

## REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: March 30, 2022

Findings Date: April 4, 2022

Project Analyst: Ena Lightbourne

Co-Signer: Lisa Pittman

### COMPETITIVE REVIEW

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Project ID #: O-12148-21  
Facility: McLeod Health Brunswick ASC  
FID #: 210832  
County: Brunswick  
Applicant(s): McLeod Health Brunswick ASC, LLC  
McLeod Loris Seacoast Hospital, Inc.  
Project: Develop a new multi-specialty ASC with no more than 2 ORs and 2 procedure rooms pursuant to the need determination in the 2021 SMFP

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Project ID #: O-12153-21  
Facility: Novant Health Leland ASC  
FID #: 210835  
County: Brunswick  
Applicant(s): Novant Health Brunswick Surgery Center, LLC  
Novant Health, Inc.  
Project: Develop a new ASC with no more than 2 ORs and 2 procedure rooms pursuant to the need determination in the 2021 SMFP

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Each application was reviewed independently against the applicable statutory review criteria found in G.S. 131E-183(a) and the regulatory review criteria found in 10A NCAC 14C. After completing an independent analysis of each application, the Healthcare Planning and Certificate of Need Section (CON Section) also conducted a comparative analysis of all the applications. The Decision, which can be found at the end of the Required State Agency Findings (Findings), is based on the independent analysis and the comparative analysis.

### 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

Both Applications

**Need Determination**

The 2021 State Medical Facilities Plan (SMFP) includes a need methodology for determining the need for additional operating rooms in North Carolina by service area. Application of the need methodology in the 2021 SMFP identified a need for two additional operating rooms in the Brunswick County service area. Two applications were received by the Healthcare Planning and Certificate of Need Section (CON Section) proposing to develop a total of 4 new operating rooms. However, pursuant to the need determination, only two operating rooms may be approved in this review.

**Policies**

*Policy GEN-3: Basic Principles* of the 2021 SMFP is applicable to both applications.

*Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities* is applicable to both applications.

**Policy GEN-3**

Policy GEN-3 on page 29 of the 2021 SMFP states:

*“A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area.”*

**Policy GEN-4**

Policy GEN-4 on page 29 of the 2021 SMFP states:

*“Any person proposing a capital expenditure greater than \$2 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178 shall include in its certificate of need application a written statement describing the project’s plan to assure improved energy efficiency and water conservation.*

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

*Any person awarded a certificate of need for a project or an exemption from review pursuant to G.S. 131E-184 is required to submit a plan of 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.”*

**O-12148-21/McLeod Health Brunswick ASC/ develop an ASC, with two operating rooms and two procedure rooms**

McLeod Health Brunswick ASC, LLC and McLeod Loris Seacoast Hospital, Inc. [McLeod Health Brunswick ASC] propose to develop McLeod Health Brunswick ASC, a multi-specialty Ambulatory Surgical Facility (ASF) with no more than two operating rooms and two procedure rooms pursuant to the need determination in the 2021 SMFP.

*Need Determination.* The applicant does not propose to develop more operating rooms than are determined to be needed in the Brunswick County service area.

*Policy GEN-3.* In Section B, pages 27-36, the applicant explains why it believes its application is conforming to Policy GEN-3.

*Policy GEN-4.* The proposed capital expenditure for this project is greater than \$5 million. In Section B, page 37, the applicant describes the project’s plan to improve energy efficiency and conserve water. The applicant adequately demonstrates that the application includes a written statement describing the project’s plan to assure improved energy efficiency and water conservation.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

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 more operating rooms than are determined to be needed in the service area.
- The applicant adequately demonstrates that the proposal is consistent with Policy GEN-3 and Policy GEN-4 for the following reasons:
  - The applicant adequately documents how the project will promote safety and quality in the delivery of operating room services in Brunswick County;
  - The applicant adequately documents how the project will promote equitable access to operating room services in Brunswick County; and
  - The applicant adequately documents how the project will maximize healthcare value for the resources expended.
  - The applicant adequately demonstrates that the application includes a written statement describing the project's plan to assure improved energy efficiency and water conservation.

**O-12153-21/Novant Health Leland ASC/ develop an ASC, with two operating rooms and two procedure rooms**

Novant Health Brunswick Surgery Center, LLC and Novant Health, Inc. [**Novant Health Leland ASC**] propose to develop Novant Health Leland ASC, a multi-specialty ASF with no more than two operating rooms and two procedure rooms pursuant to the need determination in the 2021 SMFP.

*Need Determination.* The applicant does not propose to develop more operating rooms than are determined to be needed in the Brunswick County service area.

*Policy GEN-3.* In Section B, pages 25-26, the applicant explains why it believes its application is conforming to Policy GEN-3.

*Policy GEN-4.* The proposed capital expenditure for this project is greater than \$5 million. In Section B, page 26, the applicant describes the project's plan to improve energy efficiency and conserve water. The applicant adequately demonstrates that the application includes a written statement describing the project's plan to assure improved energy efficiency and water conservation.

**Conclusion**

The Agency reviewed the:

- Application

- Exhibits to the application
- Written comments
- Responses to comments

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 more operating rooms than are determined to be needed in the service area.
- The applicant adequately demonstrates that the proposal is consistent with Policy GEN-3 and Policy GEN-4 for the following reasons:
  - The applicant adequately documents how the project will promote safety and quality in the delivery of operating room services in Brunswick County;
  - The applicant adequately documents how the project will promote equitable access to operating room services in Brunswick County; and
  - The applicant adequately documents how the project will maximize healthcare value for the resources expended.
  - 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  
Both Applications

**O-12148-21/McLeod Health Brunswick ASC/ develop an ASC with two operating rooms and two procedure rooms**

The applicant proposes to develop McLeod Health Brunswick ASC, a multi-specialty ASF with no more than two operating rooms and two procedure rooms pursuant to the need determination in the 2021 SMFP.

**Patient Origin**

On page 49, the 2021 SMFP defines the service area for operating rooms as *the single or multicounty grouping as shown in in Figure 6.1*. In Figure 6.1, page 55 of the 2021 SMFP, Brunswick County is shown as a single-county operating room service area. Thus, the service area for this facility consists of Brunswick County. Facilities may also serve residents of counties not included in their service area.

The following table illustrates projected patient origin.

<b>McLeod Health Brunswick ASC                      Projected Patient Origin                      Outpatient Surgery (Operating Rooms)</b>						
<b>County/                      Geographical                      Area</b>	<b>1/1/2025-12/31/2025                      CY 2025</b>		<b>1/1/2026-12/31/2026                      CY 2026</b>		<b>1/1/2027-12/31/2027                      CY 2027</b>	
	<b>Patients</b>	<b>% of Total</b>	<b>Patients</b>	<b>% of Total</b>	<b>Patients</b>	<b>% of Total</b>
Brunswick	1,366	90.0%	1,520	90.0%	1,693	90.0%
Other^	137	10.0%	152	10.0%	169	10.0%
<b>Total</b>	<b>1,502</b>	<b>100.0%</b>	<b>1,672</b>	<b>100.0%</b>	<b>1,862</b>	<b>100.0%</b>

Source: Section C, page 49

^Other includes the NC counties contiguous to Brunswick County: New Hanover, Pender, and Columbus counties.

In Section C, page 49, the applicant provides the assumptions and methodology used to project its patient origin. The applicant’s assumptions are reasonable and adequately supported. The applicant states that the majority of patients that are projected to be served by the proposed facility will reside in Brunswick County. The applicant’s projections are based on the historical growth rates of outpatient surgical cases performed by future members of McLeod Health Brunswick ASC and the projected population growth in Brunswick County. Therefore, projected patient origin is based on the applicant’s projected utilization. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

**Analysis of Need**

In Section C, pages 51-72, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below:

- The growth and aging of the Brunswick County population (pages 52-58)
- The need for additional freestanding ambulatory surgical capacity in Brunswick County (pages 58-67)
- The need for a freestanding multispecialty ASF in Brunswick County (pages 67-70)
- The need for a new provider as an alternative for surgical services in Brunswick County (pages 70-72)

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

- The proposed project will meet the need of projected population growth and aging in Brunswick County.
- The need for freestanding multispecialty ASF and freestanding ambulatory surgical capacity based on the historical utilization of existing operating rooms in Brunswick County.

**Projected Utilization**

In Section Q, Form C.3b, the applicant provides historical and projected utilization, as illustrated in the following table.

<b>McLeod Health Brunswick ASC Projected Utilization</b>			
	<b>1<sup>ST</sup> Full FY CY2025</b>	<b>2<sup>ND</sup> Full FY CY2026</b>	<b>3<sup>RD</sup> Full FY CY2027</b>
<b>Operating Rooms</b>			
Dedicated Ambulatory ORs	2	2	2
Outpatient Surgical Cases	1,502	1,672	1,862
Outpatient Surgical Case Time	1.16	1.16	1.16
Outpatient Surgical Hours	1,742	1,940	2,160
Group Assignment	6	6	6
Standard Hours per OR per Year	1,312	1,312	1,312
Total Surgical Hours/Standard Hours Per OR per Year	1.3	1.5	1.6
<b>Procedure Rooms</b>			
Number of Procedure Rooms	2	2	2
Total Number of Procedures	300	334	372

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

The applicant begins with the historical Brunswick County outpatient surgery cases performed by McLeod Health and Wilmington Health physicians. McLeod Health and Wilmington Health are part of a joint venture to develop the proposed ASC. Outpatients cases increased 10.8 percent annually from 2019 to annualized 2021.

<b>Historical Brunswick Outpatient Surgery Cases Served By McLeod Health or Wilmington Health</b>				
	<b>CY2019</b>	<b>CY2020</b>	<b>CY2021*</b>	<b>CY19-CY21 CAGR<sup>^</sup></b>
Outpatient Cases	1,263	1,290	1,550	10.8%

Source: Section Q, Form C, page 1; Novant Health internal data

\*CY 2021 annualized using January to July data

<sup>^</sup>Compound Annual Growth Rate

The applicant states that 17,000 surgery cases performed at facilities in North Carolina and South Carolina originated from Brunswick County in FY2019 and estimates McLeod Health and Wilmington health physicians 2019 market share to be 7.4 percent (1,263 / 17,000 x 100 = 7.4 percent).

The applicant demonstrates that the number of outpatient surgery cases originating from Brunswick County performed by McLeod Health or Wilmington Health physicians for the surgical specialties that will be offered at the proposed ASC increased by 17.0 percent annually from 2019 annualized 2021 and 15.4 % excluding GI endoscopy cases. The applicant projects a growth rate equivalent to two-thirds of the historical growth rates, as illustrated below:

<b>Projected Brunswick Outpatient Surgery Cases Served By McLeod Health or Wilmington Health</b>								
	<b>CY2021*</b>	<b>CY2022</b>	<b>CY2023</b>	<b>CY2024</b>	<b>CY2025</b>	<b>CY2026</b>	<b>CY2027</b>	<b>CAGR</b>
Outpatient Cases	1,111	1,237	1,377	1,533	1,707	1,901	2,116	11.3%

Source: Section Q, Form C, page 4  
 Annualized using January to July data

The applicant projects that the proposed McLeod Health Brunswick ASC will serve 80 percent of the outpatient surgery volume historically served by McLeod Health or Wilmington Health physicians upon project completion based on the fact that the surgical specialties included in the historical utilization of both facilities will be offered by the proposed facility. Other factors include patient choice and the exclusion of patients that require hospital-based care. The applicant assumes that 10 percent of the total outpatient surgery cases to be performed at the proposed facility will originate outside of the county based on the historical utilization of existing ambulatory surgical facilities located outside of Brunswick County. The following table illustrates the applicant’s assumptions.

<b>Projected McLeod Health Brunswick ASC Outpatient Surgery Cases</b>				
	<b>CY 2024</b>	<b>CY 2025</b>	<b>CY 2026</b>	<b>CY 2027</b>
Potential Outpatient Surgical Cases**	1,278	1,707	1,901	2,116
Percent to be served at McLeod Health Brunswick ASC	80%	80%	80%	80%
Outpatient Cases to be served at McLeod Health Brunswick ASC	1,022	1,366	1,520	1,693
In migration	10%	10%	10%	10%
In migration Outpatient Cases^	102	137	152	169
Total McLeod Health Brunswick ASC Outpatient Cases ^^	1,124	1,502	1,672	1,862

Source: Section Q, Form C, page 5

\*Adjusted to account for a March 1, 2024 start date (1,533 / 12 = 127.75 x 10 months = 1,278).

\*\*Projected Brunswick County Outpatient Surgery cases served by McLeod Health or Wilmington Health.

^Immigration Outpatient Cases = Outpatient Cases to be served at McLeod Health Brunswick ASC x 10 percent.

^^Total McLeod Health Brunswick ASC Outpatient Cases = Outpatient Cases to be served at McLeod Health Brunswick ASC + in migration.

According to NCOSBM, Brunswick County population is projected to grow 2.1 percent annually during 2021-2026. The applicant projects the number of Brunswick County outpatient cases will grow at the same rate.

<b>Projected Brunswick County Outpatient Surgery Cases</b>										
	<b>2019</b>	<b>2020</b>	<b>2021</b>	<b>2022</b>	<b>2023</b>	<b>2024</b>	<b>2025</b>	<b>2026</b>	<b>2027</b>	<b>CAGR</b>
Outpatient Cases	17,000	17,357	17,721	18,094	18,474	18,862	19,258	19,662	20,075	2.1%

Source: Section Q, Form C, page 6



As previously stated, the applicant projects that McLeod Health and Wilmington Health will serve 1,693 Brunswick County outpatient cases at the proposed facility by CY2027, which is an 8.4 percent increase from the number of cases served by McLeod Health or Wilmington Health physicians during CY2019. The applicant reasonably projects that the proposed McLeod Health Brunswick ASC’s market share of Brunswick County outpatient surgery will be 8.4 percent. Pursuant to the 2021 SMFP OR need methodology, the applicant projects the McLeod Health Brunswick ASC operating room utilization for the first three years of the project.

<b>McLeod Health Brunswick ASC Outpatient Surgery Cases Projected Utilization</b>			
	<b>CY2025</b>	<b>CY2026</b>	<b>CY2027</b>
Outpatient Cases	1,502	1,672	1,862
Outpatient Case Time	1.16	1.16	1.16
Total Surgical Hours	1,742	1,940	2,160
Group Assignment	6	6	6
Standard Hours per OR per Year	1,312	1,312	1,312
Total Surgical Hours/Standard Hours Per OR per Year	1.33	1.48	1.65
OR Needed	1	1	2

Source: Section Q, Form C, page 7

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

- The applicant’s projections of total ambulatory surgical cases by year at McLeod Health Brunswick ASC are supported by the historical growth rates of ambulatory surgical cases served by McLeod Health and Wilmington Health physicians.
- The applicant reasonably projects the market share of Brunswick County ambulatory cases projected to be served by the proposed McLeod Health Brunswick ASC based on the historical utilization of Brunswick County ambulatory cases served by McLeod Health and Wilmington Health physicians.

**Access to Medically Underserved Groups**

In Section C, page 78, the applicant states:

*“Further, McLeod Health and Wilmington Health, the future members of McLeod Health Brunswick ASC, have long-promoted economic access to their services as they historically have provided services to all person in need of medical care, regardless of race, sex, creed, age, national origin, handicap, or ability to pay...”*

In Section C, page 79, the applicant provides the estimated percentage for each medically underserved group, as shown in the following table.

Medically Underserved Groups	Percentage of Total Patients
Low income persons	
Racial and ethnic minorities	17.2%
Women	52.9%
Persons with disabilities	
Persons 65 and older	57.8%
Medicare beneficiaries	60.5%
Medicaid recipients	5.3%

On page 79, the applicant states that McLeod Health Brunswick ASC, nor any future members, maintain data that includes the number of low income or disabled persons served.

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. The applicant's estimates are based on CY2020 Brunswick County outpatient surgery cases served by McLeod Health and Wilmington Health physicians for the surgical specialties to be initially offered at the proposed facility.

### **Conclusion**

The Agency reviewed the:

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

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

### **O-12153-21/Novant Health Leland ASC/ develop an ASC, with two operating rooms and two procedure rooms**

The applicant proposes to develop Novant Health Leland ASC, a multi-specialty ASF with no more than two operating rooms and two procedure rooms pursuant to the need determination in the 2021 SMFP.

### **Patient Origin**

On page 49, the 2021 SMFP defines the service area for operating rooms as *the single or multicounty grouping as shown in in Figure 6.1*. In Figure 6.1, page 55 of the 2021 SMFP, Brunswick County is shown as a single-county operating room service area. Thus, the service area for this facility consists of Brunswick County. Facilities may also serve residents of counties not included in their service area.

The following tables illustrate historical and projected patient origin.

<b>Novant Health Brunswick Medical Center Historical Patient Origin Outpatient Surgical Cases FY 2020</b>		
<b>County/Geographical area</b>	<b>Patients</b>	<b>% of Total</b>
Brunswick	3,284	88.7%
Columbus	117	3.2%
South Carolina	143	3.9%
New Hanover	52	1.4%
Other^	106	2.9%
<b>Total</b>	<b>3,702</b>	<b>100.0%</b>

Source: Section C, page 29; 2021 License Renewal Application  
 ^Less than one percent of patients from the remaining North Carolina counties and other states.

<b>Novant Health Leland ASC Projected Patient Origin Outpatient Surgery Cases</b>						
<b>County/ Geographical Area</b>	<b>1/1/2025-12/31/2025 CY 2025</b>		<b>1/1/2026-12/31/2026 CY 2026</b>		<b>1/1/2027-12/31/2027 CY 2027</b>	
	<b>Patients</b>	<b>% of Total</b>	<b>Patients</b>	<b>% of Total</b>	<b>Patients</b>	<b>% of Total</b>
Brunswick	1,490	90.2%	2,010	91.0%	2,508	91.6%
Columbus	45	2.7%	56	2.5%	64	2.3%
South Carolina	55	3.3%	68	3.1%	78	2.9%
New Hanover	20	1.2%	25	1.1%	28	1.0%
Other^	41	2.5%	31	2.3%	58	2.1%
<b>Total</b>	<b>1,651</b>	<b>100.0%</b>	<b>2,210</b>	<b>100.0%</b>	<b>2,737</b>	<b>100.0%</b>

Source: Section C, page 31  
 ^Less than one percent of patients from the remaining North Carolina counties and other states.

In Section C, page 29, the applicant provides the assumptions and methodology used to project its patient origin. The applicant’s assumptions are reasonable and adequately supported. Novant Health currently provides surgical services in Brunswick County at Novant Health Brunswick Medical Center (NHBMC) and at Novant Health New Hanover Regional Medical Center (NHNHRMC) in New Hanover. The applicant projects patient origin based on the historical patient origin at NHBMC and the number of ASC-appropriate cases projected to shift from NHBMC and NHNHRMC to the proposed Novant Health Leland ASC.

**Analysis of Need**

In Section C, pages 34-56, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below.

- NHBMC historical surgical utilization growth (pages 34-37)

- Brunswick County ambulatory surgery outmigration resulting from rapid population growth (pages 38-40)
- The growing trend of ambulatory surgical procedures performed in the U.S. and North Carolina (pages 40-43)
- Enhanced Geographical access to ambulatory surgical services in a growing municipality in North Carolina (pages 43-45)
- Ambulatory surgery center as an alternative to hospitalization impacted by COVID-19 (pages 45-46)
- Novant Health Leland ASC will operate as a multispecialty ambulatory surgical center offering a wide-range surgical specialty such as; gynecology, ophthalmology, orthopedics and urology (pages 47-53)
- The projected population growth in Brunswick County, particularly the age cohort that is more likely to utilize ambulatory surgical services (pages 54-55)
- Novant Health Leland ASC physician support (pages 55-56)

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

- The proposed facility will be the first ASC in Brunswick County, providing access to ambulatory services in a growing county.
- The proposed Novant Health Leland ASC will offer a wide-range surgical specialty while serving as an alternative to area hospitals impacted by COVID-19.
- The proposed project will meet the need of the projected population growth and aging in Brunswick County.

Projected Utilization

In Section Q, page 115, the applicant provides projected utilization, as illustrated in the following table.

<b>Novant Health Leland ASC Projected Utilization</b>			
	<b>1<sup>ST</sup> Full FY CY2025</b>	<b>2<sup>ND</sup> Full FY CY2026</b>	<b>3<sup>RD</sup> Full FY CY2027</b>
<b>Operating Rooms</b>			
Dedicated Ambulatory ORs	2	2	2
Outpatient Surgical Cases	1,651	2,210	2,737
Outpatient Surgical Case Time	69.5	69.5	69.5
Outpatient Surgical Hours	1,912	2,559	3,170
Group Assignment	6	6	6
Standard Hours per OR per Year	1,312	1,312	1,312
Total Surgical Hours/Standard Hours Per OR per Year	1.5	2.0	2.4
<b>Procedure Rooms</b>			
Number of Procedure Rooms	2	2	2
Total Number of Procedures	210	258	306

In Section C, pages 117-135 the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

*Step 1:* The applicant begins with the review of the historical surgical utilization performed at NHBMC and NHNHRMC. NHBMC outpatient surgical cases increased by a CAGR of 2.3 percent during FY2017-FY2021. Inpatient surgical cases increase by 2.0 percent. NHNHRMC experienced a similar trend prior to the COVID-19 pandemic. The applicant projects that based on the projected population growth and aging in Brunswick County, the demand for inpatient surgery will continue to increase in Brunswick and New Hanover Counties. The applicant projects that proposed ASC will reduce the outmigration of surgical cases due to population growth and a portion of surgical cases will shift to the new facility based on the need for enhanced geographical access to surgical services.

*Step 2:* The applicant determines the projected surgical case growth rates for inpatient and outpatient surgical cases at NHBMC and NHNHRMC based on the historical growth rates at each facility and Brunswick County’s projected population growth and aging. The applicant conservatively selects the following growth rates:

Projected Growth Rates			Growth Rate Assumptions
<b>NHBMC</b>	IP	1.4%	3-YR CAGR FY17-FY20
	OP	2.3%	4-YR CAGR FY17-FY21
<b>NHNHRMC</b>	IP	1.3%	3-YR CAGR FY17-FY20
	OP	0.3%	3-YR CAGR FY17-FY20

Section Q, page 121

*Step 3:* The applicant projects surgical cases at NHBMC and NHNHRMC prior to the expected shift of cases to the proposed Novant Health Leland ASC.

		CAGR	FY2022	FY2023	FY2024	FY2025	FY2026	FY2027
<b>NHBMC</b>	IP Cases	1.4%	1,101	1,116	1,132	1,148	1,164	1,181
	OP Cases	2.3%	3,908	3,997	4,089	4,182	4,278	4,375
	<b>Total Cases</b>		5,008 [5009]	5,113	5,221	5,330	5,442	5,556
<b>NHNHRMC</b>	IP Cases	1.3%	11,167	11,310	11,456	11,603	11,753	11,904
	OP Cases	0.3%	26,151	26,218	26,285	26,353	26,420	26,488
	<b>Total Cases</b>		37,318	37,528	37,741	37,956	38,173	38,392

Section Q, page 123

*Step 4:* The applicant identifies the outpatient surgical cases performed during FY2019-FY2021 to determine the percentage of cases that would be potentially appropriate candidate for an ASC based on a specific criterion:

- Outpatient surgical cases only,
- Approved by Medicare for reimbursement in ASC setting,
- Patients who are graded as American Society of Anesthesiologists physical status (ASA) I and II (normal healthy patient and patient with mild systemic disease), and
- 50 percent of cases graded as ASA III (patient with severe systemic disease)

The following table summarizes the percent of outpatient cases that are ASC-appropriate:

<b>Novant Health Outpatient Surgical Cases Appropriate for ASC</b>	
<b>Facility</b>	<b>% of FY2019- FY2021*Total Facility OP Cases</b>
<b>NHBMC</b>	77.6%
<b>NHNHRMC</b>	73.2%

Source: Section Q, page 124

\*Annualized based on eleven months data.

*Step 5:* The applicant applies the percent of outpatient cases by facility (*Step 4*) to the projected outpatient OR cases by facility (*Step 3*), based on the historical percentage of outpatient surgical cases by specialty at Novant Health facilities during previous years and FY2020.

	FY2022	FY2023	FY2024	FY2025	FY2026	FY2027
<b>NHBMC</b>	3,032	3,102	3,173	3,245	3,319	3,395
<b>NHNHRMC</b>	19,143	19,192	19,241	19,290	19,340	19,389

Section Q, page 124

*Step 6:* The applicant is proposing a multispecialty ASC and anticipates additional surgical specialties consistent with physician recruitment efforts. The applicant conservatively projects the increase in surgical cases by specialty at NHBMC, excluding EmERGEortho's orthopedic surgical cases that are expected to shift from NHBMC to Brunswick Surgery Center.

<b>NHBMC Projected Outpatient Surgical Cases by Specialty (% of Total), FY2022-FY2027</b>	
<b>Specialty</b>	<b>NHBMC</b>
General	31.0%
Gynecology	12.7%
Ophthalmology	13.2%
Otolaryngology	5.0%
Orthopedics	11.0%
Plastic	5.1%
Urology	12.9%
All other Specialties*	9.0%
<b>Total</b>	<b>100.0%</b>

Source: Section Q, page 126; 2021 License Renewal Applications

\*All other specialties include patient management, cardiothoracic, Neurosurgery, and vascular.

*Step 7:* The applicant projects the potential number of ASC-appropriate cases available to shift to the proposed facility based on the historical percentage of by specialty (*Step 6*) applied to the projected ASC-appropriate cases by facility (*Step 5*).

<b>NHBMC ASC-Appropriate Surgery Cases before Shift to NH Leland ASC</b>							
<b>Specialty</b>	<b>% of Total Cases</b>	<b>FY2022</b>	<b>FY2023</b>	<b>FY2024</b>	<b>FY2025</b>	<b>FY2026</b>	<b>FY2027</b>
General	31.0%	941	963	985	1,007	1,030	1,054
Gynecology	12.7%	386	395	404	413	423	433
Ophthalmology	13.2%	399	408	417	427	437	447
ENT	5.0%	152	156	159	163	167	171
Orthopedics	11.0%	334	341	349	357	365	373
Plastic	5.1%	156	156	163	167	170	174
Urology	12.9%	392	401	410	470	429	439
<b>Subtotal</b>	<b>91.0%</b>	<b>2,760</b>	<b>2,823</b>	<b>2,888</b>	<b>2,954</b>	<b>3,022</b>	<b>3,091</b>
All Other Specialties	9.0%	272	278	285	291	298	305
<b>Total</b>	<b>100.0%</b>	<b>3,032</b>	<b>3,102</b>	<b>3,173</b>	<b>3,245</b>	<b>3,319</b>	<b>3,395</b>

Source: Section Q, page 127

<b>NHNHRMC ASC-Appropriate Surgery Cases before Shift to NH Leland ASC</b>							
<b>Specialty</b>	<b>% of Total Cases</b>	<b>FY2022</b>	<b>FY2023</b>	<b>FY2024</b>	<b>FY2025</b>	<b>FY2026</b>	<b>FY2027</b>
General	15.9%	3,045	3,053	3,061	3,069	3,076	3,084
Gynecology	8.6%	1,651	1,655	1,659	1,664	1,668	1,672
Oral	2.1%	404	405	406	407	408	409
Ophthalmology	16.1%	3,090	3,098	3,105	3,113	3,121	3,129
ENT	4.7%	901	903	906	908	910	913
Urology	11.1%	2,117	2,123	2,128	2,134	2,139	2,145
<b>Subtotal</b>	<b>58.6%</b>	<b>11,208</b>	<b>11,237</b>	<b>11,266</b>	<b>11,294</b>	<b>11,323</b>	<b>11,352</b>
All Other Specialties	41.4%	7,935	7,955	7,975	7,996	8,016	8,037
<b>Total</b>	<b>100.0%</b>	<b>19,143</b>	<b>19,192</b>	<b>19,241</b>	<b>19,290</b>	<b>19,340</b>	<b>19,389</b>

Source: Section Q, page 127

*Step 8:* The applicant assumes that a portion of ambulatory surgery patient volume performed at NHBMC and NHNHRMC will shift their care to the proposed facility based on factors such as enhanced geographical access and convenient location for a growing county population. The applicant projects the percentage by specialty to shift based on Novant Health Leland ASC becoming a preferred ambulatory surgery platform for Novant Health surgeons. Other considerations included historical utilization by specialty, the ASC-appropriate cases available to shift from NHBMC and NHNHRMC and capacity constraints at Novant Health's existing ORs. The following tables illustrate the percentage of the potential number of ASC-appropriate surgery cases (*Step 7*) projected to shift to Novant Health Leland ASC during the first three project years.

<b>NHBMC-Projected Outpatient Shifts to Novant Health Leland ASC</b>			
<b>Specialty</b>	<b>FY2025</b>	<b>FY2026</b>	<b>FY2027</b>
General	50.0%	60.0%	70.0%
Gynecology	50.0%	60.0%	70.0%
Ophthalmology	40.0%	50.0%	60.0%
ENT	40.0%	50.0%	60.0%
Orthopedics	30.0%	40.0%	50.0%
Plastic	50.0%	60.0%	70.0%
Urology	50.0%	60.0%	70.0%
<b>Subtotal</b>			
All Other Specialties	0.0%	0.0%	0.0%
<b>Total</b>			

Source: Section Q, page 129

<b>NHNHRMC-Projected Outpatient Shift to Novant Health Leland ASC</b>			
<b>Specialty</b>	<b>FY2025</b>	<b>FY2026</b>	<b>FY2027</b>
General	1.3%	2.5%	5.0%
Gynecology	1.25%	2.5%	5.0%
Oral	1.25%	2.5%	5.0%
Ophthalmology	2.5%	5.0%	10.0%
ENT	1.3%	2.5%	5.0%
Urology	0.6%	1.25%	2.5%
<b>Subtotal</b>			
All Other Specialties	0.0%	0.0%	0.0%
<b>Total</b>			

Source: Section Q, page 129

*Step 9:* The applicant projects the number of surgery cases projected to shift by specialty based on the percentages determined in *Step 8*.

<b>NHBMC Case Shift to Novant Health Leland ASC</b>			
<b>Specialty</b>	<b>FY2025</b>	<b>FY2026</b>	<b>FY2027</b>
General	504	618	738
Gynecology	207	254	303
Ophthalmology	171	218	268
ENT	65	83	102
Orthopedics	107	146	187
Plastic	83	102	122
Urology	210	258	308
All Other Specialties	0	0	0
<b>Total</b>	<b>1,347</b>	<b>1,680</b> <b>[1,679]</b>	<b>2,027</b> <b>[2,028]</b>

Source: Section Q, page 130



<b>NHNHRMC Case Shift to Novant Health Leland ASC</b>			
<b>Specialty</b>	<b>FY2025</b>	<b>FY2026</b>	<b>FY2027</b>
General	38	77	154
Gynecology	21	42	84
Oral	5	10	20
Ophthalmology	88	176	352
ENT	11	23	46
Urology	13	27	54
All Other Specialties	0	0	0
<b>Total</b>	<b>176</b>	<b>354</b> <b>[355]</b>	<b>710</b>

Source: Section Q, page 130

	<b>FY2025</b>	<b>FY2026</b>	<b>FY2027</b>
Shift from <b>NHBMC</b>	<b>1,347</b>	<b>1,680</b>	<b>2,027</b>
Shift from <b>NHNHRMC</b>	<b>176</b>	<b>354</b>	<b>710</b>
<b>Total</b>	<b>1,523</b>	<b>2,034</b>	<b>2,737</b>

Source: Section Q, page 130

*Step 10:* The applicant converted the federal fiscal project to the calendar year to reflect the first three full project year based on the following calculations:

	<b>CY2025</b>	<b>CY2026</b>	<b>CY2027</b>
<b>Calculation</b>	(0.75 x FY2025 + (0.25 x FY2026)	(0.75 x FY2026 + (0.25 x FY2027)	(0.75 x FY2027 + (0.25 x FY2028) *
<b>Source of Facility</b>			
<b>NHBMC</b>	(0.75 x 1,347 + (0.25 x 1,680)	(0.75 x 1,680 + (0.25 x 2,027)	(0.75 x 2,027 + (0.25 x 2027)
<b>NHNHRMC</b>	(0.75 x 176 + (0.25 x 354)	(0.75 x 354 + (0.25 x 710)	(0.75 x 710 + (0.25 x 710)
<b>Source of Facility</b>			
<b>NHBMC</b>	1,430	1,767	2027
<b>NHNHRMC</b>	221	443	710
<b>Total</b>	<b>1,651</b>	<b>2,210</b>	<b>2,737</b>

Source: Section Q, page 131

\*The applicant projects that ambulatory surgical volume will remain constant beyond FY2027.

*Step 11:* The applicant projects the number of surgical cases at NHBMC that will be performed in the ORs and procedure rooms after the projected shift of cases to Novant Health Leland ASC. The applicant states that based on FY2021 data, approximately 84 percent of NHBMC's ambulatory surgery cases were performed in ORs and 16 percent were performed in procedure

rooms. The applicant does not project that NHBMC will perform inpatient surgical cases in its procedure room in the future. The applicant illustrates its projections on page 132 of the application.

*Step 12:* The applicant projects 2027 OR need at Novant Health Brunswick County facilities

2027 OR Need at Novant Health Brunswick County Facilities							
	OR Group	Hr/Or/Yr	Case Time		2027 Surgical OR Cases	2027 Surgical Hours	Surgical ORs Required
<b>NHBMC</b>			IP	134.0	1,181	2,637	
			OP	91.3	1,963	2,986	
	4	1,500.0	Total		3,153	5,644	3.7
<b>NHNHRMC</b>	6	1,312.0	OP	69.5	2,737	3,170	2.4

Source: Section Q, page 133

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

- The applicant’s projections of total ambulatory surgical case volumes by year at Novant Health Leland ASC are supported by the historical growth rates of ambulatory surgical case volumes at NHBMC and NHNHRMC and by projected population growth and aging in the Brunswick County service area.
- The applicant’s projections of total ambulatory surgical case volumes by year that will shift from NHBMC and NHNHRMC to the Novant Health Leland ASC are supported by the applicant’s historical experience with regard to surgical volumes by specialty and the numbers and types of ASC-appropriate surgical cases that could reasonably be expected to shift to the Novant Health Leland ASC, as well as other factors such as patient cost advantages, enhanced geographic access, and the advantages to both physicians and patients of having access to a newer, more modern facility,

**Access to Medically Underserved Groups**

In Section C, pages 60-62, the applicant describes how each underserved group will have access to the proposed Novant Health Leland ASC. In Section C, page 62, the applicant provides the estimated percentage for each medically underserved group, as shown in the following table.

Medically Underserved Groups	Percentage of Total Patients
Low income persons	10.2%
Racial and ethnic minorities	25.0%
Women	52.3%
Persons with disabilities	
Persons 65 and older	54.3%
Medicare beneficiaries	54.3%
Medicaid recipients	7.0%

On page 62, the applicant states that Novant Health does not maintain the number of disabled persons it serves; however, disabled persons will not be denied access to Novant Health Leland ASC. 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.

### **Conclusion**

The Agency reviewed the:

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

Based on that review, the Agency concludes that the application is 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 [persons with disabilities], and other underserved groups and the elderly to obtain needed health care.

NA

Both Applications

Neither applicant is proposing 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

Both Applications

### **O-12148-21/McLeod Health Brunswick ASC/ develop an ASC, with two operating rooms and two procedure rooms**

The applicant proposes to develop McLeod Health Brunswick ASC, a multi-specialty ASF with no more than two operating rooms and two procedure rooms pursuant to the need determination in the 2021 SMFP.

In Section E, pages 90-92, 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:

*Develop the Proposed ASF at a Different Location*-The applicant states that the proposed location would meet the needs of patients based on the density of the population, including contiguous zip codes, and the close proximity of primary care providers and referring specialty physicians. Further, because of the uneven distribution of operating rooms, the proposed McLeod Health Brunswick ASC will meet the need for additional surgical capacity in Brunswick County.

*Develop the Proposed ASF with a Different Number of Operating Rooms*-The applicant chose two operating rooms based on the 2021 SMFP need determination in Brunswick County. The applicant states that this was not an effective alternative because developing one operating room would make scheduling surgeons and operating the facility difficult.

*Develop the Proposed ASF with a Different Complement of Services*-The applicant states that this alternative would not be effective due to the volume of cases projected to be performed at the proposed facility and the recent growth in surgical volumes in Brunswick County across surgical specialties to be offered at the new ASF.

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 2021 SMFP need determination for two operating rooms in Brunswick County and the projected need for additional surgical capacity in Brunswick County.
- 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
- Written comments
- Responses to comments

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

### **O-12153-21/Novant Health Leland ASC/ develop an ASC, with two operating rooms and two procedure rooms**

The applicant proposes to develop Novant Health Leland ASC, a multi-specialty ASF with no more than two operating rooms and two procedure rooms pursuant to the need determination in the 2021 SMFP.

In Section E, pages 71-73, 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 based on the growing ambulatory surgical demand and the 2021 SMFP need determination for two additional operating rooms, this was not an effective alternative.

*Develop Incremental Hospital-Based ORs*-The applicant states that developing an operating room at Novant Health Brunswick Medical Center was not be an effective alternative because patients would not benefit from enhanced geographical access, a non-hospital outpatient department charge structure nor a convenient, dedicated outpatient facility.

*Locate the ASC in a Different Geographic Location*-After reviewing the projected population growth in Brunswick County by zip code and reviewing the location of existing surgical facilities and Novant Health's physician practices, the applicant determined that this was not the most effective alternative.

On page 71, the applicant states that its proposal is the most effective alternative because the proposed project will meet the ambulatory surgical demand and the 2021 SMFP need determination in Brunswick County while providing enhanced geographical access to services.

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 2021 SMFP need determination for two operating rooms in Brunswick County and enhancing geographical access to ambulatory surgical services in Brunswick County.
- 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
- Written comments
- Responses to comments

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

- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of

the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C  
 Both Applications

**O-12148-21/McLeod Health Brunswick ASC/ develop an ASC, with two operating rooms and two procedure rooms**

The applicant proposes to develop McLeod Health Brunswick ASC, a multi-specialty ASF with no more than two operating rooms and two procedure rooms pursuant to the need determination in the 2021 SMFP.

**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.

<b>McLeod Health Brunswick ASC Capital Costs</b>			
	McLeod Loris Seacoast Hospital	McLeod Health Brunswick ASC, LLC	Total
Purchase Price of Land	\$417,910		\$417,910
Construction/Renovation Contract(s)	\$12,997,856		\$12,997,856
Architecture/Engineering Fees	\$1,243,343		\$1,243,343
Medical Equipment		\$4,869,405	\$4,869,405
Consultant Fees*	\$500,000		\$500,000
Other (Contingency)	\$729,772	\$221,043	\$950,815
<b>Total</b>	<b>\$15,888,881</b>	<b>\$5,090,448</b>	<b>\$20,979,329</b>

\*Includes Project Management Fees, Application Fee, CON Consultant Fee

In Section Q, the applicant provides the assumptions used to project the capital cost. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based on the following:

- Purchase price for land was based on the amount of land necessary to develop the project.
- Other costs such as construction, medical equipment and consultant fees were based on vendor estimates and Wilmington Health and McLeod Health's experience with similar projects.

In Section F, pages 94-95, the applicant projects that start-up costs will be \$354,284 and initial operating expenses will be \$1,632,424 for a total working capital of \$1,986,708. On page 95, 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 were estimated based on the costs of supplies, utilities, salary and benefits, and other expenses for the initial 30 days of operation.
- Initial operating expenses covers an 11-month initial period when operating costs are projected to exceed revenue.

**Availability of Funds**

In Section F, pages 92-93, the applicant states that the capital cost will be funded, as shown in the table below.

<b>Sources of Capital Cost Financing</b>			
<b>Type</b>	<b>McLeod Health Brunswick ASC, LLC</b>	<b>McLeod Loris Seacoast Hospital</b>	<b>Total</b>
Loans	\$0	\$0	\$0
Accumulated reserves or OE *	\$5,090,448	\$15,888,881	\$20,979,329
Bonds	\$0	\$0	\$0
Other (Specify)	\$0	\$0	\$0
<b>Total Financing</b>	<b>\$5,090,448</b>	<b>\$15,888,881</b>	<b>\$20,979,329</b>

\* OE = Owner's Equity

In Section F, page 95, the applicant states that the working capital needs of the project will be funded, as shown in the table below.

<b>Sources of Financing for Working Capital</b>	<b>Amount</b>
<b>McLeod Health Brunswick ASC, LLC</b>	
Loans	\$0
Cash or Cash Equivalents, Accumulated Reserves or Owner's Equity	\$1,986,708
Lines of credit	\$0
Bonds	\$0
<b>Total</b>	<b>\$1,986,708</b>

Exhibit F.2-1 contains a letter dated October 15, 2021, from the Chief Financial Officer of McLeod Health stating McLeod Loris Seacoast Hospital and McLeod Health Brunswick ASC, LLC commitment to funding the capital and working capital costs through funds from its parent company, McLeod Health. Exhibit F.2-1 contains the audited financial statements of the McLeod Health, which show that as of September 30, 2020, McLeod Health had over \$197 million in cash and cash equivalents, \$2.3 billion in total assets and \$1.6 billion in net assets.

The applicant adequately demonstrates the availability of sufficient funds for the capital and working capital needs of the 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 Form F.2b, the applicant projects that revenues will exceed operating expenses in the second and third full fiscal years following completion of the project, as shown in the table below.

	<b>1<sup>st</sup> Full FY CY 2025</b>	<b>2<sup>nd</sup> Full FY CY 2026</b>	<b>3<sup>rd</sup> Full FY CY 2027</b>
Total Operating Room Cases	1,502	1,672	1,862
Total Gross OR Revenues (Charges)	\$9,595,240	\$11,003,638	\$12,618,763
Total Net OR Revenue	\$4,209,895	\$4,827,828	\$5,536,461
Average Net Revenue per OR Case	\$2,803	\$2,887	\$2,973
Total Procedure Room (PR) Cases	300	334	372
Total Gross PR Revenues (Charges)	\$1,439,286	\$1,650,546	\$1,892,814
Total Net PR Revenue	\$631,484	\$724,174	\$830,469
Average Net Revenue per Cases	\$2,105	\$2,168	\$2,232
Total Gross Revenue	\$11,034,526	\$12,654,184	\$14,511,577
Total Net Revenue	\$4,841,380	\$5,552,002	\$6,366,930
Total Operating Expenses (Costs)	\$5,243,359	\$5,470,213	\$5,782,724
Net Income	(\$404,979)	\$81,789	\$584,206

Totals may not sum due to rounding

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q. 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.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

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

- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.
- The applicant adequately demonstrates that the capital and working capital costs are based on reasonable and adequately supported assumptions.
- The applicant adequately demonstrates availability of sufficient funds for the capital and working capital needs of the proposal.



- 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 costs and charges.

**O-12153-21/Novant Health Leland ASC/ develop an ASC, with two operating rooms and two procedure rooms**

The applicant proposes to develop Novant Health Leland ASC, a multi-specialty ASF with no more than two operating rooms and two procedure rooms pursuant to the need determination in the 2021 SMFP.

In Section Q, page 136, the applicant projects the total capital cost of the project, as shown in the table below.

<b>Novant Health Leland ASC Capital Costs</b>		
	<b>Novant Health, Inc.</b>	<b>Total</b>
Site Preparation	\$1,272,500	\$1,272,500
Construction/Renovation Contract(s)	\$7,198,503	\$7,198,503
Landscaping	\$71,379	\$71,379
Architecture/Engineering Fees	\$683,391	\$683,391
Medical Equipment	\$3,888,734	\$3,888,734
Furniture	\$318,685	\$318,685
Consultant Fees (CON Consultant)	\$46,000	\$46,000
Interest during Construction	\$349,129	\$349,129
Other (IT, Low Voltage, Security, DHSR Review Cost, Special Inspections, Escalation, Project Contingency)	\$2,763,368	\$2,763,368
<b>Total</b>	<b>\$16,591,690</b>	<b>\$16,591,690</b>

In Section Q, page 144. 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 and provides supporting documentation in Exhibit F.1.

In Section F, page 77, the applicant projects that start-up costs will be \$801,273 and initial operating expenses will be \$632,335 for a total working capital of \$1,433,608. On page 77, 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:

- Working capital includes start-up expenses for hiring and training staff and costs to obtain licensure and other miscellaneous expenses.
- Initial operating expenses include the 15-month initial operating period when expenses are expected to exceed revenue.

**Availability of Funds**

In Section F, page 75, the applicant states that the capital cost will be funded, as shown in the table below.

<b>Sources of Capital Cost Financing</b>		
<b>Type</b>	<b>Novant Health, Inc.</b>	<b>Total</b>
Loans	\$0	\$0
Accumulated reserves or OE *	\$16,591,690	\$16,591,690
Bonds	\$0	\$0
Other (Specify)	\$0	\$0
<b>Total Financing</b>	<b>\$16,591,690</b>	<b>\$16,591,690</b>

\* OE = Owner's Equity

In Section F, page 78, the applicant states that the working capital needs of the project will be funded, as shown in the table below.

<b>Sources of Financing for Working Capital</b>	<b>Amount</b>
<b>Novant Health, Inc.</b>	
Loans	\$0
Cash or Cash Equivalents, Accumulated Reserves or Owner's Equity	\$1,433,608
Lines of credit	\$0
Bonds	\$0
<b>Total</b>	<b>\$1,433,608</b>

Exhibit F.2 contains a letter dated October 13, 2021, from the senior vice-president of Operational Finance Revenue Cycle for Novant Health, Inc., parent entity to Novant Health Brunswick Surgery Center, LLC, stating their commitment to fund the capital and working capital costs of the project. Exhibit F.2 contains the audited financial statements of Novant Health, Inc. which show that as of December 31, 2020, Novant Health had over \$700 million in cash and cash equivalents, \$8.6 billion in total assets, and \$4.9 billion in net assets.

**Financial Feasibility**

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

	<b>1<sup>st</sup> Full FY CY 2025</b>	<b>2<sup>nd</sup> Full FY CY 2026</b>	<b>3<sup>rd</sup> Full FY CY 2027</b>
Total Operating Room Cases	1,651	2,210	2,737
Total Procedure Room (PR) Cases	210	258	306
Total Operating and Procedure Room Cases	1,861	2,468	3,043
Total Gross Revenues (Charges)	\$17,389,766	\$23,416,940	\$29,364,455
Total Net Revenue	\$4,536,338	\$6,096,403	\$7,632,114
Average Net Revenue per Case	\$2,437.58	\$2,470.17	\$2,508.08
Total Operating Expenses (Costs)	\$5,188,434	\$6,101,680	\$7,036,341
Average Operating Expenses per Cases	\$2,787.98	\$2,472.31	\$2,312.30
Net Income	(\$652,096)	(\$5,277)	\$595,773

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q. 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.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

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

- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.
- The applicant adequately demonstrates that the capital and working capital costs are based on reasonable and adequately supported assumptions.
- The applicant adequately demonstrates availability of sufficient funds for the capital and working capital needs of the proposal.
- 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 costs and charges.

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

Both Applications

On page 49, the 2021 SMFP defines the service area for operating rooms as *the single or multicounty grouping as shown in in Figure 6.1*. In Figure 6.1, page 55 of the 2021 SMFP, Brunswick County is shown as a single-county operating room service area. Thus, the service area for this facility consists of Brunswick County. Facilities may also serve residents of counties not included in their service area.

The following table identifies the existing and approved inpatient (IP), outpatient (OP), and shared ORs located in Brunswick County, and the inpatient and outpatient case volumes for each provider, from Table 6A, page 56, and Table 6B, page 68, of the 2021 SMFP.

Brunswick County	IP ORs	OP ORs	Shared ORs	Excluded C-Section, Trauma, Burn ORs	CON Adjustments	IP Surgery Cases	OP Surgery Cases
Brunswick Surgery Center	0	0	0	0	1	0	0
J. Arthur Doshier Memorial Hospital	0	0	2	0	0	219	2,206
Novant Health Brunswick Center	1	0	4	-1	0	954	3,794
<b>Total</b>	<b>1</b>	<b>0</b>	<b>6</b>	<b>-1</b>	<b>1</b>	<b>1,173</b>	<b>6,000</b>

Source: 2021 SMFP

**O-12148-21/McLeod Health Brunswick ASC/ develop an ASC, with two operating rooms and two procedure rooms**

The applicant proposes to develop McLeod Health Brunswick ASC, a multi-specialty ASF with no more than two operating rooms and two procedure rooms pursuant to the need determination in the 2021 SMFP.

In Section G, page 102, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved operating rooms in Brunswick. The applicant states:

*“...McLeod Health Brunswick ASC will be the first and only freestanding multispecialty in ASF Brunswick County...the existing surgical services in Brunswick County consist of four operating rooms at Novant Health Brunswick Medical Center and two operating rooms at J. Arthur Doshier Memorial Hospital for a total of six hospital-based operating rooms, and one recently developed operating room at Brunswick Surgery Center, a new freestanding single specialty ASF in Leland that offers only orthopedic surgical services.”*

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area based on the following:

- There is a need determination in the 2021 SMFP for two operating rooms in Brunswick County.
- The applicant adequately demonstrates that the proposed operating rooms are needed in addition to the existing or approved operating rooms.

### **Conclusion**

The Agency reviewed the:

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

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

### **O-12153-21/Novant Health Leland ASC/ develop an ASC, with two operating rooms and two procedure rooms**

The applicant proposes to develop Novant Health Leland ASC, a multi-specialty ASF with no more than two operating rooms and two procedure rooms pursuant to the need determination in the 2021 SMFP.

In Section G, page 84, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved operating room services in Brunswick County. The applicant states:

*“The proposed project effectively expands and enhances access to Novant Health ambulatory surgical services in Brunswick County via develop of OR capacity at Novant Health Leland ASC.*

...

*...the projected shift of ASC-appropriate ambulatory surgical cases from Novant Health facilities is an appropriate approach toward the delivery of cost effective ambulatory surgical services in Brunswick County.”*

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area based on the following:

- There is a need determination in the 2021 SMFP for two operating rooms in Brunswick County.

- The applicant adequately demonstrates that the proposed operating rooms are needed in addition to the existing or approved operating rooms.

**Conclusion**

The Agency reviewed the:

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

Based on that review, the Agency concludes that the application is 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  
Both Applications

**O-12148-21/McLeod Health Brunswick ASC/ develop an ASC, with two operating rooms and two procedure rooms**

The applicant proposes to develop McLeod Health Brunswick ASC, a multi-specialty ASF with no more than two operating rooms and two procedure rooms pursuant to the need determination in the 2021 SMFP.

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

Position	Projected FTE Staff
	2nd Full Fiscal Year CY 2026
Registered Nurse	10.0
LPNs/Techs	6.0
Director of Nursing	1.0
Administrator	1.0
Administrative Staff	3.0
<b>TOTAL</b>	<b>21.0</b>

The assumptions and methodology used to project staffing are provided in Section Q. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in F.3b. In Section H, pages 104-105, the applicant describes the

methods to be used to recruit or fill new positions and its proposed training and continuing education programs.

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

- Staff will be employed by Wilmington Health, an existing provider with physician clinics, diagnostics centers and an existing ASF. Wilmington will recruit staff through print advertising, applications on file, online applicants and contacts with clinical training programs.
- The applicant provides supporting documentation in I.1-1.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

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

### **O-12153-21/Novant Health Leland ASC/ develop an ASC, with two operating rooms and two procedure rooms**

The applicant proposes to develop Novant Health Leland ASC, a multi-specialty ASF with no more than two operating rooms and two procedure rooms pursuant to the need determination in the 2021 SMFP.

In Section H, page 141, the applicant provides projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table:

Position	Projected FTE Staff		
	1st Full Fiscal Year CY 2025	2nd Full Fiscal Year CY 2026	3rd Full Fiscal Year CY 2027
Registered Nurses	7.0	8.0	8.0
Certified Nurse Aides/Nursing Assistants	2.0	2.0	2.0
Certified Registered Nurses Anesthetists	2.0	2.0	2.5
Surgical Technicians	3.5	3.5	3.5
Radiology Technologists	0.5	1.0	1.0
Pharmacy Technicians	0.3	0.3	0.3
Central Sterile Supply	1.0	1.0	1.0
Administrator	1.0	1.0	1.0
Business Office	1.0	1.0	1.0
<b>TOTAL</b>	<b>18.3</b>	<b>19.8</b>	<b>20.3</b>

The assumptions and methodology used to project staffing are provided in Section Q. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in F.3b. In Section H, page 86, the applicant describes the methods 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:

- As a major employer in Brunswick County, Novant Health is able to recruit and retain clinical and non-clinical staff.
- Novant Health requires all clinical employees to complete orientation and training specific to their position.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

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

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



C  
Both Applications

**O-12148-21/McLeod Health Brunswick ASC/ develop an ASF, with two operating rooms and two procedure rooms**

The applicant proposes to develop McLeod Health Brunswick ASC, a multi-specialty ASC with no more than two operating rooms and two procedure rooms pursuant to the need determination in the 2021 SMFP.

**Ancillary and Support Services**

In Section I, page 107, the applicant identifies the necessary ancillary and support services for the proposed services. On pages 107-108, the applicant explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibit I-1.1. The applicant adequately demonstrates that the necessary ancillary and support services will be made available. The necessary ancillary and support services will be provided by two affiliated health care entities; McLeod Health and Wilmington Health.

In Section I, pages 108-109, 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:

- McLeod Health and Wilmington Health's extensive relationships with the local healthcare community.
- The proposed services will be coordinated with the existing health care system through McLeod Health and Wilmington Health's Accountable Care Alliance; a collaboration that focuses on quality of care, improved access and affordability.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

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

**O-12153-21/Novant Health Leland ASC/ develop an ASC, with two operating rooms and two procedure rooms**

The applicant proposes to develop Novant Health Leland ASC, a multi-specialty ASF with no more than two operating rooms and two procedure rooms pursuant to the need determination in the 2021 SMFP.

### **Ancillary and Support Services**

In Section I, page 88, the applicant identifies the necessary ancillary and support services for the proposed services. On pages 88-89, the applicant explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibits C.1. and I.1. On pages 88-89, the applicant adequately demonstrates that the necessary ancillary and support services will be made available.

### **Coordination**

In Section I, page 89, the applicant describes its existing and proposed relationships with other local health care and social service providers. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system. The proposed Novant Health Leland ASC will be part of Novant Health's existing healthcare system which currently collaborates with other local health care and social service providers in the service area and surrounding communities.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

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

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

NA  
Both Applications

The applicants do 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  
Both Applications

None of the applicants are 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  
Both Applications

**O-12148-21/McLeod Health Brunswick ASC/ develop an ASC, with two operating rooms and two procedure rooms**

The applicant proposes to develop McLeod Health Brunswick ASC, a multi-specialty ASF with no more than two operating rooms and two procedure rooms pursuant to the need determination in the 2021 SMFP.

In Section K, page 111, the applicant states that the project involves renovating 18,400 square feet of existing space. Line drawings are provided in Exhibit C.1-1.

On page 113, the applicant identifies the proposed site and provides information about the current owner, zoning and special use permits for the site, and the availability of water, sewer and waste disposal and power at the site. Supporting documentation is provided in Exhibits K.4-1 and K.4-2. The site appears to be suitable for the proposed multi-specialty ASC based on the applicant's representations and supporting documentation.

On page 112, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal based on the following:

- The medical office building will be constructed as part of a CON exempt project allowing construction costs to be paid overtime through a lease agreement with McLeod Health Brunswick ASC.
- The construction plan includes efforts toward energy efficiency and water conservation.
- The facility will provide a multitude of services in a lower cost setting.

On page 112, 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 project involves the development of an ambulatory surgical facility which provides care without incurring hospital-based expenses that can be passed on the patient.

On page 113, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans and provides supporting documentation in Exhibit F.1.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

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

### **O-12153-21/Novant Health Leland ASC/ develop an ASC, with two operating rooms and two procedure rooms**

The applicant proposes to develop Novant Health Leland ASC, a multi-specialty ASF with no more than two operating rooms and two procedure rooms pursuant to the need determination in the 2021 SMFP.

In Section K, page 92, the applicant states that the project involves constructing 15,647 square feet of new space Line drawings are provided in Exhibit K.1.

On pages 94-95, the applicant identifies the proposed site and provides information about the current owner, zoning and special use permits for the site, and the availability of water, sewer and waste disposal and power at the site. Supporting documentation is provided in Exhibit K.3. The site appears to be suitable for the proposed operating room services based on the applicant's representations and supporting documentation.

On pages 92-93, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal. The proposed multi-specialty ASC will perform surgical procedures at a lower cost as opposed to services performed in acute care hospital where additional costs associated with a hospital-based setting can incur.

On page 93, 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. Novant Health Leland ASC will provide services at a lower price than a full service hospital while increasing OR capacity in Brunswick County.

On page 93, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans and provides supporting documentation in Exhibit K.3.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

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

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and ... persons [with disabilities], which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:
- (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

NA  
Both Applications

Neither applicant nor any related entities own, operate or manage an existing health service facility located in the service area. Therefore, Criterion (13a) is not applicable to this review.

- (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;

NA  
 Both Applications

Neither applicant nor any related entities own, operate or manage an existing health service facility located in the service area. Therefore, Criterion (13b) is not applicable to this review.

- (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  
 Both Applications

**O-12148-21/McLeod Health Brunswick ASC/ develop an ASC, with two operating rooms and two procedure rooms**

In Section L, page 120, the applicant projects the following payor mix for the proposed services during the third full fiscal year of operation following completion of the project, as shown in the table below.

<b>McLeod Health Brunswick ASC Projected Payor Mix, CY 2027</b>	
<b>Payor Source</b>	<b>Operating Room Services as Percent of Total</b>
Self-Pay	2.6%
Charity Care <sup>^</sup>	
Medicare*	60.5%
Medicaid*	5.3%
Insurance*	25.7%
Other (Government) <sup>^^</sup>	5.9%
<b>Total</b>	<b>100.0%</b>

\*Including any managed care plans.

<sup>^</sup>McLeod Health's and Wilmington Health's internal data does not include charity care as a payor source for patients. Patients in any category can and do receive charity care.

<sup>^^</sup>Includes TRICARE and Workers Compensation

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 2.6% of total services will be provided to self-pay patients, 60.5% to Medicare patients and 5.3% to Medicaid patients.

On page 119, the applicant provides the assumptions and methodology used to project payor mix during the first three full fiscal years of operation following completion of the project. The projected payor mix is reasonable and adequately supported based on the following:

- Payor mix is based on CY 2020 payor mix of patients appropriate to be served by the proposed ASF and applied to the total number projected operating and procedure room cases at the proposed ASF through CY 2027.
- The applicant projects that the payor mix will remain constant through the first three full fiscal years of the project even with the uncertainty of healthcare reform in the coming years.

he Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

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

**O-12153-21/Novant Health Leland ASC/ develop an ASC, with two operating rooms and two procedure rooms**

In Section L, page 99, the applicant projects the following payor mix for the proposed services during the third full fiscal year of operation following completion of the project, as shown in the table below.

<b>Novant Health Leland ASC Projected Payor Mix, CY 2027</b>	
<b>Payor Source</b>	<b>Operating Room Services as Percent of Total</b>
Self-Pay	4.2%
Charity Care	3.4%
Medicare*	54.0%
Medicaid*	7.2%
Insurance*	28.7%
Other (Worker's Comp and other government payors)	2.5%
<b>Total</b>	<b>100.0%</b>

\*Including any managed care plans.

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 4.2% of total services will be provided to self-pay patients, 3.4% to charity care patients, 54.0% to Medicare patients and 7.2% to Medicaid patients.

On page 119, the applicant provides the assumptions and methodology used to project payor mix during the first three full fiscal years of operation following completion of the project. The projected payor mix is reasonable and adequately supported based on the following:

- Projected payor mix is based on surgical cases and non-surgical procedures at NHBMC and NHNHRMC and associated with the services projected to be provided by the proposed Novant Health Leland ASC.
- Projected payor mix is based on the number of cases by specialty projected to be shifted from NHBMC and NHNHRMC to Novant Health Leland ASC.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

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

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

### C

#### Both Applications

#### **O-12148-21/McLeod Health Brunswick ASC/ develop an ASC, with two operating rooms and two procedure rooms**

In Section L, page 121, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

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

#### **O-12153-21/Novant Health Leland ASC/ develop an ASC, with two operating rooms and two procedure rooms**

In Section L, page 102, the applicant adequately describes the range of means by which patients will have access to the proposed services.



The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

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

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

C

Both Applications

**O-12148-21/McLeod Health Brunswick ASC/ develop an ASC, with two operating rooms and two procedure rooms**

The applicant proposes to develop McLeod Health Brunswick ASC, a multi-specialty ASF with no more than two operating rooms and two procedure rooms pursuant to the need determination in the 2021 SMFP.

In Section M, page 123, the applicant describes the extent to which health professional training programs in the area will have access to the facility for training purposes. The applicant adequately demonstrates that health professional training programs in the area will have access to the facility for training purposes. Through Wilmington Health and McLeod Health, the proposed facility will partner with the certified medical assistant and nursing programs of colleges in the area to provide shadowing, externship, and placement opportunities. These programs will continue to have access to clinical training program opportunities at McLeod Health and Wilmington Health facilities including the freestanding outpatient surgical services proposed to be provided in the ASF, following the proposed project.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

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

**O-12153-21/Novant Health Leland ASC/ develop an ASC, with two operating rooms and two procedure rooms**

The applicant proposes to develop Novant Health Leland ASC, a multi-specialty ASF with no more than two operating rooms and two procedure rooms pursuant to the need determination in the 2021 SMFP.

In Section M, page 103, the applicant describes the extent to which health professional training programs in the area will have access to the facility for training purposes. The applicant adequately demonstrates that health professional training programs in the area have will have access to the facility for training purposes based on the following:

- Novant Health has established clinical education agreements with area health education programs which will be extended to Novant Health Brunswick ASC.
- Novant Health intends to collaborate with interested health professional programs in the area to expand their clinical training programs at the facility.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

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

(15) Repealed effective July 1, 1987.

(16) Repealed effective July 1, 1987.

(17) Repealed effective July 1, 1987.

(18) Repealed effective July 1, 1987.

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

C  
Both Applications

On page 49, the 2021 SMFP defines the service area for operating rooms as *the single or multicounty grouping as shown in in Figure 6.1*. In Figure 6.1, page 55 of the 2021 SMFP,

Brunswick County is shown as a single-county operating room service area. Thus, the service area for this facility consists of Brunswick County. Facilities may also serve residents of counties not included in their service area.

The following table identifies the existing and approved inpatient (IP), outpatient (OP), and shared ORs located in Brunswick County, and the inpatient and outpatient case volumes for each provider, from Table 6A, page 56, and Table 6B, page 68, of the 2021 SMFP.

Brunswick County	IP ORs	OP ORs	Shared ORs	Excluded C-Section, Trauma, Burn ORs	CON Adjustments	IP Surgery Cases	OP Surgery Cases
Brunswick Surgery Center	0	0	0	0	1	0	0
J. Arthur Doshier Memorial Hospital	0	0	2	0	0	219	2,206
Novant health Brunswick Center	1	0	4	-1	0	954	3,794
<b>Total</b>	<b>1</b>	<b>0</b>	<b>6</b>	<b>-1</b>	<b>1</b>	<b>1,173</b>	<b>6,000</b>

Source: 2021 SMFP

**O-12148-21/McLeod Health Brunswick ASC/ develop an ASC, with two operating rooms and two procedure rooms**

The applicant proposes to develop McLeod Health Brunswick ASC, multi-specialty ASF with no more than two operating rooms and two procedure rooms pursuant to the need determination in the 2021 SMFP.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 125, the applicant states:

*“The proposed project is expected to enhance competition in the service area by promoting cost effectiveness, quality, and access to freestanding outpatient surgical services in Brunswick County.”*

Regarding the impact of the proposal on cost effectiveness, in Section B, pages 35-36, the applicant states:

*“In a freestanding ASF, there are no other hospital-based expenses allocated to surgery services; the only expenses are those generated directly by services provided by the ASF. As a result, patients and payors do not incur the charges associated with hospital-based care.*

...

*...the proposed project will enhance competition in the service area and offer patients in the region a lower-cost alternative to the existing hospital-based services in Brunswick County.”*

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

Regarding the impact of the proposal on quality, in Section B, page 27, the applicant states:

*“McLeod Health and Wilmington Health, the future members of McLeod Health Brunswick ASC believe the proposed project exemplifies this commitment to the provision of high quality healthcare. In particular, although both organizations operate existing licensed, certified, and accredited healthcare facilities, Wilmington Health is the only one that operates and existing (and has an approved) ASF in North Carolina. As such, McLeod Health Brunswick ASC intends to use Wilmington Health’s existing policies as a baseline for the proposed ASF. Both members believe this is reasonable, and both members are committed to ensuring safety and quality in the proposed ASF, as they do their respective existing facilities today.”*

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 B, page 34, the applicant states:

*“...McLeod Health Brunswick ASC will provide, without discrimination, care of emergency medical conditions to individuals regardless of their eligibility for Compassionate Care or for government assistance. In addition, McLeod Health Brunswick ASC will accept various insurance plans, including Medicare and Medicaid, and will provide financial assistance to patients with financial hardships.”*

See also Sections 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.

### **Conclusion**

The Agency reviewed the:

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

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

**O-12153-21/Novant Health Leland ASC/ develop an ASC, with two operating rooms and two procedure rooms**

The applicant proposes to develop Novant Health Leland ASC, a multi-specialty ASF with no more than two operating rooms and two procedure rooms pursuant to the need determination in the 2021 SMFP.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 105, the applicant states:

*“...It will allow Novant Health to create a new point of access for ambulatory surgical services and to better meet the needs of its existing patient population and to ensure the timely provision of services in a new convenient location. Novant Health Leland ASC will be the first multi-specialty ASC in Brunswick County.”*

Regarding the impact of the proposal on cost effectiveness, in Section N, page 105, the applicant states:

*“...patient copays and charges are lower at freestanding ASC compared to hospital-based outpatient surgery programs. This approach will offer a new, more cost-effective option for local access to outpatient surgical care in Brunswick County.”*

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

Regarding the impact of the proposal on quality, in Section N, page 106, the applicant states:

*“Novant Health is committed to delivering high-quality care at all of its facilities. Novant Health has quality-related policies and procedures that will be applicable to the proposed new ASC.”*

See also Sections B, C and O of the application and any exhibits.

Regarding the impact of the proposal on access by medically underserved groups, in Section N, pages 106-107, the applicant states:

*“...Novant Health will continue to have a policy to provide services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age,*

*ability to pay, or any other factor that would classify a patient underserved. Novant Health's financial assistance policy will apply to the proposed services."*

See also Sections B, C and L 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

### **Conclusion**

The Agency reviewed the:

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

Based on that review, the Agency concludes that the application is 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 Both Applications

#### **O-12148-21/McLeod Health Brunswick ASC/ develop an ASC, with two operating rooms and two procedure rooms**

In Section Q, Form O, the applicant identifies the ambulatory surgical center located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of one of this type of facility located in North Carolina.

In Section O, page 129, the applicant states that the facility identified in Form O has continually maintain all relevant licensure, certification, and accreditation for the 18 months immediately preceding the submittal of the application. According to the files in the Acute Care 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 had not occurred in this facility. After reviewing and considering information provided by the applicant and by the Acute Care and Home Care Licensure and Certification Section and considering the quality of care provided at the facility, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

**O-12153-21/Novant Health Leland ASC/ develop an ASC, with two operating rooms and two procedure rooms**

In Section Q, page 142, the applicant identifies the ambulatory surgical centers located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of 12 of this type of facility located in North Carolina.

In Section O, page 110, the applicant states that Novant Health is not aware of any deficiencies in quality of care occurred in any of these facilities during the 18 months immediately preceding the submittal of the application. According to the files in the Acute Care 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 had not occurred in any of these facilities. After reviewing and considering information provided by the applicant and by the Acute Care and Home Care Licensure and Certification Section and considering the quality of care provided at all 12 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  
Both Applications

The applications are conforming with all applicable Criteria and Standards for Surgical Services and Operating Rooms. The specific criteria are discussed below.

**SECTION .2100 – CRITERIA AND STANDARDS FOR SURGICAL SERVICES AND OPERATING ROOMS**

**10A NCAC 14C .2103                      PERFORMANCE STANDARDS**

*(a) An applicant proposing to increase the number of operating rooms (excluding dedicated C-section operating rooms) in a service area shall demonstrate the need for the number of proposed operating rooms in addition to the existing and approved operating rooms in the applicant's health system in the applicant's third full fiscal year following completion of the proposed project based on the Operating Room Need Methodology set forth in the 2018 State Medical Facilities Plan. The applicant is not required to use the population growth factor.*

-C- **McLeod Health Brunswick ASC.** This proposal would develop a new ASC with two operating rooms. The applicant projects sufficient surgical cases and hours to demonstrate the need for two operating room in the third operating year of the project based on the Operating Room Need Methodology in the 2021 SMFP. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

-C- **Novant Health Leland ASC.** This proposal would develop a new ASC with two operating rooms. The applicant projects sufficient surgical cases and hours to demonstrate the need for two operating room in the third operating year of the project based on the Operating Room Need Methodology in the 2021 SMFP. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

*(b) The applicant shall document the assumptions and provide data supporting the methodology used for each projection in this Rule.*

-C- **McLeod Health Brunswick ASC.** In Section Q, Form C, pages 1-8, the applicant provides the assumptions and methodology used in the development of the projections required by this Rule. The discussion regarding analysis of need, including projected utilization, found in Criterion (3) is incorporated herein by reference.

-C- **Novant Health Leland ASC.** In Section Q, pages 117-133, the applicant provides the assumptions and methodology used in the development of the projections required by this Rule. The discussion regarding analysis of need, including projected utilization, found in Criterion (3) is incorporated herein by reference.



## COMPARATIVE ANALYSIS

Pursuant to G.S. 131E-183(a)(1) and the 2021 SMFP, no more than two operating rooms may be approved for Brunswick County in this review. Because the two applications in this review collectively propose to develop four additional operating rooms, both applications cannot be approved. Therefore, after considering all the information in each application and reviewing each application individually against all applicable statutory and regulatory review criteria, the Project Analyst conducted a comparative analysis of the proposals to decide which proposals should be approved.

Below is a brief description of each project included in this review.

- Project ID# O-12148-21/**McLeod Health Brunswick ASC**/ develop an ASC, with two operating rooms and two procedure rooms
- Project ID# O-12153-21/**Novant Health Leland ASC**/ develop an ASC, with two operating rooms and two procedure rooms

As the above description of each proposed project indicates, two applications are proposing new multispecialty ambulatory surgery facilities (ASF) with two operating rooms and two procedure rooms. **McLeod Health Brunswick ASC** is projected to perform 1,862 surgeries in Project Year 3 (PY3) and **Novant Health Leland ASC** projected to perform 2,737 surgeries in Project Year 3 (PY3). Both applicants propose new multi-specialty ASFs and both applications propose to develop two ORs each in two separate areas in Brunswick County, providing similar services.

### Conformity with Statutory and Regulatory Review Criteria

An application that is not conforming or conforming as conditioned with all applicable statutory and regulatory review criteria cannot be approved. Both applications are conforming to all applicable statutory and regulatory review criteria. Therefore, regarding this comparative factor, both applications are equally effective alternatives.

### Scope of Services

The following table shows each applicant's projected scope of services (surgical specialties) to be provided at the proposed facilities. As defined in *G.S. 131E-176 (15A)*, a multispecialty provides surgical procedures for at least three of the following specialty areas: Gynecology, Otolaryngology, Plastic Surgery, General Surgery, Ophthalmology, Orthopedic, or Oral Surgery. Generally, the application proposing to provide the greatest scope of services is the more effective alternative with regard to this comparative factor.

<b>Surgical Specialty</b>	<b>McLeod Health Brunswick ASC</b>	<b>Novant Health Leland ASC</b>
Bariatric		
Breast		
Cardiothoracic		
Cardiovascular		
Colorectal		
Gastroenterology		
General Surgery	X	X
Gynecology	X	X
Neurosurgery		
Obstetrics		
Open Heart Surgery		
Ophthalmology		X
Oral/Dental Surgery		X
Orthopedic	X	X
Otolaryngology		X
Pain Management		
Pediatrics		
Plastic Surgery		X
Podiatry		
Pulmonary		
Spine		
Thoracic		
Urology	X	
Vascular	X	

Source: McLeod Health Brunswick, page 19 and pages 67-69 of the application; Novant Health Brunswick ASC, Sections C and Q of the Application.

Therefore, the application submitted by **Novant Health Leland ASC** is more effective with respect to this comparative factor.

**Geographic Accessibility (Location within the Service Area)**

The following table identifies the existing and approved inpatient (IP), outpatient (OP), and shared ORs located in Brunswick County, and the inpatient and outpatient case volumes for each provider, from Table 6A, page 56, and Table 6B, page 68, of the 2021 SMFP.

	Location	Brunswick County	IP ORs	OP ORs	Shared ORs	Excluded C-Section, Trauma, Burn ORs	CON Adjustments	IP Surgery Cases	OP Surgery Cases
North-Eastern	Leland	Brunswick Surgery Center	0	0	0	0	1	0	0
South-Eastern	Southport (Eastern most part of the county)	J. Arthur Doshier Memorial Hospital	0	0	2	0	0	219	2,206
Central	Bolivia	Novant Health Brunswick Center	1	0	4	-1	0	954	3,794
<b>Total</b>			<b>1</b>	<b>0</b>	<b>6</b>	<b>-1</b>	<b>1</b>	<b>1,173</b>	<b>6,000</b>

Source: 2021 SMFP

**Novant Health Leland ASC** proposes to develop an ASF with two operating rooms in Leland, in northeastern part of the county. **McLeod Health Brunswick ASC** proposes to develop an ASF with two operating rooms in Sunset Beach, in the southwestern part of the county. Both applicants are proposing to develop the first multi-specialty ASC in Brunswick County. The existing ASF with one operating room is located at Brunswick Surgery Center in Leland, which according to the most recent License Renewal Application, is designated for orthopedics only. According to data from NCOSBM, as of July 1, 2020, the population in Leland was 23,049 and 4,201 in Sunset Beach. The application submitted by **McLeod Health Brunswick ASC** would expand geographical access to a larger population in Brunswick County. Therefore, with regard to expanding geographic access to surgical services, **McLeod Health Brunswick ASC** is the more effective alternative.

**Access by Service Area Residents**

On page 49, the 2021 SMFP defines the service area for operating rooms as *the single or multicounty grouping as shown in in Figure 6.1*. In Figure 6.1, page 55 of the 2021 SMFP, Brunswick County is shown as a single-county operating room service area. Thus, the service area for this facility consists of Brunswick County. Facilities may also serve residents of counties not included in their service area.

The following table illustrates access by service area residents during the third full fiscal year following project completion.

Applicant	Total Population to be Served	Brunswick County Residents to be served	Brunswick County Residents Served as a % of Total Patients
<b>McLeod Health Brunswick ASC</b>	1,862	1,693	90.9%
<b>Novant Health Leland ASC</b>	2,737	2,508	91.6%

As shown in the table above, **Novant Health Leland ASC** projects to serve 91.6 percent of the service area residents during the third full fiscal year following project completion, for a total of 2,508 Brunswick County residents. Therefore, regarding access to projected services to residents of the service area, the application submitted by **Novant Health Leland ASC** is more effective regarding percent of Brunswick County residents served and the number of Brunswick County residents; therefore, **Novant Health Leland ASC** is the more effective alternative regarding access to service area residents.

**Access by Underserved Groups**

Underserved groups are defined in G.S. 131E-183(a)(13) as follows:

*“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 access by underserved groups, applications are compared with respect to three underserved groups: charity care patients (i.e., medically indigent or low-income persons), Medicare patients and Medicaid patients. Access by each group is treated as a separate factor.

***Projected Charity Care***

Both applications propose to develop a new ASC with two operating rooms. The following table shows each applicant’s projected charity care to be provided in the project’s third full operating year. Generally, the application proposing to provide the most charity care is the more effective alternative with regard to this comparative factor.

<b>Charity Care Patients - Project Year 3</b>					
<b>Applicant</b>	<b>Projected Total Charity Care</b>	<b>of Total Net Revenue</b>	<b>Percent of Total Net Surgical Revenue</b>	<b>Surgical Cases</b>	<b>Charity Care per Surgical Case</b>
<b>McLeod Health Brunswick ASC</b>	\$228,340	\$5,536,461	4.1%	1,862	\$223
<b>Novant Health Leland ASC</b>	\$903,013	\$6,853,998	13.2%	2,737	\$330

As shown in the table above, **Novant Health Leland ASC** projects the most charity care in dollars, the highest charity care as a percent of net revenue and the highest charity care per surgical case. Therefore, the application submitted by **Novant Health Leland ASC** is the most effective alternative with regard to access to charity care.

***Projected Medicare***

Both applications propose to develop a new ASC with two operating rooms. The following table shows each applicant’s percentage of gross revenue (charges) projected to be provided to Medicare patients in the applicant’s third full year of operation following completion of their projects, based on the information provided in the applicant’s pro forma financial statements in Section Q. Generally, the application

proposing to provide a higher percentage to services to Medicare patients is the more effective alternative with regard to this comparative factor.

<b>Medicare Patients - Project Year 3</b>					
<b>Applicant</b>	<b>Medicare Gross Revenue</b>	<b>Total Gross Revenue</b>	<b>Medicare % of Total Gross Revenue</b>	<b>Surgical Cases</b>	<b>Medicare per Surgical Case</b>
<b>McLeod Health Brunswick ASC</b>	\$7,639,931	\$12,618,763	60.5%	1,862	\$4,103
<b>Novant Health Leland ASC</b>	\$14,702,244	\$26,381,293	55.7%	2,737	\$5,372

As shown in the table above, **McLeod Health Brunswick ASC** projects 60.5 percent of its surgical services will be provided to Medicare patients. The application submitted by **McLeod Health Brunswick ASC** is the most effective application with regard to serving Medicare patients.

***Projected Medicaid***

Both applications propose to develop a new ASC with two operating rooms. The following table shows each applicant’s percentage of gross revenue (charges) projected to be provided to Medicaid patients in the applicant’s third full year of operation following completion of their projects, based on the information provided in the applicant’s pro forma financial statements in Section Q. Generally, the application proposing to provide a higher percentage of services to Medicaid patients is the more effective alternative with regard to this comparative factor.

<b>Medicaid Patients - Project Year 3</b>					
<b>Applicant</b>	<b>Medicaid Gross Revenue</b>	<b>Total Gross Revenue</b>	<b>Medicaid % of Total Gross Revenue</b>	<b>Surgical Cases</b>	<b>Medicaid per Surgical Case</b>
<b>McLeod Health Brunswick ASC</b>	\$669,567	\$12,618,763	5.3%	1,862	\$360
<b>Novant Health Leland ASC</b>	\$1,961,806	\$26,381,293	7.4%	2,737	\$717

As shown in the table above, **McLeod Health Brunswick ASC** projects 5.3 percent of its surgical services will be provided to Medicaid patients which equals \$360 Medicaid per case. **Novant Health Leland ASC** projects 7.4 percent of its surgical services will be provided to Medicaid patients equaling \$717 per case. The application submitted by **Novant Health Leland ASC** is the most effective application with regard to serving Medicaid recipients.

**Projected Average Net Revenue per Case**

Both applications propose to develop a new ASC with two operating rooms. The following table shows the projected average net surgical revenue per OR and per surgical case in the third year of operation for each of the applicants, based on the information provided in the applicants’ pro forma financial statements. Generally, regarding this factor, the application proposing the lowest average net revenue per patient day, surgical case or procedure is the more effective alternative since a lower average may indicate a lower cost to the patient or third-party payer.

<b>Net Revenue per Surgical Case - Project Year 3</b>			
	<b>Net Revenue</b>	<b># of Surgical Cases</b>	<b>Net Revenue per Surgical Case</b>
<b>McLeod Health Brunswick ASC</b>	\$5,536,461	1,862	\$2,973
<b>Novant Health Leland ASC</b>	\$6,853,998	2,737	\$2,504

As shown in the table above, **Novant Health Leland ASC** projects the lowest net revenue per surgical case in the third operating year. Therefore, the application submitted by **Novant Health Leland ASC** is the most effective application with respect to net revenue per surgical case.

**Projected Average Operating Expense per Case**

Both applications propose to develop a new ASC with two operating rooms. The following table compares the projected average operating expense per surgical case in the third year of operation for each of the applicants, based on the information provided in the applicants’ pro forma financial statements (Form F.2). Generally, the application proposing the lowest average operating expense per surgical case is the more effective alternative with regard to this comparative factor since a lower average may indicate a lower cost to the patient or third-party payor or a more cost-effective service.

<b>Operating Expense per Surgical Case - Project Year 3</b>			
	<b>Operating Expense</b>	<b># of Surgical Cases</b>	<b>Operating Expense per Surgical Case</b>
<b>McLeod Health Brunswick ASC</b>	\$4,897,727	1,862	\$2,630
<b>Novant Health Leland ASC</b>	\$6,249,036	2,737	\$2,283

As shown in the table above, **Novant Health Leland ASC** projects the lowest average operating expense per surgical case in the third operating year. Therefore, the application submitted by **Novant Health Leland ASC** is the most effective application with respect to operating expense per surgical case.

**Summary**

The following table lists the comparative factors and indicates whether each application was more effective, less effective or equally effective for each factor. The comparative factors are listed in the same order they are discussed in the Comparative Analysis which should not be construed to indicate an order of importance.

Comparative Factor	McLeod Health Brunswick ASC	Novant Health Leland ASC
Conformity with Statutory and Regulatory Review Criteria	Yes	Yes
Scope of Services	Less Effective	<b>More Effective</b>
Geographic Accessibility (Location within the Service Area)	<b>More Effective</b>	Less Effective
Access by Service Area Residents	Less Effective	<b>More Effective</b>
Charity Care as a Percent of Net Revenue	Less Effective	<b>More Effective</b>
Medicare as a Percent of Gross Revenue	<b>More Effective</b>	Less Effective
Medicaid as a Percent of Gross Revenue	Less Effective	<b>More Effective</b>
Projected Average Net Revenue per Case	Less Effective	<b>More Effective</b>
Projected Average Operating Expense per Case	Less Effective	<b>More Effective</b>

Both applications are conforming to all applicable statutory and regulatory review criteria, and thus all applications are approvable standing alone. However, collectively they propose a total of four operating rooms, but the need determination is for only two operating rooms. Therefore, only two operating rooms can be approved.

As shown in the table above, **McLeod Health Brunswick ASC** was determined to be the most or more effective alternative for the following two factors:

- Geographic Accessibility
- Medicare as a Percent of Gross Revenue

As shown in the table above, **Novant Health Leland ASC** was determined to be the most or more effective alternative for the following six factors:

- Scope of Services
- Access by Service Area Residents
- Charity Care as a Percent of Net Revenue
- Medicaid as a Percent of Gross Revenue
- Average Net Revenue per Case
- Average Operating Expense per Case

### DECISION

Each application is individually conforming to the need determination in the 2021 SMFP for two additional operating rooms in Brunswick County as well as individually conforming to all review criteria. However, G.S. 131E-183(a)(1) states that the need determination in the SMFP is the

determinative limit on the number of operating rooms that can be approved by the Healthcare Planning and Certificate of Need Section.

Based upon the independent review of each application and the Comparative Analysis, the following application is approved:

- Project ID# O-12153-21/**Novant Health Leland ASC**/ develop an ASC, with two operating rooms and two procedure rooms

And the following application is denied:

- Project ID# O-12148-21/**McLeod Health Brunswick ASC**/ develop an ASC, with two operating rooms and two procedure rooms

**Novant Health Leland** is approved subject to the following conditions:

1. **Novant Health Brunswick Surgery Center and Novant Health, Inc. (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**
2. **The certificate holder shall develop a new ambulatory surgery center with no more than two operating rooms and two procedure rooms pursuant to the need determination in the 2021 SMFP.**
3. **Upon completion of the project, Novant Health Leland shall be licensed for no more than two operating rooms and two procedure rooms.**

**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 fourth month. The first progress report shall be due on April 3, 2023. The second progress report shall be due on August 1, 2023 and so forth.**
5. **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.**



6. **The certificate holder shall receive accreditation from the Joint Commission for the Accreditation of Healthcare Organizations, the Accreditation Association for Ambulatory Health Care or a comparable accreditation authority within two years following licensure of the facility.**
7. **For the first three years of operation following completion of the project, the certificate holder shall not increase charges more than 5% of the charges projected in Section Q of the application without first obtaining a determination from the Healthcare Planning and Certificate of Need Section that the proposed increase is in material compliance with the representations in the certificate of need application shall not acquire as part of this project any equipment that is not included in the project's proposed capital expenditures in Section Q of the application and that would otherwise require a certificate of need.**
8. **The procedure rooms shall not be used for procedures that should be performed only in an operating room based on current standards of practice.**
9. **Procedures performed in the procedure rooms shall not be reported for billing purposes as having been performed in an operating room and shall not be reported on the facility's license renewal application as procedures performed in an operating room.**
10. **No later than three months after the last day of each of the first three full fiscal years of operation following initiation of the services authorized by this certificate of need, the certificate holder shall submit, on the form provided by the Healthcare Planning and Certificate of Need Section, an annual report containing the:**
  - a. **Payor mix for the services authorized in this certificate of need.**
  - b. **Utilization of the services authorized in this certificate of need.**
  - c. **Revenues and operating costs for the services authorized in this certificate of need.**
  - d. **Average gross revenue per unit of service.**
  - e. **Average net revenue per unit of service.**
  - f. **Average operating cost per unit of service.**
11. **The certificate holder shall 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.**
12. **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.**