

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: May 21, 2019

Findings Date: May 21, 2019

Project Analyst: Celia C. Inman

Co-Signer: Lisa Pittman

Project ID #: G-11674-19

Facility: Lexington Dialysis Center

FID #: 944660

County: Davidson

Applicants: Wake Forest University Health Sciences

Lexington Dialysis Center of Wake Forest University

Project: Add no more than 1 dialysis station and relocate no more than 4 dialysis stations from Piedmont Dialysis Center for a total of no more than 46 stations upon completion of this project, Project ID #G-11355-17 (replace the existing 37-station facility), and Project ID #G-11639-18 (add 4 stations)

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

The “applicants”, Wake Forest University Health Sciences (WFUHS) and Lexington Dialysis Center of Wake Forest University, propose to add one dialysis station, pursuant to the facility need methodology, and relocate four dialysis stations from Piedmont Dialysis Center (PDC) in Forsyth County, pursuant to Policy ESRD-2, to the existing Lexington Dialysis Center (LXDC) facility for a total of 46 certified dialysis

stations upon completion of this project, Project ID #G-11355-17 (replace the existing 37 station facility), and Project ID #G-11639-18 (relocate four dialysis stations from High Point Kidney Center (HPKC) to LXDC).

Need Determination

The 2019 State Medical Facilities Plan (SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to Table D in the January 2019 Semiannual Dialysis Report (SDR), the county need methodology shows there is a deficit of six dialysis stations in Davidson County. Therefore, because the deficit is less than 10 stations, there is no county need determination for new dialysis stations for Davidson County.

However, the applicants are eligible to apply for additional stations based on the facility need methodology because the utilization rate reported for LXDC in the January 2019 SDR is 3.24 patients per station per week. This utilization rate was calculated based on 120 in-center dialysis patients and 37 certified dialysis stations. (120 patients / 37 stations = 3.243 patients per station per week). The facility need methodology requires a facility’s utilization rate in the latest SDR to be at least 3.2 patients per station per week to be eligible to apply for additional stations based on facility need.

Application of the facility need methodology indicates that up to a maximum of one additional station is needed for this facility, as illustrated in the following table.

APRIL 1 REVIEW-JANUARY 2019 SDR		
Required SDR Utilization		80%
Center Utilization Rate as of 6/30/18		81.08%
Certified Stations		37
Pending Stations (Project ID #G-11639-18)		4
Total Existing and Pending Stations		41
In-Center Patients as of 6/30/18 (January 2019 SDR) (SDR2)		120
In-Center Patients as of 12/31/17 (July 2018 SDR) (SDR1)		108
Step	Description	Result
(i)	Difference (SDR2 - SDR1)	12
	Multiply the difference by 2 for the projected net in-center change	24
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 12/31/17	0.2222
(ii)	Divide the result of Step (i) by 12	0.0185
(iii)	Multiply the result of Step (ii) by 6	0.1111
(iv)	Multiply the result of Step (iii) by the number of in-center patients reported in SDR2 and add the product to the number of in-center patients reported in SDR2	133.3333
(v)	Divide the result of Step (iv) by 3.2 patients per station	41.6666
	and subtract the number of certified and pending stations to determine the number of stations needed	0.6666

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is one station (rounding to the nearest whole number is allowed only in Step (v), where fractions of 0.5 and greater shall be rounded to the next highest whole number.) The applicants propose to add one station pursuant to the facility need methodology. Therefore, the facility need determination for dialysis stations is applicable to this review.

In summary, the application is consistent with the facility need determination for dialysis stations.

Policies

There are two policies in the 2019 SMFP that are applicable to this review, Policy GEN-3: Basic Principles and Policy ESRD-2: Relocation of Dialysis Stations.

Policy GEN-3: Basic Principles, page 31 of the 2019 SMFP, states:

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

Promote Safety and Quality – The applicants describe how they believe the proposed project would promote safety and quality in Section B.4(a), pages 11-16, referencing other application sections and exhibits with specific details. The information provided by the applicants is reasonable and adequately supports the determination that the applicants’ proposal would promote safety and quality.

Promote Equitable Access - The applicants describe how they believe the proposed project would promote equitable access in Section B.4(b), pages 16-21, referencing other application sections and exhibits; and Section N.1, page 78. The information provided by the applicants is reasonable and adequately supports the determination that the applicants’ proposal would promote equitable access.

Maximize Healthcare Value - The applicants describe how they believe the proposed project would maximize healthcare value in Section B.4(c), page 21, referencing Sections F and K; and in Section N.1, page 78. The information provided by the applicants is reasonable and adequately supports the determination that the applicants’ proposal would maximize healthcare value.

The applicants adequately demonstrate how LXDC's projected volumes incorporate the concepts of quality, equitable access and maximum value for resources expended in meeting the facility need. Therefore, the application is consistent with Policy GEN-3.

Policy ESRD-2: Relocation of Dialysis Stations, on page 25 of the 2019 SMFP, states:

“Relocations of existing dialysis stations are allowed only within the host county and to contiguous counties. Certificate of need applicants 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 four existing dialysis stations from PDC in Forsyth County to LXDC in Davidson County, pursuant to Policy ESRD-2.

Davidson County and Forsyth County are contiguous counties. According to Table A of the January 2019 Semiannual Dialysis Report (SDR), both LXDC and PDC are currently serving residents of Davidson County.

According to Table D of the January 2019 SDR, Davidson County has a projected deficit of six dialysis stations and Forsyth County has a projected surplus of four stations. The proposal to relocate four stations from Forsyth County will not result in a surplus, or increase an existing surplus, in the number of dialysis stations in the county that would be gaining stations. Following the applicant's proposed relocation of four existing stations from PDC in Forsyth County to LXDC in Davidson County, Forsyth County would have a surplus of zero dialysis stations ($4 - 4 = 0$). The proposal will not result in a deficit, or increase an existing deficit, in the number of dialysis stations in the county that would be losing stations. 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 that the application is conforming to this criterion for the reasons stated above.

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

C

The applicants propose to add one dialysis station, pursuant to the facility need methodology, and relocate four dialysis stations from PDC in Forsyth County, pursuant to Policy ESRD-2, to the existing LXDC facility for a total of 46 certified dialysis stations completion of this project, Project ID #G-11355-17 (replace the existing 37 station facility), and Project ID #G-11639-18 (relocate four dialysis stations from HPKC).

The following table, summarized from data on page 4 of the application and Table B of the January 2019 SDR, illustrates the current and projected number of dialysis stations at LXDC.

Stations	Description	Project ID #
37	Total existing certified stations as of the January 2019 SDR. The entire facility approved to be relocated.	G-11355-17
+4	Stations to be added as part of an application under review at the time of submission	G-11639-18
+5	Stations to be added as part of this project (add one station and relocate four stations for a total of five)	G-11674-19
46	Total stations upon completion of proposed project and previously approved projects	

Patient Origin

On page 369, the 2019 SMFP defines the service area for dialysis stations as “...the dialysis station planning area in which the dialysis station is located. Except for the

Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.” LXDC is located in Davidson County. Thus, the service area for this review is Davidson County. Facilities may serve residents of counties not included in their service area.

In Section C.8, page 30, the applicants provide the existing patient origin for the in-center (IC), home hemodialysis (HH) and peritoneal dialysis (PD) services provided at LXDC, as of February 28, 2019, as summarized in the following table.

**Lexington Dialysis Center Existing Patient Origin
 As of February 28, 2019**

County	IC Patients	HH Patients	PD Patients
Davidson	120	2	22
Forsyth	1	1	0
Randolph	0	0	1
Rowan	5	0	5
Davidson Transfers In	0	0	7
TOTAL	126	3	35

Source: Table on page 30 of the application.

Tables B and C of the January 2019 SDR, show LXDC serving 120 IC patients, three HH patients and 27 PD patients, as of June 30, 2018.

In Section C.1, page 23, the applicants provide the projected IC, HH, and PD patient origin for LXDC for operating year one (OY1), March 1, 2020 – February 28, 2021, and operating year two (OY2), March 1, 2021 – February 28, 2022, the first two full operating years following project completion, as shown in the following table:

County	End of OY1 Feb 28, 2021			End of OY2 Feb 28, 2022			Percent of Total Patients	
	IC	HH	PD	IC	HH	PD	OY1	OY2
Davidson	137.64	2.29	25.23	147.42	2.46	27.03	82.01%	82.02%
Forsyth	1.08	1.08	0.00	1.12	1.12	0.00	1.07%	1.04%
Randolph	0.00	0.00	1.03	0.00	0.00	1.04	0.51%	0.48%
Rowan	5.82	0.00	5.82	6.28	0.00	6.28	5.78%	5.82%
Davidson Transfers In	11.78	0.00	9.64	12.62	0.00	10.32	10.63%	10.64%
Total	156.32	3.37	41.72	167.43	3.58	44.67	100.00%	100.00%

Totals may not sum due to rounding

In Section C, pages 23-24, the applicants provide the assumptions and methodology used to project LXDC’s patient origin. On page 24, the applicants state that the current February 28, 2019 LXDC patient population shall increase by the January 2019 SDR 5-year Average Annual Change Rate (AACR) for each county of origin. The table above shows that at least 11 in-center Davidson County residents receiving care in Forsyth County will transfer their care to LXDC (Davidson Transfers In), projected to

increase annually at the stated Davidson County AACR. In Section C.7, page 29, the applicants state:

“In addition to the projected patient growth by county of the existing patient population, LXDC projects service for at least 11 other ICH-patient residents of Davidson County and 2 other home dialysis-patient residents of Davidson County who have expressed an interest in moving their care to LXDC upon completion of the LXDC replacement facility. The majority of those patients currently receive care at the host facility in Forsyth County, Piedmont Dialysis Center.”

Per Table A of the January 2019 SDR, PDC, the facility from which stations are being relocated, served seven IC patients from Davidson County, and other WFUHS Forsyth County dialysis facilities served another eight Davidson County IC patients, for a total of 15 Davidson County IC patients being served by a WFUHS dialysis facility in Forsyth County. The applicants’ assumptions are reasonable and adequately supported.

Analysis of Need

The applicants propose to add one dialysis station, pursuant to the facility need methodology, and relocate four dialysis stations from PDC in Forsyth County, pursuant to Policy ESRD-2, to the existing LXDC facility. In Section C, the applicants explain why they believe the population projected to utilize the proposed services needs the proposed services. In Section C.1, page 23, the applicants state the purpose of the proposed project is to:

“... expand the existing services at LXDC on all patient shifts to meet the current and projected patient needs.”

In Section C.2, page 26, the applicants state that the facility must request additional stations now to head off excessive utilization in the future. On page 25, the applicants further state that LXDC’s facility utilization rate has risen to 85.14% and is anticipated to exceed 100% capacity in less than two years.

In Section C.2, page 25, the applicants show that the utilization rate for LXDC, as of February 28, 2019, was 85.14% for 37 stations and is projected to reach 113.13% utilization by February 28, 2022, if no stations are added.

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

- the facility is currently operating at 85.14% capacity with 37 stations and is expected to reach more than 100% capacity by February 28, 2021, if no stations are added,
- the applicants base the future need for services upon the facility’s historical patient utilization, applying the January 2019 SDR’s 5-year county AACR of

7.1%, 3.8%, 1.3%, and 7.9%, for patients from Davidson, Forsyth, Randolph, and Rowan counties, respectively, to project growth in patient need at the facility.

Projected Utilization

In-Center Patients

In Section C.2, page 27, the applicants provide the calculations used to arrive at the projected in-center patient census for the first two years of operation following the completion of the project. The following table provides historical and projected utilization of in-center dialysis patients at LXDC.

LXDC In-Center Dialysis Utilization

County	January 2019 SDR 5-Yr AACR	Beginning Census 2/28/2019	Growth as of Certification 2/28/2020	End of OY1 2/28/2021	End of OY2 2/28/2022
Davidson	7.1%	120.00	128.52	137.64	147.42
Forsyth	3.8%	1.00	1.04	1.08	1.12
Randolph	1.3%	0.00	0.00	0.00	0.00
Rowan	7.9%	5.00	5.40	5.82	6.28
Davidson Transfers In	7.1%	0.00	11.00	11.78	12.62
Totals		126.00	145.95	156.32	167.43

Totals may not sum due to rounding

As the table above shows, the methodology used by the applicants achieves a projection of 156.32 in-center patients by the end of the first operating year, OY1, for a utilization rate of 3.4 patients per station per week or 84.9% (156.3 patients / 46 stations = 3.397 patients per station / 4 = 0.8494). By the end of OY2, following the applicants' methodology and assumptions, LXDC will have 167.43 in-center patients dialyzing at the center for a utilization rate of 91.0% (167.4 / 46 = 3.64 / 4 = .9097). The projected utilization of 3.4 patients per station per week for OY1 satisfies the 3.2 in-center patients per station threshold as required by 10A NCAC 14C .2203(b).

In Section C.7, pages 29-30, the applicants provide the methodology and assumptions used to project utilization at LXDC. Based on the facility need methodology, LXDC is eligible to add one dialysis station. The applicants also propose to relocate four stations from Forsyth County to LXDC and provide calculations that support the addition of the five stations.

The applicants' methodology and assumptions are summarized below:

- Existing patients are grouped by modality and county of origin, as of February 28, 2019.
- Utilization is based on current patients at LXDC, projected forward by applying the January 2019 SDR 5-year AACR, by county of patient origin, to the current patient populations to project patient census through the end of Operating Year 2.
- OY1 ends February 28, 2021; OY2 ends February 28, 2022.
- At least 11 IC patients will transfer their care from WFUHS dialysis facilities in Forsyth County along with the relocation of the four stations from PDC in Forsyth County.
- Utilization calculations include the station additions still under review in Project ID #G-11639-18.

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

- the applicants base the future utilization of services upon the facility's historical patient utilization, and
- the applicants utilize the January 2019 SDR's 5-year county AACR of 7.1%, 3.8%, 1.3%, and 7.9%, for patients from Davidson, Forsyth, Randolph, and Rowan counties, respectively, to project growth in patient need at the facility.

Home Hemodialysis and Peritoneal Patients

The following table summarized from the table on page 27 shows the historical HH and PD utilization at LXDC.

**LXDC HH and PD Dialysis Historical Utilization
As of 2/28/2019**

County	PD	HH	Total
Home-Trained	22	0	22
Home Patients	35	3	38

Following the same assumptions and methodology as above, the applicants project four HH patients and 45 PD patients in OY2, as shown in Section C.1, page 23. On page 28, the applicants make the point that any number of the HH and PD patients could change modality from home to IC or require IC backup; therefore the additional stations at LXDC will potentially improve overall access to services for those patients also.

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

- the applicants base the future utilization of services upon the facility's historical patient utilization,
- the applicants utilize the January 2019 SDR's 5-year county AACR of 7.1%, 3.8%, 1.3%, and 7.9%, for patients from Davidson, Forsyth, Randolph, and Rowan counties, respectively, to project growth in patient need at the facility, and

- two home dialysis patients have expressed an interest in moving their care to LXDC.

Access

In Section C.3, page 28, the applicants state:

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

Exhibit L-3(a) contains the facility’s Referral/Admissions Policy. The applicants project payor mix during the second full fiscal year of operation following completion of the project, as summarized in the following table from Section L.1(b), page 68.

Projected Payor Mix OY2

Payor Source	Total Patients	In-center Patients	HH & PD Patients
Private Pay	1.0%	1.0%	0.0%
Medicare	12.0%	13.0%	11.0%
Medicaid	4.0%	6.0%	1.0%
Medicare / Medicaid	17.0%	20.0%	13.0%
Commercial Insurance	12.0%	7.0%	19.0%
Medicare / Commercial	25.0%	22.0%	30.0%
VA	9.0%	9.0%	10.0%
Medicare Advantage	20.0%	22.0%	16.0%
Total	100.0%	100.0%	100.0%

In Section L.1(b), page 68, the applicants state that the projected payor mix is based upon the facility’s five-year average annual payor mix, composed of monthly snapshots. 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 applicants adequately identify the population to be served.
- The applicants adequately explain why the population to be served needs the services proposed in this application.
- Projected utilization is reasonable and adequately supported.
- The applicants project 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 applicants propose to relocate four dialysis stations from PDC in Forsyth County to LXDC in Davidson County, pursuant to Policy ESRD-2. In Section D, pages 33-34, the applicants explain why they believe 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 applicants state:

- as of February 28, 2019, PDC was operating at a utilization rate of 75.9% on 58 IC dialysis stations,
- at that time, PDC was serving five IC and six PD patients who reside in Davidson County and WFUHS dialysis facilities in Forsyth County were serving a combined 17 ESRD patients from Davidson County, and

The applicants further state that upon approval of the proposed project, PDC will have 54 IC dialysis stations. Using the 54 stations, and serving the population presently served, less those Davidson County patients who have expressed an interest in transferring their care to LXDC, the utilization rate will be approximately 80% ($171 / 54 = 3.16 / 4 = 0.7916$). If no patients transfer from PDC, PDC would be operating at 81.5% capacity ($176 / 54 = 3.25 / 4 = .8148$). The applicants state that the population presently served at PDC will continue to have their needs adequately met by the remaining 54 dialysis stations.

In Section D.2, pages, 33-34, the applicants state:

*“The facility does not discriminate, regardless of income, race, ethnicity, sex, disability, age or other defining attribute. Admission is determined by **medically defined admission criteria** [emphasis is original] - a diagnosis of ESRD. By relocating stations from an area of underutilization to an area where they will be utilized, overall access to care will be improved. Pre proposed project will enhance the ability of all person, including those determined to be medically underserved to obtain the medical care they require.”*

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 applicants propose to add one dialysis station, pursuant to the facility need methodology, and relocate four dialysis stations from PDC in Forsyth County, pursuant to Policy ESRD-2, to the existing LXDC facility for a total of 46 certified dialysis stations upon completion of this project, Project ID #G-11355-17 (replace the existing 37 station facility), and Project ID #G-11639-18 (relocate four dialysis stations from HPKC).

In Section E, pages 35-38, the applicants describe the alternatives considered and explain why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. LXDC and the patient projections and utilization calculations demonstrate that five additional stations are needed at LXDC.

The alternatives considered were:

- Maintain Status Quo – the applicants state that this alternative is not effective because failing to address the facility need at LXDC could have undesirable

consequences such as the need for a third shift, patient travel issues, and patient non-compliance.

- Policy ESRD-2, In-County Station Relocation – WFUHS owns two dialysis facilities in Davidson County: LXDC and Thomasville Dialysis Center (TVDC). TVDC recently filed a CON for additional stations via Policy ESRD-2 and a transfer of any stations from TVDC would create an immediate need at that location for additional dialysis stations, which would require another CON application and additional cost.
- Policy ESRD-2, Contiguous County Station Relocation – the applicants state that WFUHS has dialysis facilities in contiguous counties from which stations might be relocated, pursuant to Policy ESRD-2. Relocating four stations from PDC in Forsyth County meets the requirement for relocation of stations, pursuant to Policy ESRD-2, and is therefore a viable option to meet part of the need for stations at LXDC.
- Facility Need Methodology – the applicants state that LXDC is eligible to add one station pursuant to the facility need methodology; therefore, this is a viable option to meet part of the need for stations at LXDC.
- Hybrid (Combination Policy ESRD-2 and Facility Need Methodology) – the applicants state that combining Policy ESRD-2 and the facility need methodology meets the projected needs at LXDC and will improve overall access to the ESRD patients in the service area.

On pages 36-37, the applicants state that the hybrid project, as proposed, is the most effective alternative because the facility need methodology allows LXDC to add one station and Policy ESRD-2 allows LXDC to relocate four stations which meets its projected need for five additional dialysis stations. The applicants state on page 36:

“Of the alternatives considered, the one that offers the greatest impact on LXDC’s projected utilization is the hybrid model, which uses a combination of facility need methodology and ESRD-2 contiguous-county station transfer. Thus, this is the facility’s chosen alternative.”

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

- The application is conforming to all statutory and regulatory review criteria.
- The applicants provide 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 Lexington Dialysis Center of Wake Forest University shall materially comply with all representations made in the certificate of need application.**
 - 2. Pursuant to the facility need determination in the January 2019 SDR, Wake Forest University Health Sciences and Lexington Dialysis Center of Wake Forest University Dialysis shall add no more than one additional dialysis station and relocate no more than four stations from Piedmont Dialysis Center for a total of no more than 46 certified dialysis stations at Lexington Dialysis Center upon completion of this project and Project ID #G-11355-17 (replace the existing 37-station facility), and Project ID #G-11639-18 (add 4 stations), which shall include any home hemodialysis training or isolation stations.**
 - 3. Upon completion of this project, Wake Forest University Health Sciences shall take the necessary steps to decertify four stations at Piedmont Dialysis Center for a total of no more than 54 dialysis stations.**
 - 4. Wake Forest University Health Sciences and Lexington Dialysis Center of Wake Forest University shall install plumbing and electrical wiring through the walls for no more than five additional dialysis stations which shall include any isolation stations.**
 - 5. Wake Forest University Health Sciences and Lexington Dialysis Center of Wake Forest University Dialysis shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicants currently operate LXDC, a 37-station dialysis facility located in Davidson County. In this project, the applicants propose to add one station, pursuant to the facility need methodology, and relocate four stations, pursuant to Policy ESRD-2, to the existing LXDC facility for a total of 46 certified dialysis stations upon project completion.

Capital and Working Capital Costs

In Section F.1, page 39, the applicants project the total capital costs for the project as summarized below.

Projected Capital Costs		Total Costs
Dialysis Machines	\$72,500	
Other Equipment/Furniture	\$11,500	
Total Capital Costs		\$84,000

In Section F, the applicants provide the assumptions used to project the capital cost.

The project does not involve any construction costs. In Section F, page 43, the applicants state that LXDC is an existing operational facility; therefore, there are no start-up or initial operating expenses.

Availability of Funds

In Section F, page 40, the applicants state that the capital cost will be funded as shown in the table below.

Sources of Capital Cost Financing			
Type	Wake Forest University Health Sciences	Lexington Dialysis Center	Total
Loans			
Accumulated reserves or OE *	\$84,000		\$84,000
Bonds			
Other (Specify)			
Total Financing	\$84,000		\$84,000

* OE = Owner's Equity

In Exhibit F-5, the applicants provide a letter dated March 15, 2019, from the President of the Wake Forest Baptist Health System, authorizing the project and committing \$84,000 for the development of the project.

Exhibit F-7 contains Consolidated Financial Statements for Wake Forest University for the fiscal year ended June 30, 2018, showing WFUHS with \$16,242,000 in cash and cash equivalents, \$1.37 billion in total assets and \$794,745,000 in net equity.

The applicants adequately demonstrate the availability of funds for the capital needs of the project.

Financial Feasibility

The applicants provide pro forma financial statements for the first two full fiscal years of operation following completion of this project. In Form B, the applicants project

that revenues will exceed operating expenses in the first two operating years of this project, as shown in the table below.

Lexington Dialysis Center Revenue and Expenses		
	OY1 3/1/2020-2/28/2021	OY2 3/1/2021-2/28/2022
In-Center Patients*	152	162
HH and PD Patients*	43	46
In-Center Treatments	22,800	24,300
HH and PD Treatments	14,104	15,088
Gross Patient Revenue (IC, HH, and PD)	\$53,032,834	\$56,565,949
Adjustment from Gross**	\$44,248,990	\$47,144,825
Net Patient Revenue (IC, HH, and PD)	\$8,783,845	\$ 9,421,123
Average Net Revenue per IC, HH, and PD Patient	\$45,045	\$45,294
Total Operating Expenses (IC, HH, and PD)	\$5,828,510	\$6,117,000
Average Operating Expense per IC, HH, and PD Patient	\$29,890	\$29,409
Net Income	\$2,955,335	\$3,304,123

*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 applicants in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section R of the application for the assumptions 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 applicants adequately demonstrate that the capital costs are based on reasonable and adequately supported assumptions.
- The applicants adequately demonstrate availability of sufficient funds for the capital needs of the proposal.
- The applicants adequately demonstrate sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

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

C

The applicant proposes to add one station, pursuant to facility need methodology, and relocate four existing dialysis stations from PDC in Forsyth County to LXDC in Davidson County, pursuant to Policy ESRD-2, for a total of 46 stations at LXDC upon project completion.

On page 369, the 2019 SMFP defines the service area for dialysis stations as “...*the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.*” LXDC is located in Davidson County. Thus, the service area for this review is Davidson County. Facilities may serve residents of counties not included in their service area.

According to Table B of the January 2019 SDR, there are two existing or approved dialysis facilities in Davidson County which are operational. Information on both of these dialysis facilities, from Table B of the January 2019 SDR, is provided below:

Davidson County Dialysis Facilities Certified Stations and Utilization as of June 30, 2018				
Dialysis Facility	Owner	Location	# of Certified Stations	Utilization
Lexington Dialysis Center of Wake Forest University*	WFUHS	Lexington	37	81.08%
Thomasville Dialysis Center of Wake Forest University	WFUHS	Thomasville	32	75.00%

Source: January 2019 SDR, Table B.

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

In Section G, page 46, the applicants explain why they believe the proposal would not result in the unnecessary duplication of existing or approved dialysis services in Davidson County. The applicant states:

“LXDC’s need is real and immediate to assist in the rebalance of patients and stations WFUHS hopes to achieve. The requested number of dialysis stations have been shown to provide service at a level of 80% utilization by the end of OY1 based on growth of the facility’s current patient census and projected patient transfers. Approval of this project will not result in duplication of existing and approved services in the proposed service area – Davidson County.”

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

- There is a facility need determination pursuant to the 2019 SMFP for the proposed addition of one station.
- The proposal would not result in a surplus of stations or increase an existing surplus of stations in Davidson County.
- The applicants adequately demonstrate that the proposed stations are needed in addition to the existing and/or approved stations 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 H.1, page 47, the applicants provide the current and projected OY2 staffing for the proposed services, as summarized in the following table showing full-time equivalent (FTE) positions.

POSITION	Current FTE Positions as of 2/28/19	PROJECTED FTE POSITIONS OY2
RN	6.75	8.00
LPN	1.25	1.25
Patient Care Tech	10.75	12.00
Clinical Nurse Manager (DON)	1.00	1.00
Dietician	1.00	1.00
Social Worker	2.00	2.00
Home Training Nurse	1.00	1.00
Dialysis Tech	2.25	2.25
Bio-med Technician	1.00	1.00
Clerical	3.00	3.00
Total	30.00	32.50

Source: Sections H and R of the application.

The Medical Director and administrative services, including medical records, are contract services, not FTE positions and are projected at \$80,000 and \$230,753, respectively.

The assumptions and methodology used to project staffing are provided in Sections H and R. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in the pro forma financials found in Section R. In Section H, pages 51-52, the applicants describe the methods used to recruit or fill new positions and its existing training and continuing education programs. In Section H, page 49, and Section I.3, page 57, the applicants identify the current Medical Director. In Exhibit I.3(a), the applicant provides a letter from Alison Fletcher, M.D., indicating a commitment to continue to serve as Medical Director for the facility. In Exhibit H.2, the applicants provide supporting documentation.

The applicants adequately demonstrate 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 55-56, the applicants identify the necessary ancillary and support services and explains how they will be made available. The applicants provide a table on page 55, as summarized below.

**Lexington 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
(d) Psychological counseling	On Premises
(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
(l) X-ray services	Wake Forest Baptist Hospital
(m) Laboratory services	Wake Forest Baptist Hospital Meridian Lab Contract/On Premises
(n) Pediatric nephrology	On Premises
(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	Multiple in-county options

In Section I, pages 56-59, the applicants describe LXDC’s existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibits I-1, I-2, I-3, and I.4.

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

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 applicants do 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 applicants do 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 applicants are not HMOs. Therefore, Criterion (10) is not applicable to this review.

- (11) Repealed effective July 1, 1987.

- (12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

NA

The applicants do not propose any new construction or major renovations to existing space. Therefore, Criterion (12) is not applicable to this review.

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

- (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C

In Section L.7, page 75, the applicants provide the LXDC's historical payor mix for the time period ending February 28, 2019 for the proposed services, 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	13.0%	12.0%	16.0%
Medicaid	4.0%	6.0%	1.0%
Medicare / Medicaid	16.0%	18.0%	12.0%
Commercial Insurance	13.0%	9.0%	19.0%
Medicare / Commercial	24.0%	21.0%	30.0%
VA	8.0%	7.0%	10.0%
Medicare Advantage	21.0%	26.0%	12.0%
Total	100.0%	100.0%	100.0%

Totals may not sum due to rounding

The United States Census Bureau provides demographic data for North Carolina and all counties in North Carolina. The following table contains relevant demographic statistics for the applicants' service area.

Percent of Population						
County	% 65+	% Female	% Racial and Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance**
2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate
Davidson	18%	51%	20%	15%	13%	13%
Statewide	16%	51%	37%	15%	10%	12%

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

* Excludes "White alone, not Hispanic or Latino"

** "Estimates are not comparable to other geographic levels due to methodology differences that may exist between different data sources. Some estimates presented here come from sample data, and thus have sampling errors that may render some apparent differences between geographies statistically indistinguishable...The vintage year (e.g., V2017) refers to the final year of the series (2010 thru 2017). Different vintage years of estimates are not comparable."

The IPRO ESRD Network of the South Atlantic Network 6 (IPRO SA Network 6) consisting of North Carolina, South Carolina and Georgia, provides an Annual Report which includes aggregate ESRD patient data from all three states. The 2016 Annual Report does not provide state-specific ESRD patient data, but the aggregate data is likely to be similar to North Carolina's based on the Network's recent annual reports which included state-specific data.

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

Conclusion

The Agency reviewed the:

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

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

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

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

C

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L.3(d), page 73, the applicants state:

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

In Section L.6, page 74, the applicants state that there have been no civil rights access complaints filed against the facility or any facilities owned by the parent company in North Carolina within the last five years.

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 68, the applicants project 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
OY2**

Payor Source	Total Patients	In-center Patients	PD & HH Patients
Private Pay	1.00%	1.00%	0.00%
Medicare	12.00%	13.00%	11.00%
Medicaid	4.00%	6.00%	1.00%
Medicare / Medicaid	17.00%	20.00%	13.00%
Commercial Insurance	12.00%	7.00%	19.00%
Medicare / Commercial	25.00%	22.00%	30.00%
VA	9.00%	9.00%	10.00%
Medicare Advantage	20.00%	22.00%	16.00%
Total	100.0%	100.0%	100.0%

Source: Application page 68

As shown in the table above, during the second full calendar year of operation, the applicants project that 1% of the dialysis patients will be private pay patients and 78% will have all or part of their services paid for by Medicare and/or Medicaid.

On pages 68-69, the applicants provide 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 applicants' proposed patient origin is comparable to its historical patient origin, and
- the applicants project future payor mix based on the facility's average monthly payor mix by payor type for each of the last five operating 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.

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

C

In Section L.4, pages 73-74, the applicants adequately describe 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 77, the applicants describe the extent to which health professional training programs in the area have access to the facility for training purposes and provide supporting documentation in Exhibit M-1.

The Agency reviewed the:

- application, and
- exhibits to the application.

Based on that review, the Agency concludes that the applicants adequately demonstrate 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 applicants propose to add one dialysis station, pursuant to the facility need methodology, and relocate four dialysis stations, pursuant to Policy ESRD-2, for a total of 46 dialysis stations at the existing LXDC facility upon project completion.

On page 369, the 2019 SMFP defines the service area for dialysis stations as “...*the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.*” LXDC is located in Davidson County. Thus, the service area for this review is Davidson County. Facilities may serve residents of counties not included in their service area.

According to Table B of the January 2019 SDR, there are two existing or approved dialysis facilities in Davidson County which are operational. Information on both of these dialysis facilities, from Table B of the January 2019 SDR, is provided below:

Davidson County Dialysis Facilities Certified Stations and Utilization as of June 30, 2018				
Dialysis Facility	Owner	Location	# of Certified Stations	Utilization
Lexington Dialysis Center of Wake Forest University*	WFUHS	Lexington	37	81.08%
Thomasville Dialysis Center of Wake Forest University	WFUHS	Thomasville	32	75.00%

Source: January 2019 SDR, Table B.

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

In Section N, pages 78-79, the applicants describe the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality, and access to the proposed services. On page 78, the applicant states:

“This project shall have no impact on competition in Davidson County. It proposes to serve the existing and projected patients anticipated to utilize the services of LXDC, alone. Patients utilize a facility based upon physician preference, geographical location, or other reasons of convenience. An addition of stations at LXDC is necessary to serve the facility’s existing and projected patients and serve Davidson County residents suffering with ESRD.”

The applicants adequately describe the expected effects of the proposed services on competition in the service area and adequately demonstrate:

- the cost-effectiveness of the proposal (see Sections B, F, and R of the application and any exhibits),

- quality services will be provided (see Sections B and O of the application and any exhibits), and
- access will be provided to underserved groups (see Section B, pages 15-21, Section L 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 A.11, pages 5-6, the applicants identify the dialysis facilities located in North Carolina and owned, operated or managed by the applicant or a related entity. The applicants identify a total of 18 WFUHS dialysis facilities located in North Carolina.

In Section O, pages 80-81, the applicants state that during the 18 months immediately preceding the submittal of the application, incidents related to quality of care occurred in five of the 18 facilities. The applicants state that at the time of application submittal, all facilities were in compliance. After reviewing and considering information provided by the applicants and considering the quality of care provided at all 18 facilities, the applicants provide 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 End Stage Renal Disease facility shall document the need for at least 10 stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the facility, with the exception that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.

-NA- The applicants are not proposing to establish a new ESRD facility.

(b) An applicant proposing to increase the number of dialysis stations in an existing End Stage Renal Disease facility or one that was not operational prior to the beginning of the review period but which had been issued a certificate of need shall document the need for the additional stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the additional stations.

-C- In Section C.2, page 27, the applicants provide the calculations used to arrive at the projected in-center patient census for the first two years of operation following the completion of the project.

As fully discussed in Criterion (3) above, the methodology proposed by the applicants achieves a projection of 156.32 in-center patients by the end of the first operating year, OY1, for a utilization rate of 3.4 patients per station per week or 84.9% (156.3 patients / 46 stations = 3.397 patients per station / 4 = 0.8494). The projected utilization of 3.4 patients per station per week for OY1 satisfies the 3.2 in-center patients per station threshold as required by 10A NCAC 14C .2203(b). The discussion related to projected utilization in Criterion (3) is incorporated herein by reference.

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

-C- In Sections C.1 and C.7, pages 23-24 and 29-30, respectively, the applicants provide the assumptions and methodology used to project utilization of the facility.