ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming CA = Conditional NC = Nonconforming NA = Not Applicable

Decision Date:	November 16, 2021
Findings Date:	November 16, 2021
Project Analyst:	Celia C. Inman
Co-Signer:	Lisa Pittman
Project ID #:	B-12093-21
Facility:	Mission Hospital - Mission FSER
FID #:	210482
County:	Buncombe
Applicant:	MH Mission Hospital, LLLP
Project:	Develop a new satellite emergency department under Mission Hospital's license

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

С

MH Mission Hospital, LLLP (Mission or the applicant) proposes to develop Mission Hospital-Mission FSER (Mission FSER), a satellite emergency department (ED) in Arden, in Buncombe County, which will be licensed as part of Mission Hospital on a new campus. The satellite ED will offer 24-hour emergency care, diagnostic imaging, and clinical laboratory services.

Need Determination

The proposed project does not involve the addition of any new health service facility beds, services, or equipment for which there is a need determination in the 2021 State Medical Facilities Plan (SMFP). Therefore, there are no need determinations applicable to this review.

Policies

Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities (page 29 of the 2021 SMFP) is applicable to this review. *Policy GEN-4* states:

"Any person proposing a capital expenditure greater than \$2 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; therefore, Policy GEN-4 is applicable to this review. In Section B, page 30, the applicant provides a written statement describing its plan to work with a design team and facility management group to assure improved energy efficiency and water conservation. The applicant states:

"Mission Hospital is working with experienced architects and engineers to develop the proposed project. These professionals will ensure energy efficient systems are a inherent part of the proposed project. Mission will design the proposed FSER to comply with all applicable federal, state, and local building codes, and requirements for energy efficiency and consumption, including <u>Policy GEN-4</u> [emphasis in original]."

The applicant provides details of the Energy Efficiency and Water Conservation Plan in Exhibit K-3.1.

Conclusion

The Agency reviewed the:

• Application

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

Based on that review, the Agency concludes that the application could be found consistent with Policy GEN-4, and therefore, conforming to this criterion based on the following:

- The applicant states it will work with experienced architects and engineers to develop this proposed project to ensure energy efficient systems are an inherent part of the project.
- The applicant adequately demonstrates that it provides a written statement describing its plan to work with a design team and facility management group to assure improved 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, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

NC

The applicant proposes to expand its emergency services by establishing a freestanding emergency room (FSER), Mission FSER, a satellite ED, in south Buncombe County, which will offer 24-hour emergency care, diagnostic imaging, and clinical laboratory services. The satellite ED will be a new campus and will be licensed as part of Mission Hospital, which is an affiliate of HCA Healthcare, Inc. (HCA). HCA has operated hospital-affiliated FSERs since 1985 and today operates 113 FSERs in 12 states, all of which have all of the essential characteristics of a hospital-based emergency department.

In Section C, page 35, the applicant describes the proposed project as a twelve exam/treatment room satellite emergency department, including:

- Six general exam rooms, one airborne isolation exam room, one bariatric exam room, one pelvic exam room, one behavioral exam room, a triage room, and one trauma/resuscitation room
- one CT scanner (relocated and replaced from Mission Pardee Health Campus (Mission Pardee)
- one ultrasound machine
- one unit of fixed x-ray equipment
- laboratory services
- 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.

On pages 37-38, the applicant states that all other ancillary support services, including environmental, security, information technology, and maintenance services will be provided in the proposed FSER by trained on-site staff. The applicant further states, that as an extension of Mission Hospital's emergency services, administrative support services will be provided by Mission to the proposed FSER.

On page 43, the applicant states that the proposed FSER will be operated with the main purpose of providing focused emergency care for low acuity patients, thereby creating more capacity in Mission's main ED for provision of emergency care services to high acuity patients.

Patient Origin

The 2021 SMFP does not define a service area for emergency departments. In Section C, pages 43-44, the applicant defines the proposed service area as a subset of Mission's broader 18-county service area, including portions of southern Buncombe County and northern Henderson County identified as follows:

ZIP Code	County
Primary Service Area (PS	SA)
28704	Buncombe
28730	Buncombe
28732	Henderson
28759	Henderson
28791	Henderson
28803	Buncombe
Secondary Service Area	(SSA)
28806	Buncombe
28792	Henderson
28742	Henderson

On page 45, the applicant provides a service area map showing the location of the service area ZIP codes relative to the proposed FSER. Facilities may also serve residents of counties not included in their service area.

The proposed satellite ED is not an existing facility and therefore does not have historical patient origin. In Section C, page 39, the applicant provides the CY2020 patient origin by county for Mission Hospital emergency services. On page 40, the applicant provides the projected patient origin by ZIP code for the proposed ED, as summarized below.

Mission FSER Projected Patient Origin							
	CY20)23	CY20)24	CY2025		
County	# Patients	Percent	# Patients	Percent	# Patients	Percent	
28704 - Buncombe	1,715	21.8%	1,825	21.8%	1,942	21.9%	
28730 - Buncombe	692	8.8%	730	8.7%	771	8.7%	
28732 - Henderson	913	11.6%	1,009	12.1%	1,113	12.5%	
28759 - Henderson	191	2.4%	217	2.6%	246	2.8%	
28791 - Henderson	258	3.3%	291	3.5%	326	3.7%	
28803 - Buncombe	1,803	22.9%	1,901	22.7%	2,004	22.6%	
28806 - Buncombe	1,370	17.4%	1,378	16.5%	1,385	15.6%	
28792 - Henderson	302	3.8%	348	4.2%	395	4.4%	
28742 - Henderson	30	0.4%	34	0.4%	37	0.4%	
All Other In-migration*	590	7.5%	627	7.5%	666	7.5%	
Total	7,863	100.0%	8,360	100.0%	8,887	100.0%	

Source: Section C, page 40

*On page 41, the applicant states this includes patients from all other Buncombe County and Henderson County ZIP codes

Totals may not sum due to rounding

In Section C.4, page 43, the applicant states that the proposed FSER will be developed in a location situated between I-26 and US Route 25 and will provide highly needed emergency care in southern Buncombe County and northern Henderson County in the stated ZIP codes.

On page 50, the applicant states:

"With an awareness of the development in the southern portion of the county, Mission proposes to develop the FSER in a location to address the healthcare needs of the service area and ensure timely access to emergency services as congestion and traffic counts increase in the service area.

Grouping the projected patients as provided by the applicant on page 40 of the application by county results in the following patient origin by county.

Mission FSER Projected Patient Origin by County of Origin							
	CY2023		CY20	24	CY2025		
County	# Patients	Percent	# Patients	Percent	# Patients	Percent	
28704 - Buncombe	1,715	21.8%	1,825	21.8%	1,942	21.9%	
28730 - Buncombe	692	8.8%	730	8.7%	771	8.7%	
28803 - Buncombe	1,803	22.9%	1,901	22.7%	2,004	22.6%	
28806 - Buncombe	1,370	17.4%	1,378	16.5%	1,385	15.6%	
Total Buncombe Co. Patients	5,580	71.0%	5,834	69.8%	6,102	68.7%	
28732 - Henderson	913	11.6%	1,009	12.1%	1,113	12.5%	
28759 - Henderson	191	2.4%	217	2.6%	246	2.8%	
28791 - Henderson	258	3.3%	291	3.5%	326	3.7%	
28792 - Henderson	302	3.8%	348	4.2%	395	4.4%	
28742 - Henderson	30	0.4%	34	0.4%	37	0.4%	
Total Henderson Co. Patients	1,694	21.5%	1,899	22.7%	2,117	23.8%	
All Other In-migration*	590	7.5%	627	7.5%	666	7.5%	
Total	7,863	100.0%	8,360	100.0%	8,885	100.0%	

Source: Section C, page 40

*On page 41, the applicant states this includes patients from all other Buncombe County and Henderson County ZIP codes

Totals may not sum due to rounding

In Section C, page 41, the applicant states that the increase in patient origin for Buncombe and Henderson counties at the proposed facility is due to increase in incremental market share.

The applicant's assumptions for patient origin are reasonable and adequately supported based on the following:

- The proposed service area is a subset of the historical Mission main ED service area, including ZIP codes in Buncombe and Henderson counties.
- The PSA ZIP code population is growing at a faster rate than both Buncombe and Henderson Counties as a whole, as well as the state.
- The proposed patient origin is based on Mission's main ED patient origin, narrowed to PSA and SSA ZIP codes within Buncombe and Henderson counties in close proximity to the proposed facility.
- The applicant projects in-migration from outside the PSA and SSA Zip codes of 7.5%

Analysis of Need

In Section C, pages 43-54, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. The applicant discusses the proposed project as a response to emergency care need largely driven by the following factors:

- Service area population growth, especially aged 65 and older (pages 43-47)
- Access to emergency services in the service area (pages 47-48)

- Lack of geographic access to Mission's main ED due to traffic congestion (pages 48-49)
- Economic development in the service area (pages 49-50)
- Mission Hospital increasing ED volume, with 2021 volume approaching pre-COVID volumes of 2019 (pages 51-52)
- Mission's rising ED volume and increasing provision of care to high acuity ED patients (pages 52-53)
- Historical service area growth in ED services (pages 53-54)

However, the information provided by the applicant is not reasonable and adequately supported because the projected utilization is not based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization below, which is incorporated herein by reference.

Projected Utilization

ED Visits

In Section Q, the applicant provides projected utilization of the satellite ED and ancillary services during the first three full operating years, as shown in the table below.

Mission FSER Projected Utilization						
	CY2023	CY2024	CY2025			
Emergency Department						
# of Treatment Rooms	12	12	12			
# of Visits	7,863	8,360	8,887			
Observation Beds (unlicensed)						
# of Beds	0	0	0			
Days of Care	456	485	515			
CT Scans						
# of Units	1	1	1			
# of Scans	3,713	3,948	4,196			
# of HECT Units	5,644	6,000	6,378			
Fixed X-Ray (incl. fluoroscopy)						
# of Units	1	1	1			
# of Procedures	1,767	1,878	1,997			
Ultrasound						
# of Units	1	1	1			
# of Procedures	417	444	472			

In Section C and Section Q, the applicant provides the assumptions and methodology used to calculate projected utilization of the satellite ED and ancillary services. The assumptions and methodology provided by the applicant are summarized below:

• Satellite ED Services (Section C, pages 54-62)

ZIP Code-County	2017	2018	2019	2020	2017-19 CAGR
28704 - Buncombe	6,190	6,165	6,778	5,884	4.6%
28730 - Buncombe	2,735	2,734	2,954	2,197	3.9%
28732 - Henderson	4,881	5,304	5,644	4,693	7.5%
28759 - Henderson	2,175	2,257	2,510	1,983	7.4%
28791 - Henderson	5,219	5,477	5,584	4,558	3.4%
28803 - Buncombe	9,265	9,488	10,007	8,031	3.9%
Primary Service Area	30,465	31,425	33,477	27,346	4.8%
28806 - Buncombe	15,070	14,958	14,837	12,215	-0.8%
28792 - Henderson	14,993	15,512	15,469	12,729	1.6%
28742 - Henderson	1,074	1,131	1,115	884	1.9%
Secondary Service Area	31,137	31,601	31,421	25,828	0.5%
Total Service Area	61,602	63,026	64,898	53,174	2.6%

Step 1: (pages 54-55) Calculate historical trend in service area ED volume from 2017-2019

Step 2: (page 55) Analyze year to date Mission ED volume and establish average percent change during recovery period

Month	ED Volume	Month-to-Month % Change
January	7,325	
February	6,955	-5.1%
March	8,162	17.4%
April	8,481	3.9%
Total	30,923	
Average % Change (March and April)		10.6%

Step 3: (page 56) Project market ED volume based on historical trends The applicant applies the 10.6% average percent change to the 2020 market ED volume to project 2021 market ED volume.

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ZIP Code-County	2019*	2020*	2021	2022	2023	2024	2025
28704 - Buncombe	6,778	5,884	6,510	6,778	7,093	7,422	7,766
28730 - Buncombe	2,954	2,197	2,431	2,954	3,070	3,191	3,316
28732 - Henderson	5,644	4,693	5,192	5,644	6,069	6,526	7,018
28759 - Henderson	2,510	1,983	2,194	2,510	2,696	2,897	3,112
28791 - Henderson	5,584	4,558	5,043	5,584	5,776	5,975	6,180
28803 - Buncombe							
	10,007	8,031	8,885	10,007	10,400	10,808	11,233
Primary Service Area	33,477	27,346	30,253	33,477	35,104	36,818	38,625
28806 - Buncombe							
	14,837	12,215	13,514	14,837	14,722	14,608	14,494
28792 - Henderson							
	15,469	12,729	14,082	15,469	15,713	15,960	16,211
28742 - Henderson	1,115	884	978	1,115	1,136	1,158	1,179
Secondary Service Area	31,421	25,828	28,574	31,421	31,571	31,724	31,885
Total Service Area	64,898	53,174	58,827	64,898	66,675	68,542	70,510
Applicant's Calculated CAGR 2017-2019	2.6%						
Year over Year Percent Increase [^]		-18.1%	10.6%	10.3%	2.7%	2.8%	2.9%
2020-2025^							5.8%
CAGR 2021-2025^							4.6%

Note: 2022 forward projected using 2019 as baseline

*From Step 1, page 55 of application

^Agency calculation from applicant's data

Step 4: (pages 56-57) Establish base 2019 Mission market share by acuity and ZIP code

	2019 Mission Visits			2019 Market	2019 S	A Volume as	% of
				Volume	Total Market by Acuity		
ZIP Code-County	Low Acuity	High Acuity	Total	Total	Low Acuity	High Acuity	Total
28704 - Buncombe	1,191	2,526	3,717	6,778	17.6%	37.3%	54.8%
28730 - Buncombe	648	1,490	2,138	2,954	21.9%	50.4%	72.4%
28732 - Henderson	457	1,336	1,793	5,644	8.1%	23.7%	31.8%
28759 - Henderson	118	320	438	2,510	4.7%	12.7%	17.5%
28791 - Henderson	121	379	500	5,584	2.2%	6.8%	9.0%
28803 - Buncombe	2,834	5,578	8,412	10,007	28.3%	55.7%	84.1%
Primary Service Area	5,369	11,629	16,998	33,477	16.0%	34.7%	50.8%
28806 - Buncombe	4,646	8,275	12,921	14,837	31.3%	55.8%	87.1%
28792 - Henderson	345	877	1,222	15,469	2.2%	5.7%	7.9%
28742 - Henderson	39	85	124	1,115	3.5%	7.6%	11.1%
Secondary Service Area	5,030	9,237	14,267	31,421	16.0%	29.4%	45.4%
Total Service Area	10,399	20,866	31,265	64,898	16.0%	32.2%	48.2%
Inpatient Mission SA				Inpt. Admissions			
Admissions	301	6,467	6,768	as % of Visits	2.9%	31.0%	21.6%

Source: Internal data and Stratasan

Note: Low Acuity contains ED Levels 1-3 (CPT Codes 99281, 99282 and 99283). High Acuity contains ED Levels 4, 5, and Critical Care (CPT Codes 99284, 99285 and 99291)

Step 5: (pages 57-61) Establish incremental market share and projected volume for first three full operating years

The applicant describes its assumptions for incremental market share, projected total Mission ED visits, and projected shift of ED visits to Mission FSER, as summarized below:

- The applicant uses a higher incremental market share for the ZIP codes closer to the proposed FSER.
- The applicant assumes a higher percent shift for low acuity visits.
- The applicant assumes a 7.5% in-migration
- The applicant assumes a constant 2% of visits resulting in inpatient admissions for low acuity patients and 15% of visits resulting in inpatient admissions for high acuity patients, for a combined average total of 4.40% of ED visits resulting in inpatient admissions, per the applicant's table on page 61.

The applicant provides the detailed calculations for projected Mission market share, projected total Mission ED visits, projected shift of visits to Mission FSER, and projected Mission FSER ED visits for the first three full years of operation on pages 59-61, as summarized below.

Projected Mission FSER ED Visits						
ZIP Code-County	2023	2024	2025			
28704 - Buncombe	1,715	1,825	1,942			
28730 - Buncombe	692	730	771			
28732 - Henderson	913	1,009	1,113			
28759 - Henderson	191	217	246			
28791 - Henderson	258	291	326			
28803 - Buncombe	1,803	1,901	2,004			
Primary Service Area	5,572	5,973	6,403			
28806 - Buncombe	1,370	1,378	1,385			
28792 - Henderson	302	348	395			
28742 - Henderson	30	34	37			
Secondary Service Area	1,702	1,759	1,817			
Total Service Area	7,274	7,733	8,220			
In-migration 7.5%	590	627	666			
Total Utilization	7,863	8,360	8,887			
Inpatient Admissions	324	341	359			
% of Visits Resulting						
in Inpatient Admissions*	4.50%[4.12%]	4.40%[4.08%]	4.40%[4.04%]			

Projected Mission FSER ED Visits

*Agency calculations in [brackets] based on applicant's projected utilization and inpatient admissions

- Medical Equipment (Section Q, pages 126-128)
 - Number of procedures is based on the ratio of the procedure volume to ED visits at Mission's main ED for 2019
 - HECT conversion is based on the % distribution of scans for Mission Hospital main campus CT scanners (serving the ED) for FY2020 based on the 2021 LRA

• Observation Beds (Section Q, page 129) - Number of observation days of care are based on the ratio of the hours of care volume to ED visits at Mission's main ED for 2019 divided by 24 hours to get days

However, projected ED and ancillary services utilization is not reasonable and adequately supported based on the following:

- The applicant calculates what it calls a growth trend on pages 50-51 of 2.6% for the service area. The 2.6% is a two-year CAGR calculated for 2017 through 2019 and shows overall service area growth for 2018 at 2.3% and 2019 growth at 3.0%. The table shows 2020 with a decline in visits of 18.1% ((53,174-64,898)/63,898) from 2019.
- The applicant selects March and April of 2021 and calculates an average two month change of 10.6% and applies that 10.6% monthly increase to the 2020 visits to project growth for the rest of 2021. This projected growth is more than four times the applicant's calculated 2017-2019 CAGR of 2.6% (prior COVID percentages) and is not a reasonable proxy for projected monthly growth for 2021 over 2020. Step 3, page 55, results in the following total service area visits.

ZIP Code-County	2019*	2020*	2021	2022	2023	2024	2025
Total Service Area	64,898	53,174	58,827	64,898	66,675	68,542	70,510
Applicant's Calculated CAGR 2017-2019	2.6%						
Year over Year Percent Increase ^A		-18.1%	10.6%	10.3%	2.7%	2.8%	2.9%
2020-2025^							5.8%
CAGR 2021-2025^							4.6%

*From Step 1, page 55 of application

^Agency calculation from applicant's data

As the table above illustrates, the applicant's assumptions and methodology result in a 10.6% increase in total visits for 2021 over 2020, a 10.3% increase for 2022 over 2021, a five-year CAGR of 5.8% from 2020 through 2025, and a four-year CAGR of 4.6% from 2021 through 2025. Each of these growth increases far exceeds the historical pre-COVID 2.6% CAGR for Mission Hospital ED visits for the total service area. The applicant does not provide adequate support to document the reasonableness of the projected total Mission ED visits from the proposed FSER service area.

- The applicant does not provide a reasonable basis for how it determined the incremental market share growth of 0.5% for low acuity patients and 0.1% for high acuity patients, other than stating "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 the other existing hospital EDs."
- The applicant does not provide a reasonable basis for the percent shift of ED volume from Mission to FSER, other than stating higher percentages coming from ZIP codes in closer proximity to the new facility. The applicant purports the development of the FSED is to serve low acuity patients relieving capacity constraints at Mission, allowing Mission to better serve the high acuity patients. However, the methodology shifts a relatively significant portion of the high acuity market share to FSED, (7.4% or 1,030 patients from the PSA in 2025) which calculates to be 16% (1,030/6,403) of the total PSA projected

visits for FSER in 2025. This does not agree with the applicant's identified need to develop the facility, as stated on page 53 of the application:

"The proposed FSER will allow Mission to shift lower acuity ED volume from the main ED to the FSER and allow for resources at the main ED to be more appropriately focused on high acuity patients."

- The applicant does not provide reasonable support for the projected percentage of ED visits resulting in inpatient admissions.
- Medical equipment and observation days projections were based on projected ED volume, which was not reasonable and adequately supported.

Access to Medically Underserved Groups

In Section C, pages 67-68, the applicant discusses access to the medically underserved. On page 67, the applicant states that Mission provides services to all persons in need of medical care, regardless of race, color, gender, religion, nationality, or ability to pay. On page 68, the applicant provides the estimated percentage for each medically underserved group to be served at Mission FSER as shown in the following table.

Medically Underserved Groups	Percentage of Total Patients CY2025
Low income persons*	19.3%
Racial and ethnic minorities	4.4%
Women	53.6%
Persons with Disabilities+	
Persons 65 and older	27.0%
Medicare beneficiaries	33.5%
Medicaid recipients	19.7%

Source: internal Mission data, 2020 *Includes self-pay and charity care patients +Data not tracked

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

- The proposed satellite ED will be licensed as part of Mission Hospital
- The applicant states that approval of this project will allow Mission to continue serving all patient populations

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

- Written comments
- Remarks in lieu of a public hearing
- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is not 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, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

NC

The applicant proposes to expand its emergency services by establishing a freestanding satellite ED, Mission FSER, in south Buncombe County, which will offer 24-hour emergency care, diagnostic imaging, and clinical laboratory services. The satellite ED will be a new campus and will be licensed as part of Mission Hospital. The applicant proposes to relocate and replace an existing Mission Imaging CT scanner. In Section D, page 73, the applicant states that the existing CT scanner at Mission Pardee Health Campus to be relocated and replaced is an underutilized CT scanner that is operated by MH Mission Health Imaging, LLLP (Mission Imaging). The applicant further states that the existing CT scanner to be relocated is not on the Mission Hospital License. The applicant states that Mission Imaging will assign the underutilized CT unit to Mission Hospital to implement at the proposed Mission FSER.

Mission Pardee Health Campus in Arden is an outpatient campus partnership between Pardee Hospital and Mission Hospital. The campus includes imaging services, laboratory, pharmacy, physician practices and an urgent care. Mission Imaging Services provides CT, ultrasound and diagnostic x-ray at Mission Pardee Health Campus in Arden.

In Section D, page 73, the applicant explains why it believes the needs of the population presently utilizing the CT services to be relocated will be adequately met following completion of the project, stating:

"The CT scanner on the Mission Pardee Health Campus has experienced a steady decline in utilization as shown below, demonstrating that this CT scanner can be more effectively used in another location and setting."

The applicant provides a table showing that the existing CT scanner utilization has declined from 2,100 scans in CY2018 to 1,551 scans in CY2020 and states that Mission Imaging has two other CT scanners at its Biltmore campus with sufficient capacity to accommodate any patients displaced from the Mission Pardee Health Campus. As such, the applicant states that

the relocation of the proposed scanner will not impact Mission Imaging's provision of CT services.

However, the information is not reasonable and adequately supported based on the following:

- Relocating the one CT from the Mission Pardee Health Campus will remove access to CT imaging services at that location.
- Patients at Mission Pardee Health Campus who are in need of CT imaging services can access those services at Mission Imaging in Asheville. The applicant discusses the traffic congestion associated with seeking services in Asheville on pages 48-49 as support for the creation of the proposed ED, which would also speak to the difficulty of patients at Mission Pardee Health Campus seeking CT services in Asheville.

In Section Q Form D, page 130, the applicant provides projected utilization for Mission Imaging, as illustrated in the following table.

				0 0		-
	CY2020	CY2021	CY2022	CY2023	CY2024	CY2025
# of Units	3	3	3	2	2	2
# of Scans	13,176	15,079	15,113	15,146	15,179	15,212
# of HECT Units	21,421	24,467	24,552	24,635	24,718	24,801
HECT Units per CT*	7,140	8,156	8,184	12,317	12,359	12,401

Form D.2 Historical and Projected CT Util	lization Mission Imaging
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*Page 3 of Form D Assumptions and Methodology

In Section Q Form C, the applicant provides the assumptions and methodology used to project utilization, which is summarized below:

- CY2020 is based on historical utilization for Mission Imaging's three CT units
- CY2021 is annualized based on actual data through May 20, 2021
- The first full fiscal year of the proposed project will be CY2023
- HECT units are based on historical CAGR of HECT units for each Mission Imaging location
- HECT units per scan have been gradually increasing

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

- The applicant begins its projections based on historical actual utilization
- The applicant proposes growth in utilization based on historical growth

Access to Medically Underserved Groups

In Section D, page 74, the applicant states that it does not expect that the percentage of patients in each group listed on page 73 and served by Mission Imaging will change as a result of the transfer of the CT to Mission Hospital for the relocation and replacement at the proposed Mission FSER. The applicant further states:

"Additionally, the proposed relocation and subsequent replacement will result in better utilization of the underutilized CT scanner as it will be placed in an emergency services setting, which serves a large number of underserved individuals. Furthermore, as detailed in response to Section C, Question 6, Mission provides services to all persons in need of medical care regardless of race, color, gender, religion, nationality, or ability to pay."

The applicant does not adequately demonstrate that the needs of medically underserved groups that will continue to need CT services at Mission Pardee Health Campus will be adequately met following completion of the project for the following reasons:

- The existing CT to be relocated and replaced serves the Mission Pardee Health Campus in Arden.
- The patient population currently served by Mission Imaging in Arden would have to travel to Asheville to access the same services at Mission Imaging.
- The applicant provides evidence of the difficulty with traffic congestion in accessing services in Asheville.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks in lieu of a public hearing
- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is not conforming to this criterion for the following reasons:

- The applicant does not adequately demonstrate that the needs of the population currently using the services to be reduced, eliminated or relocated will be adequately met following project completion for all the reasons described above.
- The applicant does not adequately demonstrate that the project will not adversely impact the ability of underserved groups to access these services following project completion for all the reasons described above.
- (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.

NC

The applicant proposes to expand its emergency services by establishing a freestanding satellite ED, Mission FSER, in south Buncombe County, which will offer 24-hour emergency

care, diagnostic imaging, and clinical laboratory services. The satellite ED will be a new campus and will be licensed as part of Mission Hospital.

In Section E, pages 77-78, the applicant describes the alternatives 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:

- 1. Maintain the Status Quo the applicant states that maintaining the status quo would lead to delays in access to vital emergency services; therefore, this was not an effective alternative.
- 2. Expand ED capacity at Mission Hospital the applicant states that simple capacity issues at the main ED are not the main concern driving the need for the proposed FSER; adding capacity at Mission Main would not solve the issue of timely access to care for patients of South Buncombe county, who are experiencing long ED transport times and wait times. Thus, the applicant determined this was not an effective alternative.
- 3. Develop a freestanding ED at a Different Location the applicant states it determined the rapid population growth and relative lack of access to ED services in the South Buncombe County area was greater than elsewhere in the county. Thus, the applicant determined this was not an effective alternative.

On page 78, the applicant states:

"The proposed Mission FSER in Arden will provide time-critical interventions for serious emergencies requiring immediate care as well as non-emergent care to address a comprehensive array of patient needs."

However, the applicant does not adequately demonstrate the alternative proposed in this application is the most effective alternative to meet the identified need for the following reasons:

- The applicant explains why it believes the proposed project is the most effective alternative; however, the applicant does not adequately support the claims it makes because its projected utilization is not based on reasonable and adequately supported assumptions.
- The application is not conforming to all statutory and regulatory review criteria. An application that cannot be approved cannot be an effective alternative to meet the need.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

- Written comments
- Remarks in lieu of a public hearing
- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is not conforming to this criterion for the reasons stated above.

(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.

NC

The applicant proposes to expand its emergency services by establishing a freestanding satellite ED, Mission FSER, in south Buncombe County, which will offer 24-hour emergency care, diagnostic imaging, and clinical laboratory services. The satellite ED will be a new campus and will be licensed as part of Mission Hospital.

Capital and Working Capital Costs

In Section Q, Form F.1a, the applicant projects the capital costs for the proposed project, as shown in the table below.

Cost Category	Projected Capital Cost
Land Purchase/Closing Costs	\$2,858,000
Site Prep/Landscaping	\$1,250,000
Construction Contract	\$6,006,000
Architect/Engineering Fees	\$250,000
Medical Equipment	\$1,639,101
Non-Medical Equipment/Furniture	\$1,101,899
Consultant Fees	\$27,500
Interest during Construction	\$188,000
TOTAL CAPITAL COST	\$13,320,500

Source: Section Q, Form F.1a

In Form F.1a Assumptions, page 133, the applicant provides the assumptions used to project the capital cost. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based on the following:

- Land costs based on proposed contract
- Site prep, construction costs, and landscaping are based on HCA experience with similar projects
- Architect and engineering fees of Hereford-Dooley Architects
- Medical equipment costs are based on vendor quotes

- Non-medical equipment and furniture costs are based on vendor estimates and HCA experience with similar projects
- Interest during construction are based on HCA Construction Management experience with similar projects

In Section F.3, the applicant projects that start-up costs and initial operating expenses will be ongoing operational costs for provision of services on the Mission Hospital license, and are not considered start-up or initial operating costs.

Availability of Funds

In Section F.2, the applicant states that the capital cost will be funded, as shown in the table below.

Туре	The Charlotte-Mecklenburg Hospital Authority
-	The Charlotte-Mecklehburg Hospital Authority
Loans	\$
Accumulated reserves or OE *	\$
Bonds	\$
Other (Funding by Parent	\$13,320,500
Company, HCA)	
Total Financing	\$13,320,500
* OE = Owner's Equity	

Sources of Capital Cost Financing

* OE = Owner's Equity

The applicant states that Mission will fund the project and provides documentation in Exhibit F-2.1. Exhibit F-2.1 contains a letter from HCA CFO documenting the availability of intercompany funding for capital and working capital for this project. Exhibit F.2-2 contains the most recent 10K financial statements for HCA, the source of funds for the proposed project.

The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project based on the following:

- HCA CFO documents HCA's intent and ability to fund the project
- The most recent financial statements document HCA's ability to fund the project

Financial Feasibility

The applicant provides pro forma financial statements for the first three full fiscal years of operation following completion of the project. In the pro forma financial statements, Form F.2b Projected Revenues and Net Income upon Project Completion, the applicant projects that total revenues will exceed operating expenses in the first three full fiscal years of operation, as shown in the table below.

Mission FSER Projected Revenue and Operating Costs						
	CY2023		CY2024		CY2025	
Total ED Visits*		7,863		8,360		8,887
Total Gross Revenue (Charges)	\$	44,819,100	\$	51,464,160	\$	59,085,042
Total Net Revenue	\$	11,503,498	\$	12,535,838	\$	13,659,922
Average Net Revenue per Visit	\$	1,463	\$	1,500	\$	1,537
Total Operating Expenses	\$	3,814,765	\$	3,904,669	\$	4,007,701
Operating Expense/Visit	\$	485	\$	467	\$	451
Net Income (Loss)	\$	7,688,733	\$	8,631,169	\$	9,652,220

*Form C Utilization

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q. However, the assumptions used by the applicant in preparation of the pro forma financial statements are not reasonable because the projected utilization is not based on reasonable and adequately supported assumptions; and, financial feasibility, including costs and charges are impacted by utilization. See the discussion regarding projected utilization found in Criterion (3) which is incorporated herein by reference.

Conclusion

The Agency reviewed the:

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

Based on that review, the Agency concludes that the application is not conforming to this criterion for the reasons stated 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.

NC

The applicant proposes to expand its emergency services by establishing a freestanding satellite ED, Mission FSER, in south Buncombe County, which will offer 24-hour emergency care, diagnostic imaging, and clinical laboratory services. The satellite ED will be a new campus and will be licensed as part of Mission Hospital.

The 2021 SMFP does not define a service area for emergency departments. The applicant defines the proposed service area by identifying southern Buncombe and northern Henderson county ZIP codes surrounding the proposed facility. The ZIP codes identified by the applicant are 28704, 28730, 28803, and 28806 in northern Buncombe County, and 28732, 28759, 28791, 28792 and 28742 in northern Henderson County. Facilities may also serve residents of counties not included in their service area.

In Section G, page 88, the applicant identifies three other providers of ED services within its proposed service area: Margaret R. Pardee Memorial Hospital, AdventHealth Hendersonville and Mission Hospital.

In Section G, the applicant explains why it believes the proposal would not result in the unnecessary duplication of existing or approved health service capabilities or facilities in the proposed service area. On page 88, the applicant states:

"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 southern 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 northern Henderson County 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."

However, the applicant does not adequately demonstrate that the proposal would not result in an unnecessary duplication of existing or approved services in the service area because the applicant does not adequately demonstrate that the proposed ED is needed in the service area. See the discussion regarding need and projected utilization found in Criterion (3) which is incorporated herein by reference.

Conclusion

The Agency reviewed the:

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

Based on that review, the Agency concludes that the application is not conforming to this criterion based on 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.

С

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

Position	Projected FTE Positions CY2024-CY2025
Administrator (ED manager)	1.0
Registered Nurses	9.0
Nursing Assistants	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 Form H Assumptions. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in Form F.3b. In Section H, pages 90-91, 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 following:

- The applicant projects FTE staffing positions and salary based on the experience of Mission Hospital
- The applicant projects inflation at 2% year over year

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks in lieu of a 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.

(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.

С

The applicant proposes to expand its emergency services by establishing a freestanding satellite ED, Mission FSER, in south Buncombe County, which will offer 24-hour emergency care, diagnostic imaging, and clinical laboratory services. The satellite ED will be a new campus and will be licensed as part of Mission Hospital.

Ancillary and Support Services

In Section I, page 92, the applicant identifies the necessary ancillary and support services for the proposed services. On pages 92-93, 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, pages 93-94, the applicant discusses Mission's relationships with other local health care and social service providers. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the following:

- Mission FSER will be a freestanding ED licensed under Mission Hospital, an existing facility.
- The applicant states that Mission has well established relationships that will continue at Mission FSER.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks in lieu of a 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. Therefore, Criterion (9) is not applicable to this review.

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:
 - (i) would be available under a contract of at least 5 years duration;

(11)

- (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. 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.

С

The applicant proposes to expand its emergency services by establishing a freestanding satellite ED, Mission FSER, in south Buncombe County, which will offer 24-hour emergency care, diagnostic imaging, and clinical laboratory services. The satellite ED will be a new campus and will be licensed as part of Mission Hospital.

On page 98, 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 appears to be suitable for the proposed ED based on the applicant's representations and supporting documentation.

In Section K.2, page 96, the applicant states that the project involves constructing 10,860 square feet of new space. Line drawings are provided in Exhibit K.1.

On pages 96-97, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal based on the following:

- The ED has been carefully planned to provide efficient, economical, and patientcentered care.
- The facility will be developed from a prototypical design, fine-tuned to meet the needs of ED patients and staff.
- The design incorporates current codes and Facility Guidelines Institute (FGI) requirements.
- The construction design incorporates cost-saving solutions.

On page 97, 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 based on the following:

- The proposed project will offer emergency care 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.
- Patients will be charged similar rates to the current main Mission ED.

On page 97, the applicant discusses the energy saving features, identifies any applicable energy saving features that will be incorporated into the construction plans, and provides supporting documentation in Exhibit K-3.

Conclusion

The Agency reviewed the:

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

С

In Section L, page 101, the applicant provides the historical payor mix during CY2020 for Mission Hospital ED, as shown in the table below.

Payor Category	Entire Facility as Percent of Total Patients
Self-Pay	18.1%
Charity Care	4.3%
Medicare*	32.2%
Medicaid*	19.5%
Insurance*	22.0%
Workers Compensation	
TRICARE	
Other (describe)^	3.06%
Total	100.0%

Source: Mission internal data

*Including any managed care plans

^Other is not described

In Section L, page 102, the applicant provides the following comparison for Mission Hospital ED and its western NC service area.

Mission Hospital-Mission FSER Project I.D. #B-12093-21 Page 26

	Percentage of Total Patients Served by the Facility or Campus during the Last Full FY	Percentage of the Population
Female	54.1%	51.3%
Male	45.8%	48.7%
Unknown	0.1%	0.0%
64 and Younger	72.7%	76.7%
65 and Older	27.3%	23.3%
American Indian	1.0%	1.3%
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%	87.6%
Other Race	0.2%	5.3%
Declined / Unavailable	2.2%	0.0%

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks in lieu of a 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 handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

С

Regarding any obligation to provide uncompensated care, community service, or access by minorities and persons with disabilities, in Section L, pages 103-104, 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 has policies relating to financial assistance, including a Charity Financial Assistance Policy for uninsured and underinsured and provides documentation in Exhibit L.2. The applicant further states that the proposed FSER will serve any Medicaid/Medicaid HMO, charity, and uninsured patients who require health care services.

In Section L, page 105, the applicant states that, during the 18 months immediately preceding the application, no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina.

Conclusion

The Agency reviewed the:

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

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

That the elderly and the medically underserved groups identified in this subdivision (c) 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

С

In Section L, page 105, the applicant provides a table showing the projected payor mix for the proposed services in the third full fiscal year, as summarized below.

CY2025		
Payor Source	Mission FSER	
Self-Pay	14.5%	
Charity Care	3.4%	
Medicare*	23.3%	
Medicaid*	18.4%	
Insurance*	37.4%	
Workers Compensation	0.2%	
TRICARE	0.1%	
Other (other non-gov)	2.7%	
Total	100.0%	

Projected Payor Mix

*Including any managed care plan

As shown in the table above, during the third full fiscal year of operation, the applicant projects 14.5 percent of ED services at Mission FSER will be provided to self-pay patients, 23.3 percent of services will be provided to Medicare patients, and 18.4 percent of services will be provided to Medicaid patients.

Exhibit L-2 contains Mission's financial policies. The applicant provides the assumptions and methodology used to project payor mix in Section L, page 106. The projected payor mix is reasonable and adequately supported for the following reasons:

- The projected payor mix is based on NCHA-HIDI market data for ED visits in the applicant's defined service area.
- The applicant assumes that the payor mix for ED services will remain consistent through the project years.

Conclusion

The Agency reviewed the:

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

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

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

С

In Section L, page 107, the applicant describes the range of means by which a person will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks in lieu of a 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.

С

The applicant proposes to expand its emergency services by establishing a freestanding satellite ED, Mission FSER, in south Buncombe County, which will offer 24-hour emergency care, diagnostic imaging, and clinical laboratory services. The satellite ED will be a new campus and will be licensed as part of Mission Hospital.

In Section M, pages 108-109, the applicant describes the extent to which health professional training programs in the area will 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 will have access to the facility for training purposes based on the following:

- Mission maintains an affiliation with the Mountain Area Health Education Center (MAHEC) to support medical residency programs.
- Mission has existing relationships with many health professional training programs.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks in lieu of a 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.

NC

The applicant proposes to expand its emergency services by establishing a freestanding satellite ED, Mission FSER, in south Buncombe County, which will offer 24-hour emergency care, diagnostic imaging, and clinical laboratory services. The satellite ED will be a new campus and will be licensed as part of Mission Hospital.

The 2021 SMFP does not define a service area for emergency departments. The applicant defines the proposed service area by identifying southern Buncombe and northern Henderson county ZIP codes surrounding the proposed facility. The ZIP codes identified by the applicant are 28704, 28730, 28803, and 28806 in northern Buncombe County, and 28732, 28759, 28791, 28792 and 28742 in northern Henderson County. Facilities may also serve residents of counties not included in their service area.

In Section G, page 88, the applicant identifies three other providers of ED services within its proposed service area: Margaret R. Pardee Memorial Hospital, AdventHealth Hendersonville and Mission Hospital.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 110, the applicant states that the proposed project will provide access to care in a setting closer to homes and businesses in the service area, reducing travel time and freeing ambulance services from longer transports, reducing costs and improving efficiency.

"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 110-111, the applicant states that the proposed FSER will treat patients closer to homes and businesses, reducing travel times and ambulance transport distances which will reduce costs and improve efficiencies.

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 111, the applicant states:

"Mission Hospital is dedicated to ensuring quality care and patient safety. . . . 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."

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 111, the applicant states:

"Mission Hospital's Emergency Department does not turn patients away when they require emergency care – regardless of ability to pay. These same policies will be implemented at the FSER. ... 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.

However, the applicant does not adequately demonstrate the proposal would have a positive impact on cost-effectiveness, quality, and access because the applicant does not adequately demonstrate: 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. See the discussion regarding projected utilization found in Criterion (3) which is incorporated herein by reference.

Conclusion

The Agency reviewed the:

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

Based on that review, the Agency concludes that the application is not 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.

С

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, page 117, 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 Asheville Surgery Center. The applicant states that all the plan of correction has been implemented and they are awaiting confirmation of

acceptance of the Action Plan. According to the files in the Acute and Home Care Licensure and Certification Section (AHCL&C), 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. Per the AHCL&C Section, both deficiencies were corrected and the facility is back in compliance. After reviewing and considering information provided by the applicant and by the AHCL&C 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.
- (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 satellite ED, which will include relocating and replacing an existing CT scanner. There are no administrative rules that are applicable to proposals to develop a satellite ED or to relocate and replace an existing CT scanner. Therefore, this Criterion is not applicable to this review.