

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: January 28, 2016

Findings Date: January 28, 2016

Project Analyst: Bernetta Thorne-Williams

Assistant Chief: Martha J. Frisone

Project ID #: L-11067-15

Facility: FMS ENA Home, LLC

FID #: 150397

County: Edgecombe

Applicant: FMS ENA Home, LLC

Project: Develop a new freestanding home dialysis training and support program for peritoneal dialysis patients

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

NA

FMS ENA Home, LLC (FMS ENA) proposes to develop a new kidney disease treatment center dedicated to providing home training and support services for peritoneal dialysis (PD) patients. The applicant does not propose to include any certified in-center stations or home hemodialysis stations as a part of the proposed project.

Need Determination

Neither the 2015 State Medical Facilities Plan (SMFP) nor the July 2015 Semiannual Dialysis Report (SDR) provides a need methodology for determining the need for kidney disease treatment centers dedicated to providing home PD services. Therefore, there are no need determinations applicable to the review of this application.

Policies

There are no policies in the 2015 SMFP that are applicable to this review. Policy GEN-3 is not applicable to this review because the applicant does not propose to develop or offer a new institutional health service for which there is a need determination in the 2015 SMFP. Additionally, Policy GEN-4 is not applicable to this review because the proposed capital cost for the project is \$618,726 which is less than the \$2 million dollars required for this policy to be applicable.

Conclusion

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- (2) Repealed effective July 1, 1987.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

FMS ENA proposes to develop a new kidney disease treatment center dedicated to providing home training and support services for PD patients. On August 28, 2015, Bio-Medical Applications of North Carolina, Inc. (BMA) was approved in Project I.D. # L-11011-15 to develop FMC Tarboro, a new 10-station kidney disease treatment center by relocating six dialysis stations from BMA East Rocky Mount and four dialysis stations from Greenville Dialysis Center in Pitt County. Home PD services were not proposed in the FMC Tarboro application. The proposed FMS ENA facility would be located in the same building as the approved FMC Tarboro.

There are two existing kidney disease treatment centers in Edgecombe County: BMA East Rocky Mount located in Rocky Mount and Dialysis Care of Edgecombe County located in Tarboro. Home PD services are currently available only at the Dialysis Care of Edgecombe County facility.

Population to be Served

On page 361 the 2015 SMFP defines the service area for dialysis stations as “*the dialysis station planning area in which the dialysis station is located.*” The applicant does not propose to develop any certified in-center stations or home hemodialysis stations as a part of the proposed project.

In Section C, page 18, the applicant provides the projected patient origin during each of the first two years of operation following completion of the project, as illustrated in the table below.

FMS ENA	Number of PD Patients		PD Patients as Percent of Total	
	Operating Year (OY) 1	OY 2	OY 1	OY 2
Edgecombe	6	6	100%	100%
Total	6	6	100%	100%

As shown in the table above, the applicant projects that all of the patients will be residents of Edgecombe County. The applicant provides the assumptions and methodology used to project patient origin on pages 18-26.

The applicant adequately identifies the population to be served.

Analysis of Need

In Section C, pages 22-23, the applicant states:

“Patients with End Stage Renal Disease require dialysis treatment on a regular and consistent basis in order to maintain life. Peritoneal dialysis patients are assumed to dialyze daily Failure to receive dialysis care will ultimately lead to the patient’s demise.

FMS ENA has identified eight patients, by way of letter of support, who have indicated that they support the proposal and would consider transferring their care to the new facility upon certification.

- *Each of these patients resides in Edgecombe County; [sic]*
- *Each of these patients is currently receiving their dialysis care and treatment at a BMA dialysis facility in either Nash or Pitt County.*
- *Each of these patients has expressed that the proposed Edgecombe County location is more convenient for the patient and closer to their homes.*

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.

These patients are currently doing home dialysis, but must travel to their supporting dialysis center on a monthly basis for monthly visits with the staff, nephrologist, and lab draws. However:

- *that location is not as convenient for the patient;*
- *that location requires more time for travel to and from the dialysis facility;*
- *that location involves more expense related to travel*

Based on these facts, FMS ENA believes that the peritoneal home training dialysis facility is needed at the Edgecombe county location and that it will be well utilized by the ESRD patients currently dialyzing at a BMA dialysis facility”

In Section A, page 2, the applicant states:

“FMS ENA Home, LLC is currently a single member LLC, with BMA of North Carolina, Inc. as the sole member. Fresenius Medical Care Holdings Inc., parent to BMA of North Carolina, Inc., is considering offering a minority interest in FMS ENA Home, LLC to physicians from Eastern Nephrology Associates, thereby establishing a joint venture relationship in the legal entity.

If FMS ENA Home, LLC becomes a joint venture with the physicians, Fresenius Medical Care Holdings, Inc., parent organization, intends to retain at least 51% ownership of the joint venture.”

In Exhibit I-6, the applicant provides a letter dated August 11, 2015 signed by Scott Kendrick, MD, Medical Director, FMS ENA Home, LLC, a nephrologist with Eastern Nephrology Associates. The letter states:

“Development of a new home training facility for peritoneal dialysis in Tarboro is consistent with contemporary disease management and treatment plans. In the most recent years we have seen a surge in the home dialysis patient population. I and my fellow physicians believe that this trend will continue and that the ‘new normal’ will be more patients utilizing home dialysis. ...

... Development of this free standing home peritoneal dialysis program is consistent with our practice vision for the future healthcare of ERSD patients.

I am confident that our home patient population will benefit from development of a facility as proposed by FMS ENA Home, LLC.”

In Exhibit C-2, the applicant provides eight letters of support from patients who have expressed an interest in the proposed facility. The letters of support state:

“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 ... 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. ...

... I would be willing to consider transferring my care to the Fresenius Medical Care ENA Home, LLC dialysis facility.”

These eight patients live in one of three ZIP Code areas, as illustrated in the table below.

ZIP CODE	COUNTY	NUMBER OF PATIENTS	CITY
27801	Edgecombe	3	Rocky Mount
27864	Edgecombe	3	Pinetops
27886	Edgecombe	2	Tarboro

None of the letters of support are from patients who previously supported the FMC Tarboro project.

According to Google Maps¹ the proposed facility would be located 367 feet away from Vidant Edgecombe Hospital with a drive time of one minute. Thus, the proposed facility would be conveniently located to allow patients easy accessibility to the services offered at the hospital.

Each of the eight letters state: *“The location of the proposed new facility, in Tarboro is very convenient.”* The letters of support include only the ZIP code area where each patient resides and some of the signatures are not easy to read and could be interpreted more than one way. Without the street address for these patients it is not possible to determine the distance the patients would need to travel to utilize the proposed facility as compared to the facility they are currently using. However, it is reasonable to assume that the patient knows whether or not the proposed facility would be more convenient for them.

Projected Utilization

In Section C, pages 18-22, the applicant provides the assumptions and methodology used to project the number of home PD patients, as follows:

“Assumptions:

1. *The July 2015 SDR indicates that there were 21 home dialysis patients residing in Edgecombe County as of December 31, 2014. This equates to a home dialysis patient population of only 9.8%. According to the Patient Origin Report for the period ending December 31, 2014, eleven of those patients were dialyzing with DC Edgecombe County. The remaining 10 patients were dialyzing with Bio-Medical Application of North Carolina.*

... [T]he applicant has determined that three of the home patients dialyzing with BMA were actually home hemodialysis patients. Thus, BMA was serving

¹ Google Maps www.google.com/maps

seven Edgecombe County PD patients as of December 31, 2014. See Exhibit C-3.

Based upon the Medicare Compare website we know that the Dialysis Care of Edgecombe County facility does not offer home hemodialysis training and support. Thus, all of the home patients reported by that facility would be peritoneal dialysis patients.

Based upon the preceding information, ... three of 21 home dialysis patients, 14.29%, were home hemodialysis patients. Projections of future patient populations will continue to utilize this rate. This application will not include projections of home hemodialysis services at the new facility. ...

2. *... There are no performance standards applicable to dialysis facilities providing exclusively home peritoneal training and follow-up support for patients choosing to perform peritoneal dialysis in the home. ...*

... In financial projections within this application, FMS ENA will round down to the whole patient; this presents a more conservative estimate of the financial projections.

FMS ENA proposes that the center will serve six home peritoneal dialysis patients at the end of Operating Year 1.

3. *FMS ENA has determined that there are many home peritoneal dialysis patients dialyzing at BMA facilities in either Nash or Pitt Counties, but residing within Edgecombe County. Exhibit C-2 includes eight letters of support from patients who reside in this area, or nearby. Each of these patients could be better served by the proposed FMS ENA dialysis center located in Tarboro, very near the Vidant Hospital campus.*

...

4. *Based upon the expressed support of eight current home dialysis patients, and BMA service to seven PD patients from Edgecombe County, FMS ENA conservatively projects that six dialysis patients will transfer their care to the new facility ...*

5. *This project is scheduled for completion on December 31, 2016.*

Operating Year 1 is the period from January 1 – December 31, 2017

Operating Year 2 is the period from January 1 – December 31, 2017 [sic]

6. *The ESRD home patient population of North Carolina is increasing at a faster rate than the in-center dialysis patient population. ... The following information is extracted from the July SDR for the years indicated. The July SDR reports the year end census of total ESRD patients treated in dialysis*

facilities across the state. The July SDR also provides the year end number of home dialysis patients.

ESRD Patient Population at NC Facilities	July - 11	July -12	July - 13	July - 14	July - 15	Five Year Average Change
Total ESRD Patients	14217	14605	15051	15574	15932	
Raw Change		388	446	523	358	
% Change		0.027	0.031	0.035	0.023	0.029
<hr/>						
Home Patients	1554	1697	1840	1955	1896	
Raw Change		143	143	115	-59	
% Change		0.092	0.084	0.063	-0.030	0.052
<hr/>						
Home % of Total	0.109	0.116	0.122	0.126	0.119	

The table indicates that despite the slight decrease in the home patient population for 2014, on average, the home patient population is increasing at a rate of 5.2% while overall ESRD patient population is increasing at a rate of only 2.9%.

The above also demonstrates that the home patient population of North Carolina was 11.9% of the total NC ESRD population as of December 31, 2014. Over the five years reported within the table, the home population averaged 11.8% of the ESRD patient population of North Carolina.

- FMS ENA assumes that, going forward, the Edgecombe County home patient population will increase to a rate of 15% of the total count [sic] ESRD patient population, up from the current 10.4%. FMS ENA assumes this growth will be gradual and projects this to be realized by [sic] 1.5% annual increase in the home patient population over the next several years.*

FMS ENA assumes that increases in the PD patient population of Edgecombe County will occur based upon the support of the Medical Director and nephrology physicians of Eastern Nephrology Associates. ...

...

The following table demonstrates the projected ESRD patient population, beginning with the county ESRD population reported in the July 2015 SDR, through December 31, 2020. Growth of the population is projected to increase at the Edgecombe County Five Year Average Annual Change rate of 0.7%.

	Census		Projected Year End Census	Home %	Projected Home Census	Projected IC Census
December 31, 2014	202	X 0.07	203.4	10.40%	21.2	182.3
December 31, 2015	203.4	X 0.07	204.8	11.90%	24.4	180.5
December 31, 2016	204.8	X 0.07	206.3	13.40%	27.6	178.6
December 31, 2017	206.3	X 0.07	207.7	14.90%	30.9	176.8
December 31, 2018	207.7	X 0.07	209.2	15.00%	31.4	177.8
December 31, 2019	209.2	X 0.07	210.6	15.00%	31.6	179.0
December 31, 2020	210.3	X 0.07	212.1	15.00%	31.8	180.3

Based upon the above calculations, FMS ENA projects the home patient population of Edgecombe County to increase from 21 patients as of December 31, 2014 to 31.8, rounded to 32 home patients as of December 31, 2020.

... In order to provide an accurate projection of the future PD patient population for Edgecombe County, the home hemodialysis patient population must be subtracted.

... The next table demonstrates that the PD census is projected to increase from 18 patients as of December 31, 2014 to 27 patients as of December 31, 2020.

	Projected Home Census	Projected IC Census	14.29% Home Hemodialysis	Projected PD Population
December 31, 2014	21.2	182.3	3.0	18.1
December 31, 2015	24.4	180.5	3.5	20.9
December 31, 2016	27.6	178.6	3.9	23.7
December 31, 2017	30.9	176.8	4.4	26.5
December 31, 2018	31.4	177.8	4.5	26.9
December 31, 2019	31.6	179.0	4.5	27.1
December 31, 2020	31.8	180.3	4.5	27.3

8. FMS ENA ... assume[s] that half of the future PD patients will choose to dialyze with FMS ENA; half are also projected to choose to dialyze with DC Edgecombe County facility.
9. FMS ENA assumes that the initial patient population of the FMS ENA facility will be comprised of six Edgecombe County residents.

Methodology:

The next table represents BMA calculations of future patient in-center population at FMC Edgecombe County [sic].

<i>FMS ENA Home</i>	<i>In-Center [sic]</i>
<i>FMS ENA begins with 6 Edgecombe County PD dialysis patients projected to transfer their care to the new facility upon certification of the project. This is December 31, 2016 [sic]</i>	6
<i>FMS ENA projects growth of the census by the Edgecombe County Five Year Average Annual Change Rate for one year to December 31, 2017. This is the projected census for the end of Operating Year 1.</i>	$(6 \times .007) + 6 = 6.04$
<i>FMS ENA again projects growth of the patients by the Edgecombe County Five Year Average Annual Change rate for one year. This is the projected census for the end of Operating Year 2.</i>	$(6.04 \times .007) + 6.04 = 6.08$

In summary, the applicant adequately demonstrates the need for the proposal and that projected utilization is based on reasonable and adequately supported assumptions. This determination is based on the following:

- Based on the July 2015 SDR, as of December 31, 2014, there were 21 home dialysis patients residing in Edgecombe County. Ten of those patients were dialyzing at a BMA facility located in another county. Seven of the ten were home PD patients.
- Eight existing home dialysis patients provided letters stating an interest in transferring their care to the proposed facility. None of the eight who provided a letter of support for this project were one of the patients that provided a letter of support for the previously approved FMC Tarboro facility.
- The eight patients who provided a letter of support state that the proposed facility would be very convenient.
- In each of the first two years of operation following completion of the project, the applicant projects to serve six home PD patients at the proposed facility.
- There are no minimum performance standards for dedicated home PD facilities.

Access

In Section C, pages 23-24, and Section L, pages 69-74, the applicant describes the extent to which all residents, including underserved groups will have access to the proposed services. Sixty seven percent of the patients are projected to be Medicare patients (see page 70). This payor mix is based on the actual experience at BMA Rocky Mount in Nash County and Greenville Dialysis in Pitt County for home dialysis patients. The applicant states that in its experience very few home PD patients are Medicaid patients. The applicant adequately demonstrates the extent to which all residents, including underserved groups, will have access to the proposed services.

Conclusion

In summary, the applicant adequately identifies the population to be served, adequately demonstrates the need this population has for the proposed facility and adequately demonstrates the extent to which all residents, including underserved groups, will have access to the proposed services. Therefore, the application is conforming to this criterion.

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

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.

NC

FMS ENA proposes to develop a new kidney disease treatment center dedicated to providing home training and support services for PD patients. On August 28, 2015, BMA was approved in Project I.D. # L-11011-15 to develop FMC Tarboro, a new 10-station kidney disease treatment center by relocating six dialysis stations from BMA East Rocky Mount and four dialysis stations from Greenville Dialysis Center in Pitt County. Home PD services were not proposed in the FMC Tarboro application. The proposed FMS ENA facility would be located in the same building as the approved FMC Tarboro.

In Section E, pages 35-36, the applicant states it considered several alternatives, including:

- Maintaining the status quo – The applicant states that this alternative ignores the needs of the home PD patients who live in Edgecombe County but use BMA facilities in other counties for their care.
- Developing a facility in another location in Edgecombe County – The applicant indicates that the proposed location is the most effective.
- Developing a larger facility – The applicant indicates that this alternative would be more costly and a larger facility is not needed at this time.

The applicant does not state whether or not it considered adding home PD services to the proposed FMC Tarboro facility which will be located in the same building. This would appear to be an alternative method of meeting the need for home PD services in Edgecombe County which might be lower cost or more effective than the selected alternative. Since the applicant provides nothing to document that adding home PD services to the proposed FMC Tarboro facility would be more costly or less effective than the chosen alternative, the applicant does not adequately demonstrate that the selected alternative is the least costly or most effective one to meet the identified need.

Furthermore, the application is not conforming to all other applicable statutory and regulatory review criteria, and thus, is not approvable. Specifically, the applicant does not adequately demonstrate that the financial feasibility of the proposal is based on reasonable projections of costs and charges. The discussion regarding financial feasibility found in Criterion (5) is

incorporated herein by reference. A proposal that is not financially feasible cannot be a less costly or most effective alternative.

Therefore, the application is not conforming to this criterion and is denied.

- (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.

NC

FMS ENA proposes to develop a new kidney disease treatment center dedicated to providing home training and support services for PD patients. On August 28, 2015, BMA was approved in Project I.D. # L-11011-15 to develop FMC Tarboro, a new 10-station kidney disease treatment center by relocating six dialysis stations from BMA East Rocky Mount and four dialysis stations from Greenville Dialysis Center in Pitt County. Home PD services were not proposed in the FMC Tarboro application. The proposed FMS ENA facility would be located in the same building as the approved FMC Tarboro.

FMS ENA is a single member LLC whose ultimate parent is Fresenius Medical Care Holdings, Inc. (FMC).

Capital and Working Capital Costs

In Section F.1, page 38, the applicant projects that the capital cost will be as follows:

Site Costs	\$0.0
Construction / Renovation Costs	\$462,555
Miscellaneous Costs	\$156,171
Total	\$618,726

In Section F.12, page 42, the applicant projects that the working capital costs (start-up costs and initial operating costs) will be \$426,503. This includes start-up costs of \$52,037 for four weeks of clinical supplies and staff salaries and \$374,466 for initial operating costs during the estimated eight months until cash in-flow exceeds cash out-flow.

Availability of Funds

In Section F.2, page 39, the applicant states that the capital cost of the project will be financed with accumulated reserves from FMC. In Section F.13, page 43, the applicant states that the working capital costs for the project will be also be financed with FMC's accumulated reserves. In Exhibit F.1, the applicant provides a letter dated August 17, 2015 from the Senior Vice President & Treasurer of FMC, which states:

“This is to inform you that Fresenius Medical Care Holdings, Inc. is the parent company of National Medical Care, Inc., Bio-Medical Applications of North Carolina, Inc., and FMS ENA Home, LLC.

FMS ENA Home, LLC is submitting a Certificate of Need Application to develop a new End Stage Renal Disease Treatment Facility focused on the home peritoneal dialysis patient population. The new facility is planned to serve the ESRD home peritoneal dialysis patients of Edgecombe and surrounding areas. The project call for the following capital expenditure:

Capital Expense \$618,726

As Senior Vice President, I am authorized and do hereby authorize the development of this new ... dialysis facility for capital costs as identified above. Further, I am authorized and do hereby authorize and commit cash reserves for the capital cost of \$618,726 as may be needed for this project. I am also authorized, and authorize any additional funds as may be necessary for start-up costs in the new location.”

In Section F.7, page 40, the applicant states that the “most recent audited” balance sheets for FMC (2013 and 2014) are provided in Exhibit F-2. Exhibit F-2 contains a copy of the audited financial statements for FMC for the years ending December 31, 2013 and December 31, 2012. As of December 31, 2013, FMC had \$275,719,000 in cash and cash equivalents, \$16,597,314,000 in total assets and \$7,669,891,000 in net assets (total assets less total liabilities). The applicant does not explain why a balance sheet for the year ending December 31, 2014 was not provided. The application was submitted on August 17, 2015, almost eight months after the end of the calendar year. The applicant does not adequately demonstrate the availability of sufficient funds for the capital and working capital needs of the project.

Financial Feasibility

In Section C.2, pages 22-23, the applicant states that PD patients are assumed to dialyze daily; however, for billing purposes and financial projections, PD patient treatments are converted to in-center treatment equivalents.

In Section R, pages 92-99, the applicant provides pro forma financial statements for the first two years operation of the proposed facility. The applicant projects revenues will exceed operating expenses in each of the first two operating years. The following table illustrates revenues and operating expenses as reported by the applicant in Forms B and C in Section R.

	OY 1	OY 2
Gross Patient Revenue	\$3,445,632	\$4,574,302
Deductions from Gross Patient Revenue	\$2,863,207	\$3,928,290
Net Patient Revenue	\$582,425	\$646,012
Total Expenses	\$561,699	\$593,072
Net Income	\$20,726	\$52,941

However, the projected net income in OY 2 is questionable. In Section C and the assumptions provided in Section R, the applicant projects serving six home PD patients in both OY 1 and OY 2. Based on the applicant's assumptions about converting the daily home PD treatments to in-center equivalent treatments, the total number of in-center equivalent treatments should be 864 in both OY 1 and OY 2. Moreover, in Form C, the applicant projects that the average gross revenue per in-center equivalent treatment would be the same (\$3,988) in both OY 1 and OY 2. However, in OY 2 in Forms B and C, the total number of in-center equivalent treatments would be 1,147, not 864, if the average gross revenue per in-center equivalent treatment remains the same in OY 1 and OY 2. Moreover, in OY 2 in Form C, the payor mix percentages add up to 132.76%. The applicant projects six different payor sources but Medicare is projected to be 100% of the total in OY 2. This results in an overstatement of gross and net revenues in OY 2. The applicant does not project that operating expenses will remain the same in both OY 1 and OY 2. Indeed, salaries are projected to increase 6.1% between OY 1 and OY 2. See Section H.1, page 51. Insufficient assumptions are provided in the application to determine if some of the expenses in OY 2 are overstated as a result of the overstated in-center equivalent treatments. As a result, in OY 2, the applicant does not adequately demonstrate that net revenues will exceed operating expenses. Therefore, the applicant does not adequately demonstrate that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

Conclusion

In summary, the applicant does not adequately demonstrate the availability of sufficient funds for the capital and working capital needs of the project. Moreover, the applicant did not adequately demonstrate that the financial feasibility of the proposal is based on reasonable projections of costs and charges. Therefore, the application is nonconforming 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

FMS ENA proposes to develop a new kidney disease treatment center dedicated to providing home training and support services for PD patients. On August 28, 2015, BMA was approved in Project I.D. # L-11011-15 to develop FMC Tarboro, a new 10-station kidney disease treatment center by relocating six dialysis stations from BMA East Rocky Mount and four dialysis stations from Greenville Dialysis Center in Pitt County. Home PD services were not proposed in the FMC Tarboro application. The proposed FMS ENA facility would be located in the same building as the approved FMC Tarboro.

On page 361 the 2015 SMFP defines the service area for dialysis stations as "*the dialysis station planning area in which the dialysis station is located.*" The applicant does not propose to develop any certified in-center stations or home hemodialysis stations as a part of the proposed project.

There are two existing kidney disease treatment centers in Edgecombe County: BMA East Rocky Mount located in Rocky Mount and Dialysis Care of Edgecombe County located in

Tarboro. Home PD services are currently available only at the Dialysis Care of Edgecombe County facility.

According to MapQuest, the proposed facility would be located approximately 0.8 miles or one minute from Dialysis Care of Edgecombe County. According to the December 31, 2014 ESRD Data Collection Form, Dialysis Care of Edgecombe County reported serving 15 home PD patients (11 Edgecombe County residents and 4 Nash County residents). None of the home PD patients projected to utilize the proposed facility are currently utilizing Dialysis Care of Edgecombe County. The discussion regarding analysis of need, including projected utilization, found in Criterion (3) is incorporated herein by reference. The applicant adequately demonstrates that the proposed facility will not result in the unnecessary duplication of existing or approved home PD training and support services located in Edgecombe 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

FMS ENA proposes to develop a new kidney disease treatment center dedicated to providing home training and support services for PD patients.

In Section H, page 51, the applicant provides the proposed staffing for the new facility, as shown in the table below.

Position	Number of Full-Time Equivalent (FTE) Positions
Clinical Manager	1.00
Director of Operations	0.10
Dietitian	0.20
Social Worker	0.20
Home Training RN	0.75
Chief Technician	0.05
Equipment Technician	0.10
In-Service	0.10
Clerical/Medical Records	0.50
Total	3.00

In Section H.3, page 52, the applicant describes its experience and process for recruiting and retaining staff. Exhibit I-6 contains a copy of a letter from Dr. Scott Kendrick, expressing an interest in serving as the Medical Director for the proposed facility. The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services. Therefore, the application is conforming to this criterion.

- (8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support

services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

C

In Section I, page 56, the applicant describes the necessary ancillary and support services and explains how they will be provided. Exhibit I-1, I-3, I-4, and I-5 contains copies of letters from providers of these services expressing an interest in providing them to FMS ENA. Exhibit I-6 contains a copy of a letter from Eastern Nephrology Associates expressing their support for the proposed project. The applicant adequately demonstrates that 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 L.3(e), page 73, the applicant states: *“FMS ENA does not have any obligation to provide uncompensated care or community service under any federal regulations.”* In Section L.6, page 74, the applicant states that it is not aware of any civil rights equal access complaints being filed against any BMA facility in North Carolina within 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 L.1(b), page 70, the applicant provides the projected payor mix during OY 2, as shown in the following table.

	Percentage of Total
Self-Pay / Indigent / Charity	0.0%
Medicare/Medicare Managed Care	67.0%
Medicaid	0.0%
Commercial Insurance	33.0%
Managed Care	0.0%
Other (Work comp and Other Gov't)	0.0%
Total	100.0%

In Section L.b, pages 70-71, the applicant states:

“It has been Fresenius corporate experience across North Carolina that very few PD patients are Medicaid patients. Consequently, the above table does not include projections of Medicaid beneficiaries. This is not to say that the applicant will deny care to Medicaid patients.”

It is noted that the payor mix shown in the table above and on page 70 of the application is not exactly the same in Form C – Revenue Assumptions which is found in Section R. In Form C, the applicant projects six different payor sources as compared to the two shown in the table above and on page 70 of the application. The differences are not enough to determine that the applicant does not project to adequately serve underserved groups.

The Division of Medical Assistance (DMA) maintains a website which offers information regarding the number of persons eligible for Medicaid assistance and estimates of the percentage of uninsured for each county in North Carolina. The following table illustrates this information for Edgecombe County and statewide.

County	2010* Total # of Medicaid Eligibles as % of Total Population	2010* Total # of Medicaid Eligibles Age 21 and older as % of Total Population	2009* % Uninsured (Estimate by Cecil G. Sheps Center)
Edgecombe	31%	13.5%	21.3%
Statewide	17%	6.7%	19.7%

*More current data was not available.

Although the majority of Medicaid eligibles are children under the age of 21, they represent a very small percentage of those who utilize the services offered by dialysis facilities. In 2014, over 85% of dialysis patients in North Carolina were 45 years of age and older. (*Southeastern Kidney Council Network 6 Inc. 2014 Annual Report, page 59*).²

The Office of State Budget & Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina, as well as data sorted by age, race or gender. But it does not include information on the number of elderly, handicapped, minorities or women utilizing health services.

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

²<http://www.esrdnetwork6.org/utlils/pdf/annual-report/2014%20Network%206%20Annual%20Report.pdf>

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

Source: Southeastern Kidney Council Network 6 Inc. 2014 Annual Report.³

The applicant demonstrates that it provides adequate access to medically underserved populations. 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 L.4, page 73, the applicant describes the range of means by which a person will have access to the proposed services, including referrals from a nephrologist, other physicians or hospital emergency rooms. The applicant adequately demonstrates that the facility will offer a range of means by which patients will have access to the proposed 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 M, page 75, the applicant describes how the facility will accommodate the clinical needs of area health professional training programs. See Exhibit M-1 for a letter dated August 17, 2015 from Fresenius Medical Care Holdings, Inc., to the Dean of The College of Nursing

³<http://www.esrdnetwork6.org/utlils/pdf/annual-report/2014%20Network%206%20Annual%20Report.pdf>

at East Carolina University offering the FMS ENA facility as a training site to be included in the clinical rotation schedule. The information provided is reasonable and adequately supports a determination that the application is conforming to this criterion.

- (15) Repealed effective July 1, 1987.
- (16) Repealed effective July 1, 1987.
- (17) Repealed effective July 1, 1987.
- (18) Repealed effective July 1, 1987.

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

NC

FMS ENA proposes to develop a new kidney disease treatment center dedicated to providing home training and support services for PD patients. On August 28, 2015, BMA was approved in Project I.D. # L-11011-15 to develop FMC Tarboro, a new 10-station kidney disease treatment center by relocating six dialysis stations from BMA East Rocky Mount and four dialysis stations from Greenville Dialysis Center in Pitt County. Home PD services were not proposed in the FMC Tarboro application. The proposed FMS ENA facility would be located in the same building as the approved FMC Tarboro.

On page 361 the 2015 SMFP defines the service area for dialysis stations as “*the dialysis station planning area in which the dialysis station is located.*” The applicant does not propose to develop any certified in-center stations or home hemodialysis stations as a part of the proposed project.

There are two existing kidney disease treatment centers in Edgecombe County: BMA East Rocky Mount located in Rocky Mount and Dialysis Care of Edgecombe County located in Tarboro. Home PD services are currently available only at the Dialysis Care of Edgecombe County facility.

According to MapQuest, the proposed facility would be located approximately 0.8 miles or one minute from Dialysis Care of Edgecombe County. According to the December 31, 2014 ESRD Data Collection Form, Dialysis Care of Edgecombe County reported serving 15 home PD patients (11 Edgecombe County residents and 4 Nash County residents). None of the home PD patients projected to utilize the proposed facility are currently utilizing Dialysis Care of Edgecombe County.

In Section N, pages 76-77, the applicant discusses how any enhanced competition in the service area will have a positive impact on the cost effectiveness, quality and access to the proposed

services. The applicant states on page 76 that the proposed project would establish a second provider of home PD services in Edgecombe County.

The applicant adequately demonstrates that the proposal would have a positive impact on quality and access to the proposed services. The discussions regarding quality and access found in Criteria (20) and (13), respectively, are incorporated herein by reference.

However, the applicant did not adequately demonstrate that the proposal would have a positive impact on the cost effectiveness of the proposed services because the applicant does not adequately demonstrate that the proposal is financially feasible. The discussion regarding financial feasibility found in Criterion (5) is incorporated herein by reference. Consequently, the application is nonconforming 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.

C

In Section O, pages 78-81, the applicant describes the methods used or to be used to insure and maintain quality.

In Section O, page 81, the applicant states that the ultimate parent, FMC, owns or operates more than 100 kidney disease treatment centers in North Carolina. On page 82, the applicant states that two of these facilities did not meet all Medicare conditions of participation during the 18 months immediately preceding submittal of this application. One of these facilities was back in compliance at the time the application was submitted. The survey of the other facility that resulted in the deficiency occurred only one week before the application was submitted.

Based on a review of the certificate of need application and publicly available data, the applicant adequately demonstrates that it has provided quality care during the 18 months immediately preceding the submittal of the application through the date of the decision. The application is conforming to this criterion.

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

C

The Criteria and Standards for End Stage Renal Disease Services, as promulgated in 10A NCAC 14C Section .2200, are applicable to this review. The proposal is conforming to all applicable Criteria and Standards for End Stage Renal Disease Services. The specific findings 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;
- .2202(a)(2) Mortality rates;
- .2202(a)(3) The number of patients that are home trained and the number of patients on home dialysis;
- .2202(a)(4) The number of transplants performed or referred;
- .2202(a)(5) The number of patients currently on the transplant waiting list;
- .2202(a)(6) Hospital admission rates, by admission diagnosis, i.e., dialysis related versus non-dialysis related;
- .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- The applicant does not propose to increase the number of stations in an existing facility or relocate stations.

(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 I-4 contains an August 11, 2015 letter of intent to sign a written patient transfer agreement from Vidant Health Edgecombe which states the hospital will provide acute dialysis, emergency room care, diagnostic evaluation services, X-ray services, special, immunological and routine laboratory services, blood bank and surgical services, including vascular surgery.

- .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 I-5 contains an August 11, 2015 letter of intent to sign a written transplant agreement from Vidant Medical Center-Greenville, which includes the above listed items.
- .2202(b)(3) For new or replacement facilities, documentation that power and water will be available at the proposed site.*
- C- Exhibits K-5 and K-6 contain documentation that the primary and secondary sites have water and sewer service available.
- .2202(b)(4) Copies of written policies and procedures for back up for electrical service in the event of a power outage.*
- C- Exhibit K-3 contains a copy of written policies and procedures for back-up electrical service in the event of a power outage.
- .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- Exhibits K-5 and K-6 contain documentation which indicates that the applicant has identified both a primary and a secondary site (in case the primary site is unavailable upon certificate of need approval) to lease for the proposed PD facility and that the sites are available.

.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 P, page 87, Section H, page 51, and Section K.6(e-g), pages 62-64, the applicant documents that it will provide all services in conformance with all applicable laws and regulations for staffing and safety. Exhibit K-3 contains a copy of the applicant’s emergency policies and procedures including staffing, safety, physical environment, water, and other relevant health and safety requirements.

.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 C, page 18, the applicant provides the projected patient origin during each of the first two years of operation following completion of the project, as illustrated in the table below.

County	Number of Home PD Patients		Number of Patients as Percent of Total	
	OY 1	OY 2	OY 1	OY 2
Edgecombe	6	6	100%	100%
Total	6	6	100%	100%

The applicant provides the assumptions and methodology used to project patient origin in Section C, pages 18-23.

.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.*

-C- In Section C, page 18, and Section P, page 87, the applicant states: “FMS ENA Home anticipates that 100% of the patient population choosing dialysis at the new facility will reside within 30 miles of the facility.” In Section C, page 18, the applicant projects that by the end of OY 2, the proposed facility will serve six home PD patients all of whom will be residents of Edgecombe 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 P, page 87, the applicant states, “FMS ENA Home, LLC 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 the 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- The applicant proposes a dedicated home PD training facility and does not propose to develop a facility with hemodialysis stations. In Section C.1, page 19, and Section P, page 87, the applicant states: “*There are no performance standards for peritoneal dialysis facilities.*”
- .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- The applicant does not propose to increase the number of stations in an existing facility.
- .2203(c) *An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*
- C- In Section C, pages 18-23, and 26-31, the applicant provides the assumptions and methodology used to project utilization for the proposed facility. The discussion regarding analysis of need, including projected utilization, found in Criterion (3) is incorporated herein by reference.

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- See Section P, page 88. The applicant states that diagnostic evaluation services will be provided by Vidant Health.
- .2204(2) *Maintenance dialysis;*

- C- In Section I, page 56, the applicant states that maintenance dialysis will be available at other BMA facilities with certified dialysis stations. In Section P, page 88, the applicant states that the proposed facility will provide training and support for patients to perform home PD.

- .2204(3) *Accessible self-care training;*
 - C- See Section P, page 88. The applicant states those patients who are candidates for self-care training will be referred to other BMA facilities with certified dialysis stations.

- .2204(4) *Accessible follow-up program for support of patients dialyzing at home;*
 - C- See Section P, pages 88. The applicant states: “*Patients who are candidates for home peritoneal dialysis will receive training and support through FMS ENA Home. Patients who are candidates for home hemodialysis will [sic] referred to the FMC South Rock Mounty [sic], or Greenville Dialysis Center home training department.*”

- .2204(5) *X-ray services;*
 - C- See Section P, page 88. The applicant states patients will be referred to Vidant Health for X-ray services.

- .2204(6) *Laboratory services;*
 - C- See Section P, page 88. The applicant states that laboratory services will be provided on-site by Spectra Labs. See Exhibit I-3 for the agreement with Spectra Labs.

- .2204(7) *Blood bank services;*
 - C- See Section P, page 89. The applicant states that blood bank services will be provided by Vidant Health.

- .2204(8) *Emergency care;*
 - C- See Section P, page 89. The applicant states the staff of EMS ENA will provide on-site care of patients until emergency responders arrive. Patients will be transferred to Vidant Edgecombe Hospital if necessary.

- .2204(9) *Acute dialysis in an acute care setting;*
 - C- See Section P, page 89. The applicant states that Vidant Edgecombe Hospital will provide acute dialysis in an acute care setting.

- .2204(10) *Vascular surgery for dialysis treatment patients;*

-C- See Section P, page 89. The applicant states patients will be referred to Fresenius Vascular Care Greenville, Greenville Surgical Specialty, LLC or Vidant Health Systems in Greenville for vascular surgery.

.2204(11) Transplantation services;

-C- Exhibit I-5 contains a letter of intent from Vidant Medical Center in Greenville to provide transplantation services.

.2204(12) Vocational rehabilitation counseling and services; and,

-C- See Section P, page 89. The applicant states that patients will be referred to Rocky Mount or East Carolina Vocational rehabilitation programs for counseling and services.

.2204(13) Transportation;

-C- See Section P, page 89. The applicant states transportation will be provided by Tar River Transit, K&L Transport, Edgecombe and Nash Ambulance Services or Eastern Medical Transport.

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 H.1, page 51, the applicant provides the proposed staffing. In Section H.2, page 52, the applicant states the proposed facility will comply with all staffing requirements set forth in the C.F.R. The applicant adequately demonstrates that sufficient staff is proposed for the level of dialysis services to be provided. The discussion regarding staffing found in Criterion (7) is incorporated herein by reference.

.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- See Section H.4, page 52, for the qualifications or certifications required for the staff of FMS ENA Home, LLC. Also see Exhibit H-1, for the Core Training Curriculum for dialysis technicians and Exhibit H-2 for FMC's training outline.