

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: May 24, 2022

Findings Date: May 24, 2022

Project Analyst: Mike McKillip

Co-Signer: Lisa Pittman

Project ID #: B-12192-22

Facility: Mission Hospital-Mission FSER West

FID #: 220172

County: Buncombe

Applicant: MH Mission Hospital, LLLP

Project: Develop a freestanding emergency department in Candler 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 in Candler licensed under Mission Hospital.

Need Determination

There is no need determination in the 2022 State Medical Facilities Plan (SMFP) that is applicable to the proposed project.

Policies

There is one policy in the 2022 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 pages 30-31 of the 2022 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 \$5.0 million. In Section B, page 30, the applicant describes the project’s plan for energy efficiency and to conserve water. The applicant adequately demonstrates that the application includes a written statement describing the project’s plan to assure improved energy efficiency and water conservation. Therefore, the application is consistent with Policy GEN-4.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made in lieu of the public hearing
- Responses to comments

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, services or equipment for which there is a need determination in the 2022 SMFP.
 - 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 emergency department (ED) in Candler, 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 10,820 square-foot freestanding emergency room on 4.75 acres of land situated at the corner of Smokey Park Highway and Brookside Circle near I-40, exit 44, and also near the intersection of I-40 and I-26. ... 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 (All), 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 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 2022 SMFP does not define the service area for

emergency departments. In Section C.3, page 40, the applicant identifies service area for the proposed services by ZIP Code Area. Facilities may also serve residents of counties not included in their service area. The following table illustrates projected patient origin.

County or ZIP Code Area	Third Full FY of Operation following Project Completion CY2027	
	Patients	% of Total
28806-Buncombe	1,476	14.0%
28715-Buncombe	3,045	28.9%
28748-Buncombe	1,877	17.8%
28801-Buncombe	507	4.8%
28787-Buncombe	258	2.4%
28805-Buncombe	231	2.2%
28804-Buncombe	209	2.0%
28753-Madison	563	5.3%
28716-Haywood	613	5.8%
28701-Buncombe	268	2.5%
28786-Haywood	274	2.6%
28721-Haywood	147	1.4%
28743-Madison	136	1.3%
28785-Haywood	120	1.1%
28745-Haywood	15	0.1%
All Other Immigration	790	7.5%
Total	10,528	100.0%

Source: Table on page 40 of the application.

In Section C, pages 40-49, the applicant provides the assumptions and methodology used to project its patient origin. The applicant’s assumptions are reasonable and adequately supported based on the historical utilization of emergency services by patients residing in the proposed service area.

Analysis of Need

In Section C.4, pages 43-75, 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.
- The residential development and economic growth in the proposed service area.
- Problems with geographic accessibility to ED services on the Mission Hospital main campus due to traffic congestion.
- Increasing ED volumes within the Mission Hospital service area and within Mission Hospital’s ED.
- Capacity constraints at the Mission Hospital main campus ED due to rising ED volumes, increasing patient acuity, operational and bed capacity limitations.

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

- The applicant provides demographic data for the proposed service area from Claritas Spotlight to support its projections.
- The applicant provides information and data on emergency department transfers to the ED on the Mission Hospital main campus, 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 of operation, as summarized in the table below.

Mission FSER West Projected Utilization				
	Partial 1st Year 7/1/2024- 12/31/2024	1st Full FY CY2025	2nd Full FY CY2026	3rd Full FY CY2027
Emergency Department				
# of Treatment Rooms	12	12	12	12
# of Visits	4,868	9,981	10,250	10,528
Observation Beds (unlicensed)				
# of Beds	0	0	0	0
Days of Care	376	772	792	814
CT Scans				
# of Units	1	1	1	1
# of Scans	1,739	3,565	3,661	3,760
# of HECT Units	2,657	5,448	5,595	5,747
Fixed X-Ray (incl. fluoroscopy)				
# of Units	1	1	1	1
# of Procedures	1,130	2,316	2,378	2,443
Ultrasound				
# of Units	1	1	1	1
# of Procedures	241	493	506	520

In Section C.4, pages 64-75, the applicant provides the assumptions and methodology used to project utilization, which is summarized below:

Step 1 – The applicant calculated the historical average growth rate in ED utilization at all providers for the ZIP Code Areas identified by the applicant as the proposed service area from 2017 to 2019 using NCHA-HIDI Market Data. See the table on page 64 of the application. The applicant states, “*Since a full year of 2021 market data is unavailable, Mission projected the market ED volume for 2021 using the average of 11.9 percent growth (see Figure 12 above) in Mission ED volume from 2020 to 2021 as a one-year growth period which reflects Mission’s ongoing catch-up from the impact of Covid on ED utilization. Mission projected market 2021 volume by applying its 11.9 percent growth to 2020 market volume. This is a reasonable approach to projecting 2021 market volume due to Mission providing the majority of ED services in the service area.*”

Step 2 - The applicant projects the ED utilization for the proposed service area through the first three full fiscal years of the project based on the historical growth rates calculated in Step 1 above. See the table on page 65 of the application. The applicant states, “*Mission Hospital next projected that in 2022 the total market ED visit volume will rebound to 2019 levels at 86,403. After 2022, it was assumed that general market growth would resume to pre-pandemic levels based on population growth and aging. As shown in Figure 18, the service area ED visits historically increased by a CAGR of 1.4 percent. This 1.4 percent CAGR was used by Mission Hospital to project service area total visits from FY 2023 through FY 2027, the 3rd full fiscal year of the project.*”

Step 3 – The applicant projected its market share by acuity and ZIP code using 2021 data. See the table on page 67 of the application.

Step 4 - The applicant projects incremental market share from the proposed service area for the freestanding ED. See the table on page 69 of the application. The applicant states, “*Using historical market share data as a guide, Mission first conservatively established its 1st partial FFY (July to December) and its 1st FFY service area market share by acuity and ZIP code. Mission assumed greater incremental market share in ZIP codes that are closer in proximity to the proposed FSER and lower incremental market in ZIP codes closer in proximity to Mission’s main ED or close to other existing hospital EDs. 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 0.5 percent for low acuity patients and 0.1 percent for high acuity patients; the same was done for the 3rd FFY using the 2nd FFY as the base.*”

On page 70, the applicant states,

“Next, Mission projected its 1st Partial FFY ED market share by acuity, its main ED volume by acuity, established the projected percent shift of volume to the FSER by acuity, and projected the FSER volume. See Figure 24 below.

- *Using the base percent market share by acuity from Step 3, Mission added the projected incremental market share percentages for 2024 to establish Mission’s total market share by percentage for the 1st Partial FFY.*
- *Mission then took the projected partial 2024 total market ED volume from Step 2 and multiplied that volume by the percent market share by acuity to derive the projected total Mission ED visits for the 1st Partial FFY.*
- *Mission then established the percent shift to the proposed FSER by acuity. Mission assumed higher percent shift for low acuity patients from service area ZIP codes to the FSER with the higher percentages coming from ZIP codes in closer proximity to the proposed FSER location. Mission also assumed a lower percent shift in high acuity patients to the proposed FSER, as these patients will continue to be primarily seen at the main hospital ED.*

- *Finally, Mission took the total projected Mission ED visits for the 1st Partial FFY and multiplied it by the projected shift percentages to calculate the volume by acuity for the proposed FSER in the 1st Partial FFY.*
- *Additionally, Mission assumed 7.5 percent in-migration.*

The steps above were repeated for the 1st through the 3rd FFYs maintaining a constant percent shift by acuity for FSER volume.”

See the tables on pages 71-74 of the application.

On page 138 of the application, the applicant describes the assumptions and methodology for projecting utilization of the diagnostic imaging equipment as follows:

“Number of Procedures is based on the ratio of the procedure volume to ED visits at Missions Main ED for 2021.... HECT conversion is based on the average distribution % for Mission Hospital scans from 2019-2021. Projected scans, however, reflect the growing acuity of scans based on CAGR % from 2019-2021 of scans by type.”

On page 141 of the application, the applicant describes the assumptions and methodology for projecting utilization of the observation beds as follows:

“Number of observation days of care are based on the ratio of the hours of care volume to ED visits at Missions Main ED for 2021 and then divided by 24 hours to get days.”

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

- Projected utilization is supported by the historical utilization of the ED services at the Mission Hospital main campus by the residents of the applicant’s proposed service area.
- Projected utilization is supported by the applicant’s historical (2021) ED market shares by ZIP code area in the proposed service area.
- The utilization projections are supported by the projected population growth and aging in the proposed service area.

Access to Medically Underserved Groups

In Section C.6, page 80, the applicant states the proposed facility will be accessible to all persons, including low income, racial and ethnic minorities, women, persons with disabilities, the elderly, Medicare and Medicaid beneficiaries. 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	16.7%
Racial and ethnic minorities	5.3%
Women	53.8%
Persons with Disabilities	Not Available
The elderly	24.3%
Medicare beneficiaries	31.2%
Medicaid recipients	25.0%

Source: Table on page 81 of the application.

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 on the information provided in Section C.6, pages 80-81, Section L, pages 112-119, and referenced exhibits.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made in lieu of the public hearing
- Responses to comments

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 Candler licensed under Mission Hospital.

In Section E, pages 89-90, 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 that maintaining the status quo is a less effective alternative because it will result in delays in access to emergency services for residents of western Buncombe, Haywood, and Madison counties.
- Expand emergency department capacity at Mission Hospital – The applicant states that expanding emergency department capacity at Mission Hospital is a less effective alternative because it will not address the issue of timely access to emergency services by patients from the proposed service area in western Buncombe County.
- Develop a freestanding emergency department at an existing facility – The applicant states that developing a freestanding emergency department at an existing facility is a less effective alternative because there are currently no other Mission Hospital-owned facilities in the proposed service area that would accommodate a freestanding ED.
- Develop a freestanding emergency department elsewhere in the county – 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, traffic and travel times, and rapid population growth in western Buncombe County that make developing services in Candler a high priority.

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
- Remarks made in lieu of the public hearing
- Responses to comments

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 Candler that will 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 1, 2023.**
- 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. No later than three months after the last day of each of the first three full fiscal years of operation following initiation of the services authorized by this certificate of need, the certificate holder shall submit, on the form provided by the Healthcare Planning and Certificate of Need Section, an annual report containing the:**
 - a. Payor mix for the services authorized in this certificate of need.**
 - b. Utilization of the services authorized in this certificate of need.**
 - c. Revenues and operating costs for the services authorized in this certificate of need.**
 - d. Average gross revenue per unit of service.**
 - e. Average net revenue per unit of service.**
 - f. Average operating cost per unit of service.**

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.

C

The applicant proposes to develop a freestanding emergency department in Candler 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.

Purchase price of land	\$4,275,000
Closing costs	\$12,000
Site preparation	\$1,200,000
Construction/renovation costs	\$6,006,000
Landscaping	50,000
Architect/engineering fees	\$250,000
Medical equipment	\$1,639,101
Nonmedical equipment	\$1,071,000
Furniture	\$30,899
Consultant fees	\$27,500
Interest during construction	\$188,000
Total	\$14,749,500

In Section Q, the applicant provides the assumptions used to project the capital cost. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based on the 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 93, 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. It is expected that the projected additional staff required will be phased in as volumes grow and will not be in place ‘prior to’ the initiation of services. ... 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 Mission Imaging CT locations.”

Availability of Funds

In Section F.2, page 92, the applicant states that the capital cost will be funded by HCA Healthcare, Inc. (HCA), the parent company for Mission Hospital, as shown in the table below.

Sources of Financing for Capital	Amount
Loans	\$0
Cash or Cash Equivalents, Accumulated Reserves or Owner’s Equity	\$14,749,500
Lines of credit	\$0
Bonds	\$0
Total	\$14,749,500

Exhibit F-2 contains a February 10, 2022 letter from the Chief Financial Officer for HCA National Group stating its intention to commit funds for the capital costs for the proposed project. Exhibit F-2 also contains the annual report (Form 10-K) for HCA Healthcare, Inc. that indicate HCA had \$1.8 billion in cash and cash equivalents as of December 31, 2020. 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 Exhibit F-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.

Mission FSER West	1 st Full FY CY2025	2 nd Full FY CY2026	3 rd Full FY CY2027
Total ED Patient Visits*	9,981	10,250	10,528
Total Gross Revenues (Charges)	\$61,443,036	\$68,146,920	\$75,594,813
Total Net Revenue	\$10,898,024	\$11,424,581	\$11,980,126
Average Net Revenue per ED Visit	\$1,092	\$1,115	\$1,138
Total Operating Expenses (Costs)	\$4,060,778	\$4,134,805	\$4,216,285
Average Operating Expense per ED Visit	\$407	\$403	\$400
Net Income	\$6,837,246	\$7,289,776	\$7,763,841

Source: Form F.2b, Section Q, page 144 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 assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section Q of the application for the assumptions used regarding costs and charges.

The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made in lieu of the public hearing
- Responses to comments

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 Candler 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 2022 SMFP does not define the service area for emergency departments. In Section C.3, page 40, the applicant identifies service area for the proposed services by ZIP Code Area. Facilities may also serve residents of counties not included in their service area.

In Section G.1, page 100, the applicant identifies two providers of emergency services in the proposed service area: Haywood Regional Medical Center and Mission Hospital.

In Section G.2, pages 100-101, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved health service capabilities or facilities. 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. As discussed in Section C and in the numerous support letters provided by Mission physicians and community members, 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. Patients throughout Buncombe County and Haywood and Madison counties will realize two-fold benefits from the proposed FSER through greater access to care for lower acuity emergency care needs as well as more stream-lined higher-acuity care at Mission Hospital.

In terms of considering adverse impact, it is important to note that Mission Hospital is the only acute care hospital in Buncombe County and that the proposed FSER in Buncombe County is planned to directly impact and address the need for additional capacity needs at Mission Hospital as well as improving geographic access to ED services within Buncombe County. Moreover, Mission Hospital is the only trauma center in the region and the regional tertiary referral center. Therefore, improvements in access to Mission Hospital ED services will specifically improve access to trauma care for the region.

As demonstrated in Section C, there has historically been significant growth in service area ED utilization. After rebounding from COVID-19, this trend is expected to continue based on population growth and aging. As such, any small shift in market share projected in this application is merely the result of competition and is more than offset by the projected growth in service area demand for ED services. Development of the Mission FSER will not preclude the any hospitals in the service area from continuing to experience incremental growth in ED patients, volumes or market share. Finally, any impact or competition potentially claimed by Mission’s competitors from non-CON reviewable services such as CT scanners, physicians’ offices and urgent care centers is not relevant for consideration regarding Mission’s proposed FSER.”

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
- Remarks made in lieu of the public hearing
- Responses to comments

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 Candler 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.

Position	Projected FTE Positions 3rd Full FY CY2027
Manager	1.0
Registered Nurses	9.0
Patient Care Technicians	4.2
Housekeeping	2.8
Maintenance	0.5
Laboratory Technicians	4.2
Pharmacy Technicians	0.5
Ultrasound	2.1
Imaging (Dual Modality CT/Dx)	4.2
TOTAL	28.5

Source: Section Q, Form H

The assumptions and methodology used to project staffing are provided in Section Q. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in Section Q, Form F.3b. In Section H.2 and H.3, pages 102-103, 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 102-103 of the application, and reference exhibits.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made in lieu of the public hearing
- Responses to comments

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 Candler licensed under Mission Hospital.

Ancillary and Support Services

In I.1, the applicant identifies the necessary ancillary and support services for the proposed services. On pages 104-105, 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.

Coordination

In Section I.2, pages 105-106, 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
- Remarks made in lieu of the public hearing
- Responses to comments

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 Candler licensed under Mission Hospital.

In Section K.1, the applicant states that the project involves construction of 10,820 square feet of space in a new single-story building to be located at the intersection of Smokey Park Highway and Brookside Circle in Candler (Buncombe County). Line drawings are provided in Exhibit K-1.

In Section K.4, pages 110-111, 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. The site is suitable for the proposed project based on the applicant's representations and supporting documentation.

In Section K.3, page 108, 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 Candler 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 109, 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. Patient care will not be unduly impacted by the cost of construction because the design incorporates cost-saving solutions. 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."

In Section K.3, page 109, and Exhibit K-3, 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
- Remarks made in lieu of the public hearing
- Responses to comments

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 113, the applicant provides the historical payor mix for CY2021 for the Mission Hospital emergency department, as shown in the table below.

Payor Category	Mission Hospital ED Percent of Total Patients Served
Self-Pay	11.8%
Charity Care	4.1%
Medicare*	32.5%
Medicaid*	22.2%
Insurance*	22.1%
Workers Compensation	0.6%
TRICARE	0.6%
Other (Commercial, Federal, State)	6.2%
Total	100.0%

Source: Table on page 113 of the application

*Including any managed care plans

In Section L, page 114, the applicant provides the following comparison for Mission Hospital ED and its western North Carolina service area.

	Percentage of Total Patients Served by the Facility or Campus during the Last Full FY	Percentage of the Population in the Service Area
Female	54.1%	51.3%
Male	45.8%	48.7%
Unknown	0.1%	0.0%
64 and Younger	72.7%	75.3%
65 and Older	27.3%	24.7%
American Indian	1.0%	1.4%
Asian	NA	1.3%
Black or African-American	10.8%	4.4%
Native Hawaiian or Pacific Islander	0.7%	0.1%
White or Caucasian	85.1%	87.4%
Other Race	0.2%	5.5%
Declined / Unavailable	2.2%	0.0%

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made in lieu of the public hearing
- Responses to comments

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, pages 115-116, 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. The applicant states that Mission Hospital and the proposed freestanding ED will serve any Medicaid/Medicaid HMO, charity, and uninsured patients who require health care services, and will provide 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 117, the applicant states that, during the 18 months immediately preceding the application, no patient civil rights access complaints have been filed against MH Mission Hospital, LLLP facilities located in North Carolina.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made in lieu of the public hearing
- Responses to comments

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

Payor Category	Mission FSER West Percent of Total Patients Served CY2027
Self-Pay	12.5%
Charity Care	4.3%
Medicare*	31.2%
Medicaid*	25.0%
Insurance*	20.1%
Workers Compensation	0.5%
TRICARE	0.2%
Other (Commercial, Federal, State)	6.3%
Total	100.0%

Source: Table on page 117 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 12.5% of ED services at the Mission FSER in Candler will be provided to self-pay patients, 4.3% to charity care patients, 31.2% to Medicare patients and 25% to Medicaid patients.

On page 118, 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 CY2021.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made in lieu of the public hearing
- Responses to comments

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

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

C

In Section L, page 119, 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
- Remarks made in lieu of the public hearing
- Responses to comments

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 Candler licensed under Mission Hospital.

In Section M, 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 documentation provided in Section M.1, pages 120-121, and referenced exhibits.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made in lieu of the public hearing
- Responses to comments

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 Candler 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 2022 SMFP does not define the service area for emergency departments. In Section C.3, page 40, the applicant identifies service area for the

proposed services by ZIP Code Area. Facilities may also serve residents of counties not included in their service area.

In Section G.1, page 100, the applicant identifies two providers of emergency services in the proposed service area: Haywood Regional Medical Center and Mission Hospital.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 122, the applicant states,

“The proposed project will enhance competition in the area because it will promote increased access to emergency services, enhance quality of emergency services, 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 choose Mission Hospital as their provider of care, ensuring access to personal medical records, supporting ease of follow up treatments and ultimately enhancing continuity of care.”

Regarding the impact of the proposal on cost effectiveness, in Section N, pages 122-123, the applicant states,

“In addition, area residents and employers will realize the added efficiencies of a satellite emergency department, such as reduced wait times for emergency care, faster treatment, and faster turnaround time--all factors that contribute to cost effectiveness by reducing time away from work and home. This increased efficiency is possible in free-standing emergency departments because they do not shoulder the same burden of multiple roles that emergency departments on main hospital campuses do.”

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 123, 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 123, 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
- Remarks made in lieu of the public hearing
- Responses to comments

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, the applicant identifies six hospitals located in North Carolina owned, operated or managed by the applicant or a related entity.

In Section O, pages 127-129, the applicant states that, during the 18 months immediately preceding the submittal of the application, there has been a finding of immediate jeopardy involving one patient at Mission Hospital, and a second patient at Mission Hospital and Asheville Surgery Center. The applicant states that the plans of correction have been implemented and accepted by DHSR, and the immediate jeopardy citations have been lifted in both cases. 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 one of these facilities. According to the files the Acute and Home Care Licensure and Certification Section, both deficiencies were corrected and the facilities are back in compliance. 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 Candler 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.