

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: July 20, 2017

Findings Date: July 20, 2017

Project Analyst: Jane Rhoe-Jones

Team Leader: Fatimah Wilson

Project ID #: P-11346-17

Facility: RAI Care Centers - Goldsboro

FID #: 170236

County: Wayne

Applicant: RAI Care Centers of North Carolina II, LLC

Project: Relocate the existing facility to a new location in Goldsboro

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

N.C. Gen. Stat. §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.

C

RAI Care Centers of North Carolina II, LLC d/b/a RAI Care Centers – Goldsboro (RAI – Goldsboro), whose parent company is Fresenius Medical Care Holdings Inc., (FMC) proposes to relocate the existing facility to a new location in Goldsboro. RAI-Goldsboro currently has 16 certified dialysis stations and will have 16 certified dialysis stations upon project completion. The facility will continue to provide in-center hemodialysis and services for its peritoneal dialysis patients, in Goldsboro, Wayne County.

Need Determination

Not applicable as this proposed facility relocation is not in response to a county or facility need determination.

Policies

There is one policy applicable to this review - Policy ESRD-2, page 27 of the 2017 State Medical Facilities Plan (SMFP 2017). Policy ESRD-2: Relocation of Dialysis Stations states:

“Relocations of existing dialysis stations are allowed only within the host county and to contiguous counties. Certificate of need applicants proposing to relocate dialysis stations to a contiguous county shall:

- 1. Demonstrate that the facility losing dialysis stations or moving to a contiguous county is currently serving residents of that contiguous county; and*
- 2. Demonstrate that the proposal shall not result in a deficit, or increase an existing deficit in the number of dialysis stations in the county that would be losing stations as a result of the proposed project, as reflected in the most recent North Carolina Semiannual Dialysis Report, and*
- 3. Demonstrate that the proposal shall not result in a surplus, or increase an existing surplus of dialysis stations in the county that would gain stations as a result of the proposed project, as reflected in the most recent North Carolina Semiannual Dialysis Report.”*

In Section B-3, page 10, the applicant provides information as shown in the following table to support its proposal for an “in-county” relocation of the entire dialysis facility:

RAI CARE CENTERS – GOLDSBORO POLICY ESRD-2: RELOCATION OF DIALYSIS STATIONS		
(a)	County from which stations will relocate	Wayne
(b)	County to which stations will relocate	Wayne
(c)	Number of residents of county (row a) who are currently dialyzing in-center at a facility owned by the applicant or a related entity and located in each county from which stations will be relocated	46
(d)	Projected station surplus in the county that will be losing the stations (row a) as a result of the proposed project, as reflected in the most recent SDR	NA
(e)	Projected station deficit in the county that would gain stations (row b) as a result of the proposed project, as reflected in the most recent SDR	NA

The applicant proposes to relocate an existing End Stage Renal Dialysis (ESRD) facility to a new location within Wayne County that will result in no change in the total dialysis station inventory in the county. Therefore, the application is consistent with Policy ESRD-2.

Conclusion

In summary, the applicant adequately demonstrates that the application is consistent with Policy ESRD-2 in the 2017 SMFP. Therefore, the application is conforming to this criterion.

- (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

The applicant proposes to relocate an existing facility to a new location in Goldsboro, for a total of 16 stations currently and upon project completion. The facility will continue to provide in-center (IC) hemodialysis and services for its peritoneal dialysis (PD) patients, in Goldsboro, Wayne County. The existing facility is located at 2403 Wayne Memorial Drive in Goldsboro. In Section K-4 and 5, pages 45-46, the applicant identifies primary and secondary sites for the proposed facility relocation. Neither site is developed and therefore have no street addresses. The primary site, located at PIN# 3610139132 Hospital Road and secondary site, located at PIN# 3610227621/3610228659 Wayne Memorial Drive, both located in Goldsboro, Wayne County.

The applicant states in Section K-4(j), page 46, that both sites under consideration are located within one-half mile of the existing facility and are centrally located for the patient population served by the facility. The applicant provides a site map, zoning, evidence of site availability and other site specific information in Exhibit K.

Patient Origin

On page 373, the 2017 SMFP defines the service area for dialysis stations as “*the planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.*” Thus, the service area is Wayne County. Facilities may serve residents of counties not included in their service area.

In Section C-8, page 20, the applicant provides a table, as shown below with the historical patient origin for IC and PD patients served by RAI – Goldsboro.

RAI - GOLDSBORO		
As of December 31, 2016		
County	# In-Center Dialysis Patients	# Peritoneal Dialysis Patients
Wayne	46	1
Duplin	1	0
Total	47	1

In Section C-1, page 16, the applicant identifies the patient population it proposes to serve during the first two years of operation following project completion, as illustrated below in the table:

RAI - GOLDSBORO Projected Patient Origin						
County	OY1 CY2019		OY2 CY2020		% Total County Patients	
	IC	PD	IC	PD	OY1	OY2
Wayne	57	2	60	2	98.3%	98.4%
Duplin	1	0	1	0	1.7%	1.6%
Total	58	2	61	2	100.0%	100.0%

OY = Operating Year. CY = Calendar Year.

The applicant provides the assumptions and methodology for the above projections on pages 16-18. As shown in the above two tables, the applicant projects an increase of 14 Wayne County IC patients for this project by OY2; and does not project growth from the one Duplin County patient served. The applicant projects a growth by one PD patient and will serve two PD patients in OY1 and OY2. The applicant uses the 3.5% Wayne County Five Year Average Annual Change Rate as published in the January 2017 SDR. The applicant adequately identifies the population it proposes to serve.

Analysis of Need

The applicant proposes to relocate the existing RAI - Goldsboro facility to a new location for a total of 16 certified dialysis stations upon project completion. In Section B-3, page 10, the applicant states the application is filed pursuant to Policy ESRD 2: Relocation of Dialysis Stations, in the 2017 SMFP. In Section C-1, page 16, the applicant provides the assumptions used to demonstrate the need for the project. The facility’s patients who reside in Wayne County have increased at a rate commensurate with the Five-Year Average Annual Change Rate (AACR) for Wayne County, which is 3.5%, as published in the January 2017 Semiannual Dialysis Report (2017 SDR). Although there is one Duplin county patient dialyzing at RAI - Goldsboro, the applicant does not project an increase in its Duplin County patient population which represents approximately two percent of the IC patient population of RAI - Goldsboro.

In Section C-13, page 22, the applicant states the need for replacing the current facility. The applicant discusses the lack of adequate parking for patients and staff, the lack of a covered drop off and pick-up area for insufficient space for patient home training – and the inability to remedy these inadequacies in a cost-efficient manner. The upcoming expiration on the current lease offers the applicant the opportunity to remedy the shortcomings the existing facility has in its current location, by relocating to a new facility.

Projected Utilization

In Section C, page 17, the applicant provides the methodology used to project in-center utilization, as illustrated in the following table.

RAI - GOLDSBORO IN-CENTER DIALYSIS PROJECTIONS	
Begin with RAI - Goldsboro Wayne County census as of May 15, 2017.	53
Project patient population forward seven months, June 1 to December 31, 2017.	$[53 \times (.035 / 12 \times 7)] + 53 = 54.1$
Project census forward one year to December 31, 2018.	$(54.1 \times .035 + 54.1 = 56.0$
Project Wayne County patient population forward one year to December 31, 2019.	$(56 \times .035) + 56 = 57.9$
OY1: Add one patient from Duplin County. This is the ending census for OY1 (Calendar Year 2019).	$57.9 + 1 = \mathbf{58.9}$
Project growth of Wayne County population forward one year to December 31, 2020.	$(58.9 \times .035) + 58.9 = 60.0$
OY2: Add one patient from Duplin County. This is the ending census for OY2 (Calendar Year 2020).	$60.0 + 1 = \mathbf{61.0}$

The applicant projects that RAI - Goldsboro will serve a total of 58 in-center patients at the end of Operating Year One for a utilization rate of 90.6% or 3.6 patients per station per week (58 patients / 16 stations = 3.624 / 4 = .9062 or 90.6%). The projected utilization of 3.6 patients per station per week for Operating Year One satisfies the 3.2 in-center patients per station per week threshold as required by 10A NCAC 14C .2203(b). This rule is not applicable to this application because the applicant is not adding new stations pursuant to a need determination; however, the applicant did apply the threshold when projecting utilization for the facility.

The applicant also states its methodology for projecting peritoneal dialysis on page 17. The applicant states that as of May 15, 2017, RAI – Goldsboro was serving two Wayne County PD patients. The applicant states:

“Application of the Five Year AACR of 3.5% to such a small patient population is not calculated to lead to any significant change in the PD patient population. Therefore, RAI - Goldsboro will propose to serve two PD patients through Operating Years 1 and 2.”

Projected utilization is based on reasonable and adequately supported assumptions regarding continued IC and PD patient growth at RAI - Goldsboro.

Access

In Section L, pages 49-53, the applicant states that each of BMA’s 108 facilities in 48 North Carolina counties has a patient population which includes low-income, racial and ethnic minorities, women, handicapped, elderly, or other underserved persons. On page 53, the applicant states that 89.64% of total patients at RAI - Goldsboro were Medicaid or Medicaid recipients in CY2016. On page 50, the applicant projects that 89.57% of its in-center patients will be Medicare or Medicaid recipients in Project Year 2. The applicant adequately demonstrates the extent to which all residents of the service area, including underserved groups, are likely to have access to its services.

Conclusion

In summary, the applicant adequately identifies the population to be served, demonstrates the need that population has for the proposed relocation of the in-center dialysis stations and the extent to which all residents of the area, including underserved groups, are likely to 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.

C

The applicant proposes to relocate the entire RAI – Goldsboro dialysis facility to a new location within Goldsboro, Wayne County for a total of 16 stations upon project completion. The facility will continue to provide in-center hemodialysis and services for its peritoneal dialysis patients. The applicant does not propose to add dialysis stations to an existing facility or to establish any new dialysis stations in the county. The relocation of the RAI – Goldsboro dialysis facility will not result in a surplus or deficit of dialysis stations in Wayne County.

In Section K-4(j), page 46, the applicant discusses the distance between the current site and the proposed primary and secondary sites under consideration. The applicant also provides a site map depicting the distance between the current facility location and the proposed primary and secondary site locations. The applicant states:

“The primary site is only one-half mile from the existing facility. It is central to the dialysis patient population served by the facility. The site is one-half mile from the local hospital, and is in the area of many physician offices. The site allows for easy access by the patient population of the area.”

Conclusion

The applicant demonstrates that the needs of the population presently served at RAI – Goldsboro will continue to be adequately met following the proposed location of the current facility, and that access to medically underserved groups will not be negatively impacted at the proposed primary or secondary site.

Therefore, the application is conforming to this criterion.

- (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 E-1, page 24, the applicant describes the alternatives considered prior to submitting this application for the proposed project, which include:

- Maintain the Status Quo –The applicant states that maintaining the status quo is not an effective alternative because the failure to relocate the facility results in a lack of regard for the patients because the current building cannot be cost-effectively modified to better serve patient needs. Therefore, this alternative was rejected.
- Relocate RAI - Goldsboro to other sites in Goldsboro – This alternative was rejected by the applicant because the primary site is the most cost-effective of several sites considered by the applicant to meet the identified need. Also, the primary site is one half mile from the current location and nearer to the hospital than the alternative sites.

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 this proposal is the least costly or most effective alternative to meet the identified need. Therefore, the application is conforming to this criterion and approved subject to the following conditions:

- 1. RAI Care Centers of North Carolina II, LLC d/b/a RAI Care Centers - Goldsboro shall materially comply with all representations made in the certificate of need application.**
 - 2. RAI Care Centers of North Carolina II, LLC d/b/a RAI Care Centers - Goldsboro shall relocate the entire facility and operate no more than 16 certified dialysis stations, which shall include any isolation stations and home training stations upon completion of this project.**
 - 3. RAI Care Centers of North Carolina II, LLC d/b/a RAI Care Centers - Goldsboro shall install plumbing and electrical wiring through the walls for no more than 16 dialysis stations which shall include any isolation and home hemodialysis training stations.**
 - 4. RAI Care Centers of North Carolina II, LLC d/b/a RAI Care Centers - Goldsboro shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Healthcare Planning and Certificate of Need Section in writing prior to 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

RAI Care Centers - Goldsboro proposes to relocate an existing facility within Goldsboro for a total of 16 stations upon project completion.

Capital and Working Capital Costs

In Section F-1, pages 26-27, the applicant projects it will incur \$1,943,205 in capital costs to relocate the current facility, as shown below in the table. In Section F-10 through 13, page 29, the applicant states that there are no working capital needs for the proposed project since RAI - Goldsboro is an existing facility.

RAI - GOLDSBORO Capital Costs	
Category	Cost
Construction	\$1,302,456
Miscellaneous Project Costs	
(RO) Water Equipment	\$210,000
Other Equipment and Furniture	\$177,871
Architect/Engineering Fees	\$117,221
Generator	\$64,673
Contingency	\$70,984
Subtotal Miscellaneous	\$640,749
Total Project Capital Costs	\$1,943,205

Availability of Funds

In Section F-2, page 27, and Section F-13, page 29, the applicant states it will finance the capital costs with owner's equity/accumulated reserves of FMC. Exhibit F-1 contains a letter dated May 15, 2017, from the Senior Vice President and Treasurer of FMC, authorizing and committing \$1,943,205 in capital costs for the project. In addition, the letter from the Senior Vice President and Treasurer of FMC in Exhibit F-1 states, *"I am also authorized, and authorize any additional funds as may be necessary for start-up costs in the new location."*

Exhibit F-2 contains the Consolidated Financial Statements for FMC and Subsidiaries for the years ending December 31, 2016 and December 31, 2015. These statements indicate that as of December 31, 2016, FMC and Subsidiaries had \$357.9 million in cash and cash equivalents, \$20.1 billion in total assets and \$10.5 billion in net assets (total assets less total liabilities). The applicant adequately demonstrates that sufficient funds will be available for the capital needs of the project.

Financial Feasibility

In the projected revenue and expense statement in Section R, Form B, pages 69-70, the applicant projects revenues will exceed operating expenses in the first two operating years following completion of the proposed project, as shown below in the table.

RAI - GOLDSBORO		
	OY1 / CY2019	OY2 / CY2020
Total Treatments*	8,447	8,743
Total Gross Revenues (Charges)	\$34,867,084	\$36,047,532
Total Net Revenue	\$3,431,869	\$3,541,282
Total Operating Expenses (Costs)	\$2,654,364	\$2,727,718
Net Income	\$777,505	\$813,563

*Form C, pages 71 and 72. Adjusted by the applicant for missed treatments.

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section R of the application for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference. The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

Conclusion

In summary, the applicant adequately demonstrates the financial feasibility of the project is based upon reasonable and adequately supported assumptions regarding projected utilization, revenues (charges) and operating costs. Therefore, 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

RAI Goldsboro proposes to relocate an existing facility to a new location in Goldsboro, for a total of 16 stations upon project completion. The facility will continue to provide in-center (IC) hemodialysis and services for its peritoneal dialysis (PD) patients, in Goldsboro, Wayne County.

On page 373, the 2017 SMFP defines the service area for dialysis services as the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining North Carolina counties is a separate dialysis station planning area. Thus, the service area for this facility consists of Wayne County. Facilities may also serve residents of counties not included in their service area.

The January 2017 SDR indicates there are four existing dialysis facilities and one approved new dialysis facility in Wayne County, as follows:

WAYNE COUNTY DIALYSIS FACILITIES EXISTING & APPROVED CERTIFIED STATIONS & UTILIZATION as of June 30, 2016						
Dialysis Facilities	Owner	# of Patients	Location	# of Certified Stations	# of Approved Stations	Percent Utilization
Goldsboro Dialysis	DaVita	99	Goldsboro	27	-10	91.67%
Goldsboro South Dialysis	DaVita	89	Goldsboro	22	-2	101.14%
Mount. Olive Dialysis	DaVita	42	Mount Olive	15	0	70.00%
Coastal Carolina Dialysis	DaVita	0	Goldsboro	0	12	0.00%
RAI Care Centers-Goldsboro	FMC	36	Goldsboro	16	0	56.25%

As illustrated above, one of the four existing facilities is owned and operated by the applicant and has a utilization rate of 56.25%. The three existing facilities and one approved facility are owned by DaVita. The new facility owned by DaVita has been approved but is not yet operational.

The applicant is not applying for additional stations pursuant to any need determinations in the 2017 SMFP. The applicant's proposal would not increase or decrease the surplus of six dialysis stations in Wayne County; nor would it duplicate services, as it is proposing to relocate an existing facility to a new location to better serve existing patients using existing stations. The applicant proposes to relocate the facility because it is not meeting the needs of the patients in its current location due to physical restraints at the existing facility. The discussions on the analysis of need found in Criterion (3) and Criterion (3a), are incorporated herein by reference.

In Section C, pages 16-18, the applicant projects that RAI - Goldsboro will serve a total of 58 IC patients at the end of Operating Year One for a utilization rate of 90.6% or 3.6 patients per station per week (58 patients / 16 stations = 3.625 / 4 = .9062 or 90.6%). According to the January 2017 SDR, there is a surplus of six dialysis stations in Wayne County. The projected utilization of 3.6 patients per station per week for Operating Year One satisfies the 3.2 in-center patients per station per week threshold as required by 10A NCAC 14C .2203(b). The applicant is applying to relocate the entire dialysis facility but not to add any additional stations. Although the applicant did apply the threshold when projecting utilization for the facility, this rule is not applicable to this application because the applicant is not adding new stations pursuant to a need determination;

The applicant states that the projected utilization rates are based on patients currently dialyzing at RAI - Goldsboro. The applicant adequately demonstrates the need to relocate the RAI - Goldsboro based on conformance with Policy ESRD-2. The discussion on analysis of need found in Criterion (3) is incorporated herein by reference.

The applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of existing or approved health service capabilities or facilities in Wayne 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 H-1, page 35, the applicant provides the current and projected staffing for RAI - Goldsboro, which is 14.35 full-time equivalent (FTE) employees. The applicant projects that the projected staffing will not change from current staffing following completion of the project as shown below in the table.

RAI - GOLDSBORO Facility Staffing	
Position	Current & Projected FTEs
Registered Nurse	3.00
LPN	1.00
Technician (PCT)	6.00
Clinical Manager	1.00
Administrator	.20
Dietician	.50
Social Worker	.50
Home Training RN	.25
Chief Tech	.20
Equipment Tech	.50
In-Service	.20
Clerical	1.00
Total	14.35

In Section H-3, pages 35-36, the applicant describes its experience and process for recruiting and retaining staff. In Section H-7, page 37, the applicant provides the projected direct care staff for RAI - Goldsboro in OY2. Exhibit I-5 contains a copy of a letter from Carney Taylor, M.D., expressing his interest in continuing to serve as the Medical Director for the 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 38, the applicant includes a list of providers of the necessary ancillary and support services. Exhibit I-5 contains a letter from the medical director of the facility expressing his support for the proposed project. The applicant is an existing provider of dialysis services with established relationships. On pages 39-40, the applicant discusses coordination with the existing health care system. Exhibits I-1 through I-2, respectively, contain copies of

agreements, including one with FMC Vernon Dialysis for home care training, and Spectra Laboratories. 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.

C

In Section K-2, page 44, the applicant proposes to relocate RAI – Goldsboro to a newly constructed leased building. The applicant will incur the cost to upfit the building to its specifications. In Section C-13, page 22, the applicant states the need for replacing the current facility. The applicant discusses the lack of adequate parking for patients and staff, the lack of a covered drop off and pick-up area for patients, insufficient space for patient home training – and the inability to remedy these inadequacies in a cost-efficient manner. The upcoming expiration on the current lease offers the applicant the opportunity to remedy the shortcomings the existing facility has in its current location, by relocating to a new facility.

The primary site for the proposed new facility will also be located in Goldsboro, less than one-half mile from the current facility. In Section F-1, page 26, the applicant lists the project costs, including \$1,302,456 for construction, \$640,749 in miscellaneous costs including water treatment equipment, furniture, architect/engineering fees, and a contingency for a total project cost of \$1,943,205. In Section K-1 and 2, pages 42-44 the applicant describes its plans for energy-efficiency and water conservation. Costs and charges are described by the applicant in Section R – Pro formas. The discussion regarding costs and charges found in Criterion (5) is incorporated herein by reference.

The applicant adequately demonstrates that the cost, design and means of construction represent the most reasonable alternative, that energy saving features are incorporated into the construction plans, and that the construction cost will not unduly increase costs and charges for health services. Therefore, the application is conforming to this criterion.

- (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;

C

In Section L-7, page 53, the applicant reports that 89.64% of the revenue received for treatments at RAI - Goldsboro was from Medicare and Medicaid in CY 2016. The table below shows the historical payor sources of the facility:

RAI - GOLDSBORO CY 2016	
Payor Source	Percent of Total Revenue
Self-Pay/ Indigent/ Charity*	-0.15%
Medicare	71.55%
Medicaid	7.88%
Commercial Insurance	7.61%
Medicare / Commercial	10.21%
Medicare/ Medicaid	0.00%
Misc. (VA)	2.90%
Total**	100.00%

*The applicant states that the negative number is an accounting function & does not Reflect negative treatment volumes.

The United States Census Bureau provides demographic data for North Carolina and all counties in North Carolina. The following table contains relevant demographic statistics for the applicant’s service area.

Percent of Population						
County	% 65+	% Female	% Racial and Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance**
2014 Estimate	2014 Estimate	2014 Estimate	2014 Estimate	2010-2014	2010-2014	2014 Estimate
Wayne	15%	51%	46%	23%	12%	18%
Duplin	16%	51%	48%	28%	11%	26%
Statewide	15%	51%	36%	17%	10%	15%

Source: <http://www.census.gov/quickfacts/table>, 2014 Estimate as of December 22, 2015.

*Excludes "White alone" who are "not Hispanic or Latino"

**This geographic level of poverty and health estimates are not comparable to other geographic levels of these estimates. Some estimates presented here come from sample data, and thus have sampling errors that may render some apparent differences between geographies statistically indistinguishable...The vintage year (e.g., V2015) refers to the final year of the series (2010 thru 2015). Different vintage years of estimates are not comparable."

The IPRO ESRD Network of the South Atlantic Network 6 (IPRO SA Network 6) consists of North Carolina, South Carolina and Georgia. IPRO SA Network 6 provides a 2015 Annual Report which includes aggregate ESRD patient data from all three states. However, a comparison of the *Southeastern Kidney Council Network 6 Inc. 2014 Annual Report*¹ percentages for North Carolina and the aggregate data for all three states in IPRO SA Network 6 shows very little variance; therefore the statistics for IPRO SA Network 6 are representative of North Carolina.

The IPRO SA Network 6 provides prevalence data on dialysis patients by age, race, and gender in its 2015 annual report, pages 27-28². In 2015, over 85% of dialysis patients in Network 6 were 45 years of age and older, over 67% were non-Caucasian and 45% were female. (IPRO SA Network 6).

The applicant adequately demonstrates that it currently provides access to medically underserved populations. Therefore, the application is conforming to this criterion.

- (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;

¹<http://esrd.ipro.org/wp-content/uploads/2016/06/2014-Network-6-Annual-Report-web.pdf>

²<http://esrd.ipro.org/wp-content/uploads/2016/11/2015-NW-6-Annual-Report-Final-Draft-with-COR-Changes-Submitted-11-29-2016.pdf>

C

In Section L-3(e), page 51, the applicant states:

“RAI-G [sic] of North Carolina facilities do not have any obligation to provide uncompensated care or community service under any federal regulations. ... The applicant will treat all patients the same regardless of race or handicap status.”

In Section L-6, page 52, the applicant states there have been no civil rights access complaints filed against any RAI North Carolina facilities within the last five years. Therefore, 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 50, the applicant projects that 89.57% of the revenue for IC treatments at RAI - Goldsboro in the second operating year (CY2020) will be paid by Medicare and Medicaid. The table below shows the projected Year 2 payment sources at the facility for its in-center patients:

RAI – GOLDSBORO Projected PY2/CY2020	
Payor Source	In-Center Revenue by Percent of Total
Self-Pay/ Indigent/ Charity	.75%
Medicare	71.82%
Medicaid	7.98%
Medicare / Commercial	9.77%
Medicare / Medicaid	0.00%
Commercial Insurance	7.08%
Misc. (VA)	2.60%
Total	100.00%

In Section L-1, page 50, the applicant states that projections are based on recent facility experience. The applicant's projected payment sources are similar to the facility's historical (CY2016) payment sources as reported by the applicant in Section L-7, page 53 and in Section R, Form C. The applicant demonstrates that medically underserved groups will have adequate access to the services offered at RAI - Goldsboro. 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 52, the applicant describes the range of means by which a person will have access to the dialysis services at RAI - Goldsboro, including referrals from nephrologists, 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 dialysis 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-1, page 54, the applicant discusses the extent to which the facility accommodates the needs of health professional training programs in the area. Exhibit M-1 contains a copy of correspondence to the health professional training program at Wayne Community College expressing an interest on the part of the applicant to offer the facility as clinical training site. 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.

C

RAI Goldsboro proposes to relocate an existing facility to a new location in Goldsboro, for a total of 16 stations upon project completion. The facility will continue to provide in-center (IC) hemodialysis and services for its peritoneal dialysis (PD) patients, in Goldsboro, Wayne County.

On page 373, the 2017 SMFP defines the service area for dialysis services as the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining North Carolina counties is a separate dialysis station planning area. Thus, the service area for this facility consists of Wayne County. Facilities may also serve residents of counties not included in their service area.

The January 2017 SDR indicates there are four existing dialysis facilities and one approved new dialysis facility in Wayne County, as follows:

WAYNE COUNTY DIALYSIS FACILITIES EXISTING & APPROVED CERTIFIED STATIONS & UTILIZATION as of June 30, 2016						
Dialysis Facilities	Owner	# of Patients	Location	# of Certified Stations	# of Approved Stations	Percent Utilization
Goldsboro Dialysis	DaVita	99	Goldsboro	27	-10	91.67%
Goldsboro South Dialysis	DaVita	89	Goldsboro	22	-2	101.14%
Mount. Olive Dialysis	DaVita	42	Mount Olive	15	0	70.00%
Coastal Carolina Dialysis	DaVita	0	Goldsboro	0	12	0.00%
RAI Care Centers-Goldsboro	FMC	36	Goldsboro	16	0	56.25%

As illustrated above, one of the four existing facilities is owned and operated by the applicant - the facility in this application. The three existing facilities and one approved facility are owned by DaVita. The new facility owned by DaVita has been approved but is not yet operational. The applicant is projecting a utilization of 3.6 patients per station per week for Operating Year One which satisfies the 3.2 in-center patients per station per week threshold as required by 10A NCAC 14C .2203(b). The applicant is applying to relocate the entire dialysis facility but not to add any additional stations. Although the applicant did apply the threshold when projecting utilization for the facility, this rule is not applicable to this application because the applicant is not adding new stations pursuant to a need determination.

In Section N-1, page 55, the applicant discusses how this project is not expected to have any impact on competition, as the applicant does not project to serve dialysis patient currently being served by another provider. The projected patient population is calculated based on patients currently served at RAI - Goldsboro and the Wayne County Five Year AACR of 3.5%. See also Sections B, C, E, G, H, I, K, L and O where the applicant discusses the impact of the project on cost-effectiveness, quality and access.

The information provided by the applicant in the sections referenced above is reasonable and adequately demonstrates that this proposal 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 proposed project and that it is an effective alternative. The discussions regarding analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.
- The applicant adequately demonstrates that RAI - Goldsboro will continue to provide quality dialysis services. The discussion regarding quality found in Criterion (20) is incorporated herein by reference.

- The applicant demonstrates that RAI - Goldsboro will continue to provide adequate access to medically underserved populations. The discussions regarding access found in Criteria (3), (3a) and (13) are incorporated herein by reference.

Therefore, 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.

C

In Section B-4(a), page 11 and Section O, pages 57-61, the applicant discusses the methods it uses to ensure and maintain quality. In Exhibit O-1, the applicant provides additional information on how it ensures and maintains quality. In Section O, pages 59-60, the applicant states that out of more than 100 facilities located in North Carolina operated by the applicant or a related entity, the two facilities listed below were not in compliance with Medicare conditions of participation (Centers for Medicare and Medicaid Services – CMS) during the 18 months prior to submission of the application. However, at the time of submission of this application, both facilities were back in full compliance with all CMS guidelines.

BMA QUALITY CARE			
FACILITY	SURVEY DATE	BACK IN COMPLIANCE	
BMA East Rocky Mount	1/25/2017	Yes	3/1/2017
RAI West College	3/15/2016	Yes	4/11/2016

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.

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

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- RAI - Goldsboro is an existing facility.

.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- RAI - Goldsboro does not propose to increase the number of dialysis stations.

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

-C- In Section C-1, pages 16-18, the applicant provides the assumptions and methodology used to project utilization at RAI - Goldsboro. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.