

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: December 12, 2025

Findings Date: December 12, 2025

Project Analyst: Crystal Kearney

Co-Signer: Mike McKillip

Project ID #: J-12713-25

Facility: Duke University Hospital

FID #: 943138

County: Durham

Applicant: Duke University Health System, Inc.

Project: Acquire one unit of cardiac catheterization pursuant to Policy AC-3 by converting existing angiography equipment

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.

C

Duke University Health System, Inc. (hereinafter referred to as “the applicant” or “DUHS”) proposes to acquire one unit of cardiac catheterization pursuant to Policy AC-3 by converting existing angiography equipment located at Duke University Hospital.

Need Determination

The proposed project does not involve the addition of any new health service facility beds, services, or equipment for which there is a need determination in the 2025 State Medical Facilities Plan (SMFP). Therefore, there are no need determinations applicable to this review.

Policies

There is one policy in the 2025 SMFP applicable to this review: *Policy AC-3: Exemption from Plan Provisions for Certain Academic Medical Center Teaching Hospital Projects.*

Policy AC-3

Policy AC-3: Exemption from Plan Provisions for Certain Academic Medical Center Teaching Hospital Projects states:

“Projects for which certificates of need are sought by Academic Medical Center Teaching Hospitals may qualify for exemption from the need determinations of this document. The Healthcare Planning and Certificate of Need Section shall designate as an Academic Medical Center Teaching Hospital any facility whose application for such designation demonstrates the following characteristics of the hospital:

- 1. Serves as a primary teaching site for a school of medicine and at least one other health professional school, providing undergraduate, graduate and postgraduate education.*
- 2. Houses extensive basic medical science and clinical research programs, patients and equipment.*
- 3. Serves the treatment needs of patients from a broad geographic area through multiple medical specialties.*

[Note: The following paragraph is the second paragraph referenced in the questions that follow this policy.]

Exemption from the provisions of need determinations of the North Carolina State Medical Facilities Plan shall be granted to projects submitted by Academic Medical Center Teaching Hospitals designated prior to January 1, 1990 provided the projects are necessary to meet one of the following unique academic medical needs:

- 1. Necessary to complement a specified and approved expansion of the number or types of students, residents or faculty that are specifically required for an expansion of students or residents, as certified by the head of the relevant associated professional school; the applicant shall provide documentation that the project is consistent with any relevant standards, recommendations or guidance from specialty education accrediting bodies; or*
- 2. With respect to the acquisition of equipment, is necessary to accommodate the recruitment or retention of a full-time faculty member who will devote a majority of his or her time to the combined activities of teaching (including teaching within the clinical setting), research, administrative or other academic responsibilities within the academic medical center teaching hospital or medical school; or*
- 3. Necessary to accommodate patients, staff or equipment for a specified and approved expansion of research activities, as certified by the head of the entity*

sponsoring the research; and including, to the extent applicable, documentation pertaining to grants, funding, accrediting or other requirements, and any proposed clinical application of the asset; or

4. Necessary to accommodate changes in requirements of specialty education accrediting bodies, as evidenced by copies of documents issued by such bodies.

A project submitted by an Academic Medical Center Teaching Hospital under this policy that meets one of the above conditions shall demonstrate that the Academic Medical Center Teaching Hospital's teaching or research need for the proposed project cannot be achieved effectively at any non-Academic Medical Center Teaching Hospital provider which currently offers and has capacity within the service for which the exemption is requested and which is within 20 miles of the Academic Medical Center Teaching Hospital.

The Academic Medical Center Teaching Hospital shall include in its application an analysis of the cost, benefits and feasibility of engaging that provider in a collaborative effort that achieves the academic goals of the project as compared with the certificate of need application proposal. The Academic Medical Center Teaching Hospital shall also provide a summary of a discussion or documentation of its attempt to engage the provider in discussion regarding its analysis and conclusions.

The Academic Medical Center Teaching Hospital shall include in its application a discussion of any similar assets within 20 miles that are under the control of the applicant or the associated professional school and the feasibility of using those assets to meet the unique teaching or research needs of the Academic Medical Center Teaching Hospital.

For each of the first five years of operation the approved applicant shall submit to Certificate of Need a detailed description of how the project achieves the academic requirements of the appropriate section(s) of Policy AC-3, paragraph 2 [items 1 through 4] as proposed in the certificate of need application.

Applicants who are approved for Policy AC-3 projects after January 1, 1990, shall report those Policy AC-3 assets (including beds, operating rooms and equipment) on the appropriate annual license renewal application or registration form for the asset. The information to be reported for the Policy AC-3 assets shall include: (a) inventory or number of units of AC-3 Certificate of Need-approved assets (including all beds, operating rooms and equipment); (b) the annual volume of days, cases or procedures performed for the reporting year on the Policy AC-3 approved asset; and (c) the patient origin by county. Neither the assets under (a) above nor the utilization from (b) above shall be used in the annual State Medical Facilities Plan need determination formulas, but both the assets and the utilization will be available for informational purposes to users of the State Medical Facilities Plan.

This policy does not apply to a proposed project or the portion thereof that is based solely upon the inability of the State Medical Facilities Plan methodology to accurately project need for the proposed service(s), due to documented differences in patient treatment times that are attributed to education or research components in the delivery of patient care or to differences in patient acuity or case mix that are related to the applicant's academic mission. However, the applicant may submit a petition pursuant to the State Medical Facilities Plan Petitions for Adjustments to Need Determinations process to meet that need or portion thereof.

Policy AC-3 projects are required to materially comply with representations made in the certificate of need application regarding academic based need. If an asset originally developed or acquired pursuant to Policy AC-3 is no longer used for research and/or teaching, the Academic Medical Center Teaching Hospital shall surrender the certificate of need."

The Division of Health Service Regulation designated Duke University Hospital as an academic medical center teaching hospital prior to January 1, 1990. In Section B, pages 27-30, and Exhibits B.3, the applicant provides documentation that the acquisition of the proposed cardiac catheterization is necessary to accommodate the recruitment and retention needs, as well as expanded research activities, supporting this proposal. The applicant states that Duke Regional Hospital is the only non-academic medical center within 20 miles of the Duke University Hospital campus that offers cardiac catheterization. The applicant adequately demonstrates that the proposed project is consistent with the requirements of Policy AC-3.

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 the following:

- The applicant adequately demonstrates that the proposal is consistent with Policy AC-3 for the following reasons:
- The applicant adequately documents that the acquisition of the proposed cardiac catheterization services necessary to accommodate the recruitment and retention of full-time faculty members that devote a majority of their time to the combined activities of teaching (including teaching within the clinical setting), research, administrative or other academic responsibilities within Duke University Hospital.
- The applicant adequately documents that the proposed project is necessary to accommodate the expansion of research activities using cardiac catheterization.
- The applicant adequately documents there are no non-academic medical center teaching hospital providers within 20 miles that offer cardiac catheterization services.

- (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 acquire no more than one unit of fixed cardiac catheterization equipment pursuant to Policy AC-3 by converting existing angiography equipment.

In Section C.1, page 31, the applicant describes the project as follows:

“Duke University Hospital (“DUH”) seeks approval to use existing angiography equipment for statutorily defined cardiac catheterization services. This does not require any capital cost, as the existing equipment is capable of supporting these procedures subject to regulatory approval.”

Patient Origin

On page 302, the 2025 SMFP states: *“Cardiac catheterization equipment service areas are the Acute Care Bed Service Areas defined in Chapter 5 and shown in Figure 5.1.”* Thus, the service area for this facility consists of Durham, Caswell, and Warren Counties. Facilities may also serve residents of counties not included in their service area.

In Sections C.2 and C.3, pages 32 and 34, the applicant provides the historical (SFY2025) patient origin for cardiac catheterization services at Duke University Hospital, and the projected patient origin for the first three full fiscal years of operation (SFY2027-SFY2029) of the proposed project, as shown in the following tables:

| Duke University Hospital Cardiac Catheterization Services | | |
|--|---|-------------------|
| County | Historical 7/1/2024 to 6/30/2025 | |
| | Patients | % of Total |
| Durham | 1,165 | 15% |
| Wake | 1,161 | 15% |
| Alamance | 301 | 4% |
| Granville | 261 | 3% |
| Vance | 254 | 3% |
| Cumberland | 243 | 3% |
| Orange | 235 | 3% |
| Guilford | 197 | 2% |
| Person | 183 | 2% |
| Johnston | 139 | 2% |
| Lee | 132 | 2% |
| Franklin | 121 | 2% |
| Pitt | 109 | 1% |
| Harnett | 107 | 1% |
| Onslow | 104 | 1% |
| Mecklenburg | 100 | 1% |
| Robeson | 94 | 1% |
| New Hanover | 93 | 1% |
| Chatham | 80 | 1% |
| Warren | 77 | 1% |
| Forsyth | 75 | 1% |
| Brunswick | 74 | 1% |
| Nash | 69 | 1% |
| Other NC County | 1,468 | 18% |
| VA | 515 | 6% |
| SC | 227 | 3% |
| GA | 26 | 0% |
| MD | 9 | 0% |
| Other State | 350 | 4% |
| Total | 7,969 | 100.0% |

Source: Section C, page 32 of the application.

| Duke University Hospital Cath Lab Procedures | | | | | | |
|---|--|-------------|--|-------------|--|-------------|
| COUNTY | 1 st Full FY 7/1/2026 to 6/30/2027 | | 2 nd Full FY 7/1/2027 to 6/30/2028 | | 3 rd Full FY 7/1/2028 to 6/30/2029 | |
| | # Patients | % of Total | # Patients | % of Total | # Patients | % of Total |
| Durham | 1,193 | 15% | 1,215 | 15% | 1,237 | 15% |
| Wake | 1,189 | 15% | 1,210 | 15% | 1,233 | 15% |
| Alamance | 308 | 4% | 314 | 4% | 320 | 4% |
| Granville | 267 | 3% | 272 | 3% | 277 | 3% |
| Vance | 260 | 3% | 265 | 3% | 270 | 3% |
| Cumberland | 249 | 3% | 253 | 3% | 258 | 3% |
| Orange | 241 | 3% | 245 | 3% | 249 | 3% |
| Guilford | 202 | 2% | 205 | 2% | 209 | 2% |
| Person | 187 | 2% | 191 | 2% | 194 | 2% |
| Johnston | 142 | 2% | 145 | 2% | 148 | 2% |
| Lee | 135 | 2% | 138 | 2% | 140 | 2% |
| Franklin | 124 | 2% | 126 | 2% | 128 | 2% |
| Pitt | 112 | 1% | 114 | 1% | 116 | 1% |
| Harnett | 110 | 1% | 112 | 1% | 114 | 1% |
| Onslow | 106 | 1% | 108 | 1% | 110 | 1% |
| Mecklenburg | 102 | 1% | 104 | 1% | 106 | 1% |
| Robeson | 96 | 1% | 98 | 1% | 100 | 1% |
| New Hanover | 95 | 1% | 97 | 1% | 99 | 1% |
| Chatham | 82 | 1% | 83 | 1% | 85 | 1% |
| Warren | 79 | 1% | 80 | 1% | 82 | 1% |
| Forsyth | 77 | 1% | 77 | 1% | 80 | 1% |
| Brunswick | 76 | 1% | 72 | 1% | 79 | 1% |
| Nash | 71 | 1% | 72 | 1% | 73 | 1% |
| Other NC | 1,503 | 18% | 1,530 | 18% | 1,559 | 18% |
| VA | 527 | 6% | 537 | 6% | 547 | 6% |
| SC | 232 | 3% | 237 | 3% | 241 | 3% |
| GA | 27 | 0% | 27 | 0% | 28 | 0% |
| MD | 9 | 0% | 9 | 0% | 10 | 0% |
| Other States | 358 | 4% | 365 | 4% | 372 | 4% |
| Total | 8,158 | 100% | 8,308 | 100% | 8,461 | 100% |

Source: Section C, page 34 of the application

In Section C.3(c), page 35, the applicant states that the projected patient origin is based on the historical patient origin for cardiac cath labs services at Duke University Hospital. The applicant's assumptions are reasonable and adequately supported.

Analysis of Need

In Section C.4, pages 36-39, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below:

- The applicant provides utilization data demonstrating that the existing equipment is highly utilized and faces capacity constraints. The applicant states that the current utilization of the labs routinely exceeds 85% of scheduled time, which makes finding additional time to accommodate clinical research activities increasingly difficult.

- The applicant provides demographic data that supports the anticipated continued growth in demand for cardiac catheterization services at Duke University Hospital.

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

- The applicant provides reasonable and adequately supported information to support the existing equipment is highly utilized and faces capacity constraints.
- The applicant adequately demonstrates the proposed equipment would expand practical capacity necessary to recruit and retain Duke’s growing cardiology faculty as well as scheduling flexibility to accommodate research needs.

Projected Utilization

In Section Q, Form C2.b, the applicant provides projected utilization for the cardiac catheterization equipment at DUH through the first three full fiscal years of operation, as summarized in the following below.

| Projected Medical Equipment Utilization upon Project Completion Duke University Hospital | 1st Full FY 7/1/26 -6/30/27 | 2nd Full FY 7/1/27-6/30/28 | 3rd Full FY 7/1/28-6/30/29 |
|---|---|--|--|
| Cardiac Cath Equipment | | | |
| # of Units | 8 | 8 | 8 |
| # of Diagnostic Procedures | 3182 | 3214 | 3246 |
| # of Therapeutic Procedures | 3314 | 3431 | 3552 |
| # of Diagnostic Equivalent Procedures | 9165 | 9403 | 9649 |
| Other Procedures | 1663 | 1663 | 1663 |

Source: Section Q, Form C.2b of the application

In Section Q, the applicant provides the assumptions and methodology used to project utilization, which are summarized below.

1. Overview of Methodology

The applicant states that Duke Health System (DUHS) utilizes a standardized methodology to identify and report cardiac catheterization procedures performed across its adult and pediatric catheterization laboratories. This methodology is reviewed and updated annually to ensure alignment with operational practices and regulatory reporting requirements.

2. Data Sources and Scope

The applicant states that the patient-level charge data is extracted from the applicant’s internal accounting systems. Data is sorted by patient account and service date to ensure attribution of procedures.

3. Procedure Classification

The applicant states DUHS reports interventional diagnostic procedures, and EP procedures separately. Only procedures classified as interventional or diagnostic are included in the reporting for cardiac catheterization procedures.

4. Pediatric vs. Adult Encounters

The applicant states that pediatric procedures are defined as those performed on patients aged 14 years or younger.

5. Annual Crosswalk Review and FY25 Revisions

The applicant states that since 2022, DUHS has maintained and evolved CPT crosswalk to reflect procedural and coding changes. The applicant states that in Fiscal Year 2025, a significant revision was implemented after a review of all CPT codes. The applicant states that these changes were made in collaboration with Duke University Hospital (DUH) Finance and the DUH Heart Leadership Team.

6. Historical Restatement and Variance Analysis

The applicant states that to ensure consistency and comparability, DUHS reviewed data from Fiscal Years 2022 through 2025 using the FY25 methodology. The applicant states that a crosswalk was developed to reconcile prior year classification with the updated framework.

7. Clarification on the restated categories:

The applicant states that the patient shifts to a new category as a result when the FY2025 crosswalk is applied.

Projected utilization is reasonable and adequately supported because it is based on historical utilization of Duke University Hospital cardiac cath procedures performed in adult and pediatric catheterization laboratories and the procedure classification.

Access to Medically Underserved Groups

In Section C.6, pages 44-45, the applicant states it will provide services to all individuals including low-income persons, racial and ethnic minorities, women, persons with disabilities, persons 65 and older, Medicare beneficiaries, Medicaid recipients, and other underserved groups, will have access to this service, as clinically appropriate. The applicant provides the estimated percentage for each medically underserved group, as shown in the following table.

| Medically Underserved Groups | Percentage of Total Patients during the Third Full Fiscal Year |
|------------------------------|--|
| Low income persons | 15.1% |
| Racial and ethnic minorities | 38.3% |
| Women | 59.8% |
| Persons with Disabilities | NA* |
| Persons 65 and older | 38.2% |
| Medicare beneficiaries | 40.4% |
| Medicaid recipients | 12.8% |

The applicant states, " DUHS does not maintain data regarding the number of disabled persons it serves. However, as previously described, disabled persons will not be denied access to this facility, which will be accessible to persons with disabilities , as required by the Americans with Disabilities Act."

Source: Section C, page 45 of the application

The applicant adequately describes the extent to which all residents of the service area, including underserved groups, are likely to have access to the proposed services based on the following:

- The applicant states it will not discriminate against patients on the basis of a number of categories and describes its policies for assisting uninsured and low-income patients with financial assistance.
- The applicant provides Duke University Hospital's letter of support in Exhibit C.4, and its Patient Financial policies in Exhibit L.4.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is not 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 acquire no more than one unit of fixed cardiac catheterization equipment pursuant to Policy AC-3 by converting existing angiography equipment.

In Section E, page 54, 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:

Enter into a services agreement with DLP Cardiac Partners - DUHS could enter into a services agreement with DLP Cardiac Partners, which operates a fleet of grandfathered labs in the state. The applicant states such an arrangement would necessarily entail a significant payment to DLP Cardiac Partners for the provision of those services in excess of DUHS's operating costs to provide services on its own existing equipment. The applicant states this would not provide a permanent solution as the equipment would be subject to the owner's control. DUHS's current proposal entails no capital investment and therefore, this is not the most effective alternative.

Purchase new equipment – DUHS could also propose to purchase new cath equipment, which would also entail construction or renovation of space to accommodate the equipment. The applicant states that this would be more expensive than using the existing angiography equipment for a broader range of procedures. Therefore, this is not the most effective alternative.

Use Existing equipment – proposed option – The applicant states that it would be most cost effective and fastest to implement the proposed project, which increases practical capacity without any delay or capital expenditure.

The applicant adequately demonstrates that the alternative proposed in this application is the most effective alternative to meet the need based on the following:

- The application is conforming to all statutory and regulatory review criteria.
- The applicant provides information to explain why it believes the proposed project is the most effective alternative.

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. Duke University Health System, Inc. (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**
 - 2. The certificate holder shall acquire no more than one unit of fixed cardiac catheterization equipment pursuant to Policy AC-3 by converting existing angiography equipment located at Duke University Hospital.**
 - 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 Q of the application and that would otherwise require a certificate of need.**
 - 4. For each of the first five years of operation, Duke University Hospital shall submit to the Healthcare Planning and Certificate of Need Section a detailed description of how the project achieves the academic requirements of the appropriate sections of Policy AC-3, paragraph 2 [items 1 through 4] as proposed in the certificate of need application.**
 - 5. Duke University Hospital shall report the Policy AC-3 fixed cardiac catheterization on the appropriate annual license renewal application for the asset. The information to be reported for the fixed cardiac catheterization shall include: (a) the number of approved units; (b) the annual volume of cases or procedures performed for the reporting year; and (c) the patient origin by county.**
 - 6. If the fixed cardiac catheterization ceases to be used for clinical teaching or research, Duke University Hospital shall surrender the certificate of need.**
 - 7. Duke University Hospital shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to insurance 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 acquire no more than one unit of fixed cardiac catheterization equipment pursuant to Policy AC-3 by converting existing angiography equipment.

Capital and Working Capital Costs

In Section F.1, page 55, the applicant states it will not incur any capital or working capital costs to place the existing equipment into service to perform cardiac catheterization procedures.

Financial Feasibility

The applicant provided pro forma financial statements for the first three full fiscal years of operation following completion of the project. In Form F.2b, the applicant projects that revenues will exceed operating expenses for the cardiac catheterization services at Duke University Hospital during the first three full fiscal years following completion of the project, as shown in the table below.

| Duke University Hospital Cardiac Catheterization | | | |
|---|---|---|---|
| | 1st Full Fiscal Year FY2027 | 2nd Full Fiscal Year FY2028 | 3rd Full Fiscal Year FY2029 |
| Diagnostic Equivalent Procedures | 9,165 | 9,403 | 9,649 |
| Total Gross Revenues (Charges) | \$315,547,671 | \$324,590,945 | \$333,863,452 |
| Total Net Revenue | \$88,536,202 | \$92,565,659 | \$96,775,169 |
| Average Net Revenue per Procedure | \$27,824 | \$28,801 | \$29,814 |
| Total Operating Expenses (Costs) | \$54,646,654 | \$57,190,800 | \$60,088,805 |
| Average Operating Expense per Procedure | \$17,174 | \$17,794 | \$18,512 |
| Net Income | \$33,889,549 | \$35,374,858 | \$36,686,364 |

Source: Section Q, Form F.2b

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q. The applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on 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 because the applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of revenues and operating expenses for all the reasons described above.

- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

The applicant proposes to acquire no more than one unit of fixed cardiac catheterization equipment pursuant to Policy AC-3 by converting existing angiography equipment.

On page 302, the 2025 SMFP defines the service area for cardiac catheterization equipment service areas as “...the Acute Care Bed Service Areas defined in Chapter 5 and shown in Figure 5.1.” Figure 5.1, on page 38, shows Durham County as a multicounty service area. Therefore, the service area for the fixed cardiac catheterization equipment is Durham, Caswell, and Warren Counties. Facilities may also serve residents of counties not included in their service area.

According to Table 15A-1 in Chapter 15, page 305 of the 2025 SMFP, there are two facilities with a total of nine units of fixed cardiac catheterization equipment in Durham, Caswell, and Warren Counties. Information about the facilities and equipment is shown in the table below.

| Fixed Cardiac Catheterization Equipment Inventory Durham, Caswell, and Warren Counties | | |
|---|----------------|--------------------------------------|
| Facility | # Units | Total Weighted Procedures |
| Duke University Hospital | 7 | 5,978 |
| Duke Regional Hospital | 2 | 1,350 |

In Section G, page 63, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved cardiac catheterization services in Durham, Caswell, and Warren Counties. The applicant states:

“ ...this project is needed to support the academic mission of Duke University Hospital. Accommodating research and other academic activities at Duke Regional Hospital would require duplication of resources necessary to support them...This project will also not unnecessarily duplicate capacity at any other facilities in the broader region from which DUH draws patients. As described in Section B, this project is necessary to accommodate existing clinical volumes and projected academic activities. These activities cannot readily be shifted to another facility, especially any facility at any distance from academic medical center.”

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area because the applicant adequately demonstrated that the proposed cardiac catheterization is needed to support the academic activities of Duke University Hospital.

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 acquire no more than one unit of fixed cardiac catheterization equipment pursuant to Policy AC-3 by converting existing angiography equipment.

| Duke University Hospital Cardiac Catheterization Labs Projected FTE Staffing | | |
|---|---------------------------|--|
| Position | Current FTE Staff | Projected FTE Staff |
| | 7/1/2024-6/30/2025 | 1st Full Fiscal Year 7/1/2026 - 6/30/2027 |
| Registered Nurses | 30.95 | 33.83 |
| Business Office | 0.93 | 0.93 |
| Other: Nurse Manager | 1.32 | 1.37 |
| Other: Radiation Physicist | 0.70 | 0.70 |
| Other: Cardiovascular Inv. Specialist | 16.40 | 17.98 |
| Other Physician Assistants | 0.49 | 0.49 |
| TOTAL | 50.79 | 55.30 |

The assumptions and methodology used to project staffing are provided in Section Q. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in Form F.3b. In Section H, pages 65-67 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 is an existing provider of fixed cardiac catheterization services which already employs staff necessary to offer fixed cardiac catheterization services.
- The applicant anticipates no difficulty recruiting additional technical staff needed for the additional cardiac catheterization equipment.
- The applicant is part of an established healthcare system in Durham, Caswell, and Warren Counties located in a growing area of the state.

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 acquire no more than one unit of fixed cardiac catheterization equipment pursuant to Policy AC-3 by converting existing angiography equipment.

Ancillary and Support Services

In Section I, page 68, the applicant states Duke University Hospitals currently provides all of the ancillary and support services necessary for the proposed cardiac catheterization services. currently identifies the necessary ancillary and support services for the proposed services.

In Section I, the applicant states that the expenses for all necessary ancillary and support services related to this service line are included in Form H staffing and Form F.3 operating costs.

Coordination

In Section I, page 69, the applicant states that Duke University Hospital is an Academic Medical Center Teaching Hospital that serves as a primary teaching location for medical students, residents, fellows, nurses, and other health care professionals. The applicant describes its existing and proposed relationships with other local health care and social service providers. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the following:

- The applicant is an existing provider with established relationships with healthcare and social services providers in the service area.
- The applicant states that this proposed project is designed to enhance Duke's ability to fulfill its academic mission.
- The applicant states that with its own nursing and medical student and graduate medical attention education training activities, Duke University Hospital also provides training opportunities for students in the area, including students from UNC, Wake Tech, and other local training programs.

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

- (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 proposes to acquire no more than one unit of fixed cardiac catheterization equipment pursuant to Policy AC-3 by converting existing angiography equipment. In Section K, page 71, the applicant states that the project does not involve any construction or renovation. 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

In Section L, page 74, the applicant provides the historical payor mix during FY 2025 for the Duke University Hospital, as shown in the table below.

| Duke University Hospital 07/01/2024 to 6/20/2025 | |
|---|--|
| Payor Source | Percentage of Total Patients Served |
| Self-Pay | 0.7% |
| Charity Care | 2.3% |
| Medicare* | 39.7% |
| Medicaid* | 12.8% |
| Insurance* | 40.8% |
| Workers Compensation | 0.1% |
| TRICARE/Champus | 0.7% |
| Other (all other payors) | 2.9% |
| Total | 100.00% |

*Including any managed care plans
Source: Section L, page 74

In Section L, page 75, the applicant provides the following comparison.

| Duke University Hospital | % of Total Patients Served During Last Full FY | % of the Population of the service area* |
|-------------------------------------|--|--|
| Female | 59.8% | 52.0% |
| Male | 40.3% | 48.0% |
| 64 and Younger | 62.4% | 84.9% |
| 65 and Older | 37.6% | 15.1% |
| American Indian | 0.7% | 1.2% |
| Asian | 3.4% | 6.1% |
| Black or African-American | 25.8% | 34.5% |
| Native Hawaiian or Pacific Islander | 0.1% | 0.2% |
| White or Caucasian | 61.7% | 55.2% |
| Other Race | 3.0% | |
| Declined/Unavailable | 5.5% | |

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the applicant adequately documents the extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved. Therefore, the application is conforming to this criterion.

- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and ... persons [with disabilities] to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, pages 75-76, the applicant states it does not have an obligation. The applicant states,

“DUHS has no obligation under federal regulations to provide uncompensated care or community service, or access by minorities and handicapped persons.”

In Section L, page 76, 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 or any similar facilities owned by the applicant or a related entity located in North Carolina.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (c) That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services; and

C

In Section L, page 77, 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.

| Duke University Hospital Projected Payor Mix Cardiac Catheterization Services – SFY 2029 | |
|---|----------------------------------|
| Payor Source | % of Total Patient Served |
| Self-Pay/Charity | 0.2% |
| Charity Care | 1.0% |
| Medicare* | 53.7% |
| Medicaid* | 12.5% |
| Insurance* | 25.5% |
| Workers Compensation | 0 |
| TRICARE/Champus | 1.2% |
| Other | 6.0% |
| Total | 100.0% |

Source: Table on page 77 of the application

*Including any managed care plans

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 0.2% of total cardiac catheterization services will be provided to self-pay patients, 53.7% to Medicare patients, and 12.5% to Medicaid patients.

On page 77, the applicant provides the assumptions and methodology used to project payor mix during the third full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported based on the applicant's historical experience.

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 the reasons stated above.

- (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, page 79, the applicant adequately describes the range of means by which patients will have access to the proposed services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

The applicant proposes to acquire no more than one unit of fixed cardiac catheterization equipment pursuant to Policy AC-3 by converting existing angiography equipment.

In Section M, page 94, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes. The applicant states,

“Duke University Hospital is an Academic Medical Center Teaching Hospital that serves as a primary teaching location for medical students, residents, fellows, nurses, and other health care professionals. Trainees are involved in every aspect of care at the hospital. This project will enhance Duke’s ability to fulfill its educational mission.”

The applicant adequately demonstrates that health professional training programs in the area have access to the facility for training purposes based on the reasons stated 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 acquire no more than one unit of fixed cardiac catheterization equipment pursuant to Policy AC-3 by converting existing angiography equipment.

On page 302, the 2025 SMFP defines the service area for cardiac catheterization equipment service areas as “...*the Acute Care Bed Service Areas defined in Chapter 5 and shown in Figure 5.1.*” Figure 5.1, on page 38, shows Durham County as a multicounty service area. Therefore, the service area for the fixed cardiac catheterization equipment is Durham, Caswell, and Warren Counties. Facilities may also serve residents of counties not included in their service area.

According to Table 15A-1 in Chapter 15, page 305 of the 2025 SMFP, there are two facilities with a total of nine units of fixed cardiac catheterization equipment in Durham, Caswell, and Warren Counties. Information about the facilities and equipment is shown in the table below.

| Fixed Cardiac Catheterization Equipment Inventory Durham, Caswell, and Warren Counties | | |
|---|----------------|--------------------------------------|
| Facility | # Units | Total Weighted Procedures |
| Duke University Hospital | 7 | 5,978 |
| Duke Regional Hospital | 2 | 1,350 |

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 81, the applicant states:

This project will provide DUH greater flexibility in meeting the needs of its patients, which may make care more efficient and expand access to more patients. ...In addition, this project will enable DUH to continue to recruit and retain the most qualified cardiologists and cardiovascular surgeons...This will enhance patient choice.”

Regarding the impact of the proposal on cost effectiveness, in Section N, page 81, the applicant states:

“This project will not directly affect the charges or reimbursement for services for patients or payors for the proposed services because reimbursement rates are set by the federal government and commercial insurers. However, by increasing capacity and flexibility, this project may allow patients to access and initiate their care more quickly, saving costs and improving patient experience.”

See also Sections C, F, and Q of the application and any exhibits.

Regarding the impact of the proposal on quality, in Section N, pages 81-82, the applicant states:

“DUHS is committed to delivering high-quality care at all of its facilities and will continue to maintain the highest standards and quality of care, consistent with the standards that DUHS has sustained throughout its quality management programs emphasize a customer -orientated perspective that is used to determine the needs of patients, physicians, and other who utilize hospital services.”

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

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 82, the applicant states:

“Duke University Hospital’s current capacity constraints limit practical access for patients, including the medically underserved.”

See also Section Cand L 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 and the applicant's record of providing quality care in the past.
- 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 proposes to acquire no more than one unit of fixed cardiac catheterization equipment pursuant to Policy AC-3 by converting existing angiography equipment.

In Section O. page 83, the applicant identifies the 11 health care facilities located in North Carolina owned, operated or managed by the DUHS or a related entity.

In Section O, pages 84-85, the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents related to quality of care occurred in two DUHS facilities; Maria Parham Hospital and Wilson Medical Center. In Section O.5b, pages 84-85, the applicant states the problems have been corrected and both facilities have returned to full compliance. 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 DUHS facilities, the applicant provided sufficient evidence that quality care has been provided in 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 acquire cardiac catheterization equipment pursuant to Policy AC-3, and not pursuant to a need determination in the 2025 SMFP. Therefore, the Criteria and Standards for Cardiac Catheterization Equipment and Cardiac Angioplasty Equipment promulgated in 10A NCAC 14C .1600 are not applicable to this review.