

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: September 25, 2023

Findings Date: September 25, 2023

Project Analyst: Tanya M. Saporito

Co-Signer: Mike McKillip

Project ID #: B-12380-23

Facility: Mission Hospital-Mission FSER West

FID #: 230341

County: Buncombe

Applicant: MH Mission Hospital, LLLP

Project: Develop a freestanding emergency department in western Buncombe County licensed under Mission Hospital

REVIEW CRITERIA

G.S. 131E-183(a): The Department shall review all applications utilizing the criteria outlined in this subsection and shall determine that an application is either consistent with or not in conflict with these criteria before a certificate of need for the proposed project shall be issued.

- (1) The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service, health service facility, health service facility beds, dialysis stations, operating rooms, or home health offices that may be approved.

C

MH Mission Hospital, LLLP, hereinafter referred to as Mission Hospital or “the applicant,” proposes to develop a freestanding emergency department (ED), Mission Hospital-Mission FSER West (Mission FSER West) in western Buncombe County licensed under Mission Hospital.

Need Determination

There is no need determination in the 2023 State Medical Facilities Plan (SMFP) that is applicable to the proposed project.

Policies

There is one policy in the 2023 SMFP which is applicable to this review: *Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities.*

Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities, on page 30 of the 2023 SMFP states:

“Any person proposing a capital expenditure greater than \$4 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178 shall include in its certificate of need application a written statement describing the project’s plan to assure improved energy efficiency and water conservation.

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

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

The proposed capital expenditure for this project is greater than \$5 million. In Section B, page 31, the applicant provides a written statement describing the project’s plan to assure improved energy efficiency and water conservation. The applicant states that the proposed project will utilize experienced architects and engineers to ensure improved energy efficiency and water conservation in the facility design.

The applicant adequately demonstrates that the application includes a written statement describing the project’s plan to assure improved energy efficiency and water conservation. The application is consistent with Policy GEN-4.

Conclusion

The Agency reviewed the:

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

- Responses to comments
- Remarks made at the public hearing

Based on that review, the Agency concludes that the application is conforming to this criterion because the applicant adequately demonstrates the proposal is consistent with Policy GEN-4 based on its representations that the project includes a plan for energy efficiency and water conservation.

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

C

The applicant proposes to develop a freestanding ED in western Buncombe County, licensed under Mission Hospital. In Section C.1, pages 35-36, the applicant describes the project as follows:

“In this application, Mission proposes to construct a 10,800 square-foot freestanding emergency room on approximately 6 acres of a 34.78 acre plot of land situated to the northwest of the intersection of I-40 and Smokey Park Highway, approximately 7 to 8.5 driving miles from the main Mission ED depending on the route. ...

The following components will be a part of the proposed facility:

- *12 exam/treatment rooms – including 6 general exam rooms, 1 airborne infection isolation exam room (AII), 1 bariatric exam room, 1 pelvic exam room, 1 behavioral exam room, a triage room, and 1 trauma/resuscitation room;*
- *One CT scanner;*
- *One ultrasound machine;*
- *One fixed x-ray equipment;*
- *Laboratory services; and*
- *Pharmacy services.*

Mission FSER West proposes to offer only emergency services. All ancillary services, including diagnostic imaging services, lab services, and pharmacy services, will be provided solely as components of emergency visits.”

Patient Origin

N.C. Gen. Stat. §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 2023 SMFP does not define the service area for emergency departments. In Section C.3, page 45, the applicant identifies its service area for the proposed emergency services by ZIP Code. Facilities may also serve residents of counties not included in their service area. The following table, from application page 45 illustrates the applicant’s propose service area:

ZIP CODE AND COUNTY	THIRD FULL FY OF OPERATION FOLLOWING PROJECT COMPLETION CY 2028	
	PATIENTS	% OF TOTAL
28806-Buncombe	1,337	14.7%
28715-Buncombe	2,637	29.0%
28748-Buncombe	1,503	16.5%
28801-Buncombe	495	5.4%
28787-Buncombe	226	2.5%
28805-Buncombe	208	2.3%
28804-Buncombe	176	1.9%
28753-Madison	484	5.3%
28716-Haywood	535	5.9%
28701-Buncombe	234	2.6%
28786-Haywood	243	2.7%
28721-Haywood	118	1.3%
28743-Madison	115	1.3%
28785-Haywood	94	1.0%
28745-Haywood	9	0.1%
All Other Inmigration	682	7.5%
Total	9,095	100.0%

Source: Table on page 45 of the application.

In Section C, page 46, the applicant provides the assumptions and methodology used to project patient origin for the proposed ED. The applicant’s assumptions are reasonable and adequately supported based on the historical utilization of emergency services by Mission Hospital’s existing patients residing in the proposed service area.

Analysis of Need

In Section C.4, pages 47-81, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. The applicant states the need for the proposed project is based on the following:

- The projected population growth and aging in the proposed service area and the need for increased access to emergency services.
- The residential development and economic growth in the proposed service area and increasing traffic congestion issues which make access to emergency services difficult for service area residents.

- Problems with geographic accessibility to ED services on the Mission Hospital main campus in downtown Asheville due to traffic congestion.
- Documented community support that reflects resident concerns with timely access to emergency services in Asheville and the service area.
- Existing capacity constraints at the Mission Hospital main campus ED due to rising ED volumes and increasing patient acuity.
- Increasing wait times for patients in the main hospital ED and operational and bed capacity limitations in both the ED and the hospital ICU.
- Inability to accept transfers of high acuity patients in the service area due to capacity constraints, and delay for EMS providers who must wait while the patient being transported is processed.

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

- The applicant provides demographic data, including population growth projections for different age groups for the proposed service area from Claritas Spotlight to support its projections.
- The applicant provides internal information and data on emergency department transfers to the ED on the Mission Hospital main campus.
- The applicant provides data from the Buncombe County Planning Department documenting traffic congestion and residential and business development in the proposed service area.
- The applicant provides historical ED utilization data for hospital's total service area and for the primary service area for proposed project.

Projected Utilization

In Section Q, the applicant provides projected utilization of the freestanding ED through the first three full fiscal years (FYs) of operation, calendar years (CYs) 2025-2028 as summarized in the following table:

MISSION WEST FSER PROJECTED UTILIZATION				
	PARTIAL 1 ST YEAR 7/1/2025- 12/31/2025	1 ST FULL FY CY 2026	2 ND FULL FY CY 2027	3 RD FULL FY CY 2028
Emergency Department				
# of Treatment Rooms	12	12	12	12
# of Visits	4,220	8,659	8,855	9,095
Observation Beds (unlicensed)				
# of Beds	0	0	0	0
Days of Care	216	444	454	466
CT Scans				
# of Units	1	1	1	1
# of Scans	1,015	2,082	2,129	2,187
Fixed X-Ray (incl. fluoroscopy)				
# of Units	1	1	1	1
# of Procedures	1,265	2,316	2,378	2,443
Ultrasound				
# of Units	1	1	1	1
# of Procedures	139	285	291	299

In Section C.4, pages 81-91, the applicant provides the assumptions and methodology used to project utilization, which is summarized below:

Step 1: Calculate historical trend in service area ED volume from 2017-2019 – The applicant calculated the historical average growth rate in ED utilization for all service area all providers using NCHA-HIDI Market Data. See the table on page 82 of the application. On page 82, the applicant states: “While market volume has been impacted by COVID-19, it is expected that population growth and aging will continue to result in growing demand for ED services. To reflect this, Mission used the ZIP code specific CAGR (compound annual growth rate) from 2017-2019 to project market visits forward through the 3rd project year. All but three ZIP codes from the service area experienced growth in ED volume during the time frame and the service area as a whole experienced a 1.4 percent growth in ED volume....”

*Step 2: Project market ED volume based on historical trends – The applicant projects the ED utilization for the proposed service area through the first three full fiscal years of the project based on the ZIP code specific CAGR calculated in Step 1 above and using CY 2022 annualized as a base. See the table on page 83 of the application. On pages 83-84, the applicant states, “If the Agency has historically found it reasonable to accept the continuous 1.4 percent CAGR through a projection period, then the continued 1.4 percent CAGR after the COVID adjustment is very conservative. Mission could have reasonably projected for ED visits to rebound fully to the ... non-COVID trend through 2028, which has been accepted by the Agency in approving many applications for a wide variety of services over the last several uncertain years. When reviewing the projection from a macro level, Mission’s market ED visit volume is very reasonable and exceedingly conservative. **Mission’s projection of 84,896 market visits in 2028 is still well below the 2019 market experience of 86,403 before the pandemic** [emphasis in original].” See the table on page 83 that illustrates ED volume growth projections through CY 2028, the third PY, applying the 1.4% CAGR by ZIP code. On page*

84 the applicant states: *“Mission’s methodology reflects and relies upon the market’s actual decline in ED visits during the early months of the COVID pandemic; the actual historical rebound utilization experience in the ensuing months; and the historical CAGR pre-pandemic, which reflects the increasing demand generated by population growth and aging.”*

Step 3: Establish base 2022 Mission market share by ZIP code – The applicant established a baseline market share based on annualizing the first three quarters of actual utilization by ZIP code. See the table on page 85 of the application that illustrates the historical market share by ZIP code.

Step 4: Establish incremental market share and projected FFY 1 through FFY 3 volume - The applicant projects incremental market share increases from the proposed service area for the freestanding ED in west Asheville. The applicant does not project to capture any incremental market share from the ZIP codes in the secondary and tertiary service areas. See the table on page 86 of the application that illustrates the market share projections. The applicant states, *“Using historical market share data as a base, Mission first conservatively established its 1st partial FFY (July 2025 to December 2025) and its 1st FFY service area market share by ZIP code. For the 1st partial FFY, Mission assumed the incremental market share would be half of the incremental market share experienced in the 1st FFY. For the 2nd FFY, Mission grew the incremental market share from the 1st FFY by 0.6 percent; the same was done for the 3rd FFY using the 2nd FFY as the base.”*

On pages 86-87, the applicant describes the steps it took to project its partial first FFY market share:

- *“The partial 2025 market demand is based on Step 2 above divided by 2 to reflect a half year.*
- *Using the base 2022 market share by ZIP code from Step 3, Mission added the projected incremental market share percentages for partial 2025 (Step 4A) to establish Mission’s total market share by ZIP code for the first 1st Partial FFY. As stated before, there is only incremental market share from the PSA and none from the SSA and TSA.*
- *Mission then took the multiplied the 2025 market demand (Step 2) by the projected market share to derive the projected total Mission ED visits for the 1st Partial FFY.*
- *Mission then established the percent shift to the proposed FSER by ZIP code. Mission assumed a higher percent shift of patients from the service area ZIP codes that are in closer proximity to the proposed FSER location.*
- *Finally, Mission multiplied its total visits for the 1st Partial FFY by the projected shift percentages to calculate the volume for the proposed FSER in the 1st Partial FFY.*
- *Additionally, Mission assumed 7.5 percent in-migration based on the experience of FSERs operated by HCA affiliates*

The steps above were repeated for the 1st through the 3rd FFYs maintaining a constant percent shift by ZIP code for FSER volume. Note that shift projections remain the same from year to year with subtotals varying by the percent growth in each ZIP code.”

See the tables on application pages 87-90 that illustrate the projections.

In Section Q, page 153 of the application, the applicant describes the assumptions and methodology for projecting utilization of the proposed CT scanner as follows:

“To the projected Mission CT volume based on historical growth rates, the incremental CT volume associated with the FSER has been added. This represents CT scan on the portion of ED patients resulting from incremental market share and not just a shift of volume from the Mission ED to the FSER.”

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

- Projected utilization is supported by the historical utilization of existing ED services at Mission Hospital’s main campus.
- Projected utilization is supported by the applicant’s historical (FY 2022) ED market shares by ZIP code area in the proposed service area.
- The applicant provides reliable population growth and aging data to support its utilization projections.

Access to Medically Underserved Groups

In Section C.6, page 96, the applicant states the proposed freestanding ED will be accessible to all persons in need of medical and emergency care, including low income, racial and ethnic minorities, women, persons with disabilities, the elderly, Medicare and Medicaid beneficiaries. On page 97, the applicant provides the estimated percentage for each medically underserved group, as shown in the following table:

MEDICALLY UNDERSERVED GROUPS	PERCENTAGE OF TOTAL PATIENTS
Low income persons*	52.1%
Racial and ethnic minorities	18.4%
Women	54.7%
Persons with Disabilities	Applicant does not track
Persons 65 and older	18.5%
Medicare beneficiaries	22.5%
Medicaid recipients	30.5%

Source: Table on page 97 of the application.

*The applicant states “Low income persons” includes self-pay, charity care and Medicaid patients

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 information provided in Section C.6, pages 96-97, Section L, pages 131-138, and referenced exhibits.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Remarks made at the public hearing

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

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

NA

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

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

CA

The applicant proposes to develop a freestanding emergency department in western Buncombe County licensed under Mission Hospital.

In Section E, pages 105-106, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- Maintain the status quo – The applicant states the level of demand for ED and acute services at Mission Hospital necessitate the addition of the proposed FSER. The applicant states the population of Buncombe County continues to increase, as does traffic congestion that impedes easy access to downtown Asheville. Additionally, challenges faced by EMS providers in the region are forcing emergency responders to travel further than necessary. Maintaining the status quo would fail to address these issues and thus is not an effective alternative.
- Expand emergency department capacity at Mission Hospital – The applicant considered expanding emergency capacity at the existing hospital, but states this is not an effective alternative because the ED at Mission Hospital is currently at capacity.

Additionally, EMS services and patients who present to the ED experience significant delays in transportation and treatment times, respectively. The applicant states that the most effective solution is represented by this proposal: develop a freestanding ED in western Buncombe County, thereby serving more patients and relieving capacity constraints at the existing hospital-based ED.

- Develop a freestanding emergency department in an existing facility – The applicant states that there are no existing Mission-owned facilities in Buncombe County west of the downtown Asheville business district where Mission Hospital is located that would be able to accommodate an FSER. Additionally, the applicant states that HCA, Mission’s parent company, operates 130 FSERs throughout the country, and has determined that retrofitting an existing facility to accommodate an FSER is neither a viable nor cost-effective method of efficiently serving emergency patients. Thus, this is not an effective alternative.
- Develop a freestanding emergency department elsewhere – The applicant states that developing a freestanding emergency department in another location in Buncombe County is a less effective alternative because the lack of access to emergency services in western Buncombe County, traffic congestion, residential development and population growth in western Buncombe County make the proposed location a more effective alternative than elsewhere in Asheville or surrounding areas.

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

- The applicant provides reasonable information to explain why it believes the proposed project is the most effective alternative.
- The application is conforming to all other statutory review criteria. Therefore, the application can be approved.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Remarks made at the public hearing

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 develop a freestanding emergency department in western Buncombe County to be licensed under Mission Hospital.**
 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 2, 2024.**
 4. **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.**
 5. **For the first three years of operation following completion of the project, the certificate holder shall not increase charges more than 5% of the charges projected in Section Q of the application without first obtaining a determination from the Healthcare Planning and Certificate of Need Section that the proposed increase is in material compliance with the representations in the certificate of need application 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.**
 6. **The certificate holder shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicant proposes to develop a freestanding emergency department in western Buncombe County licensed under Mission Hospital.

Capital and Working Capital Costs

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

Site Costs	\$11,146,000
Construction Costs	\$9,120,000
Miscellaneous Costs	\$9,108,000
Total	\$29,374,000

In Section Q, “Assumptions: Form F.1a Capital Cost”, page 159 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 information provided in Section F.2, Exhibit F-1, and Section Q, Form F.1a of the application.

In Section F.3, the applicant projects no start-up costs or initial operating expenses for the proposed project. On page 109, the applicant states,

“MH Mission Hospital, LLLP will not experience start-up costs per the state’s definition because the proposed service will be a satellite of an existing service at Mission Hospital. Also, because the applicant currently provides emergency services, it has trained staff available for start-up. ...

MH Mission Hospital, LLLP will not incur initial operating expense as the proposed project involves developing a satellite of Mission Hospital emergency department at which revenues will exceed expenses from day one of the new project because of ongoing, existing operations at the Mission Hospital ED and Imaging locations.”

Availability of Funds

In Section F.2, page 107, the applicant states that the capital cost will be funded by MH Mission Hospital, LLLP as shown in the table below:

Loans	\$0
Accumulated Reserves or Owner’s Equity	\$29,374,000
Bonds	\$0
Other	\$0
Total	\$29,374,000

Exhibit F-1.1 contains an April 12, 2023 letter signed by a licensed architect attesting to the capital cost for the project. The letter is also signed by the Director of Facility Planning, Design and Construction for Mission Hospital certifying the applicant’s intention to commit funds for the capital costs for the proposed project. Exhibit F-2.1 contains an April 4, 2023 letter signed by the Chief Financial Officer for HCA Healthcare, the parent company to Mission Hospital, that confirms HCA’s intent to provide sufficient funding for the project development and attesting to sufficient cash reserves for the proposed capital cost. Exhibit F.-2.2 contains the

annual report (Form 10-K) for HCA Healthcare, Inc. for FY 2022 that indicates sufficient cash reserves for the project. The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project based on the information and documentation provided in Section F.2 and Exhibits F-2.1 and F-2.2 of application.

Financial Feasibility

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

	1ST FULL FY CY 2026	2ND FULL FY CY 2027	3RD FULL FY CY 2028
Total ED Patient Visits*	8,659	8,855	9,095
Total Gross Revenues (Charges)	\$52,914,898	\$57,580,461	\$61,719,937
Total Net Revenue	\$7,207,193	\$7,344,531	\$7,485,735
Average Net Revenue per ED Visit	\$832	\$829	\$823
Total Operating Expenses (Costs)	\$6,380,160	\$6,444,595	\$6,516,664
Average Operating Expense per ED Visit	\$737	\$728	\$717
Net Income	\$827,033	\$899,936	\$969,071

Source: Form F.2b, Section Q, page 160 of the application.

*Emergency department visit projections are from Form C.4b in Section Q.

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q of the application. The applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

- Projected charges and revenues are based on reasonable and adequately supported assumptions.
- Projected operating expenses are based on reasonable and adequately supported assumptions.
- The applicant reasonably projects a positive cash flow in all three project years following project completion.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Remarks made at the public hearing

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 applicant proposes to develop a freestanding emergency department in western Buncombe County licensed under Mission Hospital.

N.C. Gen. Stat. §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 2023 SMFP does not define the service area for emergency departments. In Section C.3, page 45, the applicant identifies its service area for the proposed emergency services by ZIP Code. Facilities may also serve residents of counties not included in their service area.

In Section G.1, page 116, the applicant states there are no freestanding EDs in the proposed service area but identifies two existing providers of emergency services: Duke LifePoint Haywood in Haywood County and Mission Hospital in Buncombe County.

In Section G.2, pages 116-117, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved emergency services in the service area. The applicant states:

“The proposed FSER will provide more timely access to critical care services in the west Buncombe County market and to patients in east Haywood and Madison County areas. ... timely access to critical care is of utmost importance to patients with emergent or urgent health needs. Residents of west Buncombe County already greatly depend on Mission Hospital emergency services, but at times, patients in this area experience unnecessary delays due to travel or the wait times at Mission Hospital, the region’s only trauma center.”

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

- There are no other freestanding emergency departments in the proposed service area.
- The applicant adequately demonstrates that the proposed freestanding emergency department is needed in addition to the existing or approved providers of emergency services in the service area.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Remarks made at the public hearing

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

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

C

The applicant proposes to develop a freestanding emergency department in western Buncombe County licensed under Mission Hospital.

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

Mission FSER West Projected Staffing

POSITION	3RD FULL FY CY 2028
Manager	1.0
Registered Nurses	12.6
Housekeeping	2.8
Maintenance	0.5
Pharmacy Technicians	0.5
Imaging (Dual Modality CT/Dx)	4.2
Total	21.6

Source: Section Q, Form H

The assumptions and methodology used to project staffing are provided in Section Q, page 164. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in Section Q, Form F.3b. In Sections H.2 and H.3,

pages 118-121, the applicant describes the methods to be used to recruit or fill new positions and its proposed 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 information provided in Section H, pages 118-121 of the application, and reference exhibits.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Remarks made at the public hearing

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

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

C

The applicant proposes to develop a freestanding emergency department in western Buncombe County licensed under Mission Hospital.

Ancillary and Support Services

In I.1, page 122 the applicant identifies the necessary ancillary and support services for the proposed services. On pages 122-123, the applicant explains how each ancillary and support service is or will be made available. The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on the following:

- The applicant currently provides emergency services at Mission Hospital and has ancillary and support services available for the proposed freestanding ED.
- The applicant states those services will be available for the proposed freestanding ED.

Coordination

In Section I.2, pages 123-124, the applicant describes its 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 information provided in Section I.2.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Remarks made at the public hearing

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

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

The applicant proposes to develop a freestanding emergency department in western Buncombe County licensed under Mission Hospital.

In Section K.2, the applicant states that the project involves construction of 10,800 square feet of space in a new single-story building that will include 11 exam rooms and one triage room, laboratory space, and imaging rooms. Line drawings are provided in Exhibit K-1.1.

In Section K.4, pages 127-129, the applicant identifies the proposed site and provides information about the current owner, zoning and special use permits for the site, and the availability of water, sewer and waste disposal and power at the site. Supporting documentation is provided in Exhibit K-4.4. The site appears to be suitable for the proposed project based on the applicant's representations and supporting documentation.

In Section K.3, pages 126-127, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal. The applicant states:

“The emergency room has been carefully planned to provide efficient, economical, and patient-centered care. This option will deliver quality care for patients in the proposed service area. The facility will be developed from a prototypical design, which has been tested and fine-tuned to meet the needs of ER patients and staff. The design incorporates current codes and FGI requirements.”

In Section K.3, page 127, 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. The applicant states:

“This project offers emergency care for patients in west Buncombe County, in a location that is convenient and accessible. This project proposes to provide much needed emergency service capacity at Mission Hospital, reducing the demand and allowing for improved throughput at the main hospital ED. Further, patients will be charged similar rates to the current main Mission ED, but will benefit from the closer proximity to home and will not need to have the burden of cost associated with travel to Mission Hospital. Finally, patient care will not be unduly impacted by the cost of construction because the design incorporates cost-saving solutions.”

In Section K.3, page 127, and Exhibit K-3.1, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Remarks made at the public hearing

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

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

C

In Section L, page 131, the applicant provides the historical payor mix for CY 2022 for the Mission Hospital emergency department, as shown in the table below:

Payor Category	Mission Hospital ED Percent of Total Patients Served
Self-Pay	12.5%
Charity Care	3.4%
Medicare*	33.5%
Medicaid*	23.8%
Insurance*	23.0%
Workers Compensation	0.5%
TRICARE	0.4%
Other (Other Federal, State)	2.9%
Total	100.0%

Source: Table on page 131 of the application

*Including any managed care plans

In Section L, page 132, the applicant provides the following comparison for Mission Hospital ED and its proposed service area, and states it is based on Mission internal data:

	PERCENTAGE OF TOTAL PATIENTS SERVED BY THE FACILITY OR CAMPUS DURING THE LAST FULL FY	PERCENTAGE OF THE POPULATION IN THE PROPOSED SERVICE AREA
Female	53.8%	51.8%
Male	46.0%	48.2%
Unknown	0.2%	0.0%
64 and Younger	71.9%	79.0%
65 and Older	28.1%	21.0%
American Indian	0.9%	0.6%
Asian	0.8%	1.5%
Black or African-American	10.4%	6.2%
Native Hawaiian or Pacific Islander	--	0.2%
White or Caucasian	84.3%	82.9%
Other Race	1.0%	2.3%
Declined / Unavailable	2.7%	na

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Remarks made at the public hearing

Based on that review, the Agency concludes that the applicant adequately documents the extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's

service area which is medically underserved. Therefore, the application is conforming to this criterion.

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

C

Regarding any obligation to provide uncompensated care, community service, or access by minorities and persons with disabilities, in Section L, page 133, the applicant states that Mission is not obligated under any applicable federal regulations to provide uncompensated care, community service, or access by minorities and handicapped persons. In Section L, pages 133-135 the applicant states that Mission Hospital's affiliation with HCA means that Mission and the proposed freestanding ED will serve all patients in need of health care services regardless of age, gender, disability, race, color, ancestry, citizenship, religion, pregnancy, sexual orientation, gender identity or expression, national origin, medical condition, marital status, veteran status, or payment source or ability.

In Section L, page 135, the applicant states that, during the 18 months immediately preceding the application, two patient civil rights access complaints were filed against Mission Hospital. The applicant states one complaint was referred to mediation and is still pending. The other complaint was closed by the Joint Commission effective April 22, 2022 without further action.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Remarks made at the public hearing

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 136, the applicant projects the following payor mix for the proposed emergency services during the third full fiscal year of operation following project completion, as shown in the table below:

PAYOR CATEGORY	MISSION FSER WEST PERCENT OF TOTAL PATIENTS SERVED CY 2028
Self-Pay	19.0%
Charity Care	2.6%
Medicare*	22.5%
Medicaid*	30.5%
Insurance*	21.3%
Workers Compensation	0.7%
TRICARE	0.3%
Other	3.1%
Total	100.0%

Source: Table on page 136 of the application

*Including any managed care plans

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 19.0% of emergency services at the proposed Mission FSER West will be provided to self-pay patients, 2.6% to charity care patients, 22.5% to Medicare patients and 30.5% to Medicaid patients.

On pages 136-137, the applicant provides the assumptions and methodology used to project payor mix during the third full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported because it is based on the historical payor mix for Mission Hospital ED patients from the proposed service area during CY 2022.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Remarks made at the public hearing

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.

In Section L, page 138, 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
- Written comments
- Responses to comments
- Remarks made at the public hearing

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

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

C

The applicant proposes to develop a freestanding emergency department in western Buncombe County licensed under Mission Hospital.

In Section M, pages 139-141 the applicant describes the extent to which health professional training programs in the area currently have and will continue to have access to the facility for training purposes and provides supporting documentation in Exhibit M-1.1. The applicant adequately demonstrates that health professional training programs in the area have access to the facility for training purposes based on the documentation provided in Section M, pages 139-141, and referenced exhibits.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Remarks made at the public hearing

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

- (15) Repealed effective July 1, 1987.
(16) Repealed effective July 1, 1987.
(17) Repealed effective July 1, 1987.

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

C

The applicant proposes to develop a freestanding emergency department in western Buncombe County licensed under Mission Hospital.

N.C. Gen. Stat. §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 2023 SMFP does not define the service area for emergency departments. In Section C.3, page 45, the applicant identifies its service area for the proposed emergency services by ZIP Code. Facilities may also serve residents of counties not included in their service area.

In Section G.1, page 116, the applicant states there are no freestanding EDs in the proposed service area but identifies two existing providers of emergency services: Duke LifePoint Haywood in Haywood County and Mission Hospital in Buncombe County.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 142, the applicant states,

“The proposed project will not have a substantial impact on competition for emergency services in Buncombe County because the proposed project’s primary objective is to off-load emergency visits from the heavily-utilized ED at Mission Hospital. That said, the proposed project will have a positive impact on access to emergency services, enhanced quality of emergency services through more timely access to service, and promote efficiency, which is an important contributor to cost effectiveness. The proposed project will expand Mission’s capacity to provide emergency services to area residents who already choose Mission Hospital as their provider of care, thereby ensuring continuity of care through access to personal medical records, supporting ease of follow up treatments, reducing duplication of diagnostic services and ultimately improving patient experience and outcomes.”

Regarding the impact of the proposal on cost effectiveness, in Section N, pages 142-143, the applicant states,

“By expanding its emergency services to west Buncombe, Mission will extend access to leading edge, 24/7 emergency care in a setting that is closer to homes and businesses in the service area. The proposed location of the FSER will reduce travel time and

related costs significantly for residents in the service area and will reduce travel on congested highways fraught with continual construction. The project will also improve efficiency of EMS by providing a closer location for ambulances to offload patients and quickly return to their home-base station. Enabling EMS to remain in their service area enables them to respond more quickly to calls and reduces fuel cost. Buncombe County Manager, Avril Pinder, has reached out to Mission Health leadership citing concerns around the increased ambulance truck wait time that Buncombe County EMS experiences at Mission Hospital's emergency department. Thus, this opportunity to alleviate the congested main Mission Hospital ED would be welcomed news for the county."

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

Regarding the impact of the proposal on quality, in Section N, page 143, the applicant states,

"Mission Hospital is dedicated to ensuring quality care and patient safety. Every year, Mission receives recognition by accrediting bodies and ranking organizations for outstanding performance in various clinical metrics. As a department of Mission Hospital and a satellite location for Mission's Emergency Department, the FSER will adopt and adhere to the same high standards and quality of care. Mission Hospital, as an HCA affiliate, has access to the experience of the largest provider of FSER services in the country and the policies, procedures, and protocols used by these affiliate facilities. It will also provide services according to licensure and certification standards."

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

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 144, the applicant states,

"Mission Hospital's Emergency Department does not turn patients away when they require emergent care-regardless of ability to pay. These same policies will be implemented at the FSER. The proposed satellite location will allow Mission the flexibility to meet current and future demands for emergency services in the region. It will also ensure that residents of the health service area have timely access to high quality, affordable care close to home during an emergency. More specifically, as demonstrated in the tables in Section L.4a and L.4b, the proposed FSER will serve Charity Care, Medicare, and Medicaid patients, as well as patients who need services at reduced cost--just as Mission Hospital does today."

See also Section L and C of the application and any exhibits.

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would have a positive impact on cost-effectiveness, quality, and access because the applicant adequately demonstrates that:

- 1) The proposal is cost effective because the applicant adequately demonstrated: a) the need the population to be served has for the proposal; b) that the proposal would not result in

- an unnecessary duplication of existing and approved health services; and c) that projected revenues and operating costs are reasonable.
- 2) Quality care would be provided based on the applicant's representations about how it ensures the quality of the proposed services.
 - 3) Medically underserved groups will have access to the proposed services based on the applicant's representations about access by medically underserved groups and the projected payor mix.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Remarks made at the public hearing

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

- (19) Repealed effective July 1, 1987.
- (20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C

In Section Q Form O, page 165 the applicant identifies six licensed hospitals located in North Carolina owned, operated or managed by the applicant or a related entity.

In Section O, page 147, the applicant states that, during the 18 months immediately preceding the submittal of the application, there have been no situations resulting in a finding of immediate jeopardy during the last 18 month look-back period. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, during the 18 months immediately preceding submission of the application through the date of this decision, two incidents related to quality of care occurred in two facilities. One incident occurred on July 13, 2023 in Blue Ridge Regional Hospital and is still pending. A separate incident occurred on March 17, 2023 at Transylvania Regional Hospital. According to the files the Acute and Home Care Licensure and Certification Section, the deficiency at Transylvania Regional Hospital was corrected, and the facility was back in compliance on May 24, 2023. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at the six facilities, 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.

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

NA

The applicant proposes to develop a freestanding emergency department in western Buncombe County licensed under Mission Hospital. There are no administrative rules that are applicable to proposals to develop a freestanding emergency department. Therefore, this Criterion is not applicable to this review.