

## REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: December 8, 2023

Findings Date: December 8, 2023

Project Analyst: Cynthia Bradford

Co-Signer: Mike McKillip

Project ID #: F-12414-23

Facility: Denver Surgery Center

FID #: 230716

County: Lincoln

Applicant: Atrium Health Denver ASC, LLC

Project: Develop no more than one GI endoscopy room and one procedure room at an existing ambulatory surgery 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.

C

Atrium Health Denver ASC, LLC, (hereinafter referred to as “the applicant” or Denver Surgery Center, proposes to develop no more than one GI endoscopy room and one procedure room at an existing ambulatory surgery center.

### **Policies**

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

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

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

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

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

The capital expenditure of the project is over \$5 million. In Section B, pages 28-29, the applicant describes its plan to ensure energy efficiency and water conservation. The applicant adequately demonstrates that the application includes a written statement describing the project’s plans to ensure improved energy efficiency and water conservation. Therefore, the application is consistent with Policy GEN-4.

## **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

- The applicant does not propose to develop any beds, services or acquire any equipment for which there is a need determination in the 2023 SMFP.
- The applicant adequately demonstrates that the proposal is consistent with Policy GEN-4 because the applicant adequately demonstrates that the application includes a written statement describing the project’s plan 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, persons with disabilities, the elderly, and other underserved groups are likely to have access to the services proposed.

## C

The applicant proposes to develop no more than one GI endoscopy room and one procedure room at an existing ambulatory surgery center.

In Section C.1, page 30, the applicant describes the proposed project as follows:

*“Atrium Health Denver ASC, LLC proposes to develop one GI endoscopy room and one procedure room at the existing outpatient surgery center, Atrium Health East Lincoln Surgery Center, which currently operates with one licensed operating room. As part of the proposed project, Atrium Health Denver ASC, LLC proposes to convert the existing hospital-based facility of Atrium Health Lincoln to a freestanding ambulatory surgical facility (ASF) that will do business as Denver Surgery Center. Upon completion of the proposed project, Atrium Health Denver ASC, LLC will operate one operating room (OR), one GI endoscopy room, and one procedure room at the freestanding ASF, Denver Surgery Center.”*

### **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 2023 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 county where the proposed GI endoscopy room will be developed.*” The proposed facility will be developed in Lincoln County. Thus, the service area for the proposed facility is Lincoln County. Facilities may also serve residents of counties not included in their service area.

The applicant provided patient origin data from Atrium Health East Lincoln Surgery Center, which is the hospital-based ambulatory surgery center that will be converted into a free-standing ambulatory surgery center at the completion of this project.

The following table illustrates historical patient origin, from Section C, page 33:

Entire Facility or Campus	Atrium Health East Lincoln Surgery Center	
	Last Full FY 01/01/2022 to 12/31/2022	
County or other geographic area such as ZIP code	Number of Patients	% of Total
Lincoln	324	51.8%
Catawba	102	16.3%
Gaston	69	11.1%
Mecklenburg	20	3.2%
Cleveland	20	3.2%
Caldwell	19	3.0%
Iredell	18	2.9%
Other^	53	8.5%
<b>Total</b>	<b>626</b>	<b>100.0%</b>

Source: Section C, page 33

Numbers may not sum due to rounding.

^The applicant states "other" includes other counties and other states.

The following table illustrates projected patient origin, from Section C, page 34:

Denver Surgery Center Projected Patient Origin – Procedure Room						
COUNTY/ZIP CODE	1 <sup>ST</sup> FULL FY (CY 2026)		2 <sup>ND</sup> FULL FY (CY 2027)		3 <sup>RD</sup> FULL FY (CY 2028)	
	# PTS.	% OF TOTAL	# PTS.	% OF TOTAL	# PTS.	% OF TOTAL
Lincoln	193	39.7%	195	39.7%	198	39.7%
Catawba	82	16.9%	83	16.9%	84	16.9%
Gaston	51	10.4%	51	10.4%	52	10.4%
Cleveland	26	5.4%	27	5.4%	27	5.4%
Caldwell	26	5.4%	27	5.4%	27	5.4%
Iredell	22	4.5%	22	4.5%	22	4.5%
Cabarrus	22	4.5%	22	4.5%	22	4.5%
Mecklenburg	17	3.4%	17	3.4%	17	3.4%
Other^	48	9.8%	48	9.8%	49	9.8%
<b>Total</b>	<b>487</b>	<b>100.0%</b>	<b>492</b>	<b>100.0%</b>	<b>498</b>	<b>100.0%</b>

Source: Section C, page 34

Numbers may not sum due to rounding.

^The applicant states "other" includes other counties and other states.

Denver Surgery Center Projected Patient Origin – GI Endo Room						
COUNTY/ZIP CODE	1 <sup>ST</sup> FULL FY (CY 2026)		2 <sup>ND</sup> FULL FY (CY 2027)		3 <sup>RD</sup> FULL FY (CY 2028)	
	# PTS.	% OF TOTAL	# PTS.	% OF TOTAL	# PTS.	% OF TOTAL
Lincoln	1,044	76.3%	1,056	76.3%	1,069	76.3%
Catawba	144	10.5%	145	10.5%	147	10.5%
Gaston	127	9.3%	129	9.3%	130	9.3%
Cleveland	31	2.3%	32	2.3%	32	2.3%
Other^	22	1.6%	22	1.6%	22	1.6%
<b>Total</b>	<b>1,368</b>	<b>100.0%</b>	<b>1,384</b>	<b>100.0%</b>	<b>1,400</b>	<b>100.0%</b>

Source: Section C, page 34

Numbers may not sum due to rounding.

^The applicant states “other” includes other counties and other states.

Denver Surgery Center Projected Patient Origin – OR						
COUNTY/ZIP CODE	1 <sup>ST</sup> FULL FY (CY 2026)		2 <sup>ND</sup> FULL FY (CY 2027)		3 <sup>RD</sup> FULL FY (CY 2028)	
	# PTS.	% OF TOTAL	# PTS.	% OF TOTAL	# PTS.	% OF TOTAL
Lincoln	210	53.9%	213	53.9%	215	53.9%
Gaston	85	21.9%	87	21.9%	87	21.9%
Catawba	48	12.2%	48	12.2%	49	12.2%
Mecklenburg	31	7.9%	31	7.9%	32	7.9%
Cleveland	4	1.0%	4	1.0%	4	1.0%
Other^	12	3.1%	12	3.1%	12	3.1%
<b>Total</b>	<b>390</b>	<b>100.0%</b>	<b>395</b>	<b>100.0%</b>	<b>399</b>	<b>100.0%</b>

Source: Section C, page 34

Numbers may not sum due to rounding.

^The applicant states “other” includes other counties and other states.

Denver Surgery Center Projected Patient Origin – Entire Facility						
COUNTY/ZIP CODE	1 <sup>ST</sup> FULL FY (CY 2026)		2 <sup>ND</sup> FULL FY (CY 2027)		3 <sup>RD</sup> FULL FY (CY 2028)	
	# PTS.	% OF TOTAL	# PTS.	% OF TOTAL	# PTS.	% OF TOTAL
Lincoln	1,447	64.5%	1,464	64.5%	1,482	64.5%
Catawba	274	12.2%	276	12.2%	280	12.2%
Gaston	263	11.7%	267	11.7%	269	11.7%
Cleveland	61	2.7%	63	2.7%	63	2.7%
Mecklenburg	48	2.1%	48	2.1%	49	2.1%
Other^	152	6.8%	153	6.8%	154	6.8%
<b>Total</b>	<b>2,245</b>	<b>100.0%</b>	<b>2,271</b>	<b>100.0%</b>	<b>2,297</b>	<b>100.0%</b>

Source: Section C, page 34

Numbers may not sum due to rounding.

^The applicant states “other” includes other counties and other states.

In Section C, pages 33-34, the applicant provides assumptions and methodology used to project its patient origin. The applicant's assumptions are reasonable and adequately supported based on the following:

- The applicant projects patient origin for the proposed facility based on historical patient origin for its existing Lincoln County facility.
- The applicant projects patient origin based on existing patient origins shifting from the hospital-based facility to the proposed free-standing ambulatory surgical facility.

### **Analysis of Need**

In Section C, pages 36-43, the applicant explains why it believes the population projected to be served by the proposed project needs the proposed services, summarized as follows:

- **Population Growth and Aging:** the applicant discusses how Lincoln County's population is expected to grow at a compound annual rate of 1.2 percent over the next five years, as demonstrated in the table on page 37 of the application. In addition, Lincoln County's 65 and over cohort is projected to grow at a 3.6 percent compound annual rate over the next five years, or 19.2 percent overall which is significant because, typically, older residents utilize healthcare services at a higher rate than those who are younger. (Pages 37-38)
- **Need to Convert from Hospital-Based to Freestanding:** the applicant states that procedures such as mastectomies, joint replacements, and gallbladder removals were once highly invasive procedures that required an extensive inpatient stay. Advances in technology allow these procedures to be done less invasively, where patients require minimal recovery time and are most often released within the same day. In addition, Medicare and private insurers are increasing the number of procedures that may be performed (and reimbursed) on an outpatient basis. As a result, the share of outpatient surgery cases performed in Lincoln County has steadily increased over the last decade. (pages 38-40)
- **Need for a GI Endoscopy Room at Denver Surgery Center:** the applicant states that the two GI endoscopy rooms at Atrium Health Lincoln are on track to be well over 100 percent capacity in CY 2023. A new gastroenterologist joined Atrium Health Lincoln in July of 2023 and now splits time between the hospital and Atrium Health East Lincoln Surgery Center. As a result, operators at Atrium Health Lincoln expect that actual utilization in CY 2023 will be even higher than the annualized volume in the table above. The proposed GI endoscopy room at Denver Surgery Center will not only introduce lower cost freestanding GI endoscopy services to Lincoln County, but it also will create additional capacity that, in turn, will enhance timely access to the existing hospital-based GI endoscopy services provided by Atrium Health Lincoln to those patients for whom a freestanding option is not clinically appropriate. (pages 40-41)
- **Need for a Procedure Room at Denver Surgery Center:** The applicant states that all cases at Atrium Health East Lincoln Surgery Center are performed in a one-room surgery center, which is less efficient for staff and surgeons and not

ideal given increasing demand. A number of physicians schedule “surgery days” each month at Atrium Health East Lincoln Surgery Center. The cohort of existing surgeons are asking for additional “surgery days”, and surgical groups are recruiting additional physicians to accommodate local patient demand. (pages 41-42)

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

- The applicant provides reliable data to support its projections of population growth, aging and the health status of the population in the proposed service area.
- The applicant provides reliable data to support the need to convert from a hospital based to a free standing ASF.
- The applicant uses historical data of its existing GI endoscopy services in the proposed service area to support the need for additional GI endoscopy services in the same service area.
- The applicant uses historical data of its existing outpatient procedure services in the proposed service area to support the need for additional outpatient procedure services in the same service area.

Projected Utilization

GI Endoscopy

In Section Q, Form C.3b, page 3, the applicant provides the projected utilization for GI endoscopy procedures at Denver Surgery Center as illustrated in the following table:

<b>Projected Utilization for Denver Surgery Center GI Endoscopy</b>	<b>Partial FY CY2025</b>	<b>FY1 CY2026</b>	<b>FY2 CY2027</b>	<b>FY3 CY2028</b>
GI Endoscopy Procedures	456	1,847	1,869	1,891
GI Endoscopy Rooms	1	1	1	1
Procedures per Room	456	1,847	1,869	1,891
Utilization Percent*	30.4%	123.1%	124.6%	126.1%

\*Utilization Percent = Procedures Per Room / 1,500 threshold\*100

In Section Q, Form C, page the applicant provides the assumptions and methodology used to project utilization, as summarized below.

- The applicant analyzed historical utilization of its existing GI endoscopy rooms at Atrium Health Lincoln, noting that utilization dropped significantly due to their full-time gastroenterologist in Lincoln County reduced their practice to part-time in December 2021, which impacted FY 2022 and the first part of FY 2023.
- The total number of GI endoscopy cases grew 0.6% from CY20 to CY23 as illustrated in the table below.

Atrium Health Lincoln Historical Utilization per GI Endoscopy Room					
	CY20	CY21	CY22	CY23	CAGR*
Total GI Procedures	3,261	3,898	2,601	3,320	0.6%
Endoscopy Rooms	2	2	2	2	
Procedures per Room**	1,631	1,949	1,301	1,660	
Utilization***	109%	130%	87%	111%	

Source: CMHA Internal Data reported in Form C, Assumptions and Methodology

\*Compound Annual Growth Rate

\*\*Procedures per Room = Total GI Procedures/ Endoscopy Rooms

\*\*\*Utilization = Total GI Procedures/1,500 threshold \*100

- Next, the applicant reviewed projected population growth for Lincoln County from 2023-2028, using estimates from the North Carolina Office of State Budget and Management. Lincoln County’s total population is projected to grow by 1.2% annually from 2022 to 2027. Lincoln County’s 65+ population is projected to grow by 3.6% annually from the same time period. (Section C.4) The applicant is using the Lincoln County population annual growth rate of 1.2% to project utilization of its existing and proposed GI endoscopy rooms annually through CY28.
- The applicant states that during CY2025, approximately 25% of all GI endoscopy cases treated at Atrium Health Lincoln will shift to Denver Surgery Center. This shift is supported by patient origin data from Atrium Health Lincoln, which shows that roughly 25 percent of outpatients reside in areas that are geographically closer or equidistant to the surgery center. The projected shift is illustrated in the table below:

Projected Shift of GI Endoscopy Cases to Denver Surgery Center				
Site	CY 2025 Partial FY	CY 2026 (FFY1)	CY 2027 (FFY2)	CY 2028 (FFY3)
Atrium Health Lincoln Center Shift Percentage	25%	25%	25%	25%
<b>Total GI Cases to Shift to Denver Surgery Center</b>	218	881	892	903

Source: Section Q, Form C Assumptions and Methodology, page 3

- The projected volume of GI endoscopy procedures at Atrium Health Lincoln following the proposed shift to Denver Surgery Center. The projected cases are illustrated in the table below:

Projected GI Endoscopy Procedures at all Facilities After Shift					
Site	CY2024	CY2025 Partial FY	CY2026 (FFY1)	CY2027 (FFY2)	CY2028 (FFY3)
Denver Surgery Center	0	218	881	892	903
Atrium Health Lincoln	4,091	3,922	3,307	3,347	3,387
<b>Total GI Procedures</b>	4,091	4,140	4,188	4,239	4,290

The applicant states that a growing number of Lincoln County outpatients choose to receive care at Carolinas Medical Center (CMC), Atrium Health Endoscopy Center Kenilworth, and Atrium Health Endoscopy Center Ballantyne, all of which are highly



utilized facilities and inconveniently located for Lincoln County residents. The table below shows the number of outpatient GI endoscopy procedures at these three locations that are performed on Lincoln County residents.

<b>Historical Lincoln County Outpatient GI Endoscopy Procedures at CMC, Atrium Health Endoscopy Center Kenilworth &amp; Atrium Health Endoscopy Center Ballantyne</b>					
	CY 2020	CY 2021	CY 2022	CY 2023^	CAGR
CMC	293	360	544	528	21.7%
AHEC Kenilworth & AHEC Ballantyne	102	146	330	222*	29.6%

Source: CMHA internal data.

^Annualized based on January to March data.

\*Annualized based on January to April data.

- The applicant projects that 50% of outpatient GI endoscopy procedures at CMC and 75% of GI endoscopy outpatient procedures at AHEC Kenilworth & AHEC Ballantyne will shift to Denver Surgery Center as shown in the table below.

<b>Projected Lincoln County GI Endoscopy Procedures To Shift Denver Surgery Center</b>				
Site	CY 2025 Partial FY	CY 2026 (FFY1)	CY 2027 (FFY2)	CY 2028 (FFY3)
CMC – percentage of procedures to shift	50%	50%	50%	50%
Number of GI Endo Procedures to Shift	68	274	277	280
AHEC Kenilworth & AHEC Ballantyne - percentage of procedures to shift	75%	75%	75%	75%
Number of GI Endo Procedures to Shift	43	173	175	177
<b>Total GI Procedures to Shift to Denver Surgery Center from Other GI Endo Facilities</b>	<b>111</b>	<b>447</b>	<b>452</b>	<b>457</b>

Source: Section Q, Form C Assumptions and Methodology, pages 4-5

The projected volume to move and the projected total volume to be performed in the proposed GI endoscopy room at Denver Surgery Center in CY 2028, the third full fiscal year of the proposed project, is summarized below.

<b>Denver Surgery Center Projected GI Endoscopy Room Procedures After Shifts/Move</b>				
	CY 2025 Partial FY	CY 2026 (FFY1)	CY 2027 (FFY2)	CY 2028 (FFY3)
Move from Existing Operating Room	128	516	525	532
Shift from Atrium Health Lincoln	218	881	892	903
Shift from CMC	68	274	277	280
Shift from AHEC Kenilworth & AHEC Ballantyne	43	173	175	177
<b>Total Procedures</b>	<b>456</b>	<b>1,847</b>	<b>1,869</b>	<b>1,891</b>

Source: Section Q, Form C Assumptions and Methodology, page 6

- The applicant projects that by CY 2028, the third project year for the proposed project, 1,891 GI endoscopy procedures per room will be performed at the Denver Surgery Center, which exceeds the 1,500 procedures per room performance standard.

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

- Projected utilization is based on Atrium Health East Lincoln’s historical GI endoscopy procedure data for all of its two existing Lincoln County GI endoscopy procedure rooms.
- The applicant’s projected growth rates used to project utilization of GI endoscopy procedures are supported by the growing population of Lincoln County
- The assumptions used to project the market share of GI endoscopy procedures projected to be performed at Denver Surgery Center are supported by the applicant’s historical experience.

Operating Room and Procedure Room

The table below summarizes the surgical cases performed in the existing operating room at Atrium Health East Lincoln Surgery Center (excluding the GI endoscopy procedures).

	CY 2020	CY 2021	CY2022	CY 2023^
Dentistry	176	269	355	396
OBGYN	10	43	49	54
General	29	26	11	18

Source: Section Q, Form C, page 7, Assumptions and Methodology

^Annualized based on January to April data

The applicant projects that these other surgical specialties at Denver Surgery Center will grow at the projected Lincoln County population growth rate beginning in CY 2024, as demonstrated in the table below.

<b>Atrium Health East Lincoln/Denver Surgery Center Projected OR Cases Before Shift</b>						
	CY 2024	CY 2025	CY 2026	CY2027	CY 2028	<b>CAGR</b>
Dentistry	475	481	487	492	498	1.2%
OBGYN	270	273	276	280	283	1.2%
General	24	24	25	25	25	1.2%
Urology	87	88	89	90	91	1.2%

Source: Section Q, Form C, page 8, Assumptions and Methodology

The applicant states that all the GI endoscopy procedures currently performed today in the operating room at Atrium Health East Lincoln Surgery Center will move to the GI endoscopy room following the proposed project. Additionally, all the projected dentistry cases currently performed in the operating room will move to the procedure room following the proposed project. The projected number of OR cases following these moves is summarized in the table below.

<b>Atrium Health East Lincoln/Denver Surgery Center Projected OR Cases After Shift</b>						
	<b>CY 2023^</b>	<b>CY 2024</b>	<b>CY 2025</b>	<b>CY 2026</b>	<b>CY2027</b>	<b>CY 2028</b>
GI Endoscopy	208	507	385*	0	0	0
Dentistry	396	475	361*	0	0	0
OBGYN	54	270	273	276	280	283
General	18	24	24	25	25	25
Urology	0	87	88	89	90	91
<b>Total Cases</b>	<b>676</b>	<b>1,363</b>	<b>1,131</b>	<b>390</b>	<b>395</b>	<b>399</b>

Source: Section Q, Form C, page 8, Assumptions and Methodology

^Annualized based on January to April data.

\*CY 2025 represents a partial year

The applicant projects the number of outpatient surgical cases projected to be performed in the OR from the initiation of services (October 1, 2025) through Project Year 3, as shown in the table below.

<b>Denver Surgery Center Projected OR Cases After Shift</b>				
		<b>PY1</b>	<b>PY2</b>	<b>PY3</b>
	<b>CY 2025*</b>	<b>CY 2026</b>	<b>CY2027</b>	<b>CY 2028</b>
OBGYN	273	276	280	283
General	24	25	25	25
Urology	88	89	90	91
<b>Total Cases</b>	<b>96</b>	<b>390</b>	<b>395</b>	<b>399</b>

Source: Section Q, Form C, page 9, Assumptions and Methodology

\*CY 2025 represents a partial year

The applicant projects the number of outpatient surgical cases projected to be performed in the procedure room from the initiation of services (October 1, 2025) through Project Year 3, as shown in the table below.

<b>Denver Surgery Center Projected Procedure Room Cases After Shift</b>				
	<b>CY 2025*</b>	<b>CY 2026</b>	<b>CY2027</b>	<b>CY 2028</b>
Dentistry	120	487	492	498

Source: Section Q, Form C, page 9, Assumptions and Methodology

\*CY 2025 represents a partial year

Projected utilization of the proposed procedure room is reasonable and adequately supported because it is based on the historical utilization of the existing operating room.

**Access to Medically Underserved Groups**

In Section C, page 51, the applicant states,

*“In addition to the payment policies of its ambulatory surgery facilities, CMHA provides significant access to the medically underserved, many of whom seek care at Atrium Health hospitals for care that they are not able to afford. CMHA’s total community benefit is more than \$2 billion annually, primarily driven by financial*

*assistance to uninsured patients, bad debt costs, and losses incurred by serving Medicare and Medicaid patients.”*

In Section C, page 51, the applicant provides the estimated percentage for each medically underserved group for the third full fiscal year, as shown in the following table.

<b>MEDICALLY UNDERSERVED GROUPS<sup>^</sup></b>	<b>PERCENTAGE OF TOTAL PATIENTS</b>
Racial and ethnic minorities	7.8%
Women	59.4%
Persons 65 and older	23.4%
Medicare beneficiaries	28.2%
Medicaid recipients	21.7%

<sup>^</sup> CHMA does not maintain data low-income or disabled individuals.

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 because 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.

### **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.

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

NA

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

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

C

The applicant proposes to develop no more than one GI endoscopy room and one procedure room at an existing ambulatory surgery center.

In Section E, pages 62-63, the applicant states the only alternative considered was maintaining the status quo. On page 63, the applicant states,

*“Atrium Health Lincoln (is) on track to be well over 100 percent capacity in CY 2023 despite having lost a gastroenterologist who was not replaced until recently. There is also significant demand from surgeons for additional time at Atrium Health East Lincoln Surgery Center. Today, all cases at Atrium Health East Lincoln Surgery Center are performed in a one-room surgery center, which is less efficient for staff and surgeons and not ideal given increasing demand. The proposed GI endoscopy room and procedure room will help accommodate current and future growth in procedures appropriate for the surgery center. Moreover, the conversion of the existing hospital-based facility to a freestanding ASF will introduce high-quality, lower cost surgical services to Lincoln County, reducing patient travel and encouraging outpatient procedures to shift to a freestanding setting when appropriate. Therefore, maintaining the status quo was deemed a less effective alternative.”*

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

- The applicant provides reasonable information to explain why it believes the proposed project is the most effective alternative.
- The application is conforming to all other statutory and regulatory review criteria.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

- 1. Atrium Health Denver ASC, LLC, (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**
  - 2. The certificate holder shall develop no more than one GI endoscopy room and one procedure room at the existing ambulatory surgery center.**
  - 3. Upon project completion, Denver Surgery Center shall be licensed for no more than one operating room, one GI endoscopy room and one procedure room.**
  - 4. Progress Reports:**
    - a. Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: <https://info.ncdhhs.gov/dhsr/coneed/progressreport.html>.**
    - b. The certificate holder shall complete all sections of the Progress Report form.**
    - c. The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.**
    - d. The first progress report shall be due on June 1, 2024.**
  - 5. For the first three years of operation following completion of the project, the certificate holder shall not increase charges more than 5% of the charges projected in Section Q of the application without first obtaining a determination from the Healthcare Planning and Certificate of Need Section that the proposed increase is in material compliance with the representations in the certificate of need application.**
  - 6. The certificate holder shall not acquire as part of this project any equipment that is not included in the project's proposed capital expenditures in Section Q of the application and that would otherwise require a certificate of need.**
  - 7. The certificate holder shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

The applicant proposes to develop no more than one GI endoscopy room and one procedure room at an existing ambulatory surgery center.

### **Capital and Working Capital Costs**

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

<b>Capital Costs</b>	<b>Atrium Health Denver ASC, LLC</b>
Construction/ Renovation Contracts	\$2,161,000
Architect/ Engineering Fees	\$271,000
Medical Equipment	\$2,311,000
Non-Medical Equipment	\$31,000
Furniture	\$25,000
Consultant Fees	\$100,000
Other	\$1,295,000
<b>Total Capital Cost</b>	<b>\$6,194,000</b>

In Section Q, Form F.1.a assumptions, 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 because it is based on the applicant's historical experience with similar projects.

In Section F, page 66, the applicant projects that start-up costs will be \$224,680 and initial operating expenses will be \$1,258,827 for a total working capital of \$1,483,507. In Section F, page 67, the applicant provides the assumptions and methodology used to project the working capital needs of the project. The applicant adequately demonstrates that the projected working capital needs of the project are based on reasonable and adequately supported assumptions based on the following:

- Start-up costs include the cost of utilities, mortgage or rent, equipment, supplies, marketing, and to hire and train new staff based on the first month of expenses.
- Operating costs include all non-depreciating expenses for the first 6 months.

### **Availability of Funds**

In Section F, page 64, and in Exhibits F.2-1 and F.2-2, the applicant states that the capital cost will be funded as shown in the following table:

TYPE	Atrium Health Denver ASC, LLC	TOTAL
Loans	\$0	\$0
Accumulated reserves or OE *	\$6,194,000	\$6,194,000
Bonds	\$0	\$0
Other (Specify)	\$0	\$0
<b>Total Financing</b>	<b>\$6,194,000</b>	<b>\$6,194,000</b>

\* OE = Owner's Equity

In Section F, page 67, and in Exhibit F.2-2, the applicant states that the working capital needs of the project will be funded as shown in the following table:

Sources of Working Capital Financing		
TYPE	Atrium Health Denver ASC, LLC	TOTAL
Loans		
Accumulated reserves or OE *	\$1,483,507	\$1,483,507
Bonds		
Other (Specify)		
<b>Total Financing</b>	<b>\$1,483,507</b>	<b>\$1,483,507</b>

\* OE = Owner's Equity

Exhibit F.2-1 contains a letter dated August 15, 2023, from the Executive Vice President and Chief Financial Officer of The Charlotte Mecklenburg Hospital Authority documenting their intent to provide funding for the capital and working capital for the proposed project. Exhibit F.2-2 contains the Combined Financial Statements for Atrium Health Enterprise dated December 31, 2022, that indicates sufficient cash reserves available for the proposed project.

### **Financial Feasibility**

The applicant provided pro forma financial statements for the first three full fiscal years of operation following completion of the project.

In Section Q, Form F.2b, the applicant projects that operating expenses will not exceed revenues in the first three full fiscal years following project completion. The applicant explains that the depreciation is recognized as an expense on the income statement, it is not a cash expense that the proposed facility would incur. By removing depreciation from the expenses, the proposed facility would meet financial feasibility requirements. Projected revenues and expenses are shown in the following table:



<b>PROJECTED REVENUES AND EXPENSES</b>			
<b>DENVER SURGERY CENTER</b>	<b>1<sup>ST</sup> FULL FY CY2026</b>	<b>2<sup>ND</sup> FULL FY CY2027</b>	<b>3<sup>RD</sup> FULL FY CY2028</b>
Total Procedures	5,154	5,215	5,278
Total Gross Revenues (Charges)	\$9,605,591	\$10,011,727	\$10,435,034
Total Net Revenue	\$2,815,074	\$2,934,099	\$3,058,156
Average Net Revenue / Procedure	\$546	\$563	\$579
Total Operating Expenses (Costs)	\$3,382,576	\$3,479,034	\$3,578,926
Average Operating Expense / Procedure	\$656	\$667	\$678
<b>Net Income</b>	<b>(\$567,502)</b>	<b>(\$544,935)</b>	<b>(\$520,770)</b>

In Section Q, the applicant states,

*“Due to the significant capital costs above and beyond rental expense, Denver Surgery Center shows a net income loss in project year 3. This net income is not fully representative of the financial feasibility of the facility, however. The depreciation associated with the capital costs is significant. While the depreciation is a recognized expense on the income statement, it is not a cash expense that Denver Surgery Center would incur.”*

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

- Payor mix, used to calculate gross revenue, is based on the applicant’s experience operating other similar facilities ran by CMHA.
- The assumptions used to project revenues and expenses are based on the applicant's experience with other similar facilities operated by CHMA.

**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 and working 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 and working capital needs of the proposal for all the reasons described above.
  - The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of revenues and operating expenses for all the reasons described above.
- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

C

The applicant proposes to develop no more than one GI endoscopy room and one procedure room at an existing ambulatory surgery center.

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 2023 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 county where the proposed GI endoscopy room will be developed.*” The facility will be developed in Lincoln County. Thus, the service area for this facility is Lincoln County. Facilities may also serve residents of counties not included in their service area.

Table 6F: Endoscopy Room Inventory, on pages 88 of the 2023 SMFP, shows there are two existing GI endoscopy rooms in one facility in Lincoln County. The information from Table 6F of the 2023 SMFP is summarized below.

2023 SMFP Table 6F: Endoscopy Room Inventory				
Existing Facilities	Facility Type	Endoscopy Rooms	Endoscopy Cases	Endoscopy Procedures
Atrium Health Lincoln	Hospital	2	2,679	3,679

In Section G, page 74, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved GI endoscopy services in Lincoln County. The applicant states:

*“The proposed project will not only introduce lower cost freestanding GI endoscopy services to Lincoln County, but it also will create additional capacity that, in turn, will enhance timely access to the existing hospital-based GI endoscopy services provided at Atrium Health Lincoln. Thus, the proposed project will not result in any unnecessary duplication.”*

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved GI endoscopy services in the service area because the applicant adequately demonstrates that the proposed GI endoscopy room is needed in addition to the existing or approved of GI endoscopy rooms in the proposed service area. See discussion in Criterion (3) which is incorporated here for reference.

**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 proposes to develop no more than one GI endoscopy room and one procedure room at an existing ambulatory surgery center.

In Section Q, Form H, the applicant projects full-time equivalent (FTE) staffing for the proposed services for each of the three project years, as illustrated in the following table:

<b>Denver Surgery Center- Projected Staffing</b>			
<b>POSITION</b>	<b>1<sup>ST</sup> FULL FY CY2026</b>	<b>2<sup>ND</sup> FULL FY CY2027</b>	<b>3<sup>RD</sup> FULL FY CY2028</b>
Clinical Supervisor	0.9	0.9	0.9
Pre-op Clinical Nurse	1.5	1.5	1.5
PACU Clinical Nurse	1.8	1.8	1.8
HCT/Materials Mgmt.	1.0	1.0	1.0
Pre-Post CNA	1.0	1.0	1.0
Clinical Nurse	1.8	1.8	1.8
Surgical/GI Tech	2.5	2.5	2.5
Registration/Administration	1.0	1.0	1.0
<b>Total</b>	<b>11.5</b>	<b>11.5</b>	<b>11.5</b>

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 F.3b. In Section H,

pages 76-78, the applicant describes the methods used to be used to recruit or fill new positions and its existing training and continuing education programs.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services based on the following:

- CMHA recruits new employees across multiple venues, including employee referrals. CMHA offers a competitive wage and benefits package, and a good working environment. Hard to fill positions have their recruitment plan evaluated and revised annually, and CMHA is an equal opportunity employer.
- The facility will require all clinical staff to complete orientation and training specific to their position, maintain licensure and certification, and provide annual evidence of continued qualifications.
- The facility will require all clinical staff to attend continuing education programs and regular in-service training.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

The applicant proposes to develop no more than one GI endoscopy room and one procedure room at an existing ambulatory surgery center.

### **Ancillary and Support Services**

In Section I, page 80, the applicant identifies the necessary ancillary and support services for the proposed GI endoscopy services. On page 80, the applicant explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibit I.1. The applicant adequately demonstrates that the necessary ancillary and support services will be made available.

### **Coordination**

In Section I, page 81, the applicant describes its existing and proposed relationships with other local health care and social service providers. The applicant 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 applicant's established relationships with local health care and social service 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. 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;
  - (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
  - (iii) would cost no more than if the services were provided by the HMO; and
  - (iv) would be available in a manner which is administratively feasible to the HMO.

NA

The applicant is not an HMO. Therefore, Criterion (10) is not applicable to this review.

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

### C

The applicant proposes to develop no more than one GI endoscopy room and one procedure room at an existing ambulatory surgery center.

In Section K, page 84, the applicant states that the project involves renovating 3,653 square feet of space in an existing building. Line drawings showing the areas to be renovated are provided in Exhibit C.1.

On pages 84-85, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal because the design will minimize the cost of the project by removing existing space rather than constructing new space.

On page 85, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed GI endoscopy services or the costs and charges to the public for the proposed services.

In Section B, pages 28-29, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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:

NA

The applicant proposes to develop no more than one GI endoscopy room and one procedure room at an existing ambulatory surgery center.

The applicant provided patient payor mix data from Atrium Health East Lincoln Surgery Center, which is a hospital-based surgery center that will be converted into a free-standing surgery center at the completion of this project.

The following table illustrates historical payor sources, from Section L, page 89:

<b>ATRIUM HEALTH EAST LINCOLN SURGERY CENTER LAST FULL FY 2022</b>	
<b>PAYOR CATEGORY</b>	<b>GI ENDOSCOPY SERVICES AS PERCENT OF TOTAL</b>
Self-Pay	0.6%
Medicare**	8.6%
Medicaid**	54.2%%
Insurance**	36.0%
Other (TRICARE, WC)	0.6%
<b>Total</b>	<b>100.0%</b>

\*The applicant does not include charity care as a payor source

\*\*Includes managed care plans.

In Section L, page 89, the applicant provides the following historical comparison for the last full FY prior to submission of the application, CY 2022:

<b>ATRIUM HEALTH EAST LINCOLN SURGERY CENTER</b>	<b>PERCENTAGE OF TOTAL PATIENTS SERVED BY THE FACILITY OR CAMPUS DURING THE LAST FULL FY (2022)</b>	<b>PERCENTAGE OF THE POPULATION OF THE SERVICE AREA^^</b>
Female	53.2%	50.1%
Male	46.8%	49.9%
Unknown	0.0%	0.0%
64 and Younger	92.5%	80.7%
65 and Older	7.5%	19.3%
American Indian	0.5%	0.5%
Asian	1.5%	1.1%
Black or African American	8.4%	6.2%
Native Hawaiian or Pacific Islander	0.0%	0.1%
White or Caucasian	86.2%	90.4%
Other Race	1.2%	1.8%
Declined / Unavailable	2.2%	0.0%

^^The percentages can be found online using the United States Census Bureau's QuickFacts at: <https://www.census.gov/quickfacts/fact/table/US/PST045218>.

### **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.

- (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;

In Section L, page 91, the applicant states that the proposed facility is not obligated under any applicable federal regulations to provide uncompensated care, community service or access by minorities and persons with disabilities.

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, page 92, the applicant projects the following payor mix for the proposed services during the third full fiscal year of operation (FY2028) following project completion, as shown in the following table:

<b>DENVER SURGERY CENTER 3<sup>RD</sup> FULL FY 2028</b>	
<b>PAYOR CATEGORY</b>	<b>TOTAL SERVICES AS PERCENT OF TOTAL</b>
Self-Pay	1.6%
Medicare*	26.0%
Medicaid*	25.2%
Insurance*	45.9%
Other (TRICARE, WC)	1.3%
<b>Total</b>	<b>100.0%</b>

\*Includes managed care plans.

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 1.6% of total services will be provided to self-pay patients, 26.0% to Medicare patients and 25.2% to Medicaid patients.

In Section Q, Form F.2 Assumptions, the applicant provides the assumptions and methodology used to project payor mix during the third full fiscal year of operation following project completion. The projected payor mix is reasonable and adequately supported because it is based on its historical payor mix at Atrium Health East Lincoln Surgery Center.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L, page 94, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

### C

The applicant proposes to develop no more than one GI endoscopy room and one procedure room at an existing ambulatory surgery center.

In Section M, page 96, the applicant states,

*“Atrium Health Denver ASC, LLC, as a part of CMHA, has extensive, existing relationships with health professional training programs. CMHA has established relationships with programs including Central Piedmont Community College, Queens University of Charlotte, University of North Carolina at Charlotte, Gardner-Webb University, and Presbyterian School of Nursing among many others.”*

A complete list of the applicants affiliations with health professional training programs is included in Exhibit M.1.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

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

C

The applicant proposes to develop no more than one GI endoscopy room and one procedure room at an existing ambulatory surgery center.

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 2023 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 county where the proposed GI endoscopy room will be developed.*” The facility will be developed in Lincoln County. Thus, the service area for this facility is Lincoln County. Facilities may also serve residents of counties not included in their service area.

Table 6F: Endoscopy Room Inventory, on pages 88 of the 2023 SMFP, shows there are two existing GI endoscopy rooms in one facility in Lincoln County. The information from Table 6F of the 2023 SMFP is summarized below.

2023 SMFP Table 6F: Endoscopy Room Inventory				
Existing Facilities	Facility Type	Endoscopy Rooms	Endoscopy Cases	Endoscopy Procedures
Atrium Health Lincoln	Hospital	2	2,679	3,679

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 98, the applicant states:

*“...the proposed GI endoscopy and procedure room at Denver Surgery Center will promote patient choice and competitive access to lower cost surgical services that are not currently available in Lincoln County.”*

Regarding the impact of the proposal on cost effectiveness, in Section N, pages 98-99, the applicant states:

*“As a freestanding facility, Denver Surgery Center will provide surgical procedures at a lower out-of-pocket cost to most patients. Insurance companies categorize hospital-based services in a higher tier than they do freestanding services, meaning that the patient’s out-of-pocket expenses typically are lower when receiving non-hospital-based care.”*

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

Regarding the impact of the proposal on quality, in Section N, pages 99-100, the applicant states:

*“CMHA, including Atrium Health Denver ASC, LLC, is dedicated to providing the highest quality care and is continually recognized locally and nationally for its commitment to delivering efficient, quality care. Each year, CMHA facilities are recognized by many of the top accrediting and ranking organizations in the industry.”*

See also Section O of the application and any exhibits.

Regarding the impact of the proposal on access by medically underserved groups, in Section N, pages 100-102, the applicant states:

*“Denver Surgery Center will consider all persons requesting surgical services, regardless of race, color, national origin, handicap, sex, sexual orientation, religious or fraternal organization, or age.”*

See also Sections C and L of the application and any referenced 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 based on all the reasons described above.

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

C

The applicant proposes to develop no more than one GI endoscopy room and one procedure room at an existing ambulatory surgery center.

In Section Q, Form O, the applicant identifies facilities with operating rooms and GI endoscopy rooms located in North Carolina owned, operated, or managed by the applicant or a related entity.

In Section O, page 105, the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents related to quality of care occurred in one of these facilities. The applicant states that all the problems have been corrected as of April 25, 2023. 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 two 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 twenty-one 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.

C

The Criteria and Standards for Gastrointestinal Endoscopy Procedure Rooms in Licensed Health Service Facilities, promulgated in 10A NCAC 14C .3903, are applicable to this review.

**SECTION .3900 – CRITERIA AND STANDARDS FOR GASTROINTESTINAL ENDOSCOPY PROCEDURE ROOMS IN LICENSED HEALTH SERVICE FACILITIES**

**.3903 PERFORMANCE STANDARDS**

*An applicant proposing to develop a new GI endoscopy room in a licensed health service facility shall:*

(1) *identify the proposed service area;*

-C- In Section C, page 52, the applicant states the proposed service area for Denver Surgery Center is Lincoln County.

(2) *identify all existing and approved GI endoscopy rooms owned or operated by the applicant or a related entity located in the proposed service area;*

-C- In Section C, page 53, the applicant identified two existing GI endoscopy rooms located at Atrium Health Lincoln.

(3) *provide projected utilization for each of the first three full fiscal years of operation following completion of the project for all GI endoscopy rooms identified in Item (2) of this Rule;*

-C- In Section C, page 53, the applicant provides projected utilization for the two existing GI endoscopy rooms at Atrium Health Lincoln for each of the first three fiscal years of operation following completion of the project as follows:

<b>Projected GI Endoscopy Cases at all Atrium Health Lincoln</b>			
<b>Site</b>	<b>CY2026 (FFY1)</b>	<b>CY2027 (FFY2)</b>	<b>CY2028 (FFY3)</b>
Atrium Health Lincoln	3,484	3,347	3,387

(4) *project to perform an average of at least 1,500 GI endoscopy procedures per GI endoscopy room during the third full fiscal year of operation following completion of the project in the GI endoscopy rooms identified in Item (2) of this Rule; and*

-C- In Section Q, Form C, pages 2-3, the applicant projects to perform the following number of GI endoscopy procedures per GI endoscopy room during the third full fiscal year of operation following project completion, as shown in the table below:

<b>Projected CY 2028 GI Endoscopy Procedures per Room (PY3)</b>			
<b>Site</b>	<b>CY28 (PY3) Procedures</b>	<b>GI Endo Rooms</b>	<b>Procedures per Room</b>
Denver Surgery Center	1,891	1	1,891
Atrium Health Lincoln	3,387	2	1,693

(5) *provide the assumptions and methodology used to project the utilization required by this Rule.*

-C- In Section Q, Form C, the applicant provides the assumptions and methodology used to project GI endoscopy procedures at the applicant's proposed and existing facilities. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.