

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: May 23, 2017

Findings Date: May 23, 2017

Project Analyst: Celia C. Inman

Team Leader: Lisa Pittman

Project ID #: G-11302-17

Facility: Miller Street Dialysis Center of Wake Forest University

FID #: 070671

County: Forsyth

Applicants: Wake Forest University Health Sciences and  
Miller Street Dialysis Center of Wake Forest University

Project: Add 8 dialysis stations for a total of 44 certified dialysis stations upon project completion

### REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

Wake Forest University Health Sciences (WFUHS) and Miller Street Dialysis Center of Wake Forest University (MSDC), also referred to as “the applicants”, propose to add eight dialysis stations for a total of 44 dialysis stations at the existing MSDC facility upon project completion. MSDC is a 36-station dialysis center developed in 2008 at 120 Miller Street, Winston-Salem, Forsyth County.

**Need Determination**

The 2017 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 the January 2017 Semiannual Dialysis Report (SDR), the county need methodology shows there is a surplus of eight dialysis stations in Forsyth County. Therefore, the January 2017 SDR does not indicate a need for additional stations in Forsyth County based on the county need methodology, which states that the county deficit must be 10 or greater to establish a need for additional stations.

However, the applicants are eligible to apply for additional stations based on the facility need methodology because the utilization rate reported for MSDC in the January 2017 SDR is 3.81 patients per station. This utilization rate was calculated based on 137 in-center dialysis patients and 36 certified dialysis stations. (137 patients / 36 stations = 3.81 patients per station). The facility need methodology requires a facility's utilization rate in the latest SDR to be at least 3.2 patients per station 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.

**April 1 REVIEW-January 2017 SDR**

Required SDR Utilization		80.00%
Center Utilization Rate as of 6/30/16		95.14%
Certified Stations		36
Pending Stations		0
<b>Total Existing and Pending Stations</b>		<b>36</b>
In-Center Patients as of 6/30/16 (SDR2)		137
In-Center Patients as of 12/31/15 (SDR1)		133
Step	Description	
(i)	Difference (SDR2 - SDR1)	4
	Multiply the difference by 2 for the projected net in-center change	8
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 12/31/15	0.0602
(ii)	Divide the result of Step (i) by 12	0.0050
(iii)	Multiply the result of Step (ii) by 6	0.0301
(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	141.1203
(v)	Divide the result of Step (iv) by 3.2 patients per station	44.1001
	and subtract the number of certified and pending stations as recorded in SDR2 [# of stations] to determine the number of stations needed	<b>8.10</b>

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is 8 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 applicants propose to add eight stations. Therefore, the facility need determination for dialysis stations is applicable to this review.

In summary, the applicants are consistent with the facility need determination for dialysis stations.

### **Policies**

There is one policy in the 2017 SMFP that is applicable to this review, Policy GEN-3: Basic Principles. Policy GEN-3: Basic Principles, page 33 of the 2017SMFP, 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.4(a), pages 11-16, referencing other application sections with specific details; Section K.1(g), page 61; Sections N.1-2, pages 81-82; and referenced exhibits. 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.4(b), pages 16-21; and Section N.1, page 81. 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.4(c), page 21, referencing Sections F and K. 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 MSDC’s 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**

In summary, the applicants adequately demonstrate that the application is consistent with the facility need methodology in the January 2017 SDR and Policy GEN-3 and therefore is conforming to this criterion.

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

C

The applicants propose to add eight dialysis stations for a total of 44 dialysis stations at the existing MSDC facility upon project completion. MSDC is located at 120 Miller Street, Winston-Salem in Forsyth County. MSDC has no projects currently under development. The following table, summarized from page 4 of the application, illustrates the current and projected number of dialysis stations at MSDC.

<b>Stations</b>	<b>Description</b>	<b>Project ID #</b>
36	Total existing certified stations as of the January 2017 SDR	
+8	Stations to be added at MSDC as part of this project	G-11302-17
44	Total stations upon completion of proposed project	

**Patient Origin**

On page 373, the 2017 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.*” MSDC is located in Forsyth County; 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, the applicants provide a table showing the historical patient origin for in-center (IC), home hemodialysis (HH) and peritoneal dialysis (PD) patients served by MSDC.

**Historical Patient Origin  
 MSDC  
 As of December 31, 2016**

<b>County</b>	<b>IC</b>	<b>HH</b>	<b>PD</b>
Davidson	4	0	0
Forsyth	134	0	0
Guilford	1	0	0
Davie	3	0	0
Stokes	1	0	0
Surry	1	0	0
<b>Total</b>	<b>144</b>	<b>0</b>	<b>0</b>

As shown in the table above, MSDC does not provide HH training or PD.

In Section C.1, page 23, the applicants identify the in-center patient population proposed to be served for the first two years of operation following project completion on December 31, 2017, as summarized in the table below.

**Projected MSDC Patient Origin  
 By County of Residence**

<b>County</b>	<b>Operating Year 1 (OY1)</b>	<b>Operating Year 2 (OY2)</b>	<b>County Patients as % of Total</b>	
	<b>1/1/18-12/31/18</b>	<b>1/1/19-12/31/19</b>	<b>OY1</b>	<b>OY2</b>
Davidson	4.55	4.86	3.02%	3.15%
Forsyth	139.14	141.78	92.34%	91.95%
Guilford	1.08	1.12	0.72%	0.73%
Davie	3.82	4.31	2.53%	2.79%
Stokes	1.08	1.12	0.72%	0.73%
Surry	1.00	1.00	0.67%	0.65%
<b>Total</b>	<b>150.67</b>	<b>154.20</b>	<b>100.00%</b>	<b>100.00%</b>

Totals may not sum due to rounding

The applicants provide the assumptions and methodology for the above projected patient origin on pages 23-26 of the application. However, the totals in the tables on pages 25-26 are not summed correctly. The table above, as provided on page 23, contains the correct calculations for the projections.

The applicants adequately identify the population to be served.

**Analysis of Need**

The applicants propose to add eight dialysis stations to the existing MSDC facility in Forsyth County for a total of 44 certified dialysis stations upon project completion. In Section C.1, page 23, the applicants state the purpose of the proposed project is to:

*“... expand the existing services at MSDC on all patient shifts.”*

In Section C.2, page 25, the applicant states that the current utilization rate for MSDC, as of December 31, 2016, is 100.00%

In Section N.1, page 78, the applicants discuss the need for the additional stations at MSDC. The applicants state,

*“... An addition of stations at MSDC is necessary to serve the facility’s existing and projected patients and stave off excessive utilization. By approval of this project, MSDC will have the ability to continue serving its patient base during current operating hours keeping competition at its current level. Patients will be able to keep normal treatment schedules and experience no changes in transportation or other factors that could impact the overall cost-effectiveness, quality, and access to the proposed services.”*

**Projected Utilization**

In Section C.2, page 26, 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 (as provided above and on page 23 of the application). The following table illustrates the applicants’ projection of in-center dialysis patients at MSDC.

**MSDC Projected In-Center Dialysis Utilization**

County	January 2017 SDR 5-Yr AACR	Beginning Census 12/31/16	Growth until 12/31/2017	End of OY1 12/31/2018	End of OY2 12/31/19
Davidson	6.7%	4.00	4.27	4.55	4.86
Forsyth	1.90%	134.00	136.55	139.14	141.78
Guilford	4.00%	1.00	1.04	1.08	1.12
Davie	12.8%	3.00	3.38	3.82	4.31
Stokes	3.9%	1.00	1.04	1.08	1.12
Surry	-2.6%	1.00	1.00	1.00	1.00
<b>Totals*</b>		<b>133.00[144.00]</b>	<b>144[147.28]</b>	<b>147.28[150.67]</b>	<b>150.67[154.20]</b>

Totals may not sum due to rounding

\*The totals in the table are incorrect. The number of patients by County is entered correctly, but they are not summed correctly. The Project Analyst entered the correct totals above in [brackets].

As the table above shows, the methodology used by the applicant actually achieves a projection of 150.67 patients by the end of the first operating year, OY1, for a utilization rate of 86% (150.67 patients / 44 stations = 3.42 patients per station / 4 = 0.86). By the end of OY2, following the applicants' methodology and assumptions, MSDC will have 154 in-patients dialyzing at the center for a utilization rate of 88% (154.20 / 44 = 3.5 / 4 = 0.88). The projected utilization of 3.42 patients per station per week for OY1 satisfies the 3.2 in-center patients per station threshold as required by 10A NCAC 14C .2203(b).

In Sections C.1 and C.7, pages 23-24 and 29-30, respectively, the applicants provide the methodology and assumptions used to project utilization at MSDC. The project is based upon the facility need methodology. Based on the facility need methodology, MSDC is eligible to add as many as eight stations.

The applicants' methodology is summarized below:

- Group the December 31, 2016 beginning patient census of 144 by county of origin.
- Apply the January 2017 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.
- Project utilization based on existing patients at MSDC.

The applicants' assumptions are summarized below:

- Projected completion of the project under review is December 31, 2017; OY1 ends December 31, 2018; OY2 ends December 31, 2019.
- The 5-year AACR for each county as published in the January 2017 SDR will remain an accurate indicator of patient growth through OY2.
- Surry County patient population will continue to be one patient dialyzing at the center, regardless of the -2.6% AACR in the SDR.

Patient support letters are provided in Exhibit C-7. The applicants adequately demonstrate that projected utilization is based on reasonable and adequately supported assumptions regarding continued growth.

**Access**

In Section C.3, page 27, the applicants state:

*“MSDC accepts patients based on medically defined admission criteria. There is no discrimination based on race, sex, national origin nor disability. Services are available to all area residents with ESRD. Further, the facility also accepts the needy and the homeless, through its referral system, and assists those patients in obtaining the medical care they need.”*

Exhibit L-3(a) contains the facility’s Referral/Admissions Policy. The applicants project payor mix in Section L.1(b), page 67 as summarized below:

**Projected Payor Mix  
Project Year 2 (1/1/19 – 12/31/19)**

	<b>Percent of Total Patients</b>	<b>Percent of In-center Patients</b>
Private Pay	1%	1%
Medicare	8%	8%
Medicaid	6%	6%
Medicare / Medicaid	30%	30%
Commercial Insurance	8%	8%
Medicare / Commercial	25%	25%
VA	5%	5%
Medicare Advantage	17%	17%
<b>TOTAL</b>	<b>100%</b>	<b>100%</b>

Totals may not sum due to rounding.

In Section L.7, page 75, the applicants state that the projected payor mix is based upon the current five-year average annual payor mix.

The applicants adequately demonstrate the extent to which all residents of the area, including underserved groups, are likely to have access to the proposed services.

**Conclusion**

In summary, the applicants adequately identify the population to be served, demonstrate the need the population to be served has for the proposed services, based on reasonable and supported utilization projections and assumptions; and demonstrate the extent to which all residents of the area, including underserved groups, are likely to have access to the services. Therefore, the application is conforming to this criterion.

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

NA

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

CA

In Section E.1, pages 33-35, the applicants discuss the alternatives considered prior to submitting this application, which include:

- 1) Maintain the Status Quo – the applicants state that MSDC is currently (as of December 31, 2016) certified for 36 stations with 144 patients dialyzing for a utilization rate of 100%. The applicants further state that the projected patient population would have a utilization rate of 104.64% by December 31, 2018 ( $150.67 / 36 = 4.125 / 4 = 1.0464$ ). The applicants state that existing and projected in-center patients will soon fail to be adequately served without requiring a third shift. The applicants also state that utilization nearing and at greater than 100% leaves no margin in patient shift scheduling to accommodate additional needs, which may arise. Thus, the applicants state that maintaining the status quo is not a viable option.
- 2) Submit an application for an in-county relocation of stations – the applicants state that they considered relocating stations from Northside Dialysis Center, Salem Kidney Center and Piedmont Dialysis Center, all of which are WFUHS-owned facilities in Forsyth County. The applicants state that the chart on page 34 shows that none of those dialysis facilities has an adequate surplus of stations to relocate any without soon causing a need for additional stations at that location, which would require a CON and the associated expense; therefore, the applicants state, an in-county relocation of stations is not the least costly or most effective alternative at this time.
- 3) Submit an application for a contiguous county relocation of stations– Policy ESRD-2 allows for relocation of dialysis stations within the host county and to contiguous counties currently served by the facility when a station deficit is not created or increased in the county losing stations and a station surplus is not created or increased in the county gaining stations. WFUHS owns operational dialysis facilities in Davidson, Davie, Guilford, Stokes, Surry, and Yadkin

counties, which are contiguous to Forsyth County. However, Forsyth County has an 8-station surplus; therefore the applicants could not relocate stations from contiguous counties without increasing the surplus of stations in Forsyth County, which would not be compliant with Policy ESRD-2. Therefore this option is not viable.

- 4) Submit an application for additional stations based on the facility need methodology – the applicants state that the facility need methodology demonstrates that up to eight additional stations are needed at MSDC. The applicants state that adding stations, rather than relocating stations from an existing facility is the least costly, most effective alternative because CON applications would soon need to be filed to add stations to the facilities from which the stations were relocated. Thus, the applicants state that utilizing the facility need methodology is the best option to serve MSDC’s existing and projected patient population.

After considering the above alternatives, the applicants state that adding stations based on the facility need methodology is the most cost-effective alternative for this project.

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

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

- 1. 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. Wake Forest University Health Sciences and Miller Street Dialysis Center of Wake Forest University shall develop and operate no more than eight (8) additional dialysis stations for a total of 44 certified stations upon project completion, 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 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 the existing MSDC facility for a total of 44 certified dialysis stations upon project completion.

**Capital and Working Capital Costs**

In Section F.1, page 37, the applicants project the total capital cost of the proposed project will be \$140,000, including:

<b>Costs</b>	<b>Total Costs</b>
Dialysis Machines	\$ 116,000
Equipment/Furniture	\$ 24,000
<b>Total Capital Costs</b>	<b>\$ 140,000</b>

In Section F.10-13, pages 40-41, the applicants state there are no start-up or initial operating expenses for this project because MSDC is an existing dialysis facility.

**Availability of Funds**

In Section F.5, page 38, the applicants refer to Exhibit F-5 for a commitment letter of WFUHS funds and Exhibit F-7(a) for a copy of the most recent Wake Forest University consolidated balance sheet, which includes WFUHS. The Corporate Vice President’s commitment letter states, “*Wake Forest University Health Sciences commits to provide monies to its subordinates in order to fund project costs.*” Per the consolidated balance sheet, as of June 30, 2015, WFUHS had \$32,338,000 cash and cash equivalents, \$1,293,109,000 in total assets and \$466,836,000 in unrestricted net assets (total assets less total liabilities less restricted net assets). The applicants adequately demonstrate the availability of funds for the capital and operating needs of the project.

**Financial Feasibility**

In Section R, Form C, page 91, the applicants provide the allowable charge per treatment for each payment source for in-center dialysis patients. The revenue assumptions are provided in Section R, pages 91-93.

The applicants provide the following assumptions for patient treatments:

- Average annual patients per month calculations (pages 91-92)
- In-center treatments = patients x 3 treatments per week x 52 weeks (156 treatments per patient), reduced by 6% for missed treatments (147 treatments per patient) (page 92)

The applicants project revenues and summarize operating expenses in Section R, Form B, page 90 and summarized in the table below.

<b>Miller Street Dialysis Center</b>	<b>Operating Year 1 1/1/18-12/31/18</b>	<b>Operating Year 2 1/1/19-12/31/19</b>
Total Gross Revenue	\$ 38,374,713	\$ 39,404,907
Deductions from Gross, including Contractual Allowances, Charity Care and Bad Debt	32,324,671	33,146,342
Net Revenue	6,050,042	6,258,565
Total Operating Expenses	5,206,290	5,329,938
<b>Net Profit</b>	<b>\$ 843,752</b>	<b>\$ 928,627</b>

Totals may not sum due to rounding

As shown in the table above, the applicants project a positive net income in each of the first two operating years of the project. The assumptions used by the applicants 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 regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

The applicants adequately demonstrate that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

**Conclusion**

In summary, the applicants adequately demonstrate that sufficient funds will be available for the capital and operating needs of the project. Furthermore, the applicants adequately demonstrate that the financial feasibility of the proposal is based upon reasonable projections of costs and charges. Therefore, the application is conforming to this criterion.

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

C

On page 373, the 2017 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.”* MSDC is located in Forsyth County; thus, the service area for this facility consists of Forsyth County. Facilities may also serve residents of counties not included in their service area.

The applicants propose to add eight dialysis stations to the existing MSDC in Forsyth County. The January 2017 SDR indicates there are five dialysis facilities in Forsyth County, as shown below.

**Forsyth County Dialysis Facilities**

<b>Dialysis Facility</b>	<b>Certified Stations 6/30/16</b>	<b>In-Center Patients 6/30/16</b>	<b>Percent Utilization</b>	<b>Patients Per Station</b>
Miller Street Dialysis Center (WFUHS)	36	137	95.14%	3.8056
NC Baptist Hospital ESRD (WFUBMC)	4	1	6.25%	0.2500
Northside Dialysis Center (WFUHS)	45	129	71.67%	2.8667
Piedmont Dialysis Center (WFUHS)	58	150	64.66%	2.5862
Salem Kidney Center (WFUHS)	39	127	81.41%	3.2564

Source: January 2017 SDR, Table A.

WFUHS operates four Forsyth County dialysis centers. The only other provider of dialysis services in Forsyth County is the North Carolina Baptist Hospital (Wake Forest Baptist Medical Center), which operates four dialysis stations to provide dialysis services for its in-patients, as needed. As illustrated above, three of WFUHS’ four dialysis centers are operating above 70% utilization, with Piedmont Dialysis Center operating at 64.66%, per the January 2017 SDR, the most recently published SDR. In Section G.1, page 44, the applicants state that as of December 31, 2016, all four of the WFUHS facilities are operating above 70% utilization, with MSDC operating at 100% utilization. On page 45, the applicants further state:

*“MSDC’s need is real and immediate. MSDC does not project to serve patients currently served at other locations within Forsyth County. MSDC projects to serve its current patient population plus growth based upon the 5-year AACR projected for its current patient base by county of origin as outlined in the most recent (January 2017) SDR. Approval of this project will not result in duplication of existing and approved services in the proposed service area – Forsyth County.”*

The applicants adequately demonstrate the need for additional stations at MSDC based on the number of in-center patients it proposes to serve. The discussion on analysis of need found in Criterion (3) is incorporated herein by reference. The discussion on competition found in Criterion (18a) is incorporated herein by reference.

The applicants adequately demonstrate that the proposal will not result in the unnecessary duplication of existing or approved health service capabilities or facilities in Forsyth County. Consequently, the application is conforming to this criterion.

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

C

The applicants provide the current and proposed staffing in Section H.1, page 46, as summarized in the table below.

	<b>Current FTE Positions</b>	<b>FTE Positions to be added</b>	<b>Total Projected FTE Positions</b>	<b>Current Annual Salary / FTE</b>	<b>Projected Salary Yr 2 /FTE</b>
RN	8.375	0	8.375	\$65,183	\$71,227
LPN	4.125	0	4.125	\$48,011	\$52,463
Pt Care Technician	14.875	0	14.875	\$29,971	\$32,750
Clinical Nurse Manager	1.000	0	1.000	\$76,960	\$84,096
Dietician	1.000	0	1.000	\$54,725	\$59,800
Social Worker	1.000	0	1.000	\$59,280	\$64,777
Dialysis Tech	3.000	0	3.000	\$27,602	\$30,161
Biomed	1.000	0	1.000	\$53,019	\$57,935
Clerical	2.000	0	2.000	\$30,181	\$32,980
<b>Total FTE Positions</b>	<b>36.375</b>		<b>36.375</b>		

The Medical Director, Administration and Medical Records positions are contract positions and are not salaried employees.

In Sections H.2 and H.3, pages 47-51, the applicants describe MSDC’s staff positions and responsibilities, management’s experience, the process for recruiting and retaining staff, and staff training and continuing education. In Section I.3, page 56, the applicants state that Shahriar Moossavi, M.D. will continue to serve as the Medical Director for the facility. In Exhibit I-3(a), the applicants provide a letter signed by Dr. Moossavi confirming a commitment to continue to serve as Medical Director. Exhibit H-2 includes a copy of Dr. Moossavi’s curriculum vitae. In Section I.3(b), page 57, the applicants state that medical coverage is provided seven days per week and 24 hours a day by WFUHS physicians on a rotation basis or by local area nephrologists with privileges at the facility. Exhibit I-3(b) contains a list of referral physicians and physician letters of support.

The applicants demonstrate the availability of adequate health manpower and management personnel, including the Medical Director, for the provision of the proposed dialysis services. Therefore, the application is conforming to this criterion.

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

C

In Section I, pages 54-58, the applicants describe the necessary ancillary and support services and indicate how they will be provided. Exhibit I.2(a) contains a copy of the affiliation agreement between the facility and North Carolina Baptist Hospital. Exhibit I.2(b) contains a copy of the transplant agreement. Exhibit I.2(c) contains a copy of the home care agreement with Piedmont Dialysis Center. The applicants discuss coordination with the existing health care system on pages 56-58. Exhibit I.3(b) contains a list of referring physicians and physician support letters. The applicants adequately demonstrate that the necessary ancillary and support services will be available and that the proposed services will be coordinated with the existing health care system. The information in Section I and referenced Exhibits is reasonable and supports a finding of conformity with this criterion.

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

NA

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

NA

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

health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

NA

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

C

In Section L.1, page 66, the applicants state:

*“MSDC accepts patients based on medically defined admission criteria. There is no discrimination based on race, sex, national origin nor disability. Services are available to all area residents with ESRD. Further, the facility also accepts the needy and the homeless, through its referral system, and assists those patients in obtaining the medical care they need.”*

In Section L.3(b), page 69, the applicants further state that the admission of a patient is based upon medical necessity and not the patient's ability to pay. Exhibit L-3(a) contains a copy of MSDC's Referral/Admissions Policy.

In Section L.7, page 74, the applicants report that during the last full operating year, 88% of the patients who were receiving treatments at MSDC had some or all of their services paid for by Medicare or Medicaid in the past year. The following table illustrates the facility's historical payment sources.

**HISTORICAL PAYOR MIX  
 1/1/16-12/31/16**

	<b>Percent of Total Patients</b>	<b>Percent of IC Patients</b>
Private Pay	1%	1%
Medicare	9%	9%
Medicaid	3%	3%
Medicare / Medicaid	32%	32%
Commercial Insurance	8%	8%
Medicare / Commercial	22%	22%
VA	3%	3%
Medicare Advantage	22%	22%
<b>TOTAL</b>	<b>100%</b>	<b>100%</b>

Totals may not sum due to rounding.

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.

<b>Percent of Population</b>						
<b>County</b>	<b>% 65+</b>	<b>% Female</b>	<b>% Racial and Ethnic Minority*</b>	<b>% Persons in Poverty**</b>	<b>% &lt; Age 65 with a Disability</b>	<b>% &lt; Age 65 without Health Insurance**</b>
<b>2014 Estimate</b>	<b>2014 Estimate</b>	<b>2014 Estimate</b>	<b>2014 Estimate</b>	<b>2010-2014</b>	<b>2010-2014</b>	<b>2014 Estimate</b>
Forsyth	14%	53%	42%	20%	7%	17%
Statewide	15%	51%	36%	17%	10%	15%

Source: [http://www.census.gov/quickfacts/table\\_2014\\_Estimate\\_as\\_of\\_December\\_22\\_2015](http://www.census.gov/quickfacts/table_2014_Estimate_as_of_December_22_2015).

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

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

The IPRO ESRD Network of the South Atlantic Network 6 provides prevalence data on ESRD Network 6 dialysis patients by age, race, and gender on pages 27-28<sup>1</sup>. The ESRD Network 6 service area contract, previously managed by Alliant Healthcare Solutions' Southeastern Kidney Council, was awarded to IPRO in April 2016 and is now called the IPRO ESRD Network of the South Atlantic Network 6 (IPRO SA Network 6). IPRO SA Network 6 is still comprised of North Carolina, South Carolina and Georgia. The 2015 Annual Report, submitted in

<sup>1</sup> [http://esrd.ipro.org/wp-content/uploads/2016/11/2015\\_NW-6\\_Annual-Report\\_Final-Draft-with-COR-Changes-Submitted-11-29-2016.pdf](http://esrd.ipro.org/wp-content/uploads/2016/11/2015_NW-6_Annual-Report_Final-Draft-with-COR-Changes-Submitted-11-29-2016.pdf)

November 2016 by IPRO differs somewhat from the reports submitted in the past by The Southeastern Kidney Council.

The statistics on number and percent of dialysis patients by age, gender and race are now shown only in total for Network 6; the statistics are no longer separately shown for North Carolina in the report. However, a comparison of the *Southeastern Kidney Council Network 6 Inc. 2014 Annual Report*<sup>2</sup> percentages for North Carolina and the total Network shows very little variance; therefore the statistics for the total Network 6 are representative of North Carolina's statistics. One would also assume the 2015 percentages for the total Network 6 should also very closely reflect North Carolina percentages by age, gender and race. The following table shows the North Carolina and total Network 6 data for 2014 as provided by the Southeastern Kidney Council, and compared with the IPRO 2015 Network totals.

<b>Number and Percent of Dialysis Patients by Age, Race, and Gender 2014 and 2015</b>						
	<b>2014 Patients and Percentages*</b>				<b>2015 Patients and Percentages**</b>	
	<b>NC Patients</b>	<b>NC Percentage</b>	<b>Total Network 6 Patients</b>	<b>Total Network 6 Percentage</b>	<b>Total Network 6 Patients</b>	<b>Total Network 6 Percentage</b>
<b>Age</b>						
0-19	52	0.3%	137	0.3%	137	0.3%
20-34	770	4.8%	2,173	4.9%	2,142	4.7%
35-44	1,547	9.7%	4,385	9.9%	4,493	9.8%
45-54	2,853	17.8%	8,070	18.3%	8,422	18.3%
55-64	4,175	26.1%	11,706	26.5%	12,024	26.1%
65+	6,601	41.3%	17,716	40.1%	18,817	40.9%
<b>Gender</b>						
Female	7,064	44.2%	19,923	45.1%	20,805	45.2%
Male	8,934	55.8%	24,264	54.9%	25,230	54.8%
<b>Race</b>						
African-American	9,855	61.6%	29,191	66.1%	30,092	65.4%
White	5,778	36.1%	14,222	32.2%	15,049	32.7%
Other	365	2.3%	774	1.8%	894	1.9%

\*2014 Calendar Year data from the Southeastern Kidney Council Network 6 2014 annual Report at <http://esrd.ipro.org/wp-content/uploads/2016/06/2014-Network-6-Annual-Report-web.pdf>

\*\*2015 Calendar Year data from the IPRO ESRD Network of the South Atlantic at [http://esrd.ipro.org/wp-content/uploads/2016/11/2015\\_NW-6\\_Annual-Report\\_Final-Draft-with-COR-Changes-Submitted-11-29-2016.pdf](http://esrd.ipro.org/wp-content/uploads/2016/11/2015_NW-6_Annual-Report_Final-Draft-with-COR-Changes-Submitted-11-29-2016.pdf)

<sup>2</sup><http://esrd.ipro.org/wp-content/uploads/2016/06/2014-Network-6-Annual-Report-web.pdf>

In 2014, over 85% of dialysis patients in North Carolina were 45 years of age and older and over 63% were non-Caucasian comparing with 85% of Network 6 patients being 45 and over and 69% being non-Caucasian. (*Southeastern Kidney Council Network 6 Inc. 2014 Annual Report, page 59*). In 2015, over 85% of dialysis patients in Network 6 were 45 years of age and older and over 67% were non-Caucasian. (IPRO ESRD Network of the South Atlantic).

The applicants adequately demonstrate that MSDC currently provides access to medically underserved populations. Therefore, the application is conforming to this criterion.

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

C

In Section L.3(d) page 72, the applicants state:

*“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 73, the applicants state, *“There have been no civil rights or equal access complaints filed against the existing facility and/or any facilities owned by the parent company in North Carolina in the last five years.”*

The application is conforming to this criterion.

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

C

In Section L.1(b), page 67, the applicants provide the projected payor mix for the proposed services at MSDC, as shown below.

**Projected Payor Mix  
Project Year 2 (1/1/19 – 12/31/19)**

	<b>Percent of Total Patients</b>	<b>Percent of IC Patients</b>
Private Pay	1%	1%
Medicare	8%	8%
Medicaid	6%	6%
Medicare / Medicaid	30%	30%
Commercial Insurance	8%	8%
Medicare / Commercial	25%	25%
VA	5%	5%
Medicare Advantage	17%	17%
<b>TOTAL</b>	<b>100%</b>	<b>100%</b>

Totals may not sum due to rounding.

In Section L.7, page 75, the applicants state that the projected payor mix is based upon the current five-year average annual payor mix.

In Section L.1(a), page 67, the applicants state:

*“WFUHS and MSDC are committed to admitting and providing dialysis services to patients who have no insurance or other source of payment, but for whom payment for dialysis services will be made by another healthcare provider in an amount equal to the Medicare reimbursement rate for such services.”*

On page 67, the applicants report that MSDC expects 86% of the in-center patients who receive treatments at MSDC to have all or part of their services paid for by Medicare or Medicaid, as indicated above.

The applicants adequately demonstrate that medically underserved populations will have access to the proposed services. Therefore, the application is conforming to this criterion.

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

C

In Section L.4, page 72, the applicants state:

*“Patients desiring treatment at the facility receive consideration for admission by contacting the Nurse Administrator, Medical Director, or facility Social Worker. New patients may be referred by a personal physician. ... Admission to the facility must be by a nephrologist with admitting privileges to the facility and the patient must be certified as suffering from chronic, irreversible, End Stage Renal Disease (ESRD).”*

The applicants adequately demonstrate that MSDC will offer a range of means by which patients will have access to the proposed services. Therefore, the application is conforming to this criterion.

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

C

In Section M, page 77, the applicants state:

*“WFUHS dialysis units make every attempt to provide onsite educational experiences to local training programs in the area. ... Therefore, all WFUHS dialysis facilities will provide these experiences to not only health professional training programs in the area, but other applicable training programs as well.*

...

*The dialysis facilities of WFUHS pursue and participate in encouraging applicable training programs to utilize their facilities.”*

Exhibit M-1 contains a copy of the professional training agreement between the Forsyth Technical Community College and MSDC. The information provided in Section M and the referenced exhibit is reasonable and adequately supports a determination that the application is conforming to this criterion.

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

C

On page 373, the 2017 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.*” MSDC is located in Forsyth County; thus, the service area for this facility consists of Forsyth County. Facilities may also serve residents of counties not included in their service area.

The applicants propose to add eight dialysis stations to the existing MSDC in Forsyth County. The January 2017 SDR indicates there are five dialysis facilities in Forsyth County, as shown below.

**Forsyth County Dialysis Facilities**

<b>Dialysis Facility</b>	<b>Certified Stations 6/30/16</b>	<b>In-Center Patients 6/30/16</b>	<b>Percent Utilization</b>	<b>Patients Per Station</b>
Miller Street Dialysis Center (WFUHS)	36	137	95.14%	3.8056
NC Baptist Hospital ESRD (WFUBMC)	4	1	6.25%	0.2500
Northside Dialysis Center (WFUHS)	45	129	71.67%	2.8667
Piedmont Dialysis Center (WFUHS)	58	150	64.66%	2.5862
Salem Kidney Center (WFUHS)	39	127	81.41%	3.2564

Source: January 2017 SDR, Table A.

WFUHS operates four Forsyth County dialysis centers. The only other provider of dialysis services in Forsyth County is the North Carolina Baptist Hospital (Wake Forest Baptist Medical Center), which operates four dialysis stations to provide dialysis services for its in-patients, as needed. As illustrated above, three of WFUHS’ four dialysis centers are operating above 70% utilization, with Piedmont Dialysis Center operating at 64.66%, per the January 2017 SDR, the most recently published SDR. In Section G.1, page 44, the applicants state that as of December 31, 2016, all four of the WFUHS facilities are operating above 70% utilization, with MSDC operating at 100% utilization. On page 45, the applicants further state:

*“MSDC’s need is real and immediate. MSDC does not project to serve patients currently served at other locations within Forsyth County. MSDC projects to serve its current patient population plus growth based upon the 5-year AACR projected for its current patient base by county of origin as outlined in the most recent (January 2017) SDR. Approval of this project will not result in duplication of existing and approved services in the proposed service area – Forsyth County.”*

In Section N.1, page 78, the applicants discuss how any enhanced competition in the service area will promote cost-effectiveness, quality and access to the proposed services. The applicants state,

*“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. By approval of this project MSDC will have the ability to continue serving its patient based during current operating hours keeping competition at its current level. Patients will be able to keep normal treatment schedules and experience no changes in transportation or other factors that could impact the overall cost-effectiveness, quality, and access to the proposed services. However, if MSDC’s project is not approved and its facility utilization rate is allowed to rise above 100%, cost-effectiveness and access to services could be negatively impacted as patients will have to be scheduled for treatment at times that could reduce their access to transportation availability, which would increase the occurrence of missed treatments and have a detrimental effect on patient outcomes.”*

See also Sections C, E, F, G, H, L and P where the applicants discuss the impact of the project on cost-effectiveness, quality and access.

The information provided by the applicants in the sections referred to above is reasonable and adequately demonstrates that any enhanced competition in the service area includes a positive impact on cost-effectiveness, quality and access to the proposed services. This determination is based on the information in the application, and the following analysis:

- The applicants adequately demonstrate the need for the proposed project and that it is a cost-effective alternative. The discussions regarding analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.
- The applicants adequately demonstrate MSDC will continue to provide quality services. The discussions regarding quality found in Criteria (1) and (20) are incorporated herein by reference.
- The applicants demonstrate MSDC will continue to provide adequate access to medically underserved populations. The discussions regarding access found in Criteria (3) and (13) are incorporated herein by reference.

Therefore, the application is conforming to this criterion.

(19) Repealed effective July 1, 1987.

- (20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C

In Section A.11, pages 5-6, the applicants identify the 17 kidney disease treatment centers located in North Carolina, which are owned and operated by the applicants or an affiliated company.

In Section O.1, pages 83-85, the applicants refer to Section B.4(a) and Exhibit O-1 for MSDC's methods used to insure and maintain quality. In Section O.3(a), the applicants provide a list of the nine WFUHS dialysis facilities which were surveyed during the last 18 months. In Section O.3(b), pages 80-81, the applicants summarize the deficiencies cited: all nine facilities with standard level deficiencies and one with a complaint investigation. In Section O.3(c), page 81, the applicants further state: "*All facilities are now in compliance.*"

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

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

C

The application is conforming with all applicable Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200. The specific criteria are 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- MDSC 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.1, page 23, the applicants propose to serve 150.67 in-center patients on 44 dialysis stations at the end of Operating Year 1, which equates to a utilization rate of 86% (150.67 patients / 44 stations = 3.42 patients per station / 4 = 0.86). The projected utilization of 3.42 patients per station per week for OY1 satisfies the 3.2 in-center patients per station threshold as required by 10A NCAC 14C .2203(b).

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

-C- In Section C.1, pages 23-26, the applicants provide the methodology and assumptions used to project facility patient origin. The applicants summarize the methodology and assumptions for projecting utilization on pages 28-29, in response to Question C.7. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.