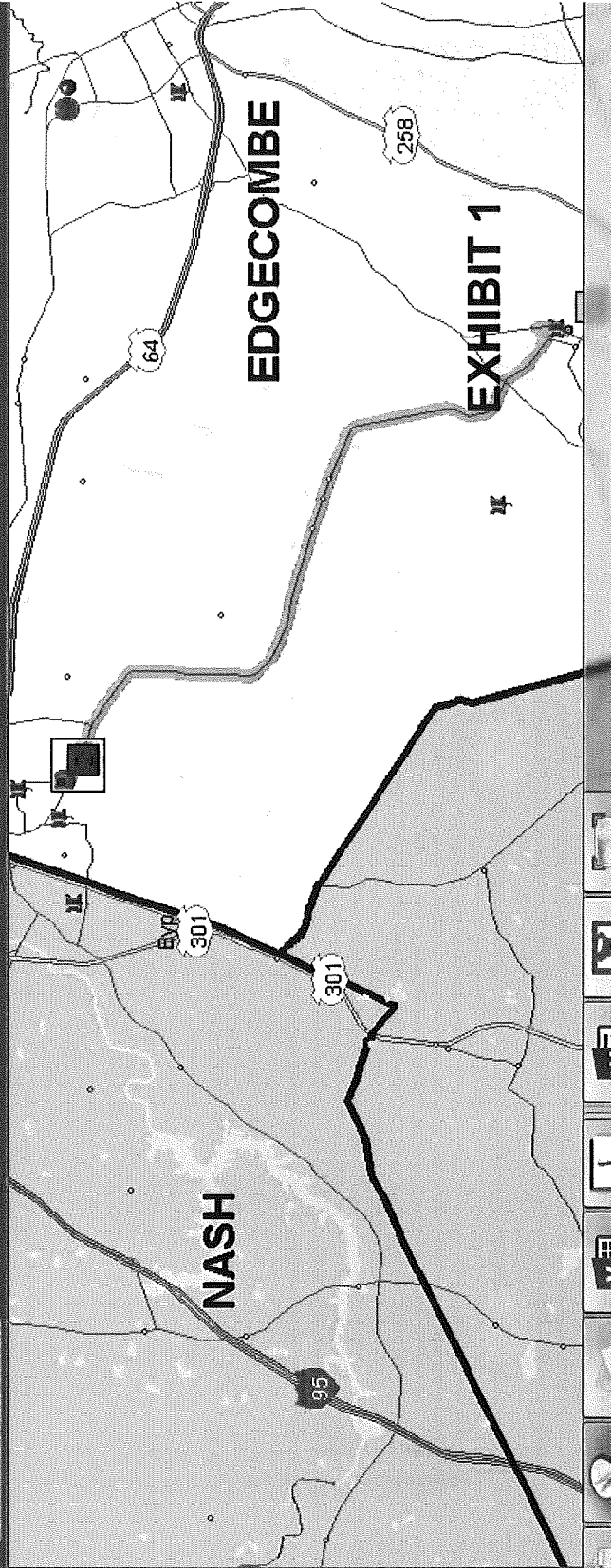
Summary: 14.3 miles (18 minutes)

Construction information for your route is out of date. Click this line to update.

- 9:00 AM 0.0 **1** Depart Jenkins [303 Pitt St, Pinetops, NC 120 yds
- 9:00 AM 0.1 Turn RIGHT (North) onto NC-122 [N 2nd St] 0.5 mi
- 9:01 AM 0.6 Turn LEFT (South) onto Maybelle-Pitt Ln [Maybelle 0.3 mi
- 9:02 AM 1.0 Bear RIGHT (North-West) onto NC-43 [NC 43 N 5.1 mi
- 9:08 AM 6.1 Keep STRAIGHT onto NC-43 [NC Highway 43 N 4.1 mi
- 9:12 AM 10.1 Keep STRAIGHT onto NC-43 [Cokey Rd] 3.0 mi
- 9:16 AM 13.1 Keep STRAIGHT onto NC-43 Branch [Cokey Rd] 1.1 mi
- 9:18 AM 14.1 Turn RIGHT (North) onto NC-43 Branch [Fairvie] 0.1 mi
- 9:18 AM 14.3 Turn LEFT (West) onto Local road(s) 43 yds
- 9:18 AM 14.3 **1** Arrive BMA of East Rocky Mount

North America

United States North Carolina Cities-



Optimize stops

Route planner ▾

Type place or address

Add to route

Get directions

Reverse route

1 Jenkins
 BMA of Rocky Mount Inc

Optimize stops

More options...

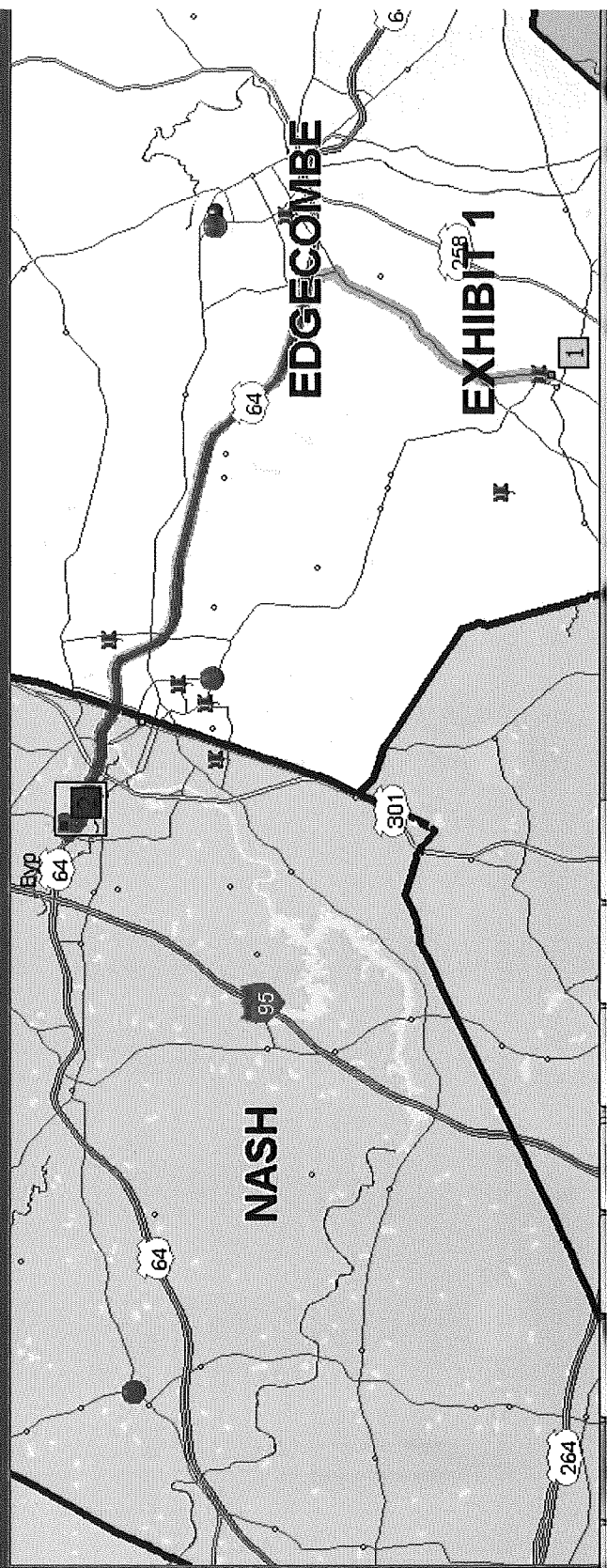
Time | Mile | Instruction | For | Toward

Summary: 24.7 miles (25 minutes)

Construction information for your route is out of date. Click this line to update.

9:00 AM	0.0	1 Depart Jenkins [303 Pitt St, Pinetops, NC 120 yds		
9:00 AM	0.1	Turn RIGHT (North) onto NC-122 [N 2nd St]	0.5 mi	
9:01 AM	0.6	Keep STRAIGHT onto NC-122	0.2 mi	
9:01 AM	0.8	Keep STRAIGHT onto NC-122 [NC 122 S]	1.1 mi	
9:02 AM	2.0	Bear RIGHT (North-East) onto NC-111 [NC-122]	4.8 mi	
9:08 AM	6.8	Turn LEFT (North) onto NC-122 [McNair Rd]	0.9 mi	
9:09 AM	7.6	Take Ramp (LEFT) onto US-64	10.5 mi	US-64 W
9:18 AM	18.2	At exit 472, road name changes to US-64 Byp	6.1 mi	
9:23 AM	24.3	At exit 466, keep RIGHT onto Ramp	0.2 mi	Winstead Avenue
9:24 AM	24.5	Keep LEFT to stay on Ramp	65 yds	

North America United States North Carolina



Route planner

Type place or address

Add to route

Get directions

Reverse route

1 Jenkins

123 Hospital Dr, Tarboro, NC 2...

Optimize stops

More options...



Time

Mile

Instruction

For

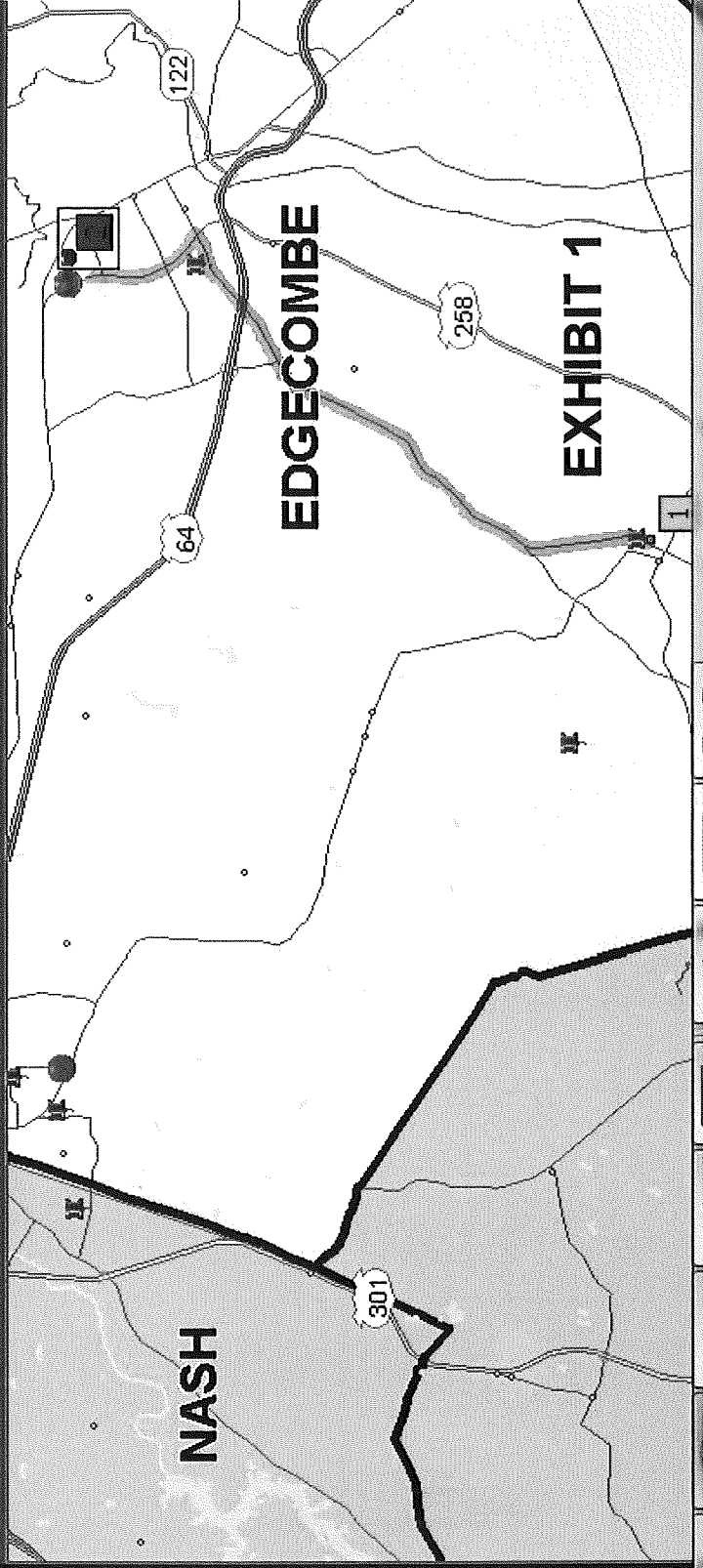
Toward

Summary: 11.4 miles (14 minutes)

Construction information for your route is out of date. Click this line to update.

Time	Mile	Instruction
9:00 AM	0.0	1 Depart Jenkins [303 Pitt St, Pinetops, NC 120 yds
9:00 AM	0.1	Turn RIGHT (North) onto NC-122 [N 2nd St] 0.5 mi
9:01 AM	0.6	Keep STRAIGHT onto NC-122 0.2 mi
9:01 AM	0.8	Keep STRAIGHT onto NC-122 [NC 122 S] 1.1 mi
9:02 AM	2.0	Bear RIGHT (North-East) onto NC-111 [NC-122] 4.8 mi
9:08 AM	6.8	Keep STRAIGHT onto NC-111 [W Wilson St] 2.3 mi
9:10 AM	9.0	Turn LEFT (North-West) onto US-64 ALT [NC-12 0.7 mi
9:12 AM	9.7	Keep STRAIGHT onto US-64 ALT [Western Blvd] 1.2 mi
9:13 AM	11.0	Turn RIGHT (East) onto Hospital Dr 0.4 mi
9:14 AM	11.4	Arrive 123 Hospital Dr, Tarboro, NC 2788

North America United States North Carolina Cities-



DATE: 7/31/2015

Ms. Martha Frisone, Chief
Certificate of Need Section
Division of Health Service Regulation
809 Ruggles Drive
Raleigh, North Carolina 27603

Dear Ms. Frisone:

I am a home dialysis patient. My residence zip code is 27801. My residence is in Edgecomb County.

I understand that Bio-Medical Applications of North Carolina and Eastern Nephrology Associates, PLLC will be submitting an application for a Certificate of Need to develop a new dialysis facility focused exclusively on home peritoneal dialysis. I understand the new home dialysis facility will be located in Tarboro, very near the hospital. I enthusiastically support development of the new Fresenius Medical Care ENA Home, LLC dialysis facility.

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I am aware that this letter will be used as support for the Bio-Medical Applications of North Carolina application for Certificate of Need. By my signature below, I consent to my name being associated with this application. I further understand that no other Protected Health Information, PHI, regarding me, my diagnosis or treatment is released as a part of this application. I wish Bio-Medical Applications of North Carolina every success in this effort.



(Patient Signature)

EXHIBIT 1

PEOPLE

BUSINESS

PHONE

Corliss Johnson

Where Rocky Mount NC

Advertisement: [Try Equifax Complete™](#) – Sign up now to see your credit scores

Corliss Johnson



Print



Download



Text Me



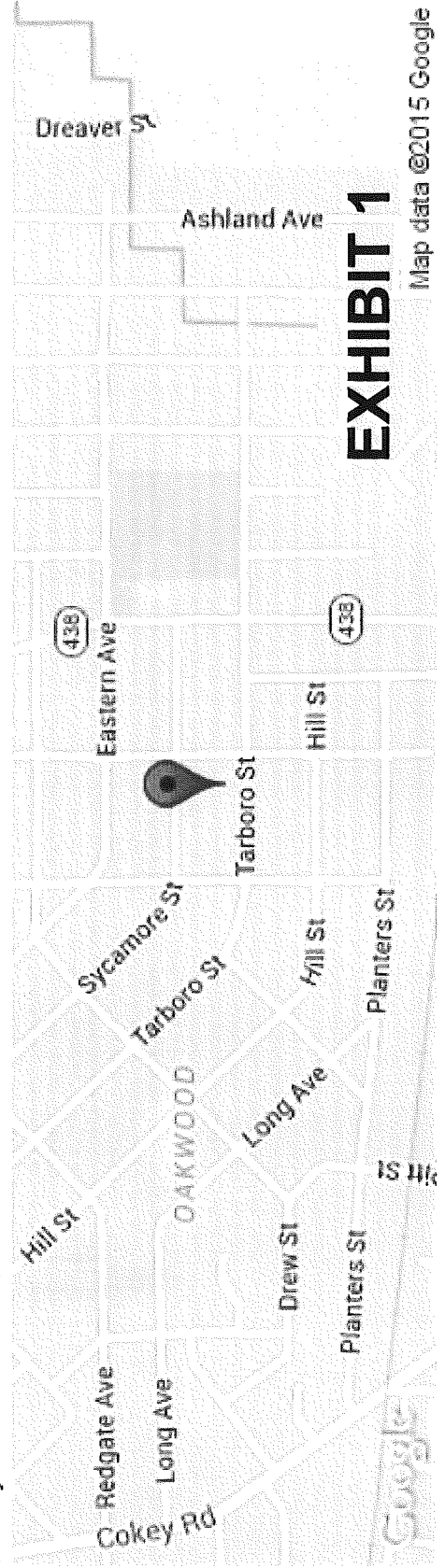
Sign Up Now
Equifax.com

Active Phone Numbers for Corliss Johnson are at [PeopleFinders.com](#)

Address

1224 Tarboro St
Rocky Mount, NC 27801-6039

Neighbors
Directions



Type place or address

Add to route

Get directions

1 Johnson - 1224 Tarboro St, Rocky M...
BMA of East Rocky Mount

Reverse route

Time | Mile | Instruction

Summary: 0.7 miles (2 minutes)

Construction information for your route is out of date. Click this line to update.

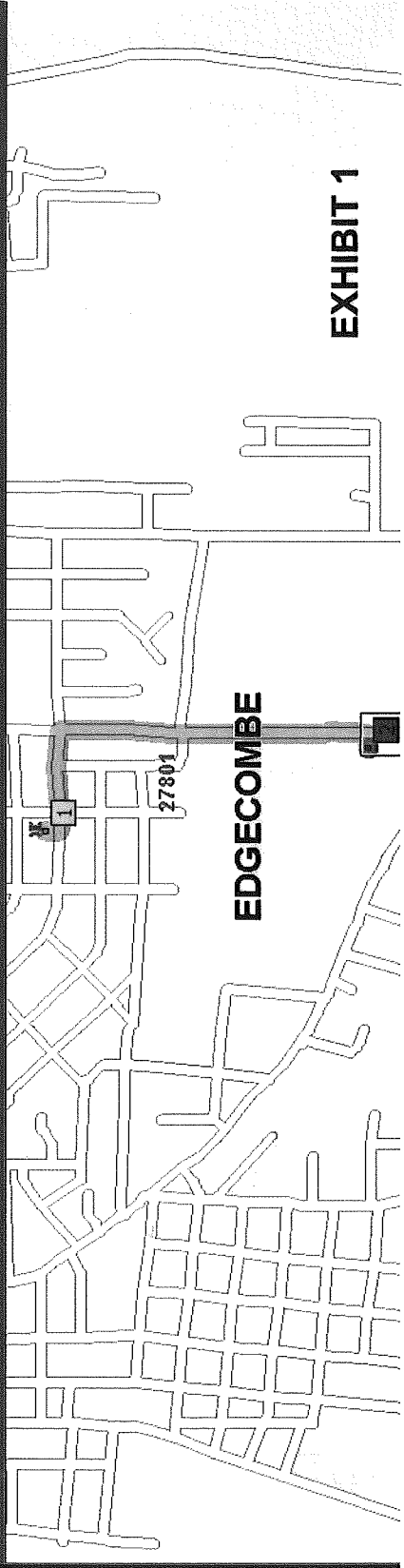
- 9:00 AM 0.0 1 Depart Johnson - 1224 Tarboro St, Rock 43 yds
- 9:00 AM 0.1 Turn LEFT (East) onto Tarboro St 0.2 mi
- 9:01 AM 0.2 Turn RIGHT (South) onto NC-43 Branch [S Fairvi 0.5 mi
- 9:02 AM 0.7 Turn RIGHT (West) onto Local road(s) 43 yds
- 9:02 AM 0.7 Arrive BMA of East Rocky Mount

For | Toward

SUMMARY

Driving distance: 0.7 miles
 Trip duration: 2 minutes
 Driving time: 2 minutes
 Cost: \$0.08

North America United States North Carolina Rocky Mount



Optimize stops

More options...

Route planner

Type place or address

Add to route

Get directions

Reverse route

Johnson - 1224 Tarboro St., Rocky M...
BMA of Rocky Mount Inc

Optimize stops

More options...

Time

Mile

Instruction

For

Toward

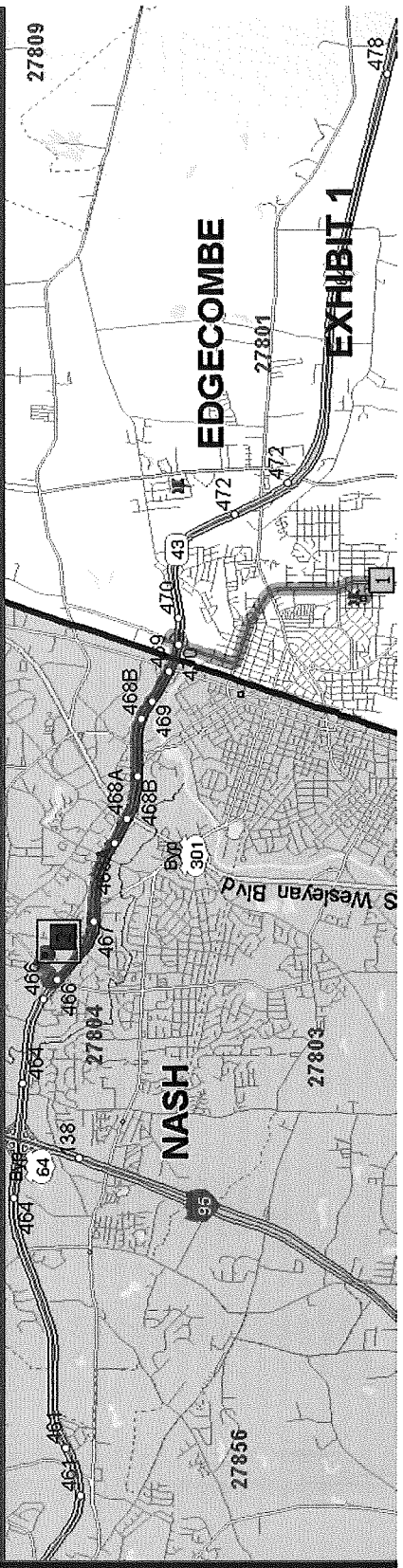
Summary: 7.2 miles (11 minutes)
Construction information for your route is out of date. Click this line to update.

Time	Mile	Instruction	For	Toward
9:00 AM	0.0	1 Depart Johnson - 1224 Tarboro St., Rock 43 yds		
9:00 AM	0.1	Turn LEFT (East) onto Tarboro St		0.2 mi
9:01 AM	0.2	Turn LEFT (North) onto NC-43 Branch [N Fairvie 1.0 mi		0.8 mi
9:03 AM	1.2	Road name changes to NC-43 [NC-43 Branch]		0.7 mi
9:05 AM	2.0	Turn RIGHT (North) onto NC-97 [E NC-97]		4.0 mi
9:06 AM	2.8	Take Ramp (RIGHT) onto US-64 Byp [NC-43]		0.2 mi
9:09 AM	6.7	At exit 466, keep RIGHT onto Ramp		65 yds
9:10 AM	6.9	Keep LEFT to stay on Ramp		0.1 mi
9:10 AM	7.0	Turn LEFT (North-East) onto N Winstead Ave		153 yds
9:11 AM	7.1	Turn RIGHT (South-East) onto English Rd		
9:11 AM	7.2	1 Arrive BMA of Rocky Mount Inc [750 Eng		

US-64-BYP W / Raleigh
Winstead Avenue

SUMMARY

North America United States North Carolina Rocky Mount



Route planner

Type place or address

Add to route

Get directions

Reverse route

Johnson - 1224 Tarboro St, Rocky M...
123 Hospital Dr, Tarboro, NC 27886

Optimize stops

Show address

Time Mile Instruction

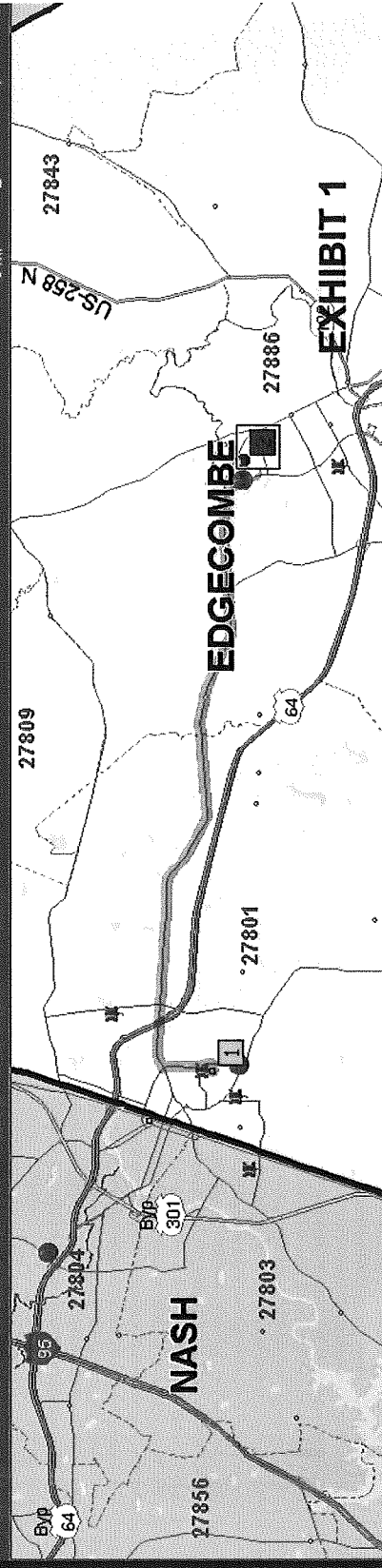
Summary: 14.4 miles (19 minutes)

Construction information for your route is out of date. Click this line to update.

- 9:00 AM 0.0 Depart Johnson - 1224 Tarboro St, Rock 43 yds
- 9:00 AM 0.1 Turn LEFT (East) onto Tarboro St 0.2 mi
- 9:01 AM 0.2 Turn LEFT (North) onto NC-43 Branch [N Fairvie 1.0 mi
- 9:03 AM 1.2 Turn RIGHT (East) onto US-64 Branch [NC-43] 0.9 mi
- 9:05 AM 2.0 Road name changes to US-64 ALT [US-64 Bram] 0.2 mi
- 9:05 AM 2.2 Keep STRAIGHT onto US-64 ALT [NC-43] 0.3 mi
- 9:06 AM 2.5 Keep STRAIGHT onto US-64 ALT [N Raleigh St] 2.4 mi
- 9:08 AM 4.9 Keep STRAIGHT onto US-64 ALT [Raleigh St] 1.2 mi
- 9:09 AM 6.1 Keep STRAIGHT onto US-64 ALT [US Highway 6 2.0 mi
- 9:11 AM 8.1 Keep STRAIGHT onto US-64 ALT 4.3 mi
- 9:16 AM 12.4 Keep STRAIGHT onto US-64 ALT [N Main St] 0.7 mi
- 9:17 AM 13.0 Keep STRAIGHT onto US-64 ALT [Western Blvd] 0.9 mi
- 9:18 AM 13.9 Turn LEFT (East) onto Hospital Dr 0.4 mi
- 9:19 AM 14.4 Arrive 123 Hospital Dr, Tarboro, NC 27886

For Toward

North America United States North Carolina Cities



DATE: 7/28/15

Ms. Martha Frisone, Chief
Certificate of Need Section
Division of Health Service Regulation
809 Ruggles Drive
Raleigh, North Carolina 27603

Dear Ms. Frisone:

I am a home dialysis patient. My residence zip code is 27886. My residence is in Edgecombe County.

I understand that Bio-Medical Applications of North Carolina and Eastern Nephrology Associates will be submitting an application for a Certificate of Need to develop a new dialysis facility focused exclusively on home peritoneal dialysis. I understand the new home dialysis facility will be located in Tarboro, very near the hospital. I enthusiastically support development of the new Fresenius Medical Care ENA Home, LLC dialysis facility.

I am pleased to learn that Fresenius Medical Care and the nephrologists of Eastern Nephrology Associates will be developing a dialysis facility with a focus on peritoneal dialysis patients. I think it is important to have staff dedicated to home dialysis patients and their needs. I will be able to have my monthly clinic visit at this facility.

The location of the proposed new facility, in Tarboro is very convenient. Having the facility near the hospital will allow me to schedule other doctor office visits for the same day as my clinic visit. Combining my doctor visits into a single day each month is very convenient and would mean less time involved in transportation and more time for me, and my needs.

I also understand that Eastern Nephrology Associates will have a nephrology trained clinician on site at all times when a patient is training to perform home peritoneal dialysis. Having the clinician on site will be very beneficial to the patient while training to perform home peritoneal dialysis. I would be willing to consider transferring my care to the Fresenius Medical Care ENA Home, LLC dialysis facility.

I am aware that this letter will be used as support for the Bio-Medical Applications of North Carolina application for Certificate of Need. By my signature below, I consent to my name being associated with this application. I further understand that no other Protected Health Information, PHI, regarding me, my diagnosis or treatment is released as a part of this application. I wish Bio-Medical Applications of North Carolina every success in this effort.

Gladys J. Lloyd
(Patient Signature)

EXHIBIT 1

PEOPLE BUSINESS PHONE ADDRESS

Gladys Lloyd

Where 27886



Filter by State

< Any State

North Carolina ✓

90 years old

Lives in: China Grove, NC

Email | Address | Phone

Gladys Lloyd

Age: 60-64

Current: Rocky Mount, NC

Prior: Princeville NC

Knows: Vincent C Richardson, Elijah Lloyd, Shirley...



View Full Profile

Filter by Zip

< Any Zip Code

27886 ✓

Gladys Lloyd

Age: 60-64

Current: Rocky Mount, NC

Prior: Tarboro NC, Princeville NC

Knows: Vincent C Richardson, Elijah Lloyd, Shirley...



View Full Profile

whitepages

PEOPLE

BUSINESS

PHONE

Gladys Lloyd

Where Rocky Mount NC

Address

409 Kingston Ave
Rocky Mount, NC 27803-4726

Neighbors Directions

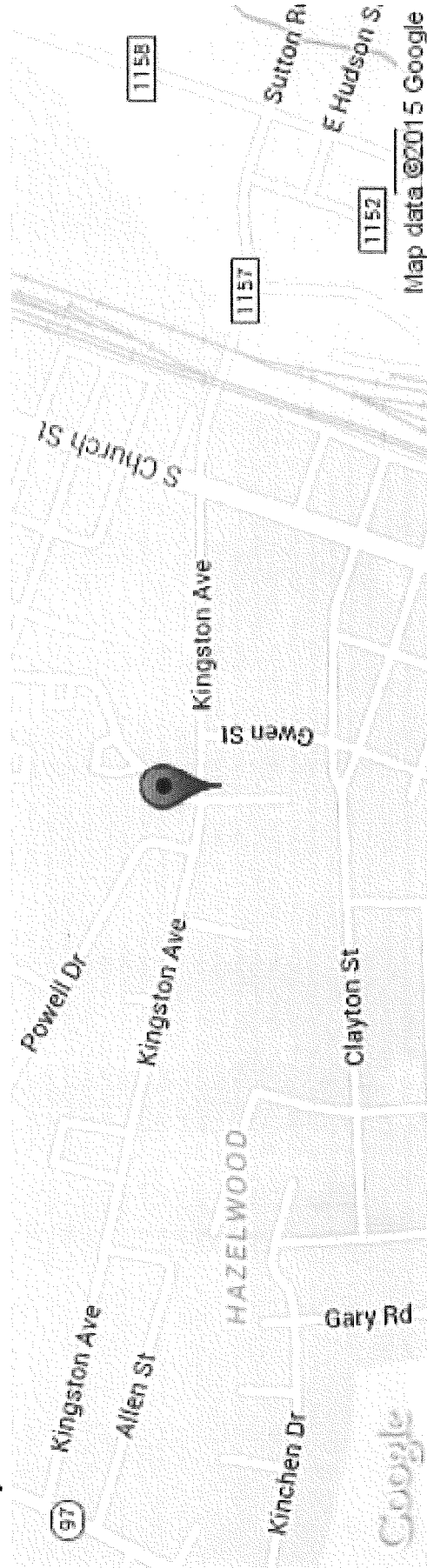


EXHIBIT 1

Route planner x

Type place or address

Add to route

Get directions Reverse route

1 Lloyd - 409 Kingston Ave, Rocky Moun...
 BMA of East Rocky Mount

Optimize stops

Time Mile Instruction For Toward

Summary: 3.3 miles (9 minutes)

Construction information for your route is out of date. Click this line to update.

9:00 AM	0.0	1 Depart Lloyd - 409 Kingston Ave, Rocky	0.4 mi
9:00 AM	0.4	Road name changes to NC-1157 [Sutton Rd]	120 yds
9:01 AM	0.4	Road name changes to Sutton Rd	0.7 mi
9:02 AM	1.1	Road name changes to NC-1157 [Sutton Rd]	0.1 mi
9:03 AM	1.3	Road name changes to Sutton Rd	0.2 mi
9:04 AM	1.4	Turn LEFT (North) onto Old Wilson Rd	0.7 mi
9:05 AM	2.2	Turn RIGHT (East) onto Rex St, then immediate	0.9 mi
9:08 AM	3.1	Turn LEFT (North) onto NC-43 Branch [Fairview	0.1 mi
9:08 AM	3.2	Turn LEFT (West) onto Local road(s)	45 yds
9:09 AM	3.3	Arrive BMA of East Rocky Mount	

SUMMARY

Driving distance: 3.3 miles

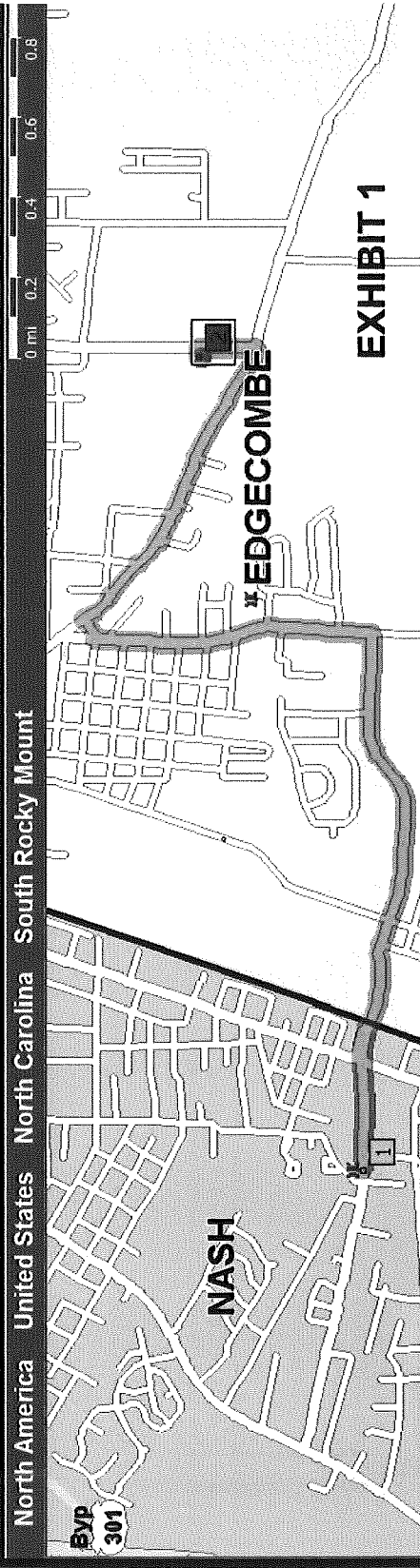


EXHIBIT 1

Type place or address

Add to route

Get directions

Reverse route

1 Lloyd - 409 Kingston Ave, Rocky Moun...
BMA of Rocky Mount Inc



Optimize stops

More options...

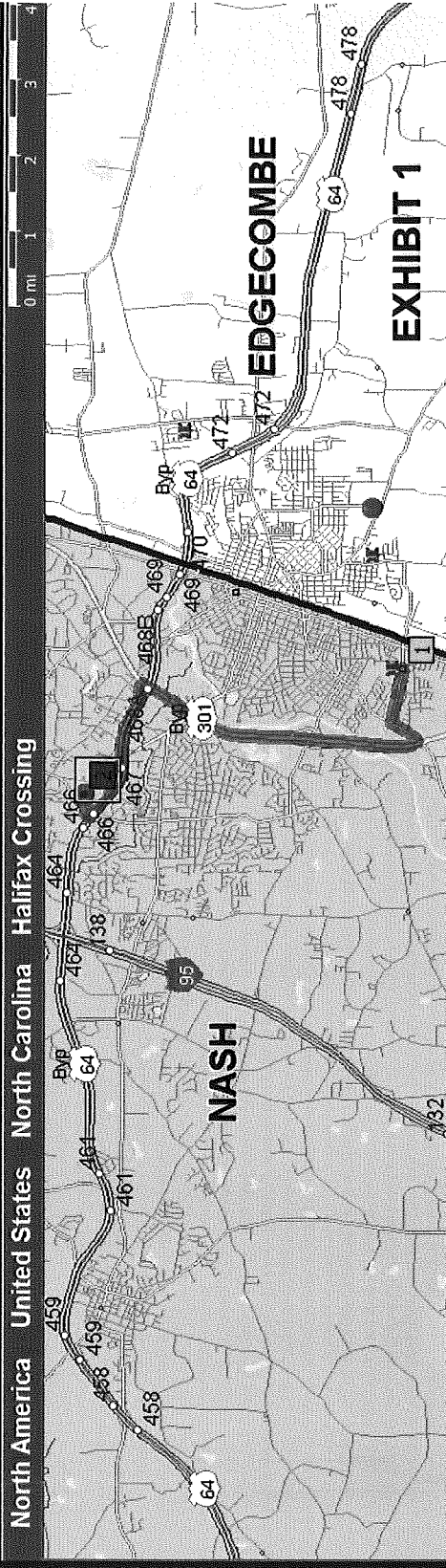
Summary: 7.4 miles (9 minutes)

Construction information for your route is out of date. Click this line to update.

9:00 AM	0.0	1	Depart Lloyd - 409 Kingston Ave, Rocky Mount	0.7 mi
9:01 AM	0.7		Turn LEFT (South) onto NC-97 [E NC-97]	0.4 mi
9:02 AM	1.1		Take Ramp (RIGHT) onto US-301 Byp [S Wesley]	3.9 mi
9:06 AM	5.0		Turn LEFT (North) onto Local road(s)	21 yds
9:06 AM	5.0		Take Ramp (LEFT) onto US-64 Byp	1.9 mi
9:07 AM	6.9		At exit 466, keep RIGHT onto Ramp	0.2 mi
9:08 AM	7.1		Keep LEFT to stay on Ramp	65 yds
9:08 AM	7.2		Turn LEFT (North-East) onto N Winstead Ave	0.1 mi
9:08 AM	7.3		Turn RIGHT (South-East) onto English Rd	153 yds
9:09 AM	7.4	2	Arrive BMA of Rocky Mount Inc [750 Eng]	

SUMMARY

Driving distance: 7.4 miles



Optimize stops

More options...

EXHIBIT 1

Route planner

Type place or address

Add to route

Get directions

Reverse route

Lloyd - 409 Kingston Ave, Rocky Moun...
123 Hospital Dr, Tarboro, NC 27886

Time Mile Instruction

Summary: 17.8 miles (22 minutes)

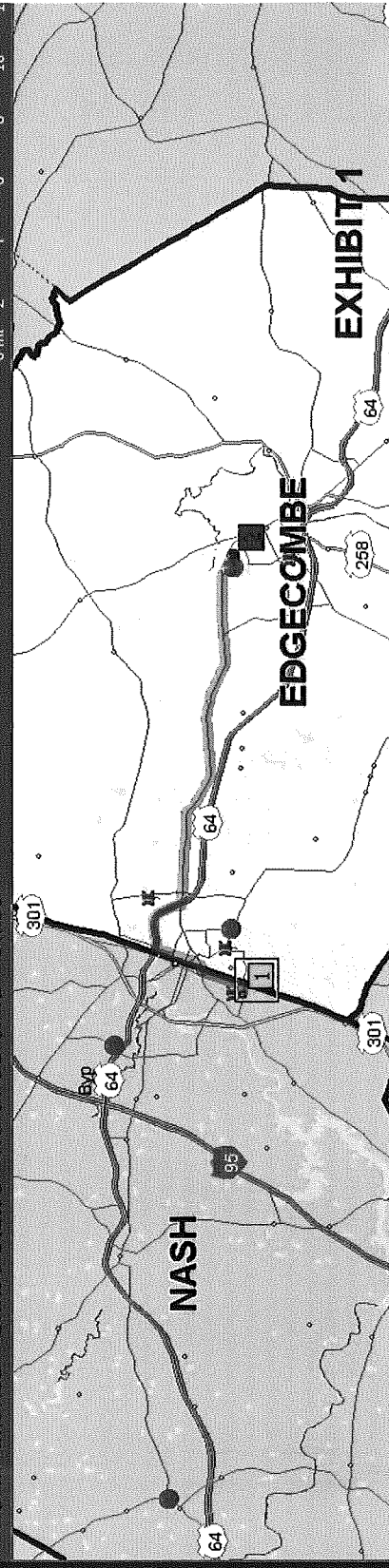
Construction information for your route is out of date. Click this line to update.

- 9:00 AM 0.0 1 Depart Lloyd - 409 Kingston Ave, Rocky 0.3 mi
- 9:00 AM 0.3 Turn LEFT (North) onto US-301 Branch [S Churc 1.4 mi
- 9:03 AM 1.7 Turn RIGHT (East) onto NC-97 [E NC-97] 0.3 mi
- 9:04 AM 2.0 Turn LEFT (North) onto NC-97 [Arlington St] 0.3 mi
- 9:05 AM 2.3 Keep STRAIGHT onto NC-97 [Atlantic Ave] 0.1 mi
- 9:05 AM 2.4 Keep STRAIGHT onto NC-97 [E NC-97] 1.1 mi
- 9:07 AM 3.5 Take Ramp (RIGHT) onto US-64 Byp [NC-43] 1.7 mi
- 9:08 AM 5.2 At exit 472, keep RIGHT onto Ramp 0.3 mi
- 9:08 AM 5.5 Turn LEFT (East) onto US-64 ALT [US-64 Branch 0.2 mi
- 9:09 AM 5.7 Keep STRAIGHT onto US-64 ALT [NC-43] 0.3 mi
- 9:09 AM 5.9 Keep STRAIGHT onto US-64 ALT [N Raleigh St] 2.4 mi
- 9:11 AM 8.4 Keep STRAIGHT onto US-64 ALT [Raleigh St] 1.2 mi
- 9:13 AM 9.6 Keep STRAIGHT onto US-64 ALT [US Highway 6 2.0 mi

US-64-BYP E / Tarboro
US-64-BR / NC-43 S / US-64-ALT / Rt

For Toward

North America United States North Carolina Cities-



Optimize stops

More options...

DATE: 7.31.15

Ms. Martha Frisone, Chief
Certificate of Need Section
Division of Health Service Regulation
809 Ruggles Drive
Raleigh, North Carolina 27603

Dear Ms. Frisone:

I am a home dialysis patient. My residence zip code is 27801. My residence is in Edgecombe County.

I understand that Bio-Medical Applications of North Carolina and Eastern Nephrology Associates, PLLC will be submitting an application for a Certificate of Need to develop a new dialysis facility focused exclusively on home peritoneal dialysis. I understand the new home dialysis facility will be located in Tarboro, very near the hospital. I enthusiastically support development of the new Fresenius Medical Care ENA Home, LLC dialysis facility.

I am pleased to learn that Fresenius Medical Care and the nephrologists of Eastern Nephrology Associates, PLLC will be developing a dialysis facility with a focus on peritoneal dialysis patients. I think it is important to have staff dedicated to home dialysis patients and their needs. I will be able to have my monthly clinic visit at this facility.

The location of the proposed new facility, in Tarboro is very convenient. Having the facility near the hospital will allow me to schedule other doctor office visits for the same day as my clinic visit. Combining my doctor visits into a single day each month is very convenient and would mean less time involved in transportation and more time for me, and my needs.

I also understand that Eastern Nephrology Associates will have a nephrology trained clinician on site at all times when a patient is training to perform home peritoneal dialysis. Having the clinician on site will be very beneficial to the patient while training to perform home peritoneal dialysis. I would be willing to consider transferring my care to the Fresenius Medical Care ENA Home, LLC dialysis facility.

I am aware that this letter will be used as support for the Bio-Medical Applications of North Carolina application for Certificate of Need. By my signature below, I consent to my name being associated with this application. I further understand that no other Protected Health Information, PHI, regarding me, my diagnosis or treatment is released as a part of this application. I wish Bio-Medical Applications of North Carolina every success in this effort.


(Patient Signature)

EXHIBIT 1

PEOPLE

BUSINESS

PHONE

Marisa W Spruill

Where Rocky Mount NC

252-977-7340
Sprint Nextel Landline

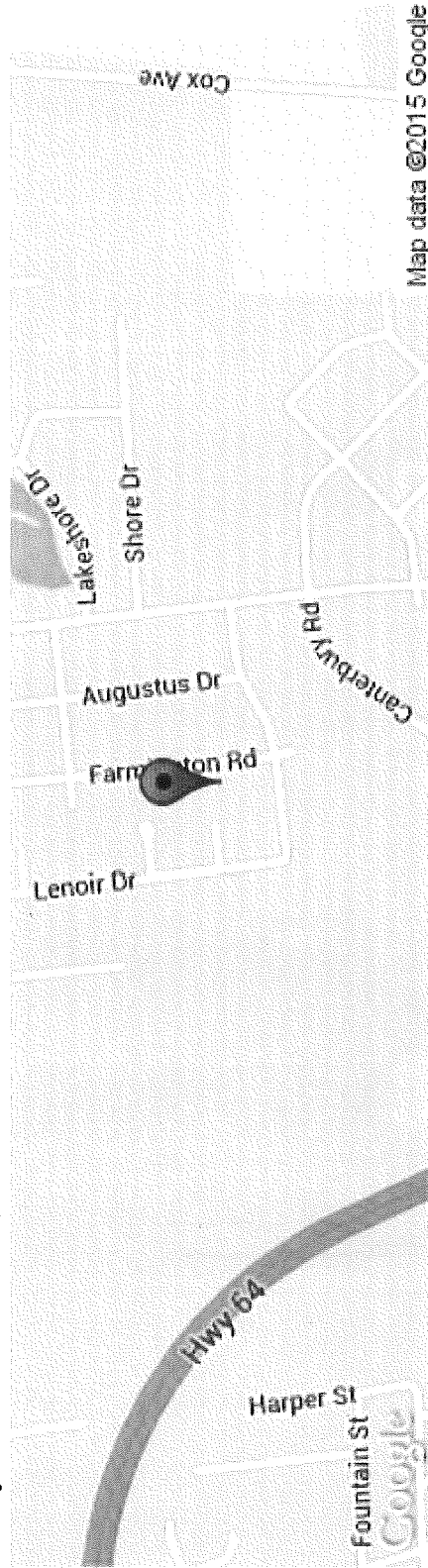
[View Marisa's Social Profiles from BeenVerified.com](#)

Address

1708 Farmington Rd
Rocky Mount, NC 27801-3025

Neighbors

Directions



People Marisa may know

Wade Spruill

Wade J Spruill II

EXHIBIT 1

Route planner

Type place or address

Add to route

Get directions

Reverse route

1708 Farmington Rd, NC 27801
BMA of East Rocky Mount

Optimize stops

Time

Mile

Instruction

For

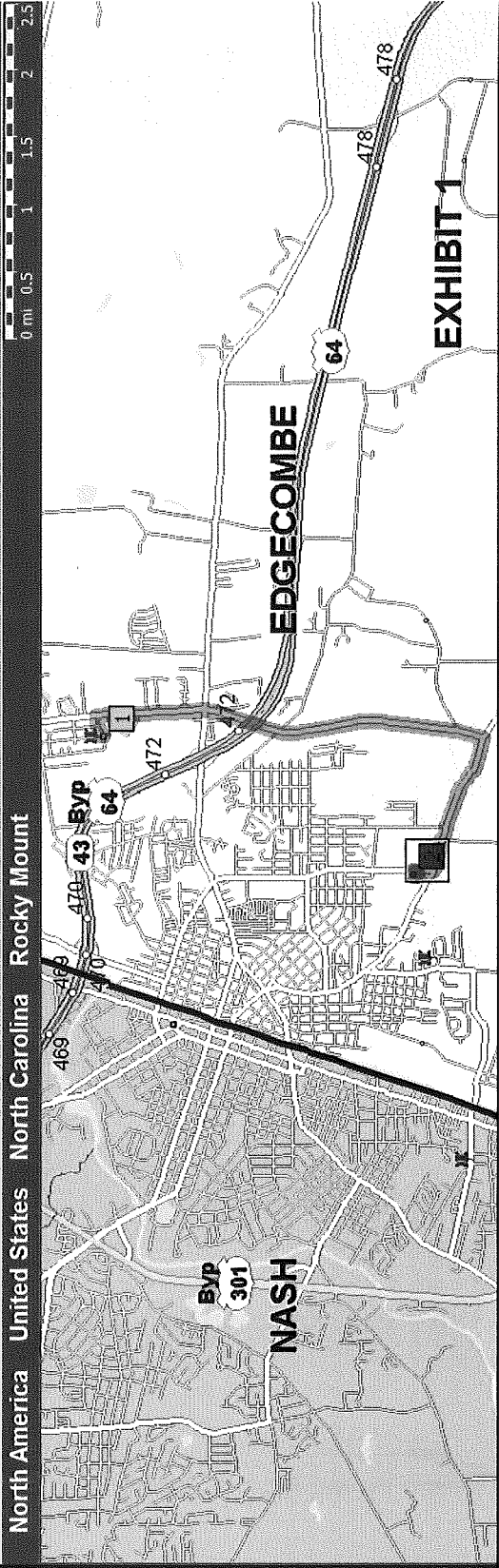
Toward

Summary: 4.3 miles (7 minutes)

Construction information for your route is out of date. Click this line to update.

- 9:00 AM 0.0 1 Depart 1708 Farmington Rd, NC 27801 at 0.2 mi
- 9:00 AM 0.2 Turn RIGHT (South) onto Springfield Rd 0.8 mi
- 9:02 AM 1.0 Road name changes to NC-43 [Springfield Rd] 2.1 mi
- 9:05 AM 3.1 Turn RIGHT (West) onto NC-43 Branch [Cokey F 1.1 mi
- 9:06 AM 4.2 Turn RIGHT (North) onto NC-43 Branch [Fairvie 0.1 mi
- 9:07 AM 4.3 Turn LEFT (West) onto Local road(s) 43 yds
- 9:07 AM 4.3 Arrive BMA of East Rocky Mount

SUMMARY



Route planner

Type place or address

Add to route

Get directions

Reverse route

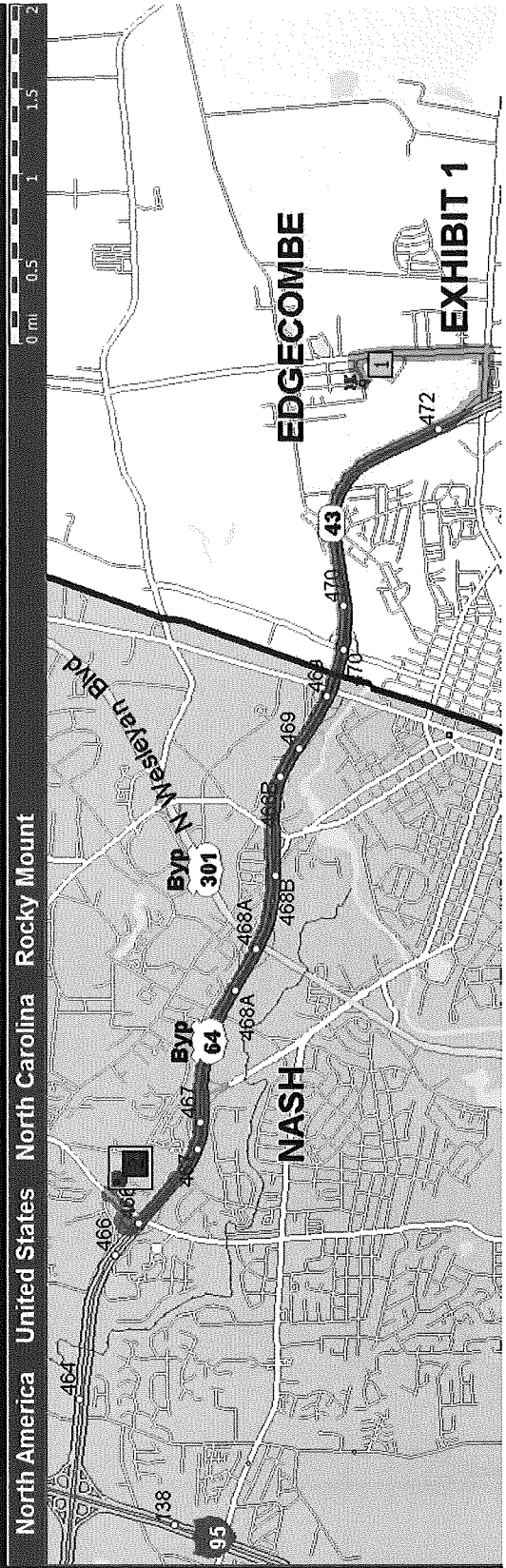
1708 Farmington Rd, NC 27801
BMA of Rocky Mount Inc

Optimize stops

Time Mile Instruction For Toward

Summary: 7.5 miles (9 minutes)
Construction information for your route is out of date. Click this line to update.

- 9:00 AM 0.0 1 Depart 1708 Farmington Rd, NC 27801 at 0.2 mi
- 9:00 AM 0.2 Turn RIGHT (South) onto Springfield Rd 0.8 mi
- 9:02 AM 1.0 Turn RIGHT (West) onto US-64 ALT [NC-43] 0.3 mi
- 9:02 AM 1.2 Take Ramp (RIGHT) onto US-64 Byp [NC-43] 5.8 mi US-64-BYP W / NC-43 N / Raleigh
- 9:07 AM 7.1 At exit 466, keep RIGHT onto Ramp 0.2 mi Winstead Avenue
- 9:08 AM 7.3 Keep LEFT to stay on Ramp 65 yds
- 9:08 AM 7.3 Turn LEFT (North-East) onto N Winstead Ave 0.1 mi
- 9:08 AM 7.4 Turn RIGHT (South-East) onto English Rd 153 yds
- 9:09 AM 7.5 Arrive BMA of Rocky Mount Inc [750 Eng]



Route planner

Type place or address

Add to route

Get directions

Reverse route

1708 Farmington Rd, NC 27801
123 Hospital Dr, Tarboro, NC 27886

Optimize stops

Time Mile Instruction

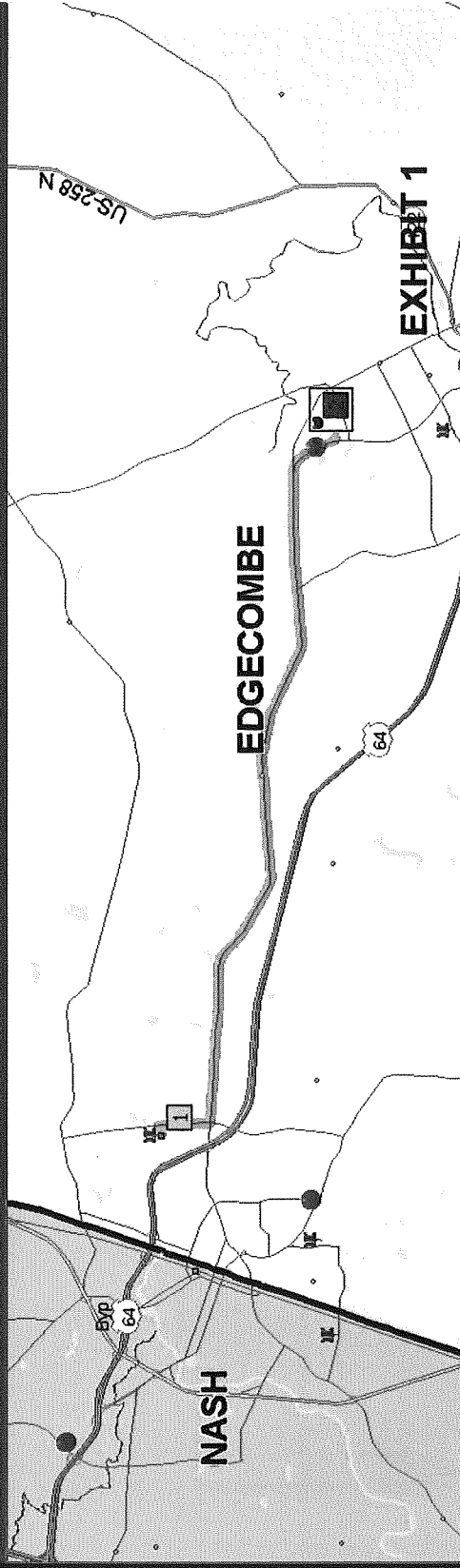
For Toward

Summary: 12.9 miles (15 minutes)

Construction information for your route is out of date. Click this line to update.

- 9:00 AM 0.0 1 Depart 1708 Farmington Rd, NC 27801 @ 0.2 mi
- 9:00 AM 0.2 Turn RIGHT (South) onto Springfield Rd 0.8 mi
- 9:02 AM 1.0 Turn LEFT (East) onto US-64 ALT [N Raleigh St] 2.4 mi
- 9:05 AM 3.4 Keep STRAIGHT onto US-64 ALT [Raleigh St] 1.2 mi
- 9:06 AM 4.6 Keep STRAIGHT onto US-64 ALT [US Highway 6] 2.0 mi
- 9:08 AM 6.6 Keep STRAIGHT onto US-64 ALT 4.3 mi
- 9:12 AM 10.9 Keep STRAIGHT onto US-64 ALT [N Main St] 0.7 mi
- 9:13 AM 11.5 Keep STRAIGHT onto US-64 ALT [Western Blvd] 0.9 mi
- 9:14 AM 12.4 Turn LEFT (East) onto Hospital Dr 0.4 mi
- 9:15 AM 12.9 Arrive 123 Hospital Dr, Tarboro, NC 27886

North America United States North Carolina Cities-



DATE: 7/31/2015

Ms. Martha Frisone, Chief
Certificate of Need Section
Division of Health Service Regulation
809 Ruggles Drive
Raleigh, North Carolina 27603

Dear Ms. Frisone:

I am a home dialysis patient. My residence zip code is 27801. My residence is in Edgecombe County.

I understand that Bio-Medical Applications of North Carolina and Eastern Nephrology Associates, PLLC will be submitting an application for a Certificate of Need to develop a new dialysis facility focused exclusively on home peritoneal dialysis. I understand the new home dialysis facility will be located in Tarboro, very near the hospital. I enthusiastically support development of the new Fresenius Medical Care ENA Home, LLC dialysis facility.

I am pleased to learn that Fresenius Medical Care and the nephrologists of Eastern Nephrology Associates, PLLC will be developing a dialysis facility with a focus on peritoneal dialysis patients. I think it is important to have staff dedicated to home dialysis patients and their needs. I will be able to have my monthly clinic visit at this facility.

The location of the proposed new facility, in Tarboro is very convenient. Having the facility near the hospital will allow me to schedule other doctor office visits for the same day as my clinic visit. Combining my doctor visits into a single day each month is very convenient and would mean less time involved in transportation and more time for me, and my needs.

I also understand that Eastern Nephrology Associates will have a nephrology trained clinician on site at all times when a patient is training to perform home peritoneal dialysis. Having the clinician on site will be very beneficial to the patient while training to perform home peritoneal dialysis. I would be willing to consider transferring my care to the Fresenius Medical Care ENA Home, LLC dialysis facility.

I am aware that this letter will be used as support for the Bio-Medical Applications of North Carolina application for Certificate of Need. By my signature below, I consent to my name being associated with this application. I further understand that no other Protected Health Information, PHI, regarding me, my diagnosis or treatment is released as a part of this application. I wish Bio-Medical Applications of North Carolina every success in this effort.

Mary Strother
(Patient Signature)

EXHIBIT 1

Whitepages™

PEOPLE

BUSINESS

PHONE

Mary L Strother

Where Rocky Mount NC

Address

1016 Blandwood Dr
Rocky Mount, NC 27801-7405

Neighbors

Directions



EXHIBIT 1

Route planner

Type place or address

- 1016 Blandwood Dr., Rocky Mount, NC 27801

Add to route

Get directions Reverse route

- 1 Strother - 1016 Blandwood Dr., Rocky...
- BMA of East Rocky Mount

Time Mile Instruction For Toward

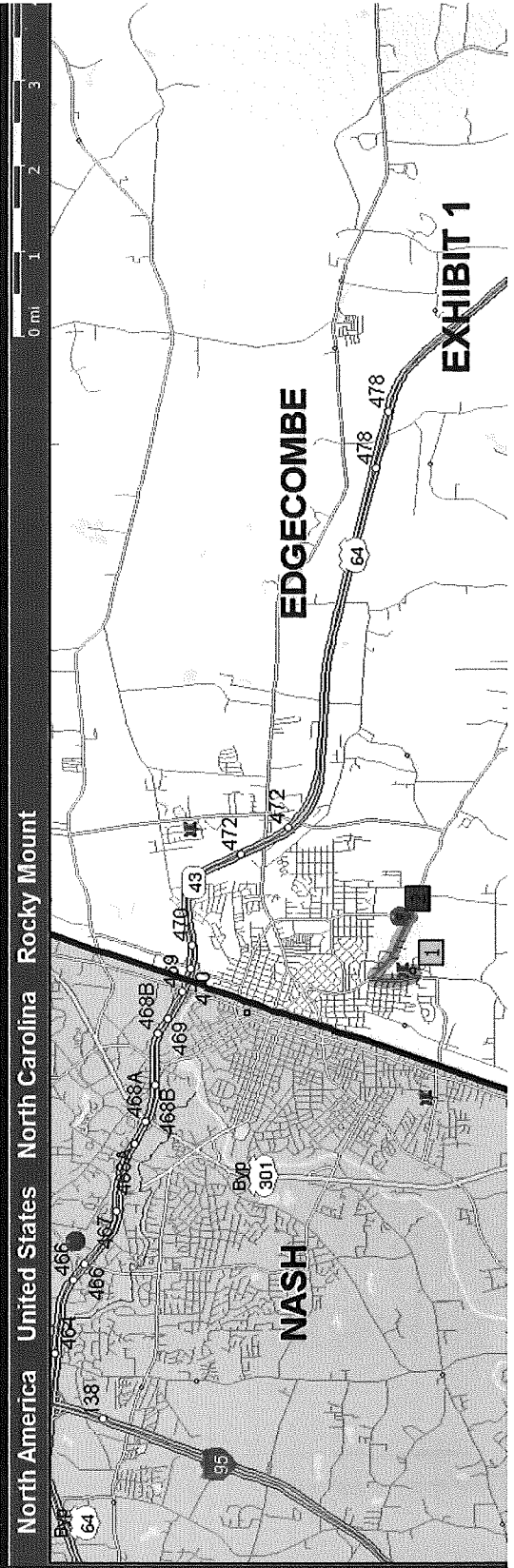
Summary: 1.6 miles (5 minutes)

Construction information for your route is out of date. Click this line to update.

- 9:00 AM 0.0 1 Depart Strother - 1016 Blandwood Dr., R 43 yds
- 9:00 AM 0.1 Turn RIGHT (West) onto Blandwood Dr, then im 0.5 mi
- 9:02 AM 0.5 Turn RIGHT (East) onto Rex St, then immediatel 0.9 mi
- 9:04 AM 1.5 Turn LEFT (North) onto NC-43 Branch [Fairview 0.1 mi
- 9:05 AM 1.6 Turn LEFT (West) onto Local road(s) 43 yds
- 9:05 AM 1.6 Arrive BMA of East Rocky Mount

SUMMARY

Driving distance: 1.6 miles



Type place or address

Add to route

Get directions

Reverse route

- 1 Strother - 1016 Blandwood Dr., Rocky...
- BMA of Rocky Mount Inc

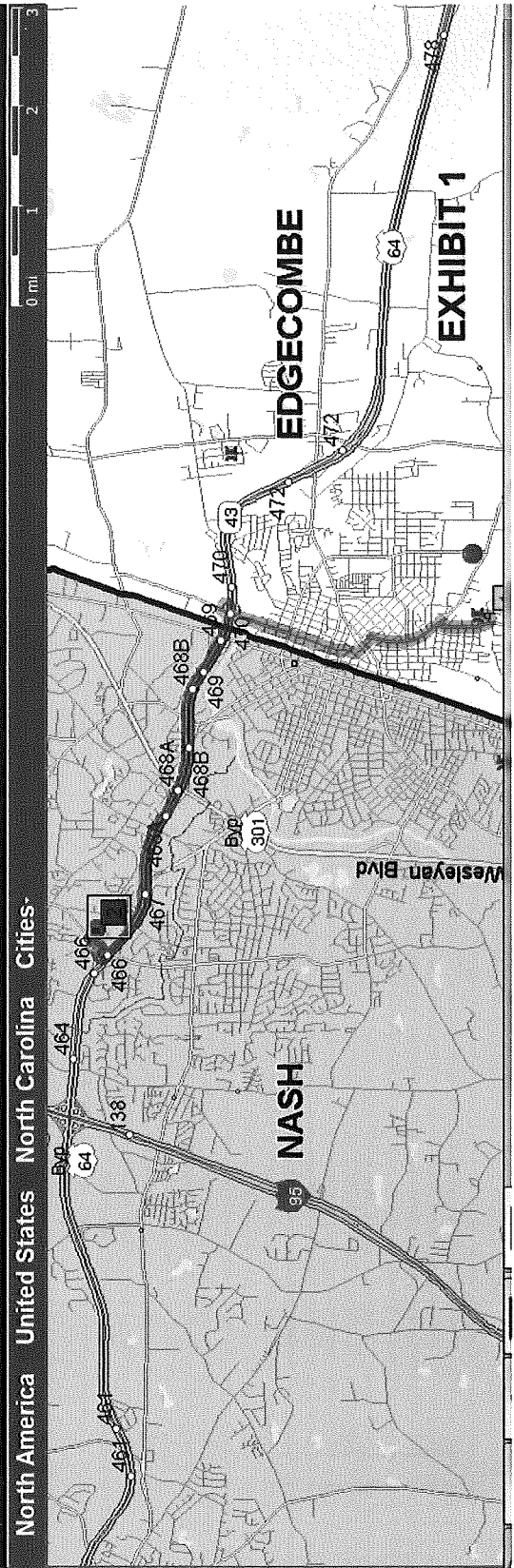
Time Mile Instruction

For Toward

Summary: 7.5 miles (13 minutes)

Construction information for your route is out of date. Click this line to update.

- 9:00 AM 0.0 1 Depart Strother - 1016 Blandwood Dr., R 43 yds
- 9:00 AM 0.1 Turn RIGHT (West) onto Blandwood Dr, then im 0.5 mi
- 9:02 AM 0.5 Turn RIGHT (East) onto Rex St, then immediate 0.8 mi
- 9:04 AM 1.4 Turn LEFT (North-West) onto Hill St 0.3 mi
- 9:05 AM 1.6 Turn RIGHT (North-East) onto NC-97 (Arlington 142 yds
- 9:06 AM 1.7 Keep STRAIGHT onto NC-97 (Atlantic Ave) 0.1 mi
- 9:06 AM 1.8 Keep STRAIGHT onto NC-97 [E NC-97] 1.3 mi
- 9:08 AM 3.1 Take Ramp (RIGHT) onto US-64 Byp [NC-43] 4.0 mi US-64-Byp W / Raleigh
- 9:11 AM 7.1 At exit 466, keep RIGHT onto Ramp 0.2 mi Winstead Avenue
- 9:12 AM 7.2 Keep LEFT to stay on Ramp 65 yds



Optimize stops

Route planner

Type place or address

Add to route

Get directions

Reverse route

1 Strother - 1016 Blandwood Dr., Rocky...
123 Hospital Dr, Tarboro, NC 27886

- ➡
- ↶
- ✕
- ⌘

Time

Mile

Instruction

For

Toward

Summary: 16.5 miles (23 minutes)

Construction information for your route is out of date. Click this line to update.

- 9:00 AM 0.0** 1 Depart Strother - 1016 Blandwood Dr., R 43 yds
- 9:00 AM 0.1 Turn RIGHT (West) onto Blandwood Dr, then im 0.5 mi
- 9:02 AM 0.5 Turn RIGHT (East) onto Rex St, then immediate 0.9 mi
- 9:04 AM 1.5 Keep STRAIGHT onto NC-43 Branch [Cokey Rd] 1.1 mi
- 9:06 AM 2.5 Turn LEFT (North) onto NC-43 [Springfield Rd] 2.1 mi
- 9:09 AM 4.6 Turn RIGHT (East) onto US-64 ALT [N Raleigh S] 2.4 mi
- 9:12 AM 7.1 Keep STRAIGHT onto US-64 ALT [Raleigh St] 1.2 mi
- 9:13 AM 8.3 Keep STRAIGHT onto US-64 ALT [US Highway 6] 2.0 mi
- 9:15 AM 10.3 Keep STRAIGHT onto US-64 ALT 4.3 mi
- 9:20 AM 14.5 Keep STRAIGHT onto US-64 ALT [N Main St] 0.7 mi
- 9:21 AM 15.2 Keep STRAIGHT onto US-64 ALT [Western Blvd] 0.9 mi
- 9:22 AM 16.1 Turn LEFT (East) onto Hospital Dr 0.4 mi
- 9:23 AM 16.5** Arrive 123 Hospital Dr, Tarboro, NC 2786

North America United States North Carolina Cities

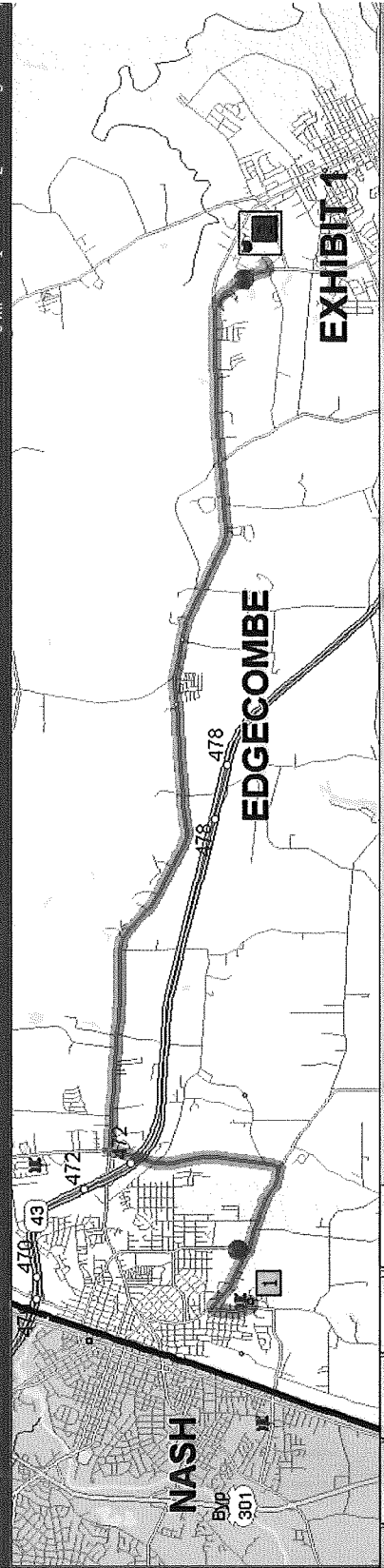


EXHIBIT 1

DATE: 7/31/15

Ms. Martha Frisone, Chief
Certificate of Need Section
Division of Health Service Regulation
809 Ruggles Drive
Raleigh, North Carolina 27603

Dear Ms. Frisone:

I am a home dialysis patient. My residence zip code is 27864. My residence is in EDGECOMBE County.

I understand that Bio-Medical Applications of North Carolina and Eastern Nephrology Associates, PLLC will be submitting an application for a Certificate of Need to develop a new dialysis facility focused exclusively on home peritoneal dialysis. I understand the new home dialysis facility will be located in Tarboro, very near the hospital. I enthusiastically support development of the new Fresenius Medical Care ENA Home, LLC dialysis facility.

I am pleased to learn that Fresenius Medical Care and the nephrologists of Eastern Nephrology Associates, PLLC will be developing a dialysis facility with a focus on peritoneal dialysis patients. I think it is important to have staff dedicated to home dialysis patients and their needs. I will be able to have my monthly clinic visit at this facility.

The location of the proposed new facility, in Tarboro is very convenient. Having the facility near the hospital will allow me to schedule other doctor office visits for the same day as my clinic visit. Combining my doctor visits into a single day each month is very convenient and would mean less time involved in transportation and more time for me, and my needs.

I also understand that Eastern Nephrology Associates will have a nephrology trained clinician on site at all times when a patient is training to perform home peritoneal dialysis. Having the clinician on site will be very beneficial to the patient while training to perform home peritoneal dialysis. I would be willing to consider transferring my care to the Fresenius Medical Care ENA Home, LLC dialysis facility.

I am aware that this letter will be used as support for the Bio-Medical Applications of North Carolina application for Certificate of Need. By my signature below, I consent to my name being associated with this application. I further understand that no other Protected Health Information, PHI, regarding me, my diagnosis or treatment is released as a part of this application. I wish Bio-Medical Applications of North Carolina every success in this effort.

P. Brent Webb
(Patient Signature)

EXHIBIT 1

PEOPLE

BUSINESS

PHONE

Patrick B Webb	Where Pinetops NC
----------------	--------------------------

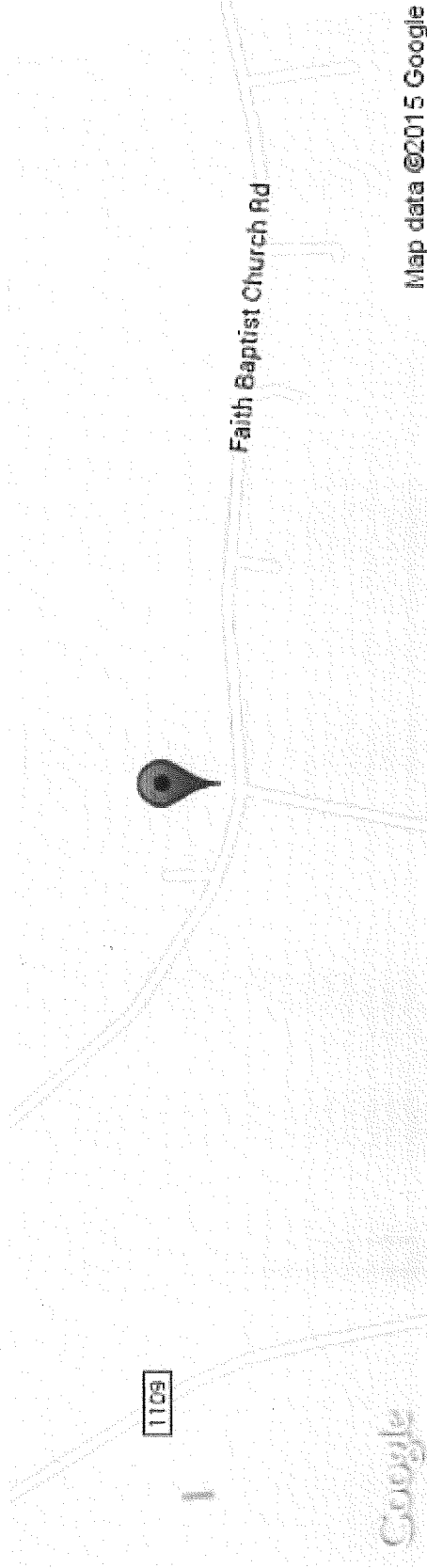
[View Patrick's Social Profiles from BeenVerified.com](#)

Address

1778 Faith Baptist Church Rd
Pinetops, NC 27864-9374

Neighbors

Directions



Map data ©2015 Google

People Patrick may know

Ida P Webb

Sonya H Webb

EXHIBIT 1

Route planner ▾

Type place or address

Add to route

Get directions

Reverse route

- 1 Webb - 1778 Faith Baptist Church Rd,...
- BMA of East Rocky Mount

Optimize stops

Time

Mile

Instruction

For

Toward

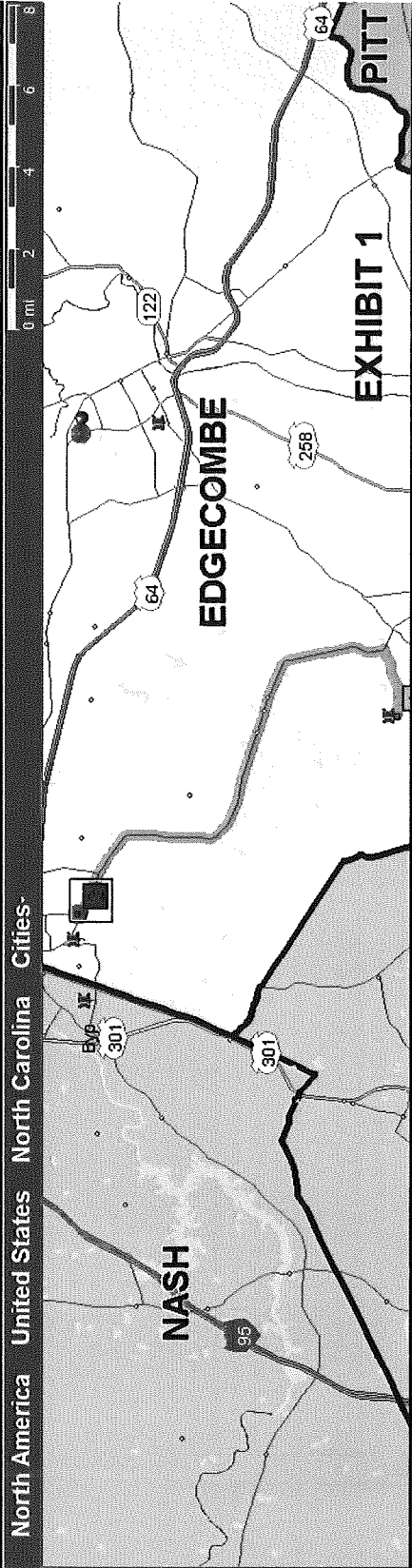
Summary: 13.6 miles (18 minutes)

Construction information for your route is out of date. Click this line to update.

- 9:00 AM 0.0 1 Depart Webb - 1778 Faith Baptist Church 1.8 mi
- 9:05 AM 1.8 Turn LEFT (North-West) onto NC-43 [NC 43 N] 3.6 mi
- 9:09 AM 5.4 Keep STRAIGHT onto NC-43 [NC Highway 43 N 4.1 mi
- 9:13 AM 9.4 Keep STRAIGHT onto NC-43 [Cokeley Rd] 3.0 mi
- 9:16 AM 12.4 Keep STRAIGHT onto NC-43 Branch [Cokeley Rd] 1.1 mi
- 9:18 AM 13.4 Turn RIGHT (North) onto NC-43 Branch [Fairvie] 0.1 mi
- 9:18 AM 13.6 Turn LEFT (West) onto Local road(s) 43 yds
- 9:18 AM 13.6 Arrive BMA of East Rocky Mount

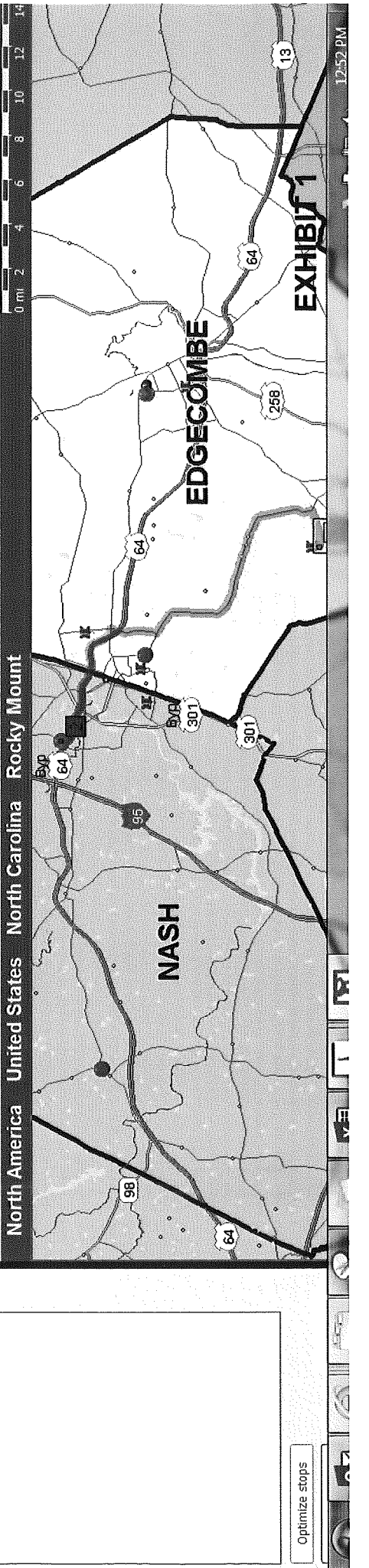
SUMMARY

Driving distance: 13.6 miles
 Trip duration: 18 minutes
 Driving time: 18 minutes



Summary: 21.1 miles (26 minutes)
 Construction information for your route is out of date. Click this line to update.

Time	Mile	Instruction	For	Toward
9:00 AM	0.0	1 Depart Webb - 1778 Faith Baptist Church 1.8 mi		
9:05 AM	1.8	Turn LEFT (North-West) onto NC-43 [NC 43 N]		
9:09 AM	5.4	Keep STRAIGHT onto NC-43 [NC Highway 43 N 4.1 mi]		
9:13 AM	9.4	Keep STRAIGHT onto NC-43 [Cokeley Rd]		
9:16 AM	12.4	Turn RIGHT (North) onto NC-43 [Springfield Rd 2.1 mi]		
9:19 AM	14.5	Turn LEFT (West) onto US-64 ALT [NC-43]		
9:20 AM	14.8	Take Ramp (RIGHT) onto US-64 Byp [NC-43]		
9:25 AM	20.6	At exit 466, keep RIGHT onto Ramp		US-64-BYP W / NC-43 N / Raleigh
9:25 AM	20.8	Keep LEFT to stay on Ramp		Winstead Avenue
9:25 AM	20.8	Turn LEFT (North-East) onto N Winstead Ave		
9:26 AM	21.0	Turn RIGHT (South-East) onto English Rd		
9:26 AM	21.1	Arrive BMA of Rocky Mount Inc [750 Eng		



Webb - 1778 Faith Baptist Church Rd, ...
 BMA of Rocky Mount Inc

Reverse route

Get directions

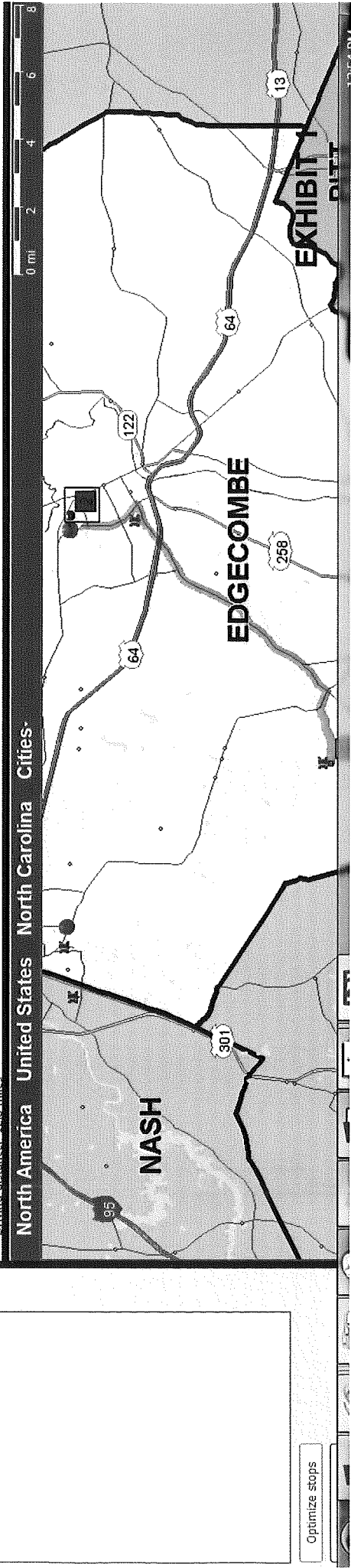
Optimize stops

Summary: 12.8 miles (19 minutes)
 Construction information for your route is out of date. Click this line to update.

Time	Mile	Instruction
9:00 AM	0.0	1 Depart Webb - 1778 Faith Baptist Church 1.8 mi
9:05 AM	1.8	Turn RIGHT (South-East) onto NC-43 [NC 43 N] 0.5 mi
9:06 AM	2.3	Turn LEFT (North-East) onto NC-111 0.6 mi
9:07 AM	2.9	Keep STRAIGHT onto NC-111 [NC 111 S] 0.5 mi
9:07 AM	3.4	Bear LEFT (North-East) onto NC-111 [NC-122] 4.8 mi
9:12 AM	8.2	Keep STRAIGHT onto NC-111 [W Wilson St] 2.3 mi
9:15 AM	10.5	Turn LEFT (North-West) onto US-64 ALT [NC-12 0.7 mi
9:16 AM	11.2	Keep STRAIGHT onto US-64 ALT [Western Blvd] 1.2 mi
9:18 AM	12.4	Turn RIGHT (East) onto Hospital Dr 0.4 mi
9:19 AM	12.8	Arrive 123 Hospital Dr, Tarboro, NC 2786

SUMMARY

Driving distance: 12.8 miles



Type place or address

Add to route

Get directions

Reverse route

1 Webb - 1778 Faith Baptist Church Rd, ...

123 Hospital Dr, Tarboro, NC 27886

Optimize stops

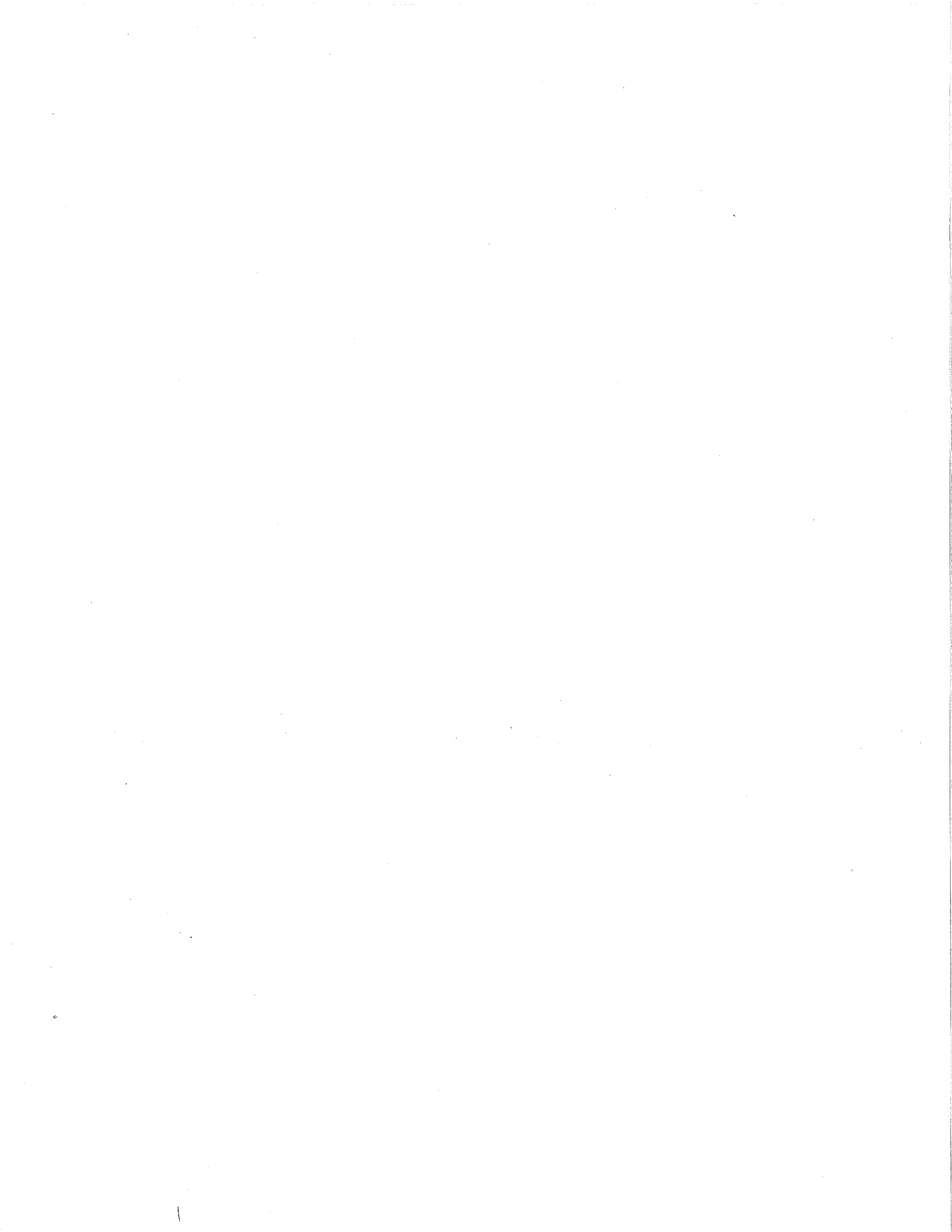


Table B: ESRD Dialysis Station Need Determinations by Planning Area

County/ Multi-County Planning Area	12.31.06 Total Patients	12.31.07 Total Patients	12.31.08 Total Patients	12.31.09 Total Patients	12.31.10 Total Patients	Average Annual Change Rate for Past Five Years	Projected 12.31.11 Total Patients	12.31.10 Home Patients	12.31.10 % Home Patients	Projected 12.31.11 Home Patients	Projected 12.31.11 In-Center Patients	Projected 12.31.11 In-Center Station Utilization	Total Available Stations	Projected Station Deficit (bolded) or Surplus	County Station Need Determination
Alamance	214	232	238	256	271	0.061	287.5	31	11.4%	32.9	254.7	80	82	Surplus of 2	0
Alexander	30	27	34	30	37	0.069	39.5	6	16.2%	6.4	33.1	10	10	0	0
Alleghany	5	5	7	12	10	0.237	12.4	3	30.0%	3.7	8.7	3	3	0	0
Anson	79	75	68	68	75	-0.011	74.2	4	5.3%	4.0	70.3	22	25	Surplus of 3	0
Ashe	17	20	18	16	21	0.068	22.5	7	33.3%	7.5	15.0	5	0	5	0
Beaufort	82	96	96	96	97	0.045	101.4	19	19.6%	19.9	81.5	25	25	0	0
Bertie	71	67	68	65	68	-0.010	67.3	4	5.9%	4.0	63.4	20	20	0	0
Bladen	64	78	89	82	95	0.107	105.1	4	4.2%	4.4	100.7	31	24	7	0
Brunswick	108	102	113	109	120	0.029	123.5	24	20.0%	24.7	98.8	31	35	Surplus of 4	0
Buncombe	223	230	225	222	226	0.004	226.8	29	12.8%	29.1	197.7	62	86	Surplus of 24	0
Burke	90	90	92	92	85	-0.013	83.9	9	10.8%	8.9	75.0	23	25	Surplus of 2	0
Cabarrus	150	170	174	201	205	0.083	222.0	28	13.7%	30.3	191.7	60	36	24	0
Caldwell	106	104	106	110	104	-0.004	103.6	13	12.5%	12.9	90.6	28	34	Surplus of 6	0
Camden	9	12	12	12	16	0.167	18.7	4	25.0%	4.7	14.0	4	0	4	0
Carteret	55	56	54	67	71	0.071	76.0	7	9.9%	7.5	68.5	21	26	Surplus of 5	0
Caswell	27	25	26	32	37	0.088	40.3	2	5.4%	2.2	38.1	12	10	2	0
Catawba	157	157	162	167	181	0.037	187.6	27	14.9%	28.0	159.6	50	56	Surplus of 6	0
Chatham	64	73	71	79	81	0.063	86.1	7	8.6%	7.4	78.6	25	28	Surplus of 3	0
Cherokee	27	29	23	20	17	-0.103	15.2	5	29.4%	4.5	10.8	3	10	Surplus of 7	0
Cherokee-Clay	9	8	9	8	8	-0.024	7.8	0	0.0%	0.0	7.8	2	0	2	0
Graham	11	11	11	12	14	0.064	14.9	1	7.1%	1.1	13.8	4	0	4	0
Graham Planning Area Total															
Chowan	35	37	39	40	41	0.040	42.7	6	14.6%	6.2	36.4	11	17	Surplus of 6	0
Cleveland	203	206	213	214	238	0.041	247.9	22	9.2%	22.9	224.9	70	59	11	0
Columbus	128	137	129	129	122	-0.011	120.7	11	9.0%	10.9	109.8	34	43	Surplus of 9	0
Craven	149	155	159	177	173	0.039	179.8	11	6.4%	11.4	168.3	53	65	Surplus of 12	0
Cumberland	479	510	521	523	555	0.038	576.0	60	10.8%	62.3	513.7	161	166	Surplus of 5	0
Currituck	17	15	14	14	17	0.007	17.1	7	41.2%	7.1	10.1	3	0	3	0
Dare	29	23	26	22	29	0.022	29.6	4	13.8%	4.1	25.5	8	9	Surplus of 1	0
Davidson	164	172	172	181	180	0.024	184.3	22	12.2%	22.5	161.8	51	54	Surplus of 3	0
Davie	30	36	39	36	41	0.084	44.5	9	22.0%	9.8	34.7	11	10	1	0
Duplin	118	118	127	131	130	0.025	133.3	10	7.7%	10.3	123.0	38	45	Surplus of 7	0
Durham	489	495	505	516	500	0.017	508.3	35	7.0%	35.6	472.7	148	164	Surplus of 16	0
Edgecombe	180	171	186	182	198	0.026	203.2	25	12.6%	25.7	177.5	55	55	0	0
Forsyth	545	556	571	588	593	0.021	605.7	84	14.2%	85.8	519.9	162	163	Surplus of 21	0
Franklin	85	85	94	92	111	0.073	119.1	17	15.3%	18.2	100.8	32	23	9	0
Gaston	234	246	277	295	278	0.046	290.8	27	9.7%	28.2	262.6	82	86	Surplus of 4	0
Gates	25	28	24	18	26	0.043	27.1	2	7.7%	2.1	25.0	8	10	Surplus of 2	0
Granville	105	116	117	106	112	0.019	114.1	11	9.8%	11.2	102.9	32	34	Surplus of 2	0
Greene	40	38	40	46	52	0.071	55.7	6	11.5%	6.4	49.3	15	16	Surplus of 1	0
Guilford	769	792	767	822	790	0.007	795.8	51	6.5%	51.4	744.4	233	270	Surplus of 37	0
Halifax	175	182	192	199	225	0.066	239.7	24	10.7%	25.6	214.2	67	61	6	0

Note: Except for the Cherokee-Clay-Graham Multi-county Planning Area and the Mitchell-Avery-Yancey Multi-county Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.

Table B: ESRD Dialysis Station Need Determinations by Planning Area

County/ Multi-County Planning Area	12.31.07 Total Patients	12.31.08 Total Patients	12.31.09 Total Patients	12.31.10 Total Patients	12.31.11 Total Patients	Average Annual Change Rate for Past Five Years	Projected 12.31.12 Total Patients	12.31.11 Home Patients	12.31.11 Percent Home Patients	Projected 12.31.12 Home Patients	Projected 12.31.12 In-Center Patients	Projected 12.31.12 In-Center Station Utilization	Total Available Stations	Projected Station Deficit (bolded) or Surplus	County Station Need Determination
Alamance	232	238	256	271	276	0.045	288.3	38	13.8%	39.7	248.6	78	85	Surplus of 7	0
Alexander	27	34	30	37	35	0.080	37.8	9	25.7%	9.7	28.1	9	9	Surplus of 1	0
Alleghany	5	7	12	10	7	0.182	8.1	3	42.9%	3.5	4.6	1	0	1	0
Anson	75	69	68	75	79	0.015	80.2	6	7.6%	6.1	74.1	23	25	Surplus of 2	0
Ashe	20	18	16	21	19	0.002	19.0	5	26.3%	5.0	14.0	4	4	4	0
Beaufort	96	96	96	97	103	0.018	104.9	16	15.5%	16.3	88.6	28	25	3	0
Bertie	67	68	65	68	65	-0.007	64.8	7	10.8%	7.0	57.8	18	20	Surplus of 2	0
Bladen	78	89	92	95	95	0.052	99.9	11	11.6%	11.6	88.4	28	27	1	0
Brunswick	102	113	109	120	124	0.062	130.4	26	21.0%	27.3	103.1	32	38	Surplus of 6	0
Buncombe	230	225	222	226	224	-0.008	222.5	31	13.8%	30.8	191.8	60	86	Surplus of 26	0
Burke	90	92	92	85	87	-0.008	86.3	15	17.2%	14.9	71.5	22	23	Surplus of 1	0
Cabarrus	170	174	201	205	198	0.041	206.1	34	17.2%	35.4	170.7	53	63	Surplus of 10	0
Caldwell	104	106	110	104	102	-0.004	101.6	12	11.8%	11.9	89.6	28	34	Surplus of 6	0
Camden	9	12	12	16	15	0.151	17.3	2	13.3%	2.3	15.0	5	5	5	0
Carteret	56	54	67	71	74	0.077	79.7	11	14.9%	11.8	67.8	21	26	Surplus of 5	0
Caswell	25	26	32	37	32	0.073	34.3	3	9.4%	3.2	31.1	10	10	0	0
Catawba	157	162	167	181	189	0.048	198.0	32	16.9%	33.5	164.5	51	50	1	0
Chatham	73	71	79	81	81	0.028	83.2	5	6.2%	5.1	78.1	24	28	Surplus of 4	0
Cherokee	29	23	20	17	19	-0.092	17.2	3	15.8%	2.7	14.5	5	10	Surplus of 5	0
Clay	8	9	8	8	10	0.066	10.7	0	0.0%	0.0	10.7	3	3	3	0
Graham	11	11	12	14	14	0.064	14.9	0	0.0%	0.0	14.9	5	5	5	0
Cherokee-Clay-Graham Planning Area Total														3	0
Chowan	37	39	40	41	36	-0.004	35.8	5	13.9%	5.0	30.9	10	17	Surplus of 7	0
Cleveland	206	213	214	238	259	0.060	274.5	31	12.0%	32.9	241.6	76	81	Surplus of 5	0
Columbus	137	137	129	122	134	-0.004	133.5	7	5.2%	7.0	126.5	40	40	0	0
Craven	155	159	177	173	169	0.023	172.9	15	8.9%	15.3	157.6	49	65	Surplus of 16	0
Cumberland	510	521	523	555	533	0.012	539.3	58	10.9%	58.7	480.6	150	170	Surplus of 20	0
Currituck	15	14	14	17	10	-0.066	9.3	5	50.0%	4.7	4.7	1	0	1	0
Dare	23	26	22	29	27	0.056	28.5	1	3.7%	1.1	27.5	9	9	0	0
Davidson	172	172	181	180	195	0.033	201.3	26	13.3%	26.8	174.5	55	54	1	0
Davie	36	39	38	41	40	0.028	41.1	7	17.5%	7.2	33.9	11	10	1	0
Duplin	118	127	131	130	134	0.033	138.4	12	9.0%	12.4	126.0	39	49	Surplus of 10	0
Durham	495	505	516	500	511	0.008	515.2	38	7.4%	38.3	476.9	149	164	Surplus of 15	0
Edgecombe	171	186	182	198	208	0.051	218.6	24	11.5%	25.2	193.4	60	65	Surplus of 5	0
Forsyth	556	571	588	593	582	0.012	588.8	77	13.2%	77.9	510.9	160	183	Surplus of 23	0
Franklin	85	94	92	111	113	0.077	121.7	14	12.4%	15.1	106.7	33	33	0	0
Gaston	246	277	295	278	270	0.026	277.1	27	10.0%	27.7	249.4	78	88	Surplus of 10	0
Gates	28	24	18	26	8	-0.160	6.7	2	25.0%	1.7	5.0	2	10	Surplus of 8	0
Granville	116	117	106	112	128	0.029	131.7	12	9.4%	12.3	119.3	37	41	Surplus of 4	0
Greene	38	40	46	52	57	0.107	63.1	4	7.0%	4.4	58.7	18	16	2	0
Guilford	792	787	822	790	819	0.009	826.4	61	7.4%	61.5	764.8	239	270	Surplus of 31	0
Halifax	182	192	199	225	233	0.064	248.0	34	14.6%	36.2	211.8	66	65	1	0
Hannett	139	153	164	199	210	0.110	233.2	18	8.6%	20.0	213.2	67	69	Surplus of 2	0
Haywood	49	52	53	57	47	-0.009	46.6	7	14.9%	6.9	39.7	12	18	Surplus of 6	0
Henderson	71	79	70	74	76	0.021	77.6	16	21.1%	16.3	61.2	19	20	Surplus of 1	0
Hertford	78	77	87	84	82	0.015	83.2	6	7.3%	6.1	77.1	24	27	Surplus of 3	0
Hoke	64	67	73	92	101	0.124	113.5	4	4.0%	4.5	109.0	34	37	Surplus of 3	0
Hyde	6	6	7	6	8	0.089	8.7	2	25.0%	2.2	6.5	2	0	2	0
Iredell	192	201	192	200	209	0.022	213.6	42	20.1%	42.9	170.7	53	74	Surplus of 21	0

Note: Except for the Cherokee-Clay-Graham Multi-county Planning Area and the Mitchell-Avery-Yancey Multi-county Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.

July 2013 SDR

Table B: ESRD Dialysis Station Need Determinations by Planning Area

County/ Multi- County Planning Area	12.31.08 Total Patients	12.31.09 Total Patients	12.31.10 Total Patients	12.31.11 Total Patients	12.31.12 Total Patients	Average Annual Change Rate for Past Five Years	Projected 12.31.13 Total Patients	12.31.12 Home Patients	12.31.12 Percent Home Patients	Projected 12.31.13 Home Patients	Projected 12.31.13 In-Center Patients	Projected 12.31.13 In-Center Station Utilization	Total Available Stations	Projected Station Deficit or Surplus	County Station Need Determi- nation
Davie	39	38	41	40	44	0.032	45.4	9	20.5%	9.3	36.1	11	10	1	0
Duplin	127	131	130	134	138	0.021	140.9	6	4.3%	6.1	134.8	42	49	Surplus of 7	0
Durham	505	516	500	511	518	0.007	521.4	45	8.7%	45.3	476.1	149	164	Surplus of 15	0
Edgecombe	186	182	198	208	206	0.027	211.5	* 8	3.9%	8.2	203.3	64	65	Surplus of 1	0
Forsyth	571	588	593	582	591	0.009	596.2	80	13.5%	80.7	515.5	161	186	Surplus of 25	0
Franklin	94	92	111	113	114	0.053	120.0	10	8.8%	10.5	109.5	34	35	Surplus of 1	0
Gaston	277	295	278	270	270	-0.005	268.6	23	8.5%	22.9	245.7	77	89	Surplus of 12	0
Gates	24	18	26	8	8	-0.124	7.0	1	12.5%	0.9	6.1	2	10	Surplus of 8	0
Granville	117	106	112	128	131	0.032	135.2	12	9.2%	12.4	122.8	38	41	Surplus of 3	0
Greene	40	46	52	57	66	0.134	74.8	8	12.1%	9.1	65.8	21	21	0	0
Guilford	787	822	790	819	830	0.014	841.6	66	8.0%	66.9	774.6	242	270	Surplus of 28	0
Halifax	192	199	225	233	186	0.000	186.0	26	14.0%	26.0	160.0	50	65	Surplus of 15	0
Harnett	153	164	199	210	139	0.001	139.1	11	7.9%	11.0	128.1	40	69	Surplus of 29	0
Haywood	52	53	52	47	64	0.066	68.3	8	12.5%	8.5	59.7	19	18	1	0
Henderson	79	70	74	76	75	-0.011	74.2	14	18.7%	13.8	60.3	19	19	0	0
Hertford	77	87	84	82	82	0.018	83.5	9	11.0%	9.2	74.3	23	27	Surplus of 4	0
Hoke	67	73	92	101	97	0.102	106.9	3	3.1%	3.3	103.6	32	37	Surplus of 5	0
Hyde	6	7	6	8	9	0.121	10.1	3	33.3%	3.4	6.7	2	0	2	0
Iredell	201	192	200	209	219	0.022	223.9	47	21.5%	48.1	175.9	55	74	Surplus of 19	0
Jackson	24	23	28	34	32	0.083	34.6	9	28.1%	9.7	24.9	8	16	Surplus of 8	0
Johnston	191	202	213	230	232	0.050	243.6	24	10.3%	25.2	218.4	68	71	Surplus of 3	0
Jones	28	32	31	33	21	-0.047	20.0	1	4.8%	1.0	19.1	6	10	Surplus of 4	0
Lee	102	107	112	108	137	0.082	148.3	10	7.3%	10.8	137.4	43	46	Surplus of 3	0
Lenoir	174	174	183	170	188	0.022	192.1	19	10.1%	19.4	172.7	54	63	Surplus of 9	0
Lincoln	78	77	87	81	99	0.068	105.7	21	21.2%	22.4	83.3	26	25	1	0
Macon	24	23	23	33	32	0.091	34.9	6	18.8%	6.5	28.4	9	9	0	0
Madison	8	13	11	13	13	0.163	15.1	0	0.0%	0.0	15.1	5	0	5	0
Martin	62	74	81	85	93	0.108	103.0	16	17.2%	17.7	85.3	27	25	2	0
McDowell	44	43	42	49	47	0.020	47.9	5	10.6%	5.1	42.8	13	14	Surplus of 1	0
Mecklenburg	1097	1122	1201	1327	1416	0.066	1,509.9	180	12.7%	191.9	1,317.9	412	405	7	0

* A 3-year average was used in analysis due to the errors contained in this SDR.
This was the first SDR in which providers directly provided data to the State Agency.

July 2014 SDR

Table B: ESRD Dialysis Station Need Determinations by Planning Area

County/ Multi- County Planning Area	12.31.09 Total Patients	12.31.10 Total Patients	12.31.11 Total Patients	12.31.12 Total Patients	12.31.13 Total Patients	Average Annual Change Rate for Past Five Years	Projected 12.31.14 Total Patients	12.31.13 Home Patients	12.31.13 Percent Home Patients	Projected 12.31.14 Home Patients	Projected 12.31.14 In-Center Patients	Projected 12.31.14 In-Center Station Utilization	Total Available Stations	Projected Station Deficit or Surplus	County Station Need Determi- nation
Davie	38	41	40	44	44	0.039	45.7	9	20.5%	9.3	36.4	11	10	1	0
Duplin	131	130	134	138	136	0.010	137.3	16	11.8%	16.2	121.2	38	50	Surplus of 12	0
Durham	516	500	511	518	565	0.024	578.5	51	9.0%	52.2	526.3	164	183	Surplus of 19	0
Edgecombe	182	198	208	227	218	0.048	228.4	19	8.7%	19.9	208.5	65	65	0	0
Forsyth	588	593	582	591	579	-0.004	576.8	80	13.8%	79.7	497.1	155	186	Surplus of 31	0
Franklin	92	111	113	114	120	0.072	128.6	11	9.2%	11.8	116.8	36	33	3	0
Gaston	295	278	270	270	297	0.003	298.0	33	11.1%	33.1	264.9	83	89	Surplus of 6	0
Gates	18	26	8	8	7	-0.093	6.3	1	14.3%	0.9	5.4	2	0	2	0
Granville	106	112	128	131	144	0.081	155.6	14	9.7%	15.1	140.5	44	44	0	0
Greene	46	52	57	66	60	0.073	64.4	6	10.0%	6.4	58.0	18	21	Surplus of 3	0
Guilford	822	790	819	830	892	0.021	911.2	60	6.7%	61.3	849.9	266	258	8	0
Halifax	199	225	233	219	217	0.024	222.3	19	8.8%	19.5	202.8	63	65	Surplus of 2	0
Harnett	164	199	210	139	175	0.047	183.3	11	6.3%	11.5	171.8	54	69	Surplus of 15	0
Haywood	53	52	47	64	59	0.042	61.5	8	13.6%	8.3	53.1	17	18	Surplus of 1	0
Henderson	70	74	76	75	89	0.064	94.7	22	24.7%	23.4	71.3	22	24	Surplus of 2	0
Hertford	87	84	82	82	82	-0.015	80.8	10	12.2%	9.9	71.0	22	27	Surplus of 5	0
Hoke	73	92	101	97	115	0.126	129.5	5	4.3%	5.6	123.9	39	37	2	0
Hyde	7	6	8	9	11	0.134	12.5	3	27.3%	3.4	9.1	3	0	3	0
Iredell	192	200	209	219	218	0.032	225.1	43	19.7%	44.4	180.7	56	74	Surplus of 18	0
Jackson	23	28	34	32	39	0.148	44.8	4	10.3%	4.6	40.2	13	16	Surplus of 3	0
Johnston	202	213	230	232	244	0.049	255.9	35	14.3%	36.7	219.2	68	71	Surplus of 3	0
Jones	32	31	33	21	31	0.036	32.1	5	16.1%	5.2	26.9	8	10	Surplus of 2	0
Lee	107	112	108	137	131	0.059	138.7	11	8.4%	11.6	127.1	40	46	Surplus of 6	0
Lenoir	174	183	170	188	180	0.011	182.0	15	8.3%	15.2	166.8	52	63	Surplus of 11	0
Lincoln	77	87	81	99	96	0.063	102.1	19	19.8%	20.2	81.9	26	25	1	0
Macon	23	23	33	32	32	0.101	35.2	10	31.3%	11.0	24.2	8	9	Surplus of 1	0
Madison	13	11	13	13	16	0.065	17.0	3	18.8%	3.2	13.8	4	0	4	0
Martin	74	81	85	93	80	0.025	82.0	8	10.0%	8.2	73.8	23	25	Surplus of 2	0
McDowell	43	42	49	47	56	0.074	60.1	12	21.4%	12.9	47.2	15	14	1	0
Mecklenburg	1122	1201	1327	1416	1473	0.071	1,577.1	180	12.2%	192.7	1,384.4	433	446	Surplus of 13	0

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Table B: ESRD Dialysis Station Need Determinations by Planning Area

County/ Multi- County Planning Area	12.31.10 Total Patients	12.31.11 Total Patients	12.31.12 Total Patients	12.31.13 Total Patients	12.31.14 Total Patients	Average Annual Change Rate for Past Five Years	Projected 12.31.15 Total Patients	12.31.14 Home Patients	12.31.14 Percent Home Patients	Projected 12.31.15 Home Patients	Projected 12.31.15 In-Center Patients	Projected 12.31.15 In-Center Station Utilization	Projected Total Available Stations	Projected Station Deficit or Surplus	County Station Need Determi- nation
Davie	41	40	44	44	51	0.059	54.0	10	19.6%	10.6	43.4	14	13	1	0
Duplin	130	134	138	136	152	0.041	158.2	21	13.8%	21.9	136.4	43	46	Surplus of 3	0
Durham	500	511	518	565	560	0.029	576.5	46	8.2%	47.4	529.1	165	191	Surplus of 26	0
Edgecombe	198	208	227	218	202	0.007	203.5	21	10.4%	21.2	182.3	57	69	Surplus of 12	0
Forsyth	593	582	591	579	604	0.005	607.0	91	15.1%	91.5	515.5	161	186	Surplus of 25	0
Franklin	111	113	114	120	111	0.001	111.1	10	9.0%	10.0	101.1	32	37	Surplus of 5	0
Gaston	278	270	270	297	317	0.035	328.0	21	6.6%	21.7	306.3	96	97	Surplus of 1	0
Gates	26	8	8	7	5	-0.276	3.6	1	20.0%	0.7	2.9	1	0	1	0
Granville	112	128	131	144	150	0.077	161.5	16	10.7%	17.2	144.3	45	48	Surplus of 3	0
Greene	52	57	66	60	48	-0.009	47.6	7	14.6%	6.9	40.6	13	21	Surplus of 8	0
Guilford	790	819	830	892	886	0.030	912.2	70	7.9%	72.1	840.1	263	270	Surplus of 7	0
Halifax	225	233	219	217	226	0.002	226.4	17	7.5%	17.0	209.4	65	65	0	0
Harnett	199	210	139	175	189	0.014	191.7	11	5.8%	11.2	180.5	56	69	Surplus of 13	0
Haywood	52	47	64	59	55	0.030	56.6	5	9.1%	5.1	51.5	16	18	Surplus of 2	0
Henderson	74	76	75	89	86	0.042	89.6	16	18.6%	16.7	72.9	23	24	Surplus of 1	0
Hertford	84	82	82	82	83	-0.003	82.8	12	14.5%	12.0	70.8	22	26	Surplus of 4	0
Hoke	92	101	97	115	106	0.041	110.4	6	5.7%	6.2	104.1	33	38	Surplus of 5	0
Hyde	6	8	9	11	6	0.057	6.3	3	50.0%	3.2	3.2	1	0	1	0
Iredell	200	209	219	218	204	0.006	205.2	27	13.2%	27.2	178.1	56	74	Surplus of 18	0
Jackson	28	34	32	39	30	0.036	31.1	8	26.7%	8.3	22.8	7	16	Surplus of 9	0
Johnston	213	230	232	244	253	0.044	264.2	30	11.9%	31.3	232.9	73	71	2	0
Jones	31	33	21	31	32	0.052	33.7	8	25.0%	8.4	25.3	8	10	Surplus of 2	0
Lee	112	108	137	131	138	0.061	146.4	16	11.6%	17.0	129.4	40	49	Surplus of 9	0
Lenoir	183	170	188	180	190	0.012	192.3	20	10.5%	20.2	172.0	54	63	Surplus of 9	0
Lincoln	87	81	99	96	73	-0.029	70.9	8	11.0%	7.8	63.1	20	25	Surplus of 5	0
Macon	23	33	32	32	26	0.054	27.4	9	34.6%	9.5	17.9	6	9	Surplus of 3	0
Madison	11	13	13	16	12	0.041	12.5	0	0.0%	0.0	12.5	4	0	4	0
Martin	81	85	93	80	83	0.010	83.9	9	10.8%	9.1	74.8	23	25	Surplus of 2	0
McDowell	42	49	47	56	49	0.048	51.4	7	14.3%	7.3	44.0	14	14	0	0
Mecklenburg	1201	1327	1416	1473	1505	0.058	1,593.0	150	10.0%	158.8	1,434.3	448	455	Surplus of 7	0

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: November 1, 2013

PROJECT ANALYST: Tanya S. Rupp
ASSISTANT CHIEF: Martha J. Frisone

PROJECT I.D. NUMBER: N-10153-13 / Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Bladen Home Dialysis / Develop a new freestanding home training and support program for peritoneal dialysis patients / Bladen 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.

NA

Bio-Medical Applications of North Carolina, Inc. (BMA) d/b/a FMC Bladen Home Dialysis proposes to develop a new freestanding home training program for peritoneal dialysis (PD) patients. Bladen Home Dialysis will lease existing space at 507 Doctors Drive, Elizabethtown, NC 28303 (primary site). BMA does not propose to include any certified in-center or home hemodialysis stations in the new facility.

Neither the 2013 State Medical Facilities Plan (SMFP) nor the July 2013 Semiannual Dialysis Report (SDR) provides a need methodology for determining the need for PD home training programs. Likewise, there are no policies in the SMFP applicable to this proposal. Therefore, this criterion is not applicable to this application.

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

minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C

Bio-Medical Applications of North Carolina, Inc. (BMA) d/b/a FMC Bladen Home Dialysis proposes to develop a home peritoneal dialysis program in leased space in Elizabethtown, Bladen County. BMA does not propose to include any certified in-center or home hemodialysis stations in the new facility.

Population to be Served

In Section III.7, page 61, the applicant projects that 100% of its patients projected to be served by FMC Bladen Home Dialysis will be from Bladen County, as illustrated in the following table:

FMC BLADEN COUNTY PD	OPERATING YEAR 1 7/1/14 - 6/30/15	OPERATING YEAR 2 7/1/15 - 6/30/16	COUNTY PATIENTS AS PERCENT OF TOTAL	
			YEAR 1	YEAR 2
Bladen County	5	6	100.0%	100.0%
Total	5	6	100.0%	100.0%

The applicant projects to serve five home PD patients in Operating Year One and six home PD patients in Operating Year Two. The applicant adequately identifies the population proposed to be served.

Demonstration of Need

In Section III.7, pages 51 – 61, the applicant describes a growing trend in patients preferring home PD training and support, both in North Carolina and in Bladen County. On pages 51 – 52, the applicant states:

“The home patient population of Bladen County is increasing. The home patient population of North Carolina is growing. The information in the following chart is extracted from the January SDR for the years indicated. The row labeled State Wide reports the total ESRD patient population across North Carolina. The row labeled Home reflects the total home patient population for each year. The row labeled Bladen Home reflects the home patient population of Bladen County for each of the years. The last column in each row calculates the five year average annual change in the ESRD patient population (the same methodology used by Medical Facilities Planning to develop the county five year average annual change rate).”

BMA notes that the home patient population of Bladen County has doubled in the 12 months between the January 2012 and January 2013 reporting.”

Below is a table from page 42 of the application that illustrates the statements made by the applicant:

SDR DATA	JANUARY 2009	JANUARY 2010	JANUARY 2011	JANUARY 2012	JANUARY 2013	AVERAGE % CHANGE
State-Wide ESRD	13,099	13,607	13,985	14,455	14,863	3.21%
Raw Change	--	508	378	470	408	
% Change	--	3.88%	2.78%	3.36%	2.82%	
State-Wide Home	1,219	1,346	1,472	1,609	1,841	10.88%
Raw Change	--	127	126	137	232	
% Change	--	10.42%	9.36%	9.31%	14.42%	
Bladen County Home	5	5	4	7	14	38.75%
Raw Change	--	0	-1	3	7	
% Change	--	0.00%	-20.00%	75.00%	100.00%	

The applicant concludes that the number of dialysis patients who choose home dialysis training and support is increasing in the state as a whole and in Bladen County. In fact, the data shows the Bladen County home patient population has grown three times faster than the North Carolina home patient population as a whole.

In addition, the applicant identified 19 North Carolina counties which it states have a similar ESRD patient population as Bladen County, which the applicant states is between 81 and 126 total patients. Within that patient population, the applicant then compares the home dialysis patient population, the number of ESRD facilities and providers, poverty and income levels, and age and race characteristics in 15 of the 19 counties. Referencing Table B on page 12 of the January 2013 SDR, on page 52, the applicant states:

“BMA suggests this range of 81 — 126 ESRD patients is reflective of Bladen and other similar sized patient ESRD patient populations. It would not be appropriate to compare Bladen County to Cumberland County which is a contiguous county. Cumberland County has a patient population more than five times the size of Bladen County. Further, while Bladen County has an ESRD patient population of only 96 patients (as reported in the SDR), BMA considered that some smaller sized populations would be appropriate since ESRD patient populations do ebb and flow with regard to total size.

However, BMA also includes populations through 126 because on the whole the ESRD patient population of North Carolina, and Bladen County specifically, is increasing. Thus, BMA offers the following list of similar sized patient populations.”

COUNTY	ESRD CENSUS	HOME PATIENTS	% HOME
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Scotland	126	9	7.4%
Orange	125	11	8.7%
Richmond	123	12	9.9%
Rutherford	119	29	25.7%
Franklin	117	14	12.4%
Surry	109	14	13.2%
Lee	109	8	7.4%
Hoke	108	4	4.0%
Person	106	10	9.8%
Beaufort	106	17	16.5%
Caldwell	100	12	11.8%
Pender	99	11	11.5%
Bladen	96	14	14.7%
Pasquotank	91	10	10.7%
Martin	88	8	9.4%
Burke	85	17	19.5%
Lincoln	83	19	23.5%
Hertford	82	6	7.3%
Chatham	81	5	6.2%

On page 54, the applicant states:

“BMA has evaluated each of the above listed Counties to determine the predominant dialysis provider serving each. Each of the above counties is currently served by a single provider within the County, with the exception of Franklin County. Within Franklin County, DaVita operates the outpatient dialysis facility and Fresenius Medical Care operates a free standing Peritoneal Dialysis facility. In addition, BMA has recently filed a CON application seeking approval to develop a new 10 station dialysis facility in Franklin County.

...

... BMA will offer comparisons between the counties served by FMC and DaVita. The facility in Surry County is operated by Health Systems Management, and is affiliated with Wake Forest School of Medicine. The facilities in Chatham, Lee and Orange Counties are managed by Renal Research Institute with strong ties to academic research. The affiliation with teaching hospitals distinguishes and separates the facilities in Surly, Chatham, Lee and Orange Counties.

Thus, BMA proposes a comparison of the following Counties and their respective dialysis patient populations:”

PRIMARY PROVIDER	COUNTY	ESRD CENSUS	HOME PATIENTS	% HOME
------------------	--------	-------------	---------------	--------

DaVita	Bladen	96	14	14.7%
DaVita	Franklin	117	14	12.4%
DaVita	Hertford	82	6	7.3%
DaVita	Hoke	108	4	4.0%
DaVita	Martin	88	8	9.4%
DaVita	Pasquotank	91	10	10.7%
DaVita	Pender	99	11	11.5%
DaVita	Person	106	10	9.8%
DaVita	Richmond	123	12	9.9%
DaVita	Rutherford	119	29	25.7%
FMC	Beaufort	106	17	16.5%
FMC	Burke	85	17	19.5%
FMC	Caldwell	100	12	11.8%
FMC	Lincoln	83	19	23.5%
FMC	Scotland	126	9	7.4%

The applicant identified 15 counties in North Carolina that have a dialysis patient population between 81 and 126 total patients served by either DaVita or FMC (parent company to BMA) as the dialysis provider.

In addition, on page 55, the applicant provides another table which ranks the percentage of home patients for each provider, as shown below:

PRIMARY PROVIDER	COUNTY	ESRD CENSUS	HOME PATIENTS	% HOME
DaVita	Bladen	96	14	14.7%
DaVita	Rutherford	119	29	25.7%
DaVita	Franklin	117	14	12.4%
DaVita	Pender	99	11	11.5%
DaVita	Pasquotank	91	10	10.7%
DaVita	Richmond	123	12	9.9%
DaVita	Person	106	10	9.8%
DaVita	Martin	88	8	9.4%
DaVita	Hertford	82	6	7.3%
DaVita	Hoke	108	4	4.0%
FMC	Lincoln	83	19	23.5%
FMC	Burke	85	17	19.5%
FMC	Beaufort	106	17	16.5%
FMC	Caldwell	100	12	11.8%
FMC	Scotland	126	9	7.4%

On pages 55 – 56, the applicant compares the percent of home dialysis patients for each of the two providers, and concludes that BMA has more patients who are home trained. The applicant states:

“Within the above table, BMA notes that in counties served by DaVita the percentage of home patients ranges from 4.0% in Hoke County to 25.7% in Rutherford County. In fact, Rutherford County is the only county higher than Bladen within the Counties

served by DaVita. Five of the counties have less than 10% of the ESRD patients dialyzing at home.

BMA also notes that there are five counties within the table served predominantly by FMC (parent to BMA). Of these five counties, three have higher percentages of home patients than does Bladen County and only one is less than 10%.”

On pages 56 – 58, the applicant compares age, race, poverty level and per capita income of those 15 counties to determine whether any of those factors are correlated to the choice of home dialysis rather than in-center dialysis. The applicant concludes that there is no significant correlation between any of the factors and whether home or in-center dialysis treatments are favored. However, the applicant concludes there is a correlation between the percentage of those patients choosing to dialyze at home and the provider of choice. On page 58, the applicant states:

“Based upon the foregoing discussion and comparison with regard to poverty levels, per capita income, age and race, BMA notes the single characteristic which seems to common [sic] among ESRD patient populations of these Counties is the predominant provider. From this comparison, BMA suggests that its presence in Bladen County will enhance patient access to home therapies. Furthermore, the BMA collaboration with Carolina Kidney Care physicians will result in more patients choosing home dialysis.”

In Section V.4(c), page 67, the applicant states the physicians of Carolina Kidney Care will provide referrals and treatment for those Bladen County patients who choose to dialyze at home. In Exhibit 21 the applicant provides a letter dated April 3, 2013, signed by Dr. Ezra McConnell, which states in part:

“I am writing on behalf of Carolina Kidney Care’s eleven nephrologists to endorse the Certificate of Need application....

... Recently, we have seen an increase in the home dialysis patient population. I and my fellow nephrologists believe that this trend will continue and that the ‘new normal’ will be more patients utilizing home dialysis....

My associates and I have been providing nephrology services for patients residing in Bladen and surrounding counties for many years. We have well established relationships with physicians in the region. Last year Carolina Kidney Care opened a clinic for patients with kidney disease in Elizabethtown. The number of patients seen at this clinic has grown rapidly. The addition of a home peritoneal dialysis training program closer to their homes will be beneficial to patients needing this service.”

Thus, the applicant states that its presence in the county, as well as its affiliation with the nephrologists associated with Carolina Kidney Care will enhance patient access to home therapies.

On pages 58 – 60, the applicant provides the following assumptions on which it bases its determination of need in Bladen County for home PD dialysis training and support services:

1. *“This project is scheduled for completion and certification at [sic] June 30, 2014. Operating Year 1 is the period from July 1, 2014 through June 30, 2015. Operating Year 2 is the period from July 1, 2015 through June 30, 2016.*
2. *BMA currently provides home PD training and support for some of the home patients from Bladen County.*
3. *BMA assumes that the nephrology physicians of Carolina Kidney Care will refer home patients to the new facility. This assumption is a function of the CKC support for this application.*
4. *BMA assumes that all of the future patients of the facility will be residents of Bladen County. BMA has home training programs in Sampson, Cumberland and Robeson Counties which are contiguous to Bladen on the west-northeast sides of the County.*
5. *BMA is not proposing that home dialysis patients being followed by the existing provider in Bladen County will transfer their care to the new facility. BMA assumes that those patients will continue to dialyze with their current facility. However, BMA will not deny admission to any patient with proper referral by a nephrology physician with admitting privileges at the facility.*
6. *BMA does assume that the home dialysis patients residing in Bladen County and being followed by Carolina Kidney Care nephrology physicians will transfer their care to the new facility. This assumption is based upon the continuity of care that the patient will receive and the significantly reduced burden of travel to either Fayetteville or Lumberton currently experienced by the patient.*
7. *BMA assumes that the home patient population of Bladen County will continue to increase, much as the ESRD patient population of North Carolina and Bladen County has in recent years. The number of home patients within the ESRD patient population as a whole is increasing at a higher rate than the ESRD patient population itself. BMA has already demonstrated that the ESRD patient population of North Carolina is growing at a rate of 3.21% annually. At the same time the home patient population of our State is increasing at a rate of 10.88% at the same time. Thus it is obvious that more and more patients needing dialysis treatment are opting for home dialysis.*
8. *BMA assumes that more patients will choose home peritoneal dialysis as a result of development of this facility, coupled with the presence of Carolina Kidney Care physicians. The January 2013 SDR Table B reports, among other things, the*

ESRD patient population for each County in our State, to include the number of patients utilizing home dialysis.

9. *BMA assumes that more patients will choose home peritoneal dialysis as a result of development of this facility, coupled with the presence of Carolina Kidney Care physicians.*
10. *BMA assumes that the home patient population of Bladen County will increase to a level of 20% home patient population. This growth is a function of more patients choosing home dialysis and more patients referred to home dialysis from by the nephrology physicians of Carolina Kidney Care. Further, Bladen County is a large rural county. To the extent that more patients may be referred to home dialysis, then fewer patients are traveling long distance for dialysis treatment in Elizabethtown three days per week.*
11. *BMA will project growth of the Bladen County ESRD patient population at the Bladen County Five Year Average Annual Change Rate as published in the January 2013 SDR. That rate is 5.2%.*
12. *BMA will project that 20% of the future ESRD patient population of Bladen County will choose home dialysis.*
13. *BMA does not assume that all of the future home patients will choose to dialyze with BMA. BMA assumes that half of the new patients in the first operating year of this project will choose to dialyze with BMA. BMA assumes that one new patient from the Second Operating Year will choose to dialyze with BMA."*

Therefore, using the dialysis patient population as of June 30, 2012 and the Bladen County Five Year Average Annual Change Rate (AACR) of 5.2%, both of which are published in the 2013 January 2013 SDR, the applicant grows the total dialysis patient population of Bladen County through June 30, 2016, the end of the second project year. See the following calculations, based on a beginning census of 96 in-center dialysis patients and a 5.2% AACR:

$$\begin{aligned} 96 \times 1.052 &= 101.0 && \text{(to June 30, 2013)} \\ 101.0 \times 1.052 &= 106.2 && \text{(to June 30, 2014)} \\ 106.2 \times 1.052 &= 111.8 && \text{(to June 30, 2015)} \\ 111.8 \times 1.052 &= 117.6 && \text{(to June 30, 2016)} \end{aligned}$$

BMA then calculates 20% of the patient population and projects the following number of dialysis patients who will receive home training in the first and second project years:

$$\text{Operating Year One (7/1/14 – 6/30/15)} \quad 111.8 \text{ patients} \times 20\% = 22.4$$

Operating Year Two (7/1/15 – 6/30/16) 117.6 patients x 20% = 23.5

On pages 60 – 61, the applicant projects how many of the home patients in Bladen County it projects to serve in Project Years 1 and 2. The applicant states:

“... BMA is currently serving some of the Bladen County home patient population. BMA will project one home peritoneal dialysis patient to transfer care to the new FMC Bladen Home Program upon certification. BMA is serving one home hemodialysis patient from Bladen County and does not project that patient to transfer to the new facility; the new facility is PD only.

Further, BMA notes that the current home patient population of Bladen County is comprised of 14 patients according to the January 2013 SDR. BMA does not anticipate that patients of the current provider in Bladen County will change their care to the new facility. However, BMA will not prohibit any patient from transferring their care with proper referral from a physician with admitting privileges. BMA projections of a patient population to be served include the one transferring patient and half of the future home patient population of Bladen County.

Thus, patient populations to be served are projected as follows:

*Current, per January 2013 SDR: 14 home patients
BMA is providing treatment for 2 (1 is home hemo dialysis)
BMA assumes DaVita is providing treatment for: 12*

*Operating Year 1, BMA projections 22.4 home patients
BMA is providing treatment for: 2
BMA assumes DaVita is providing treatment for: 12
New Home patients: 8
BMA assumes 4 patients will dialyze with BMA
BMA assumes 4 patients will dialyze with DaVita*

*Operating Year [2], BMA projections 23.5 home patients
BMA is providing treatment for 6 (1 is home hemo dialysis)
BMA assumes DaVita is providing treatment for: 16
Operating Year 2 new patients: 1
BMA assumes the one new patients [sic] will dialyze with BMA*

Thus, at the end of Operating Year 1, BMA projects to serve 5 of the 22.4 patients projected to choose home PD in Bladen County. At the end of Operating Year 2, BMA projects to serve 6 of the 23.5 patients projected to choose home PD in Bladen County.

The project analyst tested the applicant’s assumptions with regard to the home patient population comprising 20% of the entire ESRD patient population in Bladen County. The analyst looked at Table B of past SDRs from January 2010 to January 2013 for Bladen County, and found the following:

SDR VERSION	TOTAL NO. BLADEN CO. ESRD PATIENTS	NUMBER HOME PATIENTS	PERCENT HOME
January 2010	91	5	5.5%
July 2010	92	3	3.3%
January 2011	92	4	4.4%
July 2011	95	4	4.2%
January 2012	94	7	7.5%
July 2012	95	11	11.5%
January 2013	95	14	14.7%

Rates from the July 2013 SDR, which was not available when this application was submitted, showed a total ESRD patient population in Bladen County of 106 and a home patient population of 17.

The analyst notes that, according to the data provided in the January 2010 SDR through the January 2011 SDR, there was little growth in home patients. From July 2011 through July 2013, the percentage of home ESRD patients grew by 324% [(17.8% patients in July 2013 / 4.2% in July 2011) – 1 = 3.238]. Alternatively, the number of dialysis patients receiving home therapies in Bladen County grew by 345% between July 2011 and July 2013 [(17.8 patients July 2013 / 4 patients July 2011) – 1 = 3.45]. This growth occurred without offering new home PD training and support services in the County. If the percentage of home trained patients in Bladen County were increased by the AACR from the January 2013 SDR (5.2%), then by the end of Operating Year Two, the percentage of Bladen County ESRD patients who choose home dialysis training would be 17.5%, without the introduction of a new home dialysis provider in the county. Therefore, it is reasonable to assume that, with the recent growth in home training for dialysis patients in Bladen County combined with the introduction of a new provider, particularly a provider that is connected to a group of eleven nephrologists who treat patients in the county, the percentage of home trained patients in Bladen County could comprise 20% of the Bladen County dialysis patient population. Furthermore, the data in the July 2013 SDR, as noted in a note to the above table, which was not available to the applicant at the time the application was prepared, shows the percent and number of home patients in Bladen County grew by even more than the AACR that was published in the January 2013 SDR.

Additionally, the applicant projects that it will serve 5 of 22.4 home trained patients in the first Operating Year, and 6 of 23.5 home trained patients in the second Operating Year. Each number represents less than 25% of the total projected number of dialysis patients in Bladen County who will choose home training and support rather than in-center dialysis. The applicant has provided documentation of a physician referral base in Bladen County with Carolina Kidney Care, and the data provided in the SDRs shows that the number of home trained patients is increasing at a faster rate than in past years.

The applicant adequately demonstrates the need for the proposed home PD and training and support services in Bladen County.

In summary, the applicant adequately identifies the population to be served and adequately demonstrates the need for the proposal. Consequently, the application is conforming to this criterion.

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

NA

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

CA

In Section III.9, page 62 of the application, the applicant discusses the alternatives it considered prior to the submission of this application, which include:

- 1) Maintain the Status Quo – continue to offer home peritoneal dialysis for Bladen County residents through BMA Fayetteville or BMA Lumberton, which is where current home patients receive their training and support. The applicant states that, due in part to the referral trends of the nephrologists at Carolina Kidney Care, the number of home trained dialysis patients in Bladen County is increasing. To maintain the status quo would necessitate that current home dialysis patients still travel to Cumberland or Robeson counties for their training and support.
- 2) Chosen alternative – offer home PD training and support at FMC Bladen Home Dialysis. Development of the home PD dialysis program as proposed in this application will provide Bladen County residents the opportunity to receive their training and support in their county, without traveling to Cumberland or Robeson counties. This alternative, according to the applicant, provides the home training and support that the Bladen County dialysis patients need. In addition, the development of the FMC Bladen Home Dialysis program will more effectively serve the increasing numbers of home dialysis patients in Bladen County.

The applicant adequately demonstrates that the proposed alternative is the most effective or least costly alternative to meet the need for home PD training and support services in Bladen County based on the following:

- Current and future Bladen County dialysis patients will be able to receive home PD training and support in Bladen County and continue to be served by the nephrologists with Carolina Kidney Care.

- Current and future Bladen County dialysis patients who desire home PD training and support will be able to choose from two providers located in Bladen County.

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

In summary, the applicant adequately demonstrates that its proposal is the least costly or most effective alternative to meet the need for home PD training and support services in Bladen County. Therefore, the application is conforming to this criterion and approved subject to the following conditions:

1. **Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Bladen Home Dialysis shall materially comply with all representations made in the certificate of need application.**
 2. **Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Bladen Home Dialysis shall develop no more than one home peritoneal dialysis training and support program facility in Bladen County.**
 3. **Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Bladen Home Dialysis shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Certificate of Need Section in writing prior to the issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

In Section VIII.1, page 77, the applicant states that the proposed capital cost of the project is \$277,113, including \$145,418 for construction contract costs, \$51,857 for equipment and furniture costs, \$13,088 for architect/engineering fees, and \$16,750 for RO water treatment equipment and contingency fees. In Section IX.1, page 82, the applicant states there will be start-up expenses of \$23,711 and initial operating expenses of \$189,309. According to the applicant on page 83, the initial operating period is projected to last eight months (i.e. it will take eight months for revenues to exceed expenses).

In Section VIII.2, page 78 and Section IX.4, page 84, the applicant states that the project will be funded with cash reserves of Fresenius Medical Care Holdings, Inc., the parent company of Bio-Medical Applications of North Carolina, Inc. In Exhibit 24 the applicant provides a June 17, 2013 letters signed by the Vice President of Fresenius Medical Care Holdings, Inc., which states in part:

“BMA proposes to develop a new home peritoneal dialysis program in Elizabethtown, Bladen County. ... The project calls for the following capital expenditures on behalf of BMA.

Capital Expenditure \$227,113

As Vice President, I am authorized and do hereby authorize the development of this home dialysis program in Bladen County, North Carolina for capital costs of necessary cash and cash reserves for the start up and working capital which may be needed for this project.”

In addition, in Exhibit 10 the applicant provides the audited financial statements for Fresenius Medical Care Holdings, Inc. and Subsidiaries for the years ending December 31, 2012 and December 31, 2011. As of December 31, 2012, Fresenius Medical Care had \$341,071,000 in cash and cash equivalents, \$17,841,509,000 in total assets, and \$9,469,431,000 in net assets (total assets less total liabilities). The applicant adequately demonstrates the availability of sufficient funds for the capital and working capital needs of the project.

In Section VI.1(c), page 70, the applicant states reimbursement projections are based on the historical performance of home training programs in other BMA facilities. In Section X.3, pages 86 - 87, the applicant provides the assumptions with which it projects revenue for each payor source for its home PD patients. In Section X.1, page 85, the applicant states it has opted to participate in a Medicare reimbursement program which provides one basic fee which includes ancillary costs associated with dialysis treatments. Additional ancillary services are reflected separately in a table on page 87 of the application. See the following table:

Projected Reimbursement Home Peritoneal Dialysis

FMC BLADEN HOME PD TRAINING			
Revenue Source Year 1	Patient Payment % by Revenue Source	# Treatments	Reimbursement per Treatment
Medicare	71.42%	309	\$ 234.00
Commercial	28.58%	123	\$1,375.00
Revenue Source Year 2	Patient Payment % by Revenue Source	# Treatments	Reimbursement per Treatment
Medicare	71.42%	566	\$ 234.00
Commercial	28.58%	226	\$1,375.00

This information is consistent with the payor mix reported by the applicant in Section VI.1(c), page 70 of the application: Additionally, the rates shown above are consistent with the standard Medicare/Medicaid rates established by the Centers for Medicare and Medicaid Services.

In Sections X.2, on page 86; and Section X.4, page 88, the applicant reports projected revenues and expenses as illustrated in the following table:

FMC BLADEN		
	OPERATING YEAR 1	OPERATING YEAR 2
Total Net Revenue	\$241,980	\$443,630
Total Operating Costs	\$283,964	\$373,872
Net Profit	(\$ 41,984)	\$ 69,758

As shown in the above table, the applicant projects that revenues will exceed operating expenses in the second operating year. Furthermore, projected utilization is based on reasonable, credible and supported assumptions. See Criterion (3) for discussion regarding projected utilization which is incorporated hereby as if set forth fully herein. Therefore, the applicant adequately demonstrated that the financial feasibility of the proposal is based upon reasonable, credible and supported projections of costs and revenues. Consequently, the application is conforming to this criterion.

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

C

In this application, Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Bladen Home Dialysis proposes to develop a new freestanding home training program facility for peritoneal dialysis (PD) patients. BMA does not propose to offer in-center dialysis or include any hemodialysis stations in the new Bladen County Home Dialysis facility. Bladen County Home Dialysis will be located in Elizabethtown and proposes to serve home PD patients from Bladen County.

According to the January 2013 SDR, there is one Kidney Disease Treatment Center in Bladen County – Southeastern Dialysis Kenansville, in Kenansville. DaVita is the owner of the facility, which is certified for 14 in-center hemodialysis stations. Southeastern Dialysis offers home PD training and support services. There are three other dialysis facilities which offer home training and support; however, these three facilities are between 36.1 and 37.9 miles from the ZIP code for the proposed Bladen County home dialysis program. See the following table:

FACILITY	TOWN	COUNTY	PROVIDER	DISTANCE FROM 28303
Fayetteville Kidney Center	Fayetteville	Cumberland	BMA/FMC	5.5 miles
Carolina Dialysis Sanford	Sanford	Lee	BMA/FMC	36.1 miles
FMC Lumberton Dialysis	Lumberton	Robeson	BMA/FMC	37.9 miles
Dialysis Care of Moore County	Pinehurst	Moore	DaVita	36.2 miles

In addition, in Project ID #M-10115-13, BMA was recently approved to dedicate two existing, certified dialysis stations to offer home PD training and support at its facility in Clinton. Clinton is in Sampson County, which is contiguous to Bladen County along its northeastern edge. According to MapQuest®, the distance from Clinton to Elizabethtown is approximately 36 miles.

The applicant adequately demonstrates the need to develop the proposed home PD facility in Elizabethtown for the provision of home PD services to serve the residents of Bladen County. See Criterion (3) for discussion of need which is incorporated hereby as if set forth fully herein. Therefore, the applicant adequately demonstrates the proposal will not result in the unnecessary duplication of existing or approved home PD training and support services in Bladen County. Consequently, the application is conforming to this criterion.

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

C

In Section VII.1, page 74, the applicant provides the proposed staffing during the first two operating years following completion of the project, as illustrated below in the table.

POSITION	PROJECTED FULL TIME EQUIVALENT POSITIONS (FTES) YEARS 1 AND 2
Clinical Manager/HT RN	1.00
Admin.	0.10
Dietitian	0.10
Social Worker	0.10
Equipment Technician	0.10
In-Service	0.10
Clerical	0.50
Total	2.00

As shown in the above table, the applicant proposes to employ a total of 2.0 FTE positions to staff the PD home training facility during the first two operating years following completion of the project. In Section V.4(c), page 67, the applicant states that Dr. Ezra McConnell will be the Medical Director for Bladen County Home Dialysis. In Exhibit 21 the applicant provides an April 3, 2013 letter from Dr. McConnell which confirms the information on page 67. In Section VII.10, page 76, the applicant states that the Bladen County Home Dialysis will operate Monday-Friday, from 7:00 AM to 5:00 PM. The applicant states further that a qualified registered nurse will be on call 24 hours a day / 7 days a week.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel, including a medical director, for the provision of PD home training and support services. Therefore, the application is conforming to this criterion.

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

C

In Section V.1, page 64, the applicant provides a table that lists the proposed providers of ancillary and support services for FMC Bladen Home Dialysis. Exhibit 17 contains a copy of a transplantation agreement between FMC Bladen Home Dialysis and Duke University Medical Center. Exhibit 16 contains a hospital affiliation agreement between Cape Fear Valley Medical Center and BMA. Exhibit 18 contains a copy of a laboratory services agreement between BMA and SPECTRA Laboratories, Inc. for the provision of laboratory services. Exhibit 20 contains a copy of a home training agreement with BMA Lumberton, which states that facility will provide back up assistance if necessary. Exhibit 21 contains a letter from Carolina Kidney Care (CKC) which confirms referrals to the proposed home training program as well as follow up with the CKC nephrologists for home trained dialysis patients. That same letter confirms Dr. Ezra McConnell's commitment to serve as the medical director for the proposed facility. The applicant adequately demonstrates that the necessary ancillary and support services will be available and that the proposed services will be coordinated with the existing health care system. Therefore, the application is conforming to this criterion.

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

NA

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

NA

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

NA

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

NA

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

C

In Section VI.1(f), page 71, the applicant states "*BMA of North Carolina facilities do not have any obligation to provide uncompensated care or community service under any federal regulations*" In Section VI.6(a), page 72, the applicant states: "*There have been no Civil Rights complaints lodged against BMA Clinton in the past five years.*" The application is conforming to this criterion.

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

C

In Section VI.1(c), page 70, the applicant notes that FMC Bladen Home Dialysis is a proposed facility and thus has no historical payor mix on which to base its projected payor mix. On page 70, the applicant projects that 71.4% of the home PD patients will be Medicare or Medicaid beneficiaries, which it states is based on "*historical performance of the BMA Lumberton home training program, and specifically the peritoneal dialysis patients. BMA does not anticipate any significant changes to the home patient population.*" The applicant demonstrates that medically underserved

populations would have adequate access to the proposed services. Therefore, the application is conforming to this criterion.

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

C

In Section VI.5 (a), page 78 the applicant states, *“Those Nephrologists who apply for and receive medical staff privileges will admit patients with End Stage Renal Disease to the facility. FMC Bladen Home Dialysis will have an open policy, which means that any Nephrologists may apply to admit patients at the facility. The attending physicians receive referrals from other physicians or Nephrologists or hospitals.”* In Exhibit 16, the applicant provides a copy of a hospital affiliation agreement between BMA Clinton and Cape Fear Valley Health System. The applicant adequately demonstrates that FMC Bladen Home Dialysis will offer a range of means by which a person can access services. Therefore, the application is conforming to this criterion.

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

C

In Section V.3(a), page 66, the applicant states:

“Exhibit 19 includes a letter from Kristina Roberts, FMC Area Manager, to Robeson Community College Nursing Department inviting the school to include the facility in its clinical rotation for nursing students. Students are provided tours through the facilities and discussions regarding the different aspects of dialysis and facility operations.”

In Exhibit 19 the applicant provides a June 7, 2013 from the Area Manager of Fresenius Medical Care to Robeson Community College, inviting the school to include FMC Bladen Home Dialysis for clinical training. The applicant adequately demonstrates that the facility will accommodate the clinical needs of area health professional training programs. Therefore, the application is conforming to this criterion.

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

favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

C

FMC Bladen Home Dialysis proposes to offer home PD training and support services in its proposed facility. The only other kidney disease treatment center in Bladen County is Southeastern Dialysis of Kenansville, an in-center dialysis facility operated by DaVita, which provides home PD training and support services.

In Section V.7, page 68, the applicant discusses the effects of the proposal on competition, including how any enhanced competition will have a positive effect on the cost effectiveness, quality and access to the proposed services. See also Sections II, III, VI, and VII.

The information provided by the applicant in those sections is reasonable and credible and adequately demonstrates that any enhanced competition will have a positive impact on the cost effectiveness, quality and access to the proposed services. This determination is based on the information in the application and the following analysis:

- ◆ The applicant adequately demonstrates the need for the proposal and that it is a cost-effective alternative;
- ◆ The applicant will provide quality services; and
- ◆ The applicant will provide adequate access to medically underserved populations.

The application is conforming to this criterion.

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

NA

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

C

The Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200 are applicable to this review. The proposal is conforming to all applicable regulatory review criteria. The specific criteria are discussed below.

10A NCAC 14C .2202 INFORMATION REQUIRED OF APPLICANT

(a) An applicant that proposes to increase stations in an existing certified facility or relocate stations must provide the following information:

- .2202(a)(1) Utilization rates;*
-NA- FMC Bladen Home Dialysis is not an existing facility and thus and does not have historical information to report.
- .2202(a)(2) Mortality rates;*
-NA- FMC Bladen Home Dialysis is not an existing facility and thus and does not have historical information to report.
- .2202(a)(3) The number of patients that are home trained and the number of patients on home dialysis;*
-C- In Section II, page 11, the applicant states: *“BMA is currently serving several home patients who are residing in Bladen County. These patients are being followed by either BMA Fayetteville or BMA Lumberton (patient choice of providers). Upon approval of this CON application and certification of the new facility, FMC Bladen Home Dialysis will be dedicated to the peritoneal dialysis patient population. Home hemo-dialysis will continue to be followed at the BMA Fayetteville or BMA Lumberton facility....”*
- .2202(a)(4) The number of transplants performed or referred;*
-NA- FMC Bladen Home Dialysis is not an existing facility and thus and does not have historical information to report.
- .2202(a)(5) The number of patients currently on the transplant waiting list;*
-NA- FMC Bladen Home Dialysis is not an existing facility and thus and does not have historical information to report.
- .2202(a)(6) Hospital admission rates, by admission diagnosis, i.e., dialysis related versus non-dialysis related;*
-NA- FMC Bladen Home Dialysis is not an existing facility and thus and does not have historical information to report.
- .2202(a)(7) The number of patients with infectious disease, e.g., hepatitis, and the number converted to infectious status during the last calendar year.*

-NA- FMC Bladen Home Dialysis is not an existing facility and thus and does not have historical information to report.

(b) An applicant that proposes to develop a new facility, increase the number of dialysis stations in an existing facility, establish a new dialysis station, or relocate existing dialysis stations shall provide the following information requested on the End Stage Renal Disease (ESRD) Treatment application form:

.2202(b)(1) For new facilities, a letter of intent to sign a written agreement or a signed written agreement with an acute care hospital that specifies the relationship with the dialysis facility and describes the services that the hospital will provide to patients of the dialysis facility. The agreement must comply with 42 C.F.R., Section 405.2100.

-C- Exhibit 16 contains a copy of a proposed affiliation agreement between Cape Fear Valley Medical Center and FMC Bladen Home Dialysis which specifies the relationship with the dialysis facility and describes the services that the hospital will provide to patients of the dialysis facility.

.2202(b)(2) For new facilities, a letter of intent to sign a written agreement or a written agreement with a transplantation center describing the relationship with the dialysis facility and the specific services that the transplantation center will provide to patients of the dialysis facility. The agreements must include the following:

- (A) timeframe for initial assessment and evaluation of patients for transplantation,*
- (B) composition of the assessment/evaluation team at the transplant center,*
- (C) method for periodic re-evaluation,*
- (D) criteria by which a patient will be evaluated and periodically re-evaluated for transplantation, and,*
- (E) Signatures of the duly authorized persons representing the facilities and the agency providing the services.*

-C- Exhibit 17 contains a copy of a transplant agreement between Duke University Medical Center and FMC Bladen Home Dialysis dated April 1, 2013.

.2202(b)(3) For new or replacement facilities, documentation that power and water will be available at the proposed site.

-C- In Section II, on page 12, the applicant states water and power are available at the site. In Exhibit 30, the applicant provides copies of email communications which document the availability of power and water at the primary site. In Exhibit 31, the applicant provides the same documentation for the secondary site.

.2202(b)(4) Copies of written policies and procedures for back up for electrical service in the event of a power outage.

-C- Exhibit 12 contains a copy of BMA's Emergency Disaster Procedure Manual, which details procedures for back-up electrical service in the event of a power outage. In addition, in Section II, page 12, the applicant states, "All peritoneal

dialysis patients are taught to perform manual exchange in the event of a power failure which interrupts the PD cyclor.”

.2202(b)(5) For new facilities, the location of the site on which the services are to be operated. If such site is neither owned by nor under option to the applicant, the applicant must provide a written commitment to pursue acquiring the site if and when the approval is granted, must specify a secondary site on which the services could be operated should acquisition efforts relative to the primary site ultimately fail, and must demonstrate that the primary and secondary sites are available for acquisition.

-C- In Exhibits 30 and 31, the applicant provides documentation which identifies both a primary and a secondary site (in case the primary site is unavailable upon certificate of need approval) which the applicant will lease for the Bladen County Home Dialysis facility.

.2202(b)(6) Documentation that the services will be provided in conformity with applicable laws and regulations pertaining to staffing, fire safety equipment, physical environment, water supply, and other relevant health and safety requirements.

-C- In Section II, page 13, and Section VII.2, page 75, the applicant documents that Bladen County Home Dialysis will provide all services in conformity with all applicable laws and regulations for staffing and safety. In addition, in Exhibit 12, the applicant provides a copy of BMA’s emergency and disaster polices and procedures manual, and Exhibit 11 contains a copy of the applicant’s water quality standards policy.

.2202(b)(7) The projected patient origin for the services. All assumptions, including the methodology by which patient origin is projected, must be stated.

-C- In Section II, pages 13 - 22, and in Section III.7, pages 51 - 61, the applicant provides its assumptions regarding patient origin for the proposed FMC Bladen County Home Dialysis. In addition, in Section III.7, page 30, the applicant provides the projected patient origin for Bladen County Home Dialysis, which it projects will be comprised completely of Bladen County dialysis patients. See the following table:

FMC BLADEN COUNTY PD	OY 1 (9/30/14 – 6/30/15)	OY 2 (9/30/15 – 6/30/16)	COUNTY PATIENTS AS PERCENT OF TOTAL	
			OY 1	OY 2
Bladen	5	6	100.0%	100.0%
Total	5	6	100.0%	100.0%

.2202(b)(8) For new facilities, documentation that at least 80 percent of the anticipated patient population resides within 30 miles of the proposed facility.

-NA- In Section II, page 61, the applicant projects that “100% of the patient population of this facility resides within 30 miles of the facility. ... Thirty miles from the primary location for FMC Bladen Home covers the entirety of Bladen County.”

.2202(b)(9) *A commitment that the applicant shall admit and provide dialysis services to patients who have no insurance or other source of payment, but for whom payment for dialysis services will be made by another healthcare provider in an amount equal to the Medicare reimbursement for such services.*

-C- In Section II.1(9), page 24, the applicant states, “BMA will admit and provide dialysis services to patients who have no insurance or other source of payment, but for whom payment for dialysis services will be made by another healthcare provider in an amount equal to the Medicare reimbursement rate for such services.”

10 NCAC 14C .2203 PERFORMANCE STANDARDS

.2203(a) *An applicant proposing to establish a new End Stage Renal Disease facility shall document the need for at least 10 stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the facility, with the exception that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.*

-NA- FMC Bladen County Home Dialysis proposes a peritoneal dialysis home training facility and does not propose to develop a facility with hemodialysis stations.

.2203(b) *An applicant proposing to increase the number of dialysis stations in an existing End Stage Renal Disease facility or one that was not operational prior to the beginning of the review period but which had been issued a certificate of need shall document the need for the additional stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the additional stations.*

-NA- FMC Bladen County Home Dialysis proposes a new peritoneal dialysis home training facility.

.2203(c) *An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*

-C- In Section II, pages 26 – 36, Section II, pages 13 – 23, and in Section III.7, pages 51 - 61, the applicant provides the assumptions and methodology used to project utilization of the proposed facility. See discussion in Criterion (3) which is incorporated hereby as if set forth fully herein.

10 NCAC 14C .2204 SCOPE OF SERVICES

To be approved, the applicant must demonstrate that the following services will be available:

.2204(1) *Diagnostic and evaluation services;*

-C- In Section II, page 36, and in Section V.1, page 64, the applicant states that diagnostic evaluation services will be provided by Cape Fear Valley Medical Center, Bladen County Hospital, or Lumberton Radiological Associates.

.2204(2) *maintenance dialysis;*

- C- In Section II, page 36, the applicant states: *“The facility will provide training for home peritoneal dialysis. Patients dialyzing at home receive maintenance dialysis equivalent to that received in a traditional in-center setting.”* In addition, in Section V.1, page 64, the applicant indicates that maintenance dialysis will be provided at the facility.
- .2204(3) *accessible self-care training;*
-C- In Section II, page 37, the applicant states: *This facility will train patients to dialyze at home.”* In addition, in Section V.1, page 64, the applicant indicates that self-care training will be provided by the facility.
- .2204(4) *accessible follow-up program for support of patients dialyzing at home;*
-C- In Section II, page 36, the applicant states, *“This is an application to develop a new home training program. The new center will focus exclusively on home peritoneal dialysis. Patients who are candidates for home hemo-dialysis will be referred to the BMA Fayetteville or BMA Lumberton home training department.”*
- .2204(5) *x-ray services;*
-C- In Section II, page 37, and in Section V.1, page 64, the applicant states that Cape Fear Valley Medical Center, Bladen County Hospital, or Lumberton Radiological Associates will provide X-ray services.
- .2204(6) *laboratory services;*
-C- In Section II, page 37, and in Section V.1, page 64, the applicant states laboratory services will be provided by Spectra Laboratories. See Exhibit 18 for the existing agreement with Spectra Laboratories.
- .2204(7) *blood bank services;*
-C- In Section II, page 37, and in Section V.1, page 64, the applicant states that blood bank services will be provided by Cape Fear Valley Medical Center and Bladen County Hospital.
- .2204(8) *emergency care;*
-C- In Section II, page 37, and in Section V.1, page 64, the applicant states that emergency care will be provided on site by BMA staff until emergency responders arrive. The facility stocks a “crash cart” in the event of a medical emergency, and all staff are appropriately trained in emergency situations.
- .2204(9) *acute dialysis in an acute care setting;*
-C- In Section II, page 37, and in Section V.1, page 64, the applicant states that acute dialysis in an acute care setting will provided by Cape Fear Valley Medical Center and Bladen County Hospital.
- .2204(10) *vascular surgery for dialysis treatment patients;*

- C- In Section II, page 37, and in Section V.1, page 64, the applicant states that vascular surgery for dialysis treatment patients will be provided by Carolina Kidney Care Nephrology Procedure Center, Village Surgical Associates, Village Surgical Associates in Fayetteville, or by one of several surgeons who will provide services.
- .2204(11) *transplantation services;*
 - C- In Section II, page 37, and in Section V.1, page 64, the applicant states transplantation services will be provided by Duke University Medical Center. In Exhibit 17, the applicant provides a copy of the existing agreement.
- .2204(12) *vocational rehabilitation counseling and services; and*
 - C- In Section II, page 38, and in Section V.1, page 64, the applicant states vocational rehabilitation counseling and services will be provided by Vocational Rehabilitation in Lumberton.
- .2204(13) *transportation.*
 - C- In Section II, page 37, and in Section V.1, page 64, the applicant states transportation will be provided by Bladen Area Rural Transportation, or by the Department of Social Services.

10 NCAC 14C .2205 STAFFING AND STAFF TRAINING

- .2205(a) *To be approved, the state agency must determine that the proponent can meet all staffing requirements as stated in 42 C.F.R. Section 405.2100.*
 - C- In Section VII.1 – 2, on pages 74 - 75, the applicant provides the proposed staffing. In Section VII.2, page 75, the applicant states the proposed facility will comply with all staffing requirements as stated in 42 C.F.R. Section 405.2100. The applicant adequately demonstrates that sufficient staff is proposed for the level of dialysis services to be provided. See Criterion (7) for additional discussion which is incorporated hereby as if set forth fully herein.
- .2205(b) *To be approved, the state agency must determine that the proponent will provide an ongoing program of training for nurses and technicians in dialysis techniques at the facility.*
 - C- In Section II, page 38, and in Section V.1, page 64, the applicant describes the qualifications or certifications that are required for staff members of FMC Bladen County Home Dialysis. In addition, the applicant provides a copy of BMA's training outline in Exhibit 14. The applicant also provides a copy of BMA's Emergency Preparedness and Procedure Manual in Exhibit 12.