

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: April 28, 2023

Findings Date: April 28, 2023

Project Analyst: Cynthia Bradford

Co-Signer: Mike McKillip

Project ID #: J-12322-23

Facility: University of North Carolina Hospitals Hillsborough Campus

FID #: 090274

County: Orange

Applicant: University of North Carolina Hospitals at Chapel Hill

Project: Acquire no more than one unit of fixed cardiac catheterization equipment pursuant to the need determination in the 2023 SMFP

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

University of North Carolina Hospitals at Chapel Hill (hereinafter referred to as UNC Hospitals or “the applicant”) propose to develop no more than one unit of fixed cardiac catheterization equipment at University of North Carolina Hospitals Hillsborough Campus (UNC Hospitals Hillsborough Campus) for a total of no more than five units of fixed cardiac catheterization equipment upon project completion.

Need Determination

Chapter 17 of the 2023 State Medical Facilities Plan (SMFP) includes a methodology for determining the need for additional cardiac catheterization equipment in North Carolina by service area. Application of the need methodology in the 2023 SMFP, page 308, did show a need for one unit of fixed cardiac catheterization equipment in Orange County.

Policies

There is one policy in the 2023 SMFP which is applicable to this review. *Policy GEN-3: Basic Principles*, on page 30 of the 2023 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.”

In Section B, pages 27-31, the applicant explains why it believes its application is consistent with Policy GEN-3. The applicant states it is dedicated to ensuring quality care and patient safety, that it will not discriminate based on a number of characteristics and will provide resources for uninsured patients, and that its projected utilization is based on reasonable and adequately supported assumptions, including the need the population has for the services proposed.

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 develop more fixed cardiac catheterization units than are determined to be needed in the service area.
- The applicant adequately demonstrates that the proposal is consistent with Policy GEN-3, based on the following:
 - The applicant adequately documents how the project will promote safety and quality in the delivery of fixed cardiac catheterization services in Orange County.
 - The applicant adequately documents how the project will promote equitable access to fixed cardiac catheterization services in Orange County.

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

C

The applicant proposes to develop one additional unit of fixed cardiac catheterization equipment at UNC Hospitals Hillsborough Campus, pursuant to the need determination in the 2023 SMFP, for a total of no more than five units of fixed cardiac catheterization equipment upon project completion.

Patient Origin

On page 300, the 2023 SMFP defines the 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 36, shows Orange County as a single county service area. Therefore, the service area for the fixed cardiac catheterization equipment is Orange County. Facilities may also serve residents of counties not included in their service area.

UNC Hospitals Hillsborough Campus does not currently provide cardiac catheterization services. The following table illustrates the historical patient origin for all services at UNC Hospitals Hillsborough Campus.

Entire Facility or Campus	UNC Hospitals Hillsborough Campus*	
	Last Full FY 07/01/2021 to 06/30/2022	
County or other geographic area such as ZIP code	Number of Patients	% of Total
Orange	32,854	33.2%
Alamance	25,616	25.9%
Durham	8,627	8.7%
Wake	5,546	5.6%
Person	4,646	4.7%
Chatham	2,832	2.9%
Guilford	2,377	2.4%
Caswell	1,640	1.7%
Cumberland	1,066	1.1%
Lee	979	1.0%
Other ^	12,813	12.8%
Total	98,996	100.0%

^Other includes Alexander, Alleghany, Anson, Ashe, Avery, Beaufort, Bertie, Bladen, Brunswick, Buncombe, Burke, Cabarrus, Caldwell, Camden, Carteret, Catawba, Cherokee, Chowan, Cleveland, Columbus, Craven, Currituck, Dare, Davidson, Davie, Duplin, Edgecombe, Forsyth, Franklin, Gaston, Gates, Graham, Granville, Greene, Halifax, Harnett, Haywood, Henderson, Hertford, Hoke, Hyde, Iredell, Jackson, Johnston, Jones, Lenoir, Lincoln, Macon, Madison, Martin, McDowell, Mecklenburg, Mitchell, Montgomery, Moore, Nash, New Hanover, Northampton, Onslow, Pamlico, Pasquotank, Pender, Perquimans, Pitt, Polk, Randolph, Richmond, Robeson, Rockingham, Rowan, Rutherford, Sampson, Scotland, Stanly, Stokes, Surry, Transylvania, Tyrrell, Union, Vance, Warren, Washington, Watauga, Wayne, Wilkes, Wilson, Yadkin, and Yancey counties in North Carolina, as well as other states.

On page 39, the applicant provides a table with the projected patient origin for cardiac catheterization services at UNC Hospitals Hillsborough Campus for the first three full fiscal years of operation, as summarized below.

	FY 1 – CY 2024		FY 2 – CY 2025		FY 3 – CY 2026	
	# Patients	% Patients	# Patients	% Patients	# Patients	% Patients
Orange	243	41.5%	291	41.5%	324	41.5%
Alamance	135	23.0%	162	23.0%	180	23.0%
Durham	73	12.5%	88	12.5%	98	12.5%
Person	39	6.7%	47	6.7%	52	6.7%
Rockingham	37	6.3%	45	6.3%	49	6.3%
Other**	59	10.0%	70	10.0%	78	10.0%
Total	586	100.0%	703	100.0%	781	100.0%

Source: Section C, pages 37 and 39

**Other: Other counties in North Carolina as well as other states

Currently, UNC Hospitals operates four units of fixed cardiac catheterization equipment at the main campus in Chapel Hill. In Section C, page 38, the applicant provides the assumptions and methodology used to project its patient origin. The applicant projects patient origin based on the expected shift of patients who currently receive cardiac catheterization services at the main campus in Chapel Hill that will instead receive these services at UNC Hospitals Hillsborough Campus. The applicant’s assumptions are reasonable and adequately supported.

Analysis of Need

In Section C, pages 41-53, the applicant explains why it believes the population projected to utilize the proposed services needs the services, as summarized below.

- **Need for Additional Cardiac Catheterization in The Service Area;** The applicant states on pages 42-45, that population growth rates for the six counties receiving the majority of cardiac catheterization services all had annual growth rates comparable to, or surpassing the growth rate for the State of North Carolina. Additionally, growth rates for persons 65 and over is expected to grow at a rate equal or faster than the growth rate of the State. The need for the proposed unit of cardiac catheterization equipment is also driven by the rate of cardiovascular disease. Although cardiovascular disease is prevalent across the state, it is particularly significant among residents of these six counties in the 65+ age range.
- **The Need for Additional Cardiac Catheterization Services for UNC Hospital's Patients;** On pages 46-49, the applicant states UNC Hospitals is the only hospital system in Orange County and the only provider of cardiac catheterization services in that area. UNC Hospitals has experienced an increase in the number of diagnostic equivalent cardiac catheterization procedures over the past four fiscal years due to other facilities in the area not being able to provide the on-site and ancillary services as UNC Hospitals, therefore UNC Hospitals is a better option for Medicare and Medicaid patients.
- **The Need for Cardiac Catheterization Services at UNC Hospitals Hillsborough Campus;** On pages 49-53, the applicant states that the growth and evolution of services at UNC Hospitals Hillsborough Campus has proved effective at decompressing volume at UNC Medical Center, although UNC Medical Center often still faces capacity constraints for acute care beds, which can directly affect patient treatment post-procedure. For example, a patient may seek care at UNC Hospitals Hillsborough Campus, be transferred to UNC Medical Center for a procedure that can only be performed there, then be transferred back to UNC Hospitals Hillsborough Campus due to acute care bed capacity constraints.

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

- The applicant cites publicly available data to support its conclusions about population growth.
- The applicant provides documentation of growth of cardiac catheterization procedures at UNC Hospitals.
- The total cardiac catheterization procedure volume at UNC Hospitals has a FY 2019-2022 CAGR of 2.5% and a FY 2021-2022 annualized CAGR of 7.9% even with the impact of the COVID-19 pandemic.

- The applicant provides information to support the need for an additional unit of fixed cardiac catheterization equipment based on non-ST-elevation myocardial infarction (STEMI) cases and the impacts of those cases when they arrive at UNC Hospitals.

Projected Utilization

On Form C.2b in Section Q, the applicant provides projected utilization for UNC Hospitals Hillsborough Campus, as illustrated in the following table.

UNC Hospitals Hillsborough Campus Cardiac Catheterization Projected Utilization				
	Partial FY 1/1/24 – 6/30/24	FY 1 – CY 2025	FY 2 – CY 2026	FY 3 – CY 2027
# of Units	1	1	1	1
# Diagnostic Procedures	219	438	526	585
# Therapeutic Procedures	74	147	177	196
# of Diagnostic-Equivalent Procedures	348	696	835	928

UNC Hospitals Main Campus Cardiac Catheterization Projected Utilization			
	FY 1 – CY 2025	FY 2 – CY 2026	FY 3 – CY 2027
# of Units	4	4	4
# Diagnostic Procedures	1,776	1,743	1,740
# Therapeutic Procedures	950	948	956
# <=14 Yr Old Procedures	141	145	149
# of Diagnostic-Equivalent Procedures	3,723	145	3,711

Following Forms C.2a and C.2b in Section Q, the applicant provides the assumptions and methodology used to project utilization, which are summarized below.

- The applicant reviewed historical utilization and CAGRs for diagnostic, interventional, total, and weighted cardiac catheterization procedures for FYs 2019-2022. The applicant projected growth of cardiac catheterization procedures at UNC Hospitals by utilizing the growth rate from FY21 to FY22 of 3.1% for diagnostic equivalent procedures.
- The applicant began its projections with FY 2022 annualized data and applied the projected growth rate to each type of procedure to project utilization at UNC Hospitals through the first three full operating years.

A summary of the applicant’s assumptions and calculations are shown in the table below.

UNC Hospitals Projected Cardiac Catheterization Utilization							
	FY22	FY23	FY24	FY25 (PY1)*	FY26 (PY2)	FY27 (PY3)	FY22- FY27 CAGR
Diagnostic Procedures	2,058	2,109	2,161	2,214	2,269	2,325	2.5%
Interventional Procedures	1,020	1,045	1,071	1,098	1,125	1,152	2.5%
Procedures for Patients <=14 years old**	131	135	138	141	145	149	
Total Procedures	3,209	3,289	3,370	3,453	3,539	3,626	
Diagnostic-Equivalent Procedures	4,106	4,207	4,311	4,418	4,527	4,639	2.5%

Source: UNC Hospitals Internal Data.

*Project Years (PY) reflect full fiscal years (Jul-Jun) of the proposed project.

** Based on FY22 percent of total procedures.

UNC Hospitals System

Pursuant to 10A NCAC 14C .1603(a)(5), an applicant proposing to acquire fixed cardiac catheterization equipment must demonstrate that the existing, approved, and proposed fixed cardiac catheterization units owned by the applicant or a related entity in a cardiac catheterization equipment service area will perform 900 or more diagnostic-equivalent cardiac catheterization procedures per unit during the third full fiscal year following project completion.

Immediately following Forms C.2a and C.2b in Section Q, the applicant provides the assumptions and methodology used to project utilization for the entire UNC Hospital system in Orange County, which are summarized below.

- The applicant reviewed projected utilization for diagnostic, interventional, total, and weighted cardiac catheterization procedures for FY25-FY27. The applicant projected the following growth rates for types of cardiac catheterization procedures at each facility:
 - The population of the Orange County ZIP codes proximate to Hillsborough is approximately 20 percent of the total county population. As such, and because both campuses are served by the same medical staff, UNC Hospitals believes that it is reasonable to assume that 20 percent of its projected procedure volume (unweighted) will be performed at the Hillsborough campus.
 - UNC Hospitals expects that it will perform more diagnostic procedures and fewer interventional procedures and has therefore assumed a three to one ratio of diagnostic to interventional procedures for the proposed cardiac catheterization equipment at UNC Hospitals Hillsborough Campus.
 - The total projected cardiac catheterization volume at UNC Medical Center was calculated by subtracting the projected volume for UNC Hospitals Hillsborough Campus from the total projected volume for UNC Hospitals (both campuses) (e.g.: in FY24, 2,161 diagnostic procedures (UNC Hospitals total) – 219 diagnostic procedures (UNC Hospitals Hillsborough Campus) = 1,942 diagnostic procedures (UNC Medical Center))

- The applicant began its projections with FY 2024 annualized data and applied the projected growth rate to each type of procedure to project utilization at all UNC facilities through the first three full operating years.

A summary of the applicant’s assumptions and calculations are shown in the table below.

UNC Hospitals Projected Cardiac Catheterization Utilization				
	FY24*	FY25 (PY1)**	FY26 (PY2)	FY27 (PY3)
UNC Hillsborough				
Diagnostic Procedures	219	438	526	585
Interventional Procedures	74	147	177	196
Procedures for Patients <= 14 Years Old***	0	0	0	0
Total Procedures	293	586	703	781
Diagnostic Equivalent Procedures	348	696	835	928
# of Units	1	1	1	1
Units Required Based on 60% Utilization	0.4	0.8	0.9	1.0
Diagnostic Equivalent Procedures Per Unit	348	696	835	928
UNC Medical Center				
Diagnostic Procedures	1,942	1,776	1,743	1,740
Interventional Procedures	997	950	948	956
Procedures for Patients <= 14 Years Old**	138	141	145	149
Total Procedures	3,078	3,723	3,692	3,711
Diagnostic Equivalent Procedures	3,964	3,723	3,692	3,711
# of Units	4	4	4	4
UNC Hospitals Projected Utilization Per Unit				
Diagnostic Equivalent Procedures		4,418	4,527	4,639
# of Units		5	5	5
Units Required Based on 60% Utilization		4.9	5.0	5.2
Diagnostic Equivalent Procedures Per Unit		884	905	928

*FY24 is an interim year with six months of operation.

** Project Years (PYs) reflect full fiscal years (Jul-Jun) of the project.

*** <=14 year old procedures will not be performed at UNC Hillsborough campus

As shown in the table above, the applicant projects that the entire UNC system in Orange County will perform 4,639 diagnostic-equivalent cardiac catheterization procedures on five units of fixed cardiac catheterization equipment, or an average of 928 diagnostic-equivalent cardiac catheterization procedures per unit of fixed cardiac catheterization equipment during FY 2027. Each facility will also perform at least 900 diagnostic-equivalent cardiac catheterization procedures per unit of fixed cardiac catheterization equipment during FY 2027. This meets the requirement promulgated in 10A NCAC 14C .1603(a)(5).

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

- The applicant uses the assumption that once the project is complete that 20% of the projected procedure volume at UNC Hospitals in Orange County will be performed at the Hillsborough Campus.
- The applicant calculated the total projected cardiac catheterization volume at UNC Medical Center was determined by subtracting the projected volume for UNC Hospitals Hillsborough Campus from the total projected volume for UNC Hospitals in Orange County.

Access to Medically Underserved Groups

In Section C, pages 61-62, the applicant states that it will not discriminate against individuals on the basis of race, color, national origin, gender, disability, age, or payor, and discusses its charity care policies designed to provide financial assistance for uninsured patients or patients with lower income levels. The applicant states that the proposed project will be compliant with the latest State of North Carolina and Federal guidelines for handicapped accessibility and will be compliant with all applicable provisions of the Americans with Disabilities Act

On page 62, the applicant provides the estimated percentage for each medically underserved group, as shown in the following table.

Medically Underserved Groups**	% of Total Patients
Low-income persons	
Racial and ethnic minorities	34.0%
Women	59.8%
Persons 65 and older	34.9%
Medicare beneficiaries	38.8%
Medicaid recipients	10.9%

**Estimated percentage of total patients for UNC Hospitals Hillsborough Campus during the third full fiscal year of the project.

On page 62, the applicant states it does not retain data on the number of disabled persons it serves and states that disabled persons will not be denied access to UNC Hospitals.

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:

- UNC Hospitals is part of an established health system in Orange County that has established policies against discrimination.
- 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 its Patient Accessibility Policies in Exhibit B.20-5, and its Patient Financial policies in Exhibit B.20-6.

Conclusion

The Agency reviewed the:

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

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

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

NA

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

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

C

The applicant proposes to develop one additional unit of fixed cardiac catheterization equipment at UNC Hospitals Hillsborough Campus, pursuant to the need determination in the 2023 SMFP, for a total of no more than five units of fixed cardiac catheterization equipment upon project completion.

In Section E, pages 74-75, 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:

Develop the Equipment Within the Hospital's Existing Space – The applicant states the development of a modular unit would be far faster than the construction of new space or renovation of existing space within the hospital itself. New construction or renovation within the hospital would be both more costly and result in a longer time between the approval of the proposed project and the start of delivering care to patients.

Develop Cardiac Catheterization Equipment at a UNC Medical Center at Chapel Hill – The applicant states that this alternative would result in significant impacts to existing equipment and services at that facility. UNC Medical Center's existing cardiac catheterization laboratories

are currently “landlocked,” with no room to allocate additional space in which to house the proposed equipment without significant impact from relocating services.

Develop the Equipment in an Ambulatory Surgery Facility – The applicant states, inpatients in need of cardiac catheterization services need access to a hospital-based unit, as do some outpatients. The development of the proposed service at the hospital in a modular building will allow more rapid deployment of the much-needed capacity.

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 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. University of North Carolina Hospitals at Chapel Hill (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**
- 2. The certificate holder shall develop no more than one unit of fixed cardiac catheterization equipment at UNC Hospitals Hillsborough Campus pursuant to the need determination in the 2023 State Medical Facilities Plan for a total of no more than five units of fixed cardiac catheterization equipment upon project completion, including four units of fixed cardiac catheterization equipment located at UNC Hospitals main campus in Chapel Hill.**
- 3. The certificate holder shall not acquire as part of this project any equipment that is not included in the project’s proposed capital expenditures in Section Q of the application and that would otherwise require a certificate of need.**
- 4. Progress Reports:**
 - a. Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable**

- and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: <https://info.ncdhhs.gov/dhsr/coneed/progressreport.html>.
- b. The certificate holder shall complete all sections of the Progress Report form.
 - c. The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.
 - d. The first progress report shall be due on October 1, 2023.
5. No later than three months after the last day of each of the first three full fiscal years of operation following initiation of the services authorized by this certificate of need, the certificate holder 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.
6. The certificate holder shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicant proposes to develop one additional unit of fixed cardiac catheterization equipment at UNC Hospitals Hillsborough Campus, pursuant to the need determination in the 2023 SMFP, for a total of no more than five units of fixed cardiac catheterization equipment upon project completion.

Capital and Working Capital Costs

In Section Q, Form F.1a, the applicant projects the total capital cost of the project to be \$859,888; \$625,943 for medical equipment, and \$233,945 for non-medical equipment.

Immediately following Form F.1.a, in Section Q, the applicant provides the assumptions used to project the capital cost. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based on the following:

- UNC Hospitals provides copies of the vendor equipment price quotes in Exhibit C.1 of the application.
- The applicant does not project to perform any construction or renovation.

In Exhibit F.2, the applicant provides a letter from the Chief Financial Officer of UNC Hospitals, which states that the capital cost for this project are estimated to be \$859,888, with no additional start-up costs for this project. The applicant adequately demonstrates that projected working capital cost is based on reasonable and adequately supported assumptions because the applicant currently provides the services it proposes to add.

Availability of Funds

In Section F, pages 81-82, the applicant states that the capital cost will be funded through accumulated reserves. In Exhibit F.2, the applicant provides a letter from the Chief Financial Officer of UNC Hospitals, committing to providing \$859,888 in capital costs for the proposed project. Exhibit F.2 also contains the University of North Carolina Hospitals at Chapel Hill Financial Statement Audit and Supplemental Information which shows that for the fiscal year ending June 30, 2022, the applicant had adequate cash equivalents and assets to fund the proposed project.

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 not exceed operating expenses for the cardiac catheterization services at UNC Hospitals Hillsborough Campus during the first three full fiscal years following completion of the project, as shown in the table below.

UNC Hospitals Hillsborough Projected Revenues and Operating Expenses – Cardiac Catheterization Equipment			
	FFY 2024	FFY 2025	FFY 2026
Total Gross Revenues (Charges)	\$14,776,771	\$18,264,089	\$20,902,235
Total Net Revenue	\$4,178,170	\$5,164,218	\$5,910,160
Total Operating Expenses (Costs)	\$5,151,409	\$5,151,409	\$6,567,571
Net Income	(\$973,239)	(\$784,605)	(\$657,411)

However, the applicant projects that revenues will exceed operating expenses during each of the first three full fiscal years of operation for the entire UNC Hospitals facility, as shown in the table below.

UNC Hospitals (Total Facilities) Projected Revenues and Operating Expenses			
	FFY 2024	FFY 2025	FFY 2026
Total Gross Revenues (Charges)	\$7,275,614,756	\$7,567,284,517	\$7,870,650,602
Total Net Revenue	\$2,865,907,578	\$2,980,577,633	\$3,099,839,481
Total Operating Expenses (Costs)	\$2,583,283,568	\$2,685,169,382	\$2,791,090,644
Net Income	\$282,624,010	\$295,408,251	\$308,748,837

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 the following:

- The applicant's projected payor mix is based on the applicant's historical payor mix.
- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

The applicant proposes to develop one additional unit of fixed cardiac catheterization equipment at UNC Hospitals Hillsborough Campus, pursuant to the need determination in the 2023 SMFP, for a total of no more than five units of fixed cardiac catheterization equipment upon project completion.

On page 300, the 2023 SMFP defines the 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 Orange County as a single county service area. Therefore, the service area for the fixed cardiac catheterization equipment is Orange County. Facilities may also serve residents of counties not included in their service area.

According to Table 17A-3 in Chapter 17 of the 2023 SMFP, there is one facility, UNC Hospitals, with a total of 4 units of fixed cardiac catheterization equipment in Orange County. Information about the facility and equipment is shown in the table below.

Fixed Cardiac Catheterization Equipment Inventory – Orange County			
Facility	# Units	2021 Procedures	Machines Required (80% Utilization)
UNC Hospitals	4	5,014	4.18

In Section G, page 86, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved cardiac catheterization services in Orange County. The applicant states:

“The proposed equipment is needed based on the high utilization of the existing equipment in the county and will not unnecessarily duplicate existing resources...”

...UNC Hospitals projects that all its existing and proposed cardiac catheterization equipment will be well utilized, exceeding the performance standard threshold per unit by the third project year, and demonstrating that the additional unit is needed to meet projected demand...

...All four cardiac catheterization units in Orange County are currently located at UNC Medical Center, a facility that will serve a similar but different patient population, including emergent and higher acuity patients. Further, locating the proposed cardiac catheterization equipment in Hillsborough will expand geographic access at that facility in northern Orange County, as opposed to UNC Medical Center, which is in southeastern Orange County. In these ways, the proposed project will not unnecessarily duplicate any services that currently exist in the proposed service area”.

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

- There is a need determination in the 2023 SMFP for the proposed unit of fixed cardiac catheterization equipment in the service area.
- The applicant adequately demonstrates that the proposed cardiac catheterization equipment is needed in addition to the existing or approved cardiac catheterization equipment.

Conclusion

The Agency reviewed the:

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

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

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

C

The applicant proposes to develop one additional unit of fixed cardiac catheterization equipment at UNC Hospitals Hillsborough Campus, pursuant to the need determination in the 2023 SMFP, for a total of no more than five units of fixed cardiac catheterization equipment upon project completion.

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

UNC Hospitals Hillsborough Campus Cardiac Catheterization Lab Projected FTE Staffing				
	Partial FY24	FY25	FY26	FY27
Procedure Room CN II - OR	1.0	2.0	2.0	2.0
Cardiac Catheterization Specialist	1.5	3.0	3.0	3.0
CN II - Pre & Post Procedure Care	2.0	4.0	4.0	4.0
TOTAL	4.5	9.0	9.0	9.0

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 88-89, 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 is part of a large and established healthcare system in Orange County.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

The applicant proposes to develop one additional unit of fixed cardiac catheterization equipment at UNC Hospitals Hillsborough Campus, pursuant to the need determination in the 2023 SMFP, for a total of no more than five units of fixed cardiac catheterization equipment upon project completion.

Ancillary and Support Services

In Section I, page 90, the applicant identifies the necessary ancillary and support services for the proposed services. On page 90, the applicant explains how each ancillary and support service is or will be made available. The applicant adequately demonstrates that the necessary ancillary and support services will be made available because UNC Hospitals currently provides the ancillary and support services that will be necessary for the additional unit of fixed cardiac catheterization equipment.

Coordination

In Section I, page 91, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit I.2. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the following:

- The applicant is an existing provider with established relationships with healthcare and social services providers in the service area.
- In Exhibit I.2, the applicant provides letters of support from UNC Hospitals physicians supporting the addition of an additional unit of fixed cardiac catheterization equipment.

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. 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.

NA

The applicant does not propose to construct any new space or make any renovations to existing space. Therefore, Criterion (12) is not applicable to this review.

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and ... persons [with disabilities], which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:
- (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C

In Section L, page 98, the applicant provides the historical payor mix during FY 2022 for the entire UNC Hospitals Hillsborough Campus, as shown in the table below.

UNC Hospitals Hillsborough Campus	
Payor Category	% of Total – Entire Facility
Self-Pay	9.8%
Charity Care	
Medicare*	38.8%
Medicaid*	10.9%
Insurance*	29.6%
Workers Compensation	
TRICARE	
Other Gov't/Institutional	10.9%
Total	100.0%

*Including any managed care plans

In Section L, page 99, the applicant provides the following comparison.

UNC Hospitals Hillsborough Campus	% of Total Patients Served During FY 2021	% of the Population of Orange County*
Female	59.8%	52.3%
Male	40.2%	47.7%
Unknown	0.0%	0.0%
64 and Younger	65.1%	84.3%
65 and Older	34.9%	15.7%
American Indian	0.5%	0.6%
Asian	1.4%	7.9%
Black or African-American	24.4%	11.9%
Native Hawaiian or Pacific Islander	0.1%	0.1%
White or Caucasian	65.3%	76.7%
Other Race	7.5%	2.8%
Declined / Unavailable	0.8%	0.0%

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

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, page 100, the applicant states it has no such obligation.

In Section L, page 101, 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 and 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 102, 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.

UNC Hospitals Hillsborough Projected Payor Mix – FY3 (2027)		
Payor Category	% of Total – Entire Facility	% of Total – Cardiac Catheterization
Self-Pay	9.8%	9.1%
Charity Care [^]		
Medicare*	38.8%	60.0%
Medicaid*	10.9%	4.4%
Insurance*	29.6%	20.5%
Workers Compensation ^{^^}		
TRICARE ^{^^}		
Other Gov't/Institutional	10.9%	6.0%
Total	100.0%	100.0%

*Including any managed care plans.

[^]UNC Hospitals internal data does not include Charity Care as a payor source for patients. Patients in any payor category can and do receive charity care.

^{^^}Workers Compensation and TRICARE included in the Other payor category.

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 9.8% of total services and 9.1% of cardiac catheterization services will be provided to self-pay patients, 38.8% of total services and 60.0% of cardiac catheterization services to Medicare patients, and 10.9% of total services and 4.4% of cardiac catheterization services to Medicaid patients.

On page 103, 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 because it is based on the historical payor mix for UNC Hospitals Hillsborough Campus.

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 103, 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 develop one additional unit of fixed cardiac catheterization equipment at UNC Hospitals Hillsborough Campus, pursuant to the need determination in the 2023 SMFP, for a total of no more than five units of fixed cardiac catheterization equipment upon project completion.

In Section M, pages 105-106, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes. The applicant adequately demonstrates that health professional training programs in the area have access to the facility for training purposes based on the following:

- The applicant has existing clinical education agreements with area health education programs in Orange County.

- The applicant states all educational programs that have clinical agreements with UNC Hospitals will have the same access upon completion of the proposed project.
- The applicant states it is always open to considering new agreements with other clinical education 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.

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

C

The applicant proposes to develop one additional unit of fixed cardiac catheterization equipment at UNC Hospitals Hillsborough Campus, pursuant to the need determination in the 2023 SMFP, for a total of no more than five units of fixed cardiac catheterization equipment upon project completion.

On page 300, the 2023 SMFP defines the 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 Orange County as a single county service area. Therefore, the service area for the fixed cardiac catheterization equipment is Orange County. Facilities may also serve residents of counties not included in their service area.

According to Table 17A-3 in Chapter 17 of the 2023 SMFP, there is one facility UNC Hospitals with a total of 4 units of fixed cardiac catheterization equipment in Orange County. Information about the facility and equipment is shown in the table below.

Fixed Cardiac Catheterization Equipment Inventory – Orange County
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Facility	# Units	2021 Procedures	Machines Required (80% Utilization)
UNC Hospitals	4	5,014	4.18

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 108, the applicant states:

“Given its broad reach, UNC Hospitals believes that the proposed project will foster competition in the proposed service area. In particular, the proposed project will enhance competition by bolstering the cardiac catheterization services available at UNC Hospitals, which will improve its ability to compete with other providers state-wide and will promote cost-effectiveness, quality, and access to services in the proposed service area.”

Regarding the impact of the proposal on cost effectiveness, in Section N, page 108, the applicant refers to Section B.20.c which states:

“The proposed project will allow patients to access these services at another location within the county, while also decanting lower acuity diagnostic and elective interventional cardiac catheterizations to Hillsborough, with higher acuity and emergency cases remaining at UNC Medical Center in Chapel Hill. Ensuring that appropriate patients do not have to travel to Chapel Hill for care offers significant value to patients in need of service and demonstrates UNC Hospitals’ commitment to delivering that value to patients within the service area.”

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

Regarding the impact of the proposal on quality, in Section N, page 108, the applicant refers to Section B.20.a which states:

“UNC Hospitals believes that the proposed project will promote safety and quality in the provision of healthcare services to patients of the proposed services.”

See also Sections B, 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 108, the applicant refers to Section B.20.b which states:

“UNC Hospitals’ commitment to treating all patients regardless of their ability to pay is evidenced by its payor mix. UNC Hospitals has a long and proud history of serving all patients who require care, regardless of their ability to pay. UNC Hospitals expects that patients with limited financial resources will continue to benefit from access to its services upon completion of the proposed project”.

See also Sections C and 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
- 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 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 develop one additional unit of fixed cardiac catheterization equipment at UNC Hospitals Hillsborough Campus, pursuant to the need determination in the 2023 SMFP, for a total of no more than five units of fixed cardiac catheterization equipment upon project completion.

On Form O in Section Q, the applicant identifies the hospitals with fixed cardiac catheterization equipment located in North Carolina owned, operated, or managed by the applicant or a related entity. The applicant identifies a total of one hospital with fixed cardiac catheterization equipment located in North Carolina.

In Section O, page 111, the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents related to quality of care occurred at three of its facilities; UNC Health Blue Ridge, UNC Hospitals, and UNC Rex Hospital. The

applicant states that all the problems have been corrected and all of its facilities are back in compliance. After reviewing and considering the information provided by the applicant and the Acute Care and Home Care License and Certification Section and considering the quality of care provided at all nine (9) facilities, the applicant has provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

(21) Repealed effective July 1, 1987.

G.S. 131E-183 (b): The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

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 fixed cardiac catheterization equipment pursuant to a need determination in the annual State Medical Facilities Plan in effect as of the first day of the review period shall:*

(1) *identify the existing fixed cardiac catheterization equipment owned or operated by the applicant or a related entity and located in the proposed fixed cardiac catheterization equipment service area;*

-C- In Section C, page 47, the applicant identifies four existing units of fixed cardiac catheterization equipment at UNC Hospitals at Chapel Hill Campus.

(2) *identify the approved fixed cardiac catheterization equipment owned or operated by the applicant or a related entity and located in the proposed fixed cardiac catheterization equipment service area;*

-C- In Section C, page 47, the applicant does not identify any approved and operational units of fixed cardiac catheterization equipment owned or operated by the applicant or a related entity located in Orange County.

(3) *provide projected utilization of the cardiac catheterization equipment identified in Subparagraphs (1) and (2) of this Paragraph and the proposed fixed cardiac*

catheterization equipment during each of the first three full fiscal years of operation following completion of the project;

- C- On Form C.2b in Section Q, the applicant provides projected utilization of the existing, approved, and proposed fixed cardiac catheterization equipment owned or operated by the applicant or a related entity and located in Orange County during each of the first three full fiscal years of operation following completion of the project.
- (4) *provide the assumptions and methodology used to project the utilization required by Subparagraph (3) of this Paragraph; and*
- C- Immediately following Form C.2b in Section Q, the applicant provides the assumptions and methodology used to project utilization of the existing, approved, and proposed fixed cardiac catheterization equipment owned or operated by the applicant or a related entity and located in Orange County during each of the first three full fiscal years of operation following completion of the project.
- (5) *project that the cardiac catheterization equipment identified in Subparagraphs (1) and (2) of this Paragraph and the proposed fixed cardiac catheterization equipment shall perform 900 or more diagnostic-equivalent cardiac catheterization procedures per unit of cardiac catheterization equipment during the third full fiscal year of operation following completion of the project.*
- C- On Form C.2b in Section Q, the applicant projects that the existing, approved, and proposed fixed cardiac catheterization equipment owned or operated by the applicant or a related entity and located in Orange County will perform 900 or more diagnostic-equivalent procedures per unit of cardiac catheterization equipment during the third full fiscal year of operation following completion of the project. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.
- (b) *An applicant proposing to acquire shared fixed cardiac catheterization equipment pursuant to a need determination in the annual State Medical Facilities Plan in effect as of the first day of the review period shall:*
 - (1) *provide projected utilization of the proposed shared fixed cardiac catheterization equipment during each of the first three full fiscal years of operation following completion of the project;*
 - (2) *provide the assumptions and methodology used to project the utilization required by Subparagraph (1) of this Paragraph; and*
 - (3) *project that the proposed shared fixed cardiac catheterization equipment shall perform 225 or more diagnostic-equivalent cardiac catheterization and angiography procedures during the third full fiscal year of operation following completion of the project.*
- NA- The applicant does not propose to acquire shared fixed cardiac catheterization equipment.

- (c) *An applicant proposing to acquire mobile cardiac catheterization equipment pursuant to a need determination in the State Medical Facilities Plan in effect as of the first day of the review period shall:*
- (1) *identify the existing mobile cardiac catheterization equipment owned or operated by the applicant or a related entity that provides cardiac catheterization services at host sites located in the proposed mobile cardiac catheterization equipment service area;*
 - (2) *identify the approved mobile cardiac catheterization equipment owned or operated by the applicant or a related entity that will provide cardiac catheterization services at host sites located in the proposed mobile cardiac catheterization equipment service area;*
 - (3) *provide projected utilization of the cardiac catheterization equipment identified in Subparagraphs (1) and (2) of this Paragraph and the proposed mobile cardiac catheterization equipment during each of the first three full fiscal years of operation following completion of the project;*
 - (4) *provide the assumptions and methodology used to project the utilization required by Subparagraph (3) of this Paragraph; and*
 - (5) *project that the cardiac catheterization equipment identified in Subparagraphs (1) and (2) of this Paragraph and the proposed mobile cardiac catheterization equipment shall perform 225 or more diagnostic-equivalent cardiac catheterization procedures per unit of cardiac catheterization equipment during the third full fiscal year of operation following completion of the project.*
- NA- The applicant does not propose to acquire mobile cardiac catheterization equipment.