

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: May 20, 2019

Findings Date: May 20, 2019

Project Analyst: Mike McKillip

Assistant Chief: Lisa Pittman

Project ID #: G-11675-19

Facility: Miller Street Dialysis Center of Wake Forest University

FID #: 070671

County: Forsyth

Applicants: Wake Forest University Health Sciences

Miller Street Dialysis Center of Wake Forest University

Project: Add no more than four stations for a total of no more than 48 stations upon completion of the project

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

Wake Forest University Health Sciences (WFUHS) and Miller Street Dialysis Center of Wake Forest University (MSDC), collectively referred to as “the applicant,” proposes to add four dialysis stations for a total of 48 stations at MSDC upon completion of the 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 in the January 2019 Semiannual Dialysis Report (SDR), there is a surplus of four dialysis stations in Forsyth County. Therefore, there is no county need determination for new dialysis stations in Forsyth County. However, the applicant is eligible to apply for additional stations in its existing facility based on the facility need methodology because the utilization

rate reported for MSDC in the January 2019 SDR is 3.25 patients per station per week. This utilization rate was calculated based on 143 in-center dialysis patients and 44 certified dialysis stations as of June 30, 2018 (143 patients / 44 stations = 3.25 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 potential maximum of four additional stations are needed for this facility, as illustrated in the following table.

APRIL 1 REVIEW-JANUARY SDR		
Required SDR Utilization		80%
Center Utilization Rate as of 6/30/18		81.25%
Certified Stations		44
Pending Stations		0
Total Existing and Pending Stations		44
In-Center Patients as of 6/30/18 (Jan 2019 SDR) (SDR2)		143
In-Center Patients as of 12/31/17 (July 2018 SDR) (SDR1)		134
Step	Description	Result
(i)	Difference (SDR2 - SDR1)	9
	Multiply the difference by 2 for the projected net in-center change	18
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 12/31/17	0.1343
(ii)	Divide the result of step (i) by 12	0.0112
(iii)	Multiply the result of step (ii) by 6 (the number of months from 6/30/18 until 12/31/18)	0.0672
(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	152.6045
(v)	Divide the result of step (iv) by 3.2 patients per station	47.6889
	and subtract the number of certified and pending stations to determine the number of stations needed	4

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is four stations. Step (C) of the facility need methodology states, “*The facility may apply to expand to meet the need established ..., up to a maximum of ten stations.*” The applicant proposes to add four new stations and therefore, is consistent with the facility need determination for dialysis stations.

Policies

There is one policy in the 2019 SMFP which is applicable to this review. *Policy GEN-3: Basic Principles* on page 31 of the 2019 SMFP is applicable to this review because the facility need methodology is applicable to this review. Policy GEN-3 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.”

The applicant addresses *Policy GEN-3* as follows:

Promote Safety and Quality

The applicant describes how it believes the proposed project would promote safety and quality in Section B.4, pages 11-15, Section N.1, page 75, Section O, page 77 and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote safety and quality.

Promote Equitable Access

The applicant describes how it believes the proposed project would promote equitable access in Section B.4, pages 16-21, Section C.3, page 27, Section L, pages 64-73, Section N.1, page 75 and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote equitable access.

Maximize Healthcare Value

The applicant describes how it believes the proposed project would maximize healthcare value in Sections B.4, page 21, Section K.1, pages 58-60 and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would maximize healthcare value.

The applicant adequately demonstrates how its projected volumes incorporate the concepts of quality, equitable access and maximum value for resources expended in meeting the facility need as identified by the applicant. 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 applicant proposes to add four dialysis stations for a total of 48 stations at MSDC upon completion of the 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.*” Thus, the service area for this facility consists of Forsyth County. Facilities may also serve residents of counties not included in their service area.

In Section C.8, page 30 and C.1, page 23, the applicant provides the historical and the projected patient origin for in-center (IC) patients, respectively, as illustrated in the tables below.

MSDC Patient Origin Current as of February 28, 2019		
County	In-Center Patients	Percent of Total
Davidson	4	2.7%
Davie	5	3.4%
Forsyth	133	91.1%
Guilford	1	0.7%
Stokes	1	0.7%
Surry	2	1.3%
Total	146	100.0%

	OY1	OY2	County Patients as % of Total	
County	In-Center Patients	In-Center Patients	OY1	OY2
Davidson	4.59	4.91	2.90%	2.99%
Davie	5.69	6.07	3.60%	3.70%
Forsyth	143.30	148.75	90.72%	90.53%
Guilford	1.07	1.11	0.68%	0.67%
Stokes	1.13	1.21	0.72%	0.74%
Surry	2.17	2.26	1.37%	1.37%
Total	157.95	164.3	100.0%	100.0%

The applicant does not currently offer hemodialysis (HHD) training and peritoneal dialysis (PD) training and support services at MSDC, nor does the applicant plan to offer those services as a part of this application.

In Section C, pages 23-24, the applicant provides the assumptions and methodology used to project patient origin for in-center patients. The applicant’s assumptions are reasonable and adequately supported.

Analysis of Need

In Section C.2, pages 24-25, the applicant discusses the need for the four additional dialysis stations at MSDC. The applicant states:

“MSDC has experienced net patient growth of 11 patients over the last 12 months. Its utilization rate is currently nearly 83%. Without additional stations, the facility will begin approaching 90% utilization in approximately one year or sooner.”

Projected Utilization

In Section C, page 26, the applicant provides projected utilization as summarized in the following table.

**MSDC
 In-Center Patient Census**

		Prior Year	Current Year	As of Certification	End of OY1	End of OY2
County	AACR	2/28/18	2/28/19	2/29/20	2/28/21	2/28/22
Davidson	7.1%	4.00	4.00	4.28	4.59	4.91
Davie	6.7%	2.00	5.00	5.34	5.69	6.07
Forsyth	3.8%	126.00	133.00	138.05	143.30	148.75
Guilford	3.4%	1.00	1.00	1.03	1.07	1.11
Stokes	6.5%	1.00	1.00	1.07	1.13	1.21
Surry	4.1%	0.00	2.00	2.08	2.17	2.26
Total		134.00	146.00	151.85	157.95	164.30

Source: Section C.1, page 26.

In Section C, pages 24-27, the applicant provides the assumptions and methodology it uses to project patient utilization, which are summarized below.

- Existing patient population for MSDC as of 2/28/18 is grouped by county of origin.
- Existing patient population is increased by the 5-yr AACR by county of origin published in the January 2019 SDR and added to the patient population for each 12-month period identified in the table on page 26.
- The project is scheduled for certification on February 29, 2020.

The applicant projects to serve 158 patients on 48 stations, which is 3.29 patients per station per week (158 patients / 48 stations = 3.29), by the end of OY1 and 164 patients on 48 stations, which is 3.42 patients per station per week (164 patients / 48 stations = 3.42), by the end of OY2. This exceeds the minimum of 3.2 patients per station per week as of the end of the first operating year as required by 10A NCAC 14C .2203(b).

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

- The applicant projects future utilization based on the patients currently being served at MSDC by their county of residence.
- The applicant uses the 5-year AACR for each MSDC patient's county of origin, as published in the January 2019 SDR, to project patient utilization for in-center patients.
- The applicant's projected patient utilization exceeds the minimum of 3.2 patients per station per week as of the end of the first operating year as required by 10A NCAC 14C .2203(b).

Access

In Section C.3, page 27, the applicant states:

“MSDC accepts patients based on medically defined admission criteria. There is no discrimination based on race, sex, age, national origin, ability to pay, nor disability. Services are available to all area residents with ESRD.”

In Section L, pages 71 and 72, the applicant provides the historical payor mix at MSDC for the period from February 28, 2018 to February 28, 2019, and projected payor mix during the first and second full years of operation following completion of the project, as illustrated in the following table.

**Miller Street Dialysis Center
Percent of Total Patients**

Payment Source	OY2019	OY2021	OY2022
Private Pay	1%	0%	0%
Medicare	12%	9%	9%
Medicaid	5%	5%	5%
Medicare/Medicaid	29%	30%	30%
Commercial Insurance	8%	8%	8%
Medicare/Commercial	21%	23%	23%
VA	3%	4%	4%
Medicare Advantage	21%	21%	21%
Total	100%	100%	100%

The applicant provides the assumptions used to project payor mix on pages 72-73, stating that the projected payor mix represents the five year average payor mix based on monthly capture of patient payor data. The projected payor mix is reasonable and adequately supported.

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 following reasons:

- The applicant adequately identifies the population to be served.
- The applicant adequately explains why the population to be served needs the services proposed in this application.
- Projected utilization is reasonable and adequately supported.
- The applicant projects 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 applicant does not propose to reduce, eliminate or relocate a facility or a service. The applicant proposes to add four dialysis stations to an existing facility pursuant to the facility need determination. 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 applicant proposes to add four dialysis stations for a total of 48 stations at MSDC upon completion of the project.

In Section E, pages 33-34, the applicant describes the alternatives it considered and explains 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:

- **Maintain the Status Quo:** The applicant states that doing nothing to increase its service capabilities at MSDC would not meet the projected needs for in-center dialysis services at the facility, where utilization is expected to grow to 90 percent by the end of operating year one of the proposed project. Thus the applicant determines the status quo is not a viable option.
- **In-County Transfer:** The applicant states that an in-county station transfer between other facilities and MSDC was not a good alternative due to the utilization of the other Forsyth facilities. Thus the applicant determines an in-county station transfer is not a viable option.
- **Contiguous County Transfer:** Because Forsyth County does not have a deficit of dialysis stations, transferring stations from facilities located in contiguous counties was not a viable alternative.

On page 34, the applicant states that its chosen proposal to add four stations to MSDC based on the facility need methodology is the most effective alternative because the needs of the patient population at MSDC cannot be met through any of the other alternatives.

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

- The MSDC facility is operating above 80% capacity.

- The applicant's application of the facility need methodology, as published in the January 2019 SDR, indicates a need for four additional stations.
- The application is conforming to all statutory and regulatory review criteria.
- The applicant provides credible information to explain why it believes the proposed project is the most effective and least costly 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 Miller Street Dialysis Center of Wake Forest University shall materially comply with all representations made in the certificate of need application.**
 - 2. Pursuant to the facility need determination in the January 2019 SDR, the applicant shall develop no more than four additional dialysis stations for a total of no more than 48 certified stations at Miller Street Dialysis Center upon completion of the project, which shall include any home hemodialysis training or isolation stations.**
 - 3. Wake Forest University Health Sciences and Miller Street Dialysis Center of Wake Forest University 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 the issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicant proposes to add four dialysis stations for a total of 48 stations at MSDC upon completion of the project.

Capital and Working Capital Costs

In Section F.1, pages 35, the applicant projects the total capital cost of the project as shown in the table below.

Dialysis Machines	\$58,000
Equipment/Furniture	\$9,200
Total	\$67,200

In Section F, pages 38-39, the applicant states that there will be no start-up or initial operating expenses associated with the proposed project as MSDC is an existing facility.

In Section F.2, page 36, the applicant states that the capital cost will be funded as shown in the table below.

Sources of Capital Cost Financing

Type	WFUHS	Total
Loans	\$0	\$0
Accumulated reserves or OE *	\$67,200	\$67,200
Bonds	\$0	\$0
Other (Specify)	\$0	\$0
Total Financing	\$67,200	\$67,200

* OE = Owner's Equity

Exhibit F.5 contains a letter dated March 15, 2019 from the President, Health System stating their intention to fund the capital cost of the proposed project. Exhibit F.7 contains a copy of the Consolidated Financial Statement for Wake Forest University which showed that as of June 30, 2018, WFUHS had adequate cash and assets to fund the capital costs of the proposed project.

Financial Feasibility

The applicant provided pro forma financial statements for the first two operating years of the project. In the pro forma financial statement (Form B), the applicant projects that revenues will exceed operating expenses in the first two operating years of the project, as shown in the table below.

	Operating Year 1 OY2021	Operating Year 2 OY2022
Total Treatments	23,250	24,150
Total Gross Revenues (Charges)	\$42,771,398	\$44,427,065
Total Net Revenue	\$6,505,491	\$6,801,993
Average Net Revenue per Treatment	\$280	\$282
Total Operating Expenses (Costs)	\$5,365,003	\$5,525,749
Average Operating Expense per Treatment	\$231	\$229
Net Income	\$1,140,488	\$1,276,244

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.

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 applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions.
 - The applicant adequately demonstrates 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 applicant proposes to add four dialysis stations for a total of 48 stations at MSDC upon completion of the project.

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.*” Thus, the service area for this facility consists of Forsyth County. Facilities may also serve residents of counties not included in their service area.

According to the January 2019 SDR, there are five providers of dialysis services in Forsyth County, as follows:

Forsyth County Dialysis Facilities

Dialysis Facility	Certified Stations as of 6/30/18	Percent Utilization	Patients Per Station
Miller Street Dialysis Center (WFUHS)	44	81.25%	3.2500
NC Baptist Hospital ESRD (WFUHS)	4	12.50%	0.5000
Northside Dialysis Center (WFUHS)	45	78.33%	3.1333
Piedmont Dialysis Center (WFUHS)	58	78.88%	3.1552
Salem Kidney Center (WFUHS)	39	94.23%	3.7692

Source: January 2019 SDR, Table B.

In Section G, page 42, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Forsyth County. The applicant states:

“MSDC is well utilized. By adding four stations to MSDC for a total of 48 stations, a manageable utilization rate of 82.27% can be obtained by the end of OY1 of the project versus the projected utilization of 89.75% that would result by doing nothing. As described above, NDC [Northside Dialysis Center] and PDC [Piedmont Dialysis Center] are operating at less than but near 80% utilization and are involved in CONs in which their underutilized stations are planned to transfer to facilities where they are needed. ... Additional stations at MSDC will enhance access to services to the ESRD patients of Forsyth and surrounding counties without duplicating services.”

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

- The applicant demonstrates the need for the additional four stations based on the facility need methodology.
- The applicant demonstrates that the proposed stations are needed in addition to the existing or approved stations in Forsyth 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 H.1, page 44, the applicant provides current full-time equivalent (FTE) staffing for the proposed services, and states that no additional staffing will be required as part of the proposed project. The applicant provides projected direct care staff in OY2 in Section H.7, page 51. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form A, which is found in Section R. In Section H, page 49, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. In Exhibit I.3, the applicant provides a letter from the medical director indicating his interest in continuing to serve as the medical director of MSDC. In Exhibit H, the applicant provides supporting documentation.

The applicant adequately demonstrates 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.1, page 52, the applicant provides a list of the necessary ancillary and support services, as illustrated below.

Miller Street Dialysis Center Ancillary and Support Services	
Services	Provider
In-center dialysis/maintenance	MSDC
Self-care training (in-center)	MSDC
Home training: Home hemodialysis Peritoneal dialysis Accessible follow-up program	Northside Dialysis Center Piedmont Dialysis Center
Psychological counseling	MSDC
Isolation – hepatitis	MSDC
Nutritional counseling	MSDC
Social Work services	MSDC
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	MSDC
X-ray services	Wake Forest Baptist Hospital
Laboratory services	Wake Forest Baptist Hospital Laboratory Contract
Pediatric nephrology	MSDC
Vascular surgery	Wake Forest Baptist Hospital
Transplantation services	Wake Forest Baptist Hospital
Vocational rehabilitation & counseling	Appropriate referral after MSW evaluation
Transportation	WSTA

In Section I.3, pages 54-55, and Section I.4, pages 55-56, the applicant describes its existing and proposed relationships with other local health care and social services providers. The applicant provides supporting documentation in Exhibit I. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system.

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.

- (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 applicant does 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 applicant does 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 applicant is not an HMO. 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 applicant does not propose any new construction or renovation of existing space as part of this project. 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.7, page 72, the applicant provides the historical payor mix at MSDC during OY2019, as shown below.

Miller Street Dialysis Center Current Payor OY2019	
Payment Category	Percent of Total Revenue
Private Pay	1%
Medicare	12%
Medicaid	5%
Medicare/Medicaid	29%
Commercial	8%
Medicare / Commercial	21%
VA	3%
Medicare Advantage	21%
Total	100%

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**
2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate
Forsyth	15%	53%	43%	18%	7%	13%
Statewide	16%	51%	37%	15%	10%	12%

Source: <http://www.census.gov/quickfacts/table/US/PST045217> Latest Data 7/1/17 as of 7/17/18

* Excludes "White alone, not Hispanic or Latino"

** "Estimates are not comparable to other geographic levels due to methodology differences that may exist between different data sources. 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., V2017) refers to the final year of the series (2010 thru 2017). Different vintage years of estimates are not comparable."

The IPRO ESRD Network of the South Atlantic Network 6 (IPRO SA Network 6) consisting of North Carolina, South Carolina and Georgia, provides an Annual Report which includes aggregate ESRD patient data from all three states. The 2016 Annual Report does not provide state-specific ESRD patient data, but the aggregate data is

likely to be similar to North Carolina's based on the Network's recent annual reports which included state-specific data.

The IPRO SA Network 6 2016 Annual Report (pages 25-26¹) provides the following prevalence data on dialysis patients by age, race, and gender. As of December 31, 2016, over 85% of dialysis patients in Network 6 were 45 years of age and older, over 66% were other than Caucasian and 45% were female.

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 applicant adequately documents 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. 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.3, page 70, the applicant states:

*"The facility has no obligation to provide uncompensated care or community service. The facility will be accessible to minorities and handicapped persons as further described in **Section B**, **Section C**, and **Section L**, [emphasis in original] and strives to provide services to all patients with End Stage Renal Disease."*

In Section L.6, page 71, the applicant states that there have been no civil rights access complaints filed against the facility or any facilities owned by the parent company in North Carolina within the last five years.

¹ <https://network6.esrd.ipro.org/wp-content/uploads/sites/4/2017/07/NW6-2016-Annual-Report-FINAL.pdf>

The Agency reviewed the:

- Application
- Exhibits to the application

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.1, page 65, the applicant provides the projected payor mix during OY2, as illustrated below.

Miller Street Dialysis Center OY2	
Payment Category	Percent of Total Revenue
Medicare	9%
Medicaid	5%
Medicare/Medicaid	30%
Commercial	8%
Medicare / Commercial	23%
VA	4%
Medicare Advantage	21%
Total	100%

As shown in the table above, OY2, the applicant projects 83% of total services will be provided to Medicare patients (includes Medicare, Medicare/Commercial, Medicare Advantage and Medicare/Medicaid) and 5% to Medicaid patients. On pages 65-66, the applicant provides the assumptions and methodology used to project payor mix during OY2. The projected payor mix is reasonable and adequately supported because it is based on the historical utilization at MSDC.

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.

- (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 70, the applicant adequately describes 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.1, page 74, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit I-3 and Exhibit M-1.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the applicant adequately demonstrates 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 applicant proposes to add four dialysis stations for a total of 48 stations at MSDC upon completion of the project.

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.*” Thus, the service area for this facility consists of Forsyth County. Facilities may also serve residents of counties not included in their service area.

According to the January 2019 SDR, there are five providers of dialysis services in Forsyth County, as follows:

Forsyth County Dialysis Facilities

Dialysis Facility	Certified Stations as of 6/30/18	Percent Utilization	Patients Per Station
Miller Street Dialysis Center (WFUHS)	44	81.25%	3.2500
NC Baptist Hospital ESRD (WFUHS)	4	12.50%	0.5000
Northside Dialysis Center (WFUHS)	45	78.33%	3.1333
Piedmont Dialysis Center (WFUHS)	58	78.88%	3.1552
Salem Kidney Center (WFUHS)	39	94.23%	3.7692

Source: January 2019 SDR, Table B.

In Section N.1, page 75, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services. The applicant states:

“This project shall have no impact on competition in Forsyth County. Patients utilize a facility based upon physician preference, geographical location, or other reasons of convenience. An addition of stations at MSDC is necessary to serve the facility’s existing and projected patients and stave off excessive utilization.”

The applicant adequately describes 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 R 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 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 A.11, pages 5-6, the applicant identifies the kidney disease treatment centers located in North Carolina owned, operated, or managed by the applicant or a related entity. The applicant identifies a total of 18 WFUHS dialysis facilities located in North Carolina.

In Section O, pages 77-78, the applicant states that during the 18 months immediately preceding the submittal of the application, incidents related to quality of care occurred in five of the 18 facilities. The applicant states that at the time of application submittal, all facilities are in compliance. After reviewing and considering information provided by the applicant and considering the quality of care provided at all 18 facilities, the applicant provides 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 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- MSDC 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.

-C- In Section C, pages 23-26, the applicant demonstrates that MSDC will serve a total of 158 in-center patients at the end of OY 1 for a utilization rate of 82.3 or 3.29 patients per station per week ($158 \text{ patients} / 48 \text{ stations} = 3.29 / 4 = 0.823$ or 82.3%). The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

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

-C- In Section C, pages 23-26, the applicant provides the assumptions and methodology used to project utilization of the facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.