

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: April 19, 2021

Findings Date: April 19, 2021

Project Analyst: Celia C. Inman

Team Leader: Fatimah Wilson

Project ID #: G-12011-21

Facility: North Davidson Dialysis Center

FID #: 200036

County: Davidson

Applicant(s): Wake Forest University Health Sciences

North Davidson Dialysis Center of Wake Forest University

Project: Relocate no more than 7 dialysis stations from Thomasville Dialysis Center for a total of no more than 19 stations upon completion of this project and Project ID #G-11844-20 (Develop a new 12-station dialysis facility by relocating no more than 12 stations from Thomasville Dialysis Center)

REVIEW CRITERIA

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

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

NA

Wake Forest University Health Sciences (WFUHS) and North Davidson Dialysis Center of Wake Forest University (NDDC), collectively referred to as “the applicant”, proposes to relocate no more than seven dialysis stations from Thomasville Dialysis Center (TVDC) for a total of no more than 19 stations upon completion of this project and Project ID #G-11844-20 (develop a new 12-station dialysis facility by relocating no more than 12 stations from TVDC).

The applicant does not propose to:

- develop any services for which there is a need determination in the 2021 State Medical Facilities Plan (SMFP)

- offer a new institutional health service for which there are any policies in the 2021 SMFP
- (2) Repealed effective July 1, 1987.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, ... persons [with disabilities], the elderly, and other underserved groups are likely to have access to the services proposed.

C

The applicant proposes to relocate no more than seven dialysis stations from TVDC for a total of no more than 19 stations upon completion of this project and Project ID #G-11844-20 (develop a new 12-station dialysis facility by relocating no more than 12 stations from TVDC). In Section C.1, page 20, the applicant states:

“TVDC will file a CON application in March 2021 to add back 20 stations via Facility Need methodology with certification to occur simultaneously with the certification of the NDDC projects. The culmination of these projects will allow for a county-wide and regional rebalancing of the ESRD patient population and will enhance geographic accessibility for patients living in Davidson and surrounding counties.” [emphasis in original]

Thus, not only is this project dependent upon Project ID #G-11844-20 (develop a new 12-station dialysis facility by relocating stations from TVDC), it is also dependent upon the approval of a proposed application to be submitted for the April 1, 2021 review date pursuant to TVDC’s 20-station facility need determination in the 2021 SMFP (page 138).

The following table, summarized from data on pages 13-14 of the application, shows the projected number of stations at NDDC upon completion of this project and Project ID #G-11844-20 (develop a new facility by relocating 12 stations from TVDC).

NDDC		
Stations	Description	Project ID #
0	Total existing certified stations in the SMFP in effect on the day the review will begin	
+7	Stations to be added as part of this project (Relocate 7 stations from TVDC to NDDC)	G-12011-21
+12	Stations previously approved to be added and are reported in Table 9A in the SMFP, but are not yet certified (develop new 12-station facility)	G-11844-20
19	Total stations upon completion of proposed project and previously approved projects	

The table below, summarized from data in Section D.3, page 38 of the application and the 2021 SMFP, shows the projected number of stations at TVDC upon completion of this project, Project ID #G-11844-20 (develop a new facility by relocating 12 stations from TVDC), and the proposed application to be submitted for the April 1, 2021 review date (and presumed to be approved) to add no more than 20 stations at TVDC pursuant to the 2021 SMFP facility need determination for 20 additional stations.

TVDC		
Stations	Description	Project ID #
35	Total existing certified stations in the SMFP in effect on the day the review will begin	
-7	Stations to be relocated as part of this project (Relocate 7 stations from TVDC to NDDC)	G-12011-21
-12	Stations previously approved to be relocated and are reported in Table 9A in the SMFP, but are not yet certified (develop new 12-station facility)	G-11844-20
16	Total number of stations upon completion of this project and Project ID #G-11844-20	
+20	TVDC proposes to file a CON for the April 1, 2021 review date to add 20 stations pursuant to the 2021 facility need determination for 20 additional stations at TVDC	TBD
36	Total stations upon completion of proposed Project ID #G-12011-21, the previously approved Project ID #G-11844-20, and the proposed April 1, 2021 application pursuant to the 20-station 2021 need determination for 20 stations	

Patient Origin

On page 113, the 2021 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 and Graham counties and Avery, Mitchell, and 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.

The proposed facility is not yet in operation; therefore, it has no historical patient origin. The applicant provides the following historical in-center (IC) patient origin for TVDC, the facility from which the stations will be relocated. TVDC does not provide home hemodialysis (HH) or peritoneal dialysis (PD).

County	Historical (1/1/2020-12/31/2020)	
	Patients	% of Total
Davidson	97.00	90.65%
Forsyth	1.00	0.93%
Guilford	1.00	0.93%
Randolph	8.00	7.18%
Davidson Transfers Out	0.00	0.00%
Total	107.00	100.00%

Source: Section C.2, page 21.

The following table illustrates the projected patient origin at NDDC, including IC and PD patients.

County	Second Full FY of Operation following Project Completion (1/1/24-12/31/24)					
	IC Patients		HH Patients		PD Patients	
	Patients	% of Total	Patients	% of Total	Patients	% of Total
Davidson	33.26	55.93%	0.00	0.00%	5.54	62.86%
Forsyth	26.21	44.07%	0.00	0.00%	3.28	37.14%
Total	59.47	100.00%	0.00	0.00%	8.82	100.00%

Source: Section C.3, page 21.

In Section C, pages 22-25, the applicant provides the assumptions and methodology used to project its patient origin. On page 22, the applicant states that Davidson County will experience a shortage of dialysis stations, stating:

“Based on the data provided in the 2021 SMFP, there will be at least a 4-station deficit as soon as 12/31/2020.”

The applicant’s assumptions are reasonable and adequately supported based on the following:

- the Average Annual Change Rate (AACR) published in the 2021 SMFP is a reliable measure for predicting patient growth: Davidson County – 5.3%, Forsyth County – 4.5%
- The applicant states that Davidson County will experience a shortage of dialysis stations due to IC patient growth
- The applicant states that the proposed NDDC facility will enhance geographic proximity of services
- The applicant states that existing WFUHS IC patients residing in Davidson (at least 30 patients, 20 from TVDC) and Forsyth (at least 24 patients) counties are expected to transfer their care to NDDC for reasons of convenience
- NDDC will offer PD training and support services

Analysis of Need

In Section C, pages 26-27, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. On page 26, the applicant states:

- Davidson County and southern Forsyth County are growing
- The 2021 SMFP shows a Davidson County four-station deficit
- By the end of 2023, Davidson County is likely to have an 18-station deficit
- The location of NDDC in northern Davidson County will increase geographic access to dialysis services in Davidson and Forsyth counties and alleviate utilization pressures at existing WFUHS facilities
- The 2021 SMFP shows Lexington Dialysis Center (LXDC) does not qualify to add stations, while TVDC has a 20-station need determination

The information is reasonable and adequately supported based on the following:

- The applicant states Davidson and Forsyth counties are growing, but provides no supporting documentation; however, Agency research documents that both counties are projected to grow by more than 3.0% between 2020 and 2024, the second year following completion of the project
- The 2021 SMFP shows a Davidson County four-station deficit and thus, no county need determination (page 134) and a facility need determination for 20 stations at TVDC (page 121)
- The applicant provides calculations showing that by the end of 2023, Davidson County could have an 18-station deficit (page 26)
- The applicant provides documentation of better geographic accessibility to the proposed NDDC in Exhibit C-4
- WFUHS submitted a Letter of Intent (Exhibit C-4) to file an application for the April 1, 2021 review date to add 20 stations to TVDC pursuant to the 20-station need determination in the 2021 SMFP, page 121
- The applicant calculates a utilization rate for the proposed 19 stations at NDDC of 74.57% by the end of the first year of operations, December 31, 2023 (page 23)

Projected Utilization

In Section Q, the applicant provides the projected utilization, as illustrated in the following table.

Form C Utilization	First Full OY 1/1/23-12/31/23	Second Full OY 1/1/24-12/31/24
In-Center Patients		
# of Patients at the Beginning of the Year	54	57
# of Patients at the End of the Year	57	59
Average # of Patients during the Year	55	58
# of Treatments / Patient / Year	150	150
Total # of In-Center Treatments	8,250	8,700
Total # of PD Treatments	1,200	1,350
Total # of PD Training Days	56	62
Total # of Treatments	9,506	10,112

In-Center

In Section C.3, pages 21-25, the applicant provides the assumptions and methodology used to project in-center utilization, which are summarized below.

- There is no census until operations begin with the certification of the facility on December 31, 2022, when 30 Davidson County WFUHS IC dialysis patients (20 patients from TVDC) and 24 Forsyth County WFUHS IC dialysis patients are expected to transfer their care to NDDC (Section C.3, pages 22-23)
- The applicant grows the Davidson and Forsyth County patient census by 5.3% and 4.5%, respectively, the 5-year AACR for each county as found in the 2021 SMFP, page 134

The applicant provides a table in Section C, page 23, illustrating the application of its assumptions and methodology, as summarized below.

Projected In-center Patient Utilization

County	AACR	Beginning Census 12/31/22	First Full OY 1/1/23-12/31/23	Second Full OY 1/1/24-12/31/24
Davidson	5.3%	30	31.59	33.26
Forsyth	4.5%	24	25.08	26.21
Totals			56.67	59.47

Totals may not sum due to rounding.

As the table above for projected in-center utilization shows, using conventional rounding, the applicant’s methodology achieves a projection of 57 in-center patients by the end of the first operating year, OY1 (December 31, 2023), for a utilization rate of 3.0 patients per station per week or 75% (57 patients / 19 stations = 3.0 patients per station per week / 4 = 0.75). By the end of OY2 (December 31, 2024), following the applicant’s methodology and assumptions, NDDC will have 59 in-center patients dialyzing at the center for a utilization rate of 77.6% (59 / 19 = 3.1/ 4 = .776). The projected utilization of 3.0 patients per station per week for OY1 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 the expected transfer of care of existing WFUHS patients, who will experience geographic convenience at 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 5.3% and 4.5%, respectively, as reported in the 2021 SMFP.
- The projected utilization rate by the end of OY1 is above the minimum standard of 2.8 patients per station per week.

PD Patients

In Section C, pages 23, the applicant states:

“At least 5 Davidson County and 3 Forsyth County PD patients are projected to transfer their follow up care to NDDC during OY1 due to reasons of geographic convenience.”

The applicant provides a table in Section C, page 23, illustrating the application of its assumptions and methodology, as summarized below.

Projected PD Patients

County	AACR	Beginning Census 12/31/22	First Full OY 1/1/23-12/31/23	Second Full OY 1/1/24-12/31/24
Davidson	5.3%	5	5.27	5.54
Forsyth	4.5%	3	3.14	3.28
Totals			8.40	8.82

Totals may not sum due to rounding.

PD Training Days

On page 29-30 the applicant discusses PD training, stating that NDDC will be equipped with two PD training areas. The system-wide average days of training per patient trained for PD by similarly sized facilities is seven PD training days per patient. The applicant states that for it uses an average of seven training days per patient for projecting billable training days, resulting in 56 and 62 training days for CY2023 and CY2024, respectively.

Projected utilization for PD training is reasonable and adequately supported based on the following:

- The applicant bases the beginning PD patient census on the expected transfer of care of existing WFUHS patients, who will experience geographic convenience at 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 5.3% and 4.5%, respectively, as reported in the 2021 SMFP.
- The applicant also projects a 10% year over year growth in the home PD patients, based on the Presidential Directive toward home training where appropriate.
- The applicant projects billable PD training days on the WFUHS system-wide average of seven days per training patient.

Access to Medically Underserved Groups

In Section C, pages 30-33, the applicant discusses access to services at NDDC, stating on page 31:

“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.”

The applicant provides the estimated percentage for each medically underserved group, as shown in the following table.

Medically Underserved Groups	Percentage of Total Patients
Low income persons	5.00%
Racial and ethnic minorities	57.07%
Women	43.87%
Persons with Disabilities	Not Tracked
The elderly	47.43%
Medicare beneficiaries	81.00%
Medicaid recipients	27.00%

The applicant adequately describes the extent to which all residents of the service area, including underserved groups, are likely to have access to the proposed services based on the following:

- The applicant states that its admission policy is based on medical necessity
- The applicant has historically provided care and services to medically underserved populations
- The applicant states that patients are not turned away due to a lack of ability to pay

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency (if applicable)

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

- (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, ... persons [with disabilities], and other underserved groups and the elderly to obtain needed health care.

CA

The applicant proposes to relocate no more than seven dialysis stations from TVDC for a total of no more than 19 stations upon completion of this project and Project ID #G-11844-20 (develop a new 12-station dialysis facility by relocating no more than 12 stations from TVDC). In Section C.1, page 20, the applicant states:

“TVDC will file a CON application in March 2021 to add back 20 stations via Facility Need methodology with certification to occur simultaneously with the certification of the NDDC projects.” [emphasis in original]

Thus, not only is the project under review dependent upon Project ID #G-11844-20 (develop a new 12-station dialysis facility by relocating stations from TVDC), it is also dependent upon the approval of a proposed application to be submitted for the April 1, 2021 review date pursuant to TVDC’s 20-station facility need determination in the 2021 SMFP, page 138.

The table below, summarized from data in Section D.3, page 38 of the application and the 2021 SMFP, shows the projected number of stations at TVDC after the relocation of stations upon completion of this project, Project ID #G-11844-20 (develop a new facility by relocating 12 stations from TVDC), and the proposed application to be submitted for the April 1, 2021 review date (and presumed to be approved) to add no more than 20 stations at TVDC pursuant to the 2021 SMFP facility need determination for 20 additional stations.

TVDC		
Stations	Description	Project ID #
35	Total existing certified stations in the SMFP in effect on the day the review will begin	
-7	Stations to be relocated as part of this project (Relocate 7 stations from TVDC to NDDC)	G-12011-21
-12	Stations previously approved to be relocated and are reported in Table 9A in the SMFP, but are not yet certified (develop new 12-station facility)	G-11844-20
16	Total number of stations upon completion of this project and Project ID #G-11844-20	
+20	Per Letter of Intent (Exhibit C-4), TVDC proposes to file a CON for the April 1, 2021 review date to add 20 stations pursuant to the 2021 facility need determination for 20 additional stations at TVDC	TBD
36	Total stations upon completion of proposed Project ID #G-12011-21, the previously approved Project ID #G-11844-20, and the proposed April 1, 2021 application pursuant to the 20-station 2021 need determination for 20 stations	

In Section D, pages 38-39, 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 38, the applicant states:

- TVDC has a 20-station facility need determination in the 2021 SMFP.
- TVDC will file a CON to add 20 stations to be certified in conjunction with the relocation of the 19 stations (7 in Project ID #G-12011-21 and 12 in Project ID #G-11844-20).
- Upon the relocation of 19 stations, addition of 20 stations, and the transfer of 20 patients, TVDC will have 36 stations to serve its remaining patients. Because the certification of the relocated 19 stations and the proposed 20-station addition will happen simultaneously, there will be no reduction in service to the patients remaining at TVDC.
- The approvals of the project under review and the proposed project to add 20 stations at TVDC will allow WFUHS to re-balance dialysis services for its Davidson County patients.

The applicant provides a table in Section D, page 39, and Section Q, page illustrating the application of its assumptions and methodology. The following table summarizes the applicant’s assumptions and methodology, correcting it for the assumption that the 20 patients that transfer out on December 31, 2022 will not be included in the utilization after 2022. The ending Davidson County patient utilization on December 31, 2022 is simply reduced by the 20 patients who transfer to NDDC.

County	AACR	Ending Prior Yr 12/31/20	Ending Current Yr 12/31/21	Ending Interim Yr 12/31/22	OY1 12/31/23	OY2 12/31/24
Davidson	5.3%	97.00	102.14	107.55		
Davidson Transfer Out 12/31/22				-20.00		
Davidson After Transfer 12/31/22	5.3%			87.55	92.19	97.08
Forsyth	4.5%	1.00	1.05	1.09	1.14	1.19
Guilford	4.0%	1.00	1.04	1.08	1.12	1.17
Randolph	1.0%	8.00	8.08	8.16	8.24	8.32
Total Patients		107.00	112.31	97.89	102.70	107.77
Utilization*		76.43%	80.22%	67.98%	71.32%	74.84%

Totals may not sum due to rounding.

*Utilization is based on 35 existing stations for 2020 and 2021 and 36 stations assuming approval of the project under review, the development of approved Project ID #G-11844-20, and the submittal and approval of the applicant’s proposed project to add 20 stations with certification coinciding with the project under review, December 31, 2022, OY1 ending December 31, 2023 (35 – 19 + 20 = 36)

As the table above shows, assuming approval of both projects, the methodology used by the applicant achieves a projection of 102.70 in-center patients by the end of the first operating year, OY1 (December 31, 2023), for a utilization rate of 2.85 patients per station per week or 71.32% (102.7 patients / 36 stations = 2.85 patients per station per week/ 4 = 0.7132). The

projected utilization of 2.85 patients per station per week for OY1 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).

However, if the applicant fails to submit the proposed application to add 20 stations for the April 1, 2021 review date or if the application is not approved, TVDC would be left operating with only 16 stations ($35 - 19 = 16$). With only 16 certified stations, TVDC would have to operate at 6.42 patients per station per week, or 160.47% during the first full fiscal year following completion of the project under review ($102 \text{ patients} / 16 \text{ stations} = 6.42 / 4 = 1.6047$), which would not meet the needs of the population as they are presently served.

In Section Q, page 88, the applicant provides the assumptions and methodology used to project utilization, which are summarized below.

- The applicant begins its utilization projection with the existing TVDC patient census
- The applicant grows the existing patient census by the respective 5-year AACR for each county as found in the 2021 SMFP
- The applicant assumes the relocation of 19 stations and the transfer of 20 patients to NDDC following project completion with the first operating year ending December 31, 2023
- The applicant plans to apply for 20 additional stations in April 2021 pursuant to the 2021 SMFP facility need determination and assumes the approval of that project with the addition of the 20 stations being simultaneous with the relocation of the 19 stations

Projected utilization is reasonable and adequately supported based on the following:

- The applicant bases its utilization projections upon the existing TVDC patient census
- The applicant projects growth based on the 5-year AACR for each county, as found in the 2021 SMFP
- The relocation of 19 stations and the transfer of 20 patients to NDDC following project completion serves to re-balance services for the WFUHS Davidson County dialysis patients.
- The 2021 SMFP shows a TVDC facility need determination for 20 additional stations.
- The applicant provides a Letter of Intent in Exhibit C-4 to apply for 20 stations at TVDC pursuant to the 2021 SMFP facility need determination
- The projected utilization rate by the end of OY1 is above the minimum standard of 2.8 patients per station per week.

Access to Medically Underserved Groups

In Section D, page 42, 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.”

The applicant adequately demonstrates that the needs of medically underserved groups that will continue to use the services at TVDC will be adequately met following completion of the project for the following reasons:

- Admission of a patient is based solely upon medical necessity and not the patient's ability to pay
- The applicant anticipates that the percent of the patient population representing racial minorities, women, Medicaid and Medicare recipients, and persons 65 and older will remain constant or increase through the second full operating year of the proposed project.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency (if applicable)

Based on that review, the Agency concludes that the application is conforming to this criterion, pursuant to Condition (3) in Criterion (4), the submittal and approval of the proposed application to add 20 stations at TVDC pursuant to the 2021 facility need determination, for the following reasons:

- The applicant adequately demonstrates that the needs of the population currently using the services to be relocated will be adequately met following project completion only if the proposed application to add 20 stations at TVDC pursuant to the 2021 facility need determination is approved for development concurrent with the development of NDDC.
- The applicant adequately demonstrates that 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 relocate no more than seven dialysis stations from TVDC for a total of no more than 19 stations upon completion of this project and Project ID #G-11844-20 (develop a new 12-station dialysis facility by relocating no more than 12 stations from TVDC).

In Section E, pages 44-46, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- Policy ESRD-2 Transfer of Stations from a Contiguous County - the applicant states that of the contiguous counties, Davie and Forsyth have deficits of stations, WFUHS has no surplus stations in Guilford County, and the WFUHS facility in Randolph County is a 10-station facility with no available stations to transfer; thus, this alternative is not an effective alternative.
- Add Stations via Facility Need Methodology – the applicant states that the facility need determinations for the WFUHS dialysis facilities in Davidson County would not add the needed capacity without being able to relocate stations from TVDC to free up plant capacity; thus, this alternative is not an effective alternative.
- Transfer Stations from TVDC to NDDC and Apply to Add Stations at TVDC pursuant to the 2021 SMFP Need Determination for 20 Stations – the applicant states that the project as proposed in conjunction with the proposed application to add back 20 stations at TVDC is the more effective alternative to provide adequate WFUHS dialysis capacity in Davidson County.

On page 45, the applicant states that its proposal is the most effective alternative because relocating the stations to NDDC from TVDC will free up physical plant space to allow for the proposed application to add 20 stations pursuant to the 2021 facility need determination at TVDC to be certified in conjunction with the relocation of stations to NDDC, which will allow WFUHS to provide Davidson County ESRD patients with access to services at three locations in Davidson County without disruption of service at TVDC.

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

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

Conclusion

The Agency reviewed the:

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

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above. 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 (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**
- 2. The certificate holder shall relocate no more than seven in-center and home hemodialysis stations from Thomasville Dialysis Center of Wake Forest University to North Davidson Dialysis Center of Wake Forest University for a total of no more than 19 dialysis stations upon completion of this project and Project ID #G-11844-20 (develop a 12-station dialysis facility).**
- 3. Wake Forest University Health Sciences and Thomasville Dialysis Center of Wake Forest University shall file a certificate of need application proposing to add 20 stations at Thomasville Dialysis Center on or before the application deadline for the April 2021 review period.**
- 4. Upon completion of this project, Wake Forest University Health Sciences shall take the necessary steps to decertify 19 in-center and home hemodialysis dialysis stations at Thomasville Dialysis Center for a total of no more than 16 dialysis stations upon completion of this project and Project ID #G-11844-20 (develop 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).**
- 5. Progress Reports:**
 - a. Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: <https://info.ncdhhs.gov/dhsr/coneed/progressreport.html>.**
 - b. The certificate holder shall complete all sections of the Progress Report form.**
 - c. The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.**
 - d. Progress reports shall be due on the first day of every third month. The first progress report shall be due on September 1, 2021. The second progress report shall be due on December 1, 2021 and so forth.**

6. The certificate holder 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 relocate no more than seven dialysis stations from TVDC for a total of no more than 19 stations upon completion of this project and Project ID #G-11844-20 (develop a new 12-station dialysis facility by relocating no more than 12 stations from TVDC).

Capital and Working Capital Costs

In Section Q, on Form F.1a, the applicant projects the total capital cost of the project as shown below in the table.

NDDC Capital Cost	
Construction Costs	\$ 895,000
Miscellaneous Costs	\$68,700
Total	\$963,700

In Section Q, the applicant provides the assumptions used to project the capital cost. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based on the following:

- construction cost documentation in Exhibit F-1(b)
- furniture cost based on recent estimates, including shelving and other fixtures

In Section F, page 49, the applicant states that there will be no start-up or initial operating costs associated with this project.

Availability of Funds

In Section F, page 47, the applicant states that the capital cost will be funded as shown below in the table.

Sources of Capital Cost Financing

Type	WFUHS
Loans	\$0
Accumulated Reserves or OE *	\$963,700
Bonds	\$0
Other (Specify)	\$0
Total Financing	\$963,700

* OE = Owner's Equity.

WFUHS is the whole owner of NDDC and is committed to funding the project. Exhibit F.2(c)(2) contains a copy of a letter dated January 15, 2021 from the CEO of Wake Forest Baptist Health expressing WFUHS' intention to fund the capital costs of the project with accumulated reserves. Exhibit F.2(c)(3) contains a copy of the audited financial statements for Wake Forest University which indicate WFUHS had cash and cash equivalents of \$106,870,000 as of June 30, 2020.

The applicant adequately demonstrates the availability of sufficient funds for the capital and working capital needs of the project based on the following:

- documentation of its intent to fund the project in Exhibit F.2
- availability of funds documented in the audited financials provided in Exhibit F.2

Financial Feasibility

The applicant provided pro forma financial statements for the first three full fiscal years of operation following completion of the project. In Form F.2, the applicant projects that revenues will exceed operating expenses in the second full fiscal year of operation (CY2024) following completion of the proposed project, as shown in the table below.

	1 st Full FY CY2023	2 nd Full FY CY2024	3 rd Full FY CY2025
Total Billable Treatments	9,506	10,112	10,568
Total Gross Revenues (Charges)	\$21,508,561	\$22,878,810	\$23,910,931
Total Net Revenue	\$3,375,174	\$3,596,707	\$3,754,009
Average Net Revenue per Procedure	\$355	\$356	\$355
Total Operating Expenses (Costs)	\$2,811,177	\$2,958,246	\$3,084,740
Average Operating Expense per Procedure	\$296	\$293	\$292
Net Income	\$563,997	\$638,462	\$669,269

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q of the application. The applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

- Charges and expenses are based on historical facility operations projected forward

- FTEs and salaries are based on current staffing and projected to average annual salary increases of 3%
- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumption
- 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 relocate no more than seven dialysis stations from TVDC for a total of no more than 19 stations upon completion of this project and Project ID #G-11844-20 (develop a new 12-station dialysis facility by relocating no more than 12 stations from TVDC).

On page 113, the 2021 SMFP defines the service area for ESRD dialysis facilities 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 areas: Cherokee, Clay and Graham counties and Avery, Mitchell, and Yancey counties.*” Thus, the service area for this facility consists of Davidson County. Facilities may also serve residents of counties not included in their service area.

According to Table 9A of the 2021 SMFP, there are three existing or approved dialysis facilities in Davidson County, all of which are owned and operated by WFUHS. Information on these dialysis facilities, from Table 9A of the 2021 SMFP, is provided below:

Davidson County Dialysis Facilities Certified Stations and Utilization as of December 31, 2019				
Dialysis Facility	Owner	Location	# of Certified Stations	Utilization
Lexington Dialysis Center of Wake Forest University	WFUHS	Lexington	42	72.62%
North Davidson Dialysis Center of Wake Forest University	WFUHS	Winston-Salem	0	0.00%
Thomasville Dialysis Center of Wake Forest University	WFUHS	Thomasville	32	85.94%

Source: 2021 SMFP, Table 9A.

In Section G, pages 54-55, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Davidson County. The applicant provides a table depicting the 2024 station deficit in Davidson County and states:

“Since the requested station transfer in the CON does not increase the total number of stations in Davidson County, it cannot duplicate services. This CON relocates services to an area of the county where they are needed and will allow TVDC, the host facility, to file an add-back CON to prevent the projected future county station deficits not covered by the time period depicted in the SMFP, but illustrated in the table, above.”

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

- 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 seven stations from TVDC to NDDC is needed in addition to the existing and approved stations in Davidson County.

Conclusion

The Agency reviewed the:

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

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

The applicant proposes to relocate no more than seven dialysis stations from TVDC for a total of no more than 19 stations upon completion of this project and Project ID #G-11844-20 (develop a new 12-station dialysis facility by relocating no more than 12 stations from TVDC).

In Section Q Form H Staffing, page 105, 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	3.50	3.50
Patient Care Tech	5.50	6.00
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	13.25	13.75

Source: Section Q of the application.

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 Form F.4, which is found in Section Q. In Section H, pages 56-58, the applicant describes the methods to be used to recruit or fill new positions and its training and continuing education programs at its proposed facility. In Exhibit H-3, the applicant provides supporting documentation.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services based on the following:

- The applicant bases its staffing on its experience providing dialysis services in Davidson County
- The applicant provides documentation of its policies in regard to recruitment, training and continuing education

Conclusion

The Agency reviewed the:

- Application

- Exhibits to the application

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

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

C

The applicant proposes to relocate no more than seven dialysis stations from TVDC for a total of no more than 19 stations upon completion of this project and Project ID #G-11844-20 (develop a new 12-station dialysis facility by relocating no more than 12 stations from TVDC).

Ancillary and Support Services

In the table in Section I, page 60, the applicant identifies each ancillary and support service listed in the application as necessary for the proposed services. In the applicant's table on pages 61-64, the applicant explains how each ancillary and support service will be made available and provides supporting documentation in Exhibits A-4(c), H-3, and I-1 and 2.

The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on the following:

- The applicant provides evidence of its plan for the provision of services in Exhibit A-4.
- The applicant provides evidence of its contracts for services with Health Systems Management in Exhibit H-3.

Coordination

In Section I, pages 64-65, the applicant describes its efforts to develop relationships with other local health care and social service providers and provides supporting documentation in Exhibit I-2.

The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the following:

- The applicant discusses its parent company's relationships with the local health care and social service providers.
- The applicant provides evidence of its agreements with local health care and social service providers in Exhibits I-1 and 2.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

NA

The applicant does not project to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which the services will be offered. Furthermore, the applicant does not project to provide the proposed services to a substantial number of persons residing in other states that are not adjacent to the North Carolina county in which the services will be offered.

- (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:
- would be available under a contract of at least 5 years duration;
 - would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
 - would cost no more than if the services were provided by the HMO; and
 - 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

The applicant proposes to relocate no more than seven dialysis stations from TVDC for a total of no more than 19 stations upon completion of this project and Project ID #G-11844-20 (develop a new 12-station dialysis facility by relocating no more than 12 stations from TVDC).

Project ID #G-11844-20 was approved for the development of a new 12-station dialysis facility. This application relocates seven additional stations to be certified upon the opening of the 19-station facility.

In Section K, page 68, the applicant states that the project will involve new construction of 4,718 square feet in addition to the 11,500 square feet approved in Project ID #G-11844-20. The proposed floor plan is provided in Exhibit K-1(b).

On page 68, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal based on the following:

- The addition of seven stations while the facility is under construction is cost effective to ensure current and future ESRD patients in Davidson and surrounding counties will have access to the care they require.
- Additional storage can be added at the facility to accommodate the need for storage at the other WFUHS Davidson County ESRD facilities.
- Line drawings are provided in Exhibit K-1.

On page 69, 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 based on the following:

- The proposed project provides dialysis services convenient to patients' homes, which increases patient attendance to treatment, improves patient outcomes, and reduces the cost per treatment to provide the service.
- The cost of the development of the facility represents a cost to WFUHS which is necessary to prevent excessive utilization of existing services in Davidson County; a cost that will alleviate travel burdens of patients, increase overall patient health, and reduce the need for hospitalizations.

On page 69, the applicant states that the construction of the facility, as stated in Project ID #G-11844-20, and the additional square footage for this project will be completed to meet and /or exceed current building codes related to any applicable energy saving features that will be incorporated into the construction plans and provides supporting documentation in Exhibit K-1.

Conclusion

The Agency reviewed the:

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

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

- (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 ... persons [with disabilities], 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

NDDC is not an existing facility. In Section L, page 72, the applicant provides the historical payor mix during CY2020 for the host facility, TVDC, as shown in the table below.

Primary Payor Source at Admission	Thomasville Dialysis Center CY2020					
	In-center Dialysis		Home Hemodialysis **		Peritoneal Dialysis **	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Self-Pay	1	1%	0	0%	0	0%
Insurance *	11	10%	0	0%	0	0%
Medicare *	78	72%	0	0%	0	0%
Medicaid *	4	4%	0	0%	0	0%
Other (Medicare/Medicaid)	15	14%	0	0%	0	0%
Total	109	100%	0	100%	0	100%

*Including any managed care plans

** This is **not** the number of patients trained in a year. Provide the total number of patients performing their hemodialysis or peritoneal dialysis in a location other than the dialysis facility.

Source: Section L, page 72

In Section L, page 73, the applicant provides the following comparison for TVDC, the facility from which stations are to be relocated.

Thomasville Dialysis Center	Percentage of Total Patients Served by the Facility or Campus during the Last Full CY2020	Percentage of the Population of the Service Area
Female	43.63%	51.10%
Male	56.37%	48.90%
Unknown	Not Available	0.00%
64 and Younger	50.00%	81.50%
65 and Older	50.00%	18.50%
American Indian	Not Available	0.80%
Asian	2.73%	1.60%
Black or African-American	38.18%	10.10%
Native Hawaiian or Pacific Islander	Not Available	0.10%
White or Caucasian	52.73%	79.40%
Other Race	6.36%	9.20%
Declined / Unavailable	Not Available	0.00%

The Agency reviewed the:

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

Based on that review, the Agency concludes that the applicant adequately documents the extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved. Therefore, the application is conforming to this criterion.

- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and ... persons [with disabilities] 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 73, the applicant states that while the facility is not required nor obligated to provide uncompensated care nor community service; 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.

In Section L.2(b), page 75, the applicant states that during the last five years no patient civil rights access complaints have been filed against TVDC, the host facility.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L.3(a), page 75, 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.

Primary Payor Source at Admission	North Davidson Dialysis Center CY2024					
	In-center Dialysis		Home Hemodialysis **		HH/PD Peritoneal Dialysis **	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Self-Pay	0	0%	0	0%	0	0%
Insurance *	5	9%	0	0%	2	22%
Medicare *	35	60%	0	0%	6	67%
Medicaid *	3	5%	0	0%	0	3%[0%]^
Other (Medicare/Medicaid)	13	22%	0	0%	1	11%
Other (VA)	2	3%			0	0%
Total	58	100%	0	100%	9	100%

*Including any managed care plans

** This is **not** the number of patients trained in a year. Provide the total number of patients performing their hemodialysis or peritoneal dialysis in a location other than the dialysis facility.

^Applicant's table had typographical error showing 0 Medicaid PD patients at 3% of total PD patients

Source: Section L, page 75

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 0% of IC dialysis services will be provided to self-pay patients, 60% to Medicare recipients and 5% to Medicaid recipients.

On pages 75-76, the applicant provides the assumptions and methodology used to project payor mix during the second full fiscal year of operation following completion

of the project. The projected payor mix is reasonable and adequately supported based on the following:

- The applicant bases future payor mix at NDDC on the WFUHS system-wide five-year average annual payor mix CY2015-2020.
- Average payor mix by payor type is averaged over five operating years.

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (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, pages 77-78, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

The applicant proposes to relocate no more than seven dialysis stations from TVDC for a total of no more than 19 stations upon completion of this project and Project ID #G-11844-20 (develop a new 12-station dialysis facility by relocating no more than 12 stations from TVDC).

In Section M, page 79, the applicant describes the extent to which health professional training programs in the area will have access to the facility for training purposes and provides supporting documentation in Exhibit M-1(b). The applicant adequately demonstrates that health professional training programs in the area will have access to the facility for training purposes based on the following:

- The applicant projects access at the proposed facility based on its experience
- The applicant provides documentation of its association with health professional training programs in the area

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

The applicant proposes to relocate no more than seven dialysis stations from TVDC for a total of no more than 19 stations upon completion of this project and Project ID #G-11844-20 (develop a new 12-station dialysis facility by relocating no more than 12 stations from TVDC).

On page 113, the 2021 SMFP defines the service area for ESRD dialysis facilities 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 areas: Cherokee, Clay and Graham counties and Avery, Mitchell, and Yancey counties.*” Thus, the service area for this facility consists of Davidson County. Facilities may also serve residents of counties not included in their service area.

According to Table 9A of the 2021 SMFP, there are three existing or approved dialysis facilities in Davidson County, all of which are owned and operated by WFUHS. Information on these dialysis facilities, from Table 9A of the 2021 SMFP, is provided below:

Davidson County Dialysis Facilities Certified Stations and Utilization as of December 31, 2019				
Dialysis Facility	Owner	Location	# of Certified Stations	Utilization
Lexington Dialysis Center of Wake Forest University	WFUHS	Lexington	42	72.62%
North Davidson Dialysis Center of Wake Forest University	WFUHS	Winston-Salem	0	0.00%
Thomasville Dialysis Center of Wake Forest University	WFUHS	Thomasville	32	85.94%

Source: 2021 SMFP, Table 9A.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 80, the applicant states:

“WFUHS is the whole owner of the two existing dialysis facilities within Davidson County. The CON-approved, NDDC, 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. 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, page 80, 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.”

See also Sections C, F, and Q of the application and any exhibits.

Regarding the impact of the proposal on quality, in Section N, page 81, the applicant states:

“Service quality will remain of the highest standard.”

See also Sections C and O of the application and any exhibits.

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 81, the applicant states:

“The transfer [relocation] of stations to an underserved area of Davidson county 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 community resources, overall.”

See also Section L and C of the application and any exhibits.

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would have a positive impact on cost-effectiveness, quality, and access because the applicant demonstrates that:

- 1) The proposal is cost effective because the applicant adequately demonstrated: a) the need the population to be served has for the proposal; b) that the proposal would not result in an unnecessary duplication of existing and approved health services; and c) that projected revenues and operating costs are reasonable.
- 2) Quality care would be provided based on the applicant’s representations about how it will ensure the quality of the proposed services and the applicant’s record of providing quality care in the past.
- 3) Medically underserved groups will have access to the proposed services based on the applicant’s representations about access by medically underserved groups and the projected payor mix.

Conclusion

The Agency reviewed the:

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

Based on that review, the Agency concludes that the application is conforming to this criterion based on 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 O Facilities, page 107, the applicant identifies the dialysis facilities located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of 20 of this type of facility located in North Carolina; 18 of the facilities are operational and two are approved but not certified.

In Section O, page 83, the applicant states that, during the 18 months immediately preceding the submittal of the application, standard level incidents related to quality of care (not resulting in immediate jeopardy) occurred at seven facilities. One facility has a report pending. The

table on page 83 shows that the facilities 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.

(21) Repealed effective July 1, 1987.

G.S. 131E-183 (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.

NA

WFUHS and NDDC, collectively referred to as “the applicant”, proposes to relocate no more than seven dialysis stations from TVDC in Davidson County for a total of no more than 19 stations upon project completion. Therefore, there are no performance standards applicable to this review.