

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: September 26, 2019

Findings Date: September 26, 2019

Project Analyst: Ena Lightbourne

Team Leader: Fatimah Wilson

Project ID #: B-11713-19

Facility: Mission Hospital

FID #: 943349

County: Buncombe

Applicant(s): MH Mission Hospital, LLLP

Project: Add no more than one unit of fixed cardiac catheterization equipment pursuant to the need determination in the 2019 SMFP for a total of no more than five cardiac catheterization units

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

MH Mission Hospital, LLLP proposes to add one cardiac catheterization unit to the existing facility located on the campus of Mission Hospital ("Mission"), pursuant to the need determination in the 2019 State Medical Facilities Plan (2019 SMFP), for a total of five cardiac catheterization units upon project completion.

Need Determination

The 2019 SMFP includes a Need Determination for one unit of fixed cardiac catheterization equipment in the Buncombe/Graham/Madison/Yancey cardiac catheterization service area. Mission Hospital does not propose to develop more units of fixed cardiac catheterization equipment than are determined to be needed in the 2019 SMFP for the

Buncombe/Graham/Madison/Yancey cardiac catheterization service area. Therefore, the application is consistent with the need determination.

Policies

There is one policy in the 2019 SMFP that is applicable to this review: Policy GEN-3: Basic Principles, on page 31.

Policy GEN-3: Basic Principles 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 21-22; Section C, pages 24-27; Section N, page 80; Section O, pages 82-83 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, pages 21-22; Section C, pages 45-46; Section L, pages 74-77; Section N, page 80 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 21-22, Section C, pages 31-42; Section F, pages 58-59; Section K, pages 71-72, Section N, page 80; the applicant’s pro forma financial statements in Section Q and referenced exhibits.

In Section B, pages 21-22, the applicant explains why it believes its application is consistent with Policy GEN-3. On page 21, the applicant states:

“As an existing tertiary and quaternary care provider in the western region of North Carolina, Mission has policies in place to address safety, quality, access, and value that it provides to the service area.”

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 2019 SMFP. Therefore. The application is consistent with policy GEN-3.

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 does not propose to acquire more cardiac catherization units than is determined to be needed in the 2019 SMFP for the Buncombe/Graham/Madison/Yancey service area.
- The applicant adequately demonstrates that the proposal is consistent with Policy GEN-3.

- (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 unit of fixed cardiac catherization equipment, pursuant to the need determination in the 2019 SMFP for a total of five cardiac catheterization units upon project completion.

On page 173, the 2019 SMFP defines the service area for cardiac catheterization equipment (shared or fixed) as “...*the cardiac catheterization equipment planning area in which the equipment is located. The cardiac catheterization equipment planning areas are the same as the Acute Care Bed Service Areas defined in Chapter 5, Acute Care Beds, and shown in Figure 5.1. The cardiac catheterization equipment service area is a single county, except where there is no licensed acute care hospital located within the county.*” Figure 5.1 shows Buncombe County as a multicounty acute care bed service area. Thus, the service area for this proposal is Buncombe, Graham, Madison and Yancey Counties. Facilities may also serve residents of counties not include in their service area.

The following table illustrates historical and projected patient origin.

County	Historical 10/1/2017- 9/30/2018		3 rd FFY 7/1/2022- 6/30/2023	
	Patients	% of Total	Patients	% of Total
Buncombe	1,681	32.43%	1,763	32.43%
Henderson	641	12.36%	672	12.36%
Haywood	385	7.43%	404	7.43%
McDowell	367	7.08%	385	7.08%
Transylvania	246	4.75%	258	4.75%
Macon	226	4.36%	237	4.36%
Jackson	217	4.19%	228	4.19%
Madison	199	3.84%	209	3.84%
Swain	173	3.34%	181	3.34%
Yancey	166	3.20%	174	3.20%
Primary Service area	4,301	82.97%	4,510	82.97%
Rutherford	149	2.87%	156	2.87%
Mitchell	134	2.58%	141	2.58%
Cherokee	88	1.70%	92	1.70%
Burke	82	1.58%	86	1.58%
Graham	71	1.37%	74	1.37%
Polk	40	0.77%	42	0.77%
Avery	38	0.73%	40	0.73%
Clay	23	0.44%	24	0.44%
Secondary Service Areas	625	12.06%	655	12.06%
Other NC	70	1.35%	73	1.35%
Out of State	188	3.63%	197	3.63%
Total	5,184	100.00%	5,436	100.00%

Source: Section C, pages 28 and 30

In Section C, page 31, the applicant provides the assumptions and methodology used to project its patient origin. The applicant states:

“Mission accounted for the increase in patient volume subsequent to the proposed cardiac cath lab addition and population growth, and then applied the historic patient origin percent by county to the projected cardiac cath patient volume”.

The applicant’s assumptions are reasonable and adequately supported.

Analysis of Need

In Section C.4, pages 31-40, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. The applicant states that the need for the project is based on the following factors:

Service Area Definition (page 31)

On page 31, the applicant states Mission Hospital is the only the tertiary cardiovascular care and cardiac cath lab provider in the service area. Mission identifies its primary and secondary service area as shown in the table below:

Mission Health Service Area Definition	
Primary	Secondary
Buncombe	Rutherford
Henderson	Mitchell
Haywood	Cherokee
McDowell	Burke
Transylvania	Graham
Macon	Polk
Jackson	Avery
Madison	Clay
Swain	
Yancey	

Source: Section C, page 32

Population Trends of the Service Area (page 34)

The applicant uses data from the North Carolina Office of State Budget and Management (NCOSBM) to demonstrate the need based on the population growth in the service area. The applicant states that between 2019 and 2024, the primary service area is projected to grow steadily from 668,593 to 703,287 equating to over a one percent compounded growth rate (CAGR).

Primary Service Area Population			
Primary Service Area	2019	2024	CAGR 2019-2024
Buncombe	267,800	283,474	1.14%
Henderson	119,575	127,142	1.23%
Haywood	63,286	65,808	0.78%
McDowell	46,082	46,574	0.21%
Transylvania	35,123	36,674	0.87%
Macon	36,149	37,988	1.00%
Jackson	44,206	46,926	1.20%
Madison	22,769	24,092	1.14%
Swain	15,292	16,017	0.93%
Yancey	18,311	18,592	0.31%
Total	668,593	703,287	1.02%

Source: Section C, pages 34-35

Trends in Need for Mission’s Services (pages 37-39)

The applicant discusses the need for an additional cardiac catheterization unit based on an increase in adult diagnostic cardiac cath procedures and therapeutic percutaneous coronary interventional (PCI) procedures performed between 2010 and 2018. The applicant states that

Mission’s utilization continues to drive the need for additional cardiac catheterization equipment, as demonstrated in the 2019 SMFP. The following tables illustrate these trends.

Adult Diagnostic Fixed Cardiac Catheterization Procedures by Facility Totals										
Facility	2010	2011	2012	2013	2014	2015	2016	2017	2018	CAGR
Mission Hospital	3,188	3,077	3,103	3,045	2,981	3,045	3,433	3,441	3,797	2.2%

Source: Section C, page 38

Percutaneous Coronary Interventional (PCI)										
Facility	2010	2011	2012	2013	2014	2015	2016	2017	2018	CAGR
Mission Hospital	1,370	1,376	1,365	1,253	1,394	1,491	1,561	1,583	1,461	0.8%

Source: Section C, page 38

Aggregate Cardiac Catheterization Weighted Total Procedures										
Facility	2010	2011	2012	2013	2014	2015	2016	2017	2018	CAGR
Mission Hospital	5,586	5,485	5,492	5,238	5,421	5,654	6,165	6,211	6,354	1.9%

Source: Section C, page 38

High Utilization Rates Impact Access to Care (page 39)

The applicant states that Mission’s utilization rate increased by a CAGR of five percent from FY 2015 to FY 2018. The applicant states that such high utilization rates have caused capacity restraints which have ultimately led to delays in services. The following table illustrates a significant increase in utilization from FY 2015 to FY 2018.

Mission Catheterization Cases – Utilization Trends						
	FY 2015	FY 2016	FY 2017	FY 2018	% Increase	CAGR
Cases	4,536	4,994	5,024	5,258	15.9%	5.0%

Source: Section C, page 39

Delays in Service Reflect Demand for an Additional Cath Lab (pages 39-40)

The applicant states that due to the increase in demand for cardiac cath care, patients are experiencing unnecessary limitations on access to care. For non-emergent outpatients visiting the cath lab, wait times are in excess of 10 days. The applicant states the optimal wait time should be three days or less. In 2018, 294 outpatients were waitlisted for cardiac cath procedures and more than 80 have already been waitlisted in 2019. The applicant states:

“Consequently, while Mission has historically performed speedy and successful cardiac cath procedures, current and future constraints are making it harder for Mission’s physicians to offer the most advanced highest quality treatments to all patients requiring such treatment in the service area in a timely manner.”

Support for the Project (page 40)

In Exhibit I-3.1, the applicant provides letters of support from the medical director and chief of cardiology at Mission, stating how the limited capacity for cardiac cath services negatively affect both the quality and timelines of care patients receive. The letters of support discuss the delays in treatment and the inability of physicians to timely perform state-of-the-art procedures.

The information is reasonable and adequately supported for the following reasons:

- The applicant cites appropriate data that correlates with the population growth in the primary and secondary service area.
- The applicant’s proposal is in response to the need as published in the 2019 SMFP.
- The applicant provides supporting documentation regarding support for the project.
- The applicant relies on historical utilization to justify the need.

Project Utilization

In Section C, page 41, the applicant provides historical and projected utilization as illustrated in the tables below.

Mission Hospital Historical/Projected Utilization – Cardiac Catheterization Cases							
	Historical	Interim Actual	Annualized Interim CY 2019**	CY 2020	CY2021	CY 2022	CY2023
	FY 2018	10/1/18-3/31/19	1/1/19-12/31/19	1/1/20-12/31/20	1/1/21-12/31/21	1/1/22-12/31/22	1/1/23-12/31/23
Diagnostic Cases	3,797	1,897	3,792	3,830	3,868	3,909	3,946
Interventional Cases	1,461	729	1,458	1,473	1,487	1,502	1,517
Total	5,258	2,625	5,250	5,303	5,356	5,409	5,463

*Actual 6 months 10/1/18-3/31/19

**As an HCA affiliate, mission will have a fiscal year end 12/31/19. Interim year would be through 12/31/19

Mission Hospital Historical/Projected Utilization – Cardiac Catheterization Cases				
	Interim	Project Year 1	Project Year 2	Project Year 3
	1/1/20-6/30/20	7/1/20-6/30/21	7/1/21-6/30/22	7/1/22-6/30/23
Diagnostic Cases	1,915	3,849	3,888	3,926
Interventional Cases	736	1,480	1,495	1,510
Total	2,651	5,329	5,382	5,436

In Section Q, page 102, the applicant provides the assumptions and methodology used to project utilization, which are summarized below.

- Operating Year 1/Fiscal Year 1 = July 1, 2020 – June 30, 2021
 Operating Year 2/Fiscal Year 2 = July 1, 2021 – June 30, 2022
 Operating Year 3/Fiscal Year 3 = July 1, 2022 – June 30, 2023
- The applicant begins its projections based on actual utilization of diagnostic and interventional cases using data from the fiscal year ending September 30, 2018 and actual interim utilization for October 2018 through March 2019. The applicant states the interim year is a combination of actual utilization under Mission Hospital for the first four months and actual utilization under HCA for the remaining two months. As shown in the first table above, the actual interim year utilization was annualized and converted to calendar years to reflect the new fiscal year time period under HCA.
- The applicant projects utilization using a conservative one percent annual growth rate from CY2020 through CY2023 then converting it to fiscal years to reflect projected utilization for the first three operating years of the project. The applicant states that the one percent annual growth rate is based on historical trends and population growth. In Section C, page 38, the applicant demonstrates that Mission has experienced an increase in cardiac catheterization procedures from FY 2010 to FY 2018. This is based on the 2019 SMFP and Mission’s 2019 License Renewal Application (LRA).
- As shown in the table below, the applicant is projected to perform 6,568 diagnostic-equivalent procedures. If the applicant projects one percent growth through Project Year 3, the five cardiac catheterization units (four existing and one proposed) will be operating at 87.57% of capacity in OY3 [utilization percentage = procedures/ capacity = 6,568 procedures / 7,500 (5 labs x 1,500) = 0.8757 or 87.57% capacity].

Mission Hospital Weighted Projected Utilization – Cardiac Catheterization Cases				
	Interim	Project Year 1	Project Year 2	Project Year 3
	1/1/20-6/30/20	7/1/20-6/30/21	7/1/21-6/30/22	7/1/22-6/30/23
Diagnostic Cases	1,915	3,849	3,888	3,926
Interventional Cases	736	1,480	1,495	1,510
Total Equivalent	3,203	6,439	6,503	6,568

Source: Section C, page 41

This exceeds the requirement that 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;

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

- The applicant relies on historical utilization to determine projected utilization rates.
- The applicant provides information to support a projected increase in utilization based the growing need in the service area resulting from the population growth and the increase in continuous delays in service.

Access

In Section C, page 45, the applicant states:

“Like Mission’s existing cardiac cath labs, the planned lab will meet all requirements of the North Carolina Building Code, the American with Disabilities Act and any other applicable federal accessibility law, and any local accessibility ordinance. “

In Section L, page 76, 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.

Mission Hospital Projected Payor Mix 3rd FY 7/1/2022-6/30/2023		
Payor Source	Entire Hospital	Cardiac Cath Labs
Self-Pay*	3.27%	5.04%
Medicare**	53.23%	63.38%
Medicaid**	14.66%	6.68%
Insurance**	24.94%	21.93%
Other (Worker’s Comp, Tricare, Liability)	3.90%	2.97%
Total	100.00%	100.00%

*Includes charity care

**Including any managed care plans

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.
- (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 unit of fixed cardiac catheterization equipment, pursuant to the need determination in the 2019 SMFP for a total of five cardiac catheterization units upon project completion.

In Section E, page 57, the applicant states there were no alternative methods of meeting the needs for the proposed project. The applicant states that the need determination published in the 2019 SMFP was generated from the hospital's high utilization rates and as the only cardiac catheterization provider in the planning area.

The applicant adequately demonstrates that the alternative proposed in this application is the most effective alternative to meet the need for 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.
- Meet the need identified in the 2019 SMFP for an additional fixed unit of cardiac catheterization equipment.

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. Therefore, the application is approved subject to the following conditions:

- 1. MH Mission Hospital, LLLP shall materially comply with all representations made in the certificate of need application.**
 - 2. MH Mission Hospital, LLLP shall acquire no more than one unit of fixed cardiac catheterization equipment.**
 - 3. Upon completion of the project, Mission Hospital shall be licensed for no more than five units of fixed cardiac catheterization equipment.**
 - 4. MH Mission Hospital, LLLP shall not acquire as part of this project any equipment that is not included in the project's proposed capital expenditures in Section F of the application and that would otherwise require a certificate of need.**
 - 5. 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, MH Mission Hospital, LLLP 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. MH Mission Hospital, LLLP 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.

The applicant proposes to add one unit of fixed cardiac catheterization equipment, pursuant to the need determination in the 2019 SMFP for a total of five cardiac catheterization units upon project completion.

In Section Q, pages 91, the applicant projects the total capital cost of the project as shown in the table below.

Mission Hospital-Capital Expenditures	
Site Costs	\$239
Construction Costs/Contract(s)	\$495,567
Architect/Engineering Fees	\$36,459
Medical Equipment	\$760,532
Furniture	\$8,529
Consult Fees	\$48,540
Other Costs	\$5,229
Total	\$1,355,095

In Section Q, pages 102-103, the applicant provides the assumptions used to project the capital cost.

In Section F, pages 60-61, the applicant projects no start-up expenses or initial operating expenses (working capital costs) for the proposed project as it is only an expansion of existing services already being provided by the applicant.

Availability of Funds

In Section F, page 58, the applicant states that the capital cost will be funded as shown in the table below.

Sources of Capital Cost Financing	
Type	MH Mission Hospital, LLLP
Loans	\$0
Accumulated reserves or OE *	\$1,355,095
Bonds	\$0
Other (Specify)	\$0
Total Financing	\$1,355,095

* OE = Owner's Equity

In Exhibit F-2.1, the applicant provides a letter from Terence Van Arkel, Chief Financial Officer for HCA Healthcare, Inc., parent company for the applicant, which states their commitment to provide funding in the amount of \$1,355,095 through an inter-company loan. According to the supplemental information provided by the applicant, the inter-company loan is accumulated reserves/owners' equity of the parent company. It is not considered a debt and will not be repaid as a debt.

Exhibit F-2.2 contains a copy of the Consolidated Balance Sheets from HCA Healthcare, Inc., which showed that as of December 31, 2018, HCA Healthcare, Inc. had \$502,000,000 in cash

and equivalents, \$39,207,000 in total assets and \$463,000,000 in net assets (total assets less total liabilities). The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project.

Financial Feasibility

The applicant provided pro forma financial statements for the first three full fiscal years of operation following completion of the project. According to supplemental information provided by the applicant, Form F.2, page 92, reflects revenues and net income for the cardiac catheterization department. Form F.2 on page 94, reflects revenues and net income for the entire facility. In Form F.2, page 94, the applicant projects that revenues will exceed operating expenses in the first three operating years of the project, as shown in the table below.

Mission Hospital	1st FFY 7/1/2020-6/30/2021	2nd FFY 7/1/2021-6/30/2022	3rd FFY 7/1/2022-6/30/2023
Total Cardiac Catheterization Procedures	11,766	11,887	12,005
Total Gross Revenues (Charges)	\$238,393,464	\$243,185,172	\$248,073,194
Total Net Revenue	\$96,050,320	\$97,010,823	\$97,980,931
Average Net Revenue per procedure	\$8,163	\$8,161	\$8,162
Total Operating Expenses (Costs)	\$13,708,901	\$13,844,633	\$14,053,824
Average Operating Expense per procedure	\$1,165	\$1,165	\$1,171
Net Income	\$82,341,419	\$83,166,191	\$83,927,107

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
- Supplemental information requested 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 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 unit of fixed cardiac catheterization equipment, pursuant to the need determination in the 2019 SMFP for a total of five cardiac catheterization units upon project completion.

On page 173, the 2019 SMFP defines the service area for cardiac catheterization (shared or fixed) equipment as “...the cardiac catheterization equipment planning area in which the equipment is located. The cardiac catheterization equipment planning areas are the same as the Acute Care Bed Service Areas defined in Chapter 5, Acute Care Beds, and shown in Figure 5.1. The cardiac catheterization equipment service area is a single county, except where there is no licensed acute care hospital located within the county.” Figure 5-1 shows Buncombe County as a multicounty acute care bed service area. Thus, the service area for this proposal is Buncombe, Graham, Madison and Yancey Counties. Facilities may also serve residents of counties not include in their service area.

In Section G, page 64, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved cardiac catheterization services in Buncombe, Graham, Madison or Yancey County. The applicant states:

“There are no other providers of cardiac catheterization services in the service area. Mission is the only cardiac services provider on the SMFP-designated service area for cardiac cath equipment.”

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 2019 SMFP for the proposed cardiac catheterization equipment.
- The applicant adequately demonstrates that the proposed cardiac catheterization equipment is needed in addition to the existing cardiac catheterization equipment in the service area.

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, page 100, the applicant provides current and projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

Mission Hospital Cardiac Catheterization Services Staffing		
Position	Current FTE Staff As of 4/30/2019	Projected FTE Staff 2nd FY (7/1/2021 to 6/30/2022)
Register Nurse	15.50	18.50
Radiologist Technologists	12.00	15.00
Total	27.50	33.50

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.1 and H.2, pages 65 and 66, respectively, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. In Section I, page 68, the applicant identifies the current medical director. In Exhibit I-3.1, the applicant provides a letter from the medical director indicating an interest in continuing to serve as medical director for the proposed services. In Exhibits H-3.1 and H-3.2, the applicant provides supporting documentation.

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 67, the applicant states that the following ancillary and support services are necessary for the proposed services:

- Equipment Service Agreement with General Electric (GE)
- Clinical ancillary support services (include but not limited to pharmacy, laboratory, medical supplies, and any subsequent diagnostic or therapeutic follow-up procedures)
- Transfer agreements with 15 hospitals in Western North Carolina

On pages 67-68, the applicant adequately explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibit I-2.

In Section I, page 68, 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 and I-3.

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 71, the applicant states that the project involves renovating 725 square feet of existing space. Line drawings are provided in Exhibit K-2.

On page 71, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal and provides supporting documentation in Exhibit K-2.

On pages 71-72, 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.

On page 72, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans and provides supporting documentation in Exhibit C-1.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

(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 75, the applicant provides the historical payor mix during Last full fiscal year (10/1/2017-9/30/2018) for the proposed services as shown in the table below.

Mission Hospital Historical Payor Mix 10/1/2017-9/30/2018		
Payor Source	Entire Hospital	Cardiac Cath Labs
Self-Pay*	4.95%	5.04%
Medicare**	52.39%	63.38%
Medicaid**	14.07%	6.68%
Insurance**	24.57%	21.93%
Other (Worker's Comp, Tricare, Liability)	4.02%	2.97%
Total	100.00%	100.00%

Source: Section L, page 75

*Includes charity care

**Including any managed care plans

In Section L, page 74, the applicant provides the following comparison.

Mission Hospital	Percentage of Total Patients Served by the Facility or Campus during the Last Full FY	Percentage of the Population of the Service Area
Female	59.37%	51.39%
Male	40.62%	48.61%
Unknown	0.01%	0.00%
64 and Younger	58.58%	76.81%
65 and Older	41.42%	23.19%
American Indian	0.96%	1.40%
Asian	0.50%	1.26%
Black or African-American	6.18%	4.40%
Native Hawaiian or Pacific Islander	0.25%	0.12%
White or Caucasian	88.32%	87.76%
Other Race	0.01%	5.06%
Declined / Unavailable	3.79%	0.00%

Source: <https://www.census.gov/quickfacts/fact/table/us/PST045218>

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 75, the applicant states that Mission Hospital does not have any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities. On page 76, the applicant states that Mission Hospital has several policies related to financial assistance, including financial assistance policy, charity discount policy and uninsured discount policy. On page 77, the applicant states that individuals will continue to have access to cardiac catheterization services at Mission Hospital through admissions or a physician referral.

In Section L, page 75, 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 76, 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.

Mission Hospital Projected Payor Mix 3rd FY 7/1/2022-6/30/2023		
Payor Source	Entire Hospital	Cardiac Cath Labs
Self-Pay*	3.27%	5.04%
Medicare**	53.23%	63.38%
Medicaid**	14.66%	6.68%
Insurance**	24.94%	21.93%
Other (Worker's Comp, Tricare, Liability)	3.90%	2.97%
Total	100.00%	100.00%

Source: Section L, page 76

*Includes charity care

**Including any managed care plans

As shown in the table above, during the or third full fiscal year of operation, the applicant projects that 5.04% of total services will be provided to self-pay patients and charity care patients, 63.38% to Medicare patients and 6.68% to Medicaid patients.

On page 76, the applicant provides the assumptions and methodology used to project payor mix during the first three full fiscal years of operation following completion of the project. The projected payor mix is reasonable and adequately supported for the following reasons:

- On page 76, the applicant states that the projected payor mix is based on the most recent experience at Mission Hospital and has remained a constant for cardiac catheterization.
- The applicant states that Medicare and Medicaid projections are based on the slight shift from self-pay to Medicare due to the aging population and resources deployed to assist with Medicaid qualification for the uninsured.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L, page 77, 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 78, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes. In Section M, page 78, the applicant provides a list of residents and fellows.

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

- (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 unit of fixed cardiac catheterization equipment, pursuant to the need determination in the 2019 SMFP for a total of five cardiac catheterization units upon project completion.

On page 173, the 2019 SMFP defines the service area for cardiac catheterization equipment (shared or fixed) as “...*the cardiac catheterization equipment planning area in which the equipment is located. The cardiac catheterization equipment planning areas are the same as the Acute Care Bed Service Areas defined in Chapter 5, Acute Care Beds, and shown in Figure 5.1. The cardiac catheterization equipment service area is a single county, except where there is no licensed acute care hospital located within the county.*” Figure 5.1 shows Buncombe County as a multicounty acute care bed service area. Thus, the service area for this proposal is Buncombe, Graham, Madison and Yancey Counties. Facilities may also serve residents of counties not include in their service area.

In Section N, page 80, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services. On page 80, the applicant states:

“Mission is the only provider of tertiary and cardiac cath services in the region thus no other entities will be affected by the addition of a fifth cardiac cath lab at Mission.

...

“The proposed project will foster cost containment and improve quality of care through efficient design and implementation. As discussed throughout this application, the additional cardiac catheterization lab will provide Mission the flexibility to meet current and future demands for comprehensive cardiac care and ensure that its residents will continue to have readily access to comprehensive cardiac services.”

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates:

- The cost-effectiveness of the proposal (see Sections F, N, and Q of the application and any exhibits)
- Quality services will be provided (see Section N and O of the application and any exhibits)
- Access will be provided to underserved groups (see Section L and N of the application and any exhibits)

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.

- (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, page 86, the applicant identifies the hospitals located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of eight of this type of facilities located in North Carolina. However, Mission Hospital is the only facility that provides cardiac catheterization services.

In Section O, page 89, the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents related to quality of care have not occurred in any of these facilities. According to the files in the Acute Care and Home Care Licensure and Certification Section, DHSR, during the 18 months immediately preceding submission of the application through the date of this decision, incidents related to quality of care have not occurred in this facility. After reviewing and considering information provided by the applicant and by the Acute Care and Home Care Licensure and Certification Section and considering the quality of care provided at this facility, 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;*

-C- In Section C, page 49, the applicant projects cardiac catheterization utilization, including as a percentage of capacity, during the fourth quarter of the third year following completion of the proposed project, as illustrated in the table below:

	Project Year 3
	7/1/22-6/30/23
Diagnostic Cases	3,926
Interventional Cases	1,510
Total Equivalent	6,568
Number of labs	5
Capacity	7,500
% of Capacity	88.0%

- (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;*
 - C- In Section Q, the applicant projects to perform 1,517 interventional/therapeutic cardiac catheterization procedures during the third year of operation following completion of the project. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.
 - (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;*
 - C- In Section C, page 49, the applicant projects to perform 3,900 diagnostic cardiac catheterization procedures during the third year of operation following completion of the project. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.
 - (4) *at least 50 percent of the projected cardiac catheterization procedures shall be performed on patients residing within the primary cardiac catheterization service area;*
 - C- In Section C.3, pages 30-31, the applicant projects that 82.97 percent of cardiac catheterization procedures will be performed on patients residing within the primary service area; Buncombe, Henderson, Haywood, McDowell, Transylvania, Macon, Jackson, Madison, Swain and Yancey Counties. The discussion regarding patient origin found in Criterion (3) is incorporated herein by reference.
- (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;*
 - (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;*

- (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;*
- (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*
- (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;*

-C- According to the most recent licensure renewal application on file with the Division of Health Service Regulation, the facility demonstrated that its existing items of cardiac catheterization equipment operated at an average of at least 80 percent of capacity during the twelve-month period, as illustrated below:

Mission Hospital		
# of units fixed cardiac catheterization equipment		4
Diagnostic Procedures	3797	3797
Interventional (Therapeutic) Procedures x 1.75 equals Diagnostic-Equivalent Procedures	1,461 x 1.75	2,557
Total Diagnostic-Equivalent Procedures		6,354
Total Capacity (# of Units x 1,500)	4 x 1,500	6,000
Utilization of Capacity (Diagnostic-Equivalent Procedures / Capacity)		106%

Source: license renewal application 10/2017-9/2018

(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*

-C- In Section C, page 49, the applicant demonstrates that its four existing units of fixed cardiac catheterization equipment shall be utilized at an average annual rate of at least 60 percent of capacity as measured during the fourth quarter of the third year following completion of the proposed project as shown in the table below:

Mission Hospital		
# of units fixed cardiac catheterization equipment		4
Diagnostic Procedures	3,926	3,926
Interventional (Therapeutic) Procedures x 1.75 equals Diagnostic-Equivalent Procedures	1,510 x 1.75	2,642
Total Diagnostic-Equivalent Procedures		6,568
Total Capacity (# of Units x 1,500)	4 x 1,500	6,000
Utilization of Capacity (Diagnostic-Equivalent Procedures / Capacity)		109%

Source: Section C, page 49

As show in the table above, the existing units of cardiac catheterization equipment are projected to be utilized at an annual rate of 109% as measured during the fourth quarter of the third year following completion of the proposed project.

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

-C- In Section C, pages 41-49, and Form C in Section Q, the applicant documents all of the assumptions and data used in the development of this projections in this Rule.

-NA- The applicant does no propose 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*

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

(2) *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 shared fixed cardiac catheterization equipment.

(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 offer pediatric cardiac catheterization.