REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming
CA = Conforming as Conditioned
NC = Nonconforming
NA = Not Applicable

Decision Date: September 26, 2025 Findings Date: October 3, 2025

Project Analyst: Chalice L. Moore Co-Signer: Lisa Pittman

Project ID #: B-12645-25 Facility: Mission Hospital

FID #: 943349 County: Buncombe

Applicant(s): MH Mission Hospital, LLLP

Project: Acquire no more than one photon-counting CT scanner

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.

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MH Mission Hospital, LLLP (hereinafter referred to as "applicant" or "Mission Hospital") proposes to acquire no more than one photon-counting CT (PCCT) scanner for a total of no more than 10 CT scanners upon project completion.

Need Determination

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

Policies

No policies are applicable to this review.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- The applicant does not propose to develop any beds or services or acquire any medical equipment for which there is a need determination in the 2025 SMFP.
- (2) Repealed effective July 1, 1987.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.

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The applicant proposes to acquire no more than one photon-counting CT scanner for use at Mission Hospital for a total of no more than ten CT scanners upon project completion.

Patient Origin

N.C.G.S. §131E-176(24a) states: "Service area means the area of the State, as defined in the State Medical Facilities Plan or rules adopted by the Department, which receives services from a health service facility." The 2025 SMFP does not define the service area for CT scanners, nor are there any applicable rules adopted by the Department that define the service area for CT scanners. In Section 3, pages 37 and 39, the applicant defines the primary service area as 18-counties in western North Carolina, primarily Buncombe County. Providers may serve residents of counties not included in their service area.

The following table illustrates historical and projected patient origin for CT scans at Mission Hospital.

Mission Hospital CT Scan Services								
County	Historical CY 2024		1st Full FY 01/01/2027 to 12/31/2027		2nd Full FY 01/01/2028 to 12/31/2028		3rd Full FY 01/01/2029 to 12/31/2029	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Buncombe	29,385	61.3%	34,203	61.3%	35,814	61.3%	37,369	61.3%
Henderson	2,730	5.7%	3,180	5.7%	3,330	5.7%	3,475	5.7%
Madison	2,610	5.4%	3,013	5.4%	3,155	5.4%	3,292	5.4%
Haywood	2,329	4.9%	2,734	4.9%	2,863	4.9%	2,987	4.9%
McDowell	1,434	3.0%	1,674	3.0%	1,753	3.0%	1,829	3.0%
Yancey	927	1.9%	1,060	1.9%	1,110	1.9%	1,158	1.9%
Jackson	827	1.7%	949	1.7%	993	1.7%	1,036	1.7%
Transylvania	814	1.7%	949	1.7%	993	1.7%	1,036	1.7%
Macon	791	1.7%	949	1.7%	993	1.7%	1,036	1.7%
Rutherford	546	1.1%	614	1.1%	643	1.1%	671	1.1%
Swain	511	1.1%	614	1.1%	643	1.1%	671	1.1%
Burke	447	0.9%	502	0.9%	526	0.9%	549	0.9%
Mitchell	392	0.8%	446	0.8%	467	0.8%	488	0.8%
Cherokee	245	0.5%	279	0.5%	292	0.5%	305	0.5%
Polk	201	0.4%	223	0.4%	234	0.4%	244	0.4%
Graham	186	0.4%	223	0.4%	234	0.4%	244	0.4%
Avery	98	0.2%	112	0.2%	117	0.2%	122	0.2%
Clay	60	0.1%	56	0.1%	58	0.1%	61	0.1%
All Other North Carolina	1,070	2.2%	1,228	2.2%	1,285	2.2%	1,341	2.2%
North Carolina Total	45,603	95.1%	53,062	95.1%	55,561	95.1%	57,974	95.1%
Out of State	2,327	4.9%	2,734	4.9%	2,863	4.9%	2,987	4.9%
Total	47,930	100.0%	55,796	100.0%	58,424	100.0%	60,961	100.0%

Source: Section C, pages 37-39

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 its historical patient origin, the estimated CY 2024 CT Utilization for Mission Hospital (All Locations) and the projected Cardiac CT Utilization for CY 2027 – CY 2029 at Mission Hospital. The applicant does not anticipate the project to have an impact on patient origin. The applicant's assumptions are reasonable and adequately supported.

Analysis of Need

In Section C, pages 41-54, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below:

- "Population growth and increasing prevalence of cardiovascular disease in western North Carolina, particularly among residents aged 65 and older.
- Mission's leadership as the only tertiary provider of cardiac services, including open heart surgery, in western North Carolina and the trend toward less invasive cardiac care.

- Current technological limitations with existing traditional CT scanners for cardiac imaging include the inability to accommodate certain complex patients.
- The clinical benefits of a PCCT scanner to better serve cardiovascular and other complex neurology and orthopedic patients, as well as special patient populations that have difficulty accessing conventional CT services.
- The significant growth in utilization of CT services at Mission Hospital over the past four years and the resulting capacity constraints for the existing main campus CT units."

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

- Population growth, aging and the rate of cardiovascular disease in Buncombe County drive the need for the proposed photon-counting CT scanner.
- The applicant adequately demonstrates the proposed photon-counting CT scanner will not only add capacity but also improve efficiency reducing scan times for cardiac CT studies and reducing the number of patients that require beta blockers during imaging, while simultaneously delivering higher-quality images.

Projected Utilization

In Section Q, Form C.2a and Form C.2b, the applicant provides historical and projected utilization, as illustrated in the following tables.

Mission Hospital					
CT Scanner					
Historical and Interim Utilization					
Last Full FY Interim Full FY Interim Full FY					
CY 2024 CY 2025 CY 2026					
# of Units	9	9	9		
# of Scans	82,440	88,485	90,387		

Mission Hospital						
CT Scanner						
Utilization upon Project Completion						
	1 st Full FY 2 nd Full FY 3 rd Full FY					
CY2027 CY2028 CY2029						
# of Units	10	10	10			
# of Scans	95,659	100,165	104,515			

In Section Q, Form C Utilization-Assumption and Methodology, pages 116-119, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

• "The proposed project is expected to become operational on January 1, 2027. Because Mission's fiscal year corresponds to the Calendar Year (CY), the first three full fiscal years of the proposed project are CY 2027, CY 2028, and CY 2029."

• The applicant states "CT volume increased significantly from FY 2022 to FY 2023 with the addition of another CT to support the emergency department."

Step 1 - Historical Utilization at Mission Hospital (All Locations)

The applicant stated that the "total CT scans at Mission Hospital (all campuses on the Mission Hospital license) grew at a CAGR of 12.1% for FY 2021-2024, while the cardiac subset of these scans grew even more rapidly, at a CAGR of 16.7%, during this time. In Q1 2025, cardiac scans represented 5.1% of all CT scans performed on Mission CT scanners. This includes the scanners at Mission Cancer Center and Hope Women's Cancer Center that are largely dedicated to Oncology."

Step 2 – Estimate CY 2025 CT Utilization and Mission Hospital (All Locations)

The applicant states that "Volume from September 2024 to November 2024 was impacted by the effects of Hurricane Helene on western North Carolina. Hurricane Helene hit western North Carolina on September 27, 2024. The storm immediately impacted patients' ability to physically access Mission Hospital due to road closures from flooding and tree falls across major roads. ...Mission used the most recent four months of data post hurricane (December 2024 through March 2024) to estimate CY 2025 volume. Using this methodology, Mission estimates a total of 4,425 cardiac CT scans and 88,485 CT scans for CY 2025."

Estimated CY 2025 CT Utilization at Mission Hospital - All Locations						
	Dec-24	Dec-24 Jan-25 Feb -25 Mar-25 Est. 9				
Cardiac CT Scans	346	365	369	395	4,425	
Other CT Scans	6,970	6,984	6,712	7,354	84,060	
Total CT Procedures	7,316	7,349	7,081	7,749	88,485	

Source: Section Q, page 117

Step 3 – Project Cardiac CT Utilization for CY 2026 – CY 2029

"To project cardiac CT utilization for CY 2026-2029, Mission first took the estimated CY 2025 baseline cardiac CT scans and applied a 5% CAGR through 2029 to project baseline cardiac CT scans for the interim and project years, CY 2026 – CY 2029. This rate of growth is less than a third of the 16.7% CAGR from FY 2021 to FY 2024."

Projected CY 2026-2029 Cardiac CT Utilization at Mission Hospital						
	CY2026	CY2027	CY2028	CY2029		
Baseline Cardiac CT Scans	4,646	4,879	5,122	5,379		
Incremental Cardiac Scans with Photon CT		1,610	2,305	2,689		
Total CT Procedures	4,646	6,488	7,428	8,068		
Incremental Cardiac Factor		0.33	0.45	0.50		

Source: Section Q, page 118

Projected utilization is reasonable and adequately supported because the projected growth rate is conservative and based on the historical and projected growth of CT procedures Mission Hospital has experienced during the last three years.

Step 4 – Project Total CT Utilization at Mission Hospital

Projected CT Utilization at Mission Hospital - All Location							
	Estimated Interim CY 2025	Interim CY 2026	PY1	PY2	PY3		
			CY2027	CY2028	CY 2029		
Cardiac CT Scans	4,425	4,646	6,488	7,428	8,068		
Other CT Scans	84,060	85,741	89,171	92,738	96,447		
Total CT Procedures	88,485	90,387	95,659	100,165	104,515		
Number of CT Units	9	9	10	10	10		
CT Scans per Fixed CT	9,832	10,043	9,566	10,017	10,452		

Source: Section Q, page 119

Access to Medically Underserved Groups

In Section C, page 61, the applicant provides the estimated percentage for each medically underserved group, as shown in the following table.

Medically Underserved	Percentage of Total
Groups	Patients
Low income persons	24.2%
Racial and ethnic minorities	8.4%
Women	53.3%
Persons with Disabilities	Not available
Persons 65 and older	45.7%
Medicare beneficiaries	50.4%
Medicaid recipients	16.7%

Source: Section C, page 50

On page 60, the applicant states:

"Mission provides services to all persons in need of medical care regardless of race, color, religion, nationality, or ability to pay. Additionally, as the only trauma center in the region and a safety net hospital, Mission serves many underserved and uninsured individuals. Western North Carolina residents are disproportionately covered by Medicare and/or Medicaid, or are uninsured, compared to most regions of the state and nation. In fact, approximately 24.3% of Mission's inpatient admissions are for self-pay, charity, or Medicaid patients, with 21.8% Medicaid alone, as reported on its 2025 Licensure Renewal Application. Another 53.7% of patient admissions are covered by Medicare. Mission provides robust financial assistance to individuals with no insurance, high-deductible insurance, or coinsurance plans without sacrificing quality of service -- just as it has historically done to meet the health care needs of low-income individuals."

^{*}CMHA and CPN do not maintain data of the number of low income and disabled persons served.

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

- The applicant provides estimated percentages of patients from underserved groups based on historical data from Mission Hospital.
- The applicant provides written statements about offering access to all residents of the service area, including underserved groups and provides a summary of Mission Hospital Non-Discrimination Policy in Exhibit C.6.

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 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 and adequately supports its assumptions

(3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, ... 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.

The applicant proposes to acquire no more than one photon-counting CT scanner for use at Mission Hospital for a total of no more than ten CT scanners upon project completion.

In Section E, pages 69-71, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- Maintain Status Quo The applicant states "Mission Hospital, as the region's tertiary referral center and safety net hospital, has an obligation to have the resources available to meet the region's demand for the highest acuity services. Mission takes this obligation very seriously and is committed to pursuing every measure possible to ensure its life-saving services are available to the region's population. To this end, maintaining status quo, is a scenario in which Mission maintains constrained capacity on its existing CT units and is unable to provide non-invasive diagnostic imaging to many cardiac patients due to equipment limitations, in not optimal. This is not a viable option because Mission Hospital would not expand its CT diagnostic capacity and the need for an additional unit would continue to exist." (pg. 69)
- Replace Existing Traditional CT with new PCCT- The applicant states, "replacing one of Mission's existing traditional CT scanners with a new PCCT scanner was considered but ultimately found to be neither efficient nor cost-effective. As previously noted, Mission is experiencing a growing demand for cardiac CT imaging, along with increasing volume for its overall CT units. These trends highlight the need for additional CT capacity, not the replacement of existing equipment. "(pg. 70)
- **Develop the Photon-Counting CT Scanner at Another Location** The applicant states that "placing the proposed PCCT at a different location was considered. However, because cardiac imaging services are centralized on Mission's main campus, locating the PCCT scanner elsewhere would not be operationally appropriate and would not address the capacity constraints for CT services on the main campus." (pg.70)
- Add Conventional CT Instead of a PCCT Scanner The applicant states that "while the addition of a traditional CT scanner would relieve capacity constraints on existing CT units, it would not allow for enhanced imaging capabilities and increased patient access that the PCCT will afford. The PCCT is uniquely suited to meet Mission's current imaging needs as it brings enhanced cardiac imaging, quicker service delivery, and higher quality imaging that traditional CT units." (pg.70)
- The applicant provides credible information to explain why it believes the proposed project is the most effective alternative.
- The application is conforming to all other statutory and regulatory review criteria. Therefore, the application can be approved.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- 1. MH Mission Hospital, LLLP, (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.
- 2. The certificate holder shall acquire no more than one photon-counting CT scanner for a total of no more than ten CT scanners at Mission Hospital upon project completion.
- 3. 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 January 1, 2026.
- 6. 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.
- 7. 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.

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Capital and Working Capital Costs

In Section Q, page 120, the applicant projects the total capital cost of the project, as shown in the following table:

PROJECTED CAPITAL COSTS	MISSION HOSPITAL	TOTAL
Construction Contract	\$699,000	\$699,000
Architect/Engineering Fees	\$163,000	\$163,000
Medical Equipment	\$2,791,474	\$2,791,474
Furniture	\$13,000	\$13,000
Consultant Fees	\$50,000	\$50,000
Total Capital Cost	\$3,716,474	\$3,716,474

In Section F, page 74, the applicant states there will be no start-up costs or initial operating expenses because Mission Hospital already offers surgical services.

In Section Q, page 121, 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:

• The applicant states "Project costs associated with the proposed project are supported by the vendor quote for the CT unit (See Exhibit C-1.2) and the architectural letter (See Exhibit K-2.2)

Availability of Funds

In Section F, pages 72-73 the applicant states that the capital cost will be funded as shown in the following table:

Sources of Capital Cost Financing

Түре	MISSION HOSPITAL	TOTAL
Loans	\$	\$
Cash and Cash Equivalents Accumulated reserves or OE *	\$3,716,474	\$3,716,474
Bonds	\$	\$
Other (Specify)	\$	\$
Total Financing	\$	\$

^{*} OE = Owner's Equity

In Exhibit F.2 the applicant provides a June 6, 2025, letter signed by the Chief Financial Officer for MH Mission Hospital, LLLP., confirms the availability of sufficient funds for the project capital needs and commits the funds to the project development. The applicant also provides a copy of the audited financial statements which confirms the availability of sufficient funds for the project. 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 project completions. In Forms F.2 and F.3, the applicant projects that

revenues will exceed operating expenses in the first three full fiscal years following completion of the project, as shown in the table below.

Misson Hospital	1 ST FULL FY	2 ND FULL FY	3 RD FULL FY
CT Utilization	CY 2027	CY 2028	CY 2029
Total Procedures	95,659	100,165	104,515
Total Gross Revenues (Charges)	\$3,441,601,000	\$3,892,014,356	\$4,385,921,139
Total Net Revenue	\$621,204,826	\$663,475,899	\$706,135,349
Average Net Revenue per procedure	\$6,494	\$6,624	\$6,756
Total Operating Expenses (Costs)	\$573,783,613	\$618,615,736	\$664,430,050
Average Operating Expense per procedure	\$5,998	\$6,176	\$6,357
Net Income	\$47,421,213	\$44,860,163	\$41,705,299

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, including projected utilization, costs and changes. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion 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 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 2025 SMFP does not define a service area for CT scanners. In Section G, page 81, the applicant defines the service area as 18-counties in western North Carolina, though it expects to serve patients from other areas as well. Mission Hospital is not aware of a public data source that provides a county-level inventory of all existing and approved facilities, including diagnostic centers, which provide CT services. As discussed previously, the proposed PCCT scanner will be the first of its kind in western North Carolina.

In Section G, page 81, the applicant states that it is not aware of a public data source that provides a county-level inventory of all existing and approved facilities, including diagnostic centers, that provide CT services.

In Section G, page 81, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved CT services in Buncombe County. The applicant states:

"Again, the proposed PCCT scanner will be the first of its kind in western North Carolina and will be used to assess high-risk CAD and other patients that were previously unable to be diagnosed using traditional CT, including those currently operated by Mission. Further, as discussed in **Section C, Question 4** [sic], Mission's cardiac CT volume has grown rapidly in recent years and the proposed PCCT will meet a distinct and unique need. For these reasons, the proposed project will not result in any unnecessary duplication."

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area because the applicant adequately demonstrates that the proposed photon-counting CT scanner is needed in addition to the existing or approved CT scanners.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

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In Section Q, Form H, page 128, the applicant provides current and projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

Mission Hospital	Current Staff		Projected FTE Staff	•	
Mission Hospital		1 st Full FY	2 nd Full FY	3 rd Full FY	
Radiology Technologists	36	39	39	39	
Other- Transport	3	6	6	6	
TOTAL	39	45	45	45	

The assumptions and methodology used to project staffing are provided in Section Q, page 128. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in F.3b. In Section H, pages 83-84, 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:

- Mission Health has developed and implemented in-house training programs for patient care technicians/nurse assistants.
- All clinical staff are required to maintain certification by an appropriate, nationally recognized certification-accrediting body and attend in-service training.
- Mission Health collaborates with academic partners including universities and colleges in western North Carolina and beyond.

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

Ancillary and Support Services

In Section I, page 87, the applicant identifies the necessary ancillary and support services for the proposed services, and 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 Mission Hospital currently provides these services to patients and will continue to provide the service after the proposed project is developed.

Coordination

In Section I, page 88, the applicant describes its existing and proposed relationships with other local health care and social service providers. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the following:

- Mission Hospital is an established healthcare system in the service area with existing relationships with local health care and social service providers.
- Exhibit I.1 includes letters of support from physicians and other providers.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

NA

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

(10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new

members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:

- (i) would be available under a contract of at least 5 years duration;
- (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
- (iii) would cost no more than if the services were provided by the HMO; and
- (iv) would be available in a manner which is administratively feasible to the HMO.

NA

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

C

The applicant proposes to acquire no more than one photon-counting CT scanner for use at Mission Hospital for a total of no more than ten CT scanners upon project completion.

In Section K, page 91, the applicant states that the project involves the renovation of 740 square feet of existing space. Line drawings of the project are provided in Exhibit K.1-1.

In Section K, page 92, the applicant adequately explains why the proposal will not unduly increase the cost to the applicant of providing the proposed services or the cost and charges to the public for the proposed services. The applicant states:

"This project will not increase Mission Hospital's cost of care, nor will it result in higher charges to the public. In fact, it will enhance service efficiency within the hospital's radiology department by expanding CT capacity and enabling care for complex patients who cannot be adequately served by existing imaging modalities. Additionally, other hospital services that rely on imaging—such as emergency care, cardiology, oncology, and surgery—will also benefit from improved access to advanced imaging technology. The project will enhance operational efficiency and improve patient access to care, ultimately improving patient safety and experience—without increasing the cost of services or patient charges."

In Section K, pages 92-93, the applicant identifies any applicable energy saving features that will be incorporated into the construction plan.

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 ... 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;

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In Section L, page 95, the applicant provides the historical payor mix during FY2024 illustrated in the following table.

Payor Source	Percentage of Total Patients Served
Self-Pay	6.3%
Charity Care^	1.2%
Medicare*	50.4%
Medicaid*	16.7%
Insurance*	22.3%
Workers Compensation^^	Included in Other
TRICARE^^	0.3%
Other (Other Payor)^^	2.8%
Total	100.0%

^{*} Including any managed care plans.

In Section L, page 96, the applicant provides the following comparison.

	Last Full FY Before Submission of the Application	
Mission Hospital	% of Total Patients	% of the Population of the Service Area*
Female	53.3%	51.8%
Male	46.7%	48.2%
Unknown	1.0%	0.0%
64 and Younger	54.3%	78.2%
65 and Older	45.7%	21.8%
American Indian	0.7%	0.6%
Asian	0.7%	1.5%
Black or African-American	7.0%	6.0%
Native Hawaiian or Pacific Islander	0.0%	0.2%
White or Caucasian	81.1%	89.4%
Other Race	0.0%	2.3%
Declined/Unavailable	10.5%	Not applicable

^{*} The percentages can be found online using the United States Census Bureau's QuickFacts located online http://www.census.gov/quickfacts/fact/table/US/PST045218.

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 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;

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Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 97, the applicant states it has no such obligation.

In Section L, page 99, the applicant states, "on 2/24/2024, Mission Hospital received a complaint from Disability Rights North Carolina alleging that a patient was being subjected to abuse related to unlawful mechanical restraint. Records were supplied to Disability Rights North Carolina on 2/26/2024. Additionally, North Carolina Department of Health and Human Services (DHHS) reviewed this patient's record

during a recent hospital survey that concluded on May 23, 2024. No opportunities for improvement were identified regarding the care of this patient by DHHS. No additional actions are required at this time."

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

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In Section L, page 99, the applicant projects the following payor mix during the third full fiscal year of operation following completion of the project, as illustrated in the following table.

Payor Source	Percentage of Total Patient Served	
Self-Pay	6.3%	
Charity Care^	1.2%	
Medicare*	50.4%	
Medicaid*	16.7%	
Insurance*	22.3%	
Workers Compensation^^	Included in Other	
TRICARE^^	0.3%	
Other (Other Payor)^^	2.8%%	
Total	100.0%	

^{*} Including any managed care plans.

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 6.3% of total services will be provided to self-pay patients, 50.4% to Medicare patients and 16.7% to Medicaid patients.

In Section L, page 99, the applicant provides the methodology and assumptions used to calculate these projections:

[^]CPN 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.

"The payor mix of CT patients served is not expected to change from historical experience. The payor mix of patients and revenue (as shown in Form F.2b) is not exactly the same as would be expected."

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.

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In Section L, page 101, the applicant adequately describes the range of means by which patients will have access to the proposed services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

The applicant proposes to acquire no more than one photon-counting CT scanner for use at Mission Hospital for a total of no more than ten CT scanners upon project completion.

In Section M, page 102, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M.1. The applicant adequately demonstrates that health professional training programs in the area have access to the facility for training purposes based on the following:

- Mission Hospital maintains an affiliation agreement to support and serve as the major participating site for the residency programs sponsored by MAHEC.
- Mission Health, in partnership with Asheville-Buncombe Technical Community College, provides educational training opportunities for students from several programs, including but not limited to: Associate Degree in Nursing, Licensed Practical Nursing, Nurse Aide I & II, Emergency Medical Science, Sonography, Phlebotomy, Radiography, and Occupational Therapy Assistant.
- Mission Health, in partnership with Western Carolina University, provides educational training opportunities for students from several programs, including, but not limited to: Nursing (seven nursing degree programs), Physical Therapy, Speech Language Pathology, Emergency Medical Care, Social Work (bachelor's and master's level), Mental Health Counseling, and Clinical Psychology (master's and doctorate level).

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

The applicant proposes to acquire no more than one photon-counting CT scanner for use at Mission Hospital for a total of no more than ten CT scanners upon project completion.

The 2025 SMFP does not define a service area for CT scanners. In Section C, pages 37 and 39, the applicant defines the service area as 18-counties in western North Carolina, though it expects to serve patients from other areas as well. Mission is not aware of a public data source that provides a county-level inventory of all existing and approved facilities, including diagnostic centers, which provide CT services. As discussed previously, the proposed PCCT scanner will be the first of its kind in western North Carolina.

In Section G, page 81, the applicant states that it is not aware of a public data source that provides a county-level inventory of all existing and approved facilities, including diagnostic centers, that provide CT services.

In Section N, page 105, 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 cost-effectiveness, quality and access to the proposed services. The applicant states,

"The proposed project is expected to enhance competition in the service area by promoting cost effectiveness, quality, and access to CT imaging services. As discussed in **Section C, Question 4** [sic], the proposed PCCT scanner will be the first of its kind in western North Carolina, bringing significant clinical benefits – particularly in cardiac imaging. Notably, it will enable the assessment of high-risk CAD patients who were previously unable to be served due to technological limitations of existing traditional CT scanners. By advancing cardiac diagnosis and expanding imaging capabilities, this proposed project will foster greater competition and elevate care standards."

Regarding the impact of the proposal on cost effectiveness, in Section N, pages 106, the applicant states,

"The proposed project will have a positive impact on the cost effectiveness of CT diagnostics for both the patient and the facility. Patients benefit from superior imaging quality that has been shown to result in more accurate diagnoses, which positively impacts the evaluation of treatment alternatives and can result in less invasive treatment options. Further, PCCT provides the alternative for CT imaging for an entire subset of patients that cannot receive imaging due to risk or special circumstances and would otherwise require a more invasive and costly diagnostic alternative."

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

Regarding the impact of the proposal on quality, in Section N, page 107, the applicant states,

"The addition of a PCCT scanner at its main campus will enhance the quality of health services available to the community by improving access to specialized equipment. This advanced technology will facilitate the diagnosis and treatment planning of high-risk CAD patients and CABG patients, working in conjunction with Mission Hospital's cardiology services."

See also Section O of the application and any exhibits.

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 107, the applicant states,

"The PCCT scanner will provide Mission Hospital the flexibility to meet the growing need for CT services while expanding access for the most complex cardiac patients. It will also ensure that residents of the health service area have timely access to high quality, affordable diagnostic imaging. As demonstrated in the table in Section C, Question 6,

Mission Hospital proposes to continue serving those who are medically underserved, including low-income persons, racial and ethnic minorities, women, person with disabilities, persons ages 65 and older, Medicare beneficiaries, and Medicaid beneficiaries."

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:

- 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.
- 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.
- 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.

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In Form O, Section Q, page 129, the applicant identifies six diagnostic centers located in North Carolina owned, operated or managed by the applicant or a related entity.

In Section O, page 111, the applicant states that, during the 18 months immediately preceding the submittal of the application, no incidents related to quality of care occurred in any of these facilities. See Exhibits 0–5.1. 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.

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The Criteria and Standards for Computed Tomography Equipment promulgated in 10A NCAC 14C .2300 were repealed effective January 1, 2022. Therefore, there are no rules applicable to this review.