

**COMPETITIVE COMMENTS ON  
2021 BRUNSWICK COUNTY OPERATING ROOM NEED DETERMINATION**

**SUBMITTED BY:  
NOVANT HEALTH LELAND ASC PROJECT ID# O-012153-21**

**DECEMBER 1, 2021**

**OVERVIEW**

Two applicants submitted CON applications in response to the need identified in the 2021 SMFP for two (2) additional ORs in Brunswick County: CON Project ID# O-012148-21 McLeod Health Brunswick ASC (MHBA) and CON Project ID# O-012153-21 Novant Health Leland ASC.

These comments are submitted by Novant Health in accordance with N.C. Gen. Stat. § 131E-185(a1)(1) to address the representations in the competing application, including a comparative analysis and a discussion of the most significant issues regarding the applicant's conformity with the statutory and regulatory review criteria ("the Criteria") in N.C. Gen. Stat. §131E-183(a) and (b). Other non-conformities in the competing MHBA application may exist and Novant Health reserves the right to develop additional opinions, as appropriate upon further review and analysis.

**COMPARATIVE ANALYSIS FOR OPERATING ROOMS**

The Healthcare Planning and Certificate of Need Section developed a list of suggested comparative factors for competitive batch reviews. The following factors are suggested for all reviews regardless of type of services or equipment proposed:

- Conformity with Statutory and Regulatory Review Criteria
- Scope of Services
- Historical Utilization
- Geographic Accessibility (Location within the Service Area)
- Access by Service Area Residents
- Access by Underserved Groups: Charity Care
- Access by Underserved Groups: Medicaid
- Access by Underserved Groups: Medicare
- Competition (Access to a New or Alternate Provider)
- Projected Average Net Revenue per Case
- Projected Average Total Operating Cost per Case
- Patient Access to Lower Cost Surgical Services

The following additional factors are suggested for operating room proposals.

- Patient Access to Lower Cost Surgical Services
- Multispecialty versus Specialty (ASFs only, thus not applicable to this review)

The following summarizes the competing application relative to the suggested applicable comparative factors.

**Conformity to CON Review Criteria**

Two CON applications have been submitted seeking to develop ORs in Brunswick County. The applicants collectively propose to develop four additional ORs in Brunswick County. Based on the 2021 SMFP’s need determination, only two ORs can be approved. Only applicants demonstrating conformity with all applicable Criteria can be approved, and only the application submitted by Novant Health demonstrates conformity to all Criteria:

**Conformity of Applicants**

<b>Applicant</b>	<b>Project I.D.</b>	<b>Conforming/ Non-Conforming</b>
<b>McLeod Health Brunswick ASC</b>	<b>O-012148-21</b>	<b>No</b>
<b>Novant Health Leland ASC</b>	<b>O-012153-21</b>	<b>Yes</b>

The Novant Health Leland ASC application is based on reasonable and supported volume projections and adequate projections of cost and revenues. As discussed below, the MHBA application contains errors and flaws which result in one or more non-conformities with statutory and regulatory review Criteria. Therefore, the Novant Health Leland ASC application is the most effective alternative with respect to conformity.

**Scope of Services**

The following table shows each applicant’s projected scope of services (surgical specialties) to be provided at the proposed facilities. Generally, the application proposing to provide the greatest scope of services is the more effective alternative regarding this comparative factor.

<b>Facility Type</b>	<b>ASC</b>	<b>ASC</b>
<b>Surgical Specialty</b>	<b>Novant Health Leland ASC</b>	<b>McLeod Health Brunswick ASC</b>
Cardiothoracic		
Cardiovascular		
Gastroenterology		
General Surgery	X	X
Gynecology	X	X
Obstetrics		
Open Heart Surgery		
Ophthalmology	X	
Oral Surgery	X	
Orthopedic	X	X
Otolaryngology	X	
Neurology/Spine		
Pain Management		
Pediatrics		
Plastic Surgery	X	
Podiatry		
Pulmonary		
Thoracic		
Urology		
Vascular		
<b>Total Specialties</b>	<b>7</b>	<b>3</b>

Source: CON Applications, Section A.4.c

Regarding this factor, generally speaking the Agency has previously considered the application proposing to provide the greatest scope of services is the more effective alternative regarding this comparative factor. Novant Health Leland ASC will offer seven surgical specialties, which is greater compared to McLeod Health Brunswick ASC. Therefore, the **Novant Health Leland ASC** proposal is the most effective alternative for this comparative.

**Geographic Accessibility**

Not including dedicated C-Section ORs, there are seven existing and approved ORs in Brunswick County, as shown in the table below.

Facility	IP ORs	OP ORs	Shared ORs	Excluded C-Section	CON Adjustments	Total ORs*
Novant Health Brunswick Medical Center	1		4	-1		4
J. Arthur Doshier Memorial Hospital			2			2
Brunswick Surgery Center		1				1
<b>Brunswick County Total</b>	<b>1</b>	<b>1</b>	<b>6</b>	<b>-1</b>	<b>0</b>	<b>7</b>

\*Excluding dedicated C-Section ORs

The following table illustrates where the existing, approved, and proposed ORs are located within Brunswick County.

Facility	Type	Total ORs*	Address	City	Location
Novant Health Brunswick Medical Center	Existing Hospital	4	240 Hospital Dr	Bolivia	Central Brunswick County
J. Arthur Doshier Memorial Hospital	Existing Hospital	2	924 N Howe St	Southport	Southeastern Brunswick County
Brunswick Surgery Center	Existing ASF	1	1168 East Cutlar Crossing	Leland	Northeastern Brunswick County
Novant Health Leland ASC	Proposed ASF	2	9151 Ocean Highway East	Leland	Northeastern Brunswick County
McLeod Health Brunswick ASC	Proposed ASF	2	Parcel ID #s 2110004103 and 2110004105	Sunset Beach	Southwestern Brunswick County

\*Excluding dedicated C-Section ORs

While there is an existing ASC located in Leland (Brunswick Surgery Center), the facility is limited to one operating room and orthopaedic surgery only. Therefore, local access to ambulatory surgical services remains extremely limited. The following table summarizes 2020 population for the municipalities in Brunswick County.

<b>County</b>	<b>Area Name</b>	<b>April 1, 2020 Census Count</b>	<b>July 1, 2020 Certified Population Estimate</b>
<b>Brunswick</b>	<b>Leland</b>	<b>22,908</b>	<b>23,049</b>
Brunswick	Oak Island	8,396	8,448
Brunswick	St. James	6,529	6,569
Brunswick	Boiling Spring Lakes	5,943	5,980
Brunswick	Carolina Shores	4,588	4,616
Brunswick	Shalotte	4,185	4,210
Brunswick	Sunset Beach	4,175	4,201
Brunswick	Southport	3,971	4,059
Brunswick	Belville	2,406	2,421
Brunswick	Calabash	2,011	2,023
Brunswick	Navassa	1,367	1,375
Brunswick	Holden Beach	921	927
Brunswick	Ocean Isle Beach	867	872
Brunswick	Northwest	703	707
Brunswick	Varnamtown	525	528
Brunswick	Caswell Beach	395	397
Brunswick	Bald Head Island	268	270
Brunswick	Sandy Creek	248	250
Brunswick	Bolivia	149	150
Brunswick	Balance of Brunswick County	66,138	66,478

Source: North Carolina Office of State Budget and Management

Novant Health proposes to develop two ORs in a new ASC to be developed in Leland, which is the largest municipality in Brunswick County. McLeod proposes to develop two ORs in Sunset Beach, a vacation destination, which has a population of only 4,201. The following table compares the extent to which the competing proposals enhance geographic access in Brunswick County.

<b>Area</b>	<b>July 1, 2020 Certified Population Estimate</b>	<b># of ORs (Existing &amp; Proposed)</b>	<b>Avg Population Per OR</b>
Leland	23,049	3	<b>7,683</b>
Sunset Beach	4,201	2	<b>2,101</b>

Source: North Carolina Office of State Budget and Management, 2021 SMFP

Based on the Brunswick County population estimates as of July 1, 2020, the ratio of population per OR in Leland is 7,683 as opposed to only 2,101 in Sunset Beach. Based on this analysis, the geographic location of the need determined ORs in Leland is a better option enhancing geographic access to surgical services. Thus, with respect to geographic accessibility, the **Novant Health Leland ASC** proposal is the most effective alternative.

**Patient Access to Lower Cost Surgical Services**

ORs can be licensed as part of a hospital or an ASF. Many outpatient surgical services can be appropriately performed in either a hospital-based OR (either shared inpatient/outpatient ORs or dedicated ambulatory surgery ORs) or in an OR located at an ASF. However, the cost for that same service can be higher if performed in a hospital-based OR or, conversely, less expensive if performed in an OR located at an ASF.

Both applications in the Brunswick County OR review propose to develop ORs in freestanding ASFs. Therefore, the applications submitted by Novant Health Leland ASC and McLeod Health Brunswick ASC are equally effective alternatives regarding this factor. However, the McLeod Health Brunswick ASC proposal is not approvable.

**Historical Utilization**

Generally, the application submitted by the applicant with the highest utilization of its available surgical services is the more effective alternative with regard to this comparative factor.

The table below shows Brunswick County OR utilization based on FY2019 surgical hours as reported in Table 6A of the 2021 SMFP.

Provider	IP Cases	OP Cases	FY2019 Adjusted Surgical Hours	Standard Hours per OR per Year	ORs Req. Based on Surgical Hours	Adjusted Planning Inventory	FY19 OR Deficit/Surplus
Novant Health Brunswick Medical Center	954	3,794	7,906	1,500	5.3	4	1.27
J. Arthur Doshier Memorial Hospital	219	2,206	3,001	1,500	2.0	2	0.00
Brunswick Surgery Center		0	0	1,312	0.0	1	-1.00

Source: 2021 SMFP, Table 6B

Novant Health has the highest surgical utilization in Brunswick County and exhibits the greatest need for additional OR capacity. McLeod has no experience providing surgical services in Brunswick County or North Carolina. According to Section Q, page 1 of Project ID# O-12148-21, McLeod Health and Wilmington Health physicians performed only 1,550 outpatient surgery cases to Brunswick County residents during CY2021 (based on annualized data during January-July 2021). Therefore, with regard to historical utilization, the **Novant Health Leland ASC** application is the most effective alternative for this comparative factor.

**Competition (Patient Access to a New or Alternative Provider)**

Generally, the application proposing to increase patient access to a new provider in the service area is the more effective alternative with regard to this comparative factor.

Novant Health acknowledges its status as an existing provider of surgical services in Brunswick County. As described later in this document, McLeod Health Brunswick ASC is not approvable and therefore cannot be an effective alternative. Additionally, with a limited range of surgical services, McLeod Health Brunswick ASC does not offer meaningful choice and competition for residents of the service area.

**Access by Service Area Residents**

On page 50, the 2021 SMFP defines the service area for ORs as “...the service area in which the room is located. The operating room service areas are the single or multicounty groupings as shown in Figure 6.1.” Figure 6.1, on page 55, shows Brunswick County as a single county OR service area. Thus, the service area for this facility is Brunswick County. Facilities may also serve residents of counties not included in their service area.

Generally, the application projecting to serve the highest percentage of Brunswick County residents is the more effective alternative with regard to this comparative factor since the need determination is for 2 additional ORs to be located in Brunswick County.

<b>Access by Service Area Residents</b>	<b>Novant Health Leland ASC</b>	<b>McLeod Health Brunswick ASC</b>
# of Brunswick County Patients	<b>2,508</b>	1,693
% of Brunswick County Patients	<b>92%</b>	90%

Source: CON applications, Section C.3.b.

Novant Health Leland ASC proposes to serve the greatest number and percentage of Brunswick County patients during the third project year. Therefore, the **Novant Health Leland ASC** application is the most effective alternative for this comparative.

**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 handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority.”*

For 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.

The Agency may use one or more of the following metrics to compare the applications:

- Total charity care, Medicare or Medicaid patients
- Charity care, Medicare or Medicaid admissions as a percentage of total patients
- Total charity care, Medicare or Medicaid dollars
- Charity care, Medicare or Medicaid dollars as a percentage of total gross or net revenues
- Charity care, Medicare or Medicaid cases per OR

Which of the above metrics the Agency uses is determined by whether or not the applications included in the review provide data that can be compared as presented above and whether or not such a comparison would be of value in evaluating the alternative factors.

*Projected Charity Care*

The following table compares projected charity care in the third full fiscal year following project completion for the applicants.

**Projected Charity Care – 3rd Full FY**

Applicant	Form F.2b	Form C.1b	Avg Charity Care per Case	Form F.2b	% of Gross Revenue
	Total Charity Care	Surgical Cases		Gross Revenue	
Novant	\$903,013	2,737	\$330	\$26,381,293	3.4%
McLeod	\$228,340	1,862	\$123	\$12,618,763	1.8%

Sources: Forms C and F.2 for each applicant

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



*Projected Medicare*

The following table compares projected access by Medicare patients in the third full fiscal year following project completion for all the applicants in the review.

**Projected Medicare Revenue – 3rd Full FY**

Applicant	Form F.2b	Form C.1b	Avg Medicare Rev. per Case	Form F.2b	% of Gross Revenue
	Total Medicare Revenue	Surgical Cases		Gross Revenue	
Novant	<b>\$14,702,244</b>	2,737	<b>\$5,372</b>	\$26,381,293	55.7%
McLeod	\$7,639,931	1,862	\$4,103	\$12,618,763	60.5%

Sources: Forms C and F.2 for each applicant

As shown in the previous table, **Novant Health Leland ASC** projects the highest total Medicare revenue in dollars and the highest Medicare revenue per surgical case, and McLeod Health Brunswick ASC projects the highest Medicare revenue as a percentage of gross surgical revenue during each project’s third full fiscal year following project completion. Therefore, the application submitted by **Novant Health Leland ASC** is the more effective alternative with respect to service to Medicare surgical patients.

*Projected Medicaid*

The following table compares projected access by Medicaid patients in the third full fiscal year following project completion for all the applicants in the review.

**Projected Medicaid Revenue – 3rd Full FY**

Applicant	Form F.2b	Form C.1b	Avg Medicaid Rev. per Case	Form F.2b	% of Gross Revenue
	Total Medicaid Revenue	Surgical Cases		Gross Revenue	
Novant	<b>\$1,961,806</b>	2,737	<b>\$717</b>	\$26,381,293	<b>7.4%</b>
McLeod	\$669,567	1,862	\$360	\$219,738,783	0.3%

Sources: Forms C and F.2 for each applicant

As shown in the previous table, **Novant Health Leland ASC** projects the highest total Medicaid revenue in dollars, the highest Medicaid revenue per surgical case, and the highest Medicaid revenue as a percentage of gross surgical revenue during each project’s third full fiscal year following project completion. Therefore, the application submitted by **Novant Health Leland ASC** is the more effective alternative with respect to service to Medicaid surgical patients.

**Projected Average Net Revenue per Surgical Case**

The following table shows the projected average net surgical revenue 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 (Section Q). Generally, the application proposing the lowest average net revenue is the more effective alternative regarding this comparative factor since a lower average may indicate a lower cost to the patient or third-party payor.

**Projected Average Net Revenue per Patient – 3rd Full FY**

Applicant	Form C.1b	Form F.2b	Average Net Revenue per Case
	Surgical Cases	Net Revenue	
Novant	2,737	\$6,853,998	<b>\$2,504</b>
McLeod	1,862	\$5,536,461	\$2,973

Sources: Forms C and F.2 for each applicant

As shown in the previous table, **Novant Health Leland ASC** projects the lowest net revenue per surgical case in the third full fiscal year following project completion. Therefore, the application submitted by **Novant Health Leland ASC** is the most effective alternative with respect to net revenue per surgical case.

**Projected Average Operating Expense per Case**

The following table shows the projected average operating expense per patient in the third full fiscal year following project completion for each facility. Generally, the application projecting the lowest average operating expense per patient is the more effective alternative with regard to this comparative factor to the extent it reflects a more cost-effective service which could also result in lower costs to the patient or third-party payor.

**Projected Average Operating Expense per Patient – 3rd Full FY**

Applicant	Form C.1b	Form F.2b	Average Operating Expense per Case
	Case	Operating Expense	
Novant	2,737	\$6,853,998	<b>\$2,504</b>
McLeod	1,862	\$4,897,727	\$2,630

Sources: Forms C and F.2 for each applicant

As shown in the previous table, **Novant Health Leland ASC** projects the lowest operating expense per surgical case in the third full fiscal year following project completion. Therefore, the application submitted by **Novant Health Leland ASC** is the most effective alternative with respect to operating expense per surgical case.

**Summary**

The following table lists the comparative factors and states which application is the more effective alternative.

<b>Comparative Factor</b>	<b>Novant Health Leland ASC</b>	<b>McLeod Health Brunswick ASC</b>
Conformity with Review Criteria	Yes	No
Scope of Services	<b>Most Effective</b>	Least Effective
Geographic Accessibility	<b>Most Effective</b>	Least Effective
Access to Lower Cost Surgical Services	Equally Effective	Equally Effective but not approvable
Historical Utilization	<b>Most Effective</b>	Least Effective
Enhance Competition	Less Effective	More Effective but not approvable
Access by Service Area Residents	<b>Most Effective</b>	Least Effective
Access by Underserved Groups		
Projected Charity Care	<b>Most Effective</b>	Least Effective
Projected Medicare	<b>Most Effective</b>	Least Effective
Projected Medicaid	<b>Most Effective</b>	Least Effective
Projected Average Net Revenue per Case	<b>Most Effective</b>	Least Effective
Projected Average Operating Expense per Case	<b>Most Effective</b>	Least Effective

McLeod Health Brunswick ASC’s application fails to conform with all applicable statutory and regulatory review criteria; thus, it cannot be approved. Beyond the issue of McLeod’s non-conformity, the **Novant Health Leland ASC** application is comparatively superior for the following comparatives:

- Scope of Services
- Geographic Accessibility
- Historical Utilization
- Access by Service Area Residents
- Projected Access to Charity Care
- Projected Access for Medicare Surgical Patients
- Projected Access for Medicaid Surgical Patients
- Projected Average Net Revenue per Surgical Case
- Projected Average Operating Expense per Surgical Case

Thus, the application submitted by **Novant Health Leland ASC** is the most effective alternative in this competitive batch review for two additional ORs in Brunswick County.

**COMMENTS SPECIFIC TO MCCLEOD HEALTH BRUNSWICK ASC (MHBA)**  
**PROJECT ID No. O-012148-21**

Applicant 1 and Applicant 2 are misrepresented throughout the application. Section A.1 identifies Applicant 1 as McLeod Health Brunswick ASC and Applicant 2 as McLeod Loris Seacoast Hospital, Inc. Form F.1a identifies Applicant 1 as McLeod Loris Seacoast Hospital, Inc. and Applicant 2 as McLeod Brunswick, ASC.

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

**POLICY GEN-3: BASIC PRINCIPLES** 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.”*

MHBA fails to conform with Criterion (1) and Policy GEN-3 because the application is not conforming to all other applicable statutory and regulatory review criteria and thus, is not approvable. The applicant does not adequately demonstrate that the proposal is its least costly or most effective alternative to meet the need. See discussion regarding Criteria (3), (4), (5), (6), and (18a). Therefore, the application is not conforming to this criterion and cannot be approved.

**Criterion (3)** *“The applicant shall identify the population to be served by the proposed project and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.”*

MHBA failed to demonstrate that its projected surgical utilization is based on reasonable and supported assumptions.

Historical Outpatient Surgery Cases

MBHA’s assumptions and methodology for projecting OR utilization at its proposed ASC are premised upon historical utilization from CY2019-CY2021.

**Historical Brunswick County Outpatient Surgery Cases  
 Served by McLeod Health or Wilmington Health**

	<b>CY19</b>	<b>CY20</b>	<b>CY21*</b>	<b>CY19-CY21 CAGR</b>
OP Cases	1,263	1,290	1,550	10.8%

CY 2021 annualized used January to July data.

Source: MHBA CON Application, Form C Assumptions and Methodology, page 1

It is important to note that two of the three data years reflect surgical utilization that was impacted by the COVID-19 pandemic. MHBA’s decision to rely on CY2019-CY2021 data runs counter to the applicant’s discussion on application page 62 which states, “*McLeod Health Brunswick ASC has elected not to include in this application any FFY 2020 data or analysis of FFY 2020 data.*” MBHA acknowledges the suspension of elective procedures during 2020 that “*temporarily halted or impacted healthcare operations for many providers, including the future members of McLeod Health Brunswick ASC, McLeod Health and Wilmington Health.*” Furthermore, MBHA failed to describe the extent to which its CY2021 (Jan-July) utilization reflects recovery volume from those cases that were impacted by the suspension of elective procedures during 2020. Considering McLeod Health and Wilmington Health’s collective lack of growth from CY2019 to CY2020, it is probable that MBHA's CY2021 data is inflated because it reflects a portion of surgical cases that would have been performed during CY2020. This is problematic because MHBA relies on the compound annual growth rate (CAGR) of McLeod Health and Wilmington Health surgical cases during CY2019-CY2021. MHBA failed to provide any data for McLeod Health or Wilmington Health prior to CY2019; thus, it is impossible to verify the reasonableness of the CY2019-CY2021 CAGR.

The following table shows the number of outpatient surgeries performed on Brunswick County residents by a McLeod Health or Wilmington Health physician in an operating room for the surgical specialties that will be initially offered at MHBA, excluding GI endoscopy procedures.

**Historical Brunswick County Outpatient Surgery Cases  
 Served by McLeod Health or Wilmington Health –  
 Brunswick County Surgical Specialties\***

	<b>CY19</b>	<b>CY20</b>	<b>CY21*</b>	<b>CY19-CY21 CAGR</b>
OP Cases	966	1,058	1,286	15.4%

\*Excluding GI endoscopy cases

CY 2021 annualized used January to July data.

Source: MHBA CON Application, Form C Assumptions and Methodology, page 3

The following table shows the number of outpatient surgeries performed on Brunswick County residents by a McLeod Health or Wilmington Health physician in an operating room for the surgical specialties that will be initially offered at MHBA (excluding GI endoscopy procedures) excluding any surgical procedures that are not currently approved by the Centers for Medicaid and Medicare (CMS) for reimbursement at a freestanding facility.

**Historical Brunswick County Outpatient Surgery Cases  
 Served by McLeod Health or Wilmington Health –  
 Brunswick County Surgical Specialties\* and CMS Approved for an ASF**

	CY19	CY20	CY21*	CY19-CY21 CAGR
OP Cases	811	853	1,111	17.0%

\*Excluding GI endoscopy cases

CY 2021 annualized used January to July data.

Source: MHBA CON Application, Form C Assumptions and Methodology, page 3

MHBA’s data and assumptions suggest its CY2021 surgical case utilization indeed reflects recovery volume from cases that would have otherwise been performed during CY2020 but were delayed because of the temporary suspension of elective procedures during February-May 2020. As shown in the previous table, when compared to total Brunswick County outpatient surgery cases served by McLeod Health or Wilmington Health, the cohort of outpatient procedures approved by CMS for reimbursement at a freestanding facility has a comparatively higher CAGR. It is logical to presume the higher CAGR can be attributed to a comparatively larger proportion of elective cases that were postponed or rescheduled in CY2020 and recovered in CY2021 thereby inflating the CAGR. Again, this is problematic because MHBA relies on the CAGR of McLeod Health and Wilmington Health surgical cases during CY2019-CY2021. MHBA failed to provide any data for McLeod Health or Wilmington Health prior to CY2019; thus, it is impossible to verify the reasonableness of the CY2019-CY2021 CAGR as a proxy for projecting future surgical utilization.

Projected Growth Rate

MHBA assumed a growth rate equivalent to two-thirds of the 2019 to 2021 (annualized) annual growth rate of 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 initially offered at MHBA that are CMS-approved for reimbursement in an ASF. This assumption results in a CAGR of 11.3% (17.0% x 2/3 = 11.3%). There are several deficiencies with this assumption and resulting growth rate.

**First**, the CAGR is unreliable because it is premised upon data that may not be a reasonable proxy for projecting future surgical utilization. See previous discussion.

**Second**, the projected CAGR (11.3%) is higher compared to the total Brunswick County outpatient surgery cases served by McLeod Health or Wilmington Health during CY2019-CY2021 (10.8%). It is also higher compared to the FFY2017-FFY2019 CAGR for total Brunswick County outpatients served at North Carolina facilities (10.9%).<sup>1</sup>

**Third**, the CAGR reflects growth that occurred primarily during one year, i.e., CY2021, which is insufficient to project future volume. Please see the following table.

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<sup>1</sup>BHSC application page 65.

**Historical Brunswick County Outpatient Surgery Cases  
 Served by McLeod Health or Wilmington Health –  
 Brunswick County Surgical Specialties\* and CMS Approved for an ASF**

	CY19	CY20	CY21*
OP Cases	811	853	1,111
Annual Growth	--	5.2%	30.2%
Incremental Cases	--	42	258

\*Excluding GI endoscopy cases

CY 2021 annualized used January to July data.

Source: MHBA CON Application, Form C Assumptions and Methodology, page 3

Of the 300 incremental outpatient surgery cases from CY2019 to CY2021, only 42 incremental cases (14%) occurred during CY2020 and 258 incremental cases (or 86%) occurred in CY2021. MHBA failed to demonstrate it is reasonable to project surgical utilization will increase by 11.3% annually for each of the next six years when it has failed to demonstrate the ability of its prospective members to achieve similar growth during more than one year.

For these reasons, the projected growth rate of 11.3% is unreasonable and not supported.

Percentage of Outpatient Cases Served by MHBA

MBHA projects that it will serve 80% of the projected outpatient cases. MHBA states it believes the assumption is reasonable because MHBA has already excluded surgical specialties that will not be offered at the proposed ASF and procedures that are not CMS-approved for an ASF. However, MHBA failed to account for an additional cohort of patients that are not appropriate to be served in an ASF. Specifically, those patients with comorbidities that are identified by the American Society of Anesthesiologists (ASA) physical status. The ASA physical status is a global score that assesses the physical status of patients before surgery. The following summarizes the various ASA Physical Classification system scores:

- ASA I: Normal healthy patient
- ASA II: Patient with mild systemic disease
- ASA III: Patient with severe systemic disease
- ASA IV: Patient with severe systemic disease that is a constant threat to life
- ASA V: Moribund patient who is not expected to survive without the operation
- ASA VI: Declared brain-dead patient whose organs are being removed for donor purposes

Generally speaking, an ASC that employs the ASA classification system in its assessment of its patients may decide not to accept patients who are classified as ASA IV or higher. In the Novant Health Leland ASC application, Novant Health excluded all cases graded ASA IV and higher. Additionally, Novant Health

considered only 50 percent of cases graded ASA III to account for the potential cohort of patients whose severe systemic disease may require advanced anesthesia available in a hospital-based setting. MHBC failed to perform any analysis to determine what number or percentage of McLeod Health and Wilmington Health patients would be appropriately served in an ASF based on ASA physical status. Therefore, even with a capture rate of 80 percent, MHBC may be including a portion of outpatients that cannot be appropriately served at the proposed facility.

In summary, the MHBA methodology is fundamentally flawed on numerous levels. The projections are based on unstable historical utilization, the projected growth rate is artificially inflated, and the projected capture of future outpatient cases may include a portion of patients that cannot be appropriately served at the proposed facility.

For these reasons, MHBA's utilization projections are not reasonably or adequately supported. Therefore, the MHBA application does not conform to Criterion (3).

**Criterion (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."*

The MHBA application is not conforming to all other applicable statutory and regulatory review criteria and thus, is not approvable. An application that cannot be approved cannot be an effective alternative.

The applicant does not adequately demonstrate that the proposal is its least costly or most effective alternative to meet the need. Therefore, the application is not conforming to this criterion and cannot be approved. See discussion regarding Criteria (1), (3), (5), (6), and (18a).

**Criterion (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."*

Based on the facts described in these written comments specific to Criterion (3) (incorporated herein by reference), these same facts result in the MHBA application being non-conforming to Criterion (5).

BHSC is wholly owned by McLeod Loris Seacoast Hospital. BHSC application page 20 states McLeod Loris Seacoast Hospital will own the building with the ASF will be developed. BHSC application page 92 states, *"McLeod Health Brunswick ASC, LLC will be responsible for a portion of the capital costs, as will McLeod Loris Seacoast Hospital. Both entities will receive the funds for their portion from McLeod Health and have agreed to contribute the funds received to the proposed project."* It is unclear why the applicants limit BHSC's capital cost responsibility to include only medical equipment and contingency (\$5,090,448) and the remainder (\$15,888,881) to McLeod Loris Seacoast Hospital. The only apparent reason in the CON application was to exclude depreciation for construction costs (\$12,997,856) and architect fees (\$1,243,343) in Form F.3b. If the respective costs were depreciated over the life of the lease (10 years) it would result in an additional depreciation expense of over \$1 million.

Form F.3 failed to include any expense for Medical Director payments.



MHBC's operating room revenue projections (Form F.2b) include revenues for GI endoscopy procedures, which are not surgical procedures. Therefore, the MHBC's OR revenue projections are not an accurate reflection of projected surgery revenues.

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

MHBA did not adequately demonstrate that its proposal would not result in unnecessary duplication of surgical services in Brunswick County. Specifically, MHBA did not adequately demonstrate in its application that the new ORs it proposes to develop are needed, and that it will not unnecessarily duplicate the existing and approved ORs in Brunswick County. See discussion regarding projected utilization in Criterion (3). Therefore, the MHBA application is nonconforming to Review Criterion (6).

**Criterion (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."*

Based on the facts which result in MHBA being non-conforming with Criteria (1), (3), (5), (6), it should also be found non-conforming with Criterion (18a).

### **10A NCAC 14C .2103**

The MHBA application does not conform to 10A NCAC 14C .2103 because projected surgical utilization is not based on reasonable and adequately supported assumptions. See discussion regarding projected utilization in Criterion (3).

### **Conclusion**

G.S. 131E-183(a)(1) states that the need determination in the SMFP is the determinative limit on the number of ORs that can be approved by the Healthcare Planning and Certificate of Need Section. The applicants collectively propose to develop four additional ORs in Brunswick County. Based on the 2021 SMFP's need determination, only two ORs can be approved.

Novant Health Leland ASC is the only application fully conforming to all statutory and regulatory review criteria. Furthermore, Novant Health Leland ASC is comparatively superior to the MHBA proposal. Novant Health Leland ASC will:

- help meet the growing demand for ambulatory surgical services in Brunswick County,
- increase patient access to ambulatory surgical services in Brunswick County,

- enhance geographic access to ambulatory surgical services in Brunswick County; and
- improve patient satisfaction through expansion of surgical services in a convenient setting with non-HOPD charges.

Thus, the application submitted by Novant Health Leland ASC is the most effective alternative and should be approved as submitted.