

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: March 24, 2020

Findings Date: March 24, 2020

Project Analyst: Celia C. Inman

Co-Signer: Fatimah Wilson

Project ID #: G-11844-20

Facility: North Davidson Dialysis Center of Wake Forest University

FID #: 200036

County: Davidson

Applicant: Wake Forest University Health Sciences

Project: North Davidson Dialysis Center of Wake Forest University

Develop a new 12-station dialysis facility by relocating no more than 12 in-center and home hemodialysis stations from Thomasville Dialysis Center

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

Wake Forest University Health Sciences (WFUHS) and North Davidson Dialysis Center of Wake Forest University, collectively referred to as “the applicant”, proposes to develop a new 12-station dialysis facility, North Davidson Dialysis Center of Wake Forest University (NDDC), in northern Davidson County by relocating no more than 12 stations from Thomasville Dialysis Center (TVDC) in Davidson County, pursuant to Policy ESRD-2.

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 Davidson County. The applicant is proposing to develop a new facility; therefore, the facility need methodology does not apply to this proposal. Therefore, neither of the two need determination methodologies in the 2020 SMFP apply to this proposal.

Policies

There are two policies in the 2020 SMFP that are applicable to this review, Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities and Policy ESRD-2: Relocation of Dialysis Stations.

Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities on page 31 of the 2020 SMFP states:

“Any person proposing a capital expenditure greater than \$2 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178 shall include in its certificate of need application a written statement describing the project’s plan to assure improved energy efficiency and water conservation.

In approving a certificate of need proposing an expenditure greater than \$5 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178, Certificate of Need shall impose a condition requiring the applicant to develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. The plan must be consistent with the applicant’s representation in the written statement as described in paragraph one of Policy GEN-4.

Any person awarded a certificate of need for a project or an exemption from review pursuant to G.S. 131E-184 are required to submit a plan of energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation. The plan must be consistent with the applicant’s representation in the written statement as described in paragraph one of Policy GEN-4. The plan shall not adversely affect patient or resident health, safety or infection control.”

The proposed capital expenditure for this project is greater than \$2 million, but less than \$5 million; therefore, Policy GEN-4 is applicable to this review. In Section B.6, page 15, the applicant refers to Exhibit B-6, which provides the architect’s written commitment to providing energy efficient lighting, building materials, HVAC

equipment and water conservation equipment in its construction design. Therefore, the application is consistent with Policy GEN-4.

Policy ESRD-2: Relocation of Dialysis Stations, on page 20 of the 2020 SMFP, states:

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

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

The applicant proposes to relocate existing dialysis stations within Davidson County, pursuant to Policy ESRD-2. Therefore, the application is consistent with Policy ESRD-2.

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:

- Neither the county nor facility need methodology is applicable to this review.
- The applicant adequately demonstrates that the application includes a written statement describing the project’s plan to assure improved energy efficiency and water conservation.
- The applicant adequately demonstrates that the application is consistent with Policy ESRD-2 because the proposal does not change the dialysis station inventory in Davidson County.

- (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 develop NDDC, a new 12-station dialysis facility in northern Davidson County, by relocating no more than 12 certified dialysis stations from TVDC in Davidson County, pursuant to Policy ESRD-2. TVDC will be certified for 23 stations upon completion of this project and Project ID #G-11651-19 (relocate no more than 3 stations for a total of 35)

The following table, summarized from data on page 8 of the application, shows the projected number of stations at NDDC upon project completion.

NDDC		
Stations	Description	Project ID #
0	Total existing certified stations in the SMFP in effect on the day the review will begin	
+12	Stations to be added as part of this project (develop new 12-station facility)	G-11844-20
12	Total stations upon completion of proposed project and previously approved projects	

The following table, summarized from information in Table 9B of the 2020 SMFP and the application under review, illustrates the current and projected number of dialysis stations at TVDC upon completion of this project and Project ID #G-11651-19 (relocate no more than 3 stations for a total of 35).

TVDC		
Stations	Description	Project ID #
32	Total existing certified stations in the SMFP in effect on the day the review will begin	
+3	Stations previously approved to be added but not yet certified	G-11651-19
-12	Stations to be deleted as part of this project (develop new 12-station facility by relocating 12 stations from TVDC)	G-11844-20
23	Total stations upon completion of proposed project and previously approved projects	

Patient Origin

On page 113, the 2020 SMFP defines the service area for the county need methodology 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.*” Both facilities referred to in this application are located in Davidson County. Thus, the service area for this application is Davidson County. Facilities may serve residents of counties not included in their service area.

This proposal is to develop NDDC, a new 12-station dialysis facility in Davidson County; therefore, there is no historical utilization data.

In Section C.3, page 17, the applicant provides the projected in-center (IC), home hemodialysis (HH), and peritoneal dialysis (PD) patient origin for NDDC for the second full operating year following project completion, January 1, 2024 – December 31, 2024 (CY2024), 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
Davidson	24.58	65.22%	0.00	0.00%	5.59	63.03%
Forsyth	13.10	34.78%	0.00	0.00%	3.28	36.97%
Total	37.68	100.00%	0.00	0.00%	8.86	100.00%

Totals may not sum due to rounding

On page 22, the applicant states that it will offer home hemodialysis training and support services at the proposed facility but does not project serving any specific number of HH patients upon facility development “*due to the overall low numbers of patients on that modality.*”

In Section C, pages 18-19, the applicant provides the assumptions, methodology, and support documentation used to project NDDC’s patient origin. The applicant’s assumptions are reasonable and adequately supported.

Analysis of Need

In Section C.4, pages 19-22, 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 the following:

- Growth in the Davidson County patient population over the last five years, which could cause a shortage of seven dialysis stations in the next two years and 12 dialysis stations in the next three years, based on the 2020 SMFP. (page 19)
- The existing Wake Forest University Thomasville and Lexington dialysis facilities are reaching physical plant capacity with 2019 utilization of 86% and 72%,

respectively; future patients will require the development of a new facility. (page 20-21)

- The lack of convenient dialysis services available close to a large number of WFUHS dialysis patients' homes in Northern Davidson County and southern Forsyth County who would benefit if a new dialysis center was developed in northern Davidson County. (page 20)
- The identification of more than 40 WFUHS Davidson County ESRD resident patients and more than 100 WFUHS Forsyth County ESRD resident patients residing within a 15-minute drive-time radius of the proposed facility. (page 21)
- *“Given the patient maps referenced, above, the future projections for the need for dialysis services in Davidson County, the lack of future plant capacity at the existing Davidson County dialysis facilities, and the ability of TVDC to add back the proposed transfer [relocated] stations in conjunction with the development of this project, clearly, the project as proposed is both warranted and necessary to prevent a shortfall of healthcare availability in the projected service area.” (page 22)*

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

- The applicant demonstrates the need to develop a new dialysis facility to better serve WFUHS dialysis patients in northern Davidson County and southern Forsyth County by relocating existing dialysis stations consistent with Policy ESRD-2.
- The two existing Davidson County facilities are operating at 82.43% and 72.66% capacity per the 2020 SMFP.
- The applicant provides supporting documentation in Exhibit C-4 and Exhibit H-4.

Projected Utilization

In-Center Patients

In Section Q, pages 84-85, the applicant describes its need methodology and assumptions for projected utilization for the proposed facility summarized as follows:

- Beginning census on January 1, 2023 is composed of patients from WFUHS facilities that live nearer to the proposed facility who have indicated a desire to transfer their care to the new facility upon certification: 22 Davidson County resident ESRD patients and 12 Forsyth County resident ESRD patients.
- The applicant uses the 2020 SMFP Five-Year Annual Average Change Rate (AACR) of 5.7% and 4.5% for Davidson and Forsyth county patient utilization growth, respectively.

The Agency's table below summarizes the beginning in-center patient census on January 1, 2023 and its growth through the ending patient census on December 31, 2024.

NDDC In-Center Utilization	Davidson	Forsyth
Begin with the Davidson and Forsyth county in-center patients as of January 1, 2023.	22	12
Project the Davidson and Forsyth county patients forward to December 31, 2023 using the Davidson County AACR of 5.7% and the Forsyth County AACR of 4.5%.	$22 \times 1.057 = 23.25$	$12 \times 1.045 = 12.54$
Sum the Davidson and Forsyth county patients. This is the projected ending census December 31, 2023 (OY1).	$23.25 + 12.54 = 35.79$	
Project the Davidson and Forsyth county in-center patients forward one year to December 31, 2024 using the applicable AACR.	$23.25 \times 1.057 = 24.58$	$12.54 \times 1.045 = 13.10$
Sum the Davidson and Forsyth county patients. This is the ending census as of December 31, 2024, (OY2).	$24.58 + 13.10 = 37.68$	

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 36 in-center patients by the end of the first operating year, OY1 (CY2023), for a utilization rate of 3.0 patients per station per week or 75% (36 patients / 12 stations = 3.0 patients per station / 4 = 0.7500). By the end of OY2 (CY2024), following the applicant’s methodology and assumptions, NDDC will have 38 in-center patients dialyzing at the center for a utilization rate of 79.2% (38 / 12 = 3.16 / 4 = .7917). The projected utilization of 3.0 patients per station per week for CY2023 satisfies the 2.8 in-center patients per station threshold 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 WFUHS patients living relatively near the proposed facility, who have expressed a desire to transfer their care to the proposed facility.
- The applicant projects the growth of the Davidson and Forsyth county patient census using the Davidson and Forsyth county Five-Year AACR of 5.7 percent and 4.5 percent, respectively, as reported in the 2020 SMFP.

Home Hemodialysis and Peritoneal Patients

Following the same assumptions and methodology as above, the applicant projects beginning services with five Davidson County PD patients and three Forsyth County PD patients who live near the proposed facility. The applicant applies the Davidson and Forsyth county Five-Year AACR of 5.7 percent and 4.5 percent, respectively, as reported in the 2020 SMFP to grow its PD utilization, resulting in the following table produced by the Agency.

NDDC PD Utilization	Davidson	Forsyth
Begin with the Davidson and Forsyth county PD patients as of January 1, 2023.	5	3
Project the Davidson and Forsyth county patients forward to December 31, 2023 using the Davidson County AACR of 5.7% and the Forsyth County AACR of 4.5%.	$5 \times 1.057 = 5.27$	$3 \times 1.045 = 3.14$
Sum the Davidson and Forsyth county patients. This is the projected ending census December 31, 2023 (OY1).	$5.27 + 3.14 = 8.41$	
Project the Davidson and Forsyth county PD patients forward one year to December 31, 2024 using the applicable AACR.	$5.27 \times 1.057 = 5.57$	$3.14 \times 1.045 = 3.28$
Sum the Davidson and Forsyth county patients. This is the ending census as of December 31, 2024, (OY2).	$5.57 + 3.28 = 8.85$	

Totals may not sum due to rounding.

As the table above shows, using conventional rounding, the applicant projects serving eight PD patients in CY2023 and nine PD patients in CY2024.

On page 22, the applicant states that it will offer home hemodialysis training and support services at the proposed facility but does not project serving any specific number of HH patients upon facility development “*due to the overall low numbers of patients on that modality.*”

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

- The applicant bases the beginning PD patient census on existing WFUHS patients living relatively near the proposed facility, who have expressed a desire to transfer their care to the proposed facility.
- The applicant projects the growth of the Davidson and Forsyth county patient census using the Davidson and Forsyth county Five-Year AACR of 5.7 percent and 4.5 percent, respectively, as reported in the 2020 SMFP.

Access

In Section C.7, pages 25-26, 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(b), page 70.

**Projected Payor Mix
CY2024**

Payor Source	% of Total Patients	% of IC Patients	% of HH/PD Patients
Private Pay	0.0%	0.0%	0.0%
Medicare	12.0%	12.0%	9.0%
Medicaid	5.0%	5.0%	3.0%
Medicare / Medicaid	22.0%	23.0%	14.0%
Commercial Insurance	10.0%	9.0%	20.0%
Medicare / Commercial	25.0%	25.0%	30.0%
VA	4.0%	4.0%	4.0%
Medicare Advantage	22.0%	22.0%	20.0%
Total	100.0%	100.0%	100.0%

In Section L, pages 70-71, the applicant provides the assumptions for projecting payor mix, stating that the projected payor mix is based upon the WFUHS system-wide five-year average annual payor mix. 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.

C

The applicant proposes to develop NDDC, a new 12-station dialysis facility in northern Davidson County, by relocating no more than 12 stations from TVDC in Davidson County, pursuant to Policy ESRD-2. TVDC will be certified for 23 stations upon completion of this project and Project ID #G-11651-19 (relocate no more than 3 stations for a total of 35).

In Section D, pages 31-35, the applicant explains why it believes the needs of the population presently utilizing the services to be relocated will be adequately met following completion of the project. On page 33, the applicant provides a table which shows projected TVDC utilization, assuming the relocation of 12 stations to NDDC, plus the three CON-approved stations from Project ID #G-11651-19, and the planned addition of 12 stations in 2021 based on anticipated facility need, for a total of 35 stations. The table includes the transfer of four patients from TVDC to NDDC at the end of CY2022 and provides the justification for the additional stations. TVDC is projected to have a utilization rate of 3.6 patients per station per week or 89.3% ($125 \text{ patients} / 35 \text{ stations} = 3.57 / 4 = .8928$) at that time, which is above the required 2.8 patients per station per week. The applicant states that the population presently served at TVDC will continue to have their needs adequately met by the remaining and proposed addition of dialysis stations.

In Section D.3, page 35, the applicant states:

“The relocation of stations to NDDC in northern Davidson County in conjunction with an add back of stations to TVDC will increase the overall availability of convenient dialysis services in Davidson County. The end result will be an increase in the availability of healthcare to the underserved groups who make up more than 80% of all patients served by TVDC and more than 80% of the projected patients who will be served by NDDC.”

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 needs of the population currently using the services to be relocated will be adequately met following project completion.
- The project will not adversely impact the ability of underserved groups to access these services following project completion.

- (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 develop NDDC, a new 12-station dialysis facility in northern Davidson County, by relocating no more than 12 stations from TVDC in Davidson County, pursuant to Policy ESRD-2. TVDC will be certified for 23 stations upon completion of this project and Project ID #G-11651-19 (relocate no more than 3 stations for a total of 35).

In Section E, pages 37-39, 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 Davidson County with a station surplus, which prevents a contiguous county relocation of stations. Thus, this alternative is not an effective alternative.

- Add stations to the existing Davidson County facilities using the Facility Need Methodology – the applicant states that based on the utilization of the two existing Davidson County facilities, no more than two stations could be added in 2020 with one more station added in 2021. Thus, this is not a viable alternative.
- The project as proposed – the applicant states that the proposed project to relocate 12 stations from TVDC to develop the new facility in northern Davidson County along with applying to add back the stations at TVDC will improve overall access to the ESRD patients in the service area.

On page 39, the applicant states that the project, as proposed, is the most effective alternative because it will primarily serve Davidson County patients not currently served within Davidson County.

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 North Davidson Dialysis Center of Wake Forest University shall materially comply with all representations made in the certificate of need application.**
- 2. Pursuant to Policy ESRD-2, Wake Forest University Health Sciences and North Davidson Dialysis Center of Wake Forest University shall develop a new kidney disease treatment center to be known as North Davidson Dialysis Center of Wake Forest University by relocating no more than 12 in-center and home hemodialysis stations from Thomasville Dialysis Center of Wake Forest University.**
- 3. Upon completion of this project, Wake Forest University Health Sciences shall take the necessary steps to decertify 12 stations at Thomasville**

Dialysis Center for a total of no more than 23 in-center and home hemodialysis stations upon completion of this project and Project ID #G-11651-19.

- 4. Wake Forest University Health Sciences and North Davidson Dialysis Center of Wake Forest University shall install plumbing and electrical wiring through the walls for no more than 12 in-center and home hemodialysis stations.**
 - 5. Wake Forest University Health Sciences and North Davidson 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 develop NDDC, a new 12-station dialysis facility in northern Davidson County, by relocating no more than 12 stations from TVDC in Davidson County, pursuant to Policy ESRD-2.

Capital and Working Capital Costs

In Section Q Form F.1a Capital Cost, page 90, the applicant projects the total capital cost for the project as summarized below.

Projected Capital Costs	
	Total Costs
Site Costs	\$328,700
Construction Costs	\$3,650,000
Architect Fees	\$47,500
Non-Medical Equipment/Furniture	\$338,207
Total Capital Costs	\$4,364,407

The applicant provides the assumptions used to project the capital cost on in Section Q, page 90.

In Section F, page 43-44, the applicant states that the start-up costs, such as staff training, will be incurred by the WFUHS facilities currently serving patients who will transfer to NDDC upon certification; thus, NDDC will not incur start up cost. The applicant projects initial operating expenses will be \$300,000.

Availability of Funds

In Section F, pages 41 and 45, the applicant states that the capital and working capital cost, respectively, will be funded by Wake Forest University Health Sciences, as shown in the tables below.

Sources of Capital Financing

Type	Wake Forest University Health Sciences
Loans	
Accumulated reserves or OE *	\$4,364,407
Bonds	
Other (Specify)	
Total Financing	\$4,364,407

* OE = Owner's Equity

Sources of Working Capital Financing

Type	Wake Forest University Health Sciences
Loans	
Accumulated reserves or OE *	\$300,000
Bonds	
Other (Specify)	
Total Financing	\$300,000

* OE = Owner's Equity

In Exhibit F-1(c), the applicant provides a construction cost estimate letter dated January 9, 2020 from the WFUHS Project Director documenting the \$3,650,000 in construction cost. In Exhibit F-2, the applicant provides a letter dated January 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-4 Financial Feasibility, the applicant project that revenues will exceed operating expenses in the first two operating years of this project, as summarized in the table below.

North Davidson Dialysis Center Revenue and Expenses		
	CY2023	CY2024
In-Center Patients*	35	37
HH and PD Patients*	8	9
In-Center Treatments	5,250	5,550
HH and PD Treatments	1,200	1,350
Gross Patient Revenue (IC and PD)	\$11,865,614	\$12,693,447
Adjustment from Gross**	\$9,836,652	\$10,517,221
Net Patient Revenue (IC and PD)	\$2,028,961	\$2,176,226
Average Net Revenue per Treatment	\$315	\$315
Total Operating Expenses (IC and PD)	\$1,705,809	\$1,829,641
Average Operating Expense per Treatment	\$264	\$265
Net Income	\$323,152	\$346,585

*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 and working capital costs are based on reasonable and adequately supported assumptions.
 - The applicant adequately demonstrates availability of sufficient funds for the capital and working 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 develop NDDC, a new 12-station dialysis facility in northern Davidson County, by relocating no more than 12 stations from TVDC in Davidson County, pursuant to Policy ESRD-2. TVDC will be certified for 23 stations upon completion of this project and Project ID #G-11651-19 (relocate no more than 3 stations for a total of 35).

On page 113, the 2020 SMFP defines the service area for the county need methodology 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.*” Both facilities referred to in this application are located in Davidson County. Thus, the service area for this application is Davidson County. Facilities may serve residents of counties not included in their service area.

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

Davidson County Dialysis Facilities Certified Stations and Utilization as of December 31, 2018				
Dialysis Facility	Owner	Location	# of Certified Stations	Utilization
Lexington Dialysis Center of Wake Forest University*	WFUHS	Lexington	37	82.43%
Thomasville Dialysis Center of Wake Forest University	WFUHS	Thomasville	32	72.66%

Source: 2020 SMFP, Table B.

* Approved to replace the existing facility for a total of 37 stations (Project ID #G-11355-17)

In Section G, page 49, the applicant explains why it believes the proposal would not result in the unnecessary duplication of existing or approved dialysis services in Davidson County. The applicant states:

“This project proposes to transfer [relocate] existing stations from TVDC to a new location in northern Davidson County to serve Davidson resident patients who are currently traveling outside of Davidson County for their care as well as WFUHS patients residing in southern Forsyth County. Because this project is an in-county transfer [relocation] of existing stations, it does not add stations to the total county station inventory. It proposes to serve Davidson residents in an area of Davidson County that lacks a facility, but is home to a large number of ESRD patients who are traveling outside of Davidson County for their dialysis care as discussed in Section C.”

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:

- The proposal would not result in a surplus of stations or increase an existing surplus of stations in Davidson County.
- The applicant adequately demonstrates that the proposed relocation of the 12 stations for the development of a new facility is needed in addition to the operational facilities in Davidson 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 101, the applicant provides the projected staffing in full-time equivalent (FTE) positions for the first and second full operating years of the proposed services, as summarized in the following table.

POSITION	PROJECTED FTE POSITIONS CY2023	PROJECTED FTE POSITIONS CY2024
RN	2.50	3.00
Patient Care Tech	4.00	4.00
Clinical Nurse Manager (DON)	1.00	1.00
Dietician	0.50	0.50
Social Worker	0.50	0.50
Home Training Nurse	0.25	0.25
Dialysis Tech	0.50	0.50
Bio-med Technician	0.50	0.50
Clerical	1.00	1.00
Total	10.75	11.25

Source: Section Q 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. 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 51-53, 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 55-60, the applicant identifies the necessary ancillary and support services and explains how they will be made available. The applicant provides a table on page 55, as summarized below.

**North Davidson 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*	On Premises
(2) Peritoneal dialysis	On Premises
(3) Accessible follow-up program	On Premises
(4) Sister-Facility Agreement	On Premises
(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 and WFBH
(l) X-ray services	Wake Forest Baptist Hospital
(m) Laboratory services	Wake Forest Baptist Hospital Meridian Lab Contract/On Premises
(n) Pediatric nephrology	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	Davidson County Transportation Services

*On page 22, the applicant states that it will offer home hemodialysis training and support services at the proposed facility but does not project serving any specific number of HH patients upon facility development *“due to the overall low numbers of patients on that modality.”*

In Section I, pages 56-59, the applicant describes NDDC’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 62, the applicant states that the project will involve new construction of 11,500 square feet. The proposed floor plan is provided in Exhibit K-1(b).

On pages 62-63, 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 B.6, where the applicant provides a written statement from the architect describing how design and construction of the proposed facility will assure improved energy efficiency and water conservation.

On pages 63-64, 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 and provides supporting documentation in Exhibit F-1(c).

On page 64, the applicant refers to the architect's letter in Exhibit B-6 to identify any applicable energy saving features that will be incorporated into the construction 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 develop NDDC, a new 12-station dialysis facility, by relocating no more than 12 stations from TVDC. NDDC will be a new facility and therefore has no history. In Section L.1, page 68, the applicant provides the TVDC's historical payor mix for CY2019, as shown in the table below.

Payor Source	Total Patients	In-center Patients	PD & HH Patients
Private Pay	1.0%	1.0%	0.0%
Medicare	11.0%	11.0%	0.0%
Medicaid	8.0%	8.0%	0.0%
Medicare / Medicaid	18.0%	18.0%	0.0%
Commercial Insurance	8.0%	8.0%	0.0%
Medicare / Commercial	24.0%	24.0%	0.0%
VA	1.0%	1.0%	0.0%
Medicare Advantage	29.0%	29.0%	0.0%
Total	100.0%	100.0%	0.0%

Totals may not sum due to rounding

In Section L.1(a), page 67, the applicant provides comparison of the demographical information on TVDC patients and the service area patients during the last full operating year, as summarized below.

	Percentage of Total TVDC Patients Served during the Last Full OY	Percentage of the Population of the Service Area Where the Stations are Located*
Female	43.63%	51.10%
Male	56.37%	48.90%
Unknown	N/A	N/A
64 and Younger	50.00%	81.10%
65 and Older	50.00%	18.20%
American Indian	N/A	0.80%
Asian	2.73%	1.60%
Black or African-American	38.18%	9.90%
Native Hawaiian or Pacific Islander	N/A	0.10%
White or Caucasian	52.73%	79.70%
Other Race	6.36%	6.20%
Declined / Unavailable	N/A	1.70%

* 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 68, the applicant states that while the facility is not required nor obligated to provide uncompensated care nor community service; however, as a Medicare Participating Provider, it is at a minimum subject to Federal laws and regulations regarding equal access, non-discrimination, and access for handicapped persons.

The facility is not an operational facility; therefore, 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.1(b), page 70, 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 shown in the table below.

**Projected Payor Mix
CY2024**

Payor Source	Total Patients	IC Patients	PD & HH Patients
Private Pay	0.0%	0.0%	0.0%
Medicare	12.0%	12.0%	9.0%
Medicaid	5.0%	5.0%	3.0%
Medicare / Medicaid	22.0%	23.0%	14.0%
Commercial Insurance	10.0%	9.0%	20.0%
Medicare / Commercial	25.0%	25.0%	30.0%
VA	4.0%	4.0%	4.0%
Medicare Advantage	22.0%	22.0%	20.0%
Total	100.0%	100.0%	100.0%

Source: Application page 70

As shown in the table above, during the second full calendar year of operation, the applicant projects that 0% of the dialysis patients will be private pay patients and 86% will have all or part of their services paid for by Medicare and/or Medicaid.

On pages 70-71, 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 comparable to the historical TVDC payor mix, and
- the applicant projects future payor mix based on the WFUHS system-wide five-year 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 73-75, 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 76, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes.

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 develop NDDC, a new 12-station dialysis facility in northern Davidson County, by relocating no more than 12 stations from TVDC in Davidson County, pursuant to Policy ESRD-2. TVDC will be certified for 23 stations upon completion of this project and Project ID #G-11651-19 (relocate no more than 3 stations for a total of 35).

On page 113, the 2020 SMFP defines the service area for the county need methodology 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.*” Both facilities involved in this review are located in Davidson County. Thus, the service area for this application is Davidson County. Facilities may serve residents of counties not included in their service area.

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

Davidson County Dialysis Facilities Certified Stations and Utilization as of December 31, 2018				
Dialysis Facility	Owner	Location	# of Certified Stations	Utilization
Lexington Dialysis Center of Wake Forest University*	WFUHS	Lexington	37	82.43%
Thomasville Dialysis Center of Wake Forest University	WFUHS	Thomasville	32	72.66%

Source: 2020 SMFP, Table B.

* Approved to replace the existing facility for a total of 37 stations (Project ID #G-11355-17)

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 77, the applicant states that it does not expect the facility relocation to have any effect on the competitive climate in Mecklenburg County. The applicant does not project to serve dialysis patients currently being served by another provider. The applicant further states:

“WFUHS is the whole owner of the two existing dialysis facilities within Davidson County. The proposed new facility, which will be comprised of existing stations that will transfer [relocate] from TVDC, is expected to serve WFUHS existing and projected patients residing in northern Davidson and southern Forsyth County mostly who are not currently served by an existing facility in Davidson County. Because all facilities have common ownership, there will be no impact on competition in the service area.”

Regarding the impact of the proposal on cost effectiveness, in Section N, pages 77-78, the applicant states:

“The proposal will place the requested stations in an underserved area of Davidson County and provide a pathway by which additional stations may be added to the county via a future CON to be filed by TVDC preventing a persistent station shortfall that will strain existing healthcare services. By placing the facility where it is needed and planning certification for when it is needed [sic] health service resources will be maximized. The projected rise in treatment volumes due to convenience of care will result in a lower overall cost per treatment, making the proposed project more cost effective than the status quo.”

Regarding the impact of the proposal on quality, in Section N, page 78, 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 78, the applicant states:

“The transfer of stations and development of a new facility in an underserved area will represent additional access to service by all persons with ESRD, including the medically underserved, reducing their need to travel outside of their home county for dialysis care, now, and in the future. This will reduce a financial burden on the patient and the community resources, overall.”

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 C, F, N and Q of the application and any exhibits).
- Quality (see Sections C, N and O of the application and any exhibits).
- Access to medically underserved groups (see Sections 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 83, 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 18 WFUHS dialysis facilities located in North Carolina, in addition to the proposed NDDC facility.

In Section O, pages 79-80, the applicant states that during the 18 months immediately preceding the submittal of the application, incidents related to quality of care occurred in 11 of the 18 facilities. These incidents were issued standard level deficiencies (not resulting in immediate jeopardy) and the list on page 80 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.

- C- In Section Q, page 84-85, the methodology proposed by the applicant achieves a projection of 36 in-center patients by the end of the first operating year, CY2023, for a utilization rate of 3.0 patients per station per week or 75% (36 patients / 12 stations = 3.0 patients per station / 4 = 0.7500). The projected utilization of 3.0 patients per station per week satisfies the 2.8 in-center patients per station threshold as required by 10A NCAC 14C .2203(a).

- (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.

- NA- The applicant is proposing to establish a new ESRD facility.

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

- C- In Section Q, pages 84-85, the applicant provides the assumptions and methodology used to project utilization of the facility.