REQUIRED STATE AGENCY FINDINGS

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

Decision Date: May 28, 2021
Findings Date: May 28, 2021

Project Analyst: Celia C. Inman
Assistant Chief: Lisa Pittman

Project ID #: F-12024-21
Facility: Carolina Endoscopy Center-Monroe
FID #: 070116
County: Union
Applicant: Endoscopy Center-Monroe, LLC
Project: Relocate existing 2-room GI Endo Center

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.

NA

Endoscopy Center-Monroe, LLC (hereinafter referred to as EC-Monroe or "the applicant"), proposes to relocate its licensed, two-room gastrointestinal (GI) endoscopy ambulatory surgical facility (ASF), Carolina Endoscopy Center-Monroe (CEC-Monroe) to a new location approximately one mile away.

The applicant does not propose to:

- develop any beds or services for which there is a need determination in the 2021 SMFP
- acquire any medical equipment for which there is a need determination in the 2021 SMFP
- offer a new institutional health service for which there are any policies in the 2021 SMFP

Therefore, Criterion (1) is not applicable to this review.

(2) Repealed effective July 1, 1987.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, EC-Monroe, which is a joint venture between The Charlotte-Mecklenburg Hospital Authority (CMHA) and Carolina Digestive Health Associates (CDHA), proposes to relocate its existing, licensed GI endoscopy ASF, CEC-Monroe, from its current location in leased space on Sunset Drive in Monroe to a new location in leased space in a medical complex on Campus Park Drive in Monroe, approximately one mile from its current location and less than one mile from Atrium Health Union.

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 in rules adopted by the Department, which receives services from a health service facility."* The 2021 SMFP does not define the service area for GI endoscopy procedure rooms. The Criteria and Standards for Gastrointestinal Endoscopy Procedure Rooms, promulgated in 10A NCAC 14C .3901(6), defines the service area as *"…the geographical area, as defined by the applicant using county lines, from which the applicant projects to serve patients."* The facility is located in Union County and in Section C.3, page 28, the applicant projects that 62% of its patients will originate from Union County, with the next largest percentage of patients originating from South Carolina. Thus, the service area for this facility consists of Union County. Facilities may also serve residents of counties not included in their service area.

The following table summarizes CEC-Monroe's historical (CY2019) patient origin for GI endoscopy services.

CEC-M Historical Patient Origin GI Endoscopy Rooms		
County	1/1/2019-12/31/2019	
	# of Patients	% of Total
Union	2,823	61.6%
South Carolina	647	14.1%
Anson	636	13.9%
Mecklenburg	385	8.4%
Caldwell	45	1.0%
Stanly	18	0.4%
Montgomery	12	0.3%
Other*	19	0.4%
Total	**4,584**	**100.0%**

Source: Section C.2, page 27
*Other includes Cleveland, Gaston, Iredell, Richmond, and Rowan counties and other states

The following table shows CEC-M's projected patient origin for GI endoscopy services for the first three full fiscal years of operation (CY2023-CY2025).

County	CY2023		CY2024		CY2025	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Union	2,571	61.6%	2,583	61.6%	2,596	61.6%
South Carolina	589	14.1%	592	14.1%	595	14.1%
Anson	579	13.9%	582	13.9%	585	13.9%
Mecklenburg	351	8.4%	352	8.4%	354	8.4%
Caldwell	41	1.0%	41	1.0%	41	1.0%
Stanly	16	0.4%	16	0.4%	16	0.4%
Montgomery	11	0.3%	11	0.3%	11	0.3%
Other	17	0.4%	17	0.4%	17	0.4%
Total	**4,176**	**100.0%**	**4,195**	**100.0%**	**4,215**	**100.0%**

Source: Section C.3, page 28
Totals may not sum due to rounding
*Other includes Cleveland, Gaston, Iredell, Richmond, and Rowan counties and other states

In Section C.3, page 28, the applicant states projected patient origin is based on CEC-M's historical patient origin for GI endoscopy services. The applicant's assumptions are reasonable and adequately supported.

Analysis of Need

In Section C.4, pages 30-34, the applicant explains why it believes the population projected to utilize the proposed services needs the services to be relocated, as summarized below:

- Current facility issues (pages 30-32)
- Historical high utilization (page 32)

- Projected population growth and aging in Union County (pages 32-33)

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

- Reliable data is provided to support assertions that the current facility plant is no longer adequate for the services to be provided.
- Internal data is relied upon to support the five-year compound annual growth rate (CAGR) of 2.13%.
- Reliable data sources are used to support assertions about population growth and aging.
- The applicant provides reasonable and adequately supported information to support its assertion that older and aging patient populations require GI endoscopy services.

Projected Utilization

In Section Q Form C, the applicant provides the historical and projected utilization for GI endoscopy rooms at CEC-M through the first three full fiscal years of operation, as shown in the table below.

	Prior	Interim			Projected		
	CY2019	CY2020	CY2021	CY2022	CY2023	CY2024	CY2025
GI Endoscopy Rooms	2	2	2	2	2	2	2
Outpatient GI Endoscopy Procedures	5,367	4,804	4,826	4,849	4,872	4,895	4,918
Total GI Endoscopy Procedures	5,367	4,804	4,826	4,849	4,872	4,895	4,918
Average # of Procedures/Room	2,684	2,402	2,413	2,425	2,436	2,448	2,459
Need for GI Endoscopy Rooms*	1.79	1.60	1.61	1.62	1.62	1.63	1.64

*Need for GI Endoscopy rooms is based on 1,500 procedures per room

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

- CY2023-CY2025 are the first three full fiscal years following the completion of the project.
- The applicant uses annualized CY2020 historical data in order to use the most recent data available, while accounting for the unique impact of the global pandemic, excluding the month of April.

	CY2016	CY2017	CY2018	CY2019	CY2020	3-yr CAGR CY16-19	4-yr CAGR CY16-20
Procedures	4,714	4,629	5,053	5,367	4,804	4.42%	0.47%
Cases	4,039	3,918	4,302	4,584	4,103	4.31%	0.39%
Procedures/Case	1.17	1.18	1.17	1.17	1.17		

- The applicant projects future utilization using a 0.47% 4-yr CAGR from CY2016-CY2020.

- The applicant assumes the future procedure to case ratio will be the same as the procedure to case ratio for CEC-M from CY2018-CY2020.
- The applicant demonstrates that the projected utilization exceeds the required 1,500 procedures per GI endoscopy room.

	CY2021	CY2022	CY2023	CY2024	CY2025	4-yr CAGR
Procedures	4,826	4,849	4,872	4,895	4,918	0.47%
Procedures/Case	1.17	1.17	1.17	1.17	1.17	
Number of Cases	4,137	4,156	4,176	4,195	4,215	
Number of Procedures /Room	2,413	2,425	2,436	2,448	2,459	

Totals are not exact due to rounding

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

- Projected utilization is based on CEC-M's historical GI endoscopy procedure utilization
- The applicant's projected growth rates in GI endoscopy procedures are supported by historical utilization for growth rates at CEC-M
- The applicant provides reasonable and adequately supported information in Section C.3 and Section Q to support the utilization projection and to support the need for the proposed relocation of the two GI endoscopy procedure rooms.

Access to Medically Underserved Groups

In Section C.6, pages 39-40, the applicant states its services are accessible to all residents in need of GI endoscopy services, regardless of race, color, religion, national origin, sex, age, disability, or source of payment. On page 40, the applicant projects the patient percentages of underserved groups seeking GI endoscopy services at CEC-M during the third year of operation (CY2025) following completion of the project, as shown in the following table.

Medically Underserved Groups	Percentage of Total Patients
Low income persons	
Racial and ethnic minorities	17.0%
Women	55.0%
Persons with Disabilities	
The elderly	46.0%
Medicare beneficiaries	44.6%
Medicaid recipients	3.4%

Source: Table on page 40 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 following:

- The applicant bases the projected percentages of patients on CEC-M's CY2019 percentages for the patient population historically served.

- The applicant does not maintain data on the number of low-income persons or handicapped persons served; thus, has no basis on which to estimate those percentages.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- The applicant adequately identifies the population to be served.
- The applicant adequately explains why the population to be served needs the services proposed in this application.
- Projected utilization is reasonable and adequately supported.
- The applicant projects the extent to which all residents, including underserved groups, will have access to the proposed services (payor mix) and adequately supports its assumptions.

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

C

The applicant, EC-Monroe, proposes to relocate its existing GI endoscopy ASF, CEC-Monroe, from its current location in leased space on Sunset Drive in Monroe to a new location in leased space in a medical complex on Campus Park Drive in Monroe, approximately one mile from its current location and less than one mile from Atrium Health Union.

In Section D.1, page 44, the applicant states:

> *"The proposed project will not result in any reduction in access to these services; Endoscopy Center-Monroe will continue to serve the patients currently utilizing these services as the two existing GI endoscopy rooms will be relocated approximately one mile from their current location. As a result of the relocation, patients will have access to additional prep and recovery bays and other facility benefits, providers will have expanded space in the two GI endoscopy rooms allowing for better delivery of care, and the overall structural design will foster better and more efficient patient care."*

On page 44, the applicant further states:

> *"The proposed relocation of CEC-Monroe will have no impact on the ability of each group listed above to obtain the services provided by the facility as it will continue to serve the same patient population in the proposed new location that is only a mile away from the existing location."*

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the applicant adequately demonstrates that:

- The needs of the population currently using the services to be relocated will be adequately met following project completion.
- The project will not adversely impact the ability of underserved groups to access these services following project completion.

(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, EC-Monroe, proposes to relocate its licensed GI endoscopy ASF, CEC-Monroe, to a new location approximately one mile away.

In Section E, page 49, 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 it is unable to achieve operational efficiencies at the current location to be able to serve the rapidly growing county and surrounding area. Further, the current size of the existing GI endoscopy rooms does not meet the modern standards of today's healthcare delivery, and the prep and recovery bays are insufficient to accommodate continued volume growth. Thus, this alternative was rejected.
- Relocate the existing facility to a different site – the applicant states that other sites that were considered were not as convenient, would not offer ample parking, or would require additional travel time for patients. Further, the proposed location will allow CEC-M to be co-located with the CDHA practice currently located at the

proposed location. For these reasons, this alternative was not determined to be an effective alternative.

On page 49, the applicant states that its proposal is the most effective alternative because the new location will allow for operational efficiencies to meet the increasing demands of a growing community, allow for larger procedure rooms, prep and recovery bays, ample parking, and the co-location with the existing CDHA practice at the proposed location.

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

Conclusion

The Agency reviewed the:

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

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

1. **Endoscopy Center-Monroe, LLC (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**

2. **The certificate holder shall relocate two gastrointestinal endoscopy procedure rooms from 1321 East Sunset Drive, Monroe to 1663 Campus Park Drive, Monroe for a total of no more than two gastrointestinal endoscopy procedure rooms upon project completion.**

3. **Upon completion of the project, the certificate holder shall no longer be licensed for any gastrointestinal endoscopy procedure rooms at 1321 East Sunset Drive, Monroe.**

4. **The certificate holder shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditure in Sections F and 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 Sections F and 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.

6. **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. **Progress reports shall be due on the first day of every third month. The first progress report shall be due on November 1, 2021. The second progress report shall be due on February 1, 2022 and so forth.**

7. **No later than three months after the last day of each of the first three full years of operation following initiation of the services authorized by this certificate of need, 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.**

8. **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.

The applicant, EC-Monroe, proposes to relocate its licensed GI endoscopy ASF, CEC-Monroe, to a new location approximately one mile away.

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.

Construction/Renovation Costs	$924,900
Medical Equipment	$87,490
Non-Medical Equipment/Furniture	$163,232
Miscellaneous Costs	$41,975
Total	**$1,217,597**

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 following:

- Construction/renovation and architect/engineering costs are based on the experience of the project architect with similar projects
- Equipment and furniture costs are based on vendor estimates and applicant experience

In Section F, page 53, the applicant states that the relocation project does not involve start-up costs or initial operating expenses.

Availability of Funds

In Section F, page 51, the applicant states that the capital cost will be funded, as shown in the table below.

Sources of Capital Cost Financing

Type	Endoscopy Center-Monroe
Loans	
Cash, Cash Equivalents, Accumulated reserves or OE *	$517,597
Other (Capitalized Portion of Lease)	$ 531,040
Other (Tenant Improvement Allowance)	$168,960
Total Financing	$ 1,217,597

* OE = Owner's Equity

The applicant provides an explanation and documentation of EC-M's intended payment of the capital costs in Section F, page 51, and Exhibit F.2-3, respectively.

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

- Exhibit F.2-1 contains a letter from the Chair of the Board of Managers of Endoscopy Center-Monroe, documenting their intent to fund a portion of the project ($517,597) and the availability of accumulated reserves to fund a portion of the proposed project.
- Exhibit F.2-2 contains a copy of EC-M's balance sheet as of October 21, 2020, showing adequate funds to fund its portion of the project capital cost.
- Exhibit F.2-3 contains the Letter of Intent showing the landlord will be responsible for $531,040 of the construction cost paid up front and $168,960 of construction costs via the tenant improvement allowance with monthly repayment in the amount of $14,998.

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.2a, the applicant projects that revenues will exceed operating expenses in the first three full fiscal years following completion of the project, as shown in the table below.

	1st Full Fiscal Year CY2023	2nd Full Fiscal Year CY2024	3rd Full Fiscal Year CY2025
Total Procedures	4,872	4,895	4,918
Total Gross Revenues	$ 3,810,350	$ 3,943,179	$ 4,080,637
Total Net Revenue	$ 2,774,885	$ 2,871,617	$ 2,971,721
Average Net Revenue per Procedure	$ 570	$ 587	$ 604
Total Operating Expenses	$ 1,895,448	$ 1,951,587	$ 2,009,463
Average Operating Expense per Procedure	$ 389	$ 399	$ 409
Net Income	$ 879,437	$ 920,030	$ 962,258

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q, page 13. The applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

- Development of the CON application began during CY2020, as such, CY2019 data represents the most recent full fiscal year of data available and was used for estimating future financial projections.
- Gross revenue is the projected volume by payor multiplied by the projected average charge.
- Expenses are based on experience.
- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions for all the reasons described above.
- The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal for all the reasons described above.
- The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of revenues and operating expenses for all the reasons described above.

(6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

C

The applicant, EC-Monroe, proposes to relocate its licensed GI endoscopy ASF, CEC-Monroe, to a new location approximately one mile away.

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 in rules adopted by the Department, which receives services from a health service facility."* The 2021 SMFP does not define the service area for GI endoscopy procedure rooms. The Criteria and Standards for Gastrointestinal Endoscopy Procedure Rooms, promulgated in 10A NCAC 14C .3901(6), defines the service area as *"…the geographical area, as defined by the applicant using county lines, from which the applicant projects to serve patients."* The facility is located in Union County and in Section C.3, page 28, the applicant projects that 62% of its patients will originate from Union County, with the next largest percentage of patients originating from South Carolina. Thus, the service area for this facility consists of Union County. Facilities may also serve residents of counties not included in their service area.

The 2021 SMFP shows there are four existing or approved GI endoscopy rooms in two facilities in Union County, as shown below.

Union County GI Endoscopy Services – FY2019 Data			
Existing Facilities	**Endoscopy Rooms**	**Endoscopy Cases**	**Endoscopy Procedures**
Carolina Endoscopy Center-Monroe	2	3,870	4,328
Atrium Health Union	2	1,383	1,825
Total	**4**	**5,253**	**6,153**

Source: Table 6F: Endoscopy Room Inventory (page 92 of the 2021 SMFP)

In Section G.2, page 65, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved GI endoscopy services in Union County. The applicant states:

"The proposed project will not result in any unnecessary duplication of the existing or approved facilities that provide the same services and are located in the service area because the two existing GI endoscopy rooms that Endoscopy Center-Monroe proposes to relocate are existing and well utilized, as shown in the table above. There will be no change to the number of GI endoscopy rooms as a result of the proposed project. However, the size of each room will be larger and there will be additional prep and recovery bays added/available. Moreover, CECMonroe is the only [emphasis in original] *freestanding GI endoscopy ASF in Union County. Thus, the proposed project will not result in any unnecessary duplication of services; rather, the relocation of the existing GI endoscopy rooms will enhance existing resources available in the proposed service area."*

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:

- The proposal would not result in an increase in GI endoscopy rooms in Union County.
- The applicant adequately demonstrates that the proposed relocation of the ASF with two GI endoscopy rooms is needed in addition to the existing or approved GI endoscopy rooms.

Conclusion

The Agency reviewed the:

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

Based on that review, the Agency concludes that the application is conforming to this criterion for 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, EC-Monroe, proposes to relocate its licensed, two-room GI endoscopy ASF, CEC-Monroe, to a new location approximately one mile away.

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

Current & Projected Staffing by FTE Position		
Position	**CY2019**	**CY2023-CY2025**
Registered Nurse	5.00	5.00
Nurse Manager	0.50	0.50
Clinical supervisor RN	0.75	0.75
Front Desk	1.00	1.00
Endoscopy Technician	2.50	2.50
Total	**9.75**	**9.75**

The assumptions and methodology used to project staffing are provided in Section Q Form H. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.3, which is found in Section Q. In Section H.2 and Section H.3, pages 66-67, the applicant describes the methods to be used to recruit or fill new positions and its 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:

- Current FTE positions remained unchanged through CY2025, the third full fiscal year of the project.
- The number of FTEs for each position type reflects historical staffing patterns.
- Annual salary per FTE position are based on the current salary per FTE inflated 3.0% annually.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons 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, EC-Monroe, proposes to relocate its licensed GI endoscopy ASF, CEC-Monroe, to a new location approximately one mile away.

Ancillary and Support Services

In Section I, page 68, the applicant identifies the necessary ancillary and support services for the proposed services. On page 68, the applicant explains that all ancillary and support services required for CEC-M are provided by CDHA and CMHA through operating agreements and will continue to be provided by CDHA and CMHA upon completion of the proposed project. Exhibit I.1 contains a letter from EC-M Chair, Board of Managers, attesting to the availability of necessary ancillary and support services. The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on the following:

- Necessary ancillary and support services are currently being provided by CDHA and CMHA.
- The applicant provides documentation in Exhibit I.1 that the necessary ancillary and support services will continue to be provided.

Coordination

In Section I, page 69, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit I.2. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the following:

- The applicant states that the facility has established relationships with other local healthcare and social service providers.
- The applicant states that the existing relationships will continue following completion of the proposed project.
- Exhibit I.2 contains letters of support from healthcare providers.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

NA

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

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

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

NA

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, EC-Monroe, proposes to relocate its licensed, two-room GI endoscopy ASF, CEC-Monroe, from its current location in leased space on Sunset Drive in Monroe to a new location in leased space in a medical complex on Campus Park Drive in Monroe. The medical complex in which EC-M proposes to lease space to house the relocated GI endoscopy facility is located near the intersection of Highways 74 and 601 in Union County, approximately one mile from its current location and less than one mile from Atrium Health Union.

In Section K, page 72, the applicant states that the project involves the renovation of 5,632 square feet in leased space. Line drawings are provided in Exhibit C.1.

On pages 73-75, 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.3. The site appears to be suitable for the proposed ASF based on the applicant's representations and supporting documentation.

On page 73, 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 upfit for the leased space can occur within the existing footprint of the building.
- The space is designed to provide the necessary square footage to provide an efficient and accessible patient and staff experience, without undue excess space.
- The architect believes the proposed cost, design, and means of renovation represent the most reasonable approach based on experience with similar projects in North Carolina.

On page 73, 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 applicant states that CEC-M, as a freestanding ASF, represents a low-cost alternative for the provision of outpatient GI endoscopy services.
- EC-M benefits from the significant cost savings measures through the large economies of scale provided by CMHA, as majority member of EC-M.

On page 73, the applicant 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

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.1, page 76, the applicant provides the historical payor mix for CY2019 at CEC-M, as summarized in the table below.

Payment Source	Percent of Total GI Endoscopy Patients
Self-Pay	0.7%
Medicare*	44.6%
Medicaid*	3.4%
Insurance*	50.5%
Other (VA)	0.7%
Total**	**100.0%**

Source: Table on page 76 of the application.
*Includes managed care plans.
Totals may not sum due to rounding

In Section L.1, page 77, the applicant provides the following comparison of its patient population to the Union County service area population.

	% of Total Patients Served at CEC-M during CY2019	% of the Population of Union County
Female	55.0%	49.3%
Male	45.0%	50.7%
Unknown	0.0%	0.0%
64 and Younger	54.0%	87.0%
65 and Older	46.0%	13.0%
American Indian	0.0%	0.6%
Asian	1.0%	3.6%
Black or African-American	16.0%	12.5%
Native Hawaiian or Pacific Islander	0.0%	0.1%
White or Caucasian	78.0%	81.1%
Other Race	0.0%	2.1%
Declined / Unavailable	5.0%	0.0%

Source: Section L.1, page 77 of application

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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.2, page 79, the applicant states that the facility has no obligation under any applicable federal regulations to provide uncompensated care, community service, or access by minorities and handicapped persons.

In Section L.2, page 79, the applicant states that during the last five years it has not been notified of any patient civil rights equal access complaints filed against the facility identified in Section A, Question 4.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

(c) That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services; and

C

In Section L.3, page 80, the applicant projects the following payor mix for CEC-M and GI endoscopy services during the third year of operation (CY2025) following completion of the project, as shown in the following table.

Payment Source	Entire Facility	Percent of Total GI Endoscopy Patients
Self-Pay	0.70%	0.70%
Medicare*	44.60%	44.60%
Medicaid*	3.40%	3.40%
Insurance*	50.50%	50.50%
Other (VA)	0.70%	0.70%
Total**	**100.0%**	**100.0%**

Source: Table on page 80 of the application.
*Includes managed care plans.
**Totals may not foot due to rounding.

As shown in the table above, during the third full fiscal year of operation, the applicant projects 0.7 percent of GI endoscopy services will be provided to self-pay patients, 44.6 percent to Medicare patients, and 3.4 percent to Medicaid patients.

In Section L.3, page 80, the applicant provides the assumptions and methodology used to project payor mix following completion of the project. The projected payor mix is reasonable and adequately supported because it is based on the applicant's historical payor mix.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

(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.5, page 82, the applicant adequately describes the range of means by which patients will have access to the proposed services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

The applicant, EC-Monroe, proposes to relocate its licensed, two-room GI endoscopy ASF, CEC-Monroe, to a new location approximately one mile away.

In Section M.1, page 83, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes. The applicant adequately demonstrates that health professional training programs in the area have access to the facility for training purposes based on the following:

- The applicant lists the established relationships that CEC-M already has in place with health training programs in the area.
- The applicant lists the established relationships that CMHA has in place with health training programs in the area.
- The applicant states that the programs listed on page 83 will continue to have access to clinical training opportunities at CEC-M, as appropriate.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

(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, EC-Monroe, proposes to relocate its licensed, two-room GI endoscopy ASF, CEC-Monroe, to a new location approximately one mile away.

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 in rules adopted by the Department, which receives services from a health service facility."* The 2021 SMFP does not define the service area for GI endoscopy procedure rooms. The Criteria and Standards for Gastrointestinal Endoscopy Procedure Rooms, promulgated in 10A NCAC 14C .3901(6), defines the service area as *"…the geographical area, as defined by the applicant using county lines, from which the applicant projects to serve patients."* The facility is located in Union County and in Section C.3, page 28, the applicant projects that 62% of its patients will originate from Union County, with the next largest percentage of patients originating from South Carolina. Thus, the service area for this facility consists of Union County. Facilities may also serve residents of counties not included in their service area.

The 2021 SMFP shows there are four existing or approved GI endoscopy rooms in two facilities in Union County, as shown below.

Union County GI Endoscopy Services – FY2019 Data			
Existing Facilities	**Endoscopy Rooms**	**Endoscopy Cases**	**Endoscopy Procedures**
Carolina Endoscopy Center-Monroe	2	3,870	4,328
Atrium Health Union	2	1,383	1,825
Total	**4**	**5,253**	**6,153**

Source: Table 6F: Endoscopy Room Inventory (page 92 of the 2021 SMFP)

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 85, the applicant states:

> *"The proposed project is expected to enhance competition in the service area by promoting cost effectiveness, quality, and access to GI endoscopy services."*

Regarding the impact of the proposal on cost effectiveness, in Section N, page 85, the applicant states:

> *"The proposed relocation will enhance cost-effectiveness of the GI endoscopy facility through the addition of prep and recovery bays, a larger scope cleaning room, and additional storage space among other benefits associated with the new location. These*

additional spaces will allow for more efficient patient throughput, resulting in greater cost efficiency."

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 85, the applicant states:

"Endoscopy Center-Monroe is dedicated to providing the highest quality care. The relocation of CEC-Monroe will provide an increased number of prep and recovery spaces. The larger GI endoscopy rooms will foster high quality care allowing for ample clinical space at the facility. A larger centralized nurse station will enable more than two nurses to operate in the space at the same time while also allowing them to have a clear line of vision to all patients in the prep and recovery bays so that they may better monitor those patients and quickly respond when needed. The benefits of the improved floor plan of the proposed facility, including a larger waiting/reception area and the addition of a second bathroom in the prep and recovery area, will improve Endoscopy Center-Monroe's ability to deliver high quality GI endoscopy services at CEC-Monroe."

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 86, the applicant states:

"The proposed project will continue to promote access to GI endoscopy services in the service area, as demonstrated in CEC-Monroe's Indigent and Medical Underserved Fee Reduction Policy provided in Exhibit C.6. Endoscopy Center-Monroe will continue to serve this population as dictated by the mission of CMHA, the designated manager of Endoscopy Center-Monroe, LLC, which is the foundation for every action taken. The mission is simple, but unique: To improve health, elevate hope, and advance healing – for all. This includes the medically underserved."

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 will ensure the quality of the proposed services and the applicant's record of providing quality care in the past.

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
- Information publicly available during the review and used by the Agency

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

(19) Repealed effective July 1, 1987.

(20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C

In Section Q Form O, page 16, the applicant identifies the hospitals and ASFs located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of 19 other related facilities located in North Carolina.

In Section O, page 89, the applicant states that, during the 18 months immediately preceding the submittal of the application, each of the facilities listed on Form O has continually maintained all relevant licensure, certification, and accreditation. One alleged incident related to quality of care occurred at one of these facilities. The applicant states that all the problems have been corrected. 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, incidents related to quality of care occurred in one of these facilities. 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 all 20 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, EC-Monroe, proposes to relocate its licensed, two-room GI endoscopy ASF, CEC-Monroe, to a new location approximately one mile away. The Criteria and Standards for Gastrointestinal Endoscopy Procedure Rooms in Licensed Health Service Facilities, promulgated in 10A NCAC 14C .3900, are not applicable to this review because the applicant does not propose to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility.