

## REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: September 3, 2024

Findings Date: September 3, 2024

Project Analyst: Chalice L. Moore

Co-Signer: Lisa Pittman

Project ID #: E-12517-24

Facility: Prime Surgical Suites

FID #: 140087

County: Caldwell

Applicant(s): Prime Surgical Suites, LLC

Project: Relocate no more than one GI endoscopy room from Caldwell Memorial Hospital for a total of no more than three existing ORs and one GI endoscopy room upon project completion

### 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

Prime Surgical Suites, LLC (hereinafter referred to as Prime Surgical Suites or “the applicant”) proposes to relocate no more than one GI endoscopy room from Caldwell Memorial Hospital for a total of no more than three existing ORs and one GI endoscopy room upon project completion.

The applicant does not propose to:

- Develop any beds or services for which there is a need determination in the 2024 SMFP
- Acquire any medical equipment for which there is a need determination in the 2024 SMFP
- Offer a new institutional health service for which there are any policies in the 2024 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- (2) Repealed effective July 1, 1987.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

Prime Surgical Suites proposes to relocate no more than one GI endoscopy room from Caldwell Memorial Hospital for a total of no more than three existing ORs and one GI endoscopy room upon project completion.

**Patient Origin**

N.C. Gen. Stat. §131E-176(24a) states, “*Service area -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 2024 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.*”. Thus, the service area for this facility consists of Caldwell County. Facilities may also serve residents of counties not included in their service area.

The following table summarizes Prime Surgical Suites (CY2023) historical patient origin for GI endoscopy services in its procedure room.

<b>Prime Surgical Suites Historical Patient Origin GI Endoscopy Procedure Room</b>		
<b>County</b>	<b>1/1/2023-12/31/2023</b>	
	<b># of Patients</b>	<b>% of Total</b>
Caldwell	980	81.9%
Catawba	132	11.0%
Burke	29	2.4%
Lincoln	16	1.3%
Wilkes	14	1.2%
Other NC Counties	25	2.1%
Other States	1	0.1%
<b>Total</b>	<b>1,197</b>	<b>100.0%</b>

Source: Section C, page 30

The following table shows Prime Surgical Suites projected patient origin for GI endoscopy services for the first three full fiscal years of operation (CY2024-CY2027).

County	CY2024		CY2025		CY2027	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Caldwell	1,106	81.9%	1,123	81.9%	1,141	81.9%
Catawba	148	11.0%	151	11.0%	153	11.0%
Burke	32	2.4%	33	2.4%	33	2.4%
Lincoln	18	1.3%	18	1.3%	18	1.3%
Wilkes	16	1.2%	16	1.2%	17	1.2%
Other NC Counties	28	2.1%	29	2.1%	29	2.1%
Other States	1	0.1%	1	0.1%	1	0.1%
<b>Total</b>	<b>1,350</b>	<b>100.0%</b>	<b>1,371</b>	<b>100.0%</b>	<b>1,392</b>	<b>100.0%</b>

Source: Section C.3, page 32

In Section C.3, page 32, the applicant states projected patient origin is based on Prime Surgical Suites historical patient origin for GI endoscopy services in its procedure room. The applicant’s assumptions are reasonable and adequately supported.

**Analysis of Need**

In Section C.4, pages 34-47, 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 (page 36)
- Historical high utilization (page 35-36)
- Projected population growth and aging in Caldwell County (pages 36-38)
- Demographics and Health Status (pages 38-47)

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.
- 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 Prime Surgical Suites through the first three full fiscal years of operation, as shown in the table below.

	Prior	Interim	Projected CY		
	CY2023	CY2024	CY2025	CY2026	CY2027
GI Endoscopy Rooms	0	0	1	1	1
Outpatient GI Endoscopy Procedures	1,197	1,329	1,350	1,371	1,392
Total GI Endoscopy Procedures	1,197	1,329	1,350	1,371	1,392
Average # of Procedures/Room			0.90	0.91	0.93

\*Need for GI Endoscopy rooms is based on 1,500 procedures per room, page 106 & 108

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

The applicant uses annualized CY2024 historical data in order to use the most recent data available.

Historical GI Endoscopy Utilization	CY 2022	CY 2023	CY 2024	2-YR CAGR
Procedures	770	1,197	1,329	31.38%

See Section C.4, page 35

- CY2025-CY2027 are the first three full fiscal years following the completion of the project.

	CY 2025	CY 2026	CY 2027	3-YR CAGR
Procedures	1,350	1,371	1,392	1.55%

See Section C.4, page 37

The applicant projects future utilization using the projected growth rate of the Caldwell County age 65+ cohort, 1.55%, as shown in the table above.

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

- Projected utilization is based on Prime Surgical Suites historical GI endoscopy procedure utilization.
- The applicant's projected growth rate for GI endoscopy procedures is based on the projected growth rate of the Caldwell County age 65+ cohort.
- 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 one GI endoscopy procedure room.

### **Access to Medically Underserved Groups**

In Section C.6, pages 52-54, the applicant states its services are accessible to all residents in need of GI endoscopy services, regardless of race, ethnicity, religion, creed, national origin, gender, age, disability, or ability to pay. On page 52, the applicant projects the patient percentages of underserved groups seeking GI endoscopy services at Prime Surgical Suites during the third year of operation (CY2027) following completion of the project, as shown in the following table.

Medically Underserved Groups	Percentage of Total Patients
Low-income persons	16.2%
Racial and ethnic minorities	14.3%
Women	57.0%
Persons with Disabilities	13.9%
Persons 65 and older	32.0%
Medicare beneficiaries	34.3%
Medicaid recipients	8.3%

Source: Table on page 52 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 Prime Surgical Suites CY2023 percentages for the patient population historically served.
- Prime Surgical Suites historical GI Endoscopy patient origin is primarily derived from Caldwell County, the estimated percentage of low-income persons, racial and ethnic minorities, and persons with disabilities will approximate the Caldwell County population.

### **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 of 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.

### C

Prime Surgical Suites proposes to relocate no more than one GI endoscopy room from Caldwell Memorial Hospital for a total of no more than three existing ORs and one GI endoscopy room upon project completion.

In Section D.1, page 58, the applicant states:

*“Following the reduction of one GI endoscopy room from the hospital inventory via this GI endoscopy room relocation project, Caldwell Memorial Hospital will continue to provide GI endoscopy services and will be licensed with one GI endoscopy room. The GI endoscopy room relocation project will not reduce or eliminate any patient’s*

*ability to obtain GI endoscopy services at CMH, as the hospital will continue to have sufficient GI endoscopy room capacity with one GI endoscopy room on its license to meet projected GI endoscopy procedure volume in the near term.”*

On page 58, the applicant further states:

*“CMH will continue to offer GI endoscopy services at its current Lenoir hospital location, and therefore, this GI endoscopy room relocation project will have no negative impact on the ability of any of the above-listed groups to obtain services. Relocation of one GI endoscopy room to Prime Surgical Suites will enhance access to high quality, cost-effective outpatient surgical services for residents of Caldwell County and surrounding communities. All Caldwell County residents, including low-income persons, racial and ethnic minorities, women, handicapped persons, the elderly, Medicare and Medicaid beneficiaries, and other underserved groups will continue to have access to PSS, as clinically appropriate.”*

### **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.

### C

Prime Surgical Suites proposes to relocate no more than one GI endoscopy room from Caldwell Memorial Hospital for a total of no more than three existing ORs and one GI endoscopy room upon project completion.

In Section E, pages 61-64, 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 did not consider maintaining the status quo and not developing a GI endoscopy room. Prime Surgical Suites performs

a substantive volume of GI endoscopy procedures at the ASF without having a designated GI endoscopy room on the facility license.

- Add More than One GI Endoscopy Room- the applicant considered developing two designated GI endoscopy rooms. The historical utilization at the facility has been consistent, and the facility considers that, over the long term, it could utilize two GI endoscopy rooms, especially given that it is currently recruiting to add a second gastroenterologist. However, PSS determined that this route will be more costly because the addition of two rooms would necessitate a construction addition to the facility which would result in higher capital cost.
- Discontinue Providing GI Endoscopy at PSS and Direct Patients to Hospital-Based GI Endoscopy Rooms- this alternative is less cost effective for GI endoscopy patients. Currently the only designated GI endoscopy procedure rooms in Caldwell County are hospital based. Licensed freestanding facilities provide a high quality, more affordable healthcare service option for many patients. GI endoscopy rooms located in ambulatory surgical facilities can decrease the financial burden of endoscopy services for service area residents because patients incur fewer out-of-pocket costs when they utilize such facilities. Prime Surgical Suites determined that discontinuing offering GI endoscopy services and instead directing GI endoscopy patients to hospital-based endoscopy rooms is not the most cost effective.
- Maintain the CMH inventory of two GI endoscopy rooms, and develop a new GI endoscopy room at PSS- PSS considered developing a new GI endoscopy room that is not currently in the 2024 SMFP inventory. Caldwell Memorial Hospital considers that the hospital will have sufficient capacity to meet the GI endoscopy needs of hospital patients by maintaining one existing GI room, rather than develop a new GI endoscopy room in Caldwell County.
- Establish a GI Endoscopy ASF in a different geographic location- development of a dedicated GI endoscopy ASF- is a much more costly alternative. PSS states that this would be unnecessarily duplicative of the existing, cost0effect Prime Surgical Suites ambulatory surgical facility.
- Proposed Project- Development of one designated GI endoscopy room, which requires neither construction or renovation at the existing ASF, is the most effect and least costly alternative.

The applicant adequately demonstrates that the alternative proposed in this application is the most effective or less costly 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

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. Prime Surgical Suites, LLC (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**
- 2. The certificate holder shall relocate one gastrointestinal endoscopy procedure room from Caldwell Memorial Hospital for a total of no more than three ORs and one gastrointestinal endoscopy procedure room upon project completion.**
- 3. 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.**
- 4. 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.**
- 5. 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 January 1, 2025. The second progress report shall be due on May 1, 2025, and so forth.**



**6. The certificate holder shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**

- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

Prime Surgical Suites proposes to relocate no more than one GI endoscopy room from Caldwell Memorial Hospital for a total of no more than three existing ORs and one GI endoscopy room upon project completion.

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.

Consultant Fees (CON-related)	\$53,500
Other (contingency)	\$25,000
Total	\$78,500

In Section F.1, pages 67, the applicant does not project any start-up or initial operating expenses. PSS will locate the GI endoscopy room in the existing ASF procedure room, where existing equipment necessary to perform procedures is already in place.

Availability of Funds

In Section F, page 65, 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 *	\$78,500
Bonds	
Other (Describe)	
Total Financing	\$78,500

\* OE = Owner's Equity

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 Director of Prime Surgical Suites documenting their intent to fund the project.
- Exhibit F.2-2 contains a copy of Prime Surgical Suites balance sheet as of March 2024, showing adequate funds for the project capital cost.

**Financial Feasibility**

The applicant provided pro forma financial statements for GI Endoscopy services and for the entire facility including the ORs and GI Endoscopy services, for the first three full fiscal years of operation following completion of the project. In Form F.2a, page 116, the applicant projects that for GI Endoscopy services revenues will not exceed operating expenses in any of the first three full fiscal years following completion of the project, as shown in the table below.

The pro forma financial statements for the entire facility for the first three full fiscal years of operation following completion of the project. In Form F.2b, page 115, the applicant projects that revenues will exceed operating expenses in each of the first three full fiscal years following completion of the project, as shown in the table below.

<b>Prime Surgical Suites- GI Endoscopy</b>			
	<b>1<sup>st</sup> Full Fiscal Year CY2025</b>	<b>2<sup>nd</sup> Full Fiscal Year CY2026</b>	<b>3<sup>rd</sup> Full Fiscal Year CY2027</b>
Total Procedures	1,350	1,371	1,392
Total Gross Revenues	\$2,933,036	\$3,090,192	\$3,255,768
Total Net Revenue	\$884,268	\$931,648	\$981,567
Average Net Revenue per Procedure	\$655	\$680	\$705
Total Operating Expenses	\$1,136,959	\$1,159,852	\$1,184,432
Average Operating Expense per Procedure	\$842	\$846	\$851
Net Income	(\$252,691)	(\$228,204)	(\$202,865)

\*1<sup>st</sup> Full Fiscal Year: 1/1/2025-12/31/2025

<b>Prime Surgical Suites-Facility</b>			
	<b>1<sup>st</sup> Full Fiscal Year CY2025</b>	<b>2<sup>nd</sup> Full Fiscal Year CY2026</b>	<b>3<sup>rd</sup> Full Fiscal Year CY2027</b>
Total Procedures	2,697	2,738	2,781
Total Gross Revenues	\$29,247,584	\$30,814,707	\$32,465,797
Total Net Revenue	\$8,904,820	\$9,381,951	\$9,844,648
Average Net Revenue per Procedure	\$3,302	\$3,427	\$3,540
Total Operating Expenses	\$8,892,174	\$9,194,185	\$9,514,388
Average Operating Expense per Procedure	\$3,297	\$3,358	\$3,421
Net Income	\$12,646	\$187,766	\$370,260

\*1<sup>st</sup> Full Fiscal Year: 1/1/2025-12/31/2025

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs, and charges. See Section Q of the application for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

Prime Surgical Suites proposes to relocate no more than one GI endoscopy room from Caldwell Memorial Hospital for a total of no more than three existing ORs and one GI endoscopy room upon project completion.

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 2024 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 Caldwell County and in Section C.3, page 30, the applicant projects that 82% of its patients will originate from Caldwell County, with the next largest percentage of patients originating from Catawba County. Thus, the service area for this facility consists of Caldwell County. Facilities may also serve residents of counties not included in their service area.

There is a total of two existing or approved GI endoscopy rooms in one facility in Caldwell County, as shown in the table below.

Existing Facilities	# of Rooms	# of Cases	# of Procedures
Caldwell UNC Health Care	2	622	724
Total	2	622	724

Sources: Table 6D: Endoscopy Room Inventory (page 84 of the Proposed 2024 SMFP) FFY22 data

In Section G.2, pages 73-74, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved GI endoscopy services in Caldwell County. The applicant states:

“...PSS is proposing to relocate an existing GI endoscopy room within Caldwell County, not add a new GI endoscopy room in Caldwell County. Thus, the GI endoscopy room inventory of two (2) in Caldwell County will remain unchanged, and by definition there is no duplication of existing health service capabilities or facilities. Second, local patients will benefit from development of the first and only freestanding GI endoscopy room in Caldwell County. As described in Section C.4 of this application, Prime Surgical Suites demonstrates the need the population has for the freestanding designated GI endoscopy room based on demographic data specific to the Caldwell County service area, high colorectal cancer incidence rates, historical GI endoscopy utilization at PSS, and the benefit of enhanced access to freestanding GI endoscopy services at a freestanding facility with non-HOPD charges.”

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 Caldwell County.
- The applicant adequately demonstrates that the proposed relocation of one GI endoscopy room from Caldwell Memorial Hospital is needed.

### **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.

- (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.

Prime Surgical Suites proposes to relocate no more than one GI endoscopy room from Caldwell Memorial Hospital for a total of no more than three existing ORs and one GI endoscopy room upon project completion.

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.

<b>Prime Surgical Suites-Facility</b>				
<b>Current &amp; Projected Staffing by FTE Position</b>				
<b>Position</b>	<b>CY2024</b>	<b>CY2025</b>	<b>CY2026</b>	<b>CY2027</b>
Registered Nurses	9.5	9.5	9.5	9.5
Surgical Technicians	4.6	4.6	4.6	4.6
Central Sterile Supply	1	1	1	1
Materials Management	1	1	1	1
Administrator/CEO	1	1	1	1
Business Office	1.25	1.25	1.25	1.25
Clerical	1.25	1.25	1.25	1.25
Other (Medical Director)	1	1	1	1
Other (GI Endo Tech)	2	2	2	2
<b>Total</b>	<b>22.60</b>	<b>22.60</b>	<b>22.60</b>	<b>22.60</b>

Section Q, Form H

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, 76-78 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 CY2027, 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 increased 3.0% annually. (page 124)

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

Prime Surgical Suites proposes to relocate no more than one GI endoscopy room from Caldwell Memorial Hospital for a total of no more than three existing ORs and one GI endoscopy room upon project completion.

#### **Ancillary and Support Services**

In Section I, page 80, the applicant identifies the necessary ancillary and support services for the proposed services. On page 80, the applicant explains that all ancillary and support services required for Prime Surgical Suites and how they will be provided. The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on the following services that GI endoscopy patients need, but are not limited to:

- GI endoscopy services
- Medical direction
- Perioperative Services
- Sterile Processing
- Anesthesia
- Lab/Pathology
- Pharmaceuticals and medical supplies
- Medical Records/Coder
- Business Office, Information Technology
- Biomedical Engineering
- Laundry and linen

The applicant provides letters of agreement for services in Exhibits I.1.3 and I.2.

The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system.

#### **Conclusion**

The Agency reviewed the:

- application,
- exhibits to the application,

#### **Coordination**

In Section I, page 81, 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

- (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

Prime Surgical Suites proposes to relocate no more than one GI endoscopy room from Caldwell Memorial Hospital for a total of no more than three existing ORs and one GI endoscopy room upon project completion.

In Section K, page 84, the applicant states:

*“The project does not involve any facility construction or renovation, as the existing procedure room will be used for the relocated GI endoscopy room and the procedure room was designed and constructed to the necessary specifications.”*

In Section K, page 85, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services. The applicant states that the project will not increase the charges or projected reimbursement for these services, which are established by Medicare, Medicaid, and/or existing private payor contracts.

In Section K, page 85, the applicant states:

*“The ASF heating ventilation and air conditioning systems will continue to provide high energy efficiency, in accordance with energy efficiency and water conservation standards designed into the facility, consistent with the North Carolina State Building Codes. The building codes apply to systems and equipment for electrical power, lighting, heating, ventilating, air condition service, energy management, water heating, and water conservation.”*

### 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.

- (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 88, the applicant provides the historical payor mix for CY2023 at Prime Surgical Suites, as summarized in the table below.

<b>Prime Surgical Suites</b>	
<b>Payment Source</b>	<b>Percent of Total Patients Served</b>
Self-Pay	0.5%
Medicare*	35.2%
Medicaid*	8.9%
Insurance*	55.4%
<b>Total**</b>	<b>100.0%</b>

Source: Table on page 88 of the application.

\*Includes managed care plans.

Totals may not sum due to rounding

In Section L, page 89, the applicant provides the following comparison.

Prime Surgical Suites	% of Total Patients Served	% of the Population
Female	57.0%	50.2%
Male	43.0%	49.8%
Unknown	0.0%	0.0%
64 and Younger	68.0%	78.7%
65 and Older	32.0%	21.3%
American Indian	N.A.	0.7%
Asian	N.A.	0.9%
Black or African-American	N.A.	5.4%
Native Hawaiian or Pacific Islander	N.A.	0.1%
White or Caucasian	N.A.	86.4%
Other Race	N.A.	6.5%
Declined / Unavailable	N.A.	0.0%

Source: Section L, page 89 of application  
United States Census Bureau's QuickFacts

### 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, page 90, 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, page 91, the applicant states that during the last five years no patient civil rights equal access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application,

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, pages 91-92, the applicant projects the following payor mix for Prime Surgical Suites and GI endoscopy services during the third year of operation (CY2027) following completion of the project, as shown in the following table.

Payment Source	Prime Surgical Suites	Percent of Total GI Endoscopy Patients
Self-Pay	0.5%	8.4%
Medicare*	35.2%	34.3%
Medicaid*	8.9%	8.3%
Insurance*	55.4%	45.3%
Worker's Compensation	0%	2.2%
Other (VA & other government)	0%	1.5%
<b>Total**</b>	<b>100.0%</b>	<b>100.0%</b>

Source: Table on pages 91-92 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 8.4 percent of GI endoscopy services will be provided to self-pay patients, 34.3 percent to Medicare patients, and 8.3 percent to Medicaid patients.

In Section L.3, page 91, 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.

In Section L.4, the applicant states that:

*“Prime Surgical Suites projected charity care/medically indigent patients for the GI endoscopy service based on the historical GI endoscopy payor mix during CY2023. Specifically, the percent charity care/medically indigent*

*patients for PSS GI endoscopy patients in CY2023 was 8.4 percent, and thus the calculation for PY3 is  $1,392 \times .084 = 117$ .”*

In Section L.4, page 93, the applicant provides the following table:

	1 <sup>st</sup> Full FY 2025	2 <sup>nd</sup> Full FY 2026	3 <sup>rd</sup> Full FY 2027
Estimated # Charity Care Patients	114	116	117

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 93, 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

Prime Surgical Suites proposes to relocate no more than one GI endoscopy room from Caldwell Memorial Hospital for a total of no more than three existing ORs and one GI endoscopy room upon project completion.

In Section M, page 94, the applicant states:

*“Prime Surgical Suites currently informally partners with local community college and university healthcare programs to provide hands on learning experiences for students. PSS accepts students for clinical rotations who are enrolled in a Surgical Technologist academic program.”*

In Section M.1b, the applicant states Prime Surgical Suites does not have a documented formal clinical training affiliation, but it is willing to develop such an agreement. Exhibit M.1 is a letter from the Administrative Director to the Dean of Health Science at Caldwell Community College and Technical Institute regarding development of a clinical training affiliation agreement”

### Conclusion

The Agency reviewed the:

- application,
- exhibits to the application,

Based on that review, the Agency concludes that the applicant adequately demonstrates that the proposed services will accommodate the clinical needs of area health professional training programs, and therefore, the application is conforming to this criterion.

- (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

Prime Surgical Suites proposes to relocate no more than one GI endoscopy room from Caldwell Memorial Hospital for a total of no more than three existing ORs and one GI endoscopy room upon project completion.

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 2024 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 Caldwell County and in Section C.3, page 30, the applicant projects that 82% of its patients will originate from Caldwell County, with the next largest percentage of patients originating from Catawba County. Thus, the service area for this facility consists of Caldwell County. Facilities may also serve residents of counties not included in their service area.

The 2024 SMFP shows there are two existing or approved GI endoscopy rooms in two facilities in Union County, as shown below.

Existing Facilities	# of Rooms	# of Cases	# of Procedures
Caldwell UNC Health Care	2	622	724
Total	2	622	724

Sources: Table 6D: Endoscopy Room Inventory (page 84 of the 2024 SMFP) FFY22 data

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 95, the applicant states:

*“The development of one designated GI endoscopy room at Prime Surgical Suites will promote competition in the service area because it will enable the ASF to better meet the needs of existing patient population, and to ensure, going forward, time provision of and convenient access to high quality, cost-effective outpatient GI endoscopy services for residents of Caldwell County and surrounding communities.”*

Regarding the impact of the proposal on cost effectiveness, in Section N, page 96, the applicant states:

*“This GI endoscopy room relocation project will make lower cost GI endoscopy services more broadly available to credentialed physicians and their patients”*

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 97, the applicant states:

*“The proposed project will promote safety and quality in the delivery of healthcare services. Prime Surgical Suites will continue to be dedicated to providing excellent care for patients, and to creating a safe work environment for practitioners and staff.”*

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 98, the applicant states:

*“The proposed project will enhance access to GI endoscopy services in the service area. This GI endoscopy room relocation project will improve and broaden access to*

*outpatient GI endoscopy services for all patients, including medically underserved groups.”*

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

(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 126, 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 21 other related facilities located in North Carolina.

In Section O, pages 102-103, the applicant states Prime Surgical Suites has never been determined by the Division of Health Service Regulations to have had any situations resulting in a finding of immediate jeopardy, including during the 18-month look-back period (determination).

No UNC Health facilities listed in Form O Facilities have been determined by the Division of Health Service Regulation to have had any situations resulting in a finding of immediate jeopardy during the 18-month look-back period (determination)

(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, Prime Surgical Suites proposes to relocate no more than one GI endoscopy room from Caldwell Memorial Hospital for a total of no more than three existing ORs and one GI endoscopy room upon project completion. 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 GI endoscopy room in a licensed health service facility.