

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: January 8, 2025

Findings Date: January 8, 2025

Project Analyst: Crystal Kearney

Co-Signer: Lisa Pittman

Project ID #: K-12568-24

Facility: Granville Health System

FID #: 943195

County: Granville

Applicant: Granville Health System

Project: Develop an inpatient dialysis service with no more than 2 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

Granville Health System (hereinafter referred to as the “applicant”) proposes to develop an inpatient dialysis service by developing two dialysis stations at Granville Health System (GHS)

The applicant does not propose to:

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

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

- (2) Repealed effective July 1, 1987.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

C

The applicant proposes to develop an inpatient dialysis service by developing two dialysis stations at Granville Health System.

Patient Origin

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

The applicant does not currently provide inpatient dialysis services; therefore, there is no historical patient origin. The applicant states in Section C.3, page 33, that its service area for the proposed inpatient dialysis services will be similar to the hospital’s patient origin for its acute care inpatients. The facility may also serve residents of counties not included in their service area.

In Section C, page 33, the applicant provides projected patient origin for the third full fiscal year (FY) of operation, October 1-September 30, in the following table:

County	Third Full FY of Operation 10/1/2027 to 9/30/2028	
	# of Patients	% of Total
Granville	60	60.1%
Vance	23	22.9%
Warren	5	5.0%
Franklin	4	4.0%
Durham	1	1.5%
Other^	7	6.5%
Total	100	100.0%

This should match the name provided in Section A, Question 4

^Other can include a varying mix of patients from Alamance, Carteret, Chatham, Craven, Currituck, Guilford, Iredell, Johnston, Mecklenburg, Nash, Onslow, Orange, Pender, Person, Randolph, Scotland, Wake, Wayne, Wilkes, and Wilson counties in NC as well as other states.

Source: Section C, page 33

In Section C, page 33, the applicant provides the assumptions and methodology used to project its patient origin. The applicant's assumptions are reasonable and adequately supported because they are based on the applicant's historical patient origin for the hospital's acute care services.

Analysis of Need

In Section C.4, pages 35-40, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below:

- The applicant states that currently, inpatient dialysis services are not available in Granville County. The only outpatient dialysis services currently available in Granville County are via two outpatient dialysis clinics-Fresenius (FMC) Dialysis Services Neuse River, and Fresenius (FMC) Dialysis Services of Oxford. The proposed 2025 SMFP reflects that FMC Dialysis Services Neuse River was caring for 77 patients as of December 31, 2023, and FMC Dialysis Services of Oxford was caring for 90 patients as of the same date. In the event that one of these patients should require emergent or inpatient care in a hospital, patients would be transferred to the nearest acute care hospital that provides inpatient dialysis.
- The applicant states that the Granville Health System's primary need for the proposed project is qualitative in nature and is based on the lack of inpatient dialysis services for Granville County patients with chronic kidney conditions, the resulting detrimental impacts on patient care and outcomes, and the undue burden on Granville County residents that rely on dialysis who must travel outside of Granville County for inpatient care.
- The applicant states that the projected growth and aging of the Granville County population will create additional demand for inpatient care, including patients that require dialysis.
- The applicant states that the proposed inpatient dialysis services will support Granville Health System's goal of maximizing patient access to high quality, equitable care that serves the communities in Granville County.

The information is reasonable and adequately supported because the applicant demonstrates the need for inpatient dialysis services based on the information provided regarding growth of Granville County residents and of GHS's patients.

Projected Utilization

In Section Q, Form C, page 96, the applicant projects to serve the following number of dialysis patients and treatments in the first three years, federal fiscal years (FFY), FFY 2026, FFY 2027, and FFY 2028:

Granville Health System	1st Full FFY 10/1/2025 to 9/30/2026	2nd Full FFY 10/1/2026 to 9/30/2027	3rd Full FFY 10/1/2027 to 9/30/2028
# of Bedside Dialysis Machine	2	2	2
# of Dialysis Treatments	168	170	172

In Section Q, Form C Assumptions and Methodology, pages 97-100, the applicant describes its methodology and assumptions used to projected utilization of the proposed inpatient dialysis services, as summarized below:

Step 1: Historical: The applicant states that it examined historical patient data of patient’s who could not be admitted to GHS or were diverted by EMS to another county for care, as well as the historical and projected population growth in Granville County, especially those age 65 and older. The number of dialysis patients who could not be admitted at GHS in FY 2023 and year-to date FY 2024 due to lack of this service are shown below.

Historical Patients Unable to be Admitted to GHS

	FY 2023	FY 2024*
EMS Diverted from GHS	52	42
Transferred from GHS ED	N/A	72
Total Patients	52	114

Source: GHS internal data, Section Q, page 97

*FY 2024 figures represent eight months of annualized data

As shown above, a total of 114 patients were diverted by EMS or transferred from Granville Health System’s ED and out of Granville County in FY 2024, due to the lack of available inpatient dialysis services.

Step 2: Potential GHS Dialysis Patients: The applicant estimates that 100% of the patients who had been diverted by EMS initially, would have been admitted to GHS. It is estimated that 75 percent of the individuals that arrive at the ED on their own or with a family member, would be admitted to GHS instead of being transferred to receive dialysis treatment. See table below.

Potential GHS Dialysis Patients

	FY 2024	Potential % Admitted	Potential Patients
EMS Diverted from GHS	42	100%	42
Transferred from GHS ED	72	75%	54
Total Patients	114		96

Source: Section Q, page 98

Step 3: Projected Population Growth: The applicant states that the historical and projected population growth in Granville County was reviewed to determine utilization of the proposed service in the proposed project years. The total population in Granville County is forecast to grow slightly, at 1.0 percent annually through FY 2028, the third full year of the proposed project. The applicant states that the population age 65 and older, are at higher risk of developing a kidney-related condition. This older group is growing at 3.3% annually as shown below.

Projected Population Growth in Growth County

Granville County	FY 2024	FY 2028	CAGR
Total Population	62,881	65,505	1.0%
Population 65 and Older	12,369	14,090	3.3%

Source: NC OSBM data, Section Q, page 98

Step 4: Projected Potential Dialysis Patients: To be conservative, the applicant states that GHS projects the base number of dialysis patients to increase based on the county’s compound annual growth rate (CAGR) of 1.0 percent for the total population, as summarized below.

Projected Potential Dialysis Patients

	FY2024	FY2025	FY2026	FY2027	FY2028	CAGR*
Total Patients	96	97	98	99	100	1.0%

Source: * Compound Annual Growth Rate
Section Q, page 99

Step 5: Average Dialysis Treatments Per Patient: The applicant states that the total average length of stay (ALOS) for inpatients at Granville Health System is 4.0 days, and the standard treatment course for a dialysis patient is to receive three dialysis treatments per seven days. Therefore, for each admission of a patient requiring dialysis treatment, the patient will receive on average 1.72 treatments during their stay (3 treatments per 7 days x 4.0 days ALOS), as shown below.

Average Dialysis Treatments Per Patient

	FY 2024
GHS Inpatient ALOS	4.0
Average Dialysis Treatments Per Patient	1.72
Average Dialysis Treatments Per Day	0.43

Source: Section Q, page 99

Step 6: Projected Dialysis Treatments: The applicant states that the number of projected inpatient dialysis patients was multiplied by the average number of treatments per patient to calculate the total projected dialysis treatments for the first three project years. The applicant states that the GHS is projected to provide 172 dialysis treatments in FY 2028, the third project year, and is projected to serve 100 unique patients. The utilization projections for the number of treatments and dialysis-eligible patients validate the reasonableness of purchasing two dialysis machines and GHS’s ability to operate the proposed dialysis service with existing GHS staff and contracted physician consult coverage, including instances when both machines are utilized at the same time

Projected Dialysis Treatments

	FY 2026	FY 2027	FY 2028
Total Dialysis Patients	98	99	100
Dialysis Treatments	168	170	172

Source: Section Q, page 100

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

- The applicant projects growth of the GHS dialysis inpatient census using one-third of the projected Granville County 65+ population growth rate, and by using historical dialysis patient transfer data from both GHS and Granville County EMS.

- The applicant assumes that all projected inpatient transfers and EMS transfers will become expected inpatients, and that a portion of EMS transport bypasses will be treated at GHS.
- The applicant utilized historical internal data from GHS, population growth data from the NC OSBM and Granville County EMS data to determine dialysis patient admissions per FFY.

Access to Medically Underserved Groups

In Section C.6, page 47, the applicant states:

“As a county-owned facility, Granville Health System is committed to providing care to anyone in need and does not deny access to medically necessary services due to race, sex, creed, age, handicap, financial status, or lack of medical insurance. All area residents, including low-income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups, will have access to the proposed inpatient dialysis service.”

In Section C.6.b, page 47, the applicant provides the following estimated percentages of dialysis patients for each medically underserved group during the third full fiscal year of operation following completion of the project, as summarized in the following table.

Group	Estimated Percentage of Total Patients during the Third Full Fiscal Year
Low income persons	
Racial and ethnic minorities	49.7%
Women	62.4%
Persons with Disabilities	
Persons 65 and older	31.6%
Medicare beneficiaries	33.5%
Medicaid recipients	28.2%

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 GHS’s CY 2023 patient population for inpatient services in the service area.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, ... persons [with disabilities], and other underserved groups and the elderly to obtain needed health care.

NA

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

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

CA

The applicant proposes to develop an inpatient dialysis service by developing two dialysis stations at Granville Health System.

In Section E, pages 57-58, the applicant describes the 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. The alternatives considered were:

- Maintain the status quo - The applicant states that inpatient dialysis services do not currently exist in Granville County, and as such, residents reliant on dialysis are not able to utilize the emergency department at Granville Health System, nor are they able to be admitted as an inpatient, regardless of the care needed. While there are two existing outpatient clinics in Granville County for those who need chronic outpatient dialysis, any patient in need of surgical care, having an emergency, or needing acute care unrelated to their dialysis must be referred to an alternate hospital in another county. For these reasons, this alternative would have been less effective and was rejected.
- Develop a Different Number of Bedside Dialysis Machines – The applicant states that Granville Health System considered the alternative of developing a different number of dialysis machines beyond those proposed in this application. The applicant states that due to the historical data available and in order to ensure cost effectiveness, two machines were deemed to be appropriate to initially support patient volume, allowing GHS to maximize patient benefit while containing healthcare costs. The applicant states that other alternatives were less effective and rejected, and GHS decided to develop the two proposed dialysis units.

- Develop a Dedicated Inpatient Dialysis Unit: The applicant states that the development of an inpatient dialysis unit at GHS was also considered. The applicant states that this alternative was deemed more costly and less effective and was rejected.

The applicant adequately demonstrates that the alternative proposed in this application is the most effective alternative to meet the need because it has adequately demonstrated that the inpatient dialysis services are needed at GHS. Furthermore, the application is conforming to all other statutory and regulatory review criteria and can be approved.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above. Therefore, the application is approved subject to the following conditions:

- 1. Granville Health System (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 Granville Health System by developing no more than two 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 July 1, 2025.**

5. The certificate holder shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.

- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicant proposes to develop an inpatient dialysis service by developing two dialysis stations at Granville Health System.

Capital and Working Capital Costs

In Section Q, page 101, Form F.1 (a), the applicant projects the total capital cost of the project, as shown in the following table:

PROJECTED CAPITAL COSTS	
Medical Equipment	\$150,000
Total	\$150,000

The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based on the information provided by the applicant in Section Q, immediately following Form F.1a as well as Exhibit C.1-3 of the application for the assumptions used to project the capital cost.

In Section F.3, page 61, the applicant states there will be no start-up costs or initial operating expenses. The proposed project will be funded with accumulates reserves.

In Section F, 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	Amount
Loans	\$
Cash or Cash Equivalents, Accumulated Reserves or Owner's Equity	\$150,000\$
Lines of credit	\$
Bonds	\$
Total *	\$150,000

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

- In Exhibit F.2, the applicant provides a letter from the Chief Financial Officer of GHS that confirms the availability of sufficient cash reserves to fund the capital needs of the project and commits the necessary funds to the project development.
- In Exhibit F.2-2 the applicant provides copies of the audited financial statements for GHS and affiliates, which documents cash and cash equivalents of \$24.5 million as of September 2023.

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

Financial Feasibility

The applicant provided pro forma financial statements for the first three full fiscal years of operation following completion of the project. In Section Q, Form F.2b, the applicant projects the projected revenues and net income upon projected completion, as shown in the table below.

GHS Inpatient Dialysis	1st Full FY	2nd Full FY	3rd Full FY
# of treatments	168	170	172
Operating costs	\$174,651	\$179,781	\$185,081
Average Operating Expenses per treatments	\$1,040	\$1,058	\$1,076
Net Income	(\$174,651)	(\$179,781)	(\$185,081)

Section Q, Form F.2b, page 103

In Section Q, Form F.2a, the applicant projects that revenues will exceed operating expenses in the first and third full fiscal years following completion of the project, as shown in the table below.

Granville Health System	1st Full Yr	2nd Full Yr	3rd Full Yr
Total Gross Revenues (Charges)	\$330,834,297	\$344,152,002	\$358,00,962
Total Net Revenue	\$95,719,583	\$99,562,165	\$103,559,155
Total Operating Expenses (Costs)	\$75,093,786	\$77,408,217	\$80,468,147
Net Income	\$20,625,797	\$22,153,948	\$23,091,009

Section Q, Form F.2b, page 107

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q pages 103-107. The applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- The applicant adequately demonstrates that the capital cost is 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.

C

The applicant proposes to develop an inpatient dialysis service by developing two dialysis stations at Granville Health System.

N.C.G.S. §131E-176(24a) defines “service area” as “...the area of the State, as defined in the State Medical Facilities Plan or in rules adopted by the Department, which receives services from a health service facility.” The 2024 SMFP does not define a service area for inpatient dialysis services. There are no applicable rules adopted by the Department that define a service area for inpatient dialysis services. In Section C.3, page 33, the applicant projects 60.1% of its dialysis patients to come from Granville County, similar to the patient origin for acute care services for GHS. The facility may also serve residents of counties not included in their service area.

In Section G, page 69 the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved inpatient dialysis services in Granville County. The applicant states:

“Patients in Granville County do not currently have access to inpatient dialysis services, and for patients without reliable transportation resources or that experience adverse health conditions, it is not reasonable to expect they will travel outside their local community to a more distant facility to receive inpatient care. Granville Health System believes the proposed project will not result in unnecessary duplication, as dialysis is a service that is needed to serve its inpatient population, and because the service is not available in Granville County.”

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (7) The applicant shall show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided.

C

The applicant proposes to develop an inpatient dialysis service by developing two dialysis stations at Granville Health System.

In Section Q, Form H, the applicant provides the projected staffing in full-time equivalent (FTE) positions for the first three full operating years of the proposed services, as summarized in the following table:

Projected Staff			
Form H	1st Full FY	2nd Full FY	3rd Full FY
Registered Nurses	0.3	0.3	0.3
Dialysis Tech	0.3	0.3	0.3
Total	0.6	0.6	0.6

The assumptions and methodology used to project staffing are provided in Section Q and Section H, page 71. The applicant states that GHS will utilize existing nursing staff who will be cross trained to perform inpatient dialysis for patients needing this care. One part-time dialysis technician will be hired by GHS to perform specific clinical care procedures for dialysis patients. GHS will contract with an experienced dialysis provider for on-call nephrologist services on an as needed basis. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Section Q, Form F.3. In Section H, pages 71-72, 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 states that the types of positions are projected based on market research of GHS and vendor experience.
- The applicant states that the number of FTEs projected for each position type are based on market research of Granville Health System and vendor experience, paired with projected utilization for the proposed service.
- The applicant states that the annual salary per FTE and position type are projected based on the current experience and market research of Granville Health System, inflated 3.0 percent annually through the third project year. The inflation rate is based on expected annual inflation.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

The applicant proposes to develop an inpatient dialysis service by developing two dialysis stations at Granville Health System.

Ancillary and Support Services

In Section I.1, page 73, the applicant identifies the necessary ancillary and support services for the proposed services. On page 73, 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 the application and referenced exhibits as described above.

Coordination

In Section I.2, page 74, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit I.2. The applicant adequately demonstrates that the proposed services will be

coordinated with the existing health care system based on the information provided in the application and referenced exhibits as described above.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA

The applicant does not project to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which the services will be offered. Furthermore, the applicant does not project to provide the proposed services to a substantial number of persons residing in other states that are not adjacent to the North Carolina county in which the services will be offered.

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:
- (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 81, the applicant provides the following comparison based on GHS inpatients:

Granville Health System	Percentage of Total Patients Served	Percentage of the Population of the Service Area*
Female	62.4%	48.6%
Male	37.6%	51.4%
Unknown	0.0%	0.0%
64 and Younger	68.4%	81.6%
65 and Older	31.6%	18.4%
American Indian	0.0%	1.1%
Asian	0.2%	0.9%
Black or African American	44.9%	31.0%
Native Hawaiian or Pacific Islander	0.0%	0.1%
White or Caucasian	41.7%	64.6%
Other Race	4.6%	2.3%
Declined/ Unavailable	8.7%	0.0%

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

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

In Section L.2, page 82, the applicant states that during the 18 months immediately preceding the application deadline, no patient civil rights access complaints have been filed against the facility.

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 83, the applicant projects the following payor mix for the proposed services during the third full fiscal year of operation following completion of the project, as shown in the table below.

GHS Projected Payor Mix 3rd FFY 10/1/027 to 9/30/2028

Payor Category	Percentage of Total Patients Served
Self-Pay	5.6%
Charity Care ^	
Medicare*	33.5%
Medicaid*	28.2%
Insurance*	31.1%
Workers Compensation^^	
TRICARE^^	
Other (Other Govt, Worker's Comp) ^^	1.7%
Total	100.0%

Source: Section L, page 83

*Including any managed care plans.

^Granville Health System internal data does not include Charity Care as a payor source for patients. Patients in any payor category can and do receive charity care. Please see Form F.2 for charity care projections.

^^Workers Compensation, TRICARE, Department of Corrections, and other payors are included in the Other payor category.

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 5.6% of total services will be provided to self-pay patients, 33.5% to Medicare patients and 28.2% to Medicaid patients.

On page 84, the applicant provides the assumptions and methodology used to project payor mix during the third full year of operation following completion of the project. The projected payor mix is reasonable and adequately supported because it is based on its most recent historical acute care patient payor mix.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L.5, page 85, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

The applicant proposes to develop an inpatient dialysis service by developing two dialysis stations at Granville Health System.

In Section M, page 86, 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-pdf page 69. The applicant adequately demonstrates that health professional training programs in the area will have access to the facility for training purposes based on the information provided in Section M, page 85 and Exhibit M.1 as described above.

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

C

The applicant proposes to develop an inpatient dialysis service by developing two dialysis stations at Granville Health System.

N.C.G.S. §131E-176(24a) defines “service area” as “...*the area of the State, as defined in the State Medical Facilities Plan or in rules adopted by the Department, which receives services from a health service facility.*” The 2024 SMFP does not define a service area for inpatient dialysis services. There are no applicable rules adopted by the Department that define a service area for inpatient dialysis services. In Section C.3, page 23, the applicant projects 60.1% of its dialysis patients to come from Granville County, similar to the patient origin for acute care services for GHS. The facility may also serve residents of counties not included in their service area.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 87, the applicant states:

“The proposed project is expected to enhance competition in the service area by promoting cost effectiveness, quality, and access to inpatient dialysis services... .”

Regarding the impact of the proposal on cost effectiveness, in Section N, page 87, the applicant states:

“The proposed project is indicative of Granville Health System’s commitment to containing healthcare costs and maximizing healthcare benefit per dollar expended. As noted previously, the proposed inpatient dialysis service at GHS will not require construction and the dialysis units will be capable of being moved to the patient’s bedside as appropriate for dialysis treatment. This will thereby avoid unnecessary expense and provide a new service with lower costs for both the patient and GHS. Moreover, as the dialysis machines will have the capability to be easily wheeled from room to room and only require a standard voltage electrical outlet and water faucet, there will not need to be any renovations or new features implemented in patient rooms to accommodate the inpatient dialysis service, further enhancing the cost effectiveness and reasonableness of the proposed project.”

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 88, the applicant states:

“The proposed project will introduce inpatient dialysis services to residents of Granville County and will in turn mitigate the need for EMS diversions to Durham County and other counties. Therefore, patients will receive timely admissions to GHS, which will subsequently maintain high quality service, and improve patient outcomes.”

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 88, the applicant states:

“As a county-owned hospital, GHS is committed to complying with state and federal regulations and providing medically necessary care to all persons in need of care, regardless of race, sex, creed, age, national origin, handicap, or ability to pay”.

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 90 and in Form O, Section Q, page 114, the applicant states GHS is the only hospital owned and operated by the applicant in North Carolina.

In Section O, page 92, the applicant states that, during the 18 months immediately preceding the submittal of the application. The applicant states in August 2022, DHHS received a self-reported complaint from Granville Health System and evaluated the hospital's and evaluated the hospital's compliance with the Medicare Conditions of Participation. The investigation resulted in an Immediate Jeopardy involving a failure in EMTALA compliance. A plan of correction was created and submitted to DHHS in April of 2023. Findings were submitted to the Quality Improvement Organization (QIO), a group contracted by CMS. In July of 2023 the QIO reported these findings and results to the Office of the Inspector General (OIG). No penalty was given, and Granville Health System was deemed in compliance. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.

G.S. 131E-183 (b): The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of

health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

NA

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