

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: January 28, 2025

Findings Date: February 4, 2025

Project Analyst: Crystal Kearney

Co-Signer: Lisa Pittman

Project ID #: G-12564-24

Facility: Lexington Medical Center

FID #: 943307

County: Davidson

Applicant(s): Wake Forest University Baptist Medical Center

Lexington Medical Center

Project: Develop in-patient dialysis services with no more than 3 stations

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 Baptist Medical Center (“WFUBMC”) and Lexington Medical Center (“LMC”), (hereinafter referred to as the “applicant”) propose to add inpatient dialysis services at LMC in Davidson County. This proposal includes the purchase of 3 Mobile hemodialysis machines and plumbing uplift in 10 patient rooms. This will allow LMC to keep patients in Davidson County who require inpatient dialysis during their hospital stay. Currently, patients presenting at LMC who require inpatient dialysis must be transferred out to medical facilities in other counties. The addition of this service will improve the utilization of hospital resources in Davidson and surrounding counties.

The applicant does not propose to:

- develop any beds or services for which there is a need determination in the 2024 SMFP.

- acquire any medical equipment for which there is a need determination in the 2024 SMFP.
- offer a new institutional health service for which there are any policies in the 2024 SMFP.

Therefore, Criterion (1) is not applicable to this review.

- (2) Repealed effective July 1, 1987.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 develop an inpatient dialysis service by developing three dialysis stations at LMC.

Patient Origin

N.C.G.S. §131E-176(24a) defines “service area” as “*The area of the State, as defined in the State Medical Facilities Plan or in rules adopted by the Department, which receives services from a health service facility.*” The 2024 SMFP defines a service area for inpatient dialysis services as “*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.*” There are no applicable rules adopted by the Department that define a service area for inpatient dialysis services.

The applicant does not currently provide inpatient dialysis services; therefore, there is no historical patient origin. The applicant states in Section C.3, page 17, that its service area for the proposed inpatient dialysis services will be Davidson County. The facility may also serve residents of counties not included in their service area.

In Section C, page 18, the applicant provides projected patient origin for the second full fiscal year (FY) of operation, September 1-August 31, in the following table:

COUNTY	2 ND FULL FY OF OPERATION 9/1/26 TO 8/31/27					
	# OF IN-PATIENT DIALYSIS PATIENTS	% OF TOTAL	# OF HH PATENTS	# OF TOTAL	# OF PD PATIENTS	% OF TOTAL
Davidson	305.10	100%	0.00		0.00	
Total	305.10	100%	0.00	0%	0.00	0%

In Section C, page 18, the applicant provides the assumptions and methodology used to project its patient origin. The applicant’s assumptions are reasonable and adequately supported

because they are based on the applicant's historical patient origin for the applicant's dialysis clinics in Davidson County.

Analysis of Need

In Section C.4, pages 18 - 21, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below:

- The applicant states that between 9/1/2023 and 8/31/2024, WFUHS' dialysis facilities in Davidson County reported 318 patient hospitalizations where inpatient dialysis was required, reduced by 52% of TVDC's patient hospitalizations to 300 based on TVDC's proximity to High Point Regional Health versus LMC.
- The applicant states that on average patients requiring inpatient dialysis missed two hemo - equivalent treatments during each hospitalization.
- The applicant states that because LMC was not certified to provide inpatient dialysis, LMC had to be bypassed instead of utilized to provide care for those patients.
- The applicant states that the lack of inpatient dialysis services in Davidson County means ESRD patients requiring hospitalization are not able to utilize the hospital in their home county and require transportation to a facility in a contiguous county for their care. This places an unnecessary burden on patients, patient families, and transportation providers. WFUBMC is an additional 25 miles from LMC. High Point Regional Health is an additional 22 miles from LMC.

The applicant states that approval of this project for inpatient dialysis services at LMC will improve access to services for patients in Davidson and surrounding counties. The LMC facility as a whole will be better utilized since patients who require inpatient dialysis will not have to transfer out to Forsyth or Guilford Counties simply because LMC can't provide their complete care. This represents a positive scenario for patients and their families, LMC, hospitals in adjacent counties, and transportation providers.

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

- Providing dialysis services to a patient in need of those services during an inpatient stay will avoid costly transportation expenses to an out-of- county hospital and would avoid interruptions in inpatient care at LMC.
- The applicant demonstrates the need for inpatient dialysis services based on the information provided regarding the growth and health statistics of Davidson County residents and on LMC's patients.

Projected Utilization

In Section Q, Form C, page 65, the applicant projects to serve the following dialysis patients in the first two operating years, federal fiscal years (FFY), FFY 2026 and FFY 2027.

	1st Full FY 9/1/2025 to 8/31/2026	2nd Full FY 9/1/2026 to 8/31/2027
Average # Patients /Year	300	303
# Treatments/Patients/Year	2	2
Total # Treatments	600	606

In Section Q, Form C- Assumptions and Methodology, pages 65-66, the applicant describes its methodology and assumptions used to project utilization of the proposed inpatient dialysis services, as summarized below.

During the 12 months prior to filing for this CON, the patients attending the three dialysis clinics of Wake Forest University Health Sciences (a related entity) operating in Davidson County experienced 318 hospitalization events totaling 1,579 hospitalization days.

- The 318 hospitalized WFUHS dialysis patients receiving care in Davidson County missed 677 total hemo-equivalent dialysis treatments due to hospitalization during the 12 months prior to filing for this CON, equaling two missed hemo-equivalent treatments per hospitalization.
- The total 677 hemo-equivalent missed treatments were reduced to 600 hemo-equivalent missed treatments due to patient residence proximity to High Point Regional Health versus LMC.
- Using the 5-year AACR by county published in the 2024 SMFP, the projected OY1 patient population was increased, resulting in the number of patients projected by the end of each OY.
- Projected patient volumes for subsequent years were determined by the following method, as shown below:

Davidson					
In-Patient Dialysis Services Growth					
5-YEAR AACR 1.7%					
	Number of ICH Patients				
	Ending Prior Year	Ending Current Year	Ending OY1	Ending OY2	Beginning Prior Year
	8/31/2024	8/31/2025	8/31/2026	8/31/2027	8/31/2028
Number of Patients	0.00	0.00	300.00	305.10	310.29
Number of Patients	0.00	0.00	300.00	303.00	308.00

Section Q, page 66

- The Total Number of Treatments were found by multiplying the average Billable Treatments by the Average Number of Patients During the Year for each period.
- The Total Number of treatments was used to project Cost, Revenue, and Income throughout the Pro Forma.

Projected utilization is reasonable and adequately supported based on the above stated reasons.

Access to Medically Underserved Groups

In Section C.6, page 24, the applicant states:

“Admission of a patient is based solely upon medical necessity and not the patient’s ability to pay. The majority of patients are covered by Medicare, Medicaid, or some other form or combination of healthcare coverage. 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. Admission is based upon medically defined criteria.”

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

	Percentage of Total Patients
Low income persons	13.8%
Racial and ethnic minorities	39.45%
Women	42.91%
Persons with Disabilities*	
Persons 65 and older	51.21%
Medicare beneficiaries	48.9%
Medicaid recipients	13.8%

* Not tracked

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 the admission of a patient is based solely upon medical necessity and not the patient’s ability to pay.
- The applicant’s assumptions are based on LMC’s FFY 2027 patient population for inpatient services in the service area.

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 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.

NA

The applicant does not propose to reduce a service, eliminate a service or relocate a facility or service. Therefore, Criterion (3a) is not applicable to this review.

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

CA

The applicant proposes to develop an inpatient dialysis service by developing three dialysis stations at LMC.

In Section E, pages 32-33, the applicant describes the two alternatives it considered and explains why the first alternative is either more costly or less effective than the alternative proposed in this application to meet the need, as summarized below:

- Maintain the Status Quo - The applicant states this is not a reasonable alternative because does not alleviate travel burdens or improve access to care for the dialysis patients receiving ESRD services in Davidson County who may require hospitalization. Additionally, Maintaining the status quo will continue to place a burden on transportation services and hospitals in contiguous counties, represent a hurdle to patients and their families, and result in unnecessary underutilization scenarios at LMC. The applicant states that maintaining the status quo fails to address the issues for which this proposal submitted. Therefore, this alternative was not chosen.
- Add inpatient dialysis services at LMC -The applicant states that developing the proposed project to add inpatient dialysis services at LMC will result in better overall patient care and utilization at LMC, mitigate travel hardships and geographic accessibility for patients and their families, improve response times to emergent situations when inpatient dialysis may be necessary, and reduce strain on transportation services as well as overall costs. This proposal, while costlier than doing nothing, will actually represent a savings to patients, their families, transportation providers, and LMC (reduction in lost revenue due to transfer outside of Davidson County).

The applicant adequately demonstrates that the alternative proposed in this application is the most effective alternative to meet the need because it has adequately demonstrated that the inpatient dialysis services are needed at LMC. Furthermore, the

application is conforming to all other statutory and regulatory review criteria and can be approved.

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 Baptist Medical Center and Lexington Medical Center (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**
- 2. The certificate holder shall develop inpatient dialysis services at Lexington Medical Center by developing no more than three hemodialysis stations upon project completion.**
- 3. The certificate holder shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditure in Section F of the application and that would otherwise require a certificate of need.**
- 4. 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 sixth month. The first progress report shall be due on June 1, 2025.**
- 5. 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 develop an inpatient dialysis service by developing three dialysis stations at LMC.

Capital and Working Capital Costs

In Section Q, Page 68, Form F.1.(a), the applicant projects the total capital cost of the project, as shown in the table below.

Projected Capital Costs

	WFUBMC	LMC	Total
Plumbing Uplift Cost	\$5,000.00		\$5,000.00
Medical Equipment	\$165,000.00		\$165,000.00
Furniture	\$7,800.00		\$7,800.00
Consultant Fees	\$23,000.00		\$23,000.00
Total	\$200,800.00	\$0	\$ 200,800.00

In Section Q, page 68, 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 information provided by the applicant in Section Q, page 68 immediately following projected capital cost table and Exhibit F-2 (c) (2) and F-2 (c) (3) of the application.

In Section F, page 36, the applicant states there will be no start-up costs or initial operating expenses because:

- The applicant states that it is an existing acute care hospital with existing cash flows.
- The applicant states that the cost of the project will be funded by accumulated unrestricted cash reserves of the proponent.
- The applicant states that the cost to implement adding the service of inpatient dialysis, is minimal.

Availability of Funds

In Section F, page 34, the applicant states that the capital cost will be funded as shown in the table below.

Sources of Capital Cost Financing

Type	Wake Forest University Baptist Medical Center	Lexington Medical Center	Total
Loans	\$	0	\$200,800
Accumulated reserves or OE *	\$200,800	0	\$
Bonds	\$	0	\$
Other (Specify)	\$	0	\$
Total Financing	\$200,800	0	\$200,800

* OE = Owner's Equity

Financial Feasibility

The applicant provided pro forma financial statements for the first two full fiscal years of operation following completion of the project. In Section Q, Form F.2, the applicant projects that revenues will exceed operating expenses in the first and second full fiscal years following completion of the project, as shown in the following table.

Form F.2

	1 st Full Fiscal Year	2 nd Full Fiscal Year
Total # of Treatments (Form C)	600	606
Total Gross Revenues (Charges)	\$2,700,000	\$2,727,000
Total Net Revenue	\$564,094	\$569,735
Average Net Revenue per treatments	\$940	\$940
Total Operating Expenses (Costs)	\$493,419	\$498,823
Average Operating Expense per treatments	\$822	\$823
Net Income	\$70,675	\$70,911

Source: Section F, page 69

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q, pages 69-80. The applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

- The applicant provides reasonable assumptions to determine revenue and operating expenses.
- 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 and working capital costs are based on reasonable and adequately supported assumptions for all the reasons described above.
 - The applicant adequately demonstrates availability of sufficient funds for the capital and working capital needs of the proposal for all the reasons described above.
 - 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 revenues and operating expenses for all the reasons described above.
- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

C

The applicant proposes to develop an inpatient dialysis service by developing three dialysis stations at LMC.

N.C.G.S. §131E-176(24a) defines “service area” as “...*the area of the State, as defined in the State Medical Facilities Plan or in rules adopted by the Department, which receives services from a health service facility.*” The 2024 SMFP does not define a service area for inpatient dialysis services. There are no applicable rules adopted by the Department that define a service area for inpatient dialysis services. In Section C.3, pages 17-19, the applicant projects 100% of its dialysis patients to come from Davidson County. The facility may also serve residents of counties not included in their service area.

In Section G, page 40 the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved inpatient dialysis services in Davidson County. The applicant states:

“LMC proposes to provide a service that is currently unavailable to Davidson County residents within Davidson County – inpatient dialysis. LMC does not propose to offer ICH services.

The WFUHS dialysis centers in Davidson County saw more than 300 instances of their patients in need of hospitalization sent to contiguous counties in the last twelve months because inpatient dialysis services were not available in Davidson County.

A service that is unavailable in a service area cannot be duplicated.”

The applicant adequately demonstrates that the proposal will not result in an unnecessary duplication of existing or approved services in the service area because there are no existing or approved facilities that provide inpatient dialysis services in Davidson County.

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.

- (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 develop an inpatient dialysis service by developing three dialysis stations at LMC.

In Section Q, Form H, page 81, 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 Staff	Projected FTE Staff
	1 st Full Fiscal Year 8/31/2026	2 nd Full Fiscal Year 8/31/2027
RN	2	2
LPN	0	0
PATIENT CARE TECH	0	0
NURSE ASSIST	0	0
DON	0	0
DIET	0	0
SOC. WRK.	0	0
HT NURSE	0	0
DIALYSIS TECH	0	0
BIOMED	0	0
CLERICAL	0	0
TOTAL	2	2

The assumptions and methodology used to project staffing are provided in Section Q, pages 78-81, and Section H, page 41. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Section Q, Form F.4.

In Section H, pages 41-42, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs.

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

- The applicant projected staffing based on projected patient volumes and adjusted with projected treatment volumes.
- The applicant states that the staff salaries are based on industry standards and the projected number of treatments.

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 all the reasons described 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 develop an inpatient dialysis service by developing three dialysis stations at LMC.

Ancillary and Support Services

In Section I.1, pages 43-44, the applicant identifies the necessary ancillary and support services for the proposed dialysis services and explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibit I.1(a) and Exhibit I.1(b). The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on the information provided in the application and referenced exhibits as described above.

Coordination

In Section I.2, pages 45-46, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides

supporting documentation in Exhibit I-1(b), Exhibit I.2 (a), and Exhibit I.2 (b) The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the information provided in the application and referenced exhibits as described above.

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 all the reasons described above.

- (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:
- (i) would be available under a contract of at least 5 years duration;
 - (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
 - (iii) would cost no more than if the services were provided by the HMO; and
 - (iv) would be available in a manner which is administratively feasible to the HMO.

NA

The applicant is not an HMO. Therefore, Criterion (10) is not applicable to this review.

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

NA

The applicant does not propose to construct any new space or renovate any 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 ... 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

The applicant, LMC, does not currently provide inpatient dialysis and has never provided ICH services. On page 51, the applicant provides the following comparison based on LMC inpatients.

LMC	Percentage of Total Patients Served	Percentage of the Population of the Service Area
Female	42.91%	50.8%
Male	57.09%	49.2%
Unknown	N/A	N/A
64 and Younger	48.79%	81.6%
65 and Older	51.21%	19.4%
American Indian	0%	0.9%
Asian	1.7%	2.0%
Black or African American	37.72%	11.0%
Native Hawaiian or Pacific Islander	0%	0.1%
White or Caucasian	60.55%	83.8%
Other Race	0%	2.1%
Declined/Unavailable	0%	0%

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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, pages 52-53, the applicant states that the LMC fulfills the requirement for non-discrimination by providing services to all persons regardless of race, color, national origin, sex, age or disability. Patients are accepted for care based upon medically defined admission criteria.

In Section L.2, page 54, the applicant states the facility has had no patient civil rights equal access complaints.

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.

- (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, page 54, 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:

Ending OY2 9/1/2026 to 8/31/2027						
Payor Type	Average Total Patients	% of Total Patients	Average ICH Patients	% of ICH Patients	Average Home Patients	% of Home Patients (PD & HH)
Self -Pay	18.4	6.1%	18.4	6.1%	0.0	0.0%
Comm. Ins. ONLY	82.4	27.2%	82.4	27.2%	0.0	0.0%
M'Care (M'Care, M'Care/ Comm., M'Care Adv.)	148.2	48.9%	148.2	48.9%	0.0	0.0%
M'Caid (M'Caid, M'Caid Managed Care)	41.8	13.8%	41.8	13.8%	0.0	0.0%
VA	12.2	4.0%	12.2	4.0%	0.0	0.0%
State Kidney Program	0.0	0.0%	0.0	0.0%	0.0	0.0%
Total	303.0	100.0%	303.0	100.0%	0.0	0.0%

On page 54, the applicant provides the assumptions and methodology used to project payor mix during the second fiscal full years of operation following project completion. The projected payor mix is reasonable and adequately supported because it is based on its most recent historical acute care patient payor mix.

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.

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

C

In Section L.5, page 56, the applicant adequately describes the range of means by which patients will have access to the proposed services.

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.

- (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 develop an inpatient dialysis service by developing three dialysis stations at LMC.

In Section M, page 58, 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 H-3. The applicant adequately demonstrates that health professional training programs in the area will have access to the facility for training purposes based on the information provided in Section M, page 58 and Exhibit H-3 as described above.

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 all the reasons described above.

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

C

The applicant proposes to develop an inpatient dialysis service by developing three dialysis stations at LMC.

N.C.G.S. §131E-176(24a) defines “service area” as “...*the area of the State, as defined in the State Medical Facilities Plan or in rules adopted by the Department, which receives services from a health service facility.*” The 2024 SMFP does not define a service area for inpatient dialysis services. There are no applicable rules adopted by the Department that define a service area for inpatient dialysis services. The facility may also serve residents of counties not included in their service area.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 59, the applicant states:

“LMC’s ability to provide inpatient dialysis services, however, will be a wonderful benefit for the 300-plus ESRD patients annually who receive ICH services at a WFUHS dialysis center in Davidson County and require hospitalization. It will mean those patients and their families will no longer have to travel outside of Davidson County for their care due to the need to continue their dialysis treatments while hospitalized. The proposal will reduce the strain on transportation services having to transport patients out of Davidson County for care. It will also better balance utilization among healthcare facilities in surrounding counties and help to better utilize LMC. The results will yield a cost savings and improved geographical access to service.”

Regarding the impact of the proposal on cost effectiveness, in Section N, page 59, the applicant states:

“LMC’s proposal to add inpatient dialysis services will allow patients requiring inpatient dialysis during hospitalization to remain in their local hospital versus being transferred out of Davidson County. The reality of this improved access to care will mean patients and their families will not be burdened with travel expenses to Forsyth and Guilford Counties. Transportation services will no longer bypass LMC when a dialysis patient requires hospitalization, reducing a strain on that resource. The utilization balance among facilities in Davidson, Forsyth, and Guilford Counties will also improve as LMC will be able to treat more Davidson County residents within Davidson County.”

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 60, the applicant states:

“The associated nephrologists overseeing patient care will assist the medical director in guiding the direction of the inpatient dialysis services to insure [sic] quality and safety of the highest standards.”

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 60, the applicant states:

“The new inpatient dialysis service requested in this proposal will represent improved access to service by all persons with ESRD, acute kidney injury, or other conditions requiring inpatient dialysis, including the medically-underserved. This project will especially enhance services to the medically underserved by alleviating travel burdens for patients and their families when hospitalization and inpatient dialysis are required. Reductions in travel time, increased convenience of care, and enhanced access to care will also reduce a financial burden on community resources, overall. Patient access to service is not based upon a patient’s ability or inability to pay. All patients requiring inpatient dialysis will have equal access to the proposed service.”

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 will have a positive impact on cost-effectiveness, quality, and access because the applicant adequately 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.
- 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

Based on that review, the Agency concludes that the application is conforming to this criterion based on all the reasons described 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 O, pages 61-62, and in Form O, Section Q, page 83, the applicant states four existing and approved facilities of the same type that are owned, operated, or managed by the applicant or a related entity of Wake Forest University Baptist, in North Carolina.

In Section O, page 62, the applicant states that, during the 18 months immediately preceding the submittal of the application, there were no incidents related to quality of care occurred in this facility. After reviewing and considering information provided by the applicant and considering the quality of care provided at all four dialysis whose patients may need to utilize LMC facilities, the applicant provided 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.

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

The applicant proposes to develop an inpatient dialysis service by developing three inpatient dialysis stations at LMC. There are no administrative rules applicable to the provision of inpatient dialysis services in a hospital.