

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: May 27, 2021

Findings Date: May 27, 2021

Project Analyst: Tanya M. Saporito

Team Leader: Fatimah Wilson

Project ID #: M-12017-21

Facility: Betsy Johnson Hospital

FID #: 922969

County: Harnett

Applicant(s): Harnett Health System, Inc.

Project: Develop inpatient dialysis services

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

Harnett Health System, Inc. (hereinafter referred to as the “applicant” or “HHS”) operates Betsy Johnson Hospital and Central Harnett Hospital, both in Harnett County. The applicant proposes to add inpatient dialysis services at Betsy Johnson Hospital (“BJH”) in Dunn through a service agreement with Bio-Medical Applications of North Carolina, Inc. (“BMA”), by utilizing no more than two mobile hemodialysis machines provided by BMA.

The applicant does not propose to:

- develop any beds or services for which there is a need determination in the 2021 SMFP
- acquire any medical equipment for which there is a need determination in the 2021 SMFP
- offer a new institutional health service for which there are any policies in the 2021 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- (2) Repealed effective July 1, 1987.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 add inpatient dialysis services at Betsy Johnson Hospital in Dunn through a service agreement with BMA by utilizing no more than two mobile hemodialysis machines provided by BMA.

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 2021 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 19 as Harnett County. Facilities 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 to report.

The following table illustrates projected patient origin, from application page 19:

COUNTY	SECOND FULL FY OF OPERATION FOLLOWING PROJECT COMPLETION 10/1/2023-9/30/2024	
	PATIENTS	% OF TOTAL
Harnett	290	100.0%
Total	290	100.0%

In Section Q, pages 71-75, 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 relies on data available in the Semiannual Dialysis Reports (SDRs) and the recent (2020-2021) SMFPs.
- The applicant utilizes the historical Harnett County inpatient dialysis patient population as a starting point for its utilization projections.
- The applicant relies on the hospital’s experience with inpatient admissions who need dialysis services.

Analysis of Need

In Section C.4, pages 19-26, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below:

- Harnett County patient needs – the applicant states BJH is a community hospital with 87 acute care beds and provides a majority of inpatient acute care services in Dunn. However, since the hospital does not currently provide inpatient dialysis services, those patients who are in kidney failure or who suffer with End Stage Renal Disease (ESRD) are unable to receive proper treatment at BJH and must be transported to another facility. Dialysis treatments typically take four hours, and patients would be better served if BJH could provide the type of inpatient dialysis services to their patients who need those services. (pages 20-22)
- Service area demographics – relying on statistics from the North Carolina Office of State Budget and Management (NCOSBM), the applicant states Harnett County is a predominantly rural county, but the population increased by 18.7% between 2010 and 2020, and is projected to increase by a compound annual growth rate (CAGR) of 1.5% between 2021 and 2024, as shown in the following table:

**Harnett County
Projected Population Growth 2021-2024**

YEAR	POPULATION
2021	139,478
2022	141,599
2023	143,721
2024	145,839
CAGR	1.5%

The applicant states the projected Harnett County population growth rate of 1.5% is higher than the CAGR of 1.1% projected for North Carolina as a whole, and the fastest growing population group in the county is projected to be the 65+ age group. 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 also states Harnett County is largely rural and the median income is lower than in other North Carolina counties. The limited economic resources prevalent in Harnett County contribute to many residents' inability to seek necessary dialysis services at distant facilities; therefore, providing inpatient dialysis services in a community hospital would benefit many county residents who need dialysis. Additionally, the applicant states two disease processes that result in patients' being more at risk for developing ESRD are diabetes and hypertension. The applicant cites statistics from the Centers for Disease Control (CDC) to show that Harnett County has a higher incidence of both, and a higher mortality rate from each. (pages 22-25)

- Access to inpatient dialysis services – the applicant states BJH currently does not provide inpatient dialysis services and the patients who present to the hospital with ESRD must be transferred to an ESRD facility via ambulance, often out of county. Since ESRD patients often suffer from other diseases as well, travel can be not only costly but also subject patients to delay in care. The offering of inpatient dialysis services to BJH patients will enhance patient care and clinical outcomes. (See page 25)
- Dialysis utilization – the applicant examined previous SMFPs and North Carolina Semiannual Dialysis Reports (SDRs), which are dialysis need and utilization publications that preceded the inclusion of ESRD services in Chapter 9 of the SMFP. The applicant determined that the 2019 rate of ESRD patients per thousand in Harnett County is 1.92, while the incidence of ESRD among the population of North Carolina as a whole is 1.84 per 1,000. See the following table, from page 26:

AREA	TOTAL ESRD PATIENTS	TOTAL POPULATION	PTS/1,000 POPULATION
Harnett County	259	135,239	1.92
North Carolina	19,288	10,508,254	1.84

Source: application page 26

The applicant states the addition of inpatient dialysis services at BJH will result in improved access and care while decreasing cost to residents of Harnett County and surrounding areas.

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 without interrupting inpatient care at BJH.
- The applicant demonstrates the need for inpatient dialysis services based on the growth of the Harnett County population and ESRD patients in the county.

Projected Utilization

In Section Q, Form C, page 71, the applicant projects to serve the following ESRD patients in the first two operating years, FFY 2023 (10/1/2022-9/30/2023) and FFY 2024 (10/1/2023-9/30/2024):

	PARTIAL FY 1/1/2022-9/30/2022	1 ST FULL FFY 10/1/2022-9/30/2023	2 ND FULL FFY 10/1/2023-9/30/2024
Average # Patients/Year	185	281	290
# Treatments/Patient/Year	3	3	3
Total # Treatments	555	843	870

Source: 2014-2019 data from SDRs, 2020-2021 SMFPs

In Section Q, Assumptions for Form C Utilization, pages 72-75, the applicant describes its need methodology and assumptions for projected utilization for the proposed services, as summarized below:

Step 1: Review Harnett County hemodialysis patient population – relying on data from historical SDRs and SMFPs, the applicant determined that the in-center dialysis patient population in Harnett County increased by a CAGR of 6.4% between calendar years (CY) 2014 and 2019, as shown in the following table from page 72:

Harnett County Historical In-Center Dialysis Patient Population Growth

	CY 2014	CY 2015	CY 2016	CY 2017	CY 2018	CY 2019	CAGR
In-center hemodialysis patients	166	194	221	210	234	226	6.4%

Step 2: Project Harnett County dialysis patients – the applicant projected the number of dialysis patients in Harnett County would increase by one-half the CAGR calculated in Step 1. The applicant states this rate is conservative, given the historical CAGR and the projected population growth in the county. See the following table from page 72:

Harnett County Projected In-Center Dialysis Patient Population Growth

	CY 2020	CY 2021	CY 2022	CY 2023	CY 2024	CAGR
In-center hemodialysis patients	233	241	248	256	264	3.2%

Step 3 Determine annual number of inpatient hospital admissions per dialysis patient – the applicant utilized data from the United States Renal Data System (USRDS) Annual Report that showed the overall hospitalization rate among Medicare beneficiaries with ESRD was 1.58 hospitalizations per person per year in 2018 (the latest data available to the applicant at the time the application was prepared). The applicant applied the hospitalization rate reported in the USRDS report to the projected number of dialysis patients in Harnett County to determine the number of hospitalizations per dialysis patient in Harnett County, as illustrated in the following table from page 73:

Harnett County Projected Hospital Admissions per Dialysis Patient

	CY 2020	CY 2021	CY 2022	CY 2023	CY 2024
In-center hemodialysis patients	233	241	248	256	264
Admissions per person per year	1.58	1.58	1.58	1.58	1.58
Dialysis in-patient admissions	368	380	392	405	418

Numbers may not sum due to rounding

The applicant states its fiscal year is the same as the federal fiscal year (October 1-September30); therefore, the applicant converted the CY data to FFY, as shown in the following table from page 73:

	FFY 2022	FFY 2023	FFY 2024
Hemodialysis inpatient admissions	389	402	414

The applicant states that services will be offered by January 1, 2022. The partial year will therefore be January – September 2022, and the first full FFY will be FFY 2023. The applicant converted FFY 2022 as follows: $[(.25 \times \text{CY 2021} + .75 \text{CY 2022}) = (.25 \times 380) + .75 \times 392) = 95 + 294=389]$.

Step 4: Determine the number of inpatient admissions at Betsy Johnson Hospital – the applicant states it consulted with the BJH medical staff and determined that it could reasonably admit 70% of the projected Harnett County dialysis patient admissions. The applicant states it begins the first partial FY with 50% of the Harnett County dialysis inpatient admissions during the first operational quarter of that year, ending with 70% of the projected Harnett County dialysis patient hospital admissions. See the following table from page 73 of the application:

	FFY 2022					FFY 2023	FFY 2024
	QTR 1	QTR 2	QTR 3	QTR 4	TOTAL		
Dialysis inpatient admissions	97	97	97	97	389	402	414
Betsy Johnson admission %	NA	50%	70%	70%		70%	70%
Betsy Johnson inpatient dialysis pts	NA	49	68	68	185	281	290

Step 5: Total annual number of hospital days per dialysis patient – utilizing data from the 2019 USRDS report, the applicant determined that dialysis patient hospital stays averaged 11.5 days per patient in 2017. The applicant calculated the number of hospital days per patient admission by dividing the number of hospital days per patient per year (11.5) by the number of inpatient admissions per patient year (1.58), as shown in the following table from page 74:

HOSPITAL DAYS / PT / YEAR	ADMISSION / PT / YEAR	HOSPITAL DAYS / ADMISSION
11.5	1.58	7.28

Step 6: Determine the number of dialysis treatments per admission – the applicant states it determined that each patient admission would last 7.28 days, as shown in Step 5 above. Dialysis patients receive treatments three times per week, or per seven day period. The applicant states therefore that each dialysis admission is projected to require three treatments.

Step 7: Calculate total projected number of dialysis treatments at BJH – see the following table from page 75 of the application:

	PARTIAL YEAR*	1 ST FULL PROJECT YEAR	2 ND FULL PROJECT YEAR
	2022	2023	2024
BJH Inpatient Admissions	185	281	290
Treatments / Admission	3	3	3
Inpatient Dialysis Treatments	555	843	870

*The applicant states the partial year is from January – September 2022.
 Numbers may not sum due to rounding

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

- The applicant projects growth of the Harnett County dialysis patient census using the one-half the actual CAGR calculated for the Harnett County dialysis patient population, using historical SDRs and SMFPs.
- The applicant utilizes data from the United States Renal Data System, which reports ESRD patient utilization and growth data.
- The applicant utilizes historical BJH inpatient admission data on which to base future admission projections.

Access

In Section C.6, page 29, the applicant states:

“At Harnett Health all services are available to all patients upon the request of physicians with appropriate privileges, regardless of race, sex, income status, ability to pay, disability, age or other underserved characteristics.

...

As a Medicare and Medicaid certified provider, Harnett Health does and will continue to serve significant numbers of aged, disabled, and medically indigent patients.”

In Section C.6, page 30, 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		
a	Low income persons	34.9%
b	Racial and ethnic minorities	29.4%
c	Women	50.0%
d	Persons with disabilities	10.0%
e	Persons 65 and older	42.4%
f	Medicare beneficiaries	42.4%
g	Medicaid recipients	34.9%

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 BJH’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 add inpatient dialysis services at Betsy Johnson Hospital in Dunn through a service agreement with BMA by utilizing no more than two mobile hemodialysis machines provided by BMA.

In Section E, page 37, the applicant describes the one alternative it considered and explains why that 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 for necessary dialysis treatments. This is neither cost effective for the patient nor a means of providing optimum care for BJH patients.

On page 37, the applicant states that its proposal is the most effective alternative because it will provide necessary inpatient dialysis services to Harnett County residents who present to BJH 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 the hospital does not currently offer inpatient dialysis services, 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. Harnett Health System, 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 through a service agreement with Bio-Medical Applications of North Carolina, Inc. for no more than two mobile hemodialysis machines 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 third month. The first progress report shall be due on September 1, 2021. The second progress report shall be due on December 1, 2021 and so forth.**

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 add inpatient dialysis services at Betsy Johnson Hospital in Dunn through a service agreement with BMA by utilizing no more than two mobile hemodialysis machines provided by BMA.

Capital and Working Capital Costs

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

Site Costs	\$0
Construction Costs	\$32,821
Miscellaneous Costs	\$63,900
Total	\$96,721

In Section Q, page 81, 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 pages 76 and 81 of the application.

In Section F.3, page 40, the applicant states it will not incur any start-up costs or initial operating expenses associated with this project, because it will enter into a Hospital Services Agreement with Fresenius Medical Care, Inc. (“Fresenius”), parent company to BMA for the provision of dialysis services to BJH patients. The applicant states Fresenius will provide the portable dialysis machines and all equipment necessary to operate the machines.

Availability of Funds

In Section F.1, page 38, the applicant states that the capital cost will be funded as shown in the table below:

Sources of Capital Cost Financing

TYPE	HARNETT HEALTH SYSTEM, INC.	TOTAL
Loans	\$	\$
Accumulated reserves or OE *	\$96,721	\$96,721
Bonds	\$	\$
Other (Specify)	\$	\$
Total Financing	\$96,721	\$96,721

*OE = Owner's Equity

With regard to the working capital for the project, in Section F.3, page 42, the applicant states:

“There are no working capital costs associated with the development of the inpatient dialysis service at Betsy Johnson Hospital.

Harnett Health understands that the proposed inpatient dialysis service will always be a ‘loss leader’ service for Betsy Johnson Hospital. The projected reimbursement for hemodialysis treatments is less than the projected cost for performing the treatment. However, reimbursement for the projected dialysis treatments is incorporated into the inpatient encounter for which there is a positive net revenue.”

In Exhibit F.2, the applicant provides a letter from the Chief Financial Officer of Harnett Health System, Inc. 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 Harnett Health, Inc., which indicate that as of September 30, 2020 Harnett Health System, Inc. had current assets totaling \$48 million and cash and cash equivalents totaling \$35 million.

The applicant adequately demonstrates the availability of sufficient funds for the 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 three 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 operating years of the project.

In Section F, pages 40 and 43, the applicant explains that the projected reimbursement for inpatient dialysis services at BJH will be less than the projected cost of providing those services. To reconcile the apparent negative income, the applicant calculated an *“inpatient contribution margin”* that is based on incorporating the inpatient dialysis patient treatments into the entire inpatient encounter. Since there is a positive net revenue for inpatient encounters at BJH, the applicant states the apparent loss for the provision of inpatient dialysis services will actually result in a positive net revenue. The applicant based the calculations on pre-

COVID-19 pandemic patient data at BJH and held it constant through the project years. See the following tables to illustrate:

Inpatient Contribution per Patient Calculation, FFY 2020*

INPATIENT CONTRIBUTION CALCULATION	
Total BJH patient discharges	2,621
Total patient services gross revenue	\$65,709,324
Total gross revenue/patient	\$25,070.33
Total adjustments to revenue	\$47,866,723
Total net revenue	\$17,842,601
Total operating costs	\$13,869,165
Net income	\$3,973,436
Inpatient contribution margin per patient	\$1,516

*The applicant states this is based on pre-COVID-19 pandemic data (October 2019-March 2020)

The applicant calculates total inpatient contribution margin by multiplying inpatient contribution margin per patient from the table above by the number of patients, as shown in the following table prepared by the Project Analyst:

Total Inpatient Contribution Calculation

	INTERIM YEAR	1 ST FULL FFY	2 ND FULL FFY
Inpatient contribution margin per patient	\$1,516	\$1,516	\$1,516
Number of patients	185	281	290
Total inpatient contribution margin	\$280,296	\$426,214	\$439,779

*numbers may not sum due to rounding

Betsy Johnson Hospital

	PARTIAL FY (FFY 2022)	1 ST FULL FISCAL YEAR (FFY 2023)	2 ND FULL FISCAL YEAR (FFY 2024)
Total Patients	185	281	290
Total Treatments*	555	843	870
Total Gross Revenues (Charges)	\$443,740	\$694,988	\$738,620
Total Net Revenue	\$201,902	\$316,219	\$336,072
Average Net Revenue per Treatment	\$363.79	\$375.11	\$386.29
Total Operating Expenses (Costs)	\$348,323	\$464,798	\$484,382
Average Operating Expense per Treatment	\$672.62	\$551.36	\$556.76
Inpatient Contribution Margin	\$280,296	\$426,214	\$439,779
Net Income	\$133,870	\$277,635	\$291,469

*Treatments based on number of patients times 3 treatments per patient per week. Numbers may not sum due to rounding by project analyst.

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

- Projected charges and revenues are reasonable and adequately supported.

- Projected operating expenses are reasonable and adequately supported.
- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions.
 - The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal.
 - The applicant adequately demonstrates that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.
- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

C

The applicant proposes to add inpatient dialysis services at Betsy Johnson Hospital in Dunn through a service agreement with BMA by utilizing no more than two mobile hemodialysis machines provided by BMA.

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 2021 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 19 as Harnett County. Facilities may also serve residents of counties not included in their service area.

In Section G, page 47 the applicant states there are no hospitals in Harnett 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 Harnett County. The applicant states:

“There is currently no provider of inpatient dialysis in Harnett County. The proposed project is being developed [to] provide this service so residents of the

Harnett Health service area, in need of inpatient dialysis have a choice and are not forced to go out of the county for inpatient care.”

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 Harnett County.
- The applicant adequately demonstrates that the proposed inpatient dialysis services are needed for BJH 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 add inpatient dialysis services at Betsy Johnson Hospital in Dunn through a service agreement with BMA by utilizing no more than two mobile hemodialysis machines provided by BMA.

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 PARTIAL FY	PROJECTED FTE POSITIONS FFY 2022	PROJECTED FTE POSITIONS FFY 2023
Registered Nurse	0.05	0.05	0.05
Housekeeping	0.10	0.10	0.10
Administrative/Business Office	0.10	0.10	0.10
Total	0.25	0.25	0.25

Source: Section Q, Form H

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 the pro forma financials found in Section Q. The applicant states on page 48 that Fresenius will provide the clinical staff to operate the dialysis machines. In Section H, pages 48-49, 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 information provided in Section H, pages 48-49, and in Section Q, Form H, 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 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 add inpatient dialysis services at Betsy Johnson Hospital in Dunn through a service agreement with BMA by utilizing no more than two mobile hemodialysis machines provided by BMA.

Ancillary and Support Services

In Section I.1, page 51, the applicant identifies the necessary ancillary and support services for the proposed dialysis services. On pages 51-52, 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 52, 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.

C

In Section K, page 55, the applicant states that the project involves renovating 600 square feet of existing space in two hospital rooms and storage area in the hospital to accommodate the electrical and plumbing needs for the mobile dialysis machines. Line drawings are provided in Exhibit K.2.

On page 55, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal based on the following:

- the applicant engaged a general contractor to plan and design the renovation and upfit to be code compliant.
- the applicant engaged an engineer who based the projected renovation on professional experience and the latest materials and cost data.

On page 56, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services because the proposal involves upfitting a modest amount of existing space in the hospital to accommodate the proposed mobile dialysis machines.

On page 56, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans and provides supporting documentation in Exhibit F.1.

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.

- (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 BJH FFY 2020 acute care discharges:

	PERCENTAGE OF TOTAL PATIENTS SERVED BY THE FACILITY OR CAMPUS DURING THE LAST FULL FY	PERCENTAGE OF THE POPULATION OF THE SERVICE AREA
Female	60.61%	50.50%
Male	39.39%	49.50%
Unknown	0.00%	0.00%
64 and Younger	65.13%	87.20%
65 and Older	34.87%	12.80%
American Indian	0.83%	1.70%
Asian	0.24%	1.30%
Black or African-American	27.74%	21.90%
Native Hawaiian or Pacific Islander	0.0%	0.20%
White or Caucasian	59.86%	71.30%
Other Race	11.14%	--
Declined / Unavailable	0.19%	--

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 61, the applicant states there have been no civil rights access complaints filed against any of the applicant's facilities 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 61, 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:

Betsy Johnson Hospital Projected Payor Mix, FFY 2024

PAYOR CATEGORY	# OF PATIENTS	PATIENTS AS % OF TOTAL
Self-Pay	0	0.0%
Insurance*	55	19.0%
Medicare*	235	81.0%
Medicaid*	0	0.0%
Medicare/Commercial	0	0.0%
Other Miscellaneous (incl. VA)	0	0.0%
Total	290	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 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 add inpatient dialysis services at Betsy Johnson Hospital in Dunn through a service agreement with BMA by utilizing no more than two mobile hemodialysis machines provided by BMA.

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, pages 64-65 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 add inpatient dialysis services at Betsy Johnson Hospital in Dunn through a service agreement with BMA by utilizing no more than two mobile hemodialysis machines provided by BMA.

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 2021 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 19 as Harnett 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 proposed project will allow Harnett County ESRD patients requiring hospitalization to remain close to home. Expansion of inpatient services at Harnett Health will allow additional opportunity to compete with other providers outside of Harnett County.”

The proposed project will foster competition by continuing to promote cost effectiveness, quality, and access to services in the proposed service area.”

Regarding the impact of the proposal on cost effectiveness, in Section N, page 66, the applicant states:

“The proposed project will promote cost effectiveness in several ways. The addition of inpatient dialysis services at Harnett Health will decrease the costs associated with transfer of patients. The project also will increase average daily census providing economies of scale, scope, and increased expertise to ensure

that Harnett health continues to be a strong and viable competitor in the broader health care marketplace.”

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 66, the applicant states Harnett Health adheres to external quality standards and will continue to uphold those standards following the addition of inpatient dialysis services at BJH.

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:

“Harnett Health has existing strategies with specific activities designed to assure services will be accessible by indigent patients without regard to ability to pay. Harnett Health will not discriminate in the provision of services on the basis of age, race, religion, disability, or the patient’s ability to pay.”

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

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

The applicant, Harnett Health System, Inc., operates Betsy Johnson Hospital in Dunn and Central Harnett Hospital in Lillington.

In Section O, page 69, the applicant states that, during the 18 months immediately preceding the submittal of the application, no incidents related to quality of care occurred in any these facilities. The files in the Acute and Home Care Licensure and Certification Section, DHR confirm that. 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 add inpatient dialysis services at Betsy Johnson Hospital in Dunn through a service agreement with BMA by utilizing no more than two mobile hemodialysis machines provided by BMA. There are no administrative rules applicable to the provision of inpatient dialysis services in a hospital.