

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: May 22, 2020

Findings Date: May 22, 2020

Project Analyst: Gregory F. Yakaboski

Team Leader: Gloria C. Hale

Project ID #: B-11861-20

Facility: Margaret R. Pardee Memorial Hospital

FID #: 943324

County: Henderson

Applicant: Henderson County Hospital Corporation

Project: Acquire one unit of shared cardiac catheterization equipment pursuant to the adjusted need determination in the 2020 SMFP

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

N.C. Gen. Stat. §131E-183(a) The Agency 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

Henderson County Hospital Corporation (“the applicant”) proposes to add one shared cardiac catheterization unit on the campus of Margaret R. Pardee Memorial Hospital (“Pardee”), pursuant to the need determination in the 2020 State Medical Facilities Plan (2020 SMFP). Pardee Hospital currently offers cardiac catheterization and angiography services on a stationary mobile cardiac catheterization unit owned by DLP Cardiac Partners (DLP unit) pursuant to a time-limited contractual service agreement.

Need Determination

The 2020 SMFP includes a Need Determination for one unit of shared fixed cardiac catheterization equipment in the Henderson County cardiac catheterization service area.

Henderson County Hospital Corporation does not propose to develop more units of shared fixed cardiac catheterization equipment than are determined to be needed in the 2020 SMFP for the Henderson County cardiac catheterization service area. Therefore, the application is consistent with the need determination.

Policies

There are two policies in the 2020 SMFP applicable to this review: *Policy GEN-3: Basic Principles*, and *Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities*.

Policy GEN-3, on pages 30-31 of the 2020 SMFP, states:

“A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area.”

Promote Safety and Quality - The applicant describes how it believes the proposed project would promote safety and quality in Section B, pages 21-23; Section N, pages 86-89; Section O, pages 90-93 and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote safety and quality.

Promote Equitable Access - The applicant describes how it believes the proposed project would promote equitable access in Section B, page 23; Section C, pages 43-44; Section L, pages 81-84; Section N, pages 88-89 and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote equitable access.

Maximize Healthcare Value - The applicant describes how it believes the proposed project would maximize health care value in Section B, pages 23-24; Section F, pages 61-66; Section K, pages 77-78, Section N, page 86; the applicant’s pro forma financial statements in Section Q and referenced exhibits.

The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal will maximize health care value and that the applicant’s projected volumes incorporate the concepts of quality, equitable access and maximum value for resources expended in meeting the need identified in the 2020 SMFP. Therefore, the application is consistent with policy GEN-3.

Policy GEN-4, on page 31 of the 2020 SMFP, states:

“Any person proposing a capital expenditure greater than \$2 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178 shall include in its certificate of need application a written statement describing the project’s plan to assure improved energy efficiency and water conservation.

In approving a certificate of need proposing an expenditure greater than \$5 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178, Certificate of Need shall impose a condition requiring the applicant to develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. The plan must be consistent with the applicant’s representation in the written statement as described in paragraph one of Policy GEN-4.

Any person awarded a certificate of need for a project or an exemption from review pursuant to G.S. 131E-184 is required to submit a plan for energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation. The plan must be consistent with the applicant’s representation in the written statement as described in paragraph one of Policy GEN-4. The plan shall not adversely affect patient or resident health, safety or infection control.”

The proposed capital expenditure for this project is greater than \$5 million. In Section B, pages 24-25, the applicant describes the project’s plan to improve energy efficiency and conserve water. The applicant adequately demonstrates that the application includes a written statement describing the project’s plan to assure improved energy efficiency and water conservation.

Conclusion

The Agency reviewed the:

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

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

- The applicant does not propose to acquire more shared fixed cardiac catheterization units than are determined to be needed in the 2020 SMFP for the service area.
- The applicant adequately demonstrates that the proposal is consistent with Policy GEN-3 and Policy GEN-4 based on the following:

- The applicant adequately documents how the project will promote safety and quality in the delivery of cardiac catheterization services in Henderson County;
- The applicant adequately documents how the project will promote equitable access to cardiac catheterization services in Henderson County; and
- The applicant adequately documents how the project will maximize healthcare value for the resources expended.
- The applicant adequately demonstrates that the application includes a written statement describing the project’s plan to assure improved energy efficiency and water conservation.

(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, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C

The applicant proposes to add one shared fixed cardiac catheterization unit on the campus of Margaret R. Pardee Memorial Hospital pursuant to the need determination in the 2020 SMFP.

Patient Origin

On page 390, the 2020 SMFP defines the service area for cardiac catheterization equipment as “...the Acute Care Bed Service Areas defined in Chapter 5, Acute Care Beds, and shown in Figure 5.1.” Figure 5-1 on page 38 of the 2020 SMFP shows Henderson County as a single county acute care bed service area. Pardee is in Henderson County. Thus, the service area for this proposal is Henderson County. Facilities may also serve residents of counties not included in their service area.

The following table illustrates current and projected patient origin.

County	Current (7/1/2018 to 6/30/2019)		Third Full FY of Operation following Project Completion (7/1/2025 to 6/30/2026)	
	Patients	% of Total	Patients	% of Total
Henderson	317	81.7%	978	86.8%
Polk	25	6.4%	52	4.6%
Transylvania	11	2.8%	23	2.0%
Buncombe	9	2.3%	19	1.7%
Other*	26	6.8%	55	4.9%
Total	388	100.0%	1,126	100.0%

Source: Section C.2, pages 31-32.

*Other includes Gaston, Jackson, Martin, Mitchell, Randolph and Rutherford counties in North Carolina, as well as other states.

In Section C, page 32, 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 Pardee's historical patient origin for cardiac catheterization patients adjusted for an expected shift of patients that have historically left Henderson County for care.

Analysis of Need

In Section C, pages 33-39, the applicant explains why it believes the population projected to utilize the shared fixed cardiac catheterization unit needs the proposed services, including:

- The need determination in the 2020 SFMP for a shared fixed cardiac catheterization unit in the Henderson County cardiac catheterization service area (page 33).
- Constraints associated with the current stationary mobile DLP unit including contractual uncertainty regarding the DLP unit impacting Pardee's ability to guarantee continual access to cardiac catheterization equipment to its patient base, Pardee's lack of ownership of a cardiac catheterization unit creates additional uncertainty that hinders recruitment of interventional cardiologists and development of an elective cardiac catheterization program. (pages 34-35).
- Historical utilization of the DLP unit at Pardee has grown at a compound annual growth rate (CAGR) of 22.6% over the last three years and without its own equipment Pardee will struggle to meet this growing need. (pages 35-36).
- Henderson County demographics demonstrate that the population of Henderson County is projected to grow by 1.0% in the next ten years and the 65+ age cohort is expected to reach 30.3% of Henderson County's overall population in the year 2030, up from 27.4% in 2020. (pages 36-37).
- Need for full-time ST-elevation myocardial infarction (STEMI) program and elective cardiac catheterization coverage in the Henderson County and surrounding area supported by providing permanent, locally-owned cardiac catheterization and angiography capacity (pages 37-38).
- Pardee's need for permanent cardiac catheterization equipment capacity is based on the needs of its patient census and the ability to expand access to cardiac catheterization equipment and services. (pages 38-39).

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

- The applicant's need is based, in part, on its historical experience providing cardiac catheterization services utilizing the leased DLP unit.
- The applicant provides information regarding current and projected population for Henderson County from the North Carolina Office of State Budget and Management (NCOSBM).
- The need determination in the 2020 SMFP was an adjusted need determination approved by the State Health Coordinating Council based on a petition for one additional unit of shared fixed cardiac catheterization equipment in Henderson County.

Projected Utilization

In Section Q, Form C, the applicant provides historical and projected utilization, as illustrated in the following tables.

	Prior (SFY19)	Interim* (SFY20)	Interim (SFY21)	Interim (SFY22)	Interim (SFY23)	OY1 (SFY24)	OY2 (SFY25)	OY3 (SFY26)
Shared Fixed Cardiac Cath Unit								
# of Units	0	0	0	0	1	1	1	1
# of Procedures	0	0	0	0	143	950	1,033	1,126
DLP Unit								
# of Units	1	1	1	1	1			
# of Procedures	388	405	460	517	439	0	0	0
Total Procedures	388	405	460	517	582	950	1,033	1,126

*2020 is annualized based on five months of actual data.

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

Assumptions

- Pardee uses the State Fiscal Year (SFY) which is July 1st to June 30th.
- The first full Operating Year (OY) 1 for this project is July 1, 2023 to June 30, 2024 and OY3 is July 1, 2025 to June 30, 2026.
- The applicant projects the shared fixed cardiac catheterization unit to be operational as of April 1, 2023.
- The applicant, in conjunction with this application, intends to expand its STEMI program to be available 24/7.
- EMS delivers STEMI patients to the nearest percutaneous coronary intervention (PCI) Center. Pardee will be seeking EMS recognition as a PCI Center. The effect will be that EMS will be able to deliver STEMI patients to Pardee when Pardee is closer for them than Mission Hospital. Historically Henderson County residents, even though Mission Hospital is further away from most, if not all such residents, have travelled to Mission Hospital for cardiac catheterization services.
- Owning a shared fixed cardiac catheterization unit, thus assuring a permanent program, will allow Pardee to recruit additional interventional cardiologists and expand its STEMI program to a full-time basis. Further, this will permit Pardee to develop an elective cardiac catheterization program.
- Pardee currently contracts for a stationary mobile cardiac catheterization unit referred to as the DLP Unit. For contractual timing reasons the applicant expects to have the DLP unit under contract for a period of time located in its current location at Pardee. However, the

DLP unit will be used only for emergency back up and any procedures performed will not be included in projected utilization.

- Pardee also provides a detailed summary of historical utilization of all cardiac catheterization and angiography procedures.

Methodology

Historical Utilization: Pardee Cardiac Catheterization and Angiography

	SFY2017	SFY2018	SFY2019	SFY2020*	CAGR
Diagnostic	164	192	216	209	8.4%
Interventional	29	108	60	58	25.7%
EP/Angiography	27	119	112	139	72.7%
Scheduled Procedures	206	400	385	401	24.9%
Total	220	419	388	405	22.6%
Interventional (Therapeutic) as a % of Total	13.2%	25.8%	15.5%	14.2%	
Diagnostic as a % of Total	74.5%	45.8%	55.7%	51.5%	

Source: Pardee Internal Data

*2020 is annualized based on five months of actual data.

Growth of Pardee’s Scheduled Cardiac Catheterization and Angiography Procedures

- As shown in the table above, scheduled cardiac catheterization and angiography procedures historically have grown at a CAGR of 24.9% from SFY2017 through SFY2020 annualized.
- The applicant conservatively projects growth from SFY2021 to SFY2026 (OY3) based on 12.5% which is approximately half of the historical growth rate.

Projected Henderson County Residents Shift of Scheduled Cardiac Catheterization and Angiography Procedures from Mission Hospital to Pardee

- The applicant projected the number of cardiac catheterization and angiography procedures performed on Henderson County residents through OY3 (SFY2026) utilizing historic data of the number of Henderson County residents who received cardiac catheterization or angiography procedures at Mission Hospital utilizing a 0.9% growth rate. Pardee then subtracted procedures from EMS STEMI transport to Mission Hospital.
- Pardee then assumed a 50% shift of Henderson County residents projected to utilize Mission Hospital for scheduled cardiac catheterization and angiography procedures to Pardee.

	SFY2023*	SFY2024	SFY2025	SFY2026
Pardee Scheduled Procedures Only	143	642	722	812
Assumed Shift from Mission Hospital to Pardee (scheduled procedures only)	0	308	311	314
Total Procedures on Proposed Equipment	143	950	1,033	1,126
Interventional (Therapeutic) Procedures as a % of Total	13.2%	25.8%	15.5%	14.2%
Interventional (Therapeutic) Procedures Only			147	160
Interventional Procedures x 1.75 = Diagnostic Equivalent**			257	280
Diagnostic Procedures as a % of Total	74.5%	45.8%	55.7%	51.5%
Diagnostic Procedures Only			532	580

*SFY2023 represents only one quarter of projected procedures; cardiac catheterization unit to become operational on April 1, 2023.

**2020 SMFP, page 390, Cardiac Catheterization Equipment, Assumptions of the Methodology, #2 states "One interventional cardiac catheterization procedure is valued at 1.75 diagnostic-equivalent procedures."

As demonstrated in the table above, the proposed project exceeds the applicable performance standard as follows:

- Rule 10A NCAC 14C .1603(d)(1): a combined total of at least 225 cardiac catheterization and angiography procedures during the fourth quarter of the third year following completion of the project. The applicant projects to perform 1,126 cardiac catheterization and angiography procedures in OY3 (SFY2026) and assumes quarterly utilization will be consistent throughout the operating years. Therefore, the applicant expects to perform 282 cardiac catheterization and angiography procedures during the fourth quarter of its third operating year ($1,126/4 = 281.5$).

Projected utilization is reasonable and adequately supported based on the following reasons.

- There is a need determination in the 2020 SMFP for a shared fixed cardiac catheterization unit in Henderson County.
- The applicant bases its projected utilization on historical data and conservative, reasonable growth rates.
- Projected utilization exceeds the applicable all performance standard in 10A NCAC 14C .1603.
- Expansion of the Pardee cardiac catheterization program is expected with respect to EMS STEMI transport, recruitment of interventional cardiologists, projected recognition as a PCI center and expansion of its elective cardiac catheterization program.
- Projected utilization conservatively did not include EMS STEMI Transport cardiac catheterization procedures if Pardee becomes recognized by EMS as a PCI Center.

Access

In Section C, pages 43-44, the applicant states,

"Pardee Imaging is committed to providing care to anyone in need and does not deny access to non-elective care because of 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 Pardee's cardiac catheterization and angiography services as they do currently with the existing services provided since 2002."

In Section L, page 83, the applicant projects the following payor mix during the third full fiscal year of operation following completion of the project, as illustrated in the following table.

Payor Category	Shared Cardiac Catheterization Services as Percent of Total
Self-Pay	5.4%
Medicare*	73.5%
Medicaid*	4.4%
Insurance*	15.2%
Other (Specify)	1.5%
Total	100.0%

Source: Table on page 83 of the application.

*Including any managed care plans.

Note: Other includes Workers Compensation and TRICARE.

The projected payor mix is reasonable and adequately supported.

Conclusion

The Agency reviewed the:

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

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

- The applicant adequately identifies the population to be served.
- The applicant adequately explains why the population to be served needs the services proposed in this application.
- Projected utilization is reasonable and adequately supported.
- The applicant projects the extent to which all residents, including underserved groups, will have access to the proposed services (payor mix) and adequately supports its assumptions.

- (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, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

NA

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

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

CA

The applicant proposes to add one shared fixed cardiac catheterization unit on the campus of Margaret R. Pardee Memorial Hospital pursuant to the need determination in the 2020 SMFP.

In Section E, pages 59-60, 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 this option would not ensure long term access to cardiac catheterization and angiography services in the service area and not meet the need within the proposed service area for improved access to cardiac catheterization services. Therefore, this is not an effective alternative.
- Construct New Space for the Proposed Equipment- The applicant states this option would increase the capital cost of the proposed project and could create operational inefficiencies. Therefore, this is not the least costly or most effective alternative.
- Terminate the Contractual Agreement for the DLP Unit at the earliest possible date- The applicant states that this option would leave the residents of the service area without access to this vital, life-saving service as the earliest termination date is prior to the proposed completion date of the project. Therefore, this is not an effective alternative.

On page 60, the applicant states that its proposal is the most effective alternative because it assures continuous, permanent access for the residents of Henderson County to cardiac catheterization services as well as back-up for emergencies during the life of the DLP unit contractual agreement.

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

- The application is conforming to all statutory and regulatory review criteria.
- The applicant provides credible 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. Henderson County Hospital Corporation shall materially comply with all representations made in the certificate of need application.**
- 2. Henderson County Hospital Corporation shall acquire one unit of shared cardiac catheterization equipment pursuant to the need determination in the 2020 SMFP.**
- 3. Henderson County Hospital Corporation as part of this project, shall not acquire any equipment that is not included in the project's proposed capital expenditures in Section Q, Form F.1a of the application and that would otherwise require a certificate of need.**
- 4. Henderson County Hospital Corporation shall cease operation of the stationary mobile cardiac catheterization unit owned by DLP Cardiac Partners within 90 days of operation of the one unit of shared fixed cardiac catheterization equipment.**
- 5. Henderson County Hospital Corporation shall develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes.**
- 6. No later than three months after the last day of each of the first three full years of operation following initiation of the services authorized by this certificate of need, Henderson County Hospital Corporation shall submit, on the form provided by the Healthcare Planning and Certificate of Need Section, an annual report containing the:**
 - a. Payor mix for the services authorized in this certificate of need.**
 - b. Utilization of the services authorized in this certificate of need.**
 - c. Revenues and operating costs for the services authorized in this certificate of need.**
 - d. Average gross revenue per unit of service.**
 - e. Average net revenue per unit of service.**
 - f. Average operating cost per unit of service.**

7. Henderson County Hospital Corporation 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 add one shared fixed cardiac catheterization unit on the campus of Margaret R. Pardee Memorial Hospital pursuant to the need determination in the 2020 SMFP.

Capital and Working Capital Costs

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

Site Costs	\$0
Construction Costs	\$1,343,173
Miscellaneous Costs	\$3,789,527
Total	\$5,132,700

In Section Q, the applicant provides the assumptions used to project the capital cost.

Pardee is an existing operational facility. In Section F, page 63, the applicant states that the proposed project does not involve either start-up or initial operating expenses.

Availability of Funds

In Section F, page 61, the applicant states that the capital cost will be funded, as shown in the table below.

Type	Pardee	Total
Loans	\$0	\$0
Accumulated reserves or OE* of Pardee	\$5,132,700	\$5,132,700
Bonds	\$0	\$0
Other	\$0	\$0
Total Financing	\$5,132,700	\$5,132,700

* OE = Owner's Equity

Exhibit F.2-1 contains a copy of a letter dated February 17, 2020 from the Chief Financial Officer of Pardee UNC Health Care which states that *“As the Chief Financial Officer, I am responsible for the financial operations of Pardee. ... The total capital expenditure for this*

project is estimated to be \$5,132,700. ... Pardee will fund the capital cost from existing accumulated reserves.”

Exhibit F.2-2 also contains a copy of Pardee’s audited financial statements showing cash and cash equivalents of \$16.2 million and net total assets of \$117.6 million as of June 30, 2019. Therefore, the applicant demonstrated adequate availability of funds.

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.2, the applicant projects that revenues will exceed operating expenses in the first three operating years of the project, as shown in the table below.

	1st FFY SFY2024 (7/1/23 to 6/30/24)	2nd FFY SFY2025 (7/1/24 to 6/30/25)	3rd FFY SFY2026 (7/1/25 to 6/30/26)
Total Procedures	950	1,033	1,126
Total Gross Revenues (Charges)	\$23,734,734	\$26,482,491	\$29,625,878
Total Net Revenue	\$6,306,945	\$7,037,096	\$7,872,377
Average Net Revenue per Procedure	\$6,639	\$6,812	\$6,991
Total Operating Expenses (Costs)	\$5,814,017	\$6,644,635	\$7,137,214
Average Operating Expense per Procedure	\$6,120	\$6,432	\$6,338
Net Income	\$492,928	\$392,461	\$735,163

Note: In Section Q, the applicant states that the financial statements in Form F.2 and F.3 conservatively assume that the DLP unit remains in effect during the first three project years. As such, the financial statements include revenue for the emergency back-up procedures to be performed on the DLP unit (75, 77 and 79 in OY1-3 respectively) as well as the costs of the DLP service agreement. The project analyst notes that the projected emergency back-up procedures are not included in the Total Procedures.

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section Q of the application for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) 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 based on the following:

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions.

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

C

The applicant proposes to add one shared fixed cardiac catheterization unit on the campus of Margaret R. Pardee Memorial Hospital pursuant to the need determination in the 2020 SMFP.

On page 390, the 2020 SMFP defines the service area for cardiac catheterization equipment as “...the Acute Care Bed Service Areas defined in Chapter 5, Acute Care Beds, and shown in Figure 5.1.” Figure 5-1 on page 38 of the 2020 SMFP shows Henderson County as a single county acute care bed service area. Pardee is in Henderson County. Thus, the service area for this proposal is Henderson County. Facilities may also serve residents of counties not included in their service area.

In Section G, page 68, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved cardiac catheterization services in Henderson County. The applicant states:

“Pardee is the only existing provider of cardiac catheterization services in Henderson County, which is the service area for the proposed project.”

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

- There is a need determination in the 2020 SMFP for the proposed shared fixed cardiac catheterization equipment.
- The applicant adequately demonstrates that the proposed shared fixed cardiac catheterization equipment is needed in addition to the existing or approved cardiac catheterization equipment.
- The applicant will renew the contract for the existing DLP unit to enable Pardee to provide cardiac catheterization procedures until the proposed project is operational.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

- Information which was publicly available during the review and used by the Agency

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

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

C

In Section Q, Form H, the applicant provides the projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

Position	Projected FTE Staff		
	1 st Full Fiscal Year (7/1/23 to 6/30/24)	2 nd Full Fiscal Year (7/1/24 to 6/30/25)	3 rd Full Fiscal Year (7/1/25 to 6/30/26)
Registered Nurses	2.4	3.2	3.2
Other (Nurse Manager)	1.0	1.0	1.0
Other (Procedural Techs)	3.2	4.2	4.2
TOTAL	6.6	8.4	8.4

The assumptions and methodology used to project staffing are provided in Section Q, Form H. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.3, which is found in Section Q. In Section H.2 and H.3, pages 70-71, the applicant describes the methods to be used to recruit or fill new positions and its proposed training and continuing education programs. In Section I, page 75, the applicant identifies the current medical director. In Exhibit I.3, the applicant provides a letter from the medical director indicating an interest in continuing to serve as medical director for the proposed services.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide 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 for the reasons stated above.

- (8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support

services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

C

In Section I, page 72, the applicant states that the following ancillary and support services are necessary for the proposed services:

- Radiology
- Dietary
- Housekeeping
- Maintenance
- Administration
- Pharmacy
- Laboratory

On page 72, the applicant adequately explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibit I.1.

In Section I, pages 72-74, 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.

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.

- (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. Therefore, Criterion (9) is not applicable to this review.

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:
- (i) would be available under a contract of at least 5 years duration;
 - (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
 - (iii) would cost no more than if the services were provided by the HMO; and
 - (iv) would be available in a manner which is administratively feasible to the HMO.

NA

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

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

C

In Section K, page 77, the applicant states that the project involves renovating 1,089 square feet of existing space. Line drawings are provided in Exhibit C.1-1.

On page 77, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal.

On page 78, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services.

In Section B, pages 24-25 and in Section K, page 78, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

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.

- (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 handicapped persons, 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 82, the applicant provides the historical payor mix during the last full fiscal year (7/01/2018 to 6/30/2019) for the proposed services, as shown in the table below.

Payor Category	Shared Cardiac Catheterization Services as Percent of Total
Self-Pay	5.4%
Medicare*	73.5%
Medicaid*	4.4%
Insurance*	15.2%
Other (Specify)	1.5%
Total	100.0%

Source: Table on page 83 of the application.

*Including any managed care plans.

Note: Other includes Workers Compensation and TRICARE.

In Section L, page 81, the applicant provides the following comparison.

	Percentage of Total Patients Served by the Facility or Campus during the Last Full FY	Percentage of the Population of the Service Area
Female	61.6%	52.0%
Male	38.4%	48.0%
Unknown	0.0%	0.0%
64 and Younger	44.4%	74.2%
65 and Older	55.6%	25.8%
American Indian	0.2%	0.7%
Asian	0.2%	1.3%
Black or African-American	3.1%	3.4%
Native Hawaiian or Pacific Islander	0.0%	0.2%
White or Caucasian	88.2%	92.5%
Another Race	2.2%	1.9%
Declined / Unavailable	6.0%	0.0%

The Agency reviewed the:

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

Based on that review, the Agency concludes that the 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 handicapped persons 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 it is not obligated under any applicable federal regulations to provide uncompensated care, community service, or access by minorities and handicapped persons.

In Section L, page 83, the applicant states that during the last five years no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina.

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.

Payor Category	Shared Cardiac Catheterization Services as Percent of Total
Self-Pay	5.4%
Medicare*	73.5%
Medicaid*	4.4%
Insurance*	15.2%
Other (Specify)	1.5%
Total	100.0%

Source: Table on page 83 of the application.

*Including any managed care plans.

Note: Other includes Workers Compensation and TRICARE.

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 5.4% of total services will be provided to self-pay patients, 73.5% to Medicare patients and 4.4% to Medicaid patients.

On page 83, 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 historical 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 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.5, page 84, 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

In Section M, page 85, the applicant describes the extent to which health professional training programs in the area will have access to the facility for training purposes and provides supporting documentation in Exhibit M.1.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the applicant adequately demonstrates that the proposed services will accommodate the clinical needs of area health professional training programs, and therefore, the application is conforming to this criterion.

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

C

The applicant proposes to add one shared fixed cardiac catheterization unit on the campus of Margaret R. Pardee Memorial Hospital pursuant to the need determination in the 2020 SMFP.

On page 390, the 2020 SMFP defines the service area for cardiac catheterization equipment as “...the Acute Care Bed Service Areas defined in Chapter 5, Acute Care Beds, and shown in Figure 5.1.” Figure 5-1 on page 38 of the 2020 SMFP shows Henderson County as a single county acute care bed service area. Pardee is in Henderson County. Thus, the service area for this proposal is Henderson County. Facilities may also serve residents of counties not include in their service area.

In Section G, page 68, the applicant states:

“Pardee is the only existing provider of cardiac catheterization services in Henderson County, which is the service area for the proposed project.”

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 86, the applicant states:

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

Regarding the impact of the proposal on cost effectiveness, in Section N, page 86, the applicant states:

“Pardee has reduced expenses by utilizing existing space and avoiding new construction and thus has proposed the most value-conscious alternative for the installation of the proposed equipment.”

Regarding the impact of the proposal on quality, in Section N, page 88, the applicant states:

“Acquisition of the proposed shared fixed cardiac catheterization equipment will enhance the level of quality and safety for the service as it will provide permanent, locally-owned equipment to serve patients in Henderson County and the surrounding area, including areas where no cardiac catheterization capacity exists. It also will allow Pardee to provide a stable, ongoing program, which will enable it to retain and recruit additional interventional cardiologists and expand from a part-time STEMI program to a full-time STEMI and elective PCI program, which in turn will enhance the level of quality and safety for the service.”

Regarding the impact of the proposal on access by medically underserved groups, in Section N, pages 88-89, the applicant states:

“Pardee historically has demonstrated a commitment to ensuring equitable access to all persons in need of medical care, regardless of race, sex, creed, age, national origin, handicap, or ability to pay and will continue to provide such access upon completion of the

proposed project. ... Acquisition of the proposed shared fixed cardiac catheterization equipment will promote equitable access to cardiac catheterization services... Without the proposed acquisition, patients are not likely to have adequate or equitable access to these services in Henderson County and the surrounding area.”

Considering all the information in the application, 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 (see Sections C, F, N and Q of the application and any exhibits)
- Quality (see Sections C, N and O of the application and any exhibits)
- Access to medically underserved groups (see Sections C, L and N of the application and any exhibits)

Conclusion

The Agency reviewed the:

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

Based on that review, the Agency concludes that the application is conforming to this criterion based on the reasons stated 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 Q, Form A, the applicant identifies the hospital located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of one of this type of facility located in North Carolina.

In Section O, page 93, the applicant states that, during the 18 months immediately preceding the submittal of the application, no incidents related to quality of care occurred in this facility. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, during the 18 months immediately preceding submission of the application through the date of this decision no incidents related to quality of care occurred in Margaret R. Pardee Memorial Hospital. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure and Certification Section, DHSR and considering the quality of care provided at Margaret R. Pardee Memorial Hospital, the applicant provided sufficient

evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.
- (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.

C

The Criteria and Standards for Cardiac Catheterization Equipment and Cardiac Angioplasty Equipment promulgated in 10A NCAC 14C .1600 are applicable to this review. The application is conforming to all applicable criteria. The specific criteria are discussed below.

10A NCAC 14C .1603 PERFORMANCE STANDARDS

- (a) *An applicant proposing to acquire cardiac catheterization equipment shall demonstrate that the project is capable of meeting the following standards:*
- (1) *each proposed item of cardiac catheterization equipment, including mobile equipment but excluding shared fixed cardiac catheterization equipment, shall be utilized at an annual rate of at least 60 percent of capacity excluding procedures not defined as cardiac catheterization procedures in 10A NCAC 14C .1601(5), measured during the fourth quarter of the third year following completion of the project;*
- NA- The applicant is proposing to acquire shared, fixed cardiac catheterization equipment.
- (2) *if the applicant proposes to perform therapeutic cardiac catheterization procedures, each of the applicant's therapeutic cardiac catheterization teams shall be performing at an annual rate of at least 100 therapeutic cardiac catheterization procedures, during the third year of operation following completion of the project;*
- NA- The applicant is proposing to acquire shared, fixed cardiac catheterization equipment.
- (3) *if the applicant proposes to perform diagnostic cardiac catheterization procedures, each diagnostic cardiac catheterization team shall be performing*

at an annual rate of at least 200 diagnostic-equivalent cardiac catheterization procedures by the end of the third year following completion of the project;

-NA- The applicant is proposing to acquire shared, fixed cardiac catheterization equipment.

(4) *at least 50 percent of the projected cardiac catheterization procedures shall be performed on patients residing within the primary cardiac catheterization service area;*

-NA- The applicant is proposing to acquire shared, fixed cardiac catheterization equipment.

(b) *An applicant proposing to acquire mobile cardiac catheterization equipment shall:*

(1) *demonstrate that each existing item of cardiac catheterization equipment, excluding mobile equipment, located in the proposed primary cardiac catheterization service area of each host facility shall have been operated at a level of at least 80 percent of capacity during the 12 month period reflected in the most recent licensure form on file with the Division of Health Service Regulation;*

-NA- The applicant does not propose to acquire mobile cardiac catheterization equipment.

(2) *demonstrate that the utilization of each existing or approved item of cardiac catheterization equipment, excluding mobile equipment, located in the proposed primary cardiac catheterization service area of each host facility shall not be expected to fall below 60 percent of capacity due to the acquisition of the proposed mobile cardiac catheterization equipment;*

-NA- The applicant does not propose to acquire mobile cardiac catheterization equipment.

(3) *demonstrate that each item of existing mobile equipment operating in the proposed primary cardiac catheterization service area of each host facility shall have been performing at least an average of four diagnostic-equivalent cardiac catheterization procedures per day per site in the proposed cardiac catheterization service area in the 12 month period preceding the submittal of the application;*

-NA- The applicant does not propose to acquire mobile cardiac catheterization equipment.

(4) *demonstrate that each item of existing or approved mobile equipment to be operating in the proposed primary cardiac catheterization service area of each host facility shall be performing at least an average of four*

diagnostic-equivalent cardiac catheterization procedures per day per site in the proposed cardiac catheterization service area in the applicant's third year of operation; and

-NA- The applicant does not propose to acquire mobile cardiac catheterization equipment.

(5) *provide documentation of all assumptions and data used in the development of the projections required in this Rule.*

-NA- The applicant does not propose to acquire mobile cardiac catheterization equipment.

(c) *An applicant proposing to acquire cardiac catheterization equipment excluding shared fixed and mobile cardiac catheterization shall:*

(1) *demonstrate that its existing items of cardiac catheterization equipment, except mobile equipment, located in the proposed cardiac catheterization service area operated at an average of at least 80 percent of capacity during the twelve month period reflected in the most recent licensure renewal application form on file with the Division of Health Service Regulation;*

-NA- The applicant is proposing to acquire shared, fixed cardiac catheterization equipment.

(2) *demonstrate that its existing items of cardiac catheterization equipment, except mobile equipment, shall be utilized at an average annual rate of at least 60 percent of capacity, measured during the fourth quarter of the third year following completion of the project; and*

-NA- The applicant is proposing to acquire shared, fixed cardiac catheterization equipment.

(3) *provide documentation of all assumptions and data used in the development of the projections required in this Rule.*

-NA- The applicant is proposing to acquire shared, fixed cardiac catheterization equipment.

(d) *An applicant proposing to acquire shared fixed cardiac catheterization equipment as defined in the applicable State Medical Facilities Plan shall:*

(1) *demonstrate that each proposed item of shared fixed cardiac catheterization equipment shall perform a combined total of at least 225 cardiac catheterization and angiography procedures during the fourth quarter of the third year following completion of the project; and*

- C- In Section Q, Form C, the applicant projects to that the proposed shared fixed cardiac catheterization equipment shall perform 282 cardiac catheterization and angiography procedures during the fourth quarter of the third year (SFY2026) following completion of the project. The analysis regarding projected utilization found in Criterion (3) is incorporated herein by reference.
- (2) *provide documentation of all assumptions and data used in the development of the projections required in this Rule.*
- C- In Section Q, Form C, the applicant documents all the assumptions and data used in the development of the projections required in this Rule.
- (e) *If the applicant proposes to perform cardiac catheterization procedures on patients age 14 and under, the applicant shall demonstrate that it meets the following additional criteria:*
 - (1) *the facility has the capability to perform diagnostic and therapeutic cardiac catheterization procedures and open heart surgery services on patients age 14 and under; and*
 - (2) *the proposed project shall be performing at an annual rate of at least 100 cardiac catheterization procedures on patients age 14 or under during the fourth quarter of the third year following initiation of the proposed cardiac catheterization procedures for patients age 14 and under.*
- NA- The applicant does not propose to perform cardiac catheterization procedures on patients age 14 and under.