

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming
CA = Conditional
NC = Nonconforming
NA = Not Applicable

Decision Date: May 8, 2020
Findings Date: May 8, 2020

Project Analyst: Celia C. Inman
Co-Signer: Fatimah Wilson

Project ID #: F-11869-20
Facility: West Iredell Dialysis Center of Wake Forest University
FID #: 020759
County: Iredell
Applicant: Wake Forest University Health Sciences
West Iredell Dialysis Center of Wake Forest University
Project: Add no more than 4 dialysis stations pursuant to facility need for a total of no more than 24 stations upon project completion

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

Wake Forest University Health Sciences (WFUHS) and West Iredell Dialysis Center of Wake Forest University, collectively referred to as “the applicant”, proposes to add no more than four dialysis stations pursuant to facility need for a total of no more than 24 stations upon project completion.

Need Determination

Chapter 9 of the 2020 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 9D, page 170, the county need methodology shows there is no county need determination for additional dialysis stations in Iredell County.

However, the applicant is eligible to apply for additional dialysis stations in an existing facility pursuant to Condition 2 of the facility need methodology in the 2020 SMFP, if the utilization rate for the dialysis center, as reported in the 2020 SMFP, is at least 75% or 3.0 patients per station per week, as stated in Condition 2.a. The utilization rate reported for West Iredell Dialysis Center of Wake Forest University (WIDC) on page 157 of the 2020 SMFP, is 81.25% or 3.3 patients per station per week, based on 65 in-center dialysis patients and 20 certified dialysis stations [$65 / 20 = 3.25$; $3.25 / 4 = 0.8125$]. Therefore, the applicant exceeds the minimum utilization required in Condition 2.a. and is eligible to apply for additional stations based on the facility need methodology in Condition 2.b.

As shown in Table 9E, page 172 of the 2020 SMFP, based on the facility need methodology for dialysis stations, the potential number of stations needed at WIDC is six additional stations; thus, the applicant is eligible to apply to add up to six stations pursuant to the facility need methodology.

The applicant proposes to add no more than four new stations pursuant to facility need, which does not exceed the 2020 SMFP calculated facility need determination for six dialysis stations; therefore, the application is consistent with the facility need determination for dialysis stations.

Policies

There is one policy in the 2020 SMFP that is applicable to this review, Policy GEN-3: Basic Principles.

Policy GEN-3: Basic Principles, pages 30-31 of the 2020 SMFP, states:

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

Promote Safety and Quality – The applicant describes how it believes the proposed project would promote safety and quality in Section B.5(a), pages 14-18, referencing other application sections and exhibits with specific details. 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.5(b), pages 19-23, referencing other application sections and exhibits; and Section N, pages 73-74. 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 Section B.5(c), page 23, referencing Sections F and K; and in Section N, pages 73-75. 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. Therefore, the application is consistent with Policy GEN-3.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, and
- information publicly available during the review and used by the Agency.

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

- The applicant adequately demonstrates that the application is consistent with the facility need determination.
- The applicant adequately demonstrates that the application is consistent with Policy GEN-3, promoting safety and quality, equitable access, and maximizing healthcare value.

- (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 no more than four dialysis stations pursuant to facility need for a total of no more than 24 stations upon project completion.

The following table, summarized from data on page 8 of the application and page 157 of the 2020 SMFP, shows the projected number of stations at WIDC upon project completion.

WIDC		
Stations	Description	Project ID #
20	Total existing certified stations in the SMFP in effect on the day the review will begin	
+4	Stations to be added as part of this project (add four stations pursuant to facility need)	F-11869-20
24	Total stations upon completion of proposed project and previously approved projects	

Patient Origin

On page 113, the 2020 SMFP defines the service area for dialysis stations as “*the service area is the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service area: Cherokee-Clay-Graham counties and Avery-Mitchell-Yancey counties.*” The facility referred to in this application is in Iredell County. Thus, the service area for this application is Iredell County. Facilities may serve residents of counties not included in their service area.

In Section C.2, page 26, the applicant provides the historical in-center (IC), home hemodialysis (HH), and peritoneal dialysis (PD) patient origin for WIDC during the last full operating year, CY2019, as summarized in the following table:

County	In-Center		Home Hemodialysis		Peritoneal Dialysis	
	IC Patients	% of Total	HH Patients	% of Total	PD Patients	% of Total
Alexander	4.00	5.41%	0.00	0.00%	0.00	0.00%
Caldwell	1.00	1.35%	0.00	0.00%	0.00	0.00%
Catawba	7.00	9.46%	0.00	0.00%	0.00	0.00%
Iredell	62.00	83.78%	0.00	0.00%	0.00	0.00%
Total	74.00	100.00%	0.00	0.00%	0.00	0.00%

Totals may not sum due to rounding

As shown in the table above and stated on page 26 of the application, WIDC does not offer home hemodialysis training and support services.

In Section C.3, page 27, the applicant provides the projected IC, HH, and PD patient origin for WIDC for the second full operating year following project completion, January 1, 2022 – December 31, 2022 (CY2022), as summarized in the following table:

County	In-Center		Home Hemodialysis		Peritoneal Dialysis	
	IC Patients	% of Total	HH Patients	% of Total	PD Patients	% of Total
Alexander	4.78	5.83%	0.00	0.00%	0.00	0.00%
Caldwell	1.30	1.59%	0.00	0.00%	0.00	0.00%
Catawba	8.77	10.69%	0.00	0.00%	0.00	0.00%
Iredell	67.16	81.89%	0.00	0.00%	0.00	0.00%
Total	82.01	100.00%	0.00	0.00%	0.00	0.00%

Totals may not sum due to rounding

In Section C, page 27, the applicant provides the assumptions and methodology used to project WIDC’s patient origin. The applicant’s assumptions are reasonable and adequately supported.

Analysis of Need

In Section C.4, pages 28-30, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. The applicant discusses the need based on WIDC’s and Iredell County’s patient growth rate over the last year. The applicant states:

- WIDC’s patient population has increased by 13.85% since December 31, 2018. The applicant states that the patient base is extensive and growing at a rate considerably more than Iredell County. (page 28)
- WIDC is at 92.5% utilization, as of December 31, 2019. (page 28)
- The facility’s existing 20 stations will be utilized at approximately 99.03%, as of the end of 2021 and at more than 100% by the end of 2022, if no stations are added. (page 29)
- The additional four stations are needed to prevent facility utilization from rising above 100% and to preserve viable availability of services in Iredell and surrounding counties. (page 29)

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

- The applicant adequately demonstrates the need to add four dialysis stations pursuant to facility need.
- The applicant provides supporting documentation in Exhibit C-4.

Projected Utilization

In Section C, pages 33-34, the applicant describes its need methodology and assumptions for projected utilization for the existing facility, with the key elements summarized as follows:

- December 31, 2019 facility census was sorted by patient county of residence.
- The 2020 SMFP five-year Annual Average Change Rate (AACR) of 6.1%, 9.2%, 7.8%, and 2.7% was applied to Alexander, Caldwell, Catawba and Iredell counties' patient census, respectively.

The applicant applied the above assumptions and methodology in the table provided on page 33. The Agency's table below clearly summarizes the information on the applicant's table on page 33, showing the beginning in-center patient census for each county on December 31, 2019 and its projected growth, based on each county's five-year AACR, through the ending patient census on December 31, 2022.

WIDC	Alexander	Caldwell	Catawba	Iredell
Begin with the respective counties' in-center patients as of December 31, 2019. (page 28 of application)	4	1	7	62
County AACR per 2020 SMFP	6.1%	9.2%	7.8%	2.7%
Project the counties' patients forward one year using the respective county's AACR.	$4 \times 1.061 = 4.24$	$1 \times 1.092 = 1.09$	$7 \times 1.078 = 7.55$	$62 \times 1.027 = 63.67$
Sum the four counties' patients. This is the projected ending census December 31, 2020.	$4.24 + 1.09 + 7.55 + 63.67 = 76.56$			
Project the counties' patients forward one year using the respective county's AACR.	$4.24 \times 1.061 = 4.50$	$1.09 \times 1.092 = 1.19$	$7.55 \times 1.078 = 8.13$	$63.67 \times 1.027 = 65.39$
Sum the four counties' patients. This is the projected ending census December 31, 2021 (OY1).	$4.50 + 1.19 + 8.13 + 65.39 = 79.22$			
Project the counties' patients forward one year using the respective county's AACR	$4.5 \times 1.061 = 4.78$	$1.19 \times 1.092 = 1.30$	$8.13 \times 1.078 = 8.77$	$65.39 \times 1.027 = 67.16$
Sum the four counties' patients. This is the ending census as of December 31, 2022, (OY2).	$4.78 + 1.30 + 8.77 + 67.16 = 82.01$			

Totals may not sum due to rounding.

As the table above shows, using conventional rounding, the methodology used by the applicant achieves a projection of 79 in-center patients by the end of the first operating year, OY1 (CY2021), for a utilization rate of 3.3 patients per station per week or 82.5% ($79.22 \text{ patients} / 24 \text{ stations} = 3.3 \text{ patients per station} / 4 = 0.8252$). By the end of OY2 (CY2022), following the applicant's methodology and assumptions, WIDC will have 82 in-center patients dialyzing at the center for a utilization rate of 85.4% ($82.01 / 24 = 3.4 / 4 = .8542$). The projected utilization of 3.3 patients per station per week for CY2021 satisfies the 2.8 in-center patients per station threshold for the first year following completion of the project, as required by 10A NCAC 14C .2203(b).

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

- The applicant bases the beginning in-center patient census on existing WIDC patients.
- The applicant projects the growth of the Alexander, Caldwell, Catawba and Iredell county patient census using the Alexander, Caldwell, Catawba and Iredell county five-year AACR of 6.1%, 9.2%, 7.8%, and 2.7%, respectively, as reported in the 2020 SMFP.

Access

In Section C.7, pages 30-32, the applicant discusses access to services at WIDC. On pages 30-31, the applicant states:

“Admission of a patient is based solely upon medical necessity and not the patient’s ability to pay. Patients may only access the facility’s services via physician referral due to a diagnosis of ESRD. The majority of patients are covered by Medicare, Medicaid, or some other form or combination of healthcare coverage. The facility’s social worker assists patients in seeking out and obtaining coverage for their care when necessary. However, should a circumstance arise in which a patient is ineligible for healthcare coverage, that patient is not turned away due to a lack of ability to pay.”

Exhibits L-4(b) and L-5 contain the facility’s Charity/Reduced Cost Care and Referral/Admissions Policies, respectively. The applicant projects payor mix during the second full fiscal year of operation following completion of the project, as summarized in the following table from Section L.3, page 67.

**Projected Payor Mix
CY2022**

Payor Source	% of Total Patients	% of IC Patients	% of HH/PD Patients
Private Pay	1.0%	0.0%	0.0%
Medicare	13.0%	0.0%	0.0%
Medicaid	6.0%	0.0%	0.0%
Medicare / Medicaid	21.0%	0.0%	0.0%
Commercial Insurance	8.0%	0.0%	0.0%
Medicare / Commercial	32.0%	0.0%	0.0%
VA	4.0%	0.0%	0.0%
Medicare Advantage	15.0%	0.0%	0.0%
Total	100.0%	0.0%	0.0%

In Section L, page 67, the applicant provides the assumptions for projecting payor mix, stating that the total patients is the total average patients per month, as opposed to the total at year end. The monthly payor mix percentage is averaged to obtain the average annual payor mix percentages. The projected payor mix is reasonable and adequately supported.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, and
- 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 proposes to add dialysis stations pursuant to facility need. The project does not involve a reduction or elimination of a services or a relocation of a service.

- (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 no more than four dialysis stations pursuant to facility need for a total of no more than 24 stations upon project completion.

In Section E, pages 38-39, the applicant describes the alternatives considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the identified need. The alternatives considered were:

- Policy ESRD-2, Contiguous County Station Relocation – the applicant states that WFUHS has dialysis facilities in contiguous counties from which stations might be relocated pursuant to Policy ESRD-2. However, the 2020 SMFP shows Iredell County with a station surplus, which prevents a contiguous county relocation of stations. Thus, this alternative is not an effective alternative.
- Policy ESRD-2, Iredell County Station Relocation – the applicant states that WFUHS has two other dialysis facilities in Iredell County from which stations might be relocated pursuant to Policy ESRD-2; Statesville Dialysis Center (SDC) and Lake Norman Dialysis Center (LNDC). The applicant states that if either facility relocated stations to WIDC, its facility utilization rate would rise, requiring either or both to have a need to add back stations. Thus, this alternative is not an effective alternative.
- The project as proposed – the applicant states that the proposed project to add four stations pursuant to facility need will go far to address the rapid growth at WIDC, helping to assure that patient service needs are well met.

On page 39, the applicant states that the project, as proposed, will allow the facility to accept new dialysis patients and better serve its current patients.

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

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

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application.

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

- 1. Wake Forest University Health Sciences and West Iredell 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 2020 SMFP, Wake Forest University Health Sciences and West Iredell Dialysis Center of Wake Forest University shall add no more than four additional in-center**

dialysis stations for a total of no more than 24 in-center stations at West Iredell Dialysis Center of Wake Forest University upon completion of this project.

- 3. Wake Forest University Health Sciences and West Iredell 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 applicant proposes to add no more than four dialysis stations pursuant to facility need for a total of no more than 24 stations upon project completion.

Capital and Working Capital Costs

In Section Q Form F.1a Capital Cost, page 83, the applicant projects the total capital cost for the project as summarized below.

Projected Capital Costs	
	Total Costs
Medical Equipment	\$58,000
Non-Medical Equipment/Furniture	\$9,200
Total Capital Costs	\$67,200

The applicant provides the assumptions used to project the capital cost on in Section Q, page 83.

In Section F, page 42, the applicant shows that there will be no start-up or initial operating expenses because WIDC is an existing facility.

Availability of Funds

In Section F, page 40, the applicant states that the capital cost will be funded through owner's equity, as shown in the table below.

Sources of Capital Financing

Type	Wake Forest University Health Sciences
Loans	
Accumulated reserves or OE *	\$67,200
Bonds	
Other (Specify)	
Total Financing	\$67,200

In Exhibit F-2, the applicant provides a letter dated March 15, 2020, from the CEO Wake Forest Baptist Health, authorizing the project and committing to cover the development cost of the project.

Exhibit F-2 also contains pertinent pages from the Consolidated Financial Statements for Wake Forest University for the fiscal year ended June 30, 2019, showing WFUHS with \$19,175,000 in cash and cash equivalents, \$1.37 billion in total assets and \$807,739,000 in net equity.

The applicant adequately demonstrates the availability of funds for the capital and working capital needs of the project.

Financial Feasibility

The applicant provides pro forma financial statements for the first two full fiscal years of operation following completion of this project. In Section Q Form F-2 Income Statement, the applicant project that revenues will exceed operating expenses in the first two operating years of this project, as summarized in the table below.

West Iredell Dialysis Center Revenue and Expenses		
	CY2021	CY2022
In-Center Patients*	78	81
In-Center Treatments	11,700	12,150
Gross Patient Revenue	\$26,203,671	\$27,211,505
Adjustment from Gross**	\$22,386,365	\$23,247,379
Net Patient Revenue	\$3,817,306	\$3,964,126
Average Net Revenue per Treatment	\$326	\$326
Total Operating Expenses	\$3,297,010	\$3,416,055
Average Operating Expense per Treatment	\$282	\$281
Net Income	\$520,296	\$548,070

*Average patients per year = beginning + ending census / 2

**Includes charity care and bad debt

Totals may not sum due to rounding

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section Q of the application for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- application, and
- 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 availability of sufficient funds for the capital needs of the proposal.
 - The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.
- (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 no more than four dialysis stations pursuant to facility need for a total of no more than 24 stations upon project completion.

On page 113, the 2020 SMFP defines the service area dialysis stations as *“the service area is the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service area: Cherokee-Clay-Graham counties and Avery-Mitchell-Yancey counties.”* The facility referred to in this application is in Iredell County. Thus, the service area for this application is Iredell County. Facilities may serve residents of counties not included in their service area.

According to Table B, page 157 of the 2020 SMFP, there are three existing or approved dialysis facilities in Iredell County, all of which are owned and operated by WFUHS. Information on these dialysis facilities, from Table B of the 2020 SMFP, is provided below:

Iredell County Dialysis Facilities Certified Stations and Utilization as of December 31, 2018					
Dialysis Facility	Owner	# of Certified Stations	# of In-center Patients	Patients per Station per Week	Utilization
Lake Norman Dialysis Center of Wake Forest University	WFUHS	27	96	3.6	88.89%
Statesville Dialysis Center of Wake Forest University	WFUHS	27	75	2.8	69.44%
West Iredell Dialysis Center of Wake Forest University	WFUHS	20	65	3.3	81.25%

Source: 2020 SMFP, Table B

Lake Norman Dialysis Center of Wake Forest University has been approved for four additional stations

In Section G, pages 45-47, the applicant explains why it believes the proposal would not result in the unnecessary duplication of existing or approved dialysis services in Iredell County. The applicant lists a series of statements regarding Iredell County dialysis patients and the proposed addition of the stations prior to stating:

“It is the projected patient census by this project’s end of OY1 for which this CON must demonstrate utilization of 2.8 PPS according to the ESRD Performance Standards, thereby, proving the additional stations are “needed”[emphasis in original].”

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

- All three Iredell County dialysis facilities are currently operating at or above the ESRD performance standard of 2.8 patients per station per week.

- The applicant adequately demonstrates that WIDC will be operating above 2.8 patients per station per week in its projected utilization, which is based on historical patient utilization increased at the individual county growth rate.
- The applicant adequately demonstrates that the proposed addition of four stations is needed in addition to the existing and approved dialysis services in Iredell County.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, and
- information which was publicly available during the review and used by the Agency.

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

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

C

In Section Q Form H Staffing, page 95, the applicant provides the current and projected staffing in full-time equivalent (FTE) positions, as summarized in the following table.

POSITION	CURRENT FTE POSITIONS CY2019	PROJECTED FTE POSITIONS CY2020	PROJECTED FTE POSITIONS CY2021	PROJECTED FTE POSITIONS CY2022
RN	3.75	3.75	3.75	3.75
LPN	1.50	1.50	1.50	1.50
Patient Care Tech	7.00	7.50	7.50	7.75
Clinical Nurse Manager (DON)	1.00	1.00	1.00	1.00
Dietician	0.75	0.75	0.75	0.75
Social Worker	1.00	1.00	1.00	1.00
Dialysis Tech	1.00	1.00	1.00	1.00
Bio-med Technician	0.50	0.50	0.50	0.50
Clerical	1.00	1.00	1.00	1.00
Total	17.50	18.00	18.00	18.25

Source: Section Q Form H of the application.

The Medical Director and administrative services are contract and regional administration services, respectively, not FTE positions.

The assumptions and methodology used to project staffing are provided in Section Q, page 96. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in the pro forma financials found in Section Q. In Section H, pages 48-50, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. 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, and
- 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, pages 52-56, the applicant identifies the necessary ancillary and support services and explains how they will be made available. The applicant provides a table on page 52, as summarized below.

**West Iredell Dialysis Center
 Ancillary and Support Services**

Services	Provider
(a) In-center dialysis/maintenance	On Premises
(b) Self-care training (performed in-center)	On Premises
(c) Home training	
(1) Hemodialysis*	Statesville Dialysis Center (SDC)
(2) Peritoneal dialysis	SDC
(3) Accessible follow-up program	SDC
(4) Sister-Facility Agreement	SDC
(d) Psychological counseling	On Premises with appropriate referral after evaluation by MSW
(e) Isolation-hepatitis	On Premises
(f) Nutritional counseling	On Premises
(g) Social work services	On Premises
(h) Acute dialysis in an acute care setting	Wake Forest Baptist Hospital
(i) Emergency care	Wake Forest Baptist Hospital
(j) Blood bank services	Wake Forest Baptist Hospital
(k) Diagnostic and evaluation services	On Premises by Wake Forest Baptist Hospital
(l) X-ray services	Wake Forest Baptist Hospital
(m) Laboratory services	Wake Forest Baptist Hospital Meridian Lab Contract/On Premises
(n) Pediatric nephrology	On Premises by Wake Forest Baptist Hospital
(o) Vascular surgery	Wake Forest Baptist Hospital
(p) Transplantation services	Wake Forest Baptist Hospital
(q) Vocational rehabilitation counseling & services	On Premises with appropriate referral after evaluation by MSW
(r) Transportation	Iredell County Area Transit System

In Section I, pages 55-56, the applicant describes WIDC’s proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit I.

The applicant adequately demonstrates that the necessary ancillary and support services will be available and that the proposed services will be coordinated with the existing health care system.

Conclusion

The Agency reviewed the:

- application, and
- 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.

C

In Section K, page 59, the applicant states that the project will involve no new construction, but renovation of 600 square feet. The proposed floor plan is provided in Exhibit K-2(b).

On pages 59-60, the applicant adequately explains how the cost, design and means of construction represent a reasonable alternative for the proposal and provides supporting documentation in Exhibit K-2.

On page 60, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services.

On pages 60-61, the applicant discusses any applicable energy saving features that are/will be incorporated into the construction/renovation plans.

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

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

C

The applicant proposes to add no more than four dialysis stations pursuant to facility need for a total of no more than 24 stations upon project completion.

In Section L.1, page 64, the applicant provides the facility's historical payor mix for CY2019, as summarized in the table below.

Payor Source	Total Patients	In-center Patients	PD & HH Patients
Private Pay	1.0%	1.0%	0.0%
Medicare	13.0%	13.0%	0.0%
Medicaid	6.0%	6.0%	0.0%
Medicare / Medicaid	21.0%	21.0%	0.0%
Commercial Insurance	8.0%	8.0%	0.0%
Medicare / Commercial	32.0%	32.0%	0.0%
VA	4.0%	4.0%	0.0%
Medicare Advantage	15.0%	15.0%	0.0%
Total	100.0%	100.0%	0.0%

Totals may not sum due to rounding

In Section L.1(a), page 63, the applicant provides comparison of the demographical information on WIDC patients and the service area patients during the last full operating year, is summarized below.

	Percentage of Total WIDC Patients Served during the Last Full OY	Percentage of the Population of the Service Area Where the Stations are Located*
Female	38.0%	50.8%
Male	62.0%	49.2%
Unknown	N/A	N/A
64 and Younger	52.0%	84.1%
65 and Older	48.0%	15.9%
American Indian	0.0%	0.6%
Asian	0.0%	2.7%
Black or African-American	49.0%	12.3%
Native Hawaiian or Pacific Islander	0.0%	0.1%
White or Caucasian	42.0%	75.8%
Other Race	8.0%	7.8%
Declined / Unavailable	1.0%	2.0%

* The percentages can be found online using the United States Census Bureau's QuickFacts which is at: <https://www.census.gov/quickfacts/fact/table/US/PST045218>. Just enter in the name of the county.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, and
- information 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.2(a), page 64, the applicant states that while the facility is not required or obligated to provide uncompensated care or community service; but as a Medicare Participating Provider, it is at a minimum subject to Federal laws and regulations regarding equal access and non-discrimination.

On page 66, the applicant states there have been no civil rights access complaints filed against the facility within the last five years.

The Agency reviewed the:

- application, and
- 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.3, page 67, the applicant projects the following payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as summarized in the table below.

**Projected Payor Mix
CY2022**

Payor Source	Total Patients	IC Patients	PD & HH Patients
Private Pay	1.0%	1.0%	0.0%
Medicare	13.0%	13.0%	0.0%
Medicaid	6.0%	6.0%	0.0%
Medicare / Medicaid	21.0%	21.0%	0.0%
Commercial Insurance	8.0%	8.0%	0.0%
Medicare / Commercial	32.0%	32.0%	0.0%
VA	4.0%	4.0%	0.0%
Medicare Advantage	15.0%	15.0%	0.0%
Total	100.0%	100.0%	0.0%

Source: Application page 67

As shown in the table above, during the second full calendar year of operation, the applicant projects that 1% of the dialysis patients will be private pay patients and 87% will have all or part of their services paid for by Medicare and/or Medicaid.

On page 67, the applicant provides the assumptions and methodology used to project payor mix during the first and second fiscal full years of operation following completion of the project. The projected payor mix is reasonable and adequately supported for the following reasons:

- the applicant's proposed patient origin is based on the historical WIDC payor mix, and
- the monthly ending payor mix percentage by payor type for the last 12 months is averaged to obtain the average annual payor mix.

The Agency reviewed the:

- application, and
- exhibits to the application.

Based on that review, the Agency concludes that the application is conforming to this criterion.

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

C

In Section L.5, pages 70-71, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- application, and
- exhibits to the application.

Based on that review, the Agency concludes that the application is conforming to this criterion.

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

C

In Section M, page 72, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides documentation in Exhibit M-1.

The Agency reviewed the:

- application, and
- 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 no more than four dialysis stations pursuant to facility need for a total of no more than 24 stations upon project completion.

On page 113, the 2020 SMFP defines the service area for dialysis stations as “the service area is the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service area: Cherokee-Clay-Graham counties and Avery-Mitchell-Yancey counties.” The facility referred to in this application is in Iredell County. Thus, the service area for this application is Iredell County. Facilities may serve residents of counties not included in their service area.

According to Table B, page 157 of the 2020 SMFP, there are three existing or approved dialysis facilities in Iredell County, all of which are owned and operated by WFUHS. Information on these dialysis facilities, from Table B of the 2020 SMFP, is provided below:

Iredell County Dialysis Facilities Certified Stations and Utilization as of December 31, 2018					
Dialysis Facility	Owner	# of Certified Stations	# of In-center Patients	Patients per Station per Week	Utilization
Lake Norman Dialysis Center of Wake Forest University	WFUHS	27	96	3.6	88.89%
Statesville Dialysis Center of Wake Forest University	WFUHS	27	75	2.8	69.44%
West Iredell Dialysis Center of Wake Forest University	WFUHS	20	65	3.3	81.25%

Source: 2020 SMFP, Table B

Lake Norman Dialysis Center of Wake Forest University has been approved for four additional stations

Regarding the expected effects of the proposal on competition in the service area, in Section N, pages 73-75, the applicant states that it does not expect the addition of stations to have any effect on the competitive climate in Iredell County. The applicant does not project to serve dialysis patients currently being served by another provider. On page 73, the applicant further states:

“While this project will increase the number of dialysis stations at WIDC and within Iredell County, utilization of those stations is based upon the projected growth of the existing patient base from physician referrals within the network of physicians who routinely refer patients to WIDC. WIDC does not project to capture market share from competitors, it merely projects to serve its proportional market share of the market in which it currently operates.”

Regarding the impact of the proposal on cost effectiveness, in Section N, page 73, the applicant states:

“As demonstrated in the pro forma [sic] the cost of the service is not projected to dramatically increase, while the billable charge per treatment remains constant over all periods. Development of this project is cost-effective.”

Regarding the impact of the proposal on quality, in Section N, page 74, the applicant states:

“Service quality will remain of the highest standard.”

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 74, the applicant states:

“Access to service is based upon a diagnosis of ESRD and appropriate referral. All patients have equal access regardless of their gender, age, race, ethnicity, nor[sic] ability to pay. Expansion of health service resources at WIDC will expand access of services to all ESRD patients.”

Considering all the information in the application, the applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would be a positive impact on:

- Cost-effectiveness (see Sections B, C, F, N and Q of the application and any exhibits).
- Quality (see Sections B, C, N and O of the application and any exhibits).
- Access to medically underserved groups (see Sections B, C, D, L and N of the application and any exhibits).

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, and
- 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 Q Form A, page 80, the applicant identifies the dialysis facilities located in North Carolina and owned, operated or managed by the applicant or a related entity. The applicant identifies a total of 19 WFUHS dialysis facilities located in North Carolina, including North Davidson Dialysis Center, which was not yet operational.

In Section O, page 77, the applicant provides a table showing that 13 of the 18 operational WFUHS dialysis facilities were surveyed within the last 18-month look-back period. During the 18 months immediately preceding the submittal of the application, one or more incidents related to quality of care occurred in 11 of the 13 facilities surveyed. These incidents were issued standard level deficiencies (not resulting in immediate jeopardy) and the table on page 77 shows that the facilities that were back in compliance at the time of application submittal. After reviewing and considering information provided by the applicant and considering the quality of care provided at all 18 operational 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 application is conforming with all applicable Criteria and Standards for End-Stage Renal Disease Services. The specific criteria are discussed below.

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

10A NCAC 14C .2203 PERFORMANCE STANDARDS

- (a) An applicant proposing to establish a new kidney disease treatment center or dialysis facility shall document the need for at least 10 dialysis stations based on utilization of 2.8 in-center patients per station per week as of the end of the first 12 months of operation following certification of the facility. An applicant may document the need

for less than 10 stations if the application is submitted in response to an adjusted need determination in the State Medical Facilities Plan for less than 10 stations.

- NA- The applicant is not proposing to establish a new ESRD facility.

- (b) An applicant proposing to increase the number of dialysis stations in:
 - (1) an existing dialysis facility; or
 - (2) a dialysis facility that is not operational as of the date the certificate of need application is submitted but has been issued a certificate of need; shall document the need for the total number of dialysis stations in the facility based on 2.8 in-center patients per station per week as of the end of the first 12 months of operation following certification of the additional stations.

- C- In Section C, page 33, the utilization methodology proposed by the applicant achieves a projection of 79.22 in-center patients by the end of the first operating year, CY2021, for a utilization rate of 3.3 in-center patients per station per week or 82.5% ($79.22 \text{ patients} / 24 \text{ stations} = 3.3 \text{ patients per station} / 4 = 0.8252$). The projected utilization of 3.3 patients per station per week exceeds the 2.8 in-center patients per station per week threshold in the first full year following project completion, as required by 10A NCAC 14C .2203(a).

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

- C- In Section C, pages 33-34, the applicant provides the assumptions and methodology used to project utilization of the facility.