

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: December 18, 2019

Findings Date: December 18, 2019

Project Analyst: Gregory F. Yakaboski

Assistant Chief: Lisa Pittman

Project ID #: G-11797-19

Facility: Triad Dialysis Center of Wake Forest University

FID #: 980262

County: Guilford

Applicants: Triad Dialysis Center of Wake Forest University
Wake Forest University Health System

Project: Add no more than eight stations for a total of no more than 30 stations upon completion of this project and Project ID #G-11672-19 (relocate 5 stations to High Point Kidney Center)

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

Wake Forest University Health Sciences (WFUHS) and Triad Dialysis Center of Wake Forest University (Triad Dialysis Center), collectively “the applicants”, propose to add eight dialysis stations to Triad Dialysis Center for a total of 30 dialysis stations upon completion of this project and Project ID #G-11672-19 (relocate 5 stations to High Point Kidney Center). Triad Dialysis Center does not currently offer a peritoneal dialysis (PD) program or a home hemodialysis (HHD) program and is not proposing to add either a PD or a HHD program with this project.

Need Determination

The 2019 State Medical Facilities Plan (SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to Table D, page 62, in the July 2019 Semiannual Dialysis Report (SDR), the county need methodology shows there is a deficit of 20 stations in Guilford County, but because there are facilities with a reported utilization of less than 80%, there is no county need determination for new dialysis stations for Guilford County.

However, the applicants are eligible to apply for additional stations based on the facility need methodology because the utilization rate reported for Triad Dialysis Center in the July 2019 SDR is 3.4815 patients per station per week. This utilization rate was calculated based on 94 in-center dialysis patients and 27 certified dialysis stations. (94 patients / 27 stations = 3.4815 patients per station per week). The facility need methodology requires a facility’s utilization rate in the latest SDR to be at least 3.2 patients per station per week to be eligible to apply for additional stations based on facility need.

Application of the facility need methodology indicates that up to a maximum of eight additional stations are needed for this facility, as illustrated in the following table.

OCTOBER 1 REVIEW-JULY SDR		
Required SDR Utilization		80%
Center Utilization Rate as of 12/31/18		87.0%
Certified Stations		27
Pending Stations		0
Total Existing and Pending Stations		27
In-Center Patients as of 12/31/18 (July 2019 SDR) (SDR2)		94
In-Center Patients as of 6/30/18 (Jan 2019 SDR) (SDR1)		86
Step	Description	Result
	Difference (SDR2 - SDR1)	8
(i)	Multiply the difference by 2 for the projected net in-center change	16
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/18	0.1860
(ii)	Divide the result of Step (i) by 12	0.0155
(iii)	Multiply the result of Step (ii) by 12 (the number of months from 12/31/17 until 12/31/18)	0.1860
(iv)	Multiply the result of Step (iii) by the number of in-center patients reported in SDR2 and add the product to the number of in-center patients reported in SDR2	111.4884
(v)	Divide the result of Step (iv) by 3.2 patients per station	34.8401
	and subtract the number of certified and pending stations to determine the number of stations needed	7.8401

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is eight stations (rounding to the nearest whole number is allowed only in Step (v), where fractions of 0.5 and greater shall be rounded to the next highest whole number.) The applicants propose to add eight stations pursuant to the facility need

methodology. Therefore, the facility need determination for dialysis stations is applicable to this review.

In summary, the application is consistent with the facility need determination for dialysis stations.

Policies

There is one policy in the 2019 SMFP that is applicable to this review, Policy GEN-3: Basic Principles.

Policy GEN-3: Basic Principles, page 31 of the 2019 SMFP, states:

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

Promote Safety and Quality – The applicants describe how they believe the proposed project would promote safety and quality in Section B.3(a), pages 10-15, referencing other application sections and exhibits with specific details. The information provided by the applicants is reasonable and adequately supports the determination that the applicants’ proposal would promote safety and quality.

Promote Equitable Access - The applicants describe how they believe the proposed project would promote equitable access in Section B.3(b), pages 15-19, referencing other application sections and exhibits; and Section N.2(c), page 72. The information provided by the applicants is reasonable and adequately supports the determination that the applicants’ proposal would promote equitable access.

Maximize Healthcare Value - The applicants describe how they believe the proposed project would maximize healthcare value in Section B.3(c), page 19, referencing Sections F and K; and in Section N.2(a), page 72. The information provided by the applicants is reasonable and adequately supports the determination that the applicants’ proposal would maximize healthcare value.

The applicants adequately demonstrate how Triad Dialysis Center projected volumes incorporate the concepts of quality, equitable access and maximum value for resources expended in meeting the facility need. Therefore, the application is consistent with Policy GEN-3.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

- (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 applicants propose to add eight dialysis stations to Triad Dialysis Center for a total of 30 dialysis stations upon completion of this project and Project ID #G-11672-19 (relocate 5 stations to High Point Kidney Center). Triad Dialysis Center does not currently offer a PD program or a HHD program and is not proposing to add either a PD or HHD program with this project.

Patient Origin

On page 369, the 2019 SMFP defines the service area for dialysis stations 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 counties is a separate dialysis station planning area.*” Triad Dialysis Center is located in Guilford County. Thus, the service area for this review is Guilford County. Facilities may also serve residents of counties not included in their service area.

The following table illustrates current and projected patient origin.

County	Current (8/1/218 to 7/31/19)		Second Full FY of Operation following Project Completion (8/1/21 to 7/31/22)	
	Patients	% of Total	Patients	% of Total
Guilford	80.00	86.02%	93.67	86.41%
Forsyth	12.00	12.90%	13.69	12.63%
Randolph	1.00	1.08%	1.04	0.96%
Total	93.00	100.00%	108.41	100.00%

Source: Section C, pages 22-23.

In Section C, pages 23-24, the applicants provide the assumptions and methodology used to project its patient origin. The applicants assumptions are reasonable and adequately supported.

Analysis of Need

The facility need methodology shows a need to add eight dialysis stations to the existing Triad Dialysis Center facility.

In Section C, the applicants explain why they believe the population projected to utilize the proposed services needs the proposed services.

As of December 31, 2018, based on 27 certified stations, Triad Dialysis Center was operating at 87.04% utilization (See application page 45).

Pursuant to Project ID #G-11672-19 (projected to be certified March 1, 2020) five stations are to be transferred from Triad Dialysis Center to High Point Kidney Center thus reducing the number of certified stations at Triad Dialysis Center from 27 station to 22 stations.

In Sections C.3 and C.4, page 24, the applicants state that the facility must request additional stations now to head off excessive utilization in the future. In the table on page 24, based on 22 certified stations, the applicants project utilization of 111.22% at Triad Dialysis Center as of July 31, 2020 and utilization projected to reach 123.19% by July 31, 2022, if no stations are added.

In Section C.4, page 26, the applicants state that *“TDC currently serves 12 patients with infectious disease processes. As such, the need for isolation and accompanying station decontamination is real. The true 100% utilization rate for as many as 6 stations could be reduced to 2 patients per station from 4 patients per station.”*

The information is reasonable and adequately supported for the following reasons:

- The facility operated at 87.04% capacity with 27 stations as of December 31, 2018, the facility will only have 22 stations upon completion of Project ID #G-11672-19 (relocate 5 stations to High Point Kidney Center). and is expected to reach more than 111.22% capacity by July 31, 2020, if no stations are added,
- The applicants base the future need for services upon the facility’s historical patient utilization, applying the July 2019 SDR’s 5-year county AACR of 4.5%, 5.4%, 1.3 and 1.8%, for patients from Forsyth, Guilford, Randolph and Rockingham counties, respectively, to project growth in patient need at the facility.
- The facility need methodology from the July 2019 SDR, based on 27 certified stations, shows a need for eight additional dialysis stations at Triad Dialysis Center.

Projected Utilization

In Section C.3, page 24, the applicants provide the calculations used to arrive at the projected in-center patient census for the first two years of operation following the completion of the project. The following table provides historical and projected utilization of in-center dialysis patients at Triad Dialysis Center.

Triad Dialysis Center In-Center Dialysis Utilization

County	July 2019 SDR 5-Yr AACR	Beginning Census 7/31/2019	Growth as of Certification 7/31/2020	End of OY1 7/31/2021	End of OY2 7/31/2022
Guilford	5.40%	80.00	84.32	88.87	93.67
Forsyth	4.50%	12.00	12.54	13.10	13.69
Randolph	1.30%	1.00	1.01	1.03	1.04
Totals		93.00	97.87	103.00	108.41

Totals may not sum due to rounding

As the table above shows, the methodology used by the applicants achieves a projection of 103.00 in-center patients by the end of the first operating year, OY1, for a utilization rate of 3.4333 patients per station per week or 85.83% utilization (103 patients / 30 stations = 3.4333 / 4 = 0.8583 or 85.83%). By the end of OY2, following the applicants methodology and assumptions, Triad Dialysis Center will have 108.41 in-center patients dialyzing at the center for a utilization rate of 3.6 patients per station per week or 90.0% utilization (108 / 30 = 3.6 / 4 = .9 or 90.0%). The projected utilization of 3.6 patients per station per week for OY1 exceeds the 3.2 in-center patients per station threshold as required by 10A NCAC 14C .2203(b).

In Section C.3, pages 22-24, the applicants provide the methodology and assumptions used to project utilization at Triad Dialysis Center. Based on the facility need methodology, Triad Dialysis Center is eligible to add eight dialysis stations.

The applicants' methodology and assumptions are summarized below:

- OY1 ends July 31, 2021; OY2 ends July 31, 2022.
- Utilization is based on current patients at Triad Dialysis Center, projected forward by applying the July 2019 SDR 5-year Average Annual Change Rate (AACR), by county of patient origin, to the current patient populations to project patient census through the end of Operating Year 2.
- Existing patients are grouped by modality and county of origin, as of July 31, 2019.
- Utilization calculations include the 5 stations approved to be relocated from Triad Dialysis Center to High Point Kidney Center in Project ID #G-11672-19.

Projected utilization is reasonable and adequately supported for the following reasons:

- The applicants base the future utilization of services upon the facility's historical patient utilization,

- The applicants base the future need for services upon the facility’s historical patient utilization, applying the July 2019 SDR’s 5-year county AACR of 4.5%, 5.4%, 1.3 and 1.8%, for patients from Forsyth, Guilford, Randolph and Rockingham counties, respectively, to project growth in patient need at the facility.
- Based on the facility need methodology Triad Dialysis Center has a need for eight dialysis stations.

Access

In Section L.2(b), page 64, the applicants state:

“The facility fulfills its requirement for non-discrimination by accepting all persons with a diagnosis of ESRD regardless of race, color, national origin, sex, age or disability. Patients are accepted for care based upon specifically defined admissions criteria- a diagnosis of ESRD and appropriate referral for care. The facility’s design complies with ADA standards...”

In Section C.7(a), page 28, the applicants state, *“Admission of a patient is based upon medical necessity and not the patient’s ability to pay. Patients may only access the facility’s services via physician referral due to a diagnosis of ESRD.”*

In Section L, page 65, the applicants project the following payor mix during the second full fiscal year of operation following completion of the project, as illustrated in the following table.

**Projected Payor Mix
OY2**

Payor Source	% of Total Patients
Private Pay	1.0%
Medicare	15.0%
Medicaid	7.0%
Medicare / Medicaid	23.0%
Commercial Insurance	8.0%
Medicare / Commercial	24.0%
VA	2.0%
Medicare Advantage	20.0%
Total	100.0%

Source: Table on page 65 of the application.

The projected payor mix is reasonable and adequately supported.

Conclusion

The Agency reviewed the:

- Application

- Exhibits to the application
- Supplemental information requested by the Agency
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicants adequately identify the population to be served.
- The applicants adequately explain why the population to be served needs the services proposed in this application.
- Projected utilization is reasonable and adequately supported.
- The applicants project the extent to which all residents, including underserved groups, will have access to the proposed services (payor mix) and adequately supports its assumptions.

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

NA

The applicants do not propose a reduction or elimination of a service, or the relocation of a facility or a service. Therefore, Criterion (3a) is not applicable to this review.

- (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

The applicants propose to add eight dialysis stations to Triad Dialysis Center for a total of 30 dialysis stations upon completion of this project and Project ID #G-11672-19 (relocate 5 stations to High Point Kidney Center).

In Section E, pages 37-39, the applicants describe the alternatives considered and explain why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- *Transfer Stations from a Contiguous County per Policy ESRD-2*- The applicants state that WFUHS, the parent of Triad Dialysis Center has dialysis facilities in the counties of Davidson, Forsyth, Randolph and Stokes which are all contiguous to Guilford County. However, the applicants describe in detail on page 37 why transferring stations from any of those dialysis facilities to Triad Dialysis Center is not feasible. Therefore, this is not the least costly or most effective alternative.

- *Add Less than 8 Stations*- The Facility Need Methodology identifies a need for 8 additional stations at Triad Dialysis Center. The applicants state that adding less than 8 additional stations will not meet the projected patient needs. Therefore, this is not the least costly or most effective alternative.

On page 37, the applicants state that its proposal is the most effective alternative because the proposed project meets the projected patient population need of eight dialysis stations using the facility need methodology.

The applicants adequately demonstrate that the alternative proposed in this application is the most effective alternative to meet the need for the following reasons:

- The application is conforming to all statutory and regulatory review criteria.
- The applicants provide credible information to explain why they believe the proposed project is the most effective alternative.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above. Therefore, the application is approved subject to the following conditions:

- 1. Wake Forest University Health Sciences and Triad Dialysis Center of Wake Forest University shall materially comply with all representations made in the certificate of need application and any supplemental responses. In the event that representations conflict, Wake Forest University Health Sciences and Triad Dialysis Center of Wake Forest University shall materially comply with the last made representation.**
- 2. Pursuant to the facility need determination in the July 2019 SDR, Wake Forest University Health Sciences and Triad Dialysis Center of Wake Forest University shall develop no more than eight additional dialysis stations for a total of no more than thirty certified stations at Triad Dialysis Center upon completion of this project and Project ID #G-11672-19 (relocate 5 stations to High Point Kidney Center), which shall include any home hemodialysis training or isolation stations.**
- 3. Wake Forest University Health Sciences and Triad Dialysis Center of Wake Forest University shall acknowledge acceptance of and agree to comply with all**

conditions stated herein to the Agency 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

The applicants propose to add eight dialysis stations to Triad Dialysis Center for a total of 30 dialysis stations upon completion of this project and Project ID #G-11672-19 (relocate 5 stations to High Point Kidney Center).

Capital and Working Capital Costs

In Section Q, Form F-1(a), page 82, the applicants project the total capital costs for the project as summarized below.

Site Costs	\$0
Construction Costs	\$0
Miscellaneous Costs (Medical Equipment & Furniture)	\$134,400
Total	\$134,400

In Section Q, Form F.1a, the applicants provide the assumptions used to project the capital cost.

In Section F, page 42, the applicants state that Triad Dialysis Center is an existing operational facility; therefore, there are no start-up or initial operating expenses.

Availability of Funds

In Section F, page 40, the applicants state that the capital cost will be funded as shown in the table below.

Sources of Capital Cost Financing

Type	Wake Forest University Health Sciences	Total
Loans		
Accumulated reserves or OE *	\$134,400	\$134,400
Bonds		
Other (Specify)		
Total Financing	\$134,400	\$134,400

* OE = Owner's Equity

In Exhibit F-2(c)(ii), the applicants provide a letter dated September 15, 2019, from the President of the Wake Forest Baptist Health System, authorizing the project and committing \$134,400 for the development of the project. Exhibit F-2(c)(iii) contains Consolidated Financial Statements for Wake Forest University for the fiscal year ended June 30, 2018, showing WFUHS with \$16,242,000 in cash and cash equivalents, \$1.37 billion in total assets and \$794,745,000 in net assets.

The applicants adequately demonstrate the availability of funds for the capital needs of the project.

Financial Feasibility

The applicants provide pro forma financial statements for the first two full fiscal years of operation following completion of this project. In Form F.2, the applicants project that revenues will exceed operating expenses in the first two operating years of this project, as shown in the table below.

	1 st Full Fiscal Year	2 nd Full Fiscal Year
Total Treatments	15,000	15,900
Total Gross Revenues (Charges)	\$27,594,450	\$29,250,117
Total Net Revenue	\$4,319,453	\$4,578,620
Average Net Revenue per treatment	\$288	\$288
Total Operating Expenses (Costs)	\$3,747,328	\$3,910,757
Average Operating Expense per treatment	\$250	\$246
Net Income	\$572,125	\$667,863

The assumptions used by the applicants in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section Q 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.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application.

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicants adequately demonstrate that the capital costs are based on reasonable and adequately supported assumptions.
 - The applicants adequately demonstrate availability of sufficient funds for the capital needs of the proposal.
 - The applicants adequately demonstrate 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.
- (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

The applicants propose to add eight dialysis stations to Triad Dialysis Center for a total of 30 dialysis stations upon completion of this project and Project ID #G-11672-19 (relocate 5 stations to High Point Kidney Center).

On page 369, the 2019 SMFP defines the service area for dialysis stations 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 counties is a separate dialysis station planning area.*” Triad Dialysis Center is located in Guilford County. Thus, the service area for this review is Guilford County. Facilities may also serve residents of counties not included in their service area.

According to Table B of the July 2019 SDR, there are nine existing or approved dialysis facilities in Guilford County, as follows:

Guilford County Dialysis Facilities

Dialysis Facility	Certified Stations	Percent Utilization	Patients Per Station
BMA of Greensboro (FMC)	56	85.27%	3.4107
BMA of South Greensboro (FMC)	49	99.49%	3.9796
BMA of Southwest Greensboro (FMC)	33	76.52%	3.0606
FMC of East Greensboro (FMC)	39	90.38%	3.6154
Fresenius Kidney Care Garber-Olin (FMC Proposed new site)	0	0.00%	0.0000
Fresenius Medical Care High Point (FMC)	10	90.00%	3.6000
High Point Kidney Center (WFUHS)	41	91.46%	3.6585
Northwest Greensboro Kidney Center (FMC)	37	79.05%	3.1622
Triad Dialysis Center (WFUHS)	27	87.04%	3.4815

Source: July 2019 SDR, Table B.

Per the July 2019 SDR, as of December 31, 2018, Wake Forest University Health Sciences owns and operates two facilities in Guilford County. Fresenius related entities own and operate seven existing and proposed dialysis facilities in Guilford County. With the exception of the approved but undeveloped facility, each of the existing dialysis facilities is well-utilized, operating above 3.0 patients per station.

In Section G, pages 45-46, the applicants explain why they believe the proposal would not result in the unnecessary duplication of existing or approved dialysis services in Guilford County. The applicants state:

“County-wide, Davidson [Guilford] is projected to have a 20-station deficit ... The patients projected to be served by this project are the existing and projected patients who will attend TDC, only. Those patients do not reside exclusively in Guilford County, but in Guilford and multiple surrounding counties. ... this application is filed in compliance with the requirements of both Facility Need Methodology and the Performance Standards for ESRD services, all stations awarded as a result of this application will not result in an unnecessary duplication of existing or approved dialysis stations in the service area, which is Guilford County, because the applicable need is not for the service area, but it is for TDC, solely”

The applicants adequately demonstrate that the proposal would not result in an unnecessary duplication of existing or approved services in the service area for the following reasons:

- There is a facility need determination in the 2019 SMFP for the proposed addition of eight stations.
- The applicants adequately demonstrate that the proposed stations are needed in addition to the existing stations in Guilford County.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

- (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 Q, Form H, page 93, the applicants provide current and projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

POSITION	Current FTE Positions as of 7/31/19	PROJECTED FTE POSITIONS OY2 (8/1/2021 TO 7/31/2022)
RN	5.00	5.00
Patient Care Tech	13.13	14.00
Clinical Nurse Manager (DON)	1.00	1.00
Dietician	1.00	1.00
Social Worker	1.50	1.50
Dialysis Tech	2.00	2.00
Bio-med Technician	1.00	1.00
Clerical	1.50	1.50
Total	26.13	27.00

Source: Sections Q, Form H, page 93 of the application.

The assumptions and methodology used to project staffing are provided in Section Q, Form H. Adequate costs for the health manpower and management positions proposed by the applicants are budgeted in Form F.2, which is found in Section Q. In Section H.2 and H.3, pages 47-49, the applicants describe the methods used to recruit or fill new positions and its existing training and continuing education programs. In Section H, page 50, the applicants identify the current medical director. In Exhibit H-4(b), the applicants provide a letter from the medical director indicating an interest in continuing to serve as medical director for the proposed services. In Exhibits H-3, H-4(a)(i) and H-4(a)(ii), the applicants provide supporting documentation.

The applicants adequately demonstrate the availability of sufficient health manpower and management personnel to provide the proposed services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

- (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 52, and supplemental information, the applicants state that the following ancillary and support services are necessary for the proposed services:

TRIAD DIALYSIS CENTER Ancillary and Support Services	
Services	Provider
In-center dialysis/maintenance	On Premises
Self-care training (in-center)	On Premises
Home training Home Hemodialysis Peritoneal Dialysis Accessible follow-up program	High Point Kidney Center High Point Kidney Center High Point Kidney Center
Psychological counseling	On Premises with appropriate referral after evaluation by MSW
Isolation – hepatitis	On Premises
Nutritional counseling	On Premises
Social Work services	On Premises
Acute dialysis in an acute care setting	Wake Forest Baptist Hospital
Emergency care	Wake Forest Baptist Hospital
Blood bank services	Wake Forest Baptist Hospital
Diagnostic and evaluation services	On Premises
X-ray services	Wake Forest Baptist Hospital
Laboratory services	Meridian Laboratory Corp
Pediatric nephrology	Wake Forest Baptist Hospital
Vascular surgery	Wake Forest Baptist Hospital
Transplantation services	Wake Forest Baptist Hospital
Vocational rehabilitation & counseling	On Premises with appropriate referral after evaluation by MSW
Transportation	Social Workers, Department of Social Services, Grant Agencies, Individual Transport Agencies

On page 52-55, the applicants adequately explain how each ancillary and support service is or will be made available and provides supporting documentation in Exhibits I-1(b)(iii), 1(b)(v), 1(b)(xviii); Exhibits I-2(a), 2(b), 2(c)(i), Exhibits H-4(a)(i) and 4(a)(ii) and Exhibit I-2(b).

In Section I.2, pages 55-56, the applicants describe Triad Dialysis Center’s existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibits I-2(a), 2(b), 2(c)(i), 2(c)(ii), 2(c)(iii), 2c(iv) and Exhibit M-1.

The applicants adequately demonstrate that the proposed services will be coordinated with the existing health care system.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Supplemental information requested by the Agency

Based on that review, the Agency concludes that 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

The applicants do not project to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which the services will be offered. Furthermore, the applicants do not project to provide the proposed services to a substantial number of persons residing in other states that are not adjacent to the North Carolina county in which the services will be offered. Therefore, Criterion (9) is not applicable to this review.

- (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

The applicants are not HMOs. Therefore, Criterion (10) is not applicable to this review.

- (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

The applicants do not propose any new construction or major renovations to existing space. Therefore, Criterion (12) is not applicable to this review.

- (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, page 63, the applicants provide the historical payor mix during the last full OY (8/1/2018 to 7/31/2019) for the proposed services, as shown in the table below.

**Triad Dialysis Center Payor Mix
Last Full OY ((8/1/2018 to 7/31/2019)**

Payor Source	% of Total Patients
Private Pay	0.0%
Medicare	9.0%
Medicaid	8.0%
Medicare / Medicaid	27.0%
Commercial Insurance	10.0%
Medicare / Commercial	23.0%
VA	1.0%
Medicare Advantage	22.0%
Total	100.0%

Source: Table on page 63 of the application.

In Section L, page 62, the applicants provide the following comparison.

	Percentage of Total Patients Served by the Facility or Campus during the Last Full FY	Percentage of the Population of the Service Area
Female	46.24%	52.70%
Male	53.76%	47.30%
Unknown	n/a	n/a
64 and Younger	54.84%	84.80%
65 and Older	45.16%	15.20%
American Indian	n/a	0.80%
Asian	1.09%	5.4%
Black or African-American	52.69%	35.1%
Native Hawaiian or Pacific Islander	n/a	0.10%
White or Caucasian	15.05%	56.20%
Other Race	31.18%	10.60%
Declined / Unavailable	n/a	n/a

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the applicants adequately document the extent to which medically underserved populations currently use the applicants' existing services in comparison to the percentage of the population in the applicants' service area which is medically underserved. 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;

C

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L.2, pages 63-64, the applicants state:

“The facility is not required nor obligated to provide uncompensated care or community service. ... The facility fulfills its requirement for non-discrimination by accepting all persons with a diagnosis of ESRD regardless of race, color, national origin, sex, age or disability.”

In Section L.2, page 65, and supplemental information, the applicants state that there have been no civil rights access complaints filed against the facility or any similar

facilities owned by the applicants or a related entity and located in North Carolina or any facilities owned by the parent company in North Carolina within the last five years. The Agency reviewed the:

- Application
- Exhibits to the application
- Supplemental information requested by the Agency

Based on that review, the Agency concludes that 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, page 65, the applicants project the following payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as shown in the table below.

**Projected Payor Mix
OY2**

Payor Source	% of Total Patients
Private Pay	1.0%
Medicare	15.0%
Medicaid	7.0%
Medicare / Medicaid	23.0%
Commercial Insurance	8.0%
Medicare / Commercial	24.0%
VA	2.0%
Medicare Advantage	20.0%
Total	100.0%

Source: Table on page 65 of the application.

As shown in the table above, during the second full calendar year of operation, the applicants project that 1% of the dialysis patients will be private pay patients and 89% will have all or part of their services paid for by Medicare and/or Medicaid.

On pages 65-66, the applicants provide the assumptions and methodology used to project payor mix during the first and second fiscal full years of operation following completion of the project. The projected payor mix is reasonable and adequately supported for the following reasons:

- the applicants' proposed patient origin is comparable to its historical patient origin, and

- the applicants project future payor mix based on the facility's average monthly payor mix by payor type for each of the last five operating years.

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that 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.5, pages 68-69, the applicants adequately describe the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that 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 71, the applicants describe the extent to which health professional training programs in the area have access to the facility for training purposes and provide supporting documentation in Exhibit M-1.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application.

Based on that review, the Agency concludes that the applicants adequately demonstrate that the proposed services will accommodate the clinical needs of area health professional training programs, and therefore, the application is conforming to this criterion.

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

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

C

The applicants propose to add eight dialysis stations to Triad Dialysis Center for a total of 30 dialysis stations upon completion of this project and Project ID #G-11672-19 (relocate 5 stations to High Point Kidney Center).

On page 369, the 2019 SMFP defines the service area for dialysis stations 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 counties is a separate dialysis station planning area.*” Triad Dialysis Center is in Guilford County. Thus, the service area for this review is Guilford County. Facilities may also serve residents of counties not included in their service area.

According to Table B of the July 2019 SDR, there are nine existing or approved dialysis facilities in Guilford County, as follows:

Guilford County Dialysis Facilities

Dialysis Facility	Certified Stations	Percent Utilization	Patients Per Station
BMA of Greensboro (FMC)	56	85.27%	3.4107
BMA of South Greensboro (FMC)	49	99.49%	3.9796
BMA of Southwest Greensboro (FMC)	33	76.52%	3.0606
FMC of East Greensboro (FMC)	39	90.38%	3.6154
Fresenius Kidney Care Garber-Olin (FMC Proposed new site)	0	0.00%	0.0000
Fresenius Medical Care High Point (FMC)	10	90.00%	3.6000
High Point Kidney Center (WFUHS)	41	91.46%	3.6585
Northwest Greensboro Kidney Center (FMC)	37	79.05%	3.1622
Triad Dialysis Center (WFUHS)	27	87.04%	3.4815

Source: July 2019 SDR, Table B.

In Section N, page 72, the applicants describe the expected effects of the proposed services on competition in the service area and discuss how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services. On page 72, the applicants state:

“The facility has demonstrated and proven a need for the requested additional stations based on the facility need methodology and the ESRD Performance Standards. Given this application is to meet TDC’s individually-projected station need absent a county need determination, competition in the proposed service area should not be impacted.”

The applicants adequately describe the expected effects of the proposed services on competition in the service area and adequately demonstrates:

- The cost-effectiveness of the proposal (see Sections F and Q of the application and any exhibits)
- Quality services will be provided (see Section O of the application and any exhibits)
- Access will be provided to underserved groups (see Section L of the application and any exhibits)

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

- (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 Q, Form A, page 78, the applicants identify the dialysis facilities located in North Carolina and owned, operated or managed by the applicants or a related entity. The applicants identify a total of 18 WFUHS dialysis facilities located in North Carolina.

In Section O, pages 74-75, the applicants state that during the 18 months immediately preceding the submittal of the application, incidents related to quality of care occurred in eleven of the 18 facilities. The applicants state that at the time of application submittal, all facilities were in compliance. After reviewing and considering information provided by the applicants and considering the quality of care provided at all 18 facilities, the applicants provide sufficient evidence that quality care has been provided in the past.

Therefore, 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 application is conforming with all applicable Criteria and Standards for End-Stage Renal Disease Services. The specific criteria are discussed below.

SECTION .2200 – CRITERIA AND STANDARDS FOR END-STAGE RENAL DISEASE SERVICES

10A NCAC 14C .2203 PERFORMANCE STANDARDS

- (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 applicants are not proposing to establish a new ESRD facility.

(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.

-C- The projected utilization of 3.4333 patients per station per week for OY1 conforms to this Rule.

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

-C- In Section C, pages 22-24, the applicants provide the assumptions and methodology used to project utilization of the facility.