

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: April 6, 2023

Findings Date: April 6, 2023

Project Analyst: Cynthia Bradford

Co-Signer: Gloria C. Hale

Project ID #: G-12307-23

Facility: Randolph Hospital

FID #: 933425

County: Randolph

Applicant(s): American Healthcare Systems, LLC

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

American Healthcare Systems, LLC, (hereinafter referred to as the “applicant”) proposes to develop an inpatient dialysis service by acquiring and operating three dialysis stations at Randolph Hospital (RH) Asheboro.

The applicant does not propose to:

- develop any beds or services for which there is a need determination in the 2023 SMFP.
- acquire any medical equipment for which there is a need determination in the 2023 SMFP.
- offer a new institutional health service for which there are any policies in the 2023 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- (2) Repealed effective July 1, 1987.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 acquiring and operating three dialysis stations at Randolph Hospital.

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 2023 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 states in Section C.3, page 23, that its service area is to be similar to the facility’s patient origin for its acute care patients. The facility may also serve residents of counties not included in their service area. The applicant does not currently provide inpatient dialysis services; therefore, there is no historical patient origin.

In Section C, Page 23, the applicant provides projected patient origin in the following table:

COUNTY	SECOND FULL FY OF OPERATION 10/1/24 TO 9/30/25	
	# OF PATIENTS	% OF TOTAL
Randolph	349	88.5%
Davidson	12	3.1%
Guilford	10	2.6%
Montgomery	8	2.0%
Chatham	6	1.5%
Other NC Counties	6	1.5%
Other States	4	1.0%
Total	395	100.0%

In Sections C, page 23, and Q pages 74-77, and Exhibit C.3, the applicant provides the assumptions and methodology used to project its patient origin. The applicant’s assumptions are reasonable and adequately supported based on the following:

- The applicant bases its patient origin on the hospital’s historical patient origin for acute care services.

- The applicant utilizes historical data of Randolph Hospital's dialysis inpatient transfers, ED transfers, and EMS bypasses.
- The applicant utilizes the projected Randolph County population growth rate.

Analysis of Need

In Section C.4, pages 23-28, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below:

- Currently, ESRD patients in Randolph County who need acute, inpatient care must bypass Randolph Hospital. Based on the DHSR Dialysis Patient Origin Report, as of December 2021, Randolph County had 193 dialysis patients. Of these patients, 178 were in-center or home hemodialysis patients. If a dialysis patient should require acute inpatient care, they would need to transfer to a facility in Guilford County or Forsyth County because these facilities are the closest in proximity and offer inpatient dialysis services. The applicant states that the travel time to these alternative facilities would create a delay in patients receiving dialysis treatment. Additionally, these facilities are busy and have a high inpatient census, thus potentially creating more delay in the patient receiving treatment due to having to be admitted to obtain dialysis services. (Page 24)
- The overall population and the elderly (65+) population is growing, increasing the potential for hospital admissions and the need for inpatient dialysis services, especially in the 65+ population. Based on statistics from the North Carolina Office of State Budget and Management (NCOSBM), the applicant states Randolph County is the 21st most populous county in North Carolina, and is projected to increase by a compound annual growth rate (CAGR) of 0.46% overall, and by 2.31% for the 65+ population between 2022 and 2026. (Pages 25-26)
- 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 provides the annual number of dialysis patients that require transfer to an alternative acute care facility for dialysis treatment due to the lack of inpatient dialysis services at RH. (Page 25)
- The applicant projects that the population growth of the 65+ age group for Randolph County will result in an increase in patients who require dialysis in the county. (Page 26)

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

- Providing dialysis services during an inpatient stay will avoid transportation expenses to a dialysis facility and interruptions in inpatient care at RH.
- The applicant demonstrates the need for inpatient dialysis services based on the growth and aging of the Randolph County population and ESRD patients in the county.

Projected Utilization

In Section Q, Form C, page 74, the applicant projects to serve the following dialysis patients in the first two operating years, FFY 2024 (10/1/2023-9/30/2024) and FFY 2025 (10/1/2024-9/30/2025):

	1ST FULL FY 10/1/2023-9/30/2024	2ND FULL FY 10/1/2024-9/30/2025
Average # Patients/Year	392	394
# Treatments/Patient/Year	2	2
Total # Treatments	785	788

Source: Randolph Hospital Internal Data; Randolph County EMS Data

In Section Q, Assumptions for Form C Utilization, pages 75-77, the applicant describes its need methodology and assumptions for projected utilization for the proposed services, as summarized below:

In Section Q, Form C, Page 75, the applicant summarizes its patient transfers and EMS bypasses from CY2019 through CY2022 annualized in the following table:

Randolph Hospital Historical Dialysis Inpatient Transfers & Bypasses (CY2019-CY2022)					
	CY 2019	CY 2020	CY 2021	CY 2022*	4-Year Average
Inpatient Transfers	63	67	69	54	63.25
ED Transfers	115	125	99	65	101.00
EMS Transport Bypass	262	272	330	336	300.00
Totals	440	464	498	455	464.25

Source: Randolph Hospital Internal Data; Randolph County EMS Data

*Annualized based on data from January-October 2022

On page 75, the applicant projects increasing patient totals from CY 2023 through CY2026 based on the projected county population growth rate of 0.46% as illustrated in the following table:

Randolph Hospital Projected Potential Dialysis Inpatients (CY2023-CY2026*)				
	CY 2023	CY 2024	CY 2025	CY 2026
Inpatient Transfers	64	64	64	64
ED Transfers	101	102	102	103
EMS Transport Bypass	301	303	304	306
Totals	466	469	471	473

Source: Randolph Hospital Internal Data; Randolph County EMS Data
 *FY calculation based on 25% of previous calendar year total plus 75% of calendar year total.

Next, on page 76, the applicant assumes that 100% of RH inpatient transfers and ED transfers will remain at RH for inpatient dialysis, and 75% of EMS bypass will receive inpatient dialysis treatment at RH as illustrated in the following table:

Randolph Hospital Projected Dialysis Patient Admissions (CY2023-CY2026)				
	CY 2023	CY 2024	CY 2025	CY 2026
Inpatient Transfers	64	64	64	64
ED Transfers	101	102	102	103
EMS Transport Bypass	226	227	228	229
Totals	391	393	395	396

The applicant states its fiscal year is the same as the federal fiscal year (October 1-September 30); therefore, the applicant converted the CY data to FFY, as shown in the following table from page 76. The applicant states that services are projected to begin on October 1, 2023.

Randolph Hospital Expected Inpatient Dialysis Admissions (FFY2023 – FFY 2026)				
	FFY2023	FFY2024	FFY2025	FFY2026
Inpatient Transfers	64	64	64	64
ED Transfers	101	102	102	103
EMS Transport Bypass	226	227	228	229
Totals	391	392	394	396

To determine the number of dialysis treatments per admission, the applicant states it determined that, based on facility averages, each patient admission would last 3.77 days. Dialysis patients would receive treatments two times during their hospital stay (Pages 76-77).

Randolph Hospital Projected Inpatient Dialysis Treatments (FFY2023 – FFY2026)					
	FFY 2023	FFY 2024	FFY 2025	FFY 2026	Dialysis Treatments /IP Stay
Inpatient Transfers	127	128	128	129	2
ED Transfers	203	204	205	206	2
EMS Transport Bypass	452	454	456	458	2
Totals	782	785	788	792	

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

- The applicant projects growth of the Randolph Hospital dialysis inpatient census using the CAGR calculated for the Randolph County population, and by using historical dialysis patient transfer data from Randolph Hospital and Randolph County EMS data.
- 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 RH.
- The applicant utilized internal data from the facility as well as Randolph County EMS data to determine dialysis patient admissions per FFY.

Access by Medically Underserved Groups

In Section C.6, page 30, the applicant states:

“Randolph Hospital will continue to provide hospital care to all patients in need of care. All Randolph 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 Randolph Hospital...”

“...RH is committed to providing services to all persons regardless of race, ethnicity, gender, age, religion, creed, disability, national origin, or ability to pay.”

In Section C.6, page 31, 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	13.5%
Racial and ethnic minorities	18.2%
Women	59.7%
Persons with disabilities	13.6%
Persons 65 and older	40.6%
Medicare beneficiaries	44.7%
Medicaid recipients	25.8%

Based on the most recent U.S. Census Statistics for Randolph County and historical data from Randolph Hospital FFY2022.

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 RH's existing 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.

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 acquiring and operating three dialysis stations at Randolph Hospital.

In Section E, page 38, 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 out of county to other hospitals for necessary dialysis treatments. This is neither cost effective for the patient nor a means of providing optimum care for RH patients. 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 that no outpatient dialysis provider in Randolph County was willing to contract with the facility to provide inpatient dialysis support. Therefore, this is not a more effective alternative.

On page 38, the applicant states that its proposal is the most effective alternative because it will provide necessary inpatient dialysis services to Randolph County residents who are admitted to RH and need dialysis services.

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, and 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. American Healthcare Systems, LLC (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 Randolph Hospital 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 October 1, 2023.**
 - 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 acquiring and operating three dialysis stations at Randolph Hospital.

Capital and Working Capital Costs

In Section Q, Page 78, Form F.1(a), the applicant projects the total capital cost of the project as shown in the table below.

Projected Capital Costs	
Medical Equipment	\$198,880
Consultant Fees	\$43,000
Other (Project Contingency)	\$28,240
Total	\$270,120

In Section F, page 40, and Exhibit F.1, 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 on projected capital costs provided by the applicant in Form F.1(a) and in the assumptions on page 40 and in Exhibit F.1 of the application.

In Section F.3, page 42, the applicant projects that start-up costs will be \$20,000. The applicant states there will be no initial operating costs. On page 42, 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 RH currently only provides acute care inpatient services and will need to incur cost for staffing, training, and supplies to initiate its inpatient dialysis services.

Availability of Funds

In Section F.1, page 40, the applicant states that the capital cost will be funded as shown in the table below:

Sources of Capital Cost Financing		
Type	American Healthcare Systems, LLC	Total
Loans	\$0	\$0
Accumulated reserves or OE *	\$ 270,120	\$ 270,120
Bonds	\$0	\$0
Other (Specify)	\$ 0	\$ 0
Total Financing	\$ 270,120	\$ 270,120

In Section F.3, page 43, the applicant states that the working capital needs of the project will be funded, as shown in the table below:

Sources of Financing for Working Capital		
Type	American Healthcare System, LLC	Total
Loans	\$0	\$0
Cash or Cash Equivalents, Accumulated Reserves or Owner's Equity	\$20,000	\$20,000
Lines of credit	\$0	\$0
Bonds	\$0	\$0
Total Financing	\$20,000	\$20,000

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 Randolph Health that confirms the applicant has sufficient cash reserves to fund the capital needs of the project and agrees to commit the necessary funds to the capital cost of the project.
- In Exhibit F.2 the applicant provides copies of the audited financial statements for American Healthcare Systems, LLC, which indicate that as of December 31, 2022, it has current operating assets totaling \$7.5 million.

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, Forms F.2 and F.4, 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 table below.

	1st Full FY	2nd Full FY
	10/01/2023 09/30/2024	10/01/2024 09/30/2025
Total # of Procedures	785	788
Total Gross Revenue	\$3,128,349	\$3,142,739
Total Net Revenue	\$807,549	\$811,264
Average Net Revenue Per Procedure	\$1,029	\$1,029
Total Operating Expenses	\$504,544	\$532,489
Average Operating Expense per Procedure.	\$643	\$676
Net Income	\$303,005	\$278,775

Source: Section Q, Form F.2, page 79

The assumptions used by the applicant in the preparation of the pro forma financial statements are provided in Section Q pages, 80-82. 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 in determining 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 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.

In Section G, page 47, the applicant explains that they do not propose to develop an outpatient dialysis facility, therefore there is no unnecessary duplication of health services in the service area.

“Randolph Hospital does not propose to develop an in-center dialysis service, but rather to develop inpatient dialysis solely to treat hospital acute care patients who need dialysis treatment during their hospital stay”.

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 2023 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 defines its service area in Section C.3, page 23, as Randolph County. The facility may also serve residents of counties not included in their service area.

In Section G, page 48 the applicant states there are no hospitals in Randolph County that provide inpatient dialysis services. In Section G, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved inpatient dialysis services in Randolph County. The applicant states:

“Randolph Hospital is the only acute care hospital located in Randolph County. Thus, there are no other existing or approved health service facilities located in the Randolph County service that provide the same health services (inpatient dialysis treatment)”.

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 Randolph County.
- The applicant adequately demonstrates that the proposed inpatient dialysis services are being developed for RH patients only.
- The applicant adequately demonstrates that the proposed inpatient dialysis services are needed for RH patients.

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 acquiring and operating three dialysis stations at Randolph Hospital.

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:

POSITION	PROJECTED FTE POSITIONS FFY 2024	PROJECTED FTE POSITIONS FFY 2025
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

Source: Section Q, Form H, page 83

The assumptions and methodology used to project staffing are provided in Section Q. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Section Q, Form F.4. In Section H, pages 50-51, 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's staff levels are driven by their annual inpatient dialysis projections.
- Staff salaries are based on RH's current salary and wage structure which is competitive in the Randolph 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 acquiring and operating three dialysis stations at Randolph Hospital.

Ancillary and Support Services

In Section I.1, page 52, the applicant identifies the necessary ancillary and support services for the proposed dialysis services. On pages 52-53, the applicant explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibit I.1. The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on the information provided in Section I.1 and Exhibit I.1.

Coordination

In Section I.2, page 53, 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 Section I.2 and Exhibit I.2 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

Neither the applicant nor any related entities provide inpatient dialysis services in the service area. On page 60, the applicant provides the following comparison based on RH FFY 2022 acute care discharges:

RANDOLPH HOSPITAL	PERCENTAGE OF TOTAL PATIENTS SERVED BY THE FACILITY DURING THE LAST FULL FY	PERCENTAGE OF THE POPULATION OF THE SERVICE AREA
Female	59.65%	50.3%
Male	40.35%	49.7%
Unknown	0.0%	0.0%
64 and Younger	59.39%	81.8%
65 and Older	40.61%	18.2%
American Indian	0.04%	1.2%
Asian	0.26%	1.7%
Black or African American	9.18%	7.0%
Native Hawaiian or Pacific Islander	0.0%	0.1%
White or Caucasian	81.83%	77.3%
Other Race	8.45%	12.7%
Declined / Unavailable	0.24%	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 61, the applicant states that the facility is not obligated to provide uncompensated care or community service.

In Section L.2, page 62, 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 62, 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:

Randolph Hospital Projected Payor Mix, FFY 2025		
PAYOR CATEGORY	# OF PATIENTS	PATIENTS AS % OF TOTAL
Self-Pay	25	6.37%
Charity Care	8	2.07%
Insurance*	71	17.92%
Medicare*	176	44.72%
Medicaid*	102	25.80%
Other (Workman's Compensation)	0	0.07%
Other (TriCare)	7	1.82%
Other (Other Government)	5	1.23%
Total	394	100.00%

*Includes managed care plans

On pages 61-63, the applicant provides the assumptions and methodology used to project payor mix during the first and second fiscal full years of operation following completion of the project. The projected payor mix is reasonable and adequately supported because the applicant's proposed patient payor mix is based on its most historical acute care patient payor mix, the applicant's research regarding the incidence of dialysis patients who are Medicare and Medicaid recipients, and the applicant's historical provision of charity care to its patients.

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 63, 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 acquiring and operating three dialysis stations at Randolph Hospital.

In Section M, 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 have access to the facility for training purposes based on the information provided in Section M, page 65 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 acquiring and operating three dialysis stations at Randolph Hospital.

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 2023 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 defines its service area in Section C.3, page 23, as Randolph County. Facilities 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 66, the applicant states:

“The addition of inpatient dialysis services at Randolph Hospital will eliminate or decrease the need for Randolph County dialysis patients to have to be transferred to and/or admitted outside of Randolph County for inpatient care. 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 66, the applicant states:

“The proposed inpatient dialysis service is a cost-effective service for dialysis patients and their families, who primarily are Randolph County residents. Randolph County residents will no longer need to travel outside of Randolph County for inpatient services because they require dialysis treatment during their acute hospital stay. The proposed project is expected to reduce the cost of emergency medical services (EMS) transfers outside Randolph 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 67, the applicant states Randolph Hospital adheres to external quality standards and will continue to uphold those standards following the addition of inpatient dialysis services at RH.

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 67, the applicant states:

“Acute care hospital services at RH will continue to be available to all persons, including low-income persons, racial and ethnic minorities, women, handicapped 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, page 69, and in Form O, page 84, the applicant states Randolph Hospital is the only hospital owned and operated by American Healthcare Systems, LLC in North Carolina.

In Section O, page 71, 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 RH. 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 acquiring and operating three dialysis stations at Randolph Hospital. There are no administrative rules applicable to the provision of inpatient dialysis services in a hospital.