

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: April 19, 2024

Findings Date: April 19, 2024

Project Analyst: Tanya M. Saporito

Co-Signer: Gloria C. Hale

Project ID #: M-12464-24

Facility: Sampson Regional Medical Center

FID #: 943443

County: Sampson

Applicant(s): Sampson Regional Medical Center, Inc.

Project: Develop an inpatient dialysis service 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

Sampson Regional Medical Center, Inc., (hereinafter referred to as the “applicant”) proposes to develop an inpatient dialysis service by developing three dialysis stations at Sampson Regional Medical Center (SRMC).

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- (2) Repealed effective July 1, 1987.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 SRMC.

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 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 applicant does not currently provide inpatient dialysis services; therefore, there is no historical patient origin. The applicant states in Section C.3, page 23, that its service area for the proposed inpatient dialysis services will be similar to the hospital’s patient origin for its acute care inpatients. The facility may also serve residents of counties not included in their service area.

In Section C, Page 23, the applicant provides projected patient origin for the second full fiscal year (FY) of operation, October 1-September 30, in the following table:

COUNTY	2 ND FULL FY OF OPERATION 10/1/25 TO 9/30/26	
	# OF PATIENTS	% OF TOTAL
Sampson	160	84.9%
Duplin	19	9.9%
Cumberland	4	2.1%
Harnett	2	1.1%
Wayne	1	0.7%
Other NC Counties	1	0.8%
Other States	1	0.5%
Total	188	100.0%

In Sections C, page 23, 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 hospital’s acute care services.

Analysis of Need

In Section C.4, pages 24-31, 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 currently, hospital inpatient dialysis is not available in Sampson County. Additionally, based on the most recent DHSR Dialysis Patient Origin Report, there were 191 dialysis patients in Sampson County, 182 of whom were either in-center or home hemodialysis patients. Because there are no inpatient dialysis services in the county, the applicant states that any potential dialysis patient in need of acute care services would have to leave the county in order to accommodate their dialysis needs in an acute care setting. The applicant states that the travel time to these alternative facilities would create a delay in patients receiving dialysis treatment and would be burdensome on both the patient and family members, who often transport the dialysis patient to and from treatment (pages 24-26).
- The applicant states the North Carolina Department of Commerce annually ranks the 100 counties in the state on “*economic well-being*” and then assigns a “*Tier designation*” based on the ranking. The applicant states the 40 “*most distressed*” counties are designated as Tier 1; Sampson County is included in Tier 1. The applicant states that development of a hospital inpatient dialysis program would be consistent with the State’s objective of encouraging development in those counties within the Tier 1 designation (pages 26-27).
- The applicant provides data from the North Carolina Office of State Budget and Management (NCOSBM) that shows the elderly (65+) population in Sampson County is growing, increasing the potential need for both hospital admissions and inpatient dialysis services. Based on statistics from NCOSBM and the US Census Bureau, the applicant states that by 2027, 20.49% of the Sampson County population will be over the age of 65. Those same statistics indicate that the over 65 population is projected to increase by a compound annual growth rate (CAGR) of 1.14% from 2023-2027, while the total Sampson County population will decrease by a CAGR of 0.297% during the same time. The applicant states the over 65 age cohort is the group more likely to need dialysis services during an inpatient hospital stay than younger cohorts. (Pages 26-27)
- The applicant states the aging population and increased incidence of diseases in the older population supports the need for inpatient dialysis services at the hospital. The applicant states the incidence of kidney disease and other co-morbidities that also effect dialysis patients is higher in Sampson County than in other counties; in addition, the death rate from diabetes, a common condition resulting in kidney failure, is higher in Sampson County than in other counties (pages 27-30).
- The applicant states the offering of dialysis services to its hospital inpatients would provide an essential service to End Stage Renal Disease (ESRD) or acute kidney failure

patients in the county, rather than sending those patients to hospitals in neighboring counties that are distant from SRMC (pages 30-32).

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

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

Projected Utilization

In Section Q, Form C, page 78, the applicant projects to serve the following dialysis patients in the first two operating years, federal fiscal years (FFY), FFY 2025 and FFY 2026:

	1ST FULL FY 10/1/2024-9/30/2025	2ND FULL FY 10/1/2025-9/30/2026
Average # Patients/Year	187	188
# Treatments/Patient/Year	2	2
Total # Treatments	374	376

In Section Q, *Form C Assumptions and Methodology*, pages 79-81, the applicant describes its methodology and assumptions used to projected utilization of the proposed inpatient dialysis services, as summarized below:

- *Historical Dialysis Inpatients* – The applicant examined its historical inpatient dialysis transfers from SRMC to acute care hospitals outside of Sampson County. The applicant states that, during the past five years, from calendar year (CY) 2019-2023, SRMC experienced an average of 200 acute care dialysis patients who were either transferred from SRMC to an acute care hospital that offers dialysis services, or who were not admitted to SRMC because of the patient's need for dialysis services, as shown in the following table from page 79:

SRMC Historical Dialysis Inpatient Transfers and Bypasses, CY 2019-2023

	CY 2019	CY 2020	CY 2021	CY 2022	CY 2023*	5-YR. AVG.
Inpatient Transfers	10	9	5	8	5	7.4
ED Transfers	116	148	110	64	42	96.0
EMS Transport Bypass	35	23	78	196	149	96.2
Totals	161	180	193	268	196	199.6

*Annualized by the applicant based on ten months of data (January-October)

- Projected SRMC Dialysis Inpatients – The applicant consulted data from the North Carolina Office of State Budget and Management (OSBM), which shows the projected growth rate for the 65+ population in Sampson County for CYs 2024-2027 is 1.14%, which is higher than a flat growth rate projected for the Sampson County population as a whole during the same time. The applicant projected future potential dialysis inpatient transfers at SRMC by applying one-half of the projected 65+ growth rate, 0.57%, to the applicant’s average number of inpatient dialysis transfers for CY 2019-2023, as shown in the following table from page 80:

SRMC Projected Potential Dialysis Inpatients, CY 2024-2027

	CY 2024	CY 2025	CY 2026	CY 2027
Inpatient Transfers	7	7	8	8
ED Transfers	97	97	98	98
EMS Transport Bypass	97	97	98	98
Totals	201	202	203	204

- Project Expected Dialysis Inpatients – The applicant projected its *expected* dialysis inpatients to be served by SRMC by assuming the following:
 - 100% of the inpatient and ED transfers historically referred outside of SRMC will remain at SRMC for their dialysis treatments; and
 - 85% of the Sampson County EMS Transport Bypasses historically referred outside of SRMC will be transported to SRMC for their dialysis treatments, leaving 15% to be transported to other out-of-county hospitals that provide dialysis services.

See the following table that illustrates these percentages, from application page 80:

SRMC Projected Expected Dialysis Inpatients, CY 2024-2027

	CY 2024	CY 2025	CY 2026	CY 2027	CAPTURE RATE
Inpatient Transfers	7	7	8	8	100%
ED Transfers	97	97	98	98	100%
EMS Transport Bypass	82	83	83	84	85%
Totals	186	187	188	189	

- Project Inpatient Dialysis Services in FFY – The applicant states it projects to offer services beginning October 1, 2024; therefore, it converted the expected number of hospital inpatients who will need dialysis from a CY to a FFY, as shown in the following table from page 80:

SRMC Projected Potential Dialysis Inpatients, FFY 2024-2027

	FFY 2024	FFY 2025	FFY 2026	FFY 2027
Inpatient Transfers	7	7	8	8
ED Transfers	97	97	98	98
EMS Transport Bypass	82	83	83	84
Totals	186	187	188	189

- *Project Total Inpatient Dialysis Treatments* – The applicant states the current acute care average length of stay at SRMC is 3.45 days; therefore, the applicant determined a typical SRMC inpatient in need of dialysis would receive an average of two treatments per inpatient stay. See the following table from page 81 that illustrates projected total inpatient dialysis treatments:

	FFY 2024	FFY 2025	FFY 2026	FFY 2027	# DIALYSIS TREATMENTS PER STAY
Inpatient Transfers	15	15	15	15	2
ED Transfers	193	194	195	196	2
EMS Transport Bypass	164	165	166	167	2
Total	372	374	376	378	

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

- The applicant projects growth of the SRMC dialysis inpatient census using one-half of the projected Sampson County 65+ population growth rate, and by using historical dialysis patient transfer data from both SRMC and Sampson County EMS.
- The applicant assumes that all projected inpatient transfers and EMS transfers will become expected inpatients, and that a portion of EMS transport bypasses will be treated at SRMC.
- The applicant utilized historical internal data from SRMC, population growth data from the NC OSBM and Sampson County EMS data to determine dialysis patient admissions per FFY.

Access by Medically Underserved Groups

In Section C.6, page 33, the applicant states:

“Sampson Regional Medical Center will continue to provide hospital services to all patients in need of care. All Sampson County residents (plus residents of other counties), including low-income persons, racial and ethnic minorities, women, handicapped persons, the elderly, Medicare and Medicaid beneficiaries, and other

underserved groups, will continue to have access to Sampson Regional Medical Center, as clinically appropriate.

Inpatient services will continue to be available to all persons listed above, including the medically indigent, the uninsured and the underinsured.”

In Section C.6, page 34, the applicant provides the following estimated percentages of dialysis patients for each medically underserved group during the second full fiscal year of operation following completion of the project, as summarized in the following table.

ESTIMATED PERCENTAGES OF PATIENTS BY GROUP	
Low-income persons	20.4%
Racial and ethnic minorities	51.5%
Women	55.0%
Persons with disabilities	10.3%
Persons 65 and older	51.9%
Medicare beneficiaries	48.1%
Medicaid recipients	30.7%

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 projects the extent to which all residents, including underserved groups, will have access to the proposed services and adequately supports its assumptions.
- The applicant’s assumptions are based on SRMC’s CY 2022 patient population for inpatient services in the service area.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- 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 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.

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 SRMC.

In Section E, page 41, the applicant describes the three alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need, as summarized below:

- Maintain the status quo – The applicant states this is not a reasonable alternative because patients who present to the hospital and need dialysis will continue to be transported to other hospitals for necessary dialysis treatments, which is costly and disruptive to patients who need dialysis. Additionally, maintaining the status quo would continue to place a burden on local EMS transport. Therefore, this is not a more effective alternative.
- Acquiring a Different Number of Inpatient Dialysis Machines – The applicant states that developing this project with fewer dialysis machines would be suboptimal because of the likelihood of having multiple acute care patients that require dialysis simultaneously. Therefore, this is not a more effective alternative.
- Develop Inpatient Dialysis via a Service Agreement with an Outpatient Company – The applicant states there are currently two outpatient dialysis facilities in Sampson County, neither of which has specific physician coverage and thus no effective means to provide additional dialysis coverage for SRMC patients who need dialysis. Therefore, this is not a more effective alternative.

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 SRMC. 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. Sampson Regional Medical Center, Inc. (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 Sampson Regional 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 November 1, 2024.**
 - 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 SRMC.

Capital and Working Capital Costs

In Section Q, page 82, Form F.1(a), the applicant projects the total capital cost of the project as shown in the following table:

PROJECTED CAPITAL COSTS	
Construction	\$5,000
Consultant Fees	\$45,000
Other (Project Contingency)	\$15,000
Total	\$65,000

In Section F.1, page 43 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 F.1, page 43 and Exhibit I.1.2 of the application.

In Section F.3, page 45 the applicant projects that start-up costs will be \$22,000, which is the estimated cost for supplies and staff. The applicant states there will be no initial operating costs. On page 46, the applicant provides the assumptions and methodology used to project the working capital needs of the project. The applicant adequately demonstrates that the projected working capital needs of the project are based on reasonable and adequately supported assumptions because the applicant included costs it will incur for staffing, training, and supplies to initiate the proposed inpatient dialysis services.

Availability of Funds

In Section F.1, page 43, the applicant states that the capital cost will be funded as shown in the table below:

SOURCES OF CAPITAL COST FINANCING		
TYPE	SRMC, INC.	TOTAL
Loans	\$0	\$0
Accumulated Reserves or OE*	\$65,000	\$65,000
Bonds	\$0	\$0
Other (Specify)	\$ 0	\$ 0
Total Financing	\$65,000	\$65,000

*Owner's Equity

In Section F.3, pages 46-47, the applicant states that the working capital needs of the project will also be funded with cash reserves.

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

- In Exhibit F.2, the applicant provides a letter from the Chief Financial Officer of SRMC that confirms the availability of sufficient cash reserves to fund the capital needs of the project and commits the necessary funds to the project development.

- In Exhibit F.2 the applicant provides copies of the audited financial statements for SRMC, Inc. and affiliates, which documents cash and cash equivalents of \$6.1 million as of October 2023.

The applicant adequately demonstrates the availability of sufficient funds for the capital and working capital needs of the project based on documentation provided in Exhibit F.2 as described above.

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 project completion, as shown in the following table:

	1 ST FULL FY	2 ND FULL FY
	10/01/2024 - 09/30/2025	10/01/2025 - 09/30/2026
Total # of Treatments (Form C)	374	376
Total Gross Revenue	\$1,750,674	\$1,813,784
Total Net Revenue	\$526,452	\$545,336
Average Net Revenue Per Treatment	\$1,407	\$1,450
Total Operating Expenses	\$488,371	\$503,432
Average Operating Expense per Treatment	\$1,305	\$1,338
Net Income	\$38,081	\$41,904

The assumptions used by the applicant in the preparation of the pro forma financial statements are provided in Section Q pages, 86-87. 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 the 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.

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

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, page 23, the applicant projects 84.9% of its dialysis patients to come from Sampson County, similar to the patient origin for acute care services for SRMC. The facility may also serve residents of counties not included in their service area.

In Section G, page 51 the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved inpatient dialysis services in Sampson County. The applicant states:

“Sampson Regional Medical Center is the only acute care hospital located in Sampson County. Thus, there are no other existing or approved health service facilities located in the Sampson County service area that provide the same health service.”

Sampson Regional Medical Center does not propose to develop a dialysis treatment facility, and will not provide dialysis treatment to outpatients.”

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

- There are no existing or approved facilities that provide inpatient dialysis services in Sampson County.
- The applicant adequately demonstrates that the proposed inpatient dialysis services are being developed for SRMC patients only.

Conclusion

The Agency reviewed the:

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

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

- (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 SRMC.

In Section Q, Form H, 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:

SRMC Projected Staffing, First Two Project Years

POSITION	1 ST FULL FY FFY 2025	2 ND FULL FY FFY 2026
Administrator	0.05	0.05
Registered Nurse	0.50	0.50
Technicians (PCT)	0.50	0.50
Medical Records	0.05	0.05
Housekeeping	0.05	0.05
Admin/ Business Office	0.05	0.05
Total	1.20	1.20

The assumptions and methodology used to project staffing are provided in Section Q and Section H, page 52. 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 52-54, 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 its annual inpatient dialysis treatment projections.
- The applicant based staff salaries are based on its current salary and wage structure which is competitive in the Sampson County labor market.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

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

Ancillary and Support Services

In Section I.1, page 55, the applicant identifies the necessary ancillary and support services for the proposed dialysis services. On pages 55-56, the applicant explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibits I.1.1 and I.1.2. 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 56-57, the applicant describes its existing and proposed relationships with other local health care and social service providers. The applicant provides copies of support letters submitted by physicians and community health professionals in Exhibit I.2. 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:
- would be available under a contract of at least 5 years duration;
 - would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
 - would cost no more than if the services were provided by the HMO; and
 - would be available in a manner which is administratively feasible to the HMO.

NA

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

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

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

Neither the applicant nor any related entities provide inpatient dialysis services in the service area. On page 64, the applicant provides the following comparison based on SRMC inpatients:

SRMC	PERCENTAGE OF TOTAL PATIENTS SERVED BY THE FACILITY DURING THE LAST FULL FY	PERCENTAGE OF THE POPULATION OF THE SERVICE AREA
Female	55.00%	50.0%
Male	45.00%	50.0%
Unknown	0.00%	0.0%
64 and Younger	48.05%	81.7%
65 and Older	51.95%	18.3%
American Indian	0.72%	3.9%
Asian	0.14%	0.7%
Black or African American	30.34%	25.8%
Native Hawaiian or Pacific Islander	0.11%	0.4%
White or Caucasian	48.52%	47.3%
Other Race	19.50%	21.9%
Declined / Unavailable	0.68%	0.0%

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, page 65, the applicant states that the hospital is not obligated to provide uncompensated care or community service.

In Section L.2, page 66, the applicant states there have been no civil rights access complaints filed against the applicant's facility within the last five years.

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (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 66, 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:

SRMC Projected Payor Mix, FFY 2026		
PAYOR CATEGORY	# OF PATIENTS	PATIENTS AS % OF TOTAL
Self-Pay	10	5.51%
Charity Care	2	1.07%
Insurance*	24	12.70%
Medicare*	91	48.05%
Medicaid*	58	30.70%
Other (Workman's Comp)	0	0.02%
Other (TriCare)	3	1.86%
Other (Other Government)	0	0.00%
Total	188	100.00%

*Includes managed care plans

On page 66, the applicant provides the assumptions and methodology used to project payor mix during the first and 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.

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 67, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

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

In Section M, page 69 the applicant describes the extent to which health professional training programs in the area will have access to the facility for training purposes and provides supporting documentation in Exhibit M-1. 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 69 and Exhibit M.1 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 SRMC.

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, page 23, the applicant projects 84.9% of its dialysis patients to come from Sampson County, similar to the patient origin for acute care

services for SRMC. 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 70, the applicant states:

“The addition of inpatient dialysis services at Sampson Regional Medical Center will eliminate or decrease the need for Sampson County dialysis patients to have to be transferred to and/or admitted for inpatient care to a hospital located outside of Sampson County. The proposed project will enhance competition by promoting cost effectiveness, quality, and access to inpatient dialysis services... .”

Regarding the impact of the proposal on cost effectiveness, in Section N, page 70, the applicant states:

“The proposed inpatient dialysis service is a cost-effective service for dialysis patients and their families, who primarily are Sampson County residents. Sampson County residents will no longer need to travel outside of Sampson County for inpatient services because they require dialysis treatment during their acute care hospital stay. The proposed project is expected to reduce the cost of emergency medical services (EMS) transfers outside Sampson County, saving transportation costs for both patients/family members, and medical transport providers.”

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 71, the applicant states:

“SRMC will continue to adhere to high standards and quality of care, consistent with the superior standard that SRMC has sustained throughout its history of providing acute care services.”

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 71, the applicant states:

“Acute care hospital services at SRMC will continue to be available to all persons, including low-income persons, racial and ethnic minorities, women, physically and mentally disabled persons, the elderly, and other underserved persons, including the medically indigent, the uninsured and the underinsured”.

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

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would have a positive impact on cost-effectiveness, quality, and access because the applicant 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 73 and 76, and in Form O, Section Q, page 88, the applicant states SRMC is the only hospital owned and operated by the applicant in North Carolina.

In Section O, page 76, the applicant states that, during the 18 months immediately preceding the submittal of the application, no incidents related to quality of care occurred in this facility. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, during the 18 months immediately preceding submission of the application through the date of this decision, no incidents related to quality of care have occurred at SRMC. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at all five 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 SRMC. There are no administrative rules applicable to the provision of inpatient dialysis services in a hospital.