McLeod Health

WILMINGTON HEALTH

Comments on
Novant Health Brunswick Surgery Center, LLC's and Novant Health, Inc.'s Operating Room Certificate of Need Application, Project ID # O-12153-21

December 1, 2021

Competitive Comments on Brunswick County
Operating Room Applications

submitted by

McLeod Health Brunswick ASC, LLC and
McLeod Loris Seacoast Hospital

In accordance with N.C. GEN. STAT. § 131E-185(a1)(1), McLeod Health Brunswick ASC, LLC and McLeod Loris Seacoast Hospital (collectively referred to herein as McLeod Health) hereby submit the following comments related to the application filed by Novant Health Brunswick Surgery Center, LLC and Novant Health, Inc. (collectively referred to herein as Novant Health) to develop a new ambulatory surgical facility (ASF) with two operating rooms and two procedure rooms to be located at a new health service facility, Novant Health Leland ASC, in Brunswick County. McLeod Health's comments include "*discussion and argument regarding whether, in light of the material contained in the application and other relevant factual material, the application complies with the relevant review criteria, plans and standards*." *See* N.C. GEN. STAT. § 131E-185(a1)(1)(c).[1] In order to facilitate the Agency's ease in reviewing these comments, McLeod Health has organized its discussion by issue, specifically noting the general Certificate of Need (CON) statutory review criteria and specific regulatory criteria and standards creating potential non-conformity relative to each issue, as they relate to Novant Health's application, Project ID # F-12153-21. The following comments include specific comments on Novant Health's application and a comparative analysis including McLeod Health's application to develop a new ASF with two operating rooms and two procedure rooms to be located at a new health service facility, McLeod Health Brunswick ASC, in Brunswick County, Project ID # O-12148-21. Based on the following comments, McLeod Health's application should be approved.

As detailed above, given the number of applications and the number of proposed additional operating rooms, both of the applications cannot be approved as proposed. The comments below include substantial issues that McLeod Health believes may render the Novant Health application non-conforming with applicable statutory and regulatory review criteria. However, as presented at the end of these comments, even if both of these applications were conforming, the application filed by McLeod Health is comparatively superior to the application filed by Novant Health and represents the most effective alternative for expanding access to surgical services in Brunswick County.

[1] McLeod Health is providing comments consistent with this statute; as such, none of the comments should be interpreted as an amendment to its application filed on October 15, 2021 (Project ID # O-12148-21).

NOVANT HEALTH, DEVELOP A NEW ASF WITH TWO OPERATING ROOMS AND TWO PROCEDURE ROOMS, PROJECT ID # O-12153-21

Issue-Specific Comments

1. The Novant Health Leland ASC application overstates operating room cases.

In order to project utilization of the two proposed operating rooms at Novant Health Leland ASC, as demonstrated in its Form C Assumptions and Methodology, Novant Health proposes to shift outpatient surgical cases from Novant Health Brunswick Medical Center (NHBMC) and New Hanover Regional Medical Center (NHNHRMC) to Novant Health Leland ASC. In calculating the shift of outpatient cases from NHBMC and NHNHRMC to the two proposed operating rooms at Novant Health Leland ASC, Novant Health includes outpatient surgical cases that have been historically performed in procedure rooms, while failing to demonstrate or even attempt to demonstrate why these cases cannot or should not be performed in procedure rooms. This results in overstated historical and projected utilization for the proposed operating rooms at Novant Health Leland ASC.

On page 35 of its application, excerpted below, Novant Health presents the NHBMC total outpatient surgical cases by combining operating room and procedure room surgical cases.

Novant Health Brunswick Medical Center
Ambulatory Surgical Cases, FY2017-FY2021*

	FY2017	FY2018	FY2019	FY2020	FY2021*
OP Surgical Cases Performed in NHBMC ORs	3,453	3,287	3,794	3,702	3,193
OP Surgical Cases Performed in NHBMC Procedure Room	37	16	16	731	627
NHBMC Total OP Surgical Cases	**3,490**	**3,303**	**3,810**	**4,433**	**3,820**

*Annualized based on eleven months data (Oct-Aug)
Source: NHBMC License Renewal Applications and Novant Health internal data

Source: Novant Health application, page 35.

The total outpatient surgical cases are included again in the table on page 118 of Novant Health's application, excerpted below.

Novant Health Coastal Market
Surgical Cases by Facility, FY2017-FY2021*

		FY2017	FY2018	FY2019	FY2020	FY2021*
NHBMC	IP Surgical Cases Performed in NHBMC ORs	1,002	897	954	1,045	1,081
	IP Surgical Cases Performed in NHBMC PR	-	-	-	-	4
	Total IP Surgical Cases	**1,002**	**897**	**954**	**1,045**	**1,085**
	OP Surgical Cases Performed in NHBMC ORs	3,453	3,287	3,794	3,702	3,193
	OP Surgical Cases Performed in NHBMC PR	37	16	16	731	627
	Total OP Surgical Cases	**3,490**	**3,303**	**3,810**	**4,433**	**3,820**
	Total NHBMC Surgical Cases	**4,492**	**4,200**	**4,764**	**5,478**	**4,914**

*Annualized based on 11 months data (Oct-Aug)
Source: License Renewal Applications, Novant Health internal data

Source: Novant Health application, page 118.

These combined cases are used to calculate outpatient growth rates (*see* the Novant Health application, page 122, excerpted below) and are used to project NHBMC outpatient cases for Fiscal Year (FY) 2022 to FY 2027 (*see* the Novant Health application, page 123).

Novant Health Brunswick Medical Center
Historical Surgical Cases, FY2017-FY2021

	FFY2017	FFY2018	FFY2019	FFY2020	FFY2021*	*FY17-FY20 CAGR*	*FY17-FY21 CAGR*	*FY18-FY20 CAGR*	*FY18-FY21 CAGR*
IP Cases	1,002	897	954	1,045	1,085	***1.4%***	*2.0%*	*7.9%*	6.8%
OP Cases	3,490	3,303	3,810	4,433	3,820	*8.3%*	***2.3%***	*15.8%*	5.0%
Total Cases	4,492	4,200	4,764	5,478	4,906	*6.8%*	*2.2%*	*14.2%*	5.4%

*Annualized based on 11 months data (Oct-Aug)
Source: License Renewal Applications, Novant Health internal data

Source: Novant Health application, page 122.

Novant Health ultimately takes the projected baseline of outpatient cases and shifts a contrived portion of them from NHBMC to Novant Health Leland ASC through several steps. Novant Health calculates the ASF-appropriate portion in Steps 4 and 5 of its Form C Assumptions and Methodology and allocates the procedures to specialties in Step 7 of its utilization methodology. These outpatient operating room and procedure room cases are then shifted to Novant Health Leland ASC by specialty in Step 8 resulting in 2,027 of the 4,375 cases in FY 2027 being shifted from NHBMC to Novant Health Leland ASC to project operating room need at the proposed ASF.

McLeod Heath might generally agree with the reasonableness of Novant Health's approach had Novant Health provided any discussion on the clinical or operational appropriateness for shifting

its procedure room cases from a procedure room to an operating room, which it does not. In fact, the Novant Health Leland ASC application argues strongly that these procedures can be appropriately performed in procedure rooms. For example, on page 34 of the Novant Health Leland ASC application it states,

> "[*a*]s *inpatient and outpatient demand for surgical services continues to increase in Brunswick County, NHBMC's four shared ORs have become increasingly constrained in recent years. Upon reviewing CMS reimbursement and hospital licensure standards, Novant Health determined that it could accommodate some additional surgical cases in the NHBMC procedure room, including shorter and lower acuity surgical cases. As shown in Section 9.f of NHBMC's 2021 License Renewal Application, pediatric dental, cataract, small orthopaedic, and general surgery cases have been performed in the NHBMC procedure room. The procedure room in NHBMC's surgical suite is built to accommodate this range of surgical cases safely. There is typically no difference in the charge for an outpatient surgical case performed in one of NHBMC's licensed ORs compared to the NHBMC procedure room located in the surgical suite. For outpatient surgical services in the hospital, Medicare reimbursement is established by the Hospital Outpatient Prospective Payment System (OPPS) fee schedule, which does not differentiate based on the site of service within the hospital facility. For these reasons, NHBMC has accommodated a small portion of its growing surgical volume in recent years in the hospital procedure room.*"

As excerpted above, the Novant Health provides discussion regarding the appropriateness of performing the procedures proposed to shift to Novant Health Leland ASC, including pediatric dental, cataract, small orthopaedics, and general surgery cases, in procedure rooms but does not provide any clinical or operational explanation for the proposed shift of these cases <u>back</u> from a procedure room to an operating room for purposes of this application. [<u>emphasis added</u>] The only rationale that Novant Health provides for this shift in the Novant Health Leland ASC application is from a cost-perspective, as it states on page 35 of its application,

> *"Novant Health believes it would benefit patients and payors from a cost perspective to have such surgical cases performed in an ASC rather than in a hospital setting. The proposed new ASC would increase access to cost-effective, dedicated-ambulatory surgical services for many patients whose surgical cases would otherwise be performed in NHBMC's procedure room, just as it would for those whose cases would be performed in NHBMC's operating rooms"*

However, as noted in the previous excerpt, the same cost advantages would apply for surgical cases performed in procedure rooms in as ASC, and therefore, no rationale is provided for performing these cases in an operating room.

In addition to including procedure room cases in its operating room volume, Novant Health inconsistently allocates these outpatient surgical cases between the operating rooms and procedure rooms. As shown in Step 12 of its Form C Assumptions and Methodology, Novant Health allocates 16.4 percent of the remaining NHBMC outpatient surgical cases to the procedure room for NHBMC. However, Novant Health allocates 100 percent of the outpatient surgical cases to the operating room for Novant Health Leland ASC despite shifting operating room and

procedure room cases. This results in an overstatement of operating room cases in Form C for Novant Health Leland ASC as procedure room cases are incorrectly included.

Novant Health uses the same methodology in shifting outpatient surgical cases from NHNHRMC to Novant Health Leland ASC. Novant Health combines operating room and procedure room outpatient cases on page 118 of its application, grows these cases, and shifts a portion of them to the two proposed operating rooms at Novant Health Leland ASC. Similar to the methodology described above, Novant Health does not separate the operating room and procedure room cases shifted to Novant Health Leland ASC. Once again, operating room cases in Form C for Novant Health Leland ASC are overstated as procedure room cases are incorrectly included.

It should be noted that the Agency has recently (September 21, 2021) found the same issue to be a basis of non-conformity in a competitive review. Of note, in the 2021 Durham/Caswell Acute Care Bed and Durham Operating Room Review (see Attachment 1), the Agency found Southpoint Surgery Center's (SSC's) application non-conforming with Criterion 3 because its utilization projections were derived in part by shifting cases historically performed in procedure rooms to operating rooms. On page 15 of the Agency's Findings, its states, "*as the applicant's projected utilization methodology shows…the applicant proposes to shift procedure room cases from NCSH to be performed at SSC. This does not support the need for additional ORs at SSC. It would in fact support the need to maintain procedure room capacity at SSC*." Novant Health's application proposes to shift cases historically performed in procedure rooms to operating rooms, similar to the approach taken by SSC, which led to the Agency finding the SSC non-conforming with Criterion 3 and the ultimate denial of the SSC application.

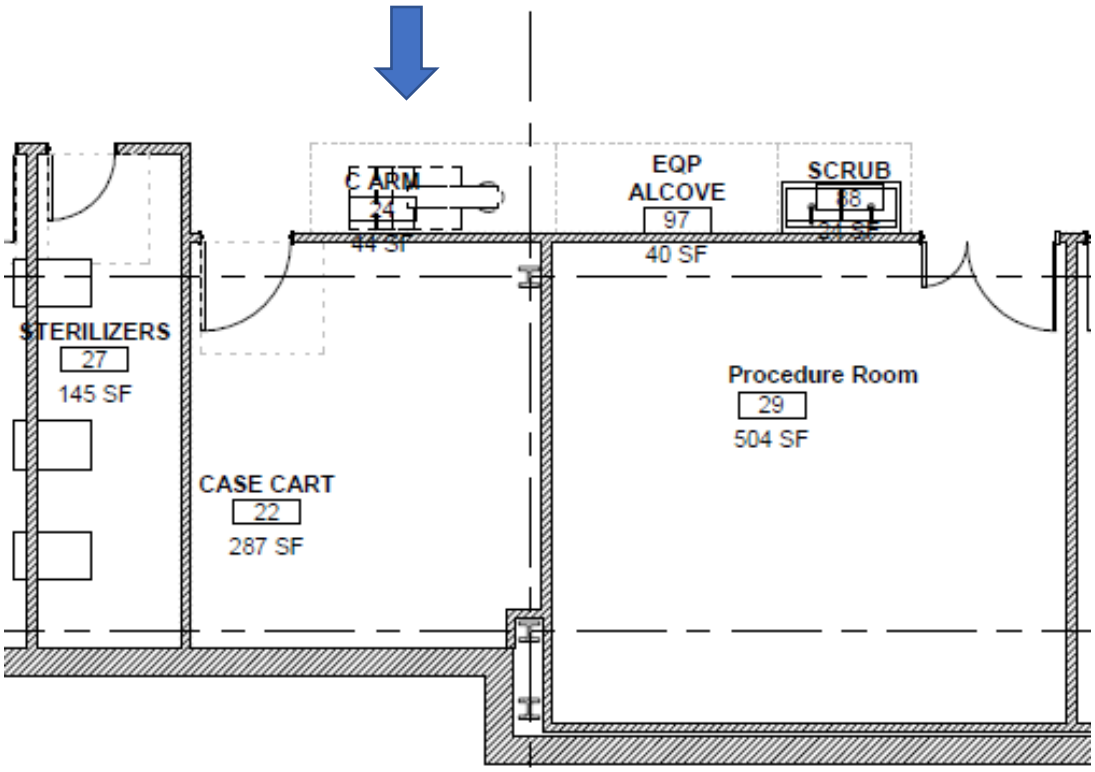
Regardless of the Agency's determination in this review concerning the conformity of the Novant Health application, based on Novant Health's proposal to utilize one of the two operating rooms needed in Brunswick County for cases that have historically been performed in procedure rooms, without any basis for doing so, the application should not be approved as proposed.

Based on the discussion above, McLeod Health believes that the Agency should consider whether Novant Health has adequately demonstrated the need for the proposed project in accordance with Criterion 3 – and as such, whether the Novant Health Leland ASC application should be found non-conforming with Criteria 1, 3 and 4.

2. <u>The Novant Health Leland ASC application fails to adequately demonstrate the need for the proposed project; in particular, the Novant Health Leland ASC application fails to adequately identify the scope of services proposed and thus to adequately demonstrate the need the population has for the services proposed.</u>

The Novant Health Leland ASC application fails to adequately demonstrate the need for the proposed project as it fails to adequately identify the scope of services to be provided. As detailed below, the Novant Health Leland ASC application contains conflicting information with regard to services that may be provided at the proposed ASF.

While the line drawings included in Exhibit K-1 of Novant Health's application (and excerpted below) include reference to a "*C-ARM*," the C-arm is not mentioned anywhere else in Novant Health's application.



In particular, the C-arm is not identified in response to Section A.5.f, which requires an applicant to identify medical equipment to be acquired in conjunction with its proposed project. In its response to Section A.5.f, Novant Health simply states "*Not applicable. The project does not involve medical equipment*." *See* the Novant Health application, page 21.

McLeod Health believes that this inconsistency makes it impossible for the Project Analyst to properly assess whether Novant Health has adequately demonstrated the need the population has for the services proposed – as the scope of the services proposed is unclear. Moreover, this inconsistency calls into question whether Novant Health has included all necessary medical equipment costs in its proposal. Finally, as discussed below relative to Criterion 12, this inconsistency makes it impossible for the Project Analyst to properly assess whether the design, cost, and means of construction is the most reasonable alternative.

Based on the discussion above, McLeod Health believes that the Agency should consider whether Novant Health has adequately demonstrated the need for the proposed project in accordance with Criterion 3 – and as such, whether the Novant Health Leland ASC application should be found non-conforming with Criteria 1 and 3.

3. The Novant Health Leland ASC application fails to demonstrate that the least costly or most effective alternative has been proposed.

Novant Health fails to demonstrate that it has proposed the least costly or most effective alternative. In Section E, pages 71 to 73, Novant Health discussed several alternatives it considered prior to the submission of its application as proposed. The alternatives considered by Novant Health include:

- "*Maintain the status quo*."
- "*Develop incremental hospital-based ORs*."
- "*Locate the ASC in a different geographic location*."

In reviewing Novant Health's alternatives, McLeod Health believes that Novant Health failed to adequately demonstrate why developing additional procedure rooms was not the most effective alternative. Notably, Novant Health's application does not include any discussion of an alternative involving the development of additional procedure rooms. Novant Health's failure to address such an alternative is particularly suspect given its discussion of procedure rooms in its application. On page 34 of its application Novant Health makes the following statements:

- "*Upon reviewing CMS reimbursement and hospital licensure standards, Novant Health determined that it could accommodate some additional surgical cases in the NHBMC procedure room, including shorter and lower acuity surgical cases*."
- "*The procedure room in NHBMC's surgical suite is built to accommodate this range of surgical cases safely*."
- "*NHBMC has accommodated a small portion of its growing surgical volume in recent years in the hospital procedure room*."

Novant Health goes on to note, however, that "*[t]he capacity of the procedure room is finite*." *See* the Novant Health application, page 34. In justifying the need for its proposed project, Novant Health indicates that the majority of these surgical cases performed in the procedure room are appropriate for an ASF setting and that "*[t]he proposed new ASC would increase access to cost-effective, dedicated-ambulatory surgical services for many patients whose surgical cases would otherwise be performed in NHBMC's procedure room…*" *See* the Novant Health application, page 35. Interestingly enough, however, given that the capacity of NHBMC's existing procedure room is finite, Novant Health fails to address why developing additional procedure rooms – which are not subject to need determinations, and which have provided relief for NHBMC's operating rooms historically – would not be the most effective alternative at this time.

In addition, McLeod Health also believes that Novant Health failed to adequately demonstrate why transferring existing assets was not the most effective alternative. Namely, the Novant Health application does not include any discussion of an alternative involving the transfer of existing assets from its existing facility – NHBMC – to the proposed new ASF. In 2016, a need for one additional operating room in Brunswick County was identified in the 2*016 SMFP*. Novant Health submitted an application (Project ID # O-11283-16) in response to the need determination in the *2016 SMFP* to develop a new ASF in Brunswick County with two operating rooms – one new operating room pursuant to the need determination and one existing operating room to be relocated from NHBMC. While Novant Health's 2016 application was denied following a competitive review, its discussion of alternatives is nonetheless informative. In its discussion of alternatives considered, Novant Health's

2016 application indicated that its proposal, which involved the relocation of an existing operating room from NHBMC, would not only permit clinically appropriate NHBMC outpatient surgical cases to shift to a freestanding multi-specialty ASF setting in Brunswick County, but also would provide additional capacity for the growing demand for outpatient surgical services at NHBMC and in Brunswick County. *See* Novant Health's 2016 application, pages 49-51. Here, there was no such discussion to address why transferring existing assets was not the most effective alternative at this time.

Based on the discussion above, McLeod Health believes that the Agency should consider whether Novant Health has proposed the least costly or most effective alternative in accordance with Criterion 4 – and as such, whether the Novant Health Leland ASC application should be found non-conforming with Criteria 1, 3, and 4.

4. The Novant Health Leland ASC application fails to adequately demonstrate the financial feasibility of the proposed project; in particular, the Novant Health Leland ASC application overstates procedure room net revenue.

On page 135 of its application, Novant Health calculates procedure room volume for Novant Health Leland ASC. Novant Health does so by shifting a percentage of the cystoscopy procedures historically performed at NHBMC. This is the only procedure included by Novant Health in the proposed procedure room volume for Novant Health Leland ASC; as such, the proposed procedure room is actually just a cystoscopy room. [emphasis added]

Notably, Novant Health does not include Forms F.2 and F.3 for the procedure room standing alone, as discussed in more detail in another issue-specific comment below. However, it is possible to compare the operating room financials on a per operating room case basis to the entire facility (presumably including operating room and procedure room cases) on a per case basis. This results in the following comparison:

	Total Facility	***Operating Room***
Gross Revenue per Case	$9,650	$9,639
Net Revenue per Case	$2,508	$2,504
Supplies Cost per Case	$896	$896
Pharmacy Cost per Case	$49	$49

Note: All numbers based on CY 2027 projections included in Forms F.2 and F.3 of Novant Health Leland ASC's Section Q Workbook.

In its gross revenue assumptions on page 144 of its application, Novant Health states "[g]*ross patient revenue is projected using the July 2020-2021 gross charges per specialty … and was adjusted for the payor mix, specialty mix, and volume*." Given the similarities in the figures above, it appears that Novant Health simply used the operating room information to calculate the procedure room financials included in the total facility. Given that Medicare reimburses freestanding ASFs for cystoscopies at rates between $285 and $2,063 with most codes reimbursed at $796 or $1,395, the net revenue attributable to procedure (cystoscopy) room volume appears to be significantly overstated. According to Form C of the Novant Health Leland ASC application, procedure room cases are projected to represent only 10 percent of total facility cases (306 /

3,043 x 100 = 0.10 or 10 percent) in the third full fiscal year of the proposed project. In light of the fact that cystoscopy procedures are the only procedures to be performed in the procedure rooms at Novant Health Leland ASC, and procedure rooms cases will represent only 10 percent of total cases in project year three, the average reimbursement for a procedure performed in a procedure room would therefore have to be higher than operating room reimbursement to result in a total facility average close to but higher than the operating room average. [emphasis added] With losses in FY 2025 and FY 2026 before a small profit in FY 2027, this calls into question the financial feasibility of Novant Health's proposed project.

Based on the discussion above, McLeod Health believes that the Agency should consider whether Novant Health has adequately demonstrated the financial feasibility of the proposed project in accordance with Criterion 5 – and as such, whether the Novant Health Leland ASC application should be found non-conforming with Criteria 1, 3, and 5.

5. The Novant Health Leland ASC application fails to adequately demonstrate the financial feasibility of the proposed project; in particular, the Novant Health Leland ASC application fails to provide Forms F.2 and F.3 for its proposed procedure rooms.

   As noted previously, Novant Health failed to provide Forms F.2 and F.3 for its proposed procedure rooms. Section F.4b of the CON Application Form states clearly that,

   > *"ASFs should complete the revenues and operating costs forms for ORs, GI endo rooms, procedure rooms, and the entire facility."*

   As described on page 27 of Novant Health's application, Novant Health proposes to develop two procedure rooms at Novant Health Leland ASC; however, Novant Health failed to provide Forms F.2 and F.3 in the Section Q Workbook of the Novant Health Leland ASC application. Novant Health provides Form F.2 and F.3 for operating rooms and the entire facility but fails to provide these forms for the two procedure rooms as required by the CON Application Form in Section F.4b. As such, Novant Health failed to provide the information necessary to respond fully to Section F.4b given it is proposing to develop two procedure rooms at Novant Health Leland ASC.

   Based on the discussion above, McLeod Health believes that the Agency should consider whether Novant Health has adequately demonstrated the financial feasibility of the proposed project in accordance with Criterion 5 – and as such, whether the Novant Health Leland ASC application should be found non-conforming with Criteria 1, 3, and 5.

6. The Novant Health Leland ASC application fails to adequately demonstrate the financial feasibility of the proposed project; in particular, the Section Q Workbook provided with Novant Health's application contains several inconsistencies.

   Below is a list of inconsistencies found within the Section Q Workbook provided with Novant Health's application:

   - While Novant Health adjusted its gross patient revenues and payor mix based on its changing blend of specialties throughout the first three full FYs of its proposed project, Novant Health failed to adjust its expenses for the shifting specialty mix. [emphasis added] Rather, Novant Health's volume-based expenses are simply increased by three

percent per year with no adjustments for the changing specialty mix. If charges and reimbursement are adjusted for the changing mix, expenses should be adjusted as well.

- In Section F of its application, Novant Health states that it will fund the capital costs, start-up costs, and initial operating expenses using cash and cash equivalents. As a result, Novant Health does not include interest expense in Form F.3b. Contradictory to this, Novant Health includes $349,129 of interest during construction in Form F.1a. This would indicate that Novant Health will be financing the project with loans instead of with cash and cash equivalents and therefore should have also included interest expense in Form F.3b.
- On page 28 of its application, Novant Health states, "*[r]eception, medical records and associated office requirements are provided by an employed receptionist and business office personnel*." However, no receptionist is included in Form H staffing (1.0 Business Office Staff is included). This indicates that salaries along with taxes and benefits are understated during the first three full FYs of the proposed project.
- On page 145 of its application, Novant Health states "[*d*]*ietary, Housekeeping/Laundry services are a contracted service and is included in "Independent Contractors.*" However, there is clearly a housekeeping / laundry expense line on Form F.3b of Novant Health's Section Q Workbook with expenses during the first three full FYs of the project.
- On page 146 of its application, Novant Health states that Building and Grounds Maintenance expenses are adjusted for volume. However, the expense line item in Form F.3b of Novant Health's Section Q Workbook is simply increased by three percent per year with no adjustment for volume. As such, this expense appears to be understated.

Based on the discussion above, McLeod Health believes that the Agency should consider whether Novant Health has adequately demonstrated the financial feasibility of the proposed project in accordance with Criterion 5 – and as such, whether the Novant Health Leland ASC application should be found non-conforming with Criteria 1, 3, and 5.

7. <u>The Novant Health Leland ASC application fails to adequately demonstrate that the proposed project will not result in unnecessary duplication.</u>

Novant Health fails to adequately demonstrate that the proposed project will not result in unnecessary duplication. Notably, and in light of the fact that Novant Health states that its proposed facility is expected to serve patients throughout Brunswick County <u>and surrounding communities</u>,[2] presumably including Wilmington in New Hanover County, it is interesting that Novant Health fails to include any discussion of existing and approved health service capabilities in the surrounding communities it proposes to serve and that are located in close proximity to its proposed facility. That is, while Novant Health's application includes discussion regarding existing surgical service capacity in Brunswick County, Novant Health fails to include *any* discussion regarding the two existing/approved multispecialty freestanding ASFs in Wilmington (New Hanover County) that are both less than 10 miles away from the proposed location of Novant Health Leland ASC. According to Google Maps, Wilmington SurgCare, an existing multispecialty

[2] On page 47 of its application, Novant Health states,"*[w]hile the proposed site was selected to expand geographic access to services in a growing portion of the county, Novant Health does not expect utilization of the proposed surgical services to be limited to only those residents within close proximity of the proposed new ASC. <u>The proposed facility is expected to serve patients from throughout the entire county and surrounding communities</u>."* [<u>emphasis added</u>].

ASF with ten existing/approved operating rooms, is less than nine miles from the proposed location of Novant Health Leland ASC and Wilmington ASC, an approved multispecialty ASF with one operating room, is less than 10 miles away. Further, according to Google Maps, NHNHRMC is nine miles from Novant Health's proposed ASF and 20 miles from NHBMC.

Based on the discussion above, McLeod Health believes that the Agency should consider whether Novant Health has adequately demonstrated that its proposal will not result in unnecessary duplication in accordance with Criterion 6 – and as such, whether the Novant Health Leland ASC application should be found non-conforming with Criteria 1, 3, and 6.

8. <u>The Novant Health Leland ASC application fails to demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative.</u>

Novant Health fails to demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative. Novant Health proposes to develop a 15,647 square foot ASF. According to Novant Health, the design architect and its team, "*developed the layout to maximize space efficiency*." *See* the Novant Health Leland ASC application, pages 92-93. Contrary to Novant Health's statement, it is not clear from the information presented in its application that the proposed layout will maximize space or efficiency.

As noted previously, not only are there inconsistencies in the scope presented in the Novant Health Leland ASC application[3] – notably, the line drawings included in Exhibit K-1 of Novant Health's application include reference to a "*C-ARM*" that is not mentioned anywhere else in its application – but also the medical equipment line item in Form F.1.a of Novant Health's application appears to be grossly understated given the mix of specialties proposed and as such, calls into question the use of, and design of, the space. As stated on page 27 of Novant Health's application, Novant Health Leland ASC proposes to offer eight different surgical specialties, including: general surgery, gynecology, ophthalmology, oral/maxillofacial surgery, orthopedics, otolaryngology, plastic surgery, and urology. However, as demonstrated on its Form F.1a, Novant Health includes only $3,888,734 for medical equipment costs, which appears to be grossly understated. By way of example, the other application involved in this review submitted by McLeod Health proposes that its ASF will initially offer five different surgical specialties, including: general, orthopedic, gynecology, urology, and vascular surgery services as well as gastroenterology and a total medical equipment cost of $4,869,405 as shown on Form F.1a. While McLeod Health is not suggesting that the applications should be compared relative to any statutory review criteria, examining the differences in medical equipment costs is nonetheless informative as there is a difference of approximately $1 million in medical equipment costs and McLeod Health is proposing to initially provide three fewer surgical specialties than Novant Health. In light of this information, it is questionable as to whether or not Novant Health included sufficient funds to equip its proposed ASF with all necessary medical equipment to support its proposal and whether its facility design can accommodate all necessary medical equipment. As such, not only does this call into question whether Novant Health adequately demonstrated that the cost, design, and means of construction proposed represent the most reasonable alternative, but also whether Novant

[3] As discussed above relative to Criterion 3, this inconsistency makes it impossible for McLeod Health or the Analyst to properly assess whether Novant Health has adequately demonstrated the need for the proposed project.

Health adequately demonstrated the financial feasibility of its proposed project in accordance with Criterion 5.

Based on the discussion above, McLeod Health believes that the Agency should consider whether Novant Health has adequately demonstrated that the cost, design, and means of construction proposed represent the most reasonable alternative in accordance with Criterion 12 – and as such, whether the Novant Health Leland ASC application should be found non-conforming with Criteria 1, 3, 5, and 12.

9. The Novant Health Leland ASC application fails to adequately demonstrate that medically underserved groups will be served by its proposal; in particular, Novant Health failed to adequately respond to Section L.4.

Section L.4.b of the CON Application Form requires applicants to answer whether or not the facility or campus identified in Section A, Question 4, will provide care to medically indigent or low-income patients at a reduced cost to the patient. If an applicant answers "yes", Section L.4.b of the CON Application Form requires the applicant to provide estimates of the total number of patients to be served by the entire facility at a reduced cost to the patients in each of the first three full FYs of operation and that it describe how such number was estimated. As demonstrated on page 100 of its application, Novant Health confirms that Novant Health Leland ASC will provide care to patients at a reduced cost but fails to provide projections for the first three full FYs of the project. Page 100 of Novant Health's application states further,

> *"Novant Health makes no differentiation between charity care and reduced cost care patients. The patients estimated in response to Section L.4.a. include patients who will receive care at a reduced cost. The patients estimated in Section L.4.a. equate to approximately 3.3 percent of projected facility patients, which is based on Novant Health's historical experience providing surgical services in freestanding ASC and the projected case volume by specialty shift to Novant Health Leland ASC."*

In light of Novant Health's response excepted above, it is impossible to discern the estimated total number of charity care and reduced cost patients independently, as required by Sections L.4.a and L.4.b of the CON Application Form.

Based on the discussion above, McLeod Health believes that the Agency should consider whether Novant Health has adequately demonstrated that medically underserved groups will be served by its proposed project in accordance with Criterion 13c – and as such, whether the Novant Health Leland ASC application should be found non-conforming with Criteria 1, 3, and 13c.

In summary, based on the numerous issues detailed above, McLeod Health believes that the Agency should consider whether Novant Health's project is consistent with the review criteria implemented under N.C. GEN. STAT. § 131E-183 and whether its project is needed, and as such, whether the Novant Health Leland ASC application should be found non-conforming with Criteria 1, 3, 4, 5, 6, 12, and 13c.

COMPARATIVE ANALYSIS

The McLeod Health application (Project ID # O-12148-21) and the Novant Health application (Project ID # O-12153-21) both propose to develop operating rooms in response to the *2021 SMFP* need determination for Brunswick County. Given that both applicants propose to meet all of the need for the two additional operating rooms in Brunswick County, both cannot be approved as proposed. To determine the comparative factors that are applicable in this review, McLeod Health examined recent Agency findings for competitive operating room reviews. Based on that examination and the facts and circumstances of the competing applications in this review, McLeod Health considered the following factors:

- Conformity with Review Criteria
- Patient Access to New Provider
- Patient Access to Lower Cost Surgical Services
- Geographic Accessibility/Access for Service Area Patients
- Scope of Services/Patient Access to Surgical Specialties
- Access by Underserved Groups
- Projected Medicare and Medicaid
- Projected Charity Care
- Projected Average Revenue per Case
- Projected Average Operating Expense per Case
- Provider Support

McLeod Health believes that the factors presented above and discussed in turn below should be used by the Analyst in reviewing the competing applications.

Conformity with Review Criteria

McLeod Health's application adequately demonstrates that its operating room proposal is conforming to all applicable statutory and regulatory review criteria. In contrast, and as discussed in the issue-specific comments above, there is a question as to whether Novant Health's application adequately demonstrates that its proposal is conforming to all applicable statutory and regulatory review criteria. An application that is not conforming to all applicable statutory and regulatory review criteria cannot be approved. Therefore, McLeod Health's application is the most effective with regard to conformity with applicable statutory and regulatory review criteria.

Patient Access to New Provider

Novant Health is an existing provider of surgical services in Brunswick County. McLeod Health represents a new provider of surgical services in the county. Therefore, McLeod Health's application is the most effective alternative with regard to providing Brunswick County patients with access to a new provider of surgical services.

Patient Access to Lower Cost Surgical Services

Operating rooms can be licensed either under a hospital license or an ASF that does not operate under a hospital license. In the review at issue, both applicants propose to develop the two additional operating rooms as part of a new ASF. Based on the Agency's historical evaluation under this comparative factor –

that generally, a proposal for the development of lower cost surgical services in ASF operating rooms would be more effective – the applications would be found equally comparable. However, as noted above, there is a question as to whether Novant Health's application adequately demonstrates that its proposal is conforming to all applicable statutory and regulatory review criteria. An application that is not conforming to all applicable statutory and regulatory review criteria cannot be approved. Therefore, the McLeod Health Brunswick ASC application submitted by McLeod Health is a more effective alternative than the Novant Health Leland ASC application submitted by Novant Health with regard to patient access to lower cost surgical services.

Geographic Accessibility/Access for Service Area Patients

The *2021 SMFP* identified a need for two additional operating rooms in Brunswick County. McLeod Health proposes to develop a new freestanding ASF with two operating rooms and two procedure rooms in southern Brunswick County. Novant Health proposes to develop a new ASF with two operating rooms and two procedure rooms in Leland, which is located in northern Brunswick County. As discussed in the issue-specific comments above, according to Google Maps, Wilmington SurgCare, an existing multispecialty ASF with ten existing/approved operating rooms, is less than nine miles from the proposed location of the Novant Health Leland ASC and Wilmington ASC, an approved multispecialty ASF with one operating room, is less than 10 miles away.

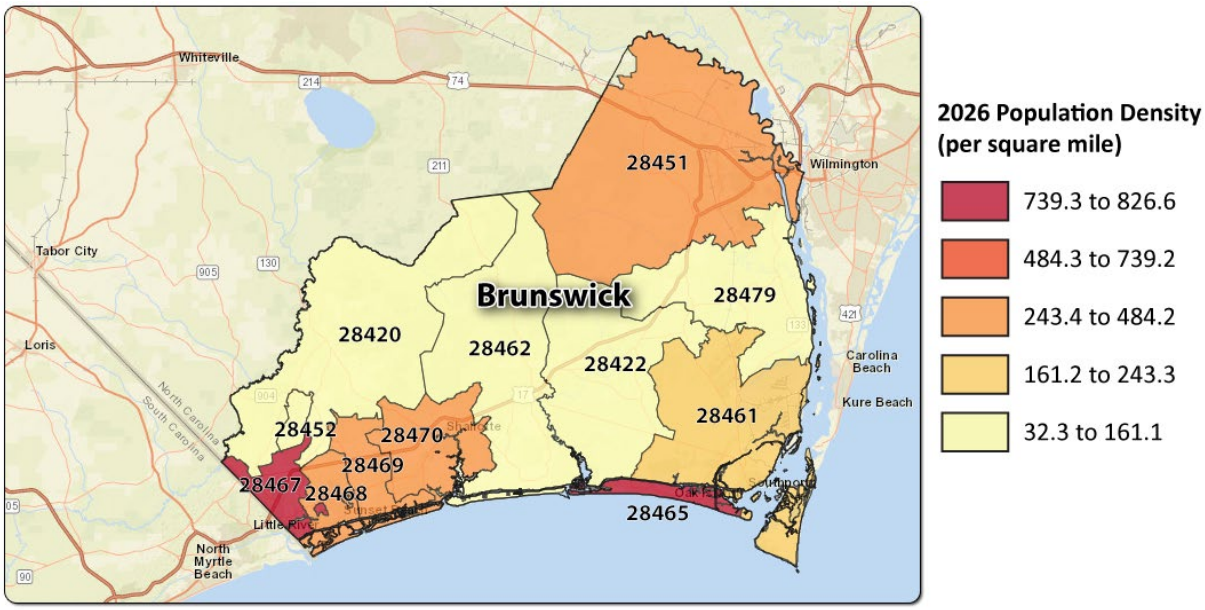
As McLeod Health discussed on pages 55-58 of its application, while the population of Brunswick County is projected to increase over the next five years, this growth will be focused within certain areas of Brunswick County, including southern Brunswick County where McLeod Health's proposed ASF will be located. In fact, in 2026, of the 12 ZIP codes in Brunswick County, three of the most populous ZIP codes (28451, 28461, and 28470) will account for over half of the total growth to be experienced in Brunswick County, as shown in the table below.

Brunswick County ZIP Codes Projected Population Growth 2021-2026

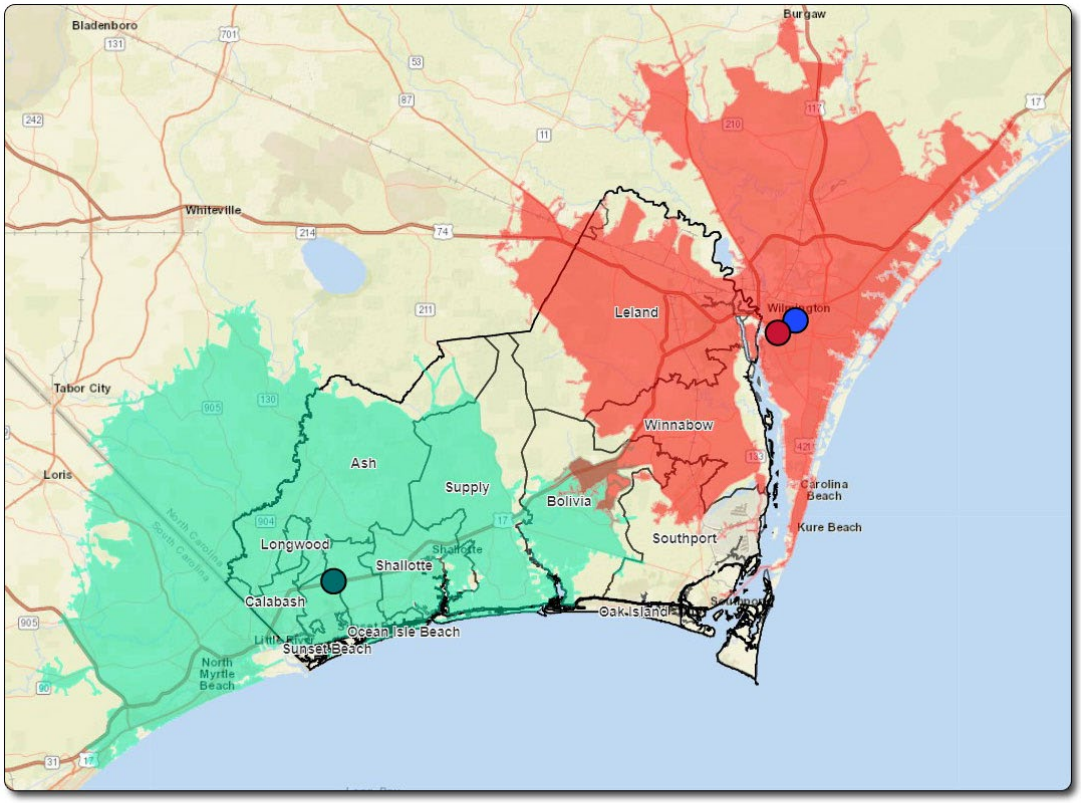
ZIP Code	*City*	*2021*	*2026*	*Numerical Growth*	*2021-2026 CAGR*	*2026 Pop. as a % of Total*
28451	Leland	40,736	46,856	6,120	2.8%	29.0%
28461	Southport	20,624	22,871	2,247	2.1%	14.2%
28470	Shallotte	13,490	15,349	1,859	2.6%	9.5%
28467	Calabash	12,243	13,925	1,682	2.6%	8.6%
28462	Supply	14,727	16,334	1,607	2.1%	10.1%
28422	Bolivia	8,895	10,083	1,188	2.5%	6.2%
28479	Winnabow	5,692	6,634	942	3.1%	4.1%
28469	Ocean Isle Beach	7,643	8,574	931	2.3%	5.3%
28465	Oak Island	8,244	9,168	924	2.1%	5.7%
28468	Sunset Beach	5,399	5,944	545	1.9%	3.7%
28420	Ash	4,778	5,202	424	1.7%	3.2%
28452	Longwood	628	691	63	1.9%	0.4%
Brunswick County Total		**143,099**	**161,631**	**18,532**	**2.5%**	**100.0%**

Source: Esri, McLeod Health application, Exhibit C.4-2.

Of particular note, four contiguous ZIP codes in southern Brunswick County that encompass the communities of Shallotte (28470), Ocean Isle Beach (28469), Sunset Beach (28468), and Calabash (28467), which are significantly smaller in land area than all but two ZIP codes in the county, are projected to have a combined population of 43,792 residents in an area roughly the size of the Southport ZIP (28461), while supporting over 20,000 more residents than Southport. Moreover, while the Leland ZIP code has a greater population than any of the others, as shown in the map below, it is also larger than the other ZIP codes, but is not as densely populated as some of the southern and coastal ZIPs. Further, Leland is adjacent to Wilmington, which as noted previously is where other multispecialty ASFs are located, providing better access to surgical services in an ASF than what is currently available to residents in equally or more dense areas of southern Brunswick County.



Furthermore, as illustrated below, the location of McLeod Health's proposed ASF in the southern area of Brunswick County is closer for residents of much of Brunswick County compared to the other two closest multispecialty ASFs that are in New Hanover County. As shown in the map below, a 25-mile drive radius from McLeod Health's proposed ASF covers more area in Brunswick County compared to the same mile drive radius from the closest multispecialty ASF to Brunswick County.



McLeod Health considered the distribution and concentration of residents in Brunswick County when determining the most effective site for its proposed ASF, McLeod Health Brunswick ASC, as well as the proximate distance to multispecialty operating room services for most of Brunswick County residents and believes that the most effective location is the one it proposes in Grissettown, in the Township of Shallotte, Brunswick County. This location is also supported by the existence of referring physicians in the area and by the surgeons who are expected to practice there. Therefore, with regard to geographic accessibility and access for service area patients, the McLeod Health Brunswick ASC application is the most effective alternative.

Scope of Services/Patient Access to Surgical Specialties

The following table illustrates the surgical specialties that each of the applicants in this review propose to offer.

	McLeod Health Brunswick ASC	***Novant Health Leland ASC***
Cardiothoracic, excl. open heart		
Open Heart		
General Surgery	x	x
Neurosurgery (incl. spine)		
OB GYN (excl. C-Section)	x	x
Ophthalmology		x
Oral Surgery/Dental		x
Orthopedic (incl. spine)	x	x
ENT		x
Plastic Surgery		x
Podiatry		
Urology	x	x
Vascular	x	
Other		
Total # of Surgical Specialties	**5**	**8**

Source: Section C.1 of the respective applications.

As demonstrated in the table above, Novant Health proposes to offer access to more surgical specialties than McLeod Health; however, as discussed in the issue-specific comments above, it appears that Novant Health may have understated its medical equipment costs in light of the number of surgical specialties that it proposes to offer at Novant Health Leland ASC. As such, it is questionable whether Novant Health Leland ASC can support the number of specialties proposed in its application. Therefore, with regard to scope of services and patient access to surgical specialties, the McLeod Health Brunswick ASC application is the most effective alternative.

Access by Underserved Groups

The following table illustrates each applicant's percentage of total operating room cases to be provided to certain underserved groups as requested in Section C.6.

Underserved Groups

	Women	*65+*	*Racial Minorities*
McLeod Health Brunswick ASC	52.9%	57.8%	17.2%
Novant Health Leland ASC	52.3%	54.3%	25.0%

Source: Section C.6 of the respective applications.

The McLeod Health Brunswick ASC application projects to serve the highest percentage of patients age 65 and older and women. The Novant Health Leland ASC application projects to serve the highest percentage of racial minorities. As such, with regard to access by underserved groups, the McLeod Health Brunswick ASC application is most effective.

Projected Medicare and Medicaid

The following table illustrates each applicant's percentage of total operating room cases to be provided to Medicare and Medicaid patients as stated in Section L.3 of the respective applications.

	% Medicare	*% Medicaid*	*% Combined*
McLeod Health Brunswick ASC	60.5%	5.3%	65.8%
Novant Health Leland ASC	54.0%	7.2%	61.2%

Source: Section L.3 of the respective applications.

As shown in the table above, the McLeod Health Brunswick ASC application projects to serve a higher portion of Medicare patients, while the Novant Health Leland ASC application projects to serve a higher portion of Medicaid patients. Overall, McLeod Health projects to serve 65.8 percent of these patients while Novant Health only projects to serve 61.2 percent of these patients. As a result, McLeod Health is a better alternative in regard to this comparative factor.

Projected Charity Care

The following table illustrates each applicant's projected charity care as a percentage of net revenue in the third full FY of operation.

	Charity Care	*Net Revenue*	*Charity Care as a % of Net Revenue*
McLeod Health Brunswick ASC	$228,340	$5,536,461	4.1%
Novant Health Leland ASC	$903,013	$6,853,998	13.2%

Source: Form F.2 of the respective applications.

On page 100 of its application, Novant Health states "*Novant Health makes no differentiation between charity care and reduced cost care patients*." Based on this statement, Novant Health's charity care includes both charity care and reduced cost patients, making a comparison of the two applications of little value. It is, however, possible to compare the two applications relative to the number of charity care and reduced cost patients as a percentage of all patients based on information provided in Section L.4 and Form C as shown in the table below.

	Total Procedures*	***Charity Care & Reduced Cost****	***% of Patients***
McLeod Health Brunswick ASC	2,234	209	9.4%
Novant Health Leland ASC	3,043	100	3.3%

*PR and OR cases combined.
**From Section L.4 and Form C of the respective applications.

Based on the analysis above, the McLeod Health Brunswick ASC application projects to serve more charity care and reduced pay patients than the Novant Health Leland ASC application. In addition, the McLeod Health Brunswick ASC application projects to serve a higher percentage of charity care and reduced pay patients than the Novant Health Leland ASC application. Based on this analysis, McLeod Health is the more effective alternative with regard to this comparative factor.

Projected Average Revenue per Case

The following table shows the projected gross revenue per operating room case in the third year of operation based on the information provided in the pro forma financial statements (Form F.2).

Applicant	***Cases***	***Gross Revenue***	***Average Gross Revenue Per Case***
McLeod Health Brunswick ASC	1,862	$12,618,763	$6,777
Novant Health Leland ASC	2,737	$26,381,293	$9,638

Source: Forms C and F.2 of the respective applications.

The following table shows the projected net revenue per operating room case in the third year of operation based on the information provided in the pro forma financial statements (Form F.2).

Applicant	***Cases***	***Net Revenue***	***Average Net Revenue Per Case***
McLeod Health Brunswick ASC	1,862	$5,536,461	$2,973
Novant Health Leland ASC	2,737	$6,853,998	$2,504

Source: Forms C and F.2 of the respective applications.

McLeod Health proposes the lowest average gross revenue per case and Novant Health proposes the lowest average net revenue per case. However, and as previously discussed, McLeod Health proposes to include five specialties in its ASF while Novant Health proposes to offer eight. Each specialty has a different revenue and expense structure. As a result of these key differences, it is difficult to make a meaningful comparison between the two applications in terms of average net revenue per case.

Projected Average Operating Expense per Case

The following table shows average operating expense per operating room case in the third full FY of operation.

Applicant	*Cases*	*Operating Expenses*	*Average Operating Expense per Case*
McLeod Health Brunswick ASC	1,862	$4,897,727	$2,630
Novant Health Leland ASC	2,737	$6,246,036	$2,282

Source: Forms C and F.2 of the respective applications.

Novant Health proposes the lowest average operating expense per case. However, and as previously discussed, McLeod Health proposes to include five specialties in its ASF while Novant Health proposes to offer eight. Each specialty has a different revenue and expense structure. As a result of these key differences, it is difficult to make a meaningful comparison between the two applications in terms of average operating expense per case.

Provider Support

The following table illustrates the number of letters of support included with each application from surgeons, other physicians/providers, and community members.

	Surgeons	*Other Physicians/Providers*	*Community*	*Total*
McLeod Health Brunswick ASC	25	47	45	**117**
Novant Health Leland ASC	39	5	2	**46**

Source: Support letter exhibits.

As shown above, McLeod Health's application included the most letters of support from other physicians/providers and community members and the most letters overall by a large margin. The Novant Health Leland ASC application provided more letters of support from surgeons but fewer letters of support from the other two groups and fewer letters combined than the McLeod Health Brunswick ASC application. Therefore, with regard to provider support,[4] McLeod Health's application is the most effective alternative.

[4] While not used in every competitive review, there have been numerous reviews recently in which provider support has been used as comparative factor, including the 2016 Brunswick County Operating Room Review, the 2019 Orange County Operating Room Review and, in 2018, the Orange County Operating Room Review, the Mecklenburg County Operating Room Review, the Durham County Operating Room Review, the Wake County Operating Room Review, the Buncombe County Operating Room Review, and the Forsyth County Operating Room Review.

Summary of Comparative Analysis

The following table summarizes the comparative analysis.

Comparative Factor	*McLeod Health Brunswick ASC*	*Novant Health Leland ASC*
Conformity with Review Criteria	Yes	Questionable
Patient Access to New Provider	Most Effective	Less Effective
Patient Access to Lower Cost Surgical Services	Equally Effective	Equally Effective, But Approvability is Questionable
Geographic Accessibility/Access for Service Area Patients	Most Effective	Less Effective
Scope of Services/Patient Access to Surgical Specialties	Less Effective	Most Effective, But Approvability is Questionable
Access by Underserved Groups	Most Effective	Less Effective
Projected Medicare and Medicaid	Most Effective	Less Effective
Projected Charity Care	Most Effective	Less Effective
Projected Average Net Revenue	Not comparable	Not comparable
Projected Average Operating Expense per Case	Not comparable	Not comparable
Provider Support	Most Effective	Less Effective

SUMMARY

Based on both its comparative analysis and the issue-specific comments above, McLeod Health believes that its application represents the most effective alternative for meeting the need identified in the *2021 SMFP* for two operating rooms in Brunswick County.

As such, the CON Section can and should approve the McLeod Health application.

Please note that in no way does McLeod Health intend for these comments to change or amend its application as filed on October 15, 2021. If the Agency considers any statements to be amending McLeod Health's application, those comments should not be considered.

Attachment 1

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS
C = Conforming
CA = Conditional
NC = Nonconforming
NA = Not Applicable

Decision Date: September 21, 2021
Findings Date: September 21, 2021

Project Analyst: Celia C. Inman
Co-Signer: Gloria C. Hale

COMPETITIVE REVIEW

Project ID #:	J-12052-21
Facility:	Southpoint Surgery Center
FID #:	180558
County:	Durham
Applicants:	Southpoint Surgery Center, LLC
Project:	Add four ORs pursuant to the need determination in the 2021 SMFP which is a change of scope to Project ID #J-11626-18 (develop two ORs and four procedure rooms) for a total of six ORs and no procedure rooms upon completion of both projects

Project ID #:	J-12065-21
Facility:	UNC Hospitals-RTP
FID #:	210266
County:	Durham
Applicants:	University of North Carolina Hospitals at Chapel Hill University of North Carolina Health Care System
Project:	Construct a new separately licensed 40-bed hospital by developing 40 acute care beds and two ORs pursuant to the need determination in the 2021 SMFP

Project ID #:	J-12069-21
Facility:	Duke University Hospital
FID #:	943138
County:	Durham
Applicant:	Duke University Health System, Inc.
Project:	Add no more than 40 acute care beds pursuant to the need determination in the 2021 SMFP for a total of no more than 1,102 beds upon completion of this project, Project ID #J-11717-19 (add 34 acute care beds for a total of 1,062) and Project ID #J-11426-17 (add 90 acute care beds for a total of 1,028)

Project ID #:	J-12070-21
Facility:	Duke University Hospital
FID #:	943138
County:	Durham
Applicant:	Duke University Health System, Inc.
Project:	Develop no more than two ORs pursuant to the need determination in the 2021 SMFP which is a change of scope for Project ID# J-11631-18 (develop two ORs and three procedure rooms) for a total of no more than 69 ORs upon completion of both projects

Project ID #:	J-12075-21
Facility:	Duke Ambulatory Surgery Center Arringdon
FID #:	180213
County:	Durham
Applicant:	Duke University Health System, Inc. Associated Health Services, Inc.
Project:	Develop no more than two ORs pursuant to the need determination in the 2021 SMFP which is a change of scope for Project ID #J-11508-18 (relocate four ORs and develop four procedure rooms) for a total of no more than six ORs and two procedure rooms upon completion of both projects

Each application was reviewed independently against the applicable statutory review criteria found in G.S. 131E-183(a) and the applicable 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.

This competitive review involves two Durham County health systems (Duke University Health System, Inc. and North Carolina Specialty Hospital/Southpoint Surgery Center), in addition to the University of North Carolina Hospitals at Chapel Hill/University of North Carolina Health System, as a new provider in Durham County.

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

N.C. Gen. Stat. §131E-183(a) The Agency 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 – All Applications

Need Determinations

Acute Care Beds – Chapter 5 of the 2021 State Medical Facilities Plan (SMFP) includes a methodology for determining the need for additional acute care beds in North Carolina by service area. Application of the need methodology in the 2021 SMFP identified a need for 40 additional acute care beds in the Durham/Caswell County service area. Two applications were submitted to the Healthcare Planning and Certificate of Need Section ("CON Section" or "Agency") proposing to develop a total of 80 new acute care beds in Durham County. However, pursuant to the need determination, only 40 acute care beds may be approved in this review for the Durham/Caswell County service area. See the Conclusion following the Comparative Analysis for the decision.

Only qualified applicants can be approved to develop new acute care beds. On page 34, the 2021 SMFP states:

> *"A qualified applicant is a person who proposes to operate the additional acute care beds in a hospital that will provide:*
>
> *(1) a 24-hour emergency services department,*
> *(2) inpatient medical services to both surgical and non-surgical patients, and*
> *(3) if proposing a new licensed hospital, medical and surgical services on a daily basis within at least five of the major diagnostic categories (MDC) recognized by the Centers for Medicare and Medicaid Services (CMS) listed below: ...* [listed on pages 34-35 of the 2021 SFMP]*."*

Operating Rooms (ORs) – Chapter 6 of the 2021 SMFP includes a methodology for determining the need for additional ORs in North Carolina by service area. Application of the need methodology in the 2021 SMFP identifies a need for four additional ORs in the Durham County OR service area. (Note: A typographical error in Table 6C, page 81, identifies the service area as Durham/Caswell. That is not correct: the service area is Durham County, as shown in Figure 6.1, page 55 of the 2021 SMFP.) Four applications were submitted to the CON Section, proposing to develop a total of ten ORs. However, pursuant to the need determination, only four ORs may be approved in this review for the Durham County OR service area. See the Conclusion following the Comparative Analysis for the decision.

Policies – There are two policies applicable to the review of the applications submitted in response to the acute care bed and OR need determinations in the 2021 SMFP for the respective Durham/Caswell County and Durham County service area.

Policy GEN-3: Basic Principles, 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: Energy Efficiency and Sustainability for Health Service Facilities, 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 for energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation. The plan must be consistent with the applicant's representation in the written statement as described in paragraph one of Policy GEN-4. The plan shall not adversely affect patient or resident health, safety or infection control."

J-12052-21/Southpoint Surgery Center/Add four ORs

Southpoint Surgery Center, LLC, "Southpoint" or "the applicant," proposes to add four ORs pursuant to the need determination in the 2021 SMFP for a total of six ORs and no procedure rooms upon project completion. This is a change of scope to Project ID #J-11626-18, which was denied and subsequently settled with an approval to develop Southpoint Surgery Center (SSC), a new ambulatory surgical facility with no more than two operating rooms and four procedure rooms.

Need Determination. The applicant does not propose to develop more ORs than are determined to be needed in the Durham County service area.

Policies. ***Policy GEN-3*****.** In Section B, pages 24-26, the applicant explains why it believes its application is consistent with Policy GEN-3. The applicant states that SSC will promote safety and quality in the delivery of the services, promote equitable access, and maximize healthcare value for the resources expended; and provides evidence and documentation of its intent.

Policy GEN-4**.** The proposed capital expenditure for this project is greater than $2 million but less than $5 million. In Section B, pages 27-28, the applicant describes the project's plan to improve energy efficiency and conserve water and provides a written statement with the description. 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

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

- The applicant adequately demonstrates that the application is consistent with the need methodology as applied from the 2021 SMFP.
- 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 OR services in the Durham County service area.
    - The applicant adequately documents how the project will promote equitable access to OR services in the Durham County service are
    - 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.

J-12065-21/UNC Hospitals-RTP/Develop 40 acute care beds and two ORs

University of North Carolina Hospitals at Chapel Hill and University of North Carolina Health Care System, collectively referred to as "UNC" or "the applicant," proposes to develop an acute care hospital, UNC Hospitals-RTP (UNC-RTP), with 40 acute care beds and two ORs pursuant to the need determinations in the 2021 SMFP.

Need Determination. The applicant does not propose to develop more acute care beds than are determined to be needed in the Durham/Caswell acute care multicounty service area or more ORs than are needed in the Durham County OR service area. In Section B, page 25, the applicant adequately demonstrates that it meets the requirements of a "qualified applicant" as defined in Chapter 5 of the 2021 SMFP.

Policies. ***Policy GEN-3*****.** In Section B, pages 26-30, the applicant explains why it believes its application is consistent with Policy GEN-3, stating that the new proposed hospital will provide access to UNC's high quality healthcare to UNC's growing number of patients in the service area, including the medically underserved.

Policy GEN-4**.** The proposed capital expenditure for this project is greater than $5 million. In Section B, page 31, 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

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

- The applicant adequately demonstrates that the application is consistent with the facility need methodology as applied from the 2021 SMFP.
- The applicant adequately demonstrates that it is a qualified applicant.
- 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 acute care and OR services in the applicable service area.
    - The applicant adequately documents how the project will promote equitable access to acute care and OR services in the applicable service area.
    - 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.

J-12069-21/Duke University Hospital/Add 40 acute care beds

Duke University Health System, Inc., "Duke" or "the applicant," proposes to add 40 acute care beds at Duke University Hospital (DUH) pursuant to the need determination in the 2021 SMFP for a total of 1,102 acute care beds upon completion of this project, Project ID #J-11717-19 (add 34 acute care beds for a total of 1,062) and Project ID #J-11426-17 (add 90 acute care beds for a total of 1,028).

Need Determination. The applicant does not propose to develop more acute care beds than are determined to be needed in the Durham/Caswell County service area. In Section C, page

27 the applicant adequately demonstrates that it meets the requirements of a "qualified applicant" as defined in Chapter 5 of the 2021 SMFP.

Policies. ***Policy GEN-3*****.** In Section B, page 25, the applicant explains why it believes its application is consistent with Policy GEN-3, stating:

> *"Please refer to Sections M, N and O of this application which include descriptions how the project will promote safety and quality, and equitable access in the delivery of health care services, and how the project will maximize healthcare value for resources expended. The need for additional inpatient acute care services in Durham County is generated by the high utilization of Duke University Hospital beds. By increasing capacity to meet ongoing demand, this project will increase safety and quality by maximizing the ability of the hospital to accept transfers and admissions of those patients who need Duke's highly specialized acute care services without delay and promote access to all patients."*

Policy GEN-4**.** The proposed capital expenditure for this project is greater than $2 million but less 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

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

- The applicant adequately demonstrates that the application is consistent with the facility need methodology as applied from the 2021 SMFP.
- The applicant adequately demonstrates that it is a qualified applicant.
- 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 acute care and OR services in the applicable service area.
    - The applicant adequately documents how the project will promote equitable access to acute care and OR services in the applicable service area.
    - 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.

J-12070-21/Duke University Hospital/Develop two ORs

Duke University Health System, Inc., "Duke", "DUHS", or "the applicant," proposes to develop two additional ORs at DUH pursuant to the need determination in the 2021 SMFP for a total of 69 ORs. This is a change of scope to Project ID #J-11631-18 (develop two ORs and three procedure rooms for a total of 67 ORs).

Need Determination. The applicant does not propose to develop more ORs than are determined to be needed in the Durham County service area.

In Section A.5, page 18, the applicant describes this application as a proposal to develop 40 additional acute care beds at DUH. In Section B.1, the applicant responds that this application is in response to the 2021 SMFP need determination for 40 acute care beds in the Durham/Caswell county service area. These appear to be inadvertent errors on the part of the applicant whereby the applicant failed to change the entries copied from the companion Project ID #J-12069-21 in which the applicant applies for 40 acute care beds. The foregoing errors bear no effect on the outcome of the review of this application to develop two additional ORs for a total of 69 ORs at DUH.

Policies. ***Policy GEN-3*****.** In Section B, page 25, the applicant explains why it believes its application is consistent with Policy GEN-3, stating:

> *"Please refer to Sections M, N and O of this application which include descriptions how the project will promote safety and quality, and equitable access in the delivery of health care services, and how the project will maximize healthcare value for resources expended. The need for additional surgical services in Durham County is generated by the high utilization of Duke University Hospital beds. By increasing capacity to meet ongoing demand, this project will increase safety and quality by maximizing the ability of the hospital to accept and treat those patients who need Duke's highly specialized acute care services without delay and promote access to all patients."*

Policy GEN-4**.** This application is a change of scope application for Project ID #J-11631-18 and does not increase the capital cost above the capital cost approved for Project ID #J-11631-18. Project ID J-11631-18 was conforming with this policy and the applicant proposes no changes in the current application which would affect that determination.

Conclusion – The Agency reviewed the:

- Application
- Exhibits to the application

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

- The applicant adequately demonstrates that the application is consistent with the facility need methodology as applied from the 2021 SMFP.
- The applicant adequately demonstrates that the proposal is consistent with Policy GEN-3 for the following reasons:

    - The applicant adequately documents how the project will promote safety and quality in the delivery of OR services in the Durham County service area.
    - The applicant adequately documents how the project will promote equitable access to OR services in the Durham County service area.
    - The applicant adequately documents how the project will maximize healthcare value for the resources expended.

J-12075-21/Duke Ambulatory Surgery Center Arringdon/Develop two ORs

Duke University Health System, Inc. and Associated Health Services, Inc., collectively referred to as "Duke" or "the applicant," proposes to develop two additional ORs pursuant to the need determination in the 2021 SMFP for a total of six ORs and two procedure rooms at Duke Ambulatory Surgery Center Arringdon (Arringdon). This is a change of scope to Project ID #J-11508-18 (develop a new ASC by relocating four operating rooms from James E. Davis ASC (DASC) and developing four procedure rooms).

Need Determination. The applicant does not propose to develop more ORs than are determined to be needed in the Durham County service area.

Policies. ***Policy GEN-3*****.** In Section B, page 26, the applicant explains why it believes its application is consistent with Policy GEN-3, stating that Section N contains a detailed discussion of how the proposed project will promote safety and quality, provide equitable access, and maximize healthcare value. The applicant further states:

> *"DUHS's projected utilization incorporates the concepts of safety, quality, access, and maximum value for resources expended in meeting the need identified in the 2021 SMFP.*
>
> . . .
>
> *The proposed project will increase access to lower cost, freestanding ambulatory surgical services for residents of the identified service area and surrounding communities.*
>
> . . .
>
> *DUHS will also continue to comply with applicable Federal civil rights laws and will not discriminate on the basis of race, color, national origin, age, disability, gender, or sexual orientation."*

Policy GEN-4**.** The proposed capital expenditure for this project is less than $2 million; thus, this policy is not applicable.

Conclusion – The Agency reviewed the:

- Application
- Exhibits to the application

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

- The applicant adequately demonstrates that the application is consistent with the facility need methodology as applied from the 2021 SMFP.
- The applicant adequately demonstrates that the proposal is consistent with Policy GEN-3 for the following reasons:

    - The applicant adequately documents how the project will promote safety and quality in the delivery of OR services in the Durham County service area.
    - The applicant adequately documents how the project will promote equitable access to OR services in the Durham County service area.
    - The applicant adequately documents how the project will maximize healthcare value for the resources expended.

(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, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

NC
Southpoint Surgery Center

C – All Other Applications

J-12052-21/Southpoint Surgery Center/Add four ORs

The applicant, Southpoint, proposes to add four ORs to SSC pursuant to the need determination in the 2021 SMFP for a total of six ORs upon project completion. This is a change of scope to Project ID #J-11626-18, which was denied and subsequently settled with an approval to develop SSC, a new ambulatory surgical facility with no more than two operating rooms and four procedure rooms. The applicant now proposes a total of six ORs and no procedure rooms.

Patient Origin – On page 49, the 2021 SMFP defines the service area for ORs as *"…the single or multicounty grouping shown in Figure 6.1."* Figure 6.1, page 55, shows Durham County as its own OR service area. Thus, the service area for this facility is Durham County. Facilities may also serve residents of counties not included in their service area.

This application is a change of scope to Project ID #J-11626-18 (develop two ORs and four procedure rooms), which is under development and thus has no current patient origin. In

Section C, page 56, the applicant provides the proposed patient origin as summarized in following table.

Southpoint Surgery Center Projected Patient Origin
Operating Rooms

County	1st Full FY - CY2023		2nd Full FY - CY2024		3rd Full FY - CY2025	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Durham	1,906	36.16%	2,231	36.16%	2,460	36.16%
Wake	713	13.52%	834	13.52%	920	13.52%
Orange	657	12.48%	770	12.48%	849	12.48%
Granville	409	7.77%	479	7.77%	529	7.77%
Alamance	356	6.75%	416	6.75%	459	6.75%
Person	325	6.18%	381	6.18%	420	6.18%
Vance	130	2.47%	152	2.47%	168	2.47%
Chatham	113	2.14%	132	2.14%	146	2.14%
Johnston	94	1.79%	111	1.79%	122	1.79%
Franklin	55	1.05%	65	1.05%	71	1.05%
Guilford	54	1.02%	63	1.02%	69	1.02%
Harnett	41	0.77%	48	0.77%	53	0.77%
Caswell	38	0.72%	45	0.72%	49	0.72%
Cumberland	24	0.45%	28	0.45%	30	0.45%
Warren	22	0.42%	26	0.42%	29	0.42%
Wilson	20	0.37%	23	0.37%	25	0.37%
Halifax	16	0.30%	18	0.30%	20	0.30%
Lee	16	0.30%	18	0.30%	20	0.30%
Moore	16	0.30%	18	0.30%	20	0.30%
Nash	13	0.25%	15	0.25%	17	0.25%
Northampton	9	0.17%	11	0.17%	12	0.17%
Randolph	9	0.17%	11	0.17%	12	0.17%
Brunswick	8	0.15%	9	0.15%	10	0.15%
Carteret	5	0.10%	6	0.10%	7	0.10%
Iredell	5	0.10%	6	0.10%	7	0.10%
Sampson	5	0.10%	6	0.10%	7	0.10%
Cabarrus	4	0.07%	5	0.07%	5	0.07%
Wayne	4	0.07%	5	0.07%	5	0.07%
Edgecombe	4	0.07%	5	0.07%	5	0.07%
Other NC Counties*	51	0.97%	60	0.97%	66	0.97%
Virginia	98	1.87%	115	1.87%	127	1.87%
Other States	48	0.92%	57	0.92%	63	0.92%
TOTAL	**5,269**	**100.00%**	**6,169**	**100.00%**	**6,803**	**100.00%**

*The applicant does not identify the counties that comprise this category on this table; however, the applicant does provide the other counties in the assumptions on page 57, which include Lenoir, Onslow, Buncombe, Duplin, Forsyth, New Hanover, Richmond, Alleghany, Hyde, Mecklenburg, Beaufort, Bladen, Caldwell, Catawba, Columbus, Craven, Dare, Davidson, Gaston, Hoke Montgomery, Pitt, Robeson, Rutherford, Transylvania, Union, and Watauga.
Totals may not sum due to rounding

In Section C, pages 56-57, the applicant provides the assumptions and methodology used to project patient origin. The applicant's assumptions are reasonable and adequately supported.

Analysis of Need – In Section C.8, as a change of scope proposal, pages 41-49, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. The applicant states that the elements of this change of scope project include:

- Developing and equipping four additional ORs for a total of six ORs
- Acquiring additional surgical equipment to perform higher complexity cases

The applicant states that the need for the proposed project is based on multiple factors, as summarized below:

- Responding to the need determination in the 2021 SMFP (page 42)
- Growth and aging of the population (pages 42-43)
- Cost savings in ASFs and changes in reimbursement supporting performance of more complex procedures in ASFs (pages 43-44)
- Preference by physicians and patients to obtain outpatient surgery in freestanding ASFs (page 45)
- Increases in ambulatory surgery utilization over inpatient surgery utilization (pages 45-46)
- Capacity constraints at NCSH (pages 46-47)
- Projected growth of the NCSH and SSC medical staff to include additional surgeons and at least one additional surgical specialty, neurosurgery (pages 47-48)
- Projected utilization based on reasonable and conservative assumptions (page 49)
- Changes in the facility plan to develop and equip a total of six ORs to include:
    - Additional capital costs for equipment (page 53)
    - Additional capital costs for surgical robot for total joint replacements (pages 53-54)
    - Cost effective expansion of surgical capacity with minimal changes to the facility (page 54)

However, the applicant does not adequately demonstrate that the need the projected population has for the proposed project is reasonable and adequately supported because the need is based in part on the applicant's assumption of a portion of the NCSH procedure room cases being shifted to SOS as OR cases. See the discussion regarding projected utilization below, which is incorporated herein by reference. Therefore, the projected need, which is based in part on projected utilization, is also questionable.

Projected Utilization **–** In Section C, page 49, the applicant provides projected utilization at SSC and NCSH. SSC's projected utilization is summarized in the following table.

SSC Projected Utilization – OR Services			
	FY 1 (CY 2023)	**FY 2 (CY 2024)**	**FY 3 (CY 2025)**
Operating Rooms			
Total # of Ambulatory ORs (1)	6	6	6
Surgical Cases			
Total # Ambulatory Surgical Cases (2)	5,269	6,169	6,803
Case Times			
Average Case Time – Minutes (3)	69.5	69.5	69.5
Surgical Hours			
Total Ambulatory Surgical Hours (4)	6,104	7,145	7,880
# of ORs Needed			
Group Assignment (5)	6	6	6
Standard Hours per OR per Year (6)	1,312	1,312	1,312
ORs Needed (total hours / 1,312)	4.7	5.4	6.0

Additional sources: Section C, page 49
(1) Proposed # of Ambulatory ORs
(2) Projected Utilization Section Q, Step 7, page 117
(3) Projected Case time Section Q, Step 7, page 117, 2021 SMFP, page 53
(4) Cases x Case Time in minutes / 60 minutes
(5) 2021 SMFP, page 52
(6) 2021 SMFP, page 52

In Section Q Form C Assumptions and Methodology, beginning on page 115, the applicant provides the assumptions and methodology used to project utilization, as summarized below.

- Step 1, page 115
  Project NCSH OR utilization, using a 2% annual growth rate based upon population growth and aging, patient satisfaction, physician recruitment, and increased market share. (Procedure room (PR) cases increase at 4.9% at NCSH in FY2021 and 2.0% thereafter.)

- Step 2, page 115
  Calculate the expected shift of ambulatory surgery OR cases and PR cases from NCSH to the ORs at SSC at 60% for PY1 and 65% for PY2 and PY3.

Projected Shift in Total Surgical Cases From NCSH to SSC

	PY1 CY2023	**PY2 CY2024**	**PY3 CY2025**
Projected Shift of OR Cases	2,512	2,776	2,831
Projected Shift of PR Cases	1,767	1,953	1,992
Projected Total Shift of Cases to SSC ORs	4,279	4,729	4,823

- Step 3, page 116
  Calculate the annual surgical hours for NCSH after the shift based on the 2021 SMFP methodology and assumptions and Step 2 shift of cases resulting in 5,596, 5,383, and 5,491 surgical hours at NCSH in CY2023, CY2024, and CY2025, respectively.

- Step 4, page 116
  Calculate number of ORs needed at NCSH based on number of annual surgical hours projected in accordance with the Group 4 assignment in the 2021 SMFP (1,500), resulting in the need for 3.7 ORs, rounded to four ORs in CY2025.

Projected NCSH Annual Hours

	PY1 CY2023	PY2 CY2024	PY3 CY2025
Inpatient Annual Surgical Hours	3,048	3,109	3,171
Ambulatory Annual Surgical Hours	2,548	2,274	2,320
Total Annual Surgical Hours	5,596	5,383	5,491
Annual Hours per OR	1,500	1,500	1,500
ORs Needed	3.7	3.6	3.7

- Step 5, page 116
  Project SSC OR utilization based solely on the proposed recruitment of 22 new surgeons through CY2025, performing 90 OR cases per surgeon per year.

Projected SSC OR Utilization
By Newly Recruited Surgeons Only

	PY1 CY2023	PY2 CY2024	PY3 CY2025
Projected New Surgeons	11	16	22
Projected OR Cases by New Surgeons	90	90	90
Projected OR Cases by New Surgeons	990	1,440	1,980

- Step 6, page 117
  Project SSC OR utilization based on the proposed shift of OR and PR cases from NCSH in Step 2. Combine the projected cases from the new surgeons, as calculated in Step 5 above.

Projected SSC OR Utilization

	PY1 CY2023	PY2 CY2024	PY3 CY2025
OR Cases Projected to Shift from NCSH to SSC in Step 2	4,279	4,729	4,823
Projected OR Cases by New Surgeons	990	1,440	1,980
Total Projected OR Cases	5,269	6,169	6,803

- Step 7, page 117
  Calculate the annual surgical hours based on the 2021 SMFP assigned Group 6 average case time of 69.5 minutes per case and the total cases calculated in Step 6.

Projected SSC OR Surgical Hours

	PY1 CY2023	**PY2 CY2024**	**PY3 CY2025**
Total OR Cases (Step 6)	5,269	6,169	6,803
Average Case Time	69.5	69.5	69.5
Total Annual Surgical Hours	6,104	7,145	7,880

- Step 8, page 117
  Calculate the number of ORs needed at SSC based on the 2021 SMFP Group 6 assignment of standard hours per OR of 1,312.5.

Projected SSC OR Need

	PY1 CY2023	**PY2 CY2024**	**PY3 CY2025**
Total Annual Surgical Hours	6,104	7,145	7,880
Standard Surgical Hours per OR (Group 6)	1,312.5	1,312.5	1,312.5
Total ORs Needed	4.7	5.4	6.0

As the table above shows, the applicant projects a need for six ORs at SSC in the third project year.

However, as the applicant's projected utilization methodology shows, in Step 2 above, the applicant proposes to shift procedure room cases from NCSH to be performed at SSC. This does not support the need for additional ORs at SSC. It would in fact support the need to maintain procedure room capacity at SSC, as opposed to converting all four of them to ORs. Furthermore, removing the PR cases being shifted to SSC leaves a total of the following OR cases being projected at SSC, per the applicant's methodology.

Projected SSC OR Surgical Hours

	PY1 CY2023	PY2 CY2024	PY3 CY2025
Total OR Cases (Step 6)	5,269	6,169	6,803
Less the PR Cases shifted from NCSH (Step 2)	1,767	1,953	1,992
Total OR Cases	3,502	4,216	4,811
Average Case Time	69.5	69.5	69.5
Total Annual Surgical Hours	4,056	4,884	5,573
Standard Surgical Hours per OR (Group 6)	1,312.5	1,312.5	1,312.5
Total ORs Needed	3.1	3.7	4.2

As the table above summarizes, the total number of projected OR cases at SSC does not support the need for six total ORs at SSC.

Projected utilization is not reasonable and is not adequately supported for the following reasons:

- The applicant counted the projected shift of PR cases from NCSH to SSC as projected OR cases. Cases that can be performed in procedure rooms do not support the need for adding the proposed number of ORs and eliminating all existing procedure rooms.
- Without the PR cases, the applicant does not show a need for the proposed four additional ORs.
- The applicant's projected utilization of OR surgical cases does not meet the performance standard promulgated in 10A NCAC 14C .2013(a).

Access to Medically Underserved Groups

In Section C.8(e), pages 59-60, in response to the change of scope questions, the applicant states:

> *"The projected patient access for Southpoint Surgery Center is expected to be largely the same as the previous Southpoint application #J-11626-18 because the facility location is the same and projected types of ambulatory surgery are largely the same. While the proposed project increases the surgical capacity, Southpoint Surgery center will still be a multispecialty ASC that will have a similar payor mix as the NCSH ambulatory surgery."*

The applicant also discusses access to medically underserved groups in Section B, pages 25-26, and Section L, pages 100-103. The application for Project ID #J-11626-18 adequately demonstrates the extent to which all residents of the area, including underserved groups, were likely to have access to the proposed services. The applicant proposes no changes in the current application which would affect that determination.

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 not conforming to this criterion for all the reasons described above.

J-12065-21/UNC Hospitals-RTP/Develop 40 acute care beds and two ORs

The applicant proposes to develop an acute care hospital, UNC-RTP, with 40 acute care beds and two ORs pursuant to the need determinations in the 2021 SMFP.

On page 32, the applicant states that the hospital will be located at the convergence of NC Highway 54 and NC Highway 147 (in close proximity to I-40) in Research Triangle Park. In Exhibit K.4-1, the applicant also identifies an alternate site for the hospital in the same general

vicinity of Durham County. The applicant states that the proposed UNC-RTP hospital is the first and only acute care facility owned and operated by UNC Health in Durham County, ideally located in a growing metropolitan area that is home to a significant regional population without an acute care hospital facility nearby.

The applicant states that the new hospital facility will bring high quality, convenient healthcare to the residents of the service area by offering emergency, inpatient, and outpatient care, including:

- 40 acute care beds comprised of 32 medical/surgical beds and eight postpartum beds
- Four unlicensed labor, deliver, and recovery (LDR) beds
- 10 unlicensed observation beds
- Two operating rooms
- Two dedicated C-Section operating rooms
- Two unlicensed procedure rooms
- 12 Emergency Department (ED) bays
- Imaging services, including the following:
  - One fixed CT scanner
  - Three X-ray units (two general radiography and one fluoroscopy)
  - Two Ultrasound units
  - One SPECT (nuclear) scanner
  - One mammography unit
  - Mobile pad for contracted mobile MRI services or other mobile technologies
- Other diagnostics, laboratory, and physical and other therapy

Patient Origin – On page 31, the 2021 SMFP defines the service area for acute care beds as *". . . the single or multicounty grouping shown in Figure 5.1."* Figure 5.1, on page 36, shows the multicounty grouping of Durham and Caswell counties as the acute care bed service area. Thus, the service area for acute care beds for this facility is the Durham/Caswell service area. On page 49, the 2021 SMFP defines the service area for ORs as *"...the single or multicounty grouping shown in Figure 6.1."* Figure 6.1, page 55, shows Durham County as its own OR service area. Thus, the service area for ORs for this facility is Durham County. (Note: A typographical error in Table 6C, page 81, identifies the service area as Durham/Caswell. That is not correct: the service area is Durham County, as shown in Figure 6.1, page 55 of the 2021 SMFP.) Facilities may also serve residents of counties not included in their service area. The following table illustrates UNC's projected patient origin for the entire UNC-RTP facility for the first three full fiscal years. UNC's fiscal years run from July 1 through June 30.

UNC-RTP Projected Patient Origin – Entire Facility

County	FY2027		FY2028		FY2029	
	# Patients	% of Total	# Patients	% of Total	# Patients	% of Total
Durham	85,505	90.0%	133,304	90.0%	184,865	90.0%
Wake	8,709	9.2%	13,578	9.2%	18,829	9.2%
Chatham	609	0.6%	950	0.6%	1,318	0.6%
Caswell	182	0.2%	284	0.2%	394	0.2%
Total	**95,006**	**100.0%**	**148,115**	**100.0%**	**205,405**	**100.0%**

Source: Section C, page 41

The following tables illustrate projected patient origin for the proposed project's stated service components.

Projected Patient Origin – Acute Care Discharges

Area	FY2027		FY2028		FY2029	
	# Patients	% of Total	# Patients	% of Total	# Patients	% of Total
Durham	943	90.0%	1,461	90.0%	2,014	90.0%
Wake	96	9.2%	149	9.2%	205	9.2%
Chatham	7	0.6%	10	0.6%	14	0.6%
Caswell	2	0.2%	3	0.2%	4	0.2%
Total	**1,048**	**100.0%**	**1,624**	**100.0%**	**2,238**	**100.0%**

Source: Section C, page 39

Projected Patient Origin – Outpatient Surgical Services

Area	FY2027		FY2028		FY2029	
	# Patients	% of Total	# Patients	% of Total	# Patients	% of Total
Durham	671	90.0%	1,078	90.0%	1,539	90.0%
Wake	68	9.2%	110	9.2%	157	9.2%
Chatham	5	0.6%	8	0.6%	11	0.6%
Caswell	1	0.2%	2	0.2%	3	0.2%
Total	**745**	**100.0%**	**1,198**	**100.0%**	**1,711**	**100.0%**

Source: Section C, page 39

Projected Patient Origin – Emergency Department

Area	FY2027		FY2028		FY2029	
	# Patients	% of Total	# Patients	% of Total	# Patients	% of Total
Durham	4,134	90.0%	6,404	90.0%	8,827	90.0%
Wake	421	9.2%	652	9.2%	899	9.2%
Chatham	29	0.6%	46	0.6%	63	0.6%
Caswell	9	0.2%	14	0.2%	19	0.2%
Total	**4,593**	**100.0%**	**7,116**	**100.0%**	**9,807**	**100.0%**

Source: Section C, page 39

Projected Patient Origin – Imaging						
Area	FY2027		FY2028		FY2029	
	# Patients	% of Total	# Patients	% of Total	# Patients	% of Total
Durham	10,214	90.0%	15,927	90.0%	22,090	90.0%
Wake	1,040	9.2%	6,622	9.2%	2,250	9.2%
Chatham	73	0.6%	114	0.6%	157	0.6%
Caswell	22	0.2%	34	0.2%	47	0.2%
Total	**11,349**	**100.0%**	**17,696**	**100.0%**	**24,544**	**100.0%**

Source: Section C, page 40

Projected Patient Origin – Therapy						
Area	FY2027		FY2028		FY2029	
	# Patients	% of Total	# Patients	% of Total	# Patients	% of Total
Durham	12,476	90.0%	19,452	90.0%	26,980	90.0%
Wake	1,271	9.2%	1,981	9.2%	2,748	9.2%
Chatham	89	0.6%	139	0.6%	192	0.6%
Caswell	27	0.2%	41	0.2%	57	0.2%
Total	**13,862**	**100.0%**	**21,614**	**100.0%**	**29,978**	**100.0%**

Source: Section C, page 40

Projected Patient Origin – Lab						
Area	FY2027		FY2028		FY2029	
	# Patients	% of Total	# Patients	% of Total	# Patients	% of Total
Durham	57,067	90.0%	88,981	90.0%	123,415	90.0%
Wake	5,813	9.2%	9,063	9.2%	12,570	9.2%
Chatham	407	0.6%	634	0.6%	880	0.6%
Caswell	122	0.2%	190	0.2%	263	0.2%
Total	**63,408**	**100.0%**	**98,868**	**100.0%**	**137,128**	**100.0%**

Source: Section C, page 40

In Section C, pages 38-39, the applicant discusses the assumptions and methodology used to project patient origin and provides an explanation of the Durham County service area by ZIP code in Form C Utilization – Assumptions and Methodology, page 2. The applicant's assumptions are reasonable and adequately supported.

Analysis of Need

In Section C, pages 42-67, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. On page 42, the applicant states that the need for the proposed project is comprised of several factors, including:

- Population growth and aging in Durham County (pages 43-45)
- Need for a new hospital in Durham County (pages 46-53)
- Need for UNC Hospitals hospital-based services in Durham County (pages 53-59
- Need for acute care beds (pages 59-64)
  - SMFP acute care bed need methodology

  - Need for lower acuity community hospital beds in Durham County
- Need for operating rooms (pages 64-66)
  - SMFP operating room need methodology
  - Surgical services demand trends
- Need for other services to support the inpatient beds and operating rooms (page 66)

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

- The applicant uses reliable and publicly available data to demonstrate the projected population growth and aging in the service area.
- The applicant provides data to support its belief that there is a need for a new hospital in Durham County, located in an area away from the three existing acute care hospitals in Durham County.
- The applicant provides reasonable and adequately supported data as well as practical reasons to support its belief that there is a need for UNC Hospitals hospital-based services in Durham County.
- The applicant provides reasonable and adequately supported data to support the need for additional acute care beds and operating rooms in Durham County.
- The applicant provides reasonable and adequately supported data as well as practical reasons as to the need for other ancillary and support services to support the proposed acute care beds and operating rooms.

The information provided above adequately supports the need for the applicant to develop a new hospital with 40 acute care beds and two ORs in Research Triangle Park in Durham County.

Projected Utilization

In Section Q, Forms C.1b-4b, pages 1-5, the applicant provides projected utilization, as illustrated in the following tables.

UNC-RTP Projected Utilization Acute Care Services			
	FY2027	**FY2028**	**FY2029**
UNC-RTP Acute Care Beds			
# of Beds	40	40	40
# of Patient Days	4,970	7,750	10,749
Total Patients (Discharges per Section Q, page 1)	1,048	1,624	2,238
ALOS*	4.7	4.8	4.8
Occupancy Rate	34.0%	53.1%	73.6%
CT Scanner (Tab C - not filled out)			
# of Units	1	1	1
# of Scans	3,208	5,002	6,937
# of HECT Units (1.66:1)	5,332	8,313	11,530
Fixed X-ray (including Fluoroscopy)			
# of Units	3	3	3
# of Procedures	4,994	7,786	10,799
Mammography			
# of Units	1	1	1
# of Procedures	1,291	1,966	2,727
Nuclear Medicine			
# of Units	1	1	1
# of Procedures	151	236	327
Ultrasound			
# of Units	2	2	2
# of Procedures	1,736	2,707	3,754
Emergency Department			
# of Bays (Rooms)	12	12	12
# of Visits	4,593	7,116	9,807
Observation Beds			
# of Beds	10	10	10
Days of Care	516	805	1,116
Laboratory			
# of Tests	63,408	98,868	137,128
Therapy			
PT Treatments	7,665	11,952	16,577
ST Treatments	688	1,073	1,489
OT Treatments	5,508	8,589	11,912

*ALOS = Average Length of Stay

Totals may not sum due to rounding

UNC-RTP Projected Operating Room and Procedure Room Services			
	FY2027	**FY2028**	**FY2029**
ORs - # of Rooms by Type			
# of Dedicated C-Section ORs	2	2	2
# of Shared ORs	2	2	2
Total ORs	4	4	4
# of Excluded ORs	2	2	2
Adjusted Planning Inventory	2	2	2
Surgical Cases			
# of Inpatient Cases (excludes C-Section)	333	535	764
# of Outpatient Cases	506	813	1,161
Total # Surgical Cases	839	1,348	1,926
Case Times (Section C, Question 5(c))			
Inpatient	113.8	113.8	113.8
Outpatient	71.5	71.5	71.5
Surgical Hours			
Inpatient	632	1,015	1,450
Outpatient	603	969	1,384
Total Surgical Hours	1,235	1,984	2,834
# of ORs Needed			
Group Assignment	4	4	4
Standard Hours per OR per Year	1,500	1,500	1,500
Total Surgical Hours / Standard Hours per OR per Year (ORs Needed)	0.82	1.32	1.89
Procedure Rooms			
Rooms	2	2	2
Procedures	239	385	549

Totals may not sum due to rounding

In Section Q Form C Utilization–Assumptions and Methodology, pages 1-20, the applicant provides the assumptions and methodology used to project utilization, which are summarized below.

Acute Care Services

- The applicant provides days of care for Durham County residents for CY2017-CY2019 and calculates a CAGR of 2.1% for Medicine, 6.4% for surgery, -3.8% for obstetrics and 1.9% for total days of care. (page 2)
- The applicant states that certain higher acuity services are not projected to be provided. (page 3)
- The applicant provides potential days of care, after excluding the higher acuity services, from the CY2017-CY2019 days of care for Durham County residents provided on page 2 and calculates a CAGR of 2.9% for Medicine, 7.1% for surgery, -0.9% for obstetrics and 3.4% for total days of care. (page 3)
- The applicant assumes the identified potential days of care will grow through 2029 at a rate equal to the CY2017-CY2019 CAGR for each service, resulting in the following days of care. (pages 3-4)

UNC-RTP Potential Days of Care for Durham County Residents by Calendar Year

	CY2019	CY2020	CY2021	CY2022	CY2023	CY2024	CY2025	CY2026	CY2027	CY2028	CY2029
Medicine	54,817	56,404	58,037	59,717	61,445	63,224	65,054	66,937	68,875	70,869	72,920
Surgery	22,187	23,767	25,460	27,273	29,215	31,296	33,524	35,912	38,469	41,209	44,144
Obstetrics	11,530	11,421	11,313	11,206	11,100	10,996	10,892	10,789	10,687	10,586	10,486
Total Days	88,534	91,592	94,809	98,196	101,761	105,515	109,470	113,638	118,031	122,664	127,550

- The applicant converts calendar year to the hospital's fiscal year (FY2027 = 0.5 x CY2026 + 0.5 x CY2027), resulting in the following potential days of care for Durham County residents. (page 4)

UNC-RTP Potential Days of Care for Durham County Residents

	FY2027	FY2028	FY2029
Medicine	67,906	69,872	71,895
Surgery	37,191	39,839	42,677
Obstetrics	10,738	10,636	10,536
Total Days	115,835	120,348	125,107

- The applicant analyzed UNC Health's CY2017-CY2019 market share of the Durham County residents' potential days of care, resulting in an average of 8.5% for medicine, 12.1% for surgery, 15.6% for obstetrics, and 10.3% for total days of care. These percentages reflect UNC Health's market share of Durham County residents without a facility in Durham County. (pages 4-5)
- The applicant states that for conservatism, it projects that UNC-RTP will serve 75 percent of the average UNC Health CY2017-CY2019 market share in FY2029 (for example 75% of 8.5% for medicine = 6.3%). The applicant states that it ramps up to the 75% over the three years with the projected share in FY2027 and FY2028 assumed to be one-half and three-quarters, respectively, of the FY2029 assumption, as shown below. (page 5)

	FY2027	FY2028	FY2029	UNC Health 2017-19 Avg
Medicine	3.2%	4.8%	6.3%	8.5%
Surgery	4.5%	6.8%	9.1%	12.1%
Obstetrics	5.9%	8.8%	11.7%	15.6%

- Based on the above assumptions, the applicant proposes the following acute care days at UNC-RTP from Durham County residents. (pages 5-6)

UNC-RTP Projected Days of Care for Durham County Residents

	FY2027	FY2028	FY2029
Medicine	2,156	3,327	4,565
Surgery	1,688	2,712	3,873
Obstetrics	630	936	1,236
Durham County Days	4,473	6,975	9,674
Durham County ADC	12.3	19.1	26.5

- The applicant then estimates the number of patients that would seek care at UNC-RTP from outside of Durham County (in-migration). The applicant analyzed the in-migration for DUH, DRH, and NCSH at 71.2%, 50.1% and 71.6%, respectively. The applicant states that it also examined the in-migration of all 116 North Carolina acute care hospitals (Exhibit C.5-1) to determine a reasonable and appropriate in-migration rate for the proposed facility and found that fewer than ten facilities had in-migration of less than 10%. For conservatism, the applicant estimates in-migration at only 10%, resulting in the following projection. (pages 6-7)

UNC-RTP Projected ADC and Occupancy

	FY2027	FY2028	FY2029
Durham County Days	4,473	6,975	9,674
In-migration (10%)	497	775	1,075
Total Acute Care Days	4,970	7,750	10,749
Total ADC	13.6	21.2	29.4
Facility Beds	40	40	40
Occupancy	34.0%	53.1%	73.6%

- The applicant bases projected discharges on its projected days of care, including the in-migration, and the CY2019 average length of stay for Durham County residents at UNC hospitals, resulting in the following UNC-RTP projected discharges. (pages 7-8)

UNC-RTP Projected Discharges

	CY2019 ALOS	FY2027	FY2028	FY2029
Medicine	5.3	453	699	959
Surgery	5.6	333	535	764
Obstetrics	2.7	262	389	514
Total Discharges		1,048	1,624	2,238

Based on the fact that UNC-RTP projects to serve approximately 9,600 of the approximately 39,000 Durham County resident days of care and in-migration of approximately 1,000 in FY2029, the applicant states that it does not expect UNC-RTP to impact the other hospitals currently serving Durham County.

Surgical Services

Operating Room

- The applicant assumes one inpatient surgical case for each inpatient surgery discharge. Accordingly, the applicant projects the following inpatient surgical cases, as shown in the table for total UNC-RTP discharges in the projections for acute care services above and on page 8 of the assumptions and methodology. (page 15)

UNC-RTP
Projected Inpatient Surgical Cases

	FY2027	FY2028	FY2029
Surgery	333	535	764

- The applicant determines the number of inpatient surgical cases to be 90% of the total projected discharges, or 688 in FY2029 (764 x .90). (page 16)
- The applicant projects the number of outpatient surgical cases based on the ratio of hospital-based outpatient surgical cases to inpatient surgical cases for Durham County residents during FY2019 (1.5:1), resulting in the following total number of surgical cases. (pages 16-17)

UNC-RTP Surgical Cases

	FY2027	FY2028	FY2029
Inpatient Cases	333	535	764
Outpatient Cases	506	813	1,161
Total Surgical Cases	839	1,348	1,926

Procedure Room

The applicant bases the projected utilization of its procedure rooms on the experience of UNC Hillsborough's FY2019 ratio of procedure room cases to operating room cases (0.29), resulting in projected UNC-RTP procedure room cases of 239, 385, and 549 for FY2027, FY2028 and FY2029, respectively. (page 18) The applicant states:

> *"Given the robust utilization of the two surgical operating rooms and the efficiencies of segregating typically shorter, fast-turnaround procedures from longer surgical cases performed in operating rooms, the proposed facility needs two procedure rooms to accommodate these cases especially in instances of overlap in planned and unplanned surgeries."*

LDR and C-Section Rooms

- The applicant projects the following obstetrical discharges, as shown in the table for total UNC-RTP discharges in the projections for acute care services above and on page 8 of the assumptions and methodology. (page 19)

UNC-RTP Projected Obstetrical Discharges

	FY2027	FY2028	FY2029
Obstetrics	262	389	514

- According to Truven data, in CY2019, 90.0% of Durham County obstetrics acute care discharges within the services expected to be provided by UNC-RTP resulted in a delivery and, of those deliveries, 23.7% were performed by C-Section, resulting in the following number of deliveries and C-Sections. (page 19)

UNC-RTP Projected Births and C-Sections

	FY2027	FY2028	FY2029
Obstetric Discharges	262	389	514
Deliveries (90.0%)	236	350	463
C-Sections (23.7%)	56	83	110

- Following the recommendations from the American College of Obstetricians and Gynecologists (ACOG), the applicant chooses to develop two dedicated C-section rooms. On page 20, the applicant states that the need to develop a second dedicated C-section room is not driven by expected utilization of the room, but by the need to mitigate the risk of a lack of timely surgical availability for emergency cases.

Emergency Department

- The applicant uses Truven data to determine that 61.4% of Durham County resident acute care discharges in CY2019 were admitted through the ED. Consistent with that historical experience, the applicant projects that 61.4% of UNC-RTP's projected discharges will be admitted through the ED, resulting in the following ED admissions. (page 9)

	FY2027	FY2028	FY2029
Total Discharges	1,048	1,624	2,238
% Admitted from ED	61.4%	61.4%	61.4%
ED Admissions	644	997	1,374

- Truven data provides that 14% of ED visits for Durham County residents in UNC Hospitals result in an acute care admission. The following table projects UNC-RTP's projected ED visits. (page 9)

	FY2027	FY2028	FY2029
ED Admissions	644	997	1,374
ED Admissions as a % of Visits	14.0%	14.0%	14.0%
ED Visits	4,593	7,116	9,807
Visits Per ED Bay (12)	383	593	817

Imaging and Ancillary Services

- The applicant examines the FY2019 imaging and ancillary hospital data per acute care day for selected like-sized and suburban hospitals (as reported on their LRAs) and finds that UNC Hillsborough provides the lowest per day ratios in each imaging service category. Thus, the applicant states its belief that using similar ratios would be reasonable to project imaging and ancillary ratios at UNC-RTP. (pages 11-12)
- The applicant states that other ancillary services offered at the proposed facility do not have publicly available utilization data. The applicant states that using the UNC Hillsborough experience for projecting those services at UNC-RTP would be a consistent and conservative approach. (pages 12-13)
- The following table reflects UNC-RTP's projected imaging and ancillary services based on the two assumptions listed above and UNC-RTP's projected acute care days. (page 14)

UNC-RTP Imaging and Ancillary Projected Utilization

	Ratio to Days	FY2027	FY2028	FY2029
Projected AC Days		4,970	7,750	10,749
CT Scans	0.60	3,208	5,002	6,937
Ultrasound Procedures	0.30	1,736	2,707	3,754
X-ray Procedures	1.00	4,994	7,786	10,799
Nuclear Procedures	0.03	151	236	327
Mammography Procedures	0.30	1,261	1,966	2,727
Physical Therapy Units	1.50	7,665	11,952	16,577
Occupational Therapy Units	1.10	5,508	8,589	11,912
Speech Therapy Units	0.10	688	1,073	1,489
Lab Tests	12.80	63,408	98,868	137,128

- The applicant provides the calculations for CT HECT units using UNC Hillsborough's FY2019 ratio of HECT units to CT scans (1.66), as shown below. (page 14)

	FY2027	FY2028	FY2029
CT Scans	3,208	5,002	6,937
HECT Units per Scan	1.66	1.66	1.66
HECT Units	5,332	8,313	11,530

Observation Beds

The applicant bases the projected utilization of its observation beds on the experience of UNC Hillsborough's FY2019 ratio of observation days to acute care days (0.10), resulting in projected observation patient days of 516, 805, and 1,116 for FY2027, FY2028 and FY2029, respectively.

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

- The applicant uses publicly available data to determine Durham County residents' potential days of care for UNC-RTP's projected services.
- The applicant uses an historical 2-yr CAGR to project days of care going forward.
- The applicant bases projected surgical, obstetrics, emergency, imaging/ancillary, observation bed services on historical Truven data reported for Durham County residents, historical UNC Hillsborough experience and/or historical UNC health system services for Durham County residents.

Access to Medically Underserved Groups

In Section C, pages 72-73, the applicant states:

"As North Carolina's only state-owned, comprehensive, full-service hospital system, UNC Health, including UNC Hospitals as well as the new acute care hospital proposed in this application, has the obligation to accept any North Carolina citizen requiring medically necessary treatment. No North Carolina citizen is presently denied access to non-elective care because of race, sex, creed, age, handicap, financial status, or lack of medical insurance."

On page 73, the applicant provides the estimated percentage for medically underserved groups during the third full fiscal year, as shown in the following table.

Medically Underserved Groups	Percentage of Total Patients
Low income persons	
Racial and ethnic minorities	51.9%
Women	64.4%
Persons with disabilities	
Persons 65 and older	21.6%
Medicare beneficiaries	24.4%
Medicaid recipients	12.2%

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.

J-12069-21/Duke University Hospital/Add 40 acute care beds

The applicant proposes to add 40 acute care beds at DUH pursuant to the need determination in the 2021 SMFP for a total of 1,102 acute care beds upon completion of this project, Project ID #J-11717-19 (add 34 acute care beds for a total of 1,062) and Project ID #J-11426-17 (add 90 acute care beds for a total of 1,028). The additional 40 beds will be adult medical/surgical inpatient acute care beds developed in space in the Duke Medial Pavilion (DMP) bed tower after the relocation of existing beds from the DMP into other space within the hospital facility. The applicant is not proposing to acquire additional major medical equipment or develop any other health services as part of this proposed project.

Patient Origin – On page 31, the 2021 SMFP defines the service area for acute care beds as *". . . the single or multicounty grouping shown in Figure 5.1."* Figure 5.1, on page 36, shows the multicounty grouping of Durham and Caswell counties as the acute care bed service area. DUH is located in Durham County; thus, the service area for acute care beds for this facility is the Durham/Caswell service area. Facilities may also serve residents of counties not included in their service area. The following table illustrates DUH's last full fiscal year (page 28) and projected (page 30) patient origin for acute care beds.

DUH Patient Origin – Acute Care Beds (adult inpatient)

County	Last Full FY 7/19-6/20		FY2026 7/25-6/26		FY2027 7/26-6/27		FY2028 7/27-6/28	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Alamance	1,411	4.0%	1,611	3.9%	1,627	3.9%	1,643	3.9%
Caswell	215	0.6%	196	0.5%	198	0.5%	199	0.5%
Chatham	188	0.5%	276	0.7%	279	0.7%	282	0.7%
Cumberland	833	2.4%	976	2.4%	985	2.4%	995	2.4%
Durham	10,022	28.5%	11,674	28.1%	11,791	28.1%	11,909	28.1%
Franklin	538	1.5%	725	1.7%	732	1.7%	739	1.7%
Granville	1,481	4.2%	1,629	3.9%	1,645	3.9%	1,662	3.9%
Guilford	585	1.7%	628	1.5%	634	1.5%	641	1.5%
Harnett	309	0.9%	357	0.9%	360	0.9%	364	0.9%
Johnston	365	1.0%	534	1.3%	539	1.3%	544	1.3%
Lee	241	0.7%	297	0.7%	300	0.7%	303	0.7%
Nash	268	0.8%	405	1.0%	409	1.0%	413	1.0%
Orange	1,406	4.0%	1,645	4.0%	1,661	4.0%	1,678	4.0%
Person	1,100	3.1%	1,272	3.1%	1,285	3.1%	1,298	3.1%
Robeson	588	1.7%	676	1.6%	683	1.6%	690	1.6%
Vance	1,007	2.9%	1,176	2.8%	1,187	2.8%	1,199	2.8%
Wake	4,439	12.6%	5,110	12.3%	5,161	12.3%	5,213	12.3%
Warren	333	0.9%	357	0.9%	360	0.9%	364	0.9%
Wilson	254	0.7%	262	0.6%	265	0.6%	268	0.6%
Other NC Counties*	5,485	15.6%	6,633	16.0%	6,699	16.0%	6,766	16.0%
Virginia	2,094	6.0%	2,823	6.8%	2,851	6.8%	2,880	6.8%
Other States	1,945	5.5%	2,236	5.4%	2,259	5.4%	2,281	5.4%
TOTAL	**35,107**	**100.0%**	**41,496**	**100.0%**	**41,911**	**100.0%**	**42,330**	**100.0%**

*The applicant does not identify the counties that comprise this category of other NC counties

The applicant also provides the historical and projected patient origin for the entire DUH facility on pages 29 and 31, respectively.

In Section C, page 30, the applicant provides the assumptions and methodology used to project patient origin, stating:

> *"The disruption in utilization patterns in March-June 2020 as a result of the COVID-19 public health emergency also affected patient origin patterns, and DUHS believes that FY 2021 experience is a more reasonable baseline for projecting future patient origin. DUHS is not projecting any material change in patient origin for any service line based on geography as a result of this project."*

The applicant's assumptions are reasonable and adequately supported.

Analysis of Need – In Section C, pages 32-41, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. Pursuant to

the need determination in the 2021 SMFP, DUHS proposes to develop 40 additional acute care beds at DUH. The applicant states that the need for the proposed project is based on and supported by the following:

- The 2021 SMFP acute care bed methodology (pages 32-33)
- DUH inpatient utilization (pages 33-36)
- DUH service area growth (pages 36-37)
- DUHS provider network and strategic growth (page 37)

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

- There is a need determination for 40 acute care beds in the Durham/Caswell county acute care service area in the 2021 SMFP. The applicant is applying to develop 40 acute care beds in Durham County in accordance with the need determination in the 2021 SMFP.
- The applicant uses clearly cited, reasonable, and verifiable historical and demographical data to make the assumptions with regard to identifying the population to be served.
- The applicant uses a reasonable methodology and reasonable assumptions to demonstrate the need the population projected to be served has for the proposed acute care services.

Projected Utilization

In Section Q Forms C.1a and Forms C.1b, the applicant provides DUH's historical, interim and projected utilization for its acute care beds. The following tables summarize the historical, interim and projected utilization for all types of acute care beds at DUH.

DUH Historical and Interim Acute Care Bed Utilization

	Last Full FY2020	Interim FY2021	Interim FY2022	Interim FY2023	Interim FY2024	Interim FY2025
Total # of Beds	960 (979*)	960	1,025	1,042	1,062	1,062
# of Discharges	40,059	40,852	42,384	42,994	43,614	44,242
# of Patient Days	290,824	309,448	321,803	326,333	330,926	335,587
Average Length of Stay	7.26	7.57	7.59	7.59	7.59	7.59
Occupancy Rate	82% [81%]	87% [88%]	84% [86%]	84% [86%]	85%	87%

*979 includes 19 inpatient beds temporarily operated pursuant to COVID-19 emergency waivers and not permanently licensed

DUH Projected Acute Care Bed Utilization

	1st Full FY FY2026	2nd Full FY FY2026	3rd Full FY FY2026
Total # of Beds	1,102	1,102	1,102
# of Discharges	44,879	45,526	46,182
# of Patient Days	340,313	345,108	349,972
Average Length of Stay	7.58	7.58	7.58
Occupancy Rate	85%	86%	87%

In Section Q Forms C.1 assumptions, pages 89-90, the applicant provides the methodology and assumptions for projecting utilization, as summarized below.

- All fiscal years run from July through June.
- FY2021 data are annualized based on July through December 2020.
- Impacts of COVID-19 are expected to decrease into 2022 with FY2022 discharges projected to return to FY2019 utilization levels.
- The applicant projects growth rate assumptions of 1.5% and 1.0% for adult and pediatric discharges, respectively. These growth rates are below the growth experienced for FY2017-FY2019. The applicant expects that the growth rates will return to prior years when the existing capacity constraints are eased with the implementation of additional beds.
- Inpatient (IP) days are based on the projected discharges, average daily census (ADC), and the FY2021 actual average length of stay (ALOS), as shown in the tables below.

DUH Inpatient Adult Discharges

	FY2020	FY2021	FY2022	FY2023	FY2024	FY2025	FY2026	FY2027	FY2028
Growth Rate				1.5%	1.5%	1.5%	1.5%	1.5%	1.5%
Discharges	35,107	36,072	37,302	37,862	38,429	39,006	39,591	40,185	40,788
IP Days	238,726	253,430	262,246	266,180	270,172	274,225	278,338	282,513	286,751
ADC	654	694	718	729	740	751	763	774	786
ALOS	6.80	7.03	7.03	7.03	7.03	7.03	7.03	7.03	7.03

DUH Inpatient Pediatric Discharges

	FY2020	FY2021	FY2022	FY2023	FY2024	FY2025	FY2026	FY2027	FY2028
Growth Rate				1.00%	1.00%	1.00%	1.00%	1.00%	1.00%
Discharges	4,952	4,780	5,082	5,133	5,184	5,236	5,288	5,341	5,395
IP Days	52,098	56,018	59,557	60,153	60,754	61,362	61,975	62,595	63,221
ADC	143	153	163	165	166	168	170	171	173
ALOS	10.52	11.72	11.72	11.72	11.72	11.72	11.72	11.72	11.72

DUH Total Inpatient Discharges

	FY2020	FY2021	FY2022	FY2023	FY2024	FY2025	FY2026	FY2027	FY2028
Total Beds	979	960	1,025	1,042	1,062	1,062	1,102	1,102	1,102
Total Discharges	40,059	40,852	42,384	42,994	43,614	44,242	44,879	45,526	46,182
Total IP Days	290,824	309,448	321,803	326,333	330,926	335,587	340,313	345,108	349,972
Total ADC	797	848	882	894	907	919	932	946	959
Total Bed Utilization	82% [81%]	87% [88%]	84% [86%]	84% [86%]	85%	87%	85%	86%	87%
ALOS	7.26	7.57	7.59	7.59	7.59	7.59	7.58	7.58	7.58

As shown in the table above, the applicant projects DUH will have a utilization rate of 87% in the third year of operation following project completion.

Duke Health System

The Duke System of acute care beds in the Durham/Caswell county service area consists of DUH and Duke Regional Hospital (DRH). Pursuant to 10A NCAC 14C .3803(a), an applicant proposing to add new acute care beds to a service area must reasonably project that all acute care beds in the service area under common ownership will have a utilization of at least 75.2 percent when the projected ADC is greater than 200 patients.

However, DUH is an academic medical center teaching hospital, and NC Gen. Stat. 131E-183(b) provides, in part:

> *". . . 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."*

Thus, this applicant is not required to provide the projected utilization of acute care beds at DRH. The applicant adequately demonstrates that DUH will have a utilization rate of at least 75.2%.

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

- There is a need determination in the 2021 SMFP for 40 acute care beds in the Durham/Caswell county acute care bed service area.
- The applicant relies on its historical utilization in projecting future utilization.
- The applicant's projected utilization meets the performance standard promulgated in 10A NCAC 14C .3803(a).

Access to Medically Underserved Groups

In Section C, page 42, the applicant states:

> *"All individuals including low-income persons, racial and ethnic minorities, women, persons with disabilities, persons 65 and older, Medicare beneficiaries, Medicaid recipients, and other underserved groups, will have access to DUH, as clinically appropriate."*

On page 42, the applicant provides the estimated percentage for medically underserved groups to the proposed service component in the third full fiscal year, as shown in the following table.

Medically Underserved Groups	Percent of Total Patients
Low income persons^	20.0%
Racial and ethnic minorities	40.6%
Women	52.6%
Persons with disabilities	*
Persons 65 and older	50.0%
Medicare beneficiaries	50.2%
Medicaid recipients	13.1%

^Estimated to include Medicaid beneficiaries and charity/reduced care financial assistance recipients
*DUHS does not maintain data regarding 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.

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.

J-12070-21/Duke University Hospital/Develop two ORs

The applicant proposes to develop two additional ORs pursuant to the need determination in the 2021 SMFP for a total of 69 ORs. This is a change of scope to Project ID #J-11631-18 (develop two ORs and three procedure rooms for a total of 67 ORs).

Patient Origin – On page 49, the 2021 SMFP defines the service area for ORs as *"…the single or multicounty grouping shown in Figure 6.1."* Figure 6.1, page 55, shows Durham County as its own OR planning area. Thus, the service area for this facility is the Durham County. Facilities may also serve residents of counties not included in their service area.

The following table illustrates the current and projected OR patient origin at DUH.

DUH Projected Patient Origin Operating Rooms

County	Last Full FY 7/19-6/20		FY2026 7/25-6/26		FY2027 7/26-6/27		FY2028 7/27-6/28	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Alamance	1,345	3.8%	1,471	3.8%	1,489	3.8%	1,518	3.8%
Caswell	171	0.5%	182	0.5%	184	0.5%	188	0.5%
Chatham	239	0.7%	271	0.7%	274	0.7%	279	0.7%
Cumberland	1,046	2.9%	1,173	3.0%	1,188	3.0%	1,211	3.0%
Durham	7,722	21.7%	8,536	21.8%	8,640	21.8%	8,807	21.8%
Franklin	442	1.2%	471	1.2%	476	1.2%	486	1.2%
Granville	1,123	3.1%	1,238	3.2%	1,253	3.2%	1,277	3.2%
Guilford	745	2.1%	856	2.2%	866	2.2%	883	2.2%
Harnett	334	0.9%	370	0.9%	374	0.9%	382	0.9%
Johnston	449	1.3%	530	1.4%	537	1.4%	547	1.4%
Lee	245	0.7%	315	0.8%	319	0.8%	325	0.8%
Nash	324	0.9%	391	1.0%	395	1.0%	403	1.0%
Orange	1,780	5.0%	1,939	4.9%	1,963	4.9%	2,001	4.9%
Person	946	2.7%	1,121	2.9%	1,134	2.9%	1,156	2.9%
Robeson	557	1.6%	533	1.4%	539	1.4%	550	1.4%
Vance	736	2.1%	788	2.0%	798	2.0%	813	2.0%
Wake	5,596	15.7%	6,253	15.9%	6,329	15.9%	6,452	15.9%
Warren	216	0.6%	243	0.6%	246	0.6%	251	0.6%
Wilson	302	0.8%	258	0.7%	261	0.7%	266	0.7%
Other NC Counties*	6,801	19.1%	7,405	18.9%	7,496	18.9%	7,641	18.9%
Virginia	2,326	6.5%	2,689	6.9%	2,722	6.9%	2,774	6.9%
Other States	2,222	6.2%	2,180	5.6%	2,206	5.6%	2,249	5.6%
TOTAL	**35,667**	**100.0%**	**39,212**	**100.0%**	**39,690**	**100.0%**	**40,458**	**100.0%**

*The applicant does not identify the counties that comprise this category of other NC counties

In Section C, page 29, the applicant provides the assumptions and methodology used to project patient origin, providing both service line and facility patient origin on pages 27-30. The applicant's assumptions are reasonable and adequately supported.

Analysis of Need – In Section C, pages 31-37, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. Pursuant to the need determination in the 2021 SMFP, DUHS proposes to develop two additional ORs at DUH. The applicant states that the factors supporting need in the previously approved Project ID #J-11631-18 continue to apply. The applicant states that the need for the project is further supported by the following updated factors:

- Historical growth in surgical volumes at DUH and DUHS facilities and need for access to DUH's tertiary and quaternary services (pages 32-34)
- Growth in provider network (pages 36-37)
- Growth in inpatient capacity (pages 34-35)
- Projected demographic changes in DUH's service area (pages 35-36)

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

- There is a need determination for four ORs in Durham County in the 2021 SMFP. In this application, the applicant is applying to develop two of the four ORs in Durham County in accordance with the OR need determination in the 2021 SMFP
- The applicant uses DUHS historical and updated demographic data to identify the population to be served, its projected growth, and the need that the identified population to be served has for the proposed services.

Projected Utilization

In Section Q Forms C.3a and Forms C.3b, the applicant provides DUH's interim and projected OR utilization. The following tables summarize the historical, interim and projected utilization at DUH.

DUH Interim Utilization – ORs

	Interim FY2021 7/20-6/21	Interim FY2022 7/21-6/22	Interim FY2023 7/22-6/23	Interim FY2024 7/23-6/24	Interim FY2025 7/24-6/25
Operating Rooms					
Open Heart ORs	10	10	10	10	10
Dedicated C-Section ORs					
Shared ORs	46	46	46	46	46
Dedicated Ambulatory ORs	9	9	9	9	9
Total # of ORs	65	65	65	65	65
Excluded # of ORs	1	1	1	1	1
Adjusted Planning Inventory of ORs (1)	66	66	66	66	66
Surgical Cases					
# of C-Section Surgical Cases					
# of Inpatient Surgical Cases (2)	19,121	19,402	19,688	19,978	20,272
# of Outpatient Surgical Cases	23,246	22,456	22,300	22,040	21,669
Total # of Surgical Cases (2)	42,366	41,858	41,988	42,017	41,941
Case Times					
Inpatient	262.1	262.1	262.1	262.1	262.1
Outpatient	139.5	139.5	139.5	139.5	139.5
Surgical Hours					
Inpatient (3)	83,525	84,755	86,003	87,270	88,555
Outpatient (4)	54,046	52,210	51,848	51,242	50,381
Total	137,571	136,965	137,852	138,512	138,936
# of ORs Needed					
Group Assignment (5)	1	1	1	1	1
Standard Hours/OR/Year (6)	1,950	1,950	1,950	1,950	1,950
Total Surgical Hours/OR/Year	70.5	70.2	70.7	71.0	71.2

(1) Includes two approved but undeveloped ORs (J-11631-18)
(2) Exclude C-Sections performed in Dedicated C-Section ORs
(3) Inpatient Cases (exclude C-Sections performed in dedicated C-Section ORs) x Inpatient Case Time in minutes] / 60 minutes
(4) (Outpatient Cases x Outpatient Case Time in minutes) / 60 minutes
(5) From Section C, Question 12(a)
(6) From Section C, Question 12(b)

DUH Projected Utilization – ORs

	Interim FY2026 7/25-6/26	Interim FY2027 7/26-6/27	Interim FY2028 7/27-6/28
Operating Rooms			
Open Heart ORs	10	10	10
Dedicated C-Section ORs			
Shared ORs	46	46	46
Dedicated Ambulatory ORs	13	13	13
Total # of ORs	69	69	69
Excluded # of ORs	1	1	1
Adjusted Planning Inventory of ORs (1)	68	68	68
Surgical Cases			
# of C-Section Surgical Cases			
# of Inpatient Surgical Cases (2)	20,571	20,813	21,103
# of Outpatient Surgical Cases	21,955	22,230	22,754
Total # of Surgical Cases (2)	42,526	43,042	43,857
Case Times			
Inpatient	262.1	262.1	262.1
Outpatient	139.5	139.5	139.5
Surgical Hours			
Inpatient (3)	89,859	90,916	92,185
Outpatient (4)	51,046	51,684	52,903
Total	140,906	142,600	145,088
# of ORs Needed			
Group Assignment (5)	1	1	1
Standard Hours/OR/Year (6)	1,950	1,950	1,950
Total Surgical Hours/OR/Year	72.3	73.1	74.4

(1) Includes two ORs from Project ID #J-11631-18 and the proposed two additional ORs
(2) Exclude C-Sections performed in Dedicated C-Section ORs
(3) Inpatient Cases (exclude C-Sections performed in dedicated C-Section ORs) x Inpatient Case Time in minutes] / 60 minutes
(4) (Outpatient Cases x Outpatient Case Time in minutes) / 60 minutes
(5) From Section C, Question 12(a)
(6) From Section C, Question 12(b)

Duke Health System ORs

The Duke health system of ORs in Durham County consists of Arringdon, DASC, DUH and DRH. Pursuant to 10A NCAC 14C .2103(a), the applicant must demonstrate the need for all existing, approved, and proposed ORs in the health system at the end of the third full fiscal year following project completion, using the Operating Room Need Methodology in the 2021 SMFP.

In Section Q Form C.3a and C.3b Utilization Assumptions and Methodology, pages 94-102, the applicant provides the assumptions and methodology used to project utilization at DUH and in the Durham County Duke health system, as summarized below.

- Step 1: Review historical DUHS OR cases (DASC, DUH and DRH), FY2018-2020 Annualized, resulting in a CAGR of 1.2% for inpatient cases, 3.5% for outpatient cases and 2.6% for all DUHS inpatient and outpatient surgery cases (page 94)
- Step 2: Determine projected surgical case CAGR (IP and OP) by DUHS by facility (page 96)
- Step 3: Apply the CAGR to each DUHS facility before the shift of cases to approved and proposed DUHS facilities (page 97)

	FY2021	FY2022	FY2023	FY2024	FY2025	FY2026	FY2027	FY2028
DASC OP Cases	7,384	7,753	8,140	8,547	8,975	9,424	9,895	10,389
DUH OP Cases	19,121	19,402	19,688	19,978	20,272	20,571	20,874	21,181
DUH IP Cases	23,560	24,026	24,502	24,987	25,481	25,986	26,500	27,024
DUH Total	42,681	43,429	44,190	44,965	45,753	46,556	47,374	48,205
DRH OP Cases	4,061	4,061	4,061	4,061	4,061	4,061	4,061	4,061
DRH IP Cases	3,921	4,041	4,165	4,293	4,424	4,560	4,700	4,844
DRH Total	7,982	8,102	8,226	8,354	8,485	8,621	8,761	8,905
DUHS Durham County Facility Total								
DUHS OP Cases	23,182	23,463	23,749	24,039	24,333	24,632	24,935	25,242
DUHS IP Cases	34,865	35,820	36,807	37,827	38,880	39,970	41,095	42,257
DUHS Total	58,047	59,283	60,556	61,866	63,213	64,602	66,030	67,499

- Step 4: Identify remaining DUHS OR surgical cases by facility after the projected shifts to existing, approved, and proposed facilities. (pages 98-101)

  The applicant provides the projected shift of cases from DUH and the projected DUH OR Cases after the proposed shifts to existing, approved and proposed DUHS facilities by IP, OP, and Total Cases in the table on page 99.

  The applicant provides the projected shift of cases from DRH and the projected DRH OR Cases after the proposed shifts to existing, approved and proposed DUHS facilities by IP, OP, and Total Cases in the table on page 100.

  The applicant provides the projected shift of cases from DASC and the projected DASC OR Cases after the proposed shifts to existing, approved and proposed DUHS facilities by OP and Total Cases in the table on page 101.

  The following table summarizes the results of Step 4, pages 99-101, showing total OR surgical cases at the DUHS hospital facilities.

	FY2021	FY2022	FY2023	FY2024	FY2025	FY2026	FY2027	FY2028
DASC OP (Total) Cases	7,107	5,685	5,864	6,046	6,232	6,680	7,151	7,646
DUH Total Cases	42,366	41,858	41,988	42,017	41,941	42,526	43,042	43,857
DRH Total Cases	7,982	8,069	8,168	8,249	8,371	8,507	8,630	8,771

- Step 5: Project 2028 OR Need at DUHS Facilities

	OR Group	Hr/OR/Yr	Case Times		2028 Surgical OR Cases	2028 Surgical hours	Surgical ORs Required
DASC	5	1,312.5	OP	50.4	7,646	6,423	4.9
DUH	1	1,950.0	IP	262.1	21,103	92,185	
			OP	139.5	22,754	52,903	
				Total	43,857	145,088	74.4
DRH	3	1,755.0	IP	202.0	4,041	13,605	
			OP	138.2	4,730	10,894	
				Total	8,771	24,449	14.0
Arringdon*	6	1,312.5	OP	69.5	6,943	8,043	6.1

* The table incorporates the Duke Ambulatory Surgery Center Arringdon (Arringdon) projected OR Need from the complimentary application submitted in this review batch, Project ID #J-12075-21, with the resulting volume for its first three project years (FY2023-FY2025), held constant from FY2025-FY2028.

As shown in the table above, using the Operating Room Need Methodology in Chapter 6 of the 2021 SMFP, the applicant projects the need for 4.9 ORs at DASC, 74.4 ORs at DUH, 14 ORs at DRH, and 6.1 ORs at Arringdon in FY2028, the third year of operation following project completion.

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

- There is a need determination in the 2021 SMFP for four ORs in the Durham County OR service area.
- The applicant relies on its historical utilization in projecting future utilization.
- The applicant demonstrates the need for as many as 74.4 ORs at DUH after the projected shift of surgical cases in the DUHS Durham County health system and proposes to add two ORs at DUH for a total of 69 ORs upon completion of this project and Project ID#J-11631-18.
- The applicant's projected utilization meets the performance standard promulgated in 10A NCAC 14C .2013(a).

Access to Medically Underserved Groups

In Section C, page 42, the applicant states:

> *"As* [sic] *forth in the application for J-11631-18, all individuals including low-income persons, racial and ethnic minorities, women, persons with disabilities, persons 65 and older, Medicare beneficiaries, Medicaid recipients, and other underserved groups, will have access to DUH, as clinically appropriate."*

On page 42, the applicant provides the estimated percentage of medically underserved groups for the proposed service component, as shown in the following table.

Medically Underserved Groups	Percent of Total Patients
Low income persons^	20.0%
Racial and ethnic minorities	34.5%
Women	51.3%
Persons with disabilities	*
Persons 65 and older	40.0%
Medicare beneficiaries	40.5%
Medicaid recipients	11.6%

^Estimated to include Medicaid beneficiaries and charity/reduced care financial assistance recipients
*DUHS does not maintain data regarding 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.

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.

J-12075-21/Duke Ambulatory Surgery Center Arringdon/Develop two ORs

The applicant proposes to develop two additional ORs pursuant to the need determination in the 2021 SMFP for a total of six ORs and two procedure rooms. This is a change of scope to Project ID #J-11508-18 (develop a new ASC by relocating four operating rooms from James E. Davis ASC and developing four procedure rooms) because though the facility is licensed, performed its first surgical case on December 15, 2020, and received its Medicare and Medicaid certification in February 2021, adequate data has not been provided up to this point for the project to be deemed complete.

Patient Origin – On page 49, the 2021 SMFP defines the service area for ORs as *"…the single or multicounty grouping shown in Figure 6.1."* Figure 6.1, page 55, shows Durham County as its own OR planning area. Thus, the service area for this facility is Durham County. Facilities may also serve residents of counties not included in their service area.

Because the facility only began operations in December 2020, patient origin data for a full fiscal year is not available. The following table summarizes the projected patient origin for the ASC, as provided by the applicant on pages 30 and 31.

Arringdon Projected Patient Origin Operating Rooms

County	1st Full FY – FY2023		2nd Full FY - FY2024		3rd Full FY - FY2025	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Durham	1,343	26.0%	1,587	26.0%	1,816	26.2%
Wake	1,002	19.4%	1,157	19.0%	1,286	18.5%
Orange	552	10.7%	635	10.4%	715	10.3%
Alamance	211	4.1%	250	4.1%	287	4.1%
Person	179	3.5%	212	3.5%	243	3.5%
Granville	168	3.3%	198	3.3%	226	3.3%
Cumberland	91	1.8%	109	1.8%	126	1.8%
Guilford	80	1.6%	97	1.6%	113	1.6%
Vance	71	1.4%	85	1.4%	99	1.4%
Johnston	74	1.4%	85	1.4%	95	1.4%
Franklin	64	1.2%	74	1.2%	83	1.2%
Chatham	85	1.6%	97	1.6%	109	1.6%
Harnett	44	0.9%	53	0.9%	60	0.9%
Nash	41	0.8%	48	0.8%	55	0.8%
Other States	391	7.6%	479	7.9%	561	8.1%
Other NC Counties*	765	14.8%	925	15.2%	1,069	15.4%
TOTAL	**5,162**	**100.0%**	**6,093**	**100.0%**	**6,943**	**100.0%**

*The applicant does not identify the counties that comprise this category of other NC counties

In Section C, page 30, the applicant provides the assumptions and methodology used to project patient origin. The applicant's assumptions are reasonable and adequately supported.

Analysis of Need – In Section C, pages 33-53 the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. Pursuant to the need determination in the 2021 SMFP, DUHS proposes to develop two additional ORs at Arringdon in space currently dedicated for procedure rooms. The applicant states that Arringdon currently offers and will continue to offer Gynecology, Ophthalmology, Orthopedic and Plastic Surgery; and intends to include additional surgical specialties. The applicant states that the need for the project is supported by the following:

- Ambulatory surgery trends (pages 34-36)
- Growing ambulatory surgery volumes at DUHS facilities (pages 36-40)
- DUHS initiatives to enhance access to ambulatory services (pages 40-42)
- Physician recruitment plans (pages 42-51)
- Projected population growth in the service area (pages 52-53)

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

- There is a need determination for four ORs in Durham County in the 2021 SMFP. The applicant is applying to develop two of the four ORs in Durham County in accordance with the OR need determination in the 2021 SMFP.

- The applicant uses DUHS historical and demographic data to identify the population to be served, its projected growth, and the need that the identified population to be served has for the proposed services.

Projected Utilization

In Section Q Form C.3a and Form C.3b, the applicant provides Arringdon's interim and projected utilization as summarized in the following table.

Arringdon Interim, and Projected Utilization – Surgical Services

	Interim FY2021 7/20-6/21	Interim FY2022 7/21-6/22	1st Full FY FY2023 7/22-6/23	2nd Full FY FY2024 7/23-6/24	3rd Full FY FY2025 7/24-6/25
Operating Rooms					
Open Heart ORs					
Dedicated C-Section ORs					
Shared ORs					
Dedicated Ambulatory ORs	4	4	6	6	6
Total # of ORs	4	4	6	6	6
Excluded # of ORs					
Adjusted Planning Inventory of ORs (1)	4	4	6	6	6
Surgical Cases					
# of C-Section Surgical Cases					
# of Inpatient Surgical Cases (2)					
# of Outpatient Surgical Cases	591	4,094	5,162	6,093	6,943
Total # of Surgical Cases (2)	591	4,094	5,162	6,093	6,943
Case Times					
Inpatient					
Outpatient	69.5	69.5	69.5	69.5	69.5
Surgical Hours					
Inpatient (3)					
Outpatient (4)	685	4,742	5,979	7,058	8,043
Total	685	4,742	5,979	7,058	8,043
# of ORs Needed					
Group Assignment (5)	6	6	6	6	6
Standard Hours/OR/Year (6)	1,312.5	1,312.5	1,312.5	1,312.5	1,312.5
Total Surgical Hours/OR/Year	0.5	3.6	4.6	5.4	6.1

(1) Excluding C-Sections performed in a dedicated C-Section OR
(2) Exclude C-Sections performed in Dedicated C-Section ORs
(3) Inpatient Cases (exclude C-Sections performed in dedicated C-Section ORs) x Inpatient Case Time in minutes] / 60 minutes
(4) (Outpatient Cases x Outpatient Case Time in minutes) / 60 minutes
(5) From Section C, Question 12(a)
(6) From Section C, Question 12(b)

Duke Health System ORs

The Duke health system of ORs in Durham County consists of Arringdon, DASC, DUH and DRH. Pursuant to 10A NCAC 14C .2103(a), the applicant must demonstrate the need for all existing, approved, and proposed ORs in the health system at the end of the third full fiscal year following project completion, using the Operating Room Need Methodology in the 2021 SMFP.

In Section Q Form C.3a and C.3b Utilization Assumptions and Methodology, pages 118-132, the applicant provides the assumptions and methodology used to project utilization at Arringdon and in the Durham County Duke health system, as summarized below.

- Step 1: Review historical DUHS OR cases, FY2018-2020 Annualized, resulting in a CAGR of 2.9% for all DUHS ambulatory surgery cases (pages 118-119)
- Step 2: Determine projected surgical case CAGR (IP and OP) by DUHS by facility (page 120)
- Step 3: Apply the CAGR to each DUHS facility before the shift of cases to Arringdon -Cases will shift from DASC, DUH, DRH, and Duke Raleigh Hospital (DRAH) (page 121)
- Step 4: Identify historical cases appropriate for an ASF (page 122)
- Step 5: Projected surgical cases appropriate for an ASF (page 123)
- Step 6: Identify percentage of outpatient cases by facility and specialty (pages 123-124)
- Step 7: Determine potential cases available to shift to an ASF (pages 124-125)
- Step 8: Determine potential cases available to shift to Arringdon (page 126)
- Step 9: Project percentage shift to existing and proposed Arringdon ORs (pages 126-128)
- Step 10: Projected Cases at Arringdon based on the shift of cases (pages 129-130)

	Interim FY2021 7/20-6/21	**Interim FY2022 7/21-6/22**	**1st Full FY FY2023 7/22-6/23**	**2nd Full FY FY2024 7/23-6/24**	**3rd Full FY FY2025 7/24-6/25**
Shift from DASC	277	2,068	2,277	2,502	2,743
Shift from DUH	315	1,571	2,202	2,833	3,433
Shift from DRH	0	33	58	105	114
Shift from DRAH	0	422	625	653	643
Total Cases Shifted to Arringdon	591	4,094	5,162	6,093	6,943

- Step 11: Remaining DUHS OR cases after projected shifts to approved and proposed DUHS facilities (pages 130-131)

	Interim FY2021 7/20-6/21	Interim FY2022 7/21-6/22	1st Full FY FY2023 7/22-6/23	2nd Full FY FY2024 7/23-6/24	3rd Full FY FY2025 7/24-6/25
DASC OP Cases	7,107	5,685	5,864	6,046	6,232
DUH OP Cases	23,246	22,456	22,300	22,040	21,669
DUH IP Cases	19,121	19,402	19,688	19,978	20,272
DRH OP Cases	3,921	4,008	4,107	4,188	4,310
DRH IP Cases	4,061	4,061	4,061	4,061	4,061

- Step 12: Project 2025 OR need at DUHS Durham County facilities (page 132)

	OR Group	Hrs/OR /Yr	Case Time	2025 Surgical Cases	2025 Surgical Hours	Surgical ORs Needed
DASC	5	1,312.5	50.4	6,232	5,235	4.0
DUH OP Cases	1		262.1	20,272	88,555	
DUH IP Cases	1		139.5	21,669	50,381	
DUH Total	1	1,950.0		41,941	138,936	71.2
DRH OP Cases	3		202.0	4,061	13,672	
DRH IP Cases	3		138.2	4,310	9,928	
DRH Total	3	1,755.0		8,371	23,600	13.4
Arringdon	6	1,312.5	69.5	6,943	8,043	6.1

As shown in the table above, using the Operating Room Need Methodology in Chapter 6 of the 2021 SMFP, the applicant projects the need for Durham County Duke ORs: four ORs at DASC, 71 ORs at DUH, 13 ORs at DRH, and 6 ORs at Arringdon. However, there is some question as to how DRAH reports its surgical procedures to include those performed in procedure rooms. Therefore, the Agency analyzed the projected need for ORs at Arringdon (Step 10 above) without the shift of surgical procedures from DRAH (6,943 – 643 = 6,300 surgical cases and 7,298 surgical hours, resulting in a need for 5.6 ORs, rounded to 6 ORs).

Procedure Rooms

The applicant proposes to develop two additional ORs pursuant to the need determination in the 2021 SMFP for a total of six ORs and two procedure rooms at Arringdon, which is a change of scope to Project ID #J-11508-18. On page 133, the applicant states:

> *"Procedure rooms are not regulated by CON. DUHS intends to convert two of Arringdon ASC's existing four procedure rooms to ORs."*

The proposed project reduces the number of procedure rooms at Arringdon from four to two.

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

- There is a need determination in the 2021 SMFP for four ORs in the Durham County OR planning area.

- The applicant relies on its historical utilization in projecting future utilization at its Durham County facilities.
- The applicant's projected utilization meets the performance standard promulgated in 10A NCAC 14C .2013(a).

Access to Medically Underserved Groups

In Section C, page 59, the applicant states:

> *"All individuals including low-income persons, racial and ethnic minorities, women, persons with disabilities, persons 65 and older, Medicare beneficiaries, Medicaid recipients, and other underserved groups, will continue to have access to Arringdon ASC, as clinically appropriate."*

On page 60, the applicant provides the estimated percentage for medically underserved groups in the project's third fiscal year, as shown in the following table.

Medically Underserved Groups	Percent of Total Patients
Low income persons	14.0%
Racial and ethnic minorities	37.0%
Women	56.5%
Persons with disabilities	*
Persons 65 and older	42.6%
Medicare beneficiaries	42.6%
Medicaid recipients	5.4%

*DUHS does not maintain data regarding 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.

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, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

NC
Southpoint Surgery Center

NA – All Other Applications

Southpoint Surgery Center proposes to add four ORs pursuant to the need determination in the 2021 SMFP for a total of six ORs upon project completion. On page 53 of its application, Southpoint Surgery Center states that it plans to relocate one of NCSH's two units of Stryker Mako Robotic-Arm Assistant equipment from NCSH to SSC. The applicant discusses the need for the equipment at SSC but does not explain why it believes the needs of the population presently utilizing the services to be relocated will be adequately met at NCSH following the completion of the project. The applicant does not address the utilization of the equipment at NCSH in Criterion (3) or Criterion (3a).

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on its review, the Agency concludes that the application is not conforming to this criterion because the applicant does not adequately demonstrate that the needs of the population currently using the services to be relocated will be adequately met following project completion because it fails to even discuss the utilization of the equipment at NCSH.

UNC Hospitals-RTP, Duke University Hospital and Duke Ambulatory Surgery Center Arringdon do not propose to reduce, eliminate, or relocate a facility or service. Therefore, Criterion (3a) is not applicable to those applications in 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.

NC
Southpoint Surgery Center

C – All Other Applications

J-12052-21/Southpoint Surgery Center/Add four ORs

The applicant proposes to add four ORs pursuant to the need determination in the 2021 SMFP for a total of six ORs and no procedure rooms upon project completion. This is a change of scope to Project ID #J-11626-18, which was denied and subsequently settled with an approval

to develop SSC, a new ambulatory surgical facility with no more than two operating rooms and four procedure rooms.

In Section E, pages 67-68, the applicant describes the alternatives 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 other alternatives considered were:

- *Maintaining the status quo*: The applicant states that, under the status quo, NCSH and SSC will not be able to accommodate growth in future surgery demand. Project ID #J-11626-18 limits the SSC facility to two ORs which is not sufficient capacity for the high volume of more complex cases that can be shifted from NCSH, in conjunction with the physician recruitment.
- *Developing SSC with three additional ORs for a total of five ORs and one procedure room*: The applicant states that this alternative would not be effective because procedure rooms are not appropriate for all types of ambulatory surgery cases and all specialties; and developing only five ORs would not meet the projected volumes for the third year of operation.

On pages 67-68, the applicant states the proposed project to develop four additional ORs for a total of six ORs and no procedure rooms is the most effective alternative to meet the need for surgical capacity at NCSH and SSC because more cases can be shifted from NCSH to the freestanding ASF with tremendous cost savings to patients.

However, the applicant does not adequately demonstrate that the alternative proposed in this application is the most effective alternative to meet the need for the following reasons:

- Projected utilization is not based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.
- The application is not conforming to all statutory and regulatory review criteria. An application that cannot be approved cannot be an effective alternative to meet the need.

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 not conforming to this criterion for the reasons stated above. Therefore, the application is denied.

J-12065-21/UNC Hospitals-RTP/Develop 40 acute care beds and two ORs

The applicant proposes to develop an acute care hospital, UNC-RTP, with 40 acute care beds and two ORs pursuant to the need determinations in the 2021 SMFP.

In Section E, pages 86-87, the applicant describes the alternatives 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 other alternatives considered were:

- *Maintain the status quo*: The applicant states that, under the status quo, the county would continue to lack geographic distribution of hospital-based services for its growing and aging population. It would also mean that Durham County residents who choose UNC health for inpatient and surgical services would continue to be without access to care within their home county. Therefore, maintaining the status quo is not an effective alternative.
- *Develop the hospital at another location*: The applicant states that the south region, where the proposed site is located, has the greatest unmet need for a hospital, based on its population, number of patients receiving inpatient care, projected growth in the area and the lack of acute care beds and ORs in the region; therefore, locating the hospital elsewhere is not an effective alternative.
- *Develop the hospital with a different number of beds and/or OR services*: The applicant states that a smaller facility likely would not meet the need in that area and though a larger facility would likely be supported by the growing patient population, the need determination limits the number of beds to 40. The applicant states that it believes that a 40-bed hospital is well-suited to deliver the much-needed lower acuity services described in Section C.4. The applicant further states that the number of ORs and types of services proposed are the appropriate number needed to complement the 40 acute care beds; therefore, developing a different number of beds and/or OR services is not an effective alternative.

On page 87, the applicant states that the project, as proposed, is the most effective alternative to meet the need for additional acute care beds and operating rooms in the applicable service area.

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

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

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 applicant demonstrates that this proposal is its least costly or most effective alternative to meet the identified need for additional acute care beds and ORs. Therefore, the application is conforming to this criterion.

J-12069-21/Duke University Hospital/Add 40 acute care beds

The applicant proposes to add 40 acute care beds at DUH pursuant to the need determination in the 2021 SMFP for a total of 1,102 acute care beds upon completion of this project, Project ID #J-11717-19 (add 34 acute care beds for a total of 1,062) and Project ID #J-11426-17 (add 90 acute care beds for a total of 1,028).

In Section E, pages 51-52, 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:

- *Status quo*: The applicant states maintaining the status quo would not allow DUH to accommodate inpatient volume growth and would force ongoing pressures on DUH to meet existing demand for services. Thus, maintaining the status quo is not an effective alternative.
- *Develop beds at a new campus or facility in Durham County*: The applicant states that developing a new hospital location would require incremental utility and infrastructure construction and other timely and costly challenges, along with not capitalizing on DUH's resource-intense specialized facilities and services. Thus, this alternative is not an effective alternative.
- *Develop additional beds at Duke Regional Hospital*: The applicant states that DRH cannot necessarily accommodate the demand for DUH's tertiary and quaternary care. Meeting that demand at DRH would require duplicating DUH's specialized academic services, equipment and other infrastructure and operational resources. Thus, this alternative is not an effective alternative.
- *Use existing space for incremental beds at DUH, as proposed*: DUH is in the process of constructing a new patient bed tower, exempt from CON review. This will free up space to develop the proposed project.

On page 52, the applicant states:

> *"The new bed tower project affords an opportunity for the efficient and cost-effective development of additional acute care bed capacity in vacated space at DUH. Specifically, upon completion of the tower and a series of subsequent renovations and relocations of existing beds into that space, DUH will be able to develop additional beds in existing hospital space."*

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

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

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 applicant demonstrates that this proposal is its least costly or most effective alternative to meet the identified need. Therefore, the application is conforming to this criterion.

J-12070-21/Duke University Hospital/Develop two ORs

The applicant proposes to develop two additional ORs at DUH pursuant to the need determination in the 2021 SMFP for a total of 69 ORs. This is a change of scope to Project ID #J-11631-18 (develop two ORs and three procedure rooms for a total of 67 ORs).

In Section E, pages 51-53, the applicant describes the alternatives 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, under the status quo, DUH would be unable to accommodate surgical volume growth, and would face ongoing pressures to meet the existing demand for services; therefore, maintaining the status quo is not an effective alternative.
- *Develop all operating rooms at a new or different campus or facility in Durham County*: DUH specifically needs additional OR capacity to meet the demand for its specialized tertiary and quaternary care and cannot readily duplicate all of the resources necessary to support those services at another facility; therefore, this is not an effective alternative.
- *Develop all operating rooms at DUH*: The applicant states that while DUH will continue to demonstrate a deficit of ORs even with the approval of this project, DUHS determined that by expanding both hospital and ambulatory surgery center capacity, it could meet the need of a broader range of patients. Thus, developing all four of the 2021 SMFP need determination ORs at DUH was not an effective alternative.
- *Use existing spaces for two incremental ORs at DUH, as proposed*: the applicant states that DUH has already been approved to incur a capital expenditure for the increase in surgical capacity at North Pavilion. This project allows it to further increase that capacity without incurring any additional costs, effectively meeting the needs of patients without an additional expenditure.

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

- The application is conforming to all statutory and regulatory review criteria.

- The applicant provides reasonable information to explain why it believes the proposed project is the most effective alternative.

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 applicant demonstrates that this proposal is its least costly or most effective alternative to meet the identified need. Therefore, the application is conforming to this criterion.

J-12075-21/Duke Ambulatory Surgery Center Arringdon/Develop two ORs

The applicant proposes to develop two additional ORs pursuant to the need determination in the 2021 SMFP for a total of six ORs and two procedure rooms. This is a change of scope to Project ID #J-11508-18 (develop a new ASC by relocating four operating rooms from DASC and developing four procedure rooms).

In Section E, pages 70-72, 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 other alternatives considered were:

- *Maintain the status quo*: The applicant states this alternative is not an effective alternative based on the growing demand for outpatient surgery at DUHS facilities and the need for additional ORs in Durham County.
- *Develop the ORs as incremental hospital-based ORs*: The applicant states that DUHS has submitted two applications to develop four ambulatory ORs-two at Arringdon and two at DUH. Developing the additional OR capacity as at DRH, instead of Arringdon, would not address the need for additional ambulatory OR capacity in the DUHS system.
- *Develop all four need-determined ORs in freestanding ASFs* – DUHS has identified a need for additional ORs at both Arringdon and DUH. Developing all the ORs in as ASF would not address the capacity constraint within DUH's surgical platform; thus, it would not be the most effective alternative.

On page 72, the applicant states that the two proposed DUHS projects, developing two ORs at Arringdon and two at DUH, will effectively increase access to DUHS surgical services. Developing additional ambulatory OR capacity at Arringdon is a cost-effective alternative to developing a new ASF in Durham County.

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

- The application is conforming to all statutory and regulatory review criteria.

- The applicant provides reasonable information to explain why it believes the proposed project is the most effective alternative.

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 the applicant demonstrates that this proposal is the least costly or most effective alternative to meet the identified need. Therefore, the application is conforming to this 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.

NC
Southpoint Surgery Center

C – All Other Applications

J-12052-21/Southpoint Surgery Center/Add four ORs

The applicant proposes to add four ORs pursuant to the need determination in the 2021 SMFP for a total of six ORs and no procedure rooms upon project completion. This is a change of scope to Project ID #J-11626-18, which was denied and subsequently settled with an approval to develop SSC, a new ambulatory surgical facility with no more than two operating rooms and four procedure rooms.

Capital and Working Capital Costs – In Section Q, page 129, the applicant provides Form F.1, as summarized below.

SSC– Previously Approved & Proposed Capital Cost			
	Previously Approved (J-11626-18)	**New Total Projected Capital Cost**	**Projected Changes to Capital Cost (J-12052-21)**
Construction/Renovation Contract(s)	$5,500,000	$5,510,000	$10,000
Architect Fees	$325,000	$325,000	$0
Medical Equipment	$4,157,900	$5,101,900	$944,000
Non-Medical Equipment	$1,113,968	$1,113,968	$0
Furniture	$309,159	$309,159	$0
Financing Costs	$20,000	$20,000	$0
Interest During Construction	$50,000	$50,000	$0
Contingency	$590,603	$590,603	$0
Total Application Capital Cost	$12,066,630	$13,020,630	$954,000
CON Appeal Delay Adjustment	$458,531	$458,531	$0
Total CON Amount on Certificate	**$12,525,161**	**$13,479,161**	**$954,000**

In Section C.8, pages 53-54, the applicant provides a table projecting the cost of the additional equipment proposed in this change of scope application as shown below.

Anesthesia Equipment	$173,251
Electrosurgical	$43,442
Video Monitors, systems	$361,900
Lights and Tables	$254,783
Waste Disposal Systems	$29,232
Other Surgical Equipment	$81,392
Total	**$944,000**

In addition to the cost of acquiring the equipment above, the applicant also proposes leasing a Stryker Mako Robotic-Arm system for joint replacement procedures from NCSH, as documented in Exhibit C.8.

On page 78, the applicant states that the previously approved project included a budget of $750,000 for working capital and the applicant does not expect that amount to increase because the proposed projected revenues will exceed expenses within the initial six-month period, as previously projected.

Availability of Funds – In Section F, page 76, the applicant states the capital cost of the proposed project will be funded through a loan to the applicant, Southpoint Surgery Center, LLC.

Exhibit F-2 contains letters from the Senior Vice President Commercial Banking, First Citizens Bank stating that the financial position of North Carolina Specialty Hospital, LLC, Southpoint's parent company, was sufficient for First Citizens Bank to consider financing the $954,000 capital and $750,000 working capital cost of the proposed project.

Exhibit F-2 also contains a letter from the CEO of NCSH committing to borrow the capital and working capital funding for the proposed project, as well as the FY2020 Operating Statement showing adequate cash and assets to fund the proposed project.

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

SSC Projected Revenues and Operating Expenses – ORs			
	1st Full FY CY2023	2nd Full FY CY2024	3rd Full FY CY2025
Total # of Cases (Form C)	5,269	6,169	6,803
Total Gross Revenues	$40,033,862	$48,278,224	$54,837,066
Adjustments to Revenue*	$26,259,254	$31,638,183	$35,903,575
Total Net Revenue	$13,804,780[$13,774,608]	$16,647,663[$16,640,041]	$18,909,333[$18,933,491]
Avg Net Revenue / Case	$2,614	$2,697	$2,783
Total Operating Expenses	$12,970,656	$14,330,575	$15,467,192
Avg Operating Expense /Case	$2,462	$2,323	$2,274
Net Income	$834,124[$803,952]	$2,317,089[$2,309,466]	$3,442,141[$3,466,299]

* The table in Section Q Assumptions Regarding Adjustments and Contractual, page 128, results in a miscalculation of Adjustments to Revenue of $26,229,082, $31,630,560, and $35,927,733 for the respective three years.
Correct calculations using the correct totals for Adjustments to Revenue are provided by the Agency in [brackets]
Adjustments to Revenue includes Charity Care as follows:

	CY2023	CY2024	CY2025
Charity Care	$252,213	$304,153	$345,474
Bad Debt	$400,339	$482,782	$548,371

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q, pages 126-128. However, the applicant does not adequately demonstrate that the financial feasibility of the proposal is reasonable and adequately supported because the projected utilization is not based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference. Therefore, projected revenues and operating expenses, which are based in part on projected utilization, are also questionable.

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 not conforming to this criterion for the following reasons:

- The applicant does not adequately demonstrate that projected utilization is based on reasonable and adequately supported assumptions.
- The applicant does not adequately demonstrate that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

J-12065-21/UNC Hospitals-RTP/Develop 40 acute care beds and two ORs

The applicant proposes to develop an acute care hospital, UNC-RTP, with 40 acute care beds and two ORs pursuant to the need determinations in the 2021 SMFP.

Capital and Working Capital Costs – In Section Q on Form F.1a, the applicant projects the total capital cost of the project as shown in the table below.

Purchase Price of Land	$35,000,000
Closing Costs	$184,000
Site Preparation	$26,868,714
Construction Contract	$126,448,482
Landscaping	$398,401
Architect/Engineering Fees	$14,846,480
Medical Equipment	$22,833,519
Non-Medical Equipment	$8,924,842
Furniture	$3,880,484
Consultant Fees (Inspections and commissioning authority fees)	$2,203,391
Other (Contingency)	$10,320,216
Total	**$251,908,529**

In Section Q Form F.1a Assumptions, the applicant provides the assumptions used to project the capital cost.

In Section F, pages 91-92, the applicant projects estimated start-up costs at $2,457,426 and initial operating costs at $3,686,140 for a total working capital of $6,143,566.

Availability of Funds – In Section F, pages 89 and 92, the applicant states both the capital cost and working capital cost of the proposed project will be funded by accumulated reserves of UNC Hospitals.

Exhibit F-2.1 contains a letter from the Chief Financial Officer of UNC Hospitals, agreeing to commit accumulated reserves to fund the capital and working capital costs of the proposed project.

Exhibit F-2.2 contains the Consolidated Financial Statements for UNC Hospitals for the year ending June 30, 2020. The Consolidated Financial Statements indicate that as of June 30, 2020, UNC Hospitals had adequate cash and assets to fund the capital cost of the proposed project.

Financial Feasibility – The applicant provided pro forma financial statements for the first three full fiscal years of operation following project completion for each proposed service component and for the entire facility. In Form F.2, the applicant projects total revenues for the

proposed facility will exceed operating expenses in the third full fiscal year following project completion, as summarized in the table below.

UNC-RTP Revenues and Operating Expenses – Entire Facility			
	1st Full FY FY2027	2nd Full FY FY2028	3rd Full FY FY2029
Total Gross Revenues (Charges)	$94,269,490	$152,600,765	$219,738,783
Adjustments to Revenue*	$61,065,516	$98,797,529	$142,187,377
Total Net Revenue	$33,203,974	$53,803,236	$77,551,406
Total Operating Expenses (Costs)	$40,622,703	$56,495,351	$75,137,868
Net Income	($7,418,730)	($2,692,115)	$2,413,538

*Includes Charity Care and Bad Debt as follows:

	FY2027	FY2028	FY2029
Charity Care	$11,527,232	$18,536,369	$26,517,350
Bad Debt	$1,337,455	$2,165,034	$3,117,559

The applicant also provides a Form F.2 for inpatient services, as summarized in the table below.

UNC-RTP Revenues and Operating Expenses – Inpatient Services			
	1st Full FY FY2027	2nd Full FY FY2028	3rd Full FY FY2029
Total Gross Revenues (Charges)	$51,501,230	$83,349,788	$119,988,055
Adjustments to Revenue*	$31,167,370	$50,466,220	$72,683,573
Total Net Revenue	$20,333,860	$32,883,567	$47,304,482
Total Operating Expenses (Costs)	$22,879,125	$31,940,416	$42,521,459
Net Income	($2,545,265)	$943,152	$4,783,022

*Includes Charity Care and Bad Debt as follows:

	FY2027	FY2028	FY2029
Charity Care	$4,488,728	$7,277,035	$10,493,509
Bad Debt	$730,677	$1,182,531	$1,702,339

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

- Gross revenue is based on FY2020 UNC Hillsborough average charge for each service component, adjusted to reflect the services expected to be provided by UNC-RTP, inflated 3.0% annually.
- Payor mix for each service component is based on historical Durham County payor mix for the services projected to be provided.
- Expenses are based on UNC Hospitals and UNC Hillsborough experience.
- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.

Conclusion – The Agency reviewed the:

- Application

- Exhibits to the application
- 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 the following reasons:

- The applicant adequately demonstrates 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.

J-12069-21/Duke University Hospital/Add 40 acute care beds

The applicant proposes to add 40 acute care beds at DUH pursuant to the need determination in the 2021 SMFP for a total of 1,102 acute care beds upon completion of this project, Project ID #J-11717-19 (add 34 acute care beds for a total of 1,062) and Project ID #J-11426-17 (add 90 acute care beds for a total of 1,028).

Capital and Working Capital Costs – In Section Q Form F.1a Capital Cost, the applicant projects the total capital cost of the project is $3,500,000, based primarily on the addition of medical equipment.

In Section F, page 55, the applicant states there are no projected working capital costs associated with this project.

Availability of Funds – In Section F, page 53, the applicant states the capital cost of the proposed project will be funded by accumulated reserves of Duke University Health System, Inc.

Exhibit F-2 contains a letter from DUHS Chief Financial Officer committing accumulated reserves to fund the proposed project.

Exhibit F-2 contains the most recent DUHS audited financial statements demonstrating the availability of more than adequate cash and assets to fund the capital cost of the proposed project.

Financial Feasibility – The applicant provides pro forma financial statements for the first three full fiscal years of operation following project completion. In Form F.2b, the applicant projects that DUH adult inpatient services' operating expenses will exceed revenues in the first three full fiscal years following project completion, as shown in the table below.

DUH Adult Inpatient Services

	PY1 FY2026	PY2 FY2027	PY3 FY2028
Total Discharges	39,591	40,185	40,788
Total Gross Revenues (Charges)	$3,538,576,663	$3,591,655,313	$3,645,530,143
Total Contractual Adjustments*	$2,435,320,583	$2,463,875,230	$2,492,669,771
Total Net Patient Revenue	$1,103,256,080	$1,127,780,083	$1,152,860,372
Average Net Revenue per Discharge	$27,866	$28,065	$28,265
Total Operating Expenses (Costs)	$1,408,089,670	$1,458,245,790	$1,510,709,079
Average Operating Expense per Discharge	$35,566	$36,288	$37,038
Net Income	($304,833,589)	($330,465,707)	($357,848,707)

Totals may not sum due to rounding
*Includes Charity Care and Bad Debt as follows:

	PY1 FY206	PY2 FY2027	PY3 FY2028
Charity Care	$114,460,067	$115,802,136	$117,155,479
Bad Debt	$12,176,603	$12,319,376	$12,463,349

However, Form F.2b Revenues and Operating Expenses for DUHS, shows that total revenues will exceed total expenses in the first three operating years of the project, as shown in the following table.

DUHS Revenues and Expenses
(In Thousands)

	PY1 FY2026*	PY2 FY2027*	PY3 FY2028*
Total Gross Revenues /Other Revenue	$15,394,757	$15,733,870	$16,043,881
Total Net Patient Revenue	$4,667,463	$4,769,941	$4,863,975
Total Operating Expenses	$4,434,091	$4,531,445	$4,638,063
Net Income	$233,372	$238,496	$225,912

Totals may not sum due to rounding
*The applicant's Form F.2b incorrectly shows the project years as FY2025, FY2026, and FY2027, respectively.

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 applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

- DUH is operated as part of DUHS and does not maintain separate balance sheets. DUH services with a negative net revenue are supported by the systems' net revenues.
- Inpatient discharges are projected based on Truven Health market share estimates and Inpatient Sg2 projections, trended volume data, and anticipated impact of strategic initiatives.
- Revenue is anticipated to increase by 10.9% from FY2020 to FY2021

- Payor mix is adjusted based on actual, observed share of business and the anticipated impacts of changing population demographics and enacted legislation.
- Expenses are based on FY2020 actual with appropriate applied inflation rates.
- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.

Conclusion – The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Response 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 the following reasons:

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions.
- The applicant adequately demonstrates the availability of sufficient funds for the 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.

J-12070-21/Duke University Hospital/Develop two ORs

The applicant proposes to develop two additional ORs at DUH pursuant to the need determination in the 2021 SMFP for a total of 69 ORs. This is a change of scope to Project ID #J-11631-18 (develop two ORs and three procedure rooms for a total of 67 ORs).

Capital and Working Capital Costs – In Section Q Form F.1b, the applicant projects the total capital cost of the project is $0. The change of scope application to add two ORs at DUH is not expected to increase the capital cost of the previously approved capital cost of Project ID #J-11631-18.

In Section F, page 56, the applicant states there are no projected working capital costs associated with this project.

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

DUH Operating Rooms

	PY1 FY2026	PY2 FY2027	PY3 FY2028
Total Surgical Cases	42,526	43,042	43,857
Total Gross Revenues (Charges)	$2,832,923,413	$2,866,667,083	$2,912,069,681
Total Contractual Adjustments*	$2,003,337,840	$2,020,725,876	$2,046,689,839
Total Net Patient Revenue	$829,585,573	$845,941,207	$865,679,841
Average Net Revenue per Case	$19,508	$19,654	$19,739
Total Operating Expenses (Costs)	$1,106,026,726	$1,142,692,666	$1,182,568,353
Average Operating Expense per Case	$26,008	$26,548	$26,964
Net Income	($276,441,153)	($296,751,459)	($316,888,511)

Totals may not sum due to rounding
*Includes Charity Care and Bad Debt as follows:

	PY1 FY2026	PY2 FY2027	PY3 FY2028
Charity Care	$94,156,878	$94,974,116	$96,180,322
Bad Debt	$10,016,689	$10,103,629	$10,231,949

However, Form F.2b Revenues and Operating Expenses for DUHS, shows that total revenues will exceed total expenses in the first three operating years of the project, as shown in the following table.

DUHS Revenues and Expenses
(In Thousands)

	PY1 FY2026*	PY2 FY2027*	PY3 FY2028*
Total Gross Revenues /Other Revenue	$15,394,757	$15,733,870	$16,043,881
Total Net Patient Revenue	$4,667,463	$4,769,941	$4,863,975
Total Operating Expenses	$4,434,091	$4,531,445	$4,638,063
Net Income	$233,372	$238,496	$225,912

Totals may not sum due to rounding
*The applicant's Form F.2b incorrectly shows the project years as FY2025, FY2026, and FY2027, respectively.

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 applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

- DUH is operated as part of DUHS and does not maintain separate balance sheets. DUH services with a negative net revenue are supported by the systems' net revenues.
- Revenues and collections are based on FY2021 YTD actual. Payor mix is adjusted based on the aging population.
- Expenses are based on FY2021 YTD actual with appropriate applied inflation rates.

- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.

Conclusion – The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Response 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 the following reasons:

- The applicant adequately demonstrates there will be no capital costs.
- 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.

J-12075-21/Duke Ambulatory Surgery Center Arringdon/Develop two ORs

The applicant proposes to develop two additional ORs pursuant to the need determination in the 2021 SMFP for a total of six ORs and two procedure rooms. This is a change of scope to Project ID #J-11508-18 (develop a new ASC by relocating four operating rooms from DASC and developing four procedure rooms).

Capital and Working Capital Costs – In Section Q Form F.1a Capital Cost for Change of Scope Application, the applicant projects the total capital cost of the project as shown in the table below.

	Previously Approved Capital Cost J-11508-18	New Total Capital Cost	Capital Cost for this Project
Land	$540,000	$540,000	$0
Site Preparation	$1,320,000	$1,320,000	$0
Construction/Renovation	$22,360,000	$22,360,000	$0
Landscaping	$30,000	$30,000	$0
Architect/Engineering Fees	$1,390,000	$1,390,000	$0
Medical Equipment	$7,590,000	$8,190,000	$600,000
Non-Medical Equipment	$626,000	$626,000	$0
Furniture	$320,000	$320,000	$0
Consultant Fees	$60,000	$110,000	$50,000
Other	$50,000	$50,000	$0
Total	**$34,286,000**	**$34,936,000**	**$650,000**

In Section Q Form F.1a Capital Cost Assumptions, page 152, the applicant provides the assumptions used to project the capital cost.

In Section F, pages 75-76, the applicant states there are no projected working capital costs because the facility is already operational.

Availability of Funds – In Section F, page 73, the applicant states the capital cost of the proposed project will be funded by accumulated reserves of Duke University Health System, Inc.

Exhibit F-2 contains a letter from DUHS Chief Financial Officer committing accumulated reserves to fund the proposed project.

Exhibit F-2 contains the most recent DUHS audited financial statements demonstrating the availability of more than adequate cash and assets to fund the capital cost of the proposed project.

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

Duke Ambulatory Surgery Center Arringdon Operating Rooms Revenues and Operating Expenses			
	1st Full FY FY2023	2nd Full FY FY2024	3rd Full FY FY2025
Total # of Surgical OR Cases	5,162	6,093	6,943
Total Gross Revenues (Charges)	$64,437,440	$77,145,899	$89,034,432
Total Net Revenue*	$24,957,679	$30,506,198	$35,614,388
Average Net Revenue per Patient	$4,835	$5,007	$5,130
Total Operating Expenses (Costs)	$16,393,762	$19,909,692	$23,686,740
Average Operating Expense per Patient	$3,176	$3,268	$3,412
Net Income	$8,563,917	$10,596,506	$11,927,648

*Adjustments to Gross Revenue includes Charity Care and Bad Debt as follows:

	FY2026	FY2027	FY2028
Charity Care	$653,556	$818,549	$971,420
Bad Debt	$394,798	$466,397	$534,200

In addition, the entire Arringdon ASC facility's revenues exceed expenses in each of the first three full fiscal years by $7.1 million, $9.4 million and $10.9 million, respectively.

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q, pages 152-157. The applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

- Gross revenue is projected based on the IDTF CDM Charge Master, effective July 1, 2020, with price increases of 2% annually.

- Expenses are based on the applicant's current experience. Salaries are projected to increase 2.5% in FY2021-2022 and 3.5% in FY2023-2025.
- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.

Conclusion – The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Response 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 the following reasons:

- The applicant adequately demonstrates the capital costs are based on reasonable and adequately supported assumptions.
- The applicant adequately demonstrates availability of sufficient funds for the 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.

NC
Southpoint Surgery Center

C – All Other Applications

The 2021 SMFP includes need determinations for 40 acute care beds and four ORs in the applicable service area.

Acute Care Beds. On page 31, the 2021 SMFP defines the service area for acute care beds as *". . . the single or multicounty grouping shown in Figure 5.1."* Figure 5.1, on page 36, shows the multicounty grouping of Durham and Caswell counties as the acute care bed service area. Thus, the service area for acute care beds for this facility is the Durham/Caswell service area. Facilities may also serve residents of counties not included in their service area.

The 2021 SMFP shows there are 1,280 licensed acute care beds in three existing acute care hospitals in Durham County, as shown below. Caswell County does not have any acute care beds.

Durham/Caswell County Acute Care Beds 2019 Data			
Existing Facilities	Licensed Acute Care Beds	CON Adjustments	Inpatient Days of Care
Duke Regional Hospital	316	0	69,947
Duke University Hospital	946	102	295,221
Duke University Health System	1,262	102	365,168
North Carolina Specialty Hospital	18	6	3,144
Total	**1,280**	**108**	

Source: 2021 SMFP Table 5A, page 39

Operating Rooms. On page 49, the 2021 SMFP defines the service area for ORs as *"...the single or multicounty grouping shown in Figure 6.1."* Figure 6.1, page 55, shows Durham County as its own OR planning area. Thus, the service area for ORs for this facility is Durham 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 operating rooms located in Durham County, and the inpatient and outpatient case volumes for each provider, from pages 58-59 and 71 of the 2021 SMFP, respectively.

Durham County FFY2019 Operating Room Inventory and Cases
As Reported in the 2021 SMFP from the 2020 License Renewal Applications

	IP ORs	OP ORs	Shared ORs	Excluded C-Section/ Trauma/Burn ORs	CON Adjust-ments	IP Surgery Cases	OP Surgery Cases	Group
Duke Ambulatory Surgery Center Arringdon	0	0	0	0	4	0	0	
James E. Davis Ambulatory Surgical Center (DASC)	0	8	0	0	-4	0	6,079	5
Duke University Hospital	6	9	50	-1	2	18,733	22,139	1
Duke Regional Hospital	2	0	13	-2	0	3,991	3,555	3
Duke University Health System	8	17	63	-3	2			
Southpoint Surgery Center	0	0	0	0	2	0	0	
North Carolina Specialty Hospital	0	0	4	0	0	1,588	4,128	4
Total Durham County ORs	**8**	**17**	**67**	**-3**	**4**			

Source: 2021 SMFP

J-12052-21/Southpoint Surgery Center/Add four ORs

The applicant proposes to add four ORs pursuant to the need determination in the 2021 SMFP for a total of six ORs and no procedure rooms upon project completion. This is a change of scope to Project ID #J-11626-18, which was denied and subsequently settled with an approval to develop SSC, a new ambulatory surgical facility with no more than two operating rooms and four procedure rooms.

In Section G, pages 80-82, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved surgical services in Durham County. On page 80, the applicant states:

"The proposed project responds to the need determination in the 2021 SMFP that includes four additional operating rooms in the Durham/Caswell [Durham County] *Operating Room Service Area. The proposed project does not exceed the need determination."*

On page 82, the applicant further states:

"The proposed project offers greater capacity to enhance patient access and deliver high quality and cost-effective surgery. The proposed additional operating rooms will support higher volumes of surgery in the initial years of operation with economies of scale."

However, the applicant does not adequately demonstrate that the proposal would not result in an unnecessary duplication of existing or approved services in the service area for the following reasons:

- The applicant does not adequately demonstrate that the four ORs are needed in addition to the existing or approved ORs in Durham County.
- Projected utilization is not based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.
- The application is not conforming to all statutory and regulatory review criteria. An application that cannot be approved cannot be an effective alternative to meet the need.

Conclusion – The Agency reviewed the:

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

Based on that review, the Agency concludes that the application is not conforming to this criterion for all the reasons stated above.

J-12065-21/UNC Hospitals-RTP/Develop 40 acute care beds and two ORs

The applicant proposes to develop an acute care hospital, UNC-RTP, with 40 acute care beds and two ORs pursuant to the need determinations in the 2021 SMFP.

In Section G, pages 99-100, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved acute care and surgical services in Durham County. The applicant states:

"The proposed UNC Hospitals-RTP will not result in unnecessary duplication of the existing or approved health service facilities located in the proposed service area that

provide the same service components as the 2021 SMFP includes need determinations for 40 additional acute care beds and four additional operating rooms in Durham county, and, as such, the core components for the proposed project, acute care beds and operating rooms, have been determined as needed in the service area, beyond the existing and approved facilities providing these services."

The applicant states that North Carolina Specialty Hospital provides limited inpatient services and is currently prohibited from adding more beds; and Duke Regional Hospital is a full-service, tertiary-level care hospital and Duke University Hospital is an academic medical center providing quaternary-level care to patients from a broad service area. As such, the applicant states that Durham County lacks a hospital designed and operated to serve the local community. The applicant further states that UNC's proposed hospital will represent the first community-focused hospital in the county and the only hospital in the southern region of the county.

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

- There is a need determination in the 2021 SMFP for 40 acute care beds in the Durham/Caswell service area and the applicant proposes to develop 40 acute care beds in Durham County.
- The applicant adequately demonstrates that the 40 beds are needed in addition to the existing or approved acute care beds in Durham/Caswell counties.
- There is a need determination in the 2021 SMFP for four ORs in the Durham County service area and the applicant proposes to develop two ORs.
- The applicant adequately demonstrates that the two ORs are needed in addition to the existing or approved ORs in Durham County.

Conclusion – The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Response 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 the reasons stated above.

J-12069-21/Duke University Hospital/Add 40 acute care beds

The applicant proposes to add 40 acute care beds at DUH pursuant to the need determination in the 2021 SMFP for a total of 1,102 acute care beds upon completion of this project, Project ID #J-11717-19 (add 34 acute care beds for a total of 1,062) and Project ID #J-11426-17 (add 90 acute care beds for a total of 1,028).

In Section G, pages 61-62, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved acute care services in Durham County. The applicant states:

> *"As described in Section C.4, the need for additional inpatient capacity was driven by the demand for DUH's highly specialized services. The proposed 40 additional acute care beds are specifically needed at DUH to expand access to the hospital's well-utilized inpatient acute care services which do not duplicate the services provided by any other facility. As set forth in Section C, DUH patients come from across the state, and it is their need that drives the demand for additional capacity."*

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

- There is a need determination in the 2021 SMFP for 40 acute care beds in the Durham/Caswell county service area and the applicant proposes to develop 40 acute care beds in this application.
- The applicant adequately demonstrates that the incremental beds are needed in addition to the existing or approved acute care beds in Durham County.

Conclusion – The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Response 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 the reasons stated above.

J-12070-21/Duke University Hospital/Develop two ORs

The applicant proposes to develop two additional ORs at DUH pursuant to the need determination in the 2021 SMFP for a total of 69 ORs. This is a change of scope to Project ID #J-11631-18 (develop two ORs and three procedure rooms for a total of 67 ORs).

In Section G, page 64, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved surgical services in Durham County. The applicant states the proposed project will not result in unnecessary duplication of existing or approved services or facilities because it demonstrates the need the population has for the proposed operating rooms based on demographic data specific to the proposed service area and historical patient data at DUH. The applicant further states:

> *"As a tertiary and quaternary care referral center, DUH serves a fundamentally different patient population from any other facility in the county. The scope of acute care services at DUH cannot be replicated at other hospitals or ambulatory surgery centers. As set forth in Section Q, all DUHS facilities will be fully utilized upon project*

completion. In addition, the 2021 SMFP reflects that NCSH does not have unused surgical capacity. Therefore, this project will not duplicate any existing or approved services."

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

- There is a need determination in the 2021 SMFP for four ORs in the Durham County service area and the applicant proposes to develop two ORs in this application.
- The applicant adequately demonstrates that the two ORs are needed in addition to the existing or approved ORs in Durham County.

Conclusion – The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Response 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 the reasons stated above.

J-12075-21/Duke Ambulatory Surgery Center Arringdon/Develop two ORs

The applicant proposes to develop two additional ORs pursuant to the need determination in the 2021 SMFP for a total of six ORs and two procedure rooms. This is a change of scope to Project ID #J-11508-18 (develop a new ASC by relocating four operating rooms from DASC and developing four procedure rooms).

In Section G, page 82, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved surgical services in Durham County. The applicant states:

"The proposed project effectively expands and enhances access to DUHS ambulatory surgical services in Durham County via develop [sic] *of additional OR capacity at Arringdon ASC."*

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

- There is a need determination in the 2021 SMFP for four ORs in the Durham County service area and the applicant proposes to develop two ORs.
- The applicant adequately demonstrates that the two ORs are needed in addition to the existing or approved ORs in Durham County.

Conclusion – The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Response 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 the reasons stated 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 – All Applications

J-12052-21/Southpoint Surgery Center/Add four ORs

In Section Q Form H, page 131, the applicant provides the projected staffing by number of full time equivalent (FTE) positions for the proposed services, as illustrated in the following table.

SSC –Projected OR Staffing By FTE Position			
Position	**1st Full FY**	**2nd Full FY**	**3rd Full FY**
Registered Nurses-Surgical	24.0	25.0	26.0
Registered Nurses- Recovery	4.5	5.0	5.5
Director of Nursing	1.0	1.0	1.0
Nursing Supervisor	1.0	1.0	1.0
Surgical Technicians and Sterile Supply	10.0	10.5	11.0
Materials Management Technician	2.0	2.0	2.0
Administrator/CEO	1.0	1.0	1.0
Clerical	3.5	3.5	3.5
Total	**47.0**	**49.0**	**51.0**

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 Form F.3, which is found in Section Q. This a change of scope project for Project ID #J-11626-18, which was found conforming to this criterion. In Section H.4, page 84, the applicant states that SSC's project is based on additional ORs and higher surgery utilization projections and increases in the volumes of surgery cases. The applicant further states that the staffing projections are based on Surgery Partner's experience in managing ambulatory surgery centers.

Conclusion – The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments

- Response 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 the reasons stated above.

J-12065-21/UNC Hospitals-RTP/Develop 40 acute care beds and two ORs

In Section Q Form H Staffing, page 20, the applicant provides the projected staffing by number of full time equivalent (FTE) positions for the proposed services, as illustrated in the following table.

UNC-RTP Projected Staffing
By FTE Position

Position	PY1 FY2027	PY2 FY2028	PY3 FY2029
Registered Nurses	39.9	64.6	93.0
Director of Nursing	1.0	1.0	1.0
Surgical Technicians	10.4	16.8	24.2
Lab Technicians	4.8	7.8	11.2
Radiology Technologists	7.9	12.8	18.5
Pharmacists	1.2	1.9	2.8
Pharmacy Technicians	2.1	3.3	4.8
Physical Therapists	1.0	1.6	2.3
Speech Therapists	1.2	1.2	1.2
Occupational Therapists	0.5	0.8	1.2
Respiratory Therapists	4.3	6.9	10.0
Dieticians	1.0	1.0	1.0
Cooks	3.4	5.6	8.0
Dietary Aides	1.3	2.1	3.0
Social Workers	1.0	1.0	1.0
Housekeeping	7.3	11.8	17.0
Bio-medical Engineering	1.0	1.0	1.0
Maintenance/ Engineering	9.0	9.0	9.0
Chief Operating Officer	1.0	1.0	1.0
Clerical	7.6	12.3	17.7
Other*	36.2	53.5	73.3
Total	**143.1**	**217.1**	**302.2**

*Other is described by applicant on Form H, page 20

The assumptions and methodology used to project staffing are provided in Section Q Form H Assumptions, page 21. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in Form F.3 Projected Operating Costs UNC-RTP Total Facility, which is found in Section Q, page 11. In Section H, pages 101-102, the applicant describes the methods used to recruit or fill vacant or new positions and its existing

training and continuing education programs. The applicant provides supporting documentation in Exhibits H-2.1 through H-2.4 and H-3.

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

- Types of positions are based on UNC Hospitals experience at existing facilities.
- Number of FTE positions for each position type reflects UNC Hospitals experience at existing facilities and expected utilization.
- Annual salary per FTE position are based on UNC Hospitals experience, inflated 3.0% annually.

Conclusion – The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Response 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 the reasons stated above.

J-12069-21/Duke University Hospital/Add 40 acute care beds

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

DUH Adult Inpatient Projected Staffing
By FTE Position

Position	Current FY2021	PY1 FY2026	PY2 FY2027	PY3 FY2028
Nurse Practitioners	3.9	4.3	4.8	5.4
Registered Nurses	1,774.8	1,947.9	2,170.0	2,453.7
Licensed Practical Nurses	3.7	4.1	4.5	5.1
Certified Nurse Aides /Nursing Assistants	457.3	501.9	559.1	632.2
Surgical Technicians	2.4	2.6	2.9	3.3
Clerical	5.6	6.2	6.9	7.8
Other (Nurse Manager)	24.6	24.6	24.6	24.6
Other (Physicians)	1.0	1.1	1.2	1.4
Total	**2,273.0**	**2,493.0**	**2,774.0**	**3,133.0**

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 Form F.3, which is found in Section Q. In Section H, pages 63-64, the applicant describes the methods used to recruit or fill vacant or new positions and its

existing training and continuing education programs. The applicant provides supporting documentation in Exhibits H-2 and H-3.

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

- Form H Staffing represents FTEs in non-pediatric and non-psych inpatient cost centers.
- Current staff columns are based on FY2021 actual FTE positions and annualized dollars.
- The number of FTEs for each position type are increased at the same rate as patient volume, except for Nurse Manger, which is a fixed position and remains constant.
- Annual salary per FTE position is based on the current salary per FTE inflated 3.5% annually.
- Total salary on Form H does not tie to labor cost on Form F.3 because F.3 includes both salary and fringe, and F.3 represents financial data from entire inpatient encounters, while Form H Staffing only represents FTEs in non-pediatric and non-psych inpatient encounters only.

Conclusion – The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Response 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 the reasons stated above.

J-12070-21/Duke University Hospital/Develop two ORs

In Section Q Form H Staffing, the applicant provides current and projected staffing for the existing and proposed services as illustrated in the following table.

DUH Current and Projected Staffing by FTE Position				
Position	**Current, as of 6/30/2021**	**FY2026**	**FY2027**	**FY2028**
Surgical Positions				
Nurse Practitioners/PAs	23.1	23.2	23.5	23.9
Registered Nurses	535.0	537.0	545.6	554.3
Licensed Practical Nurses	2.7	2.7	2.7	2.8
Nurse Aides/Assistants	38.3	38.5	39.1	39.7
Nurse Anesthetists	118.6	119.1	121.0	122.9
Surgical Technicians	120.2	120.7	122.6	124.5
Clerical	19.4	19.5	19.8	20.1
Sterile Processing Tech	141.0	141.6	143.8	146.1
CRNA Manager	4.0	4.0	4.0	4.0
Sterile Processing Manager	2.8	2.8	2.8	2.8
Nurse Manager	8.6	8.6	8.6	8.6
Anesthesia Technicians	50.8	51.0	51.8	52.6
Associated Inpatient Nursing Positions				
Nurse Practitioners/PAs	3.9	3.9	3.9	3.9
Registered Nurses	2,230.4	2,230.4	2,230.4	2,230.4
Licensed Practical Nurses	5.0	5.0	5.0	5.0
Nurse Aides/Assistants	522.2	522.2	522.2	522.2
Clerical	23.0	23.0	23.0	23.0
Nurse Manager	30.1	30.1	30.1	30.1
Total	**3,879.0**	**3,883.0**	**3,900.0**	**3,917.0**

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 Form F.3, which is found in Section Q. In Section H, pages 65-66, the applicant describes the methods used to recruit or fill vacant or new positions and its existing training and continuing education programs. The applicant provides supporting documentation in Exhibits H-2 and H-3.

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

- Projected FTE positions are based on Current FTE positions increased through the third full fiscal year of the project for the added ORs.
- The number of FTEs for each position type reflects historical staffing patterns.
- Annual salary per FTE position is based on the current salary per FTE inflated 3.5% annually.
- Total salary on Form H does not tie to labor cost on Form F.3 because F.3 includes both salary and fringe, and F.3 represents financial data from entire surgical encounters, while Form H Staffing represents only DUH surgical platform cost centers, whereas relevant surgical encounters may get charges from other cost centers with additional associated labor cost.

Conclusion – The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Response 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 the reasons stated above.

J-12075-21/Duke Ambulatory Surgery Center Arringdon/Develop two ORs

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

Arringdon ASC Historical and Projected Staffing By FTE Position				
Position	**Current**	**FY2023**	**FY2024**	**FY2025**
Radiology Technologists	0.30	1.50	2.00	2.48
Pharmacy Technicians	0.30	1.00	1.00	1.05
Anesthesia Technician	0.25	2.50	3.00	3.00
Nurse Anesthetist	0.00	4.00	4.00	4.00
Clinical Operations Director	0.30	0.50	1.00	1.05
Pre/ Post Clinical Nurse III	1.20	6.00	6.00	7.80
Pre/ Post Clinical Nurse II	1.20	6.00	8.00	9.90
OR Clinical Nurse III	1.20	8.00	8.00	9.15
OR Clinical Nurse IV	1.20	2.00	3.00	3.90
Surgical Technologist Advanced	0.60	3.00	3.00	4.65
Surgical Technologist	1.20	6.00	7.00	8.10
Sterile Processing Tech III	0.60	2.00	3.00	3.15
Nursing Care Asst II/Health Unit Coord	0.90	2.00	3.00	3.15
Supply Chain Associate	0.60	1.00	2.00	2.10
Surgical Attendant	0.60	2.00	2.50	3.00
Financial Care Counselor	1.20	2.00	2.00	2.85
Total	**11.65**	**49.50**	**58.50**	**69.33**

The assumptions and methodology used to project staffing are provided in Section Q. Operating expenses for the health manpower and management positions proposed for the ASF by the applicant are budgeted in Section Q Form F.3b Arringdon ASC: Entire Facility and appear to be $1,070,808 ($5,467,619 - $4,396,811) short in FY2025; however, Form F.2b Arringdon ASC: Entire Facility shows a net income in FY2025 in excess of $10 million and would more than cover the shortage in staffing expense. Though there may be an explanation for why the salaries would differ from Form H to Form F.3b, the applicant does not provide any explanation in Section H or in the Form H Staffing Assumptions.

In Section H, pages 84-85, the applicant describes the methods used to recruit or fill vacant or new positions and its existing training and continuing education programs. The applicant provides supporting documentation in Exhibit H-2.

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

- Projected FTE positions are based on Arringdon and DASC experience in staffing an ASF.
- Annual salary per FTE position is based on the current salary per FTE inflated at 2.5% for FY2021-2022 and 3.5% in FY2023-2025.

Conclusion – The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Response 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 the reasons stated 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 – All Applications

J-12052-21/Southpoint Surgery Center/Add four ORs - This is a change of scope application for Project ID #J-11626-18.

Ancillary and Support Services

In Section I, page 86, the applicant states:

"No changes are expected in the provision of ancillary and support services. Surgery Partners will provide administration and management services. Professional services will be the same as those indicated in CON Project ID # J-11626-18. These include:

Regional Anesthesia PLLC and/or UNC Anesthesia
Durham Radiology
UNC Department of Pathology and Laboratory Medicine
North Carolina Specialty Hospital Pharmacy"

Coordination

In Section I, page 87, the applicant states:

> *"North Carolina Specialty Hospital is developing this project with the continued support and coordination with numerous physicians and healthcare organizations and clinics in the service area. As seen in the Exhibit C.8, Southpoint Surgery Center has obtained widespread support from healthcare providers. The proposed project will be coordinated with the health care and social services providers consistent with CON Project ID #J-11626-18. In addition, NCSH and Southpoint Surgery Center intend to continue to recruit additional physicians to join the medical staff."*

The application for Project ID #J-11626-18 adequately demonstrated the availability of the ancillary and support services necessary to the provision of the proposed services and adequately demonstrated the proposed services would be coordinated with the existing healthcare system and no changes are proposed in this application which would affect that determination.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

J-12065-21/UNC Hospitals-RTP/Develop 40 acute care beds and two ORs

The applicant proposes to develop an acute care hospital, UNC-RTP, with 40 acute care beds and two ORs pursuant to the need determinations in the 2021 SMFP.

Ancillary and Support Services

In Section I, pages 103-104, the applicant identifies the necessary ancillary and support services for the proposed services and explains how each of the necessary ancillary and support services required will be provided. Exhibit I.1 contains a letter from the President of UNC Hospitals, attesting to the availability of necessary ancillary and support services. The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on the following:

- Necessary ancillary and support services will be provided on site by UNC-RTP staff with UNC Hospitals leadership support or through centralized UNC Health Shared Services with on-site support.
- The applicant provides documentation in Exhibit I.1 that the necessary ancillary and support services will continue to be provided.

Coordination

In Section I, page 104, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit I.2. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the following:

- The applicant states that UNC-RTP, as part of UNC Health will be a part of an established healthcare system.
- UNC Health has established relationships with other local healthcare and social service providers.
- The applicant states that the existing relationships will continue following completion of the proposed project.
- Exhibit I.2 contains letters of support from healthcare providers.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

J-12069-21/Duke University Hospital/Add 40 acute care beds

The applicant proposes to develop 40 additional acute care beds at DUH.

Ancillary and Support Services

In Section I, page 65, the applicant identifies the necessary ancillary and support services for the proposed services. The applicant states that DUH already provides all of the necessary services in connection with its existing acute care beds. The applicant states that it will continue to provide the necessary ancillary and support services. The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on the following:

- Necessary ancillary and support services are currently being provided at DUH.
- The applicant states that the necessary ancillary and support services will continue to be provided upon project completion.

Coordination

In Section I, page 66, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides the website where supporting documentation can be found. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the following:

- The applicant states that the facility has established relationships with other local healthcare and social service providers.
- The applicant states that the existing relationships will continue following completion of the proposed project.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

J-12070-21/Duke University Hospital/Develop two ORs

This is a change of scope application for Project ID #J-11631-18.

Ancillary and Support Services

In Section I, page 68, the applicant checked each of the boxes listed as ancillary and support services. On page 69, the applicant states:

> *"The services checked are all related to the provision of hospital services. DUH already provides all of these services in connection with its existing operating rooms. It will continue to provide these services pursuant to its existing arrangements."*

Coordination

In Section I, page 69, the applicant states:

> *"DUH is part of the Duke University Health System, which includes inpatient acute care, outpatient surgery, psychiatric, and rehabilitation services, primary care, home health and hospice services. DUHS works closely with the Private Diagnostic Clinic, PLLC, the Duke University School of Medicine faculty practice which provides a full range of specialty physician services across the Triangle. Duke Health primary care, specialty care, and ambulatory surgery will be provided on an adjacent ambulatory campus, and this project was developed in consultation with all of those providers to ensure that the proposed services would meet the needs of patients."*

The application for Project ID #J-11631-18 adequately demonstrated the availability of the ancillary and support services necessary to the provision of the proposed services and adequately demonstrated the proposed services would be coordinated with the existing healthcare system and no changes are proposed in this application which would affect that determination.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

J-12075-21/Duke Ambulatory Surgery Center Arringdon/Develop two ORs

This is a change of scope application for Project ID #J-11508-18.

Ancillary and Support Services

In Section I, page 86, the applicant states:

> *"Arringdon ASC is an existing ASC, thus, all necessary ancillary and support services will continue to be in place upon completion of the proposed project."*

On pages 86-87, the applicant lists the services required at the facility and states how they are provided.

Coordination

In Section I, page 87, the applicant states:

> *"Arringdon ASC is part of DUHS which is a longstanding existing healthcare system in North Carolina and collaborates with other local health care and social service providers. Duke University Health System, along with Duke Health, works within the communities it serves to promote wellness and access to care. . . . Duke and its local partners continue collaborative efforts to eliminate healthcare disparities and to improve access to high-quality medical care."*

The application for Project ID #J-11508-18 adequately demonstrated the availability of the ancillary and support services necessary to the provision of the proposed services and adequately demonstrated the proposed services would be coordinated with the existing healthcare system and no changes are proposed in this application which would affect that determination.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

(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 – All Applications

None of the applications include projections 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, none of the applications include projections 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 any of the applications in 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 – All Applications

None of the applicants is an HMO. Therefore, Criterion (10) is not applicable to any of the applications in 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 – All Applications

J-12052-21/Southpoint Surgery Center/Add four ORs

In Section K, page 91, the applicant states that Project ID #J-11626-18 involves the construction of 24,628 square feet in leased space. Line drawings are provided in Exhibit K.8. The proposed project replaces four procedure rooms with ORs. No additional square feet are proposed with this change of scope project, only minor changes costing $10,000 to equip the PRs being converted to ORs with surgical lights and anesthesia gas systems mounted to the walls and ceilings.

On pages 92-93, 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 total capital cost of developing a new ambulatory surgery center with six ORs supports cost savings due to the economies of scale related to fixed costs for building infrastructure that would be incurred for a facility with less capacity.
- The proposed changes in the space can occur within the existing footprint of the building.
- Multispecialty ORs provide for greater cost effectiveness
- Greater diversification of services at SSC permits a broader more reliable reimbursement base.

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 based on the following:

- The addition of the ORs will allow for more cases to be performed in a lower cost ambulatory setting as compared to a hospital outpatient department.
- Expanding the surgical capacity of SSC will maximize healthcare value because additional systems will not have to be duplicated to serve the additional ORs.
- Greater economies of scale and staffing efficiencies can be achieved.

On pages 93-94, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Response 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.

J-12065-21/UNC Hospitals-RTP/Develop 40 acute care beds and two ORs

In Section K, page 107, the applicant states that the proposed project involves 189,838 square feet of new construction. Line drawings are provided in Exhibit C.1.

On pages 109-111, 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.4. The applicant also identifies an alternate site in the same general vicinity and provides information on that site in Exhibit K.4. Both sites appear to be suitable for the proposed facility based on the applicant's representations and supporting documentation. However, there is some question as to whether or not the first site can be rezoned for a hospital.

On pages 107-108, 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 applicant states that the layout for the hospital is based on a configuration that provides the most efficient circulation and through put for patients and caregivers.
- The applicant states that sizes of spaces are based on best practice methodologies, as well as relationships and adjacencies to support functions while also preventing unnecessary costs.
- Daylighting is proposed where feasible, to reduce energy consumption, as well as other sustainable strategies, including the exterior envelope being a mixture of materials that provide energy efficiency and low maintenance.

On page 108, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services based on the fact that through careful planning and conservative fiscal management, UNC Hospitals has set aside excess revenues to be used to develop the proposed project, without the need to increase costs or charges to the public to pay for the project.

On page 108, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Response 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.

J-12069-21/Duke University Hospital/Add 40 acute care beds

In Section K, page 69, the applicant states that the project does not involve the construction or renovation of any space. The beds will be developed in existing space that meets licensure standards. Line drawings are provided in Exhibit C.1.

On page 69, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal based on the fact that the proposed beds will be developed in existing space and requires no construction or renovation.

On page 70, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services based on the following:

- The applicant states that the project does not include construction or renovation and will not increase the charges or projected reimbursement for the proposed services.
- The applicant states that the costs to be incurred to develop and operate the project are necessary and appropriate to enhance acute care access for patients in the area.

On page 70, in identifying any applicable energy saving features that will be incorporated into the construction plans, the applicant states that the proposed project requires no construction.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Response 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.

J-12070-21/Duke University Hospital/Develop two ORs

This application is a change of scope application for Project ID #J-11631-18. In Section K, page 72, the applicant states that this project involves the renovation of the same total square feet in North Pavilion as was proposed for renovation in Project ID #J-11631-18. Line drawings are provided in Exhibit K.1.

The application for Project ID #J-11631-18 adequately demonstrated conformance with this Criterion and no changes are proposed in this application which would affect that determination.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Response 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 the reasons stated above.

J-12075-21/Duke Ambulatory Surgery Center Arringdon/Develop two ORs

This application is a change of scope application for Project ID #J-11508-18. In Section K, page 90, the applicant states that the project involves the renovation of 800 square feet to add surgical lights, booms, etc. to two procedure rooms, converting them to operating rooms. The project does not involve a change to the footprint of the facility. Line drawings are provided in Exhibit K.2

On page 90, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal based on the fact that Duke's project manager based the projected cost on a detailed review of the project and upon DUHS' experience with similar projects. Exhibit F.1 contains the project manager's equipment cost letter.

On page 91, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services based on the following:

- The applicant states that developing the ORs in an ASC is a cost-effective approach to increasing OR capacity in Durham County, saving money for the patient, government, and third-party payors.
- The applicant states that ASCs are highly specialized and function on a much smaller scale, so they can provide services at a lower price than a full-service hospital.

On page 91, in identifying any applicable energy saving features that will be incorporated into the construction plans, the applicant states that as a new facility, Arringdon is compliant with all applicable federal, state, and local building codes, and requirements for energy efficiency and consumption, including Policy GEN-4. The applicant further states that DUHS will ensure the proposed additional ORs will be developed in similar fashion.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Response 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 the reasons stated 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 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 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
Southpoint Surgery Center
UNC Hospitals -RTP
Duke Ambulatory Surgery Center Arringdon

C
All Other Applications

J-12052-21/Southpoint Surgery Center/Add four ORs

SSC is not an existing facility. Therefore, Criterion (13a) is not applicable to this review.

J-12065-21/UNC Hospitals-RTP/Develop 40 acute care beds and two ORs

UNC-RTP is not an existing facility. Therefore, Criterion (13a) is not applicable to this review.

J-12069-21/Duke University Hospital/Add 40 acute care beds

In Section L.1, page 72, the applicant provides the historical payor mix for FY2020 at DUH, as summarized in the table below.

Payment Source	Percent of Total Patients
Self-Pay	0.8%
Charity Care	4.3%
Medicare*	38.1%
Medicaid*	11.3%
Insurance*	41.8%
Other (including Workers Comp and TRICARE)	3.6%
Total	**100.0%**

Source: Table on page 72 of the application.
*Includes managed care plans.
Totals may not sum due to rounding

In Section L.1, page 73, the applicant provides the following comparison of its patient population to the service area population.

	% of Total Patients Served Last Full FY	% of the Population of Service Area
Female	58.6%	52.3%
Male	41.4%	Not reported
Unknown		
64 and Younger	65.5%	Not reported
65 and Older	34.5%	13.6%
American Indian	0.5%	0.9%
Asian	2.8%	5.5%
Black or African-American	26.4%	36.9%
Native Hawaiian or Pacific Islander	0.1%	0.1%
White or Caucasian	61.4%	54.0%
Other Race	2.3%	2.6%
Declined / Unavailable	6.5%	

Source: Section L.1, page 73 of application

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the applicant adequately documents the extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved. Therefore, the application is conforming to this criterion.

J-12070-21/Duke University Hospital/Develop two ORs

In Section L.1, page 76, the applicant provides the historical payor mix for FY2020 at DUH, as summarized in the table below.

Payment Source	Percent of Total Patients
Self-Pay	0.8%
Charity Care	4.3%
Medicare*	38.1%
Medicaid*	11.3%
Insurance*	41.8%
Other (including Workers Comp and TRICARE)	3.6%
Total	**100.0%**

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

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

	% of Total Patients Served Last Full FY	% of the Population of Service Area
Female	58.6%	52.3%
Male	41.4%	Not reported
Unknown		
64 and Younger	65.5%	Not reported
65 and Older	34.5%	13.6%
American Indian	0.5%	0.9%
Asian	2.8%	5.5%
Black or African-American	26.4%	36.9%
Native Hawaiian or Pacific Islander	0.1%	0.1%
White or Caucasian	61.4%	54.0%
Other Race	2.3%	2.6%
Declined / Unavailable	6.5%	

Source: Section L.1, page 77 of application

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the applicant adequately documents the extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's

service area which is medically underserved. Therefore, the application is conforming to this criterion.

J-12075-21/Duke Ambulatory Surgery Center Arringdon/Develop two ORs

Arringdon became operational in December 2020; thus, the facility does not have historical data for the previous year. 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 handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

NA
Southpoint Surgery Center
UNC Hospitals -RTP

C
All Other Applications

J-12052-21/Southpoint Surgery Center/Add four ORs

SSC is not an existing facility. Therefore, Criterion (13b) is not applicable to this review.

J-12065-21/UNC Hospitals-RTP/Develop 40 acute care beds and two ORs

UNC-RTP is not an existing facility. Therefore, Criterion (13b) is not applicable to this review.

J-12069-21/Duke University Hospital/Add 40 acute care beds

Regarding any obligation to provide uncompensated care, community service, or access by minorities and persons with disabilities, in Section L, page 74, the applicant states it has no such obligation. In Section L, page 75, the applicant states that DUHS received notification of an investigation concerning two ADA complaints relative to accessibility to interpreter services. DUHS has responded detailing its interpreter services and has received no further requests for information.

Conclusion – The Agency reviewed the:

- Application
- Exhibits to the application

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

J-12070-21/Duke University Hospital/Develop two ORs

Regarding any obligation to provide uncompensated care, community service, or access by minorities and persons with disabilities, in Section L, pages 78-79, the applicant states it has no such obligation. In Section L, page 79, the applicant states that DUHS received notification of an investigation concerning two ADA complaints relative to accessibility to interpreter services. DUHS has responded detailing its interpreter services and has received no further requests for information.

Conclusion – The Agency reviewed the:

- Application
- Exhibits to the application

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

J-12075-21/Duke Ambulatory Surgery Center Arringdon/Develop two ORs

Regarding any obligation to provide uncompensated care, community service, or access by minorities and persons with disabilities, in Section L, page 96, the applicant states it has no such obligation. In Section L, page 97, the applicant states that DUHS received notification of an investigation concerning two ADA complaints relative to accessibility to interpreter services. DUHS has responded detailing its interpreter services and has received no further requests for information.

Conclusion – The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C – All Applications

J-12052-21/Southpoint Surgery Center/Add four ORs

In Section L.6, page 101, the applicant projects the following payor mix for SSC and during the third year of operation (CY2025) following completion of the project, as shown in the following table.

Payment Source	Percent of Total Facility and OR Patients
Self-Pay	1.82%
Charity Care	0.48%
Medicare*	44.32%
Medicaid*	4.12%
Insurance*	43.98%
Workers Compensation	5.29%
Total**	**100.0%**

Source: Table on page 101 of the application.
*Includes managed care plans.
**Totals may not foot due to rounding.

As shown in the table above, during the third full fiscal year of operation, the applicant projects 1.82 percent of OR services will be provided to self-pay patients, 44.32 percent to Medicare patients, and 4.12 percent to Medicaid patients.

On page 102, the applicant provides the assumptions and methodology used to project payor mix during the third full fiscal year of operation following project completion. The projected payor mix is reasonable and adequately supported for the following reasons:

- The applicant relies on its own historical ambulatory surgery data from NCSH for the last two years in projecting future utilization.
- The applicant adequately explains why there are minor differences from the payor mix projected in Project ID #J-11626-18.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

J-12065-21/UNC Hospitals-RTP/Develop 40 acute care beds and two ORs

In Section L.3, page 115, the applicant projects the following payor mix for UNC-RTP services during the third year of operation (FY2029) following completion of the project, as shown in the following table.

Payment Source	Percent of Patients Entire Facility	Percent of Total Inpatients
Self-Pay	16.9%	8.9%
Medicare*	24.4%	44.6%
Medicaid*	12.2%	19.0%
Insurance*	35.5%	25.3%
Other (Workers Comp, TRICARE)	10.7%	2.2%
Total	**100.0%**	**100.0%**

Source: Table on page 115 of the application.
*Includes managed care plans.
Totals may not foot due to rounding.

As shown in the table above, during the third full fiscal year of operation, the applicant projects 16.9 percent of total facility services will be provided to self-pay patients, 24.4 percent to Medicare patients, and 12.2 percent to Medicaid patients. The applicant also provides the same data for ambulatory surgical services, emergency department, and ambulatory imaging on page 116.

On page 117, the applicant provides the assumptions and methodology used to project payor mix during the third full fiscal year of operation following project completion. The projected payor mix is reasonable and adequately supported for the following reasons:

- The applicant relies on Truven data and UNC Hospitals' historical data in projecting future payor mix.
- The applicant explains why there are no changes to projected payor mix based on healthcare reform, Medicaid expansion and other policy initiatives.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

J-12069-21/Duke University Hospital/Add 40 acute care beds

In Section L.3, page 76, the applicant projects the following payor mix for DUH and adult acute care bed patients during the third year of operation (FY2028) following completion of the project, as shown in the following table.

Payment Source	Percent of Total DUH Patients	Percent of Adult AC Bed Patients
Self-Pay	1.1%	2.4%
Charity Care	4.4%	2.1%
Medicare*	39.7%	50.2%
Medicaid*	11.2%	13.1%
Insurance*	40.4%	28.1%
Other (including Workers Comp, TRICARE)	3.1%	4.0%
Total	**100.0%**	**100.0%**

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

As shown in the table above, during the third full fiscal year of operation, the applicant projects 2.4 percent of adult acute care inpatient services will be provided to self-pay patients, 50.2 percent to Medicare patients, and 13.1 percent to Medicaid patients.

On page 76, the applicant provides the assumptions and methodology used to project payor mix during the third full fiscal year of operation following project completion. The projected payor mix is reasonable and adequately supported for the following reasons:

- The applicant relies on its own historical data in projecting future payor mix.
- The applicant adequately explains projected changes to its historical payor mix.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

J-12070-21/Duke University Hospital/Develop two ORs

In Section L.3, page 80, the applicant projects the following payor mix for DUH and surgical services during the third year of operation (FY2028) following completion of the project, as shown in the following table.

Payment Source	Percent of Total DUH Patients	Percent of Total Surgical Patients
Self-Pay	1.1%	1.6%
Charity Care	4.4%	1.9%
Medicare*	39.7%	40.5%
Medicaid*	11.2%	11.6%
Insurance*	40.4%	39.1%
Other (including Workers Comp, TRICARE)	3.1%	5.2%
Total	**100.0%**	**100.0%**

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

As shown in the table above, during the third full fiscal year of operation, the applicant projects 1.6 percent of surgical services will be provided to self-pay patients, 40.5 percent to Medicare patients, and 11.6 percent to Medicaid patients.

On page 80, the applicant provides the assumptions and methodology used to project payor mix during the third full fiscal year of operation following project completion. The projected payor mix is reasonable and adequately supported for the following reasons:

- The applicant relies on its own historical data in projecting future payor mix.
- The applicant adequately explains projected changes to its historical payor mix.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

J-12075-21/Duke Ambulatory Surgery Center Arringdon/Develop two ORs

In Section L.3, page 98, the applicant projects the following payor mix for Arringdon during the third year of operation following completion of the project, as shown in the following table.

Payment Source	Percent of Total Facility and OR Patients FY2025
Self-Pay	0.18%
Charity Care	1.72%
Medicare*	42.56%
Medicaid*	5.38%
Insurance*	45.60%
Workers Compensation	0.95%
TRICARE	2.04%
Other	1.58%
Total	**100.0%**

Source: Table on page 98 of the application.
*Includes managed care plans.
Totals may not sum due to rounding.

As shown in the table above, during the third full fiscal year of operation, the applicant projects 0.18 percent of OR services will be provided to self-pay patients, 42.56 percent to Medicare patients, and 5.38 percent to Medicaid patients.

On page 98, the applicant provides the assumptions and methodology used to project payor mix during the third full fiscal year of operation following project completion. The projected payor mix is reasonable and adequately supported because the applicant relies on its own historical data from DUHS facilities for like surgical cases to project payor mix at Arringdon.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C – All Applications

J-12052-21/Southpoint Surgery Center/Add four ORs

Project ID# J-11626-18 was conforming to this criterion and the applicant proposes no changes in the current application which would affect that determination.

The Agency reviewed the:

- Application
- Exhibits to the application

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

J-12065-21/UNC Hospitals-RTP/Develop 40 acute care beds and two ORs

In Section L, page 118, the applicant adequately describes the range of means by which patients will have access to the proposed services.

Conclusion – The Agency reviewed the:

- Application
- Exhibits to the application

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

J-12069-21/Duke University Hospital/Add 40 acute care beds

In Section L, page 78, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application

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

J-12070-21/Duke University Hospital/Develop two ORs

This project proposes to add two ORs at DUH pursuant to the need determination in the 2021 SMFP for a total of 69 ORs, as a change of scope to Project ID #J-11631-18.

Project ID# J-11631-18 was conforming to this criterion and the applicant proposes no changes in the current application which would affect that determination.

The Agency reviewed the:

- Application
- Exhibits to the application

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

J-12075-21/Duke Ambulatory Surgery Center Arringdon/Develop two ORs

In Section L, page 100, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C – All Applications

J-12052-21/Southpoint Surgery Center/Add four ORs.

The applicant proposes a change of scope, adding ORs to the ASF approved for development in Project ID #J-11626-18 and reducing the number of procedure rooms to zero. The application for Project ID#J-11626-18 adequately demonstrated that the proposed health services will accommodate the clinical needs of health professional training programs in the area. The applicant proposes no changes in the current application which would affect that determination.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

J-12065-21/UNC Hospitals-RTP/Develop 40 acute care beds and two ORs

In Section M, pages 119-120, the applicant describes the extent to which health professional training programs in the area will have access to the facility for training purposes and provides a listing of UNC Hospitals residencies and fellowships. The applicant adequately demonstrates that health professional training programs in the area will have access to the facility for training purposes based on the following:

- The applicant states that UNC Health has established relationships in place with health training programs in the area that will be extended to UNC-RTP.
- The applicant provides a listing of the UNC Hospitals Accredited Residencies and Fellowships.

Conclusion – The Agency reviewed the:

- Application
- Exhibits to the application

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

J-12069-21/Duke University Hospital/Add 40 acute care beds

In Section M, pages 79-80, 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 continue to have access to the facility for training purposes based on the following:

- The applicant lists the established relationships that DUH already has in place with health training programs in the area.
- The applicant lists the training programs that are based at DUH, including those in the School of Medicine, Nursing and Medical and Health Professions.

Conclusion – The Agency reviewed the:

- Application
- Exhibits to the application

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

J-12070-21/Duke University Hospital/Develop two ORs

The applicant proposes a change of scope to Project ID #J-11631-18, adding two ORs at DUH for a total of 69 ORs. The application for Project ID#J-11631-18 adequately demonstrated that the proposed health services will accommodate the clinical needs of health professional training programs in the area. The applicant proposes no changes in the current application which would affect that determination.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

J-12075-21/Duke Ambulatory Surgery Center Arringdon/Develop two ORs

In Section M, page 101, 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 continue to have access to the facility for training purposes based on the following:

- The applicant states that as an Academic Medical Center Teaching Hospital, DUH serves as a primary teaching location for medical students, residents, fellows, nurses, and other health care professionals. The applicant states that Arringdon offers a unique setting to provide clinical training rotations.
- The applicant states that DUHS has established relationships in place with health training programs at UNC, Wake Tech, and Johnston Community College that may be rotated through Arringdon pursuant to existing training agreements.

Conclusion – The Agency reviewed the:

- Application
- Exhibits to the application

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

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

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

NC
Southpoint Surgery Center

C – All Other Applications

The 2021 SMFP includes need determinations for 40 acute care beds and four ORs in the applicable service area.

Acute Care Beds. On page 31, the 2021 SMFP defines the service area for acute care beds as *". . . the single or multicounty grouping shown in Figure 5.1."* Figure 5.1, on page 36, shows the multicounty grouping of Durham and Caswell counties as the acute care bed service area. Thus, the service area for acute care beds for this facility is the Durham/Caswell service area. Facilities may also serve residents of counties not included in their service area.

The 2021 SMFP shows there are 1,280 licensed acute care beds in three existing acute care hospitals in Durham County, as shown below. Caswell County does not have any acute care beds.

Durham County 2019 Acute Care Beds and Days of Care
As Reported in the 2021 SMFP from the 2020 License Renewal Applications

Existing Facilities	Licensed Acute Care Beds	CON Adjustments	Inpatient Days of Care
Duke Regional Hospital	316	0	69,947
Duke University Hospital	946	102	295,221
Duke University Health System	1,262	102	365,168
North Carolina Specialty Hospital	18	6	3,144
Total	**1,280**	**108**	

Source: 2021 SMFP Table 5A, page 39

Operating Rooms. On page 49, the 2021 SMFP defines the service area for ORs as *"...the single or multicounty grouping shown in Figure 6.1."* Figure 6.1, page 55, shows Durham County as its own OR planning area. Thus, the service area for ORs for this facility is Durham 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 operating rooms located in Durham County, and the inpatient and outpatient case volumes for each provider, from pages 58-59 and 71 of the 2021 SMFP, respectively.

Durham County 2019 Operating Room Inventory and Cases
As Reported in the 2021 SMFP from the 2020 License Renewal Applications

	IP ORs	OP ORs	Shared ORs	Excluded C-Section/ Trauma/Burn ORs	CON Adjust-ments	IP Surgery Cases	OP Surgery Cases	Group
Duke Ambulatory Surgery Center Arringdon	0	0	0	0	4	0	0	
James E. Davis Ambulatory Surgical Center (DASC)	0	8	0	0	-4	0	6,079	5
Duke University Hospital	6	9	50	-1	2	18,733	22,139	1
Duke Regional Hospital	2	0	13	-2	0	3,991	3,555	3
Duke University Health System	8	17	63	-3	2			
Southpoint Surgery Center	0	0	0	0	2	0	0	
North Carolina Specialty Hospital	0	0	4	0	0	1,588	4,128	4
Total Durham County ORs	**8**	**17**	**67**	**-3**	**4**			

Source: 2021 SMFP, Tables 6A and 6B

J-12052-21/Southpoint Surgery Center/Add four ORs

The applicant proposes to add four ORs pursuant to the need determination in the 2021 SMFP for a total of six ORs and no procedure rooms upon project completion. This is a change of scope to Project ID #J-11626-18, which was denied and subsequently settled with an approval to develop SSC, a new ambulatory surgical facility with no more than two operating rooms and four procedure rooms.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 107, the applicant states:

> *"Approval of the Southpoint Surgery Center proposal will foster positive competition by expanding access to high quality ambulatory surgery for all categories of patients including larger numbers of medically underserved patients."*

Regarding the impact of the proposal on cost effectiveness, in Section N, pages 106-107, the applicant states that the proposed project will enhance Southpoint Surgery Center's capacity to compete in terms of cost-effectiveness because SSC will:

- provide more patients and payors with access to lower cost ambulatory surgery
- achieve higher productivity and operating efficiency

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

Regarding the impact of the proposal on quality, in Section N, pages 107-108, the applicant states:

> *"Expansion of the facility capacity will promote quality of care and patient safety because the scope of the project includes additional operating rooms to support advanced surgical technologies, greater scheduling flexibility and overall improvements in productivity. The facility will meet all federal, state and local regulatory requirements including the North Carolina Ambulatory Surgical Licensure standards and the NC Division of Health Service Regulation facility construction*

standards for ambulatory surgical facilities. As seen in Exhibit 0.3, the applicant is committed to achieved [sic] *and maintain AAAHC accreditation."*

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, page 108, the applicant states:

"Southpoint Surgery Center will obtain Medicare and Medicaid certification and accreditation for all of its ORs in support of expanded patient access. In addition, the facility will not discriminate against anyone due to age, race, color, religion, ethnicity, gender, disability or ability to pay. Southpoint Surgery Center is committed to provide services to low-income persons, racial and ethnic minorities, women, handicapped persons, the elderly and other underserved persons including the medically indigent, the uninsured and the underinsured. Southpoint Surgery Center's renovations and expansion will be designed and constructed for use by handicapped persons. The facility design will be in compliance with ADA requirements and state, local and federal building codes."

See also Section L, B and C of the application and any exhibits.

However, the applicant does not adequately describe the expected effects of the proposed services on competition in the service area or adequately demonstrate the proposal would have a positive impact on cost-effectiveness, quality, and access because the applicant does not adequately demonstrate that the proposal is cost effective because the applicant does not adequately demonstrate: 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.

Conclusion

The Agency reviewed the:

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

Based on that review, the Agency concludes that the application is not conforming to this criterion for all the reasons described above.

J-12065-21/UNC Hospitals-RTP/Develop 40 acute care beds and two ORs

The applicant proposes to develop an acute care hospital, UNC-RTP, with 40 acute care beds and two ORs pursuant to the need determinations in the 2021 SMFP.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 121, the applicant states:

"The proposed project is expected to enhance competition in the service area by promoting cost effectiveness, quality, and access to acute care services. Notably, the development of a community hospital by UNC Health in Durham County will enhance competition by introducing another choice to Durham County patients in need of hospital and related healthcare services."

Regarding the impact of the proposal on cost effectiveness, in Section N, pages 121-122, the applicant states:

"The proposed application is indicative of UNC Health's commitment to containing healthcare costs and maximizing healthcare benefit per dollar expended, while also ensuring that patients have sufficient access to acute care and surgical services. . . . While the development of new hospitals is often capital-intensive, UNC Hospitals believes such a conservatively-sized community hospital, which can be expanded in the future as demand warrants, is the most cost effective approach to address the needs of the patients proposed to be served.

. . .

Further, UNC Hospitals, as a member of the larger UNC Health Care System, benefits from significant cost saving measures through the consolidation of multiple services and large economies of scale. This efficiency results in lower costs that are passed to patients in the form of lower charges."

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 122, the applicant states:

"UNC Hospitals has a demonstrated reputation for providing high quality healthcare services to its patients and is committed to continuing to offer a high level of care in a new community by expanding into Durham County."

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, page 124, the applicant states:

"As North Carolina's only state-owned, comprehensive, full-service hospital system, UNC Hospitals has the obligation to accept any North Carolina citizen requiring medically necessary treatment. No North Carolina citizen is presently denied access to non-elective care because of race, sex, creed, age, handicap, financial status, or lack of medical insurance as demonstrated in Section C."

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

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would have a positive impact on cost-effectiveness, quality, and access because the applicant adequately demonstrates that:

1) The proposal is cost effective because the applicant adequately demonstrated: a) the need the population to be served has for the proposal; b) that the proposal would not result in an unnecessary duplication of existing and approved health services; and c) that projected revenues and operating costs are reasonable.
2) Quality care would be provided based on the applicant's representations about how it will ensure the quality of the proposed services and the applicant's record of providing quality care in the past.
3) Medically underserved groups will have access to the proposed services based on the applicant's representations about access by medically underserved groups and the projected payor mix.

Conclusion

The Agency reviewed the:

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

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

J-12069-21/Duke University Hospital/Add 40 acute care beds

The applicant proposes to add 40 acute care beds at DUH pursuant to the need determination in the 2021 SMFP for a total of 1,102 acute care beds upon completion of this project, Project ID #J-11717-19 (add 34 acute care beds for a total of 1,062) and Project ID #J-11426-17 (add 90 acute care beds for a total of 1,028).

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 81, the applicant states:

> *"DUH's service area includes Durham County, the Triangle, and surrounding counties, and the hospital attracts patients from across the state and nation. By ensuring sufficient capacity to meet demand for DUH's specialized inpatient services, this project will increase patient choice for patients throughout this region. DUH currently operates on divert status a significant percentage of the time, which affects its ability to accept transfers and provide meaningful choice for patients."*

Regarding the impact of the proposal on cost effectiveness, in Section N, page 81, the applicant states:

> *"This project will not affect the cost to patients or payors for the services provided by DUH because reimbursement rates are set by the federal government and commercial*

insurers. The capital expenditure for this project is necessary to ensure that DUHS will continue to provide high quality services that are accessible to patients.

Also, DUHS will continue to participate in initiatives aimed at promoting cost effectiveness and optimizing quality healthcare."

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

Regarding the impact of the proposal on quality, in Section N, page 81, the applicant states:

"DUH has existing quality-related policies and procedures, and its quality management programs emphasize a customer-oriented perspective that is used to determine the needs of patients, physicians, and others who utilize hospital services."

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

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 82, the applicant states:

"As previously stated, DUHS 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 as underserved."

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 payor mix.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

J-12070-21/Duke University Hospital/Develop two ORs

The applicant proposes to develop two additional ORs at DUH pursuant to the need determination in the 2021 SMFP for a total of 69 ORs. This is a change of scope to Project ID #J-11631-18 (develop two ORs and three procedure rooms for a total of 67 ORs).

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 86, the applicant states:

> *"DUH's service area includes Durham County, the Triangle, and surrounding counties, and the hospital attracts patients from across the state and nation. By ensuring sufficient capacity to meet demand for DUH's specialized surgical services, this project is necessary to provide meaningful choice for patients throughout this region."*

Regarding the impact of the proposal on cost effectiveness, in Section N, page 86, the applicant states:

> *"This project will not affect the cost to patients or payors for the services provided by DUH because reimbursement rates are set by the federal government and commercial insurers. The capital expenditure for this project is necessary to ensure that DUHS will continue to provide high quality services that are accessible to patients.*
>
> *Also, DUHS will continue to participate in initiatives aimed at promoting cost effectiveness and optimizing quality healthcare."*

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

Regarding the impact of the proposal on quality, in Section N, page 87, the applicant states:

> *"DUH has existing quality-related policies and procedures, and its quality management programs emphasize a customer-oriented perspective that is used to determine the needs of patients, physicians, and others who utilize hospital services."*

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

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 87, the applicant states:

> *"As previously stated, DUHS 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 as underserved."*

See also Section L and C of the application and any exhibits.

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would have a positive impact on cost-effectiveness, quality, and access because the applicant adequately demonstrates that:

1) The proposal is cost effective because the applicant adequately demonstrated: a) the need the population to be served has for the proposal; b) that the proposal would not result in an unnecessary duplication of existing and approved health services; and c) that projected revenues and operating costs are reasonable.
2) Quality care would be provided based on the applicant's representations about how it will ensure the quality of the proposed services and the applicant's record of providing quality care in the past.
3) Medically underserved groups will have access to the proposed services based on the applicant's representations about access by medically underserved groups and the projected payor mix.

Conclusion

The Agency reviewed the:

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

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

J-12075-21/Duke Ambulatory Surgery Center Arringdon/Develop two ORs

The applicant proposes to develop two additional ORs pursuant to the need determination in the 2021 SMFP for a total of six ORs and two procedure rooms. This is a change of scope to Project ID #J-11508-18 (develop a new ASC by relocating four operating rooms from James E. Davis ASC and developing four procedure rooms).

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 103, the applicant states:

> *"DUHS has described how the project will positively impact cost-effectiveness, quality and access by medically underserved groups."*

Regarding the impact of the proposal on cost effectiveness, in Section N, page 102, the applicant states:

> *"The project will not affect the cost to patients or payors for the services provided by Arringdon ASC because reimbursement rates are set by the federal government and commercial insurers. The capital expenditure for this project is necessary to ensure*

that DUHS will continue to provide high-quality services that are accessible to patients.

. . .

Also, DUHS will continue to participate in initiatives aimed at promoting cost-effectiveness and optimizing quality healthcare."

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 103, the applicant states:

"DUHS is committed to delivering high-quality care at all of its facilities and will continue to maintain the highest standards and quality of care, consistent with the standards that that DUHS has sustained throughout its illustrious history of providing patient care."

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, page 103, the applicant states:

"As previously stated, DUHS 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 as underserved. DUHS's financial assistance policy will apply to the proposed services."

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

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would have a positive impact on cost-effectiveness, quality, and access because the applicant adequately demonstrates that:

1) The proposal is cost effective because the applicant adequately demonstrated: a) the need the population to be served has for the proposal; b) that the proposal would not result in an unnecessary duplication of existing and approved health services; and c) that projected revenues and operating costs are reasonable.
2) Quality care would be provided based on the applicant's representations about how it will ensure the quality of the proposed services and the applicant's record of providing quality care in the past.
3) Medically underserved groups will have access to the proposed services based on the applicant's representations about access by medically underserved groups and the projected payor mix.

Conclusion

The Agency reviewed the:

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

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

(19) Repealed effective July 1, 1987.

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

C – All Applications

J-12052-21/Southpoint Surgery Center/Add four ORs

On Section Q Form O, the applicant provides a list of all healthcare facilities with ORs located in North Carolina which are owned, operated, or managed by the applicant or a related entity. The applicant identifies a total of three hospitals and ASFs located in North Carolina.

In Section O, page 110, the applicant states that, during the 18 months immediately preceding the submittal of the application, there were no incidents which resulted in a finding of immediate jeopardy that occurred in any of these facilities. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, during the 18 months immediately preceding submission of the application through the date of this decision, incidents related to quality of care occurred in one of these facilities and were thereafter resolved. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at all three facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

J-12065-21/UNC Hospitals-RTP/Develop 40 acute care beds and two ORs

Section Q Form O, the applicant provides a list of all healthcare facilities located in North Carolina which are owned, operated, or managed by the applicant or a related entity. The applicant identifies a total of 11 hospitals located in North Carolina.

In Section O, pages 126-127, the applicant states that, during the 18 months immediately preceding the submittal of the application, each of the facilities listed in Form O has continually maintained all relevant licensure, certification, and accreditation and no facility had an incident resulting in an immediate jeopardy. The applicant provides data related to alleged incidents at two related hospital entities, both of which have been resolved. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, during the 18 months

immediately preceding submission of the application through the date of this decision, no incidents related to quality of care occurred in any of these facilities. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at all 11 facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

J-12069-21/Duke University Hospital/Add 40 acute care beds

Section Q Form O, the applicant provides a list of three hospitals in North Carolina which are owned, operated, or managed by the applicant or a related entity.

In Section O, page 85, the applicant states that DUHS is not aware of any deficiencies in quality of care at its acute care hospitals during the 18 months immediately preceding the submittal of the application. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, during the 18 months immediately preceding submission of the application through the date of this decision, there were no incidents related to quality of care that occurred in the three listed hospitals or the other related facilities providing surgical services. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at all related facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

J-12070-21/Duke University Hospital/Develop two ORs

Section Q Form O, the applicant provides a list of three hospitals in North Carolina which are owned, operated, or managed by the applicant or a related entity.

In Section O, page 90, the applicant states that DUHS is not aware of any deficiencies in quality of care at its acute care hospitals during the 18 months immediately preceding the submittal of the application. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, during the 18 months immediately preceding submission of the application through the date of this decision, there were no incidents related to quality of care that occurred in the three listed hospitals or the other related facilities providing surgical services. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at all related facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

J-12075-21/Duke Ambulatory Surgery Center Arringdon/Develop two ORs

In Section Q Form O, the applicant provides a list of all healthcare facilities with ORs located in North Carolina which are owned, operated, or managed by the applicant or a related entity. The applicant identifies a total of seven hospitals and ASFs located in North Carolina.

In Section O, pages 105-107, the applicant states that it is not aware of any deficiencies in quality of care that occurred in any of its licensed facilities during the 18 months immediately preceding the submittal of the application. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, during the 18 months immediately preceding submission of the application through the date of this decision, there were no incidents related

to quality of care at any of these facilities. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at all seven 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.

(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.

NC
Southpoint Surgery Center

C – All Other Applications

SECTION .2100 – CRITERIA AND STANDARDS FOR SURGICAL SERVICES AND OPERATING ROOMS are applicable to:

- Project ID #J-12052-21/**Southpoint Surgery Center**/Add four ORs
- Project ID #J-12065-21/ **UNC Hospitals-RTP**/Develop 40 acute care beds and two ORs
- Project ID #J-12070-21/**Duke University Hospital**/Develop two ORs
- Project ID #J-12075-21/**Duke Ambulatory Surgery Center Arringdon**/Develop two ORs

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.

-NC- **Southpoint Surgery Center.** This proposal would add four new ORs to Southpoint Surgery Center for a total of six ORs upon completion of this project and Project ID #J-11626-18. In Section Q Form C, page 118, the applicant projects sufficient surgical cases and hours to demonstrate the need for the additional ORs in the applicant's health system (SSC and NCSH) in the third full fiscal year following completion of the

proposed project. However, as discussed in Criterion (3), the applicant's projected utilization is not based on reasonable and adequately supported assumptions. Following the Operating Room Need Methodology in the 2021 SMFP, the applicant demonstrates the need for only four total ORs, not six, as proposed. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

-C- **UNC Hospitals-RTP.** This proposal would create a new hospital with 40 acute care beds and two new ORs. The applicant projects sufficient surgical cases and hours to demonstrate the need for two additional ORs in the Durham County service area in the third full fiscal year following completion of the proposed project based on the Operating Room Need Methodology in the 2021 SMFP. The discussions regarding analysis of need and projected utilization found in Criterion (3) are incorporated herein by reference.

-C- **Duke University Hospital.** This proposal would add two new ORs to DUH for a total of 69 ORs upon completion of this project and Project I.D. #F-11631-18 (add two ORs). The applicant projects sufficient surgical cases and hours to demonstrate the need for two additional ORs in the applicant's health system in the third full fiscal year following completion of the proposed 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- **Duke Ambulatory Surgery Center Arringdon.** This proposal would add two new ORs to Arringdon for a total of six ORs upon completion of this project and Project ID #J-11508-18 (relocate 4 ORs and develop ASF). The applicant projects sufficient surgical cases and hours to demonstrate the need for two additional ORs in the applicant's health system in the third full fiscal year following completion of the proposed 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.

-NC- **Southpoint Surgery Center.** In Section Q, pages 115-121, the applicant provides the assumptions and data supporting the methodology for its utilization projections. However, as discussed in Criterion (3), the applicant's projected utilization is not based on reasonable and adequately supported assumptions. The discussion regarding utilization found in Criterion (3) is incorporated herein by reference.

-C- **UNC Hospitals-RTP.** In Section Q Form C Utilization- Assumptions and Methodology, pages 15-18, the applicant provides the assumptions and data supporting the methodology for its surgical utilization projections. The discussion regarding analysis of need and projected utilization found in Criterion (3) are incorporated herein by reference.

-C- **Duke University Hospital.** In Section Q Form C.3a and C.3b Utilization Assumptions and Methodology, the applicant provides the assumptions and the methodology for its utilization projections. The discussion regarding utilization found in Criterion (3) is incorporated herein by reference.

-C- **Duke Ambulatory Surgery Center Arringdon.** In Section Q Form C.3a and C.3b Utilization Assumptions and Methodology, pages 118-132, the applicant provides the assumptions and methodology used to project utilization at Arringdon and in the Durham County Duke health system. The discussion regarding utilization found in Criterion (3) is incorporated herein by reference.

SECTION .2300 – CRITERIA AND STANDARDS FOR COMPUTED TOMOGRAPHY EQUIPMENT is applicable to:

Project ID #J-12065-21/ **UNC Hospitals-RTP**/Develop 40 acute care beds and two ORs

10A NCAC 14C .2303 PERFORMANCE STANDARDS

An applicant proposing to acquire a CT scanner shall demonstrate each of the following:

(1) each fixed or mobile CT scanner to be acquired shall be projected to perform 5,100 HECT units annually in the third year of operation of the proposed equipment;

-C- **UNC Hospitals-RTP.** The applicant proposes to develop a new hospital and proposes to acquire a CT scanner. In Section Q Form C.2b, the applicant projects to perform 11,530 HECT units in the third year of operation of the proposed equipment. The discussions regarding analysis of need and projected utilization found in Criterion (3) are incorporated herein by reference. Therefore, the application is conforming with this Rule.

(2) each existing fixed or mobile CT scanner which the applicant or a related entity owns a controlling interest in and is located in the applicant's CT service area shall have performed at least 5,100 HECT units in the 12 month period prior to submittal of the application; and

-NA- **UNC Hospitals-RTP.** Neither UNC Hospitals, nor any related entities, own any CT scanners located in the Durham/Caswell county service area.

(3) each existing and approved fixed or mobile CT scanner which the applicant or a related entity owns a controlling interest in and is located in the applicant's CT service area shall be projected to perform 5,100 HECT units annually in the third year of operation of the proposed equipment.

-NA- **UNC Hospitals-RTP.** Neither UNC Hospitals, nor any related entities, own any CT scanners located in the Durham/Caswell county service area.

SECTION .3800 – CRITERIA AND STANDARDS FOR ACUTE CARE BEDS are applicable to:

- Project ID #J-12065-21/ **UNC Hospitals-RTP**/Develop 40 acute care beds and two ORs
- Project ID #J-12069-21/**Duke University Hospital**/Add 40 acute care beds

10A NCAC 14C .3803 PERFORMANCE STANDARDS

(a) An applicant proposing to develop new acute care beds shall demonstrate that the projected average daily census (ADC) of the total number of licensed acute care beds proposed to be licensed within the service area, under common ownership with the applicant, divided by the total number of those licensed acute care beds is reasonably projected to be at least 66.7 percent when the projected ADC is less than 100 patients, 71.4 percent when the projected ADC is 100 to 200 patients, and 75.2 percent when the projected ADC is greater than 200 patients, in the third operating year following completion of the proposed project or in the year for which the need determination is identified in the State Medical Facilities Plan, whichever is later.

-C- **UNC Hospitals-RTP.** The applicant proposes to develop a new hospital with 40 acute care beds and two ORs. The projected ADC of the total number of licensed acute care beds proposed to be licensed within the service area and owned by UNC Hospitals is less than 100. The applicant adequately demonstrates that the projected utilization of the total number of licensed acute care beds proposed to be licensed within the service area and which are owned by UNC Hospitals is reasonably projected to be at least 66.7 percent by the end of the third operating year following completion of the proposed project. The discussion regarding utilization found in Criterion (3) is incorporated herein by reference.

-C- **Duke University Hospital.** The applicant proposes to add 40 acute care beds at DUH for a total of 1,102 acute care beds. DUH is an academic medical center teaching hospital, and NC Gen. Stat. 131E-183(b) provides, in part:

> *". . . 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."*

Thus, this applicant is not required to provide the projected utilization of acute care beds at DRH. The applicant adequately demonstrates that DUH will have a utilization rate of at least 75.2%. The discussions regarding analysis of need and projected utilization found in Criterion (3) are incorporated herein by reference. Therefore, the application is conforming with this Rule.

(b) An applicant proposing to develop new acute care beds shall provide all assumptions and data used to develop the projections required in this rule and demonstrate that they support the projected inpatient utilization and average daily census.

-C- **UNC Hospitals-RTP.** See Section Q for the applicant's data, assumptions, and methodology used to project utilization. The applicant adequately demonstrates the need for the proposed project and that its assumptions and methodology support the projected inpatient utilization and average daily census. The discussions regarding analysis of need and projected utilization found in Criterion (3) are incorporated herein by reference. Therefore, the application is conforming with this Rule.

-C- **Duke University Hospital.** See Section Q for the applicant's data, assumptions, and methodology used to project utilization. The applicant adequately demonstrates the need for the proposed project and that its assumptions and methodology support the projected inpatient utilization and average daily census. The discussions regarding analysis of need and projected utilization found in Criterion (3) are incorporated herein by reference. Therefore, the application is conforming with this Rule.

COMPARATIVE ANALYSIS FOR ACUTE CARE BEDS

Pursuant to G.S. 131E-183(a)(1) and the 2021 State Medical Facilities Plan, no more than 40 acute care beds may be approved for the Durham/Caswell service area in this review. Because the applications in this review collectively propose to develop 80 additional acute care beds in Durham County, both applications cannot be approved for the total number of beds proposed. Therefore, after considering all the information in each application and reviewing each application individually against all applicable review criteria, the Project Analyst conducted a comparative analysis of the proposals to decide which proposal should be approved.

Below is a brief description of each project included in the Acute Care Bed Comparative Analysis.

- Project ID #J-12065-21 / **UNC Hospitals-RTP (UNC-RTP)** / Develop a new hospital with 40 acute care beds and two ORs pursuant to the 2021 SMFP Need Determination
- Project ID #J-12069-21 / **Duke University Hospital** / Develop 40 additional acute care beds pursuant to the 2021 SMFP Need Determination

As the above description of each proposed project indicates, one applicant is seeking to develop 40 acute care beds at a new, separately licensed hospital and the other applicant is proposing to add 40 acute care beds to its existing quaternary care hospital. UNC's proposed new hospital would be a small, community hospital with 40 beds, treating patients with low acuity levels, and projects 10,749 acute care days and 2,238 discharges in its third full fiscal year (FY2029). Duke's 40 acute care beds are proposed to be added to a Level I trauma quaternary care academic medical center, which would have 1,102 acute care beds and projects 349,972 acute care days and 46,182 discharges in its third full fiscal year (FY2028). The proposed new hospital projects significantly lower numbers of acute care days and discharges than the quaternary care hospital projects. If both projects could be approved, UNC's proposed new hospital would have 3.6 percent of the acute care beds that Duke' quaternary care center would have. Because of the significant differences in types of facilities, numbers of total acute care beds, numbers of projected acute care days and discharges, levels of patient acuity which can be served, total revenues and expenses, and the differences in presentation of pro forma financial statements, some comparatives may be of less value and result in less than definitive outcomes than if all applications were for like facilities of like size proposing like services and reporting in like formats.

Further, the analysis of comparative factors and what conclusions the Agency reaches (if any) with regard to specific comparative analysis factors is determined in part by whether or not the applications included in the review provide data that can be compared and whether or not such a comparison would be of value in evaluating the competitive applications.

Conformity with Review Criteria

Table 5B on page 46 of the 2021 SMFP identifies a need for 40 additional acute care beds in the Durham/Caswell county service area. As shown in Table 5A, page 39, the Duke health system shows a projected deficit of 40 acute care beds for 2023. However, the application process is not limited to the provider (or providers) that show a deficit and create the need for additional acute care beds. Any provider can apply to develop the 40 acute care beds in Durham County. Furthermore, it is not necessary that an existing provider have a projected deficit of acute care beds to apply for more acute care beds. However, it is necessary that an applicant adequately demonstrate the need to develop its project, as proposed.

Both applications are conforming to all applicable statutory and regulatory review criteria. Therefore, with regard to conformity with review criteria, both applications are equally effective alternatives.

Scope of Services

Generally, the application proposing to provide the greatest scope of services is the more effective alternative with regard to this comparative factor.

Duke University Hospital is an existing acute care hospital which provides numerous types of medical services. **UNC Hospitals-RTP** is a proposed new separately licensed community hospital; however, as a smaller, community hospital, it will not provide as many types of medical services as **Duke University Hospital**, a Level I trauma center and a quaternary care academic medical center.

Therefore, **Duke University Hospital** is a more effective alternative with respect to this comparative factor and **UNC Hospitals-RTP** is a less effective alternative.

Geographic Accessibility

There are 1,388 existing and approved acute care beds in Durham County and none in Caswell County, allocated between three existing facilities, as shown in the table below.

Facility	Licensed Acute Care Beds	CON Adjustments	Total Acute Care Beds
Duke University Hospital	946	102	1,048
Duke Regional Hospital	316	0	316
Duke Health System Total	**1,262**	**102**	**1,364**
North Carolina Specialty Hospital	18	6	24
Durham County Total	**1,280**	**108**	**1,388**

Sources: Table 5A, 2021 SMFP; 2020 LRAs; Agency records

The following table illustrates where the existing and approved acute care beds are located within Durham County.

Facility	Total AC Beds	Address	Location
Duke University Hospital	1,048	2301 Erwin Rd, Durham 27710	Central Durham County
Duke Regional Hospital	316	3643 N. Roxboro Rd, Durham 27704	Central Durham County
North Carolina Specialty Hospital	24	3916 Ben Franklin Blvd, Durham 27704	Central Durham County

As shown in the table above, the three existing hospitals are all located in Central Durham County, within approximately five miles of one another. **Duke University Hospital** proposes to add 40 acute care beds at its existing facility in Central Durham County. **UNC Hospitals-RTP** proposes to develop a new hospital with two ORs in South Durham County.

UNC Hospitals-RTP proposes to develop acute care beds in South Durham County where there are currently no existing acute care beds. Therefore, **UNC Hospitals-RTP** is a more effective alternative with regard to geographic accessibility and **Duke University Hospital** is a less effective alternative.

Historical Utilization

The table below shows acute care bed utilization for existing facilities based on acute care days as reported in Table 5A of the 2021 SMFP. Generally, the applicant with the higher historical utilization is the more effective alternative with regard to this comparative analysis factor.

Facility	FFY2019 Acute Care Days	ADC	Total Acute Care Beds*	Utilization	Projected (Surplus)/Deficit
Duke University Hospital	295,221	809	946	85.5%	79
Duke Regional Hospital	69,947	192	316	60.6%	(39)
North Carolina Specialty Hospital	3,144	9	18	47.9%	(10)

Sources: Table 5A, 2021 SMFP; 2020 LRAs; Agency records
*Existing acute care beds during FFY2019 only.

As shown in the table above, **Duke University Hospital** has a higher historical utilization than the other two acute care facilities in Durham County. However, Duke University Hospital is the only existing facility applying to add acute care beds in Durham County. **UNC Hospitals-RTP** is not an existing facility and thus has no historical utilization.

Therefore, a comparison of historical utilization cannot be effectively evaluated.

Competition (Patient Access to a New or Alternative Provider)

There are 1,388 existing and approved acute care beds located in Durham County. Duke University Hospital and Duke Regional Hospital are affiliated with Duke Health, which currently controls 1,364 of the 1,388 acute care beds in Durham County, or 98 percent. **Duke University Hospital** controls 75.5 percent of the acute care beds in Durham County.

If **Duke University Hospital's** application to add 40 beds is approved, **Duke University Hospital** would control 1,088 of the 1,428 existing and approved acute care beds in Durham County, or 76.2 percent, with the Duke Health system controlling 98.3 percent of all Durham County acute care beds. If **UNC Hospitals-RTP's** application is approved, **UNC Hospitals-RTP** would control 40 of the 1,428 existing and approved acute care beds in Durham County, or 2.8 percent of the Durham County acute care beds.

Therefore, with regard to competition, the application submitted by **UNC Hospitals-RTP** is the more effective alternative, and the application submitted by **Duke University Hospital** is the less effective alternative.

Access by Service Area Residents

On page 31, the 2021 SMFP defines the service area for acute care beds as *". . . the single or multicounty grouping shown in Figure 5.1."* Figure 5.1, on page 36, shows the multicounty grouping of Durham and Caswell counties as the acute care bed service area. Thus, the service area for this review of acute care beds is Durham and Caswell counties. Facilities may also serve residents of counties not included in their service area. Generally, the application projecting to serve the highest percentage of Durham and Caswell county residents is the more effective alternative with regard to

this comparative factor since the need determination is for 40 additional acute care beds to be located in the Durham/Caswell county service area.

However, the acute care bed need determination methodology is based on utilization of all patients that utilize acute care beds in Durham or Caswell County and is not based on patients originating from Durham and Caswell counties. Further, Durham County is a relatively large urban county, currently served by Duke University Hospital, a full-service tertiary and quaternary care hospital with specialists serving patients from all over North Carolina. UNC Hospitals-RTP is proposing a small, community hospital in south Durham County. Obviously the two hospitals are different types of facilities and offer a different scope of services.

Considering the discussion above, the Agency believes that in this specific instance attempting to compare the applicants based on the projected acute care bed access of Durham and Caswell County residents would be ineffective. Therefore, a comparison of access by service area residents cannot be effectively evaluated.

Access by Underserved Groups

"Underserved groups" is 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, the applications in this review 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

The following table shows projected charity care during the third full fiscal year following project completion for each facility. Generally, the application projecting to provide the most charity care is the more effective alternative with regard to this comparative factor.

Projected Charity Care Inpatient Services – 3rd Full FY			
Applicant	**Total Charity Care**	**Average Charity Care per Discharge**	**% of Gross Revenue**
Duke University Hospital *	$117,155,479	$2,872	3.2%
UNC Hospitals-RTP	$10,493,509	$4,689	8.7%

Sources: Forms C and F.2 for each applicant
*Adult inpatient services

In Section L, page 77, **Duke University Hospital** defines charity care as free or discounted care provided to persons in medical need who are unable to financially afford to pay for their care, and who do not qualify for public or private assistance.

In its Form F.2 Assumptions, **UNC Hospitals-RTP** states that projected charity care is the difference between projected gross revenue and projected net revenue for self-pay patients.

Based on the differences in how each applicant categorizes charity care and the differences in presentation of pro forma financial statements, the Agency determined it could not make a valid comparison of the charity care provided by each applicant for purposes of evaluating which application was more effective with regard to this comparative factor.

However, even if the applicants had provided pro forma financial statements in a manner that would allow the Agency to compare reasonably similar kinds of data, differences in the acuity level of patients at each facility, and the level of care (community hospital, tertiary care hospital, and quaternary care academic medical center) at each facility would make any comparison of little value.

Projected Medicare

The following table shows projected Medicare revenue during the third full fiscal year following project completion for each facility. Generally, the application projecting the highest Medicare revenue is the more effective alternative with regard to this comparative factor to the extent the Medicare revenue represents the number of Medicare patients served.

Projected Medicare Revenue – 3rd Full FY			
Applicant	**Total Medicare Rev.**	**Av. Medicare Rev./Discharge**	**% of Gross Rev.**
Duke University Hospital *	$ 1,930,001,447	$ 47,318	52.9%
UNC Hospitals-RTP	$ 60,881,892	$ 27,204	50.7%

Sources: Forms C and F.2 for each applicant
*Adult inpatient services

Based on the differences in presentation of pro forma financial statements, the number of patients, and the level of care at each facility, the Agency determined it could not make a valid comparison for purposes of evaluating which application was more effective with regard to this comparative factor. **Duke University Hospital**, an existing large quaternary care academic medical center proposing to add adult inpatient beds, has pro forma financial statements that are structured differently than **UNC Hospitals-RTP**, which is proposing to develop a new, relatively small community hospital.

However, even if the applicants had provided pro forma financial statements in a manner that would allow the Agency to compare reasonably similar kinds of data, differences in the acuity level of patients at each facility, and the level of care (community hospital and quaternary care academic medical center) at each facility would make any comparison of little value.

Projected Medicaid

The following table shows projected Medicaid revenue during the third full fiscal year following project completion for each facility. Generally, the application projecting the highest Medicaid revenue is the more effective alternative with regard to this comparative factor to the extent the Medicaid revenue represents the number of Medicaid patients served.

Projected Medicaid Revenue – 3rd Full FY			
Applicant	**Total Medicaid Rev.**	**Av. Medicaid Rev./Discharge**	**% of Gross Rev.**
Duke University Hospital *	$ 396,406,070	$ 9,719	10.9%
UNC Hospitals-RTP	$ 18,865,906	$ 8,430	15.7%

Sources: Forms C and F.2 for each applicant
*Adult inpatient services

Based on the differences in presentation of pro forma financial statements, the Agency determined it could not make a valid comparison for purposes of evaluating which application was more effective with regard to this comparative factor. **Duke University Hospital**, an existing large quaternary care academic medical center proposing to add adult inpatient beds, has pro forma financial statements that are structured differently than **UNC Hospitals-RTP**, which is proposing to develop a new, relatively small community hospital.

However, even if the applicants had provided pro forma financial statements in a manner that would allow the Agency to compare reasonably similar kinds of data, differences in the acuity level of patients at each facility, and the level of care (community hospital and quaternary care academic medical center) at each facility would make any comparison of little value.

Projected Average Net Revenue per Patient

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

Projected Average Net Revenue per Discharge – 3rd Full FY			
Applicant	**Total # of Discharges**	**Net Revenue**	**Average Net Revenue / Discharge**
Duke University Hospital *	40,788	$1,152,860,372	$28,265
UNC Hospitals-RTP	2,238	$ 47,304,485	$21,137

Sources: Forms C and F.2 for each applicant
*Adult inpatient services

Based on the differences in presentation of pro forma financial statements, the Agency determined it could not make a valid comparison for purposes of evaluating which application was more effective with regard to this comparative factor. **Duke University Hospital**, an existing large quaternary care academic medical center proposing to add adult inpatient beds, has pro forma financial statements that are structured differently than **UNC Hospitals-RTP**, which is proposing to develop a new, relatively small community hospital.

However, even if the applicants had provided pro forma financial statements in a manner that would allow the Agency to compare reasonably similar kinds of data, differences in the acuity level of patients at each facility, and the level of care (community hospital and quaternary care academic medical center) at each facility would make any comparison of little value.

Projected Average Operating Expense per Patient

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 Operating Expense per Discharge – 3rd Full FY			
Applicant	**Total # of Discharges**	**Operating Expense**	**Average Operating Expense / Discharge**
Duke University Hospital *	40,788	$1,510,709,079	$37,038
UNC Hospitals-RTP	2,238	$ 42,521,459	$19,000

Sources: Forms C and F.2 for each applicant
*Adult inpatient services

Based on the differences in presentation of pro forma financial statements, the Agency determined it could not make a valid comparison for purposes of evaluating which application was more effective with regard to this comparative factor. **Duke University Hospital**, an existing large quaternary care academic medical center proposing to add adult inpatient beds, has pro forma financial statements that are structured differently than **UNC Hospitals-RTP**, which is proposing to develop a new, relatively small community hospital.

However, even if the applicants had provided pro forma financial statements in a manner that would allow the Agency to compare reasonably similar kinds of data, differences in the acuity level of patients at each facility, and the level of care (community hospital and quaternary care academic medical center) at each facility would make any comparison of little value.

SUMMARY

Due to significant differences in the size of hospitals, levels of acuity each hospital can serve, total revenues and expenses, and the differences in presentation of pro forma financial statements, some of the comparatives may be of less value and result in less than definitive outcomes than if all applications were for like facilities of like size and reporting in like formats.

The following table lists the comparative factors and states which application is the more effective alternative with regard to that particular comparative factor. Note: 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 AC Beds	DUH	UNC-RTP
Conformity with Review Criteria	Yes	Yes
Scope of Services	**More Effective**	Less Effective
Geographic Accessibility	Less Effective	**More Effective**
Historical Utilization	Not Evaluated	Not Evaluated
Competition/Access to New Provider	Less Effective	**More Effective**
Access by Service Area Residents	Not Evaluated	Not Evaluated
Access by Underserved Groups		
Projected Charity Care	Inconclusive	Inconclusive
Projected Medicare	Inconclusive	Inconclusive
Projected Medicaid	Inconclusive	Inconclusive
Projected Average Net Revenue per Case	Inconclusive	Inconclusive
Projected Average Operating Expense per Case	Inconclusive	Inconclusive

- With respect to Conformity with Review Criteria, **Duke University Hospital and UNC Hospital-RTP** offer equally effective alternatives. See Comparative Analysis for discussion.

- With respect to Scope of Services, **Duke University Hospital** offers the more effective alternative. See Comparative Analysis for discussion.

- With respect to Geographic Accessibility, **UNC Hospital-RTP** offers the most effective alternative. See Comparative Analysis for discussion.

- With respect to Competition/Access to New Provider, **UNC Hospital-RTP** offers the more effective alternative. See Comparative Analysis for discussion.

CONCLUSION

G.S. 131E-183(a)(1) states that the need determination in the SMFP is the determinative limit on the number of acute care beds that can be approved by the Healthcare Planning and Certificate of Need Section. Approval of both applications submitted during this review would result in acute care beds in excess of the need determination for Durham County. Both applications submitted for acute care beds in this review are conforming to all applicable statutory and regulatory review criteria and are approvable standing alone. However, collectively they propose 80 acute care beds while the need determination is for 40 acute care beds; therefore, only 40 acute care beds can be approved.

As discussed above, **UNC Hospital-RTP** was determined to be the more effective alternative for two factors:

- Geographic Accessibility
- Competition/Access to a New Provider

As discussed above, **Duke University Hospital** was determined to be the more effective alternative for one factor:

- Scope of Services

With regard to acute care beds, the **Project ID #J-12065-21** submitted by **UNC Hospital-RTP** is comparatively superior and is approved as submitted.

1. University of North Carolina Hospitals at Chapel Hill and University of North Carolina Health Care System (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.

2. The certificate holder shall develop a new, separately licensed hospital, with no more than 40 acute care beds and no more than two shared ORs pursuant to the need determinations in the 2021 SMFP.

3. The certificate holder shall also develop no more than two dedicated C-Section ORs, no more than two unlicensed procedure rooms, 10 unlicensed observation beds and no more than one CT scanner at the new, separately licensed hospital, to be named UNC Hospitals-RTP.

4. Upon completion of the project, UNC Hospital-RTP shall be licensed for no more than 40 acute care beds and no more than two shared ORs, and two dedicated C-Section ORs.

5. Progress Reports:
   a. Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: https://info.ncdhhs.gov/dhsr/coneed/progressreport.html.
   b. The certificate holder shall complete all sections of the Progress Report form.
   c. The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.
   d. Progress reports shall be due on the first day of every third month. The first progress report shall be due on December 1, 2021. The second progress report shall be due on March 1, 2022 and so forth.

6. The certificate holder shall not acquire as part of this project any equipment that is not included in the project's proposed capital expenditures in Section Q of the application and that would otherwise require a certificate of need.

7. The certificate holder shall 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.

8. 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.

9. 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.

COMPARATIVE ANALYSIS FOR OPERATING ROOMS

Pursuant to G.S. 131E-183(a)(1) and the 2021 State Medical Facilities Plan, no more than four ORs may be approved for Durham County in this review. Because the four applications in this review collectively propose to develop 10 additional ORs in Durham County, all the applications cannot be approved for the total number of ORs proposed. Therefore, after considering all the information in each application and reviewing each application individually against all applicable 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 the Operating Room Comparative Analysis:

- Project ID #J-12052-21/**Southpoint Surgery Center (SSC)**/Add four ORs
- Project ID #J-12065-21/**UNC Hospitals-RTP (UNC-RTP)**/Develop a new hospital with 40 acute care beds and two ORs
- Project ID #J-12070-21/**Duke University Hospital (DUH)**/Add two ORs
- Project ID #J-12075-21/**Duke Ambulatory Surgery Center Arringdon (Arringdon)** /Add two ORs

As the above description of each proposed project indicates, **Southpoint Surgery Center** is seeking to add four ORs for a total of six ORs to an approved, but undeveloped ASF, and projects to perform 6,803 surgeries in its third full fiscal year (CY2025). **UNC Hospitals-RTP** is seeking to develop a new, separately licensed community hospital with 40 beds and two ORs, treating patients with low acuity levels, and projects to perform 1,926 surgeries in its third full fiscal year (FY2029). **Duke University Hospital** is proposing to add two ORs at an existing quaternary care academic medical center, which would have 69 ORs (excluding dedicated C-Section ORs) and projects to perform 43,857 surgeries in its third full fiscal year (FY2028). **Duke Ambulatory Surgery Center Arringdon** is seeking to add two ORs for a total of six ORs at an ASF that opened for operations in December 2020 and projects to perform 6,943 surgeries in its third full fiscal year (FY2025). The proposed new hospital will have only two ORs and projects a minimal number of surgeries. The two ASFs, each with a proposed six ORs, project three times as many surgeries as the new hospital and the existing hospital projects an exponentially higher number of surgeries than projected by the other applicants. Because of the significant differences in types of facilities, numbers of total ORs, numbers of projected surgeries, types of proposed surgical services offered, total revenues and expenses, and the differences in presentation of pro forma financial statements, some comparatives may be of less value and result in less than definitive outcomes than if all applications were for like facilities of like size proposing like services and reporting in like formats.

Further, the analysis of comparative factors and what conclusions the Agency reaches (if any) with regard to specific comparative analysis factors is determined in part by whether or not the applications included in the review provide data that can be compared and whether or not such a comparison would be of value in evaluating the competitive applications.

Conformity with Review Criteria

Table 6C on page 81 of the 2021 SMFP identifies a need for four additional ORs in the Durham/Caswell county service area. This is an error in the SMFP. As shown in figure 6.1, page 55 of the 2021 SMFP, Durham county is a separate OR service area. Caswell and Guilford counties are a multicounty service area. Table 6A, pages 58-59, shows that Durham County has two health systems providing surgical

services: Duke University Health System and North Carolina Specialty Hospital. The Duke health system is composed of Duke Ambulatory Surgery Center Arringdon, James E. Davis Ambulatory Surgical Center, Duke University Hospital and Duke Regional Hospital. The NCSH health system is composed of Southpoint Surgery Center and North Carolina Specialty Hospital.

As shown in Table 6B, page 71, the Duke system shows a projected deficit of 2.49 ORs for 2023 and the NCSH system shows a projected deficit of 1.04 ORs in 2023, which results in the Durham County need determination for four ORs. However, the application process is not limited to the provider (or providers) that show a deficit and create the need for additional ORs. Any provider can apply to develop the four ORs in Durham County. Furthermore, it is not necessary that an existing provider have a projected deficit of ORs to apply for more ORs. However, it is necessary that an applicant adequately demonstrate the need to develop its project, as proposed.

The applications submitted by **UNC Hospitals-RTP, Duke University Hospital**, and **Duke Ambulatory Surgery Center Arringdon** are conforming to all applicable statutory and regulatory review criteria. However, the application submitted by **Southpoint Surgery Center** is not conforming to all applicable statutory and regulatory review criteria. An application that is not conforming to all applicable statutory and regulatory review criteria cannot be approved. Therefore, regarding this comparative factor, the applications submitted by **UNC Hospitals-RTP, Duke University Hospital**, and **Duke Ambulatory Surgery Center Arringdon** are equally effective alternatives.

Scope of Services

Generally, the application proposing to provide the greatest scope of services is the more effective alternative with regard to this comparative factor.

UNC Hospitals-RTP and **Duke University Hospital** are acute care hospitals which provide numerous types of surgical services, both inpatient and ambulatory. **Southpoint Surgery Center** and **Duke Ambulatory Surgery Center Arringdon** are both newly approved ASFs providing ambulatory surgical services only: Southpoint Surgery Center is still under development and Duke Ambulatory Surgery Center Arringdon became operational in December 2020.

Therefore, **UNC Hospitals-RTP** and **Duke University Hospital** are more effective alternatives with respect to this comparative factor and **Southpoint Surgery Center** and **Duke Ambulatory Surgery Center Arringdon** are less effective alternatives. However, **Southpoint Surgery Center** is not approvable and therefore cannot be an effective alternative.

Geographic Accessibility

Not including dedicated C-Section ORs and trauma ORs, there are 93 existing and approved ORs in Durham County, allocated between six existing and/or approved facilities, as shown in the table below.

Durham County OR Inventory						
Facility	**IP ORs**	**OP ORs**	**Shared ORs**	**Excluded C-Section and Trauma ORs**	**CON Adjustments**	**Total ORs**
Duke Ambulatory Surgery Center Arringdon*	0	0	0	0	4	4
James E. Davis Ambulatory Surgical Center*	0	8	0	0	-4	4
Duke University Hospital	6	9	50	-1	2	66
Duke Regional Hospital	2	0	13	-2	0	13
Duke Health System Total	**8**	**17**	**63**	**-3**	**2**	**87**
Southpoint Surgery Center**	0	0	0	0	2	2
North Carolina Specialty Hospital	0	0	4	0	0	4
NC Specialty Hospital System Total	**0**	**0**	**4**	**0**	**2**	**6**
Durham County Total	**8**	**17**	**67**	**-3**	**4**	**93**

Sources: Table 6A, 2021 SMFP; 2020 LRAs; Agency records

*Arringdon was approved in Project ID #J-11508-18 (relocate four ORs from DASC to develop Duke Ambulatory Surgery Center Arringdon). Arringdon became operational in December 2020.

**SSC, an approved ASF under development, will have 2 ORs pursuant to Project ID #J-11626-18

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

Facility	Type	Durham SA OR System	Total ORs	Address	Location
NCSH	Existing Hospital	NCSH	4	3916 Ben Franklin Blvd, Durham 27704	Central Durham County
DUH	Existing Hospital	Duke	66	2301 Erwin Rd, Durham 27710	Central Durham County
DRH	Existing Hospital	Duke	13	3643 N. Roxboro Rd, Durham 27704	Central Durham County
DASC	Existing ASF	Duke	4	2400 Pratt St, Durham 27710	Central Durham County
Arringdon	Existing ASF	Duke	4	5601 Arringdon Park Dr, Morrisville 27560	South Durham, near I540 at I40
SSC	Approved ASF	NCSH	2	7810 NC Hwy 751, Durham 27713	South Durham, near Hwy 147
UNC-RTP	Proposed Hospital	UNC	2	Parcels in Research Triangle Park 27709	South Durham, just below I40

As shown in the table above, the three existing hospitals and one existing ASF are located in Central Durham County, within approximately five miles of one another, and account for 87 of the existing and approved 93 ORs in Durham County. Two recently approved ASFs are located in South Durham along with the proposed UNC-RTP hospital. The Duke health system proposes to add two ORs to the existing **Duke University Hospital** in Central Durham and two ORs to its existing **Duke Ambulatory Surgery Center Arringdon** ASF in South Durham. The NCSH health system proposes to add four ORs to the approved, but not operational **Southpoint Surgery Center** in South Durham. **UNC Hospitals-RTP** proposes to develop a new hospital with two ORs in South Durham.

UNC Hospitals-RTP, Duke Ambulatory Surgery Center Arringdon, and **Southpoint Surgery Center** propose to develop ORs in South Durham County where there are currently only six of 93 existing/approved Durham County ORs. Therefore, **UNC Hospitals-RTP, Duke Ambulatory Surgery Center Arringdon,** and **Southpoint Surgery Center** are more effective alternatives with regard to geographic accessibility and **Duke University Hospital** is a less effective alternative. However, **Southpoint Surgery Center** is not approvable and therefore cannot be an effective alternative.

Patient Access to Lower Cost Surgical Services

There are currently 93 existing or approved ORs (excluding dedicated C-Section and trauma ORs) in the Durham County OR service area. ORs can be licensed as part of a hospital or an ASF. Based on the applications, written comments, and response to comments, 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 will often be much higher if performed in a hospital-based OR or, conversely, much less expensive if performed in an OR located at an ASF. While many outpatient surgical services can be performed in an OR located at an ASF, not all of them are appropriate for an OR located at an ASF, and inpatient surgical services must be performed in a hospital-based OR.

The following table identifies the existing and approved inpatient (IP), outpatient/dedicated ambulatory surgery (OP), and shared inpatient/outpatient ORs in Durham County.

	Total ORs*	IP ORs	% IP of Total ORs	OP ORs	% OP of Total ORs	Shared ORs	% Shared of Total ORs
Durham County ORs	93	7	7.5%	19	20.4%	67	72.0%

Sources: 2021 SMFP, Agency records

*Includes existing and approved ORs and excludes 3 dedicated C-Section and/or designated trauma ORs.

The table below shows the percentage of total Durham County surgical cases that were outpatient surgeries in FFY 2019, based on data reported in the 2021 SMFP.

Outpatient Surgical Cases as Percent of Total Durham County Surgical Cases					
Facility	**Type of ORs**	**IP Cases**	**OP Cases**	**Total Cases**	**OP %**
Duke Ambulatory Surgery Center Arringdon	ASF	0	0	0	0%
James E. Davis Ambulatory Surgical Center	ASF	0	6,079	6,079	100%
Duke University Hospital	Hospital/Shared	18,733	22,139	40,872	54%
Duke Regional Hospital	Hospital/Shared	3,991	3,555	7,546	47%
Southpoint Surgery Center	ASF	0	0	0	0%
North Carolina Specialty Hospital	Hospital/Shared	1,588	4,128	5,716	72%
Total Cases and Average OP Percentage		**24,312**	**35,901**	**60,213**	**60%**

Source: Table 6B, 2021 SMFP

As the table above shows, an average of 60% percent of the total Durham County surgical cases in FFY 2019 were outpatient surgical cases. Durham County currently has three existing and approved ASFs with a total of 10 dedicated ambulatory ORs and nine dedicated ambulatory ORs in a hospital setting. Based on the fact that 60 percent of Durham County's FFY 2019 surgical cases were ambulatory surgery cases and that dedicated ambulatory surgery ORs represent 20.4 percent of the total existing and approved Durham County ORs, projects proposing the development of dedicated ambulatory surgery ORs would represent more effective alternatives.

Therefore, the applications submitted by **Duke Ambulatory Surgery Center Arringdon,** and **Southpoint Surgery Center** are the more effective proposals with respect to this comparative factor and the applications submitted by **Duke University Hospital** and **UNC Hospitals-RTP** are less effective with respect to this comparative factor. However, **Southpoint Surgery Center** is not approvable and therefore cannot be an effective alternative.

Historical Utilization

The table below shows OR utilization for both Duke and NCSH facilities based on surgical hours as reported in Table 6A of the 2021 SMFP. Generally, the applicant with the highest historical utilization is the more effective alternative with regard to this comparative analysis factor.

Durham County Historical OR Utilization (Table 6A of 2021 SMFP)				
Facility	**FFY 2019 Surgical Hours**	**Surgical Hours for Group**	**Total ORs***	**Utilization Rate**
DUH	133,311.4	1,950	64	106.82%
DRH	22,099.9	1,755	13	96.87%
DASC^	6,329.3	1,312	8	60.30%
NCSH	10,775.4	1,500	4	179.59%

*Existing ORs during FFY 2019 only

^Project ID #J-11508-18 approves the relocation of four of DASC's eight ORs to Arringdon

As shown in the table above, each of the existing hospitals has a high utilization rate. DASC, the ASF from which four of eight ORs are approved to be relocated to Arringdon, would have a utilization rate of 120% with four ORs. There is only one existing facility that reported utilization for FFY2019 that is proposing to develop additional operating rooms in this review - **Duke University Hospital. Duke Ambulatory Surgery Center Arringdon** and **Southpoint Surgery Center** were not yet operational in FFY2019 and as such have no historical utilization. Thus, this comparative is inconclusive and of no value in this review.

Competition (Patient Access to a New or Alternative Provider)

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

There are 93 existing and approved ORs (excluding dedicated C-Section ORs and trauma ORs) located in Durham County. The table below shows the number and percentage of ORs in which each applicant or health system has ownership.

ORs in Durham County by Health System/Applicant		
Health System (Applicants)	**Number of ORs**	**Percent of ORs**
Duke (DUH, DRH, DASC, and Arringdon)	87	93.5%
NCSH (NCSH and SSC)	6	6.5%
Total	93	100.0%

There is a need determination in the 2021 SMFP for four ORs, which increases the total number of existing and approved ORs (excluding dedicated C-Section ORs and trauma ORs) located in Durham County to 97 ORs. The table below shows the number of ORs and percentage of the total each applicant or health system would control if all applications were approved as submitted, which would add 10 ORs, not four.

ORs in Durham County by Health System/Applicant – If Approved		
Health System (Applicants)	**Number of ORs**	**Percent of ORs**
Duke (DUH, DRH, DASC, and Arringdon)	91	88.3%
NCSH (NCSH and SSC)	10	9.7%
UNC-RTP	2	1.9%
Total	103	100.0%

If both Duke health system applications (**Duke University Hospital** and **Duke Ambulatory Surgery Center Arringdon**) are approved as submitted, Duke would control 91 of the 103 existing and approved ORs located in Durham County, or 88.3 percent. If **Southpoint Surgery Center's** application was approvable, the NCSH health system would control 10 of the 103 existing and approved ORs located in Durham County, or 9.7 percent. **UNC Hospitals-RTP** would be a new provider in the Durham County OR service area with 1.9 percent of all Durham County ORs.

Therefore, with regard to competition, the application submitted by **UNC Hospitals-RTP** is the more effective alternative and the applications submitted by **Duke University Hospital**, **Duke Ambulatory Surgery Center Arringdon**, and **Southpoint Surgery Center** are less effective alternatives. Furthermore, **Southpoint Surgery Center** is not approvable and therefore cannot be an effective alternative.

Access by Service Area Residents

On page 49, the 2021 SMFP defines the service area for ORs as *"…the single or multicounty grouping shown in Figure 6.1."* Figure 6.1, page 55, shows Durham County as its own OR service area. Thus, the service area for this facility is Durham County. Facilities may also serve residents of counties not included in their service area.

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

3rd Full FY	
Applicant	**% of Durham County Residents**
DUH	21.8%
Arringdon	26.2%
SSC	36.2%
UNC-RTP	90.0%

Source: Section C.3 (all applications)

As shown in the table above, **UNC Hospitals-RTP** projects to serve the highest percentage of Durham County residents during the third full fiscal year of operation following project completion, followed by **Southpoint Surgery Center**, **Duke Ambulatory Surgery Center Arringdon**, and then **Duke University Hospital**. However, differences in the acuity level of patients at each facility, the level of care (community hospital, quaternary care hospital, ASF, etc.) at each facility, and the number and types of surgical services vs. all patient services proposed by each of the facilities may impact the averages shown in the table above. Thus, the result of this analysis is inconclusive.

Access by Underserved Groups

"Underserved groups" is 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."*

Projected Charity Care

The following table shows projected charity care during the third full fiscal year following project completion for each facility. Generally, the application projecting to provide the most charity care is the more effective alternative with regard to this comparative factor.

Projected Charity Care – 3rd Full FY			
Applicant	Projected Surgical Charity Care	Charity Care per Surgical Case	% of Gross Surgical Revenue
DUH	$96,180,322	$2,193	3.3%
Arringdon	$971,420	$140	1.1%
SSC	$345,474	$51	0.6%

Source: Form F.2 for each applicant

Projected Charity Care – 3rd Full FY		
Applicant	Projected Facility Charity Care	% of Facility Gross Revenue
UNC-RTP	$26,517,350	12.1%

Source: Form F.2. the applicant did not provide a Form F.2 for OR services alone

As shown in the table above, in regard to OR services, **Duke University Hospital** 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. **UNC Hospitals-RTP** did not provide a Form F.2 for surgical services alone; thus, it cannot be compared to the other three projects. Therefore, the application submitted by **Duke University Hospital** is the more effective alternative with regard to access to charity care for surgical services, and the applications submitted by **Southpoint Surgery Center** and **Duke Ambulatory Surgery Center Arringdon** are less effective alternatives. However, differences in the acuity level of patients at each facility, the level of care (community hospital, tertiary care hospital, quaternary care hospital, ASF, etc.) at each facility, and the number and types of surgical services proposed by each of the facilities may impact the averages shown in the table above. Thus, the result of this analysis is inconclusive.

Projected Medicare

The following table shows projected Medicare revenue during the third full fiscal year following project completion for each facility. Generally, the application projecting the highest Medicare revenue is the more effective alternative with regard to this comparative factor to the extent the Medicare revenue represents the number of Medicare patients served.

Projected Medicare Revenue – 3rd Full FY			
Applicant	**Projected Total Medicare Revenue**	**Medicare Revenue per Surgical Case**	**% of Gross Surgical Revenue**
DUH	$1,302,112,452	$29,690	44.7%
Arringdon	$43,171,242	$ 6,218	48.5%
SSC	$24,304,014	$ 3,573	44.3%

Source: Form F.2 for each applicant

Projected Medicare Revenue – 3rd Full FY		
Applicant	**Projected Facility Medicare Revenue**	**% of Gross Facility Revenue**
UNC-RTP	$26,517,350	34.2%

Source: Form F.2. the applicant did not provide a Form F.2 for OR services alone

As shown in the table above, **Duke University Hospital** projects the highest total Medicare revenue in dollars and the highest Medicare revenue per surgical case, and **Duke Ambulatory Surgery Center Arringdon** projects the highest Medicare revenue as a percentage of gross surgical revenue in each project's third full fiscal year following project completion. **UNC Hospitals-RTP** did not provide a Form F.2 for surgical services alone; thus, it cannot be compared to the other three projects. Therefore, the applications submitted by **Duke University Hospital** and **Duke Ambulatory Surgery Center Arringdon** are more effective alternatives with respect to service to Medicare surgical patients and the application submitted by **Southpoint Surgery Center** is a less effective alternative. However, differences in the acuity level of patients at each facility, the level of care (community hospital, tertiary care hospital, quaternary care hospital, etc.) at each facility, and the number and types of surgical services proposed by each of the facilities may impact the averages shown in the table above. Thus, the result of this analysis is inconclusive.

Projected Medicaid

The following table shows projected Medicaid revenue during the third full fiscal year following project completion for each facility. Generally, the application projecting the highest Medicaid revenue is the more effective alternative with regard to this comparative factor to the extent the Medicaid revenue represents the number of Medicaid patients served.

Projected Medicaid Revenue – 3rd Full FY			
Applicant	**Projected Total Medicaid Revenue**	**Medicaid Revenue per Surgical Case**	**% of Gross Surgical Revenue**
DUH	$423,316,953	$9,652	14.54%
Arringdon	$3,526,102	$508	3.96%
SSC	$2,260,213	$332	4.12%

Source: Form F.2 for each applicant

Projected Medicaid Revenue – 3rd Full FY		
Applicant	**Projected Facility Medicaid Revenue**	**% of Gross Facility Revenue**
UNC-RTP	$31,256,132	14.2%

Source: Form F.2. the applicant did not provide a Form F.2 for OR services alone

As shown in the table above, **Duke University Hospital** projects the highest total Medicaid revenue in dollars, the highest Medicaid revenue per case, and the highest Medicaid revenue as a percentage of gross surgical revenue in the project's third full fiscal year following project completion. **UNC Hospitals-RTP** did not provide a Form F.2 for surgical services alone; thus, it cannot be compared to the other three projects. Therefore, the application submitted by **Duke University Hospital** is the more effective alternative with respect to service to Medicaid surgical patients, and the applications submitted by **Duke Ambulatory Surgery Center Arringdon** and **Southpoint Surgery Center** are less effective alternatives. However, differences in the acuity level of patients at each facility, the level of care (community hospital, tertiary care hospital, quaternary care hospital, etc.) at each facility, and the number and types of surgical services proposed by each of the facilities may impact the averages shown in the table above. Thus, the result of this analysis is inconclusive.

Projected Average Net Revenue per Surgical Case/Patient

The following table shows the projected average net surgical revenue per surgical case in the third full fiscal year following project completion for each facility. Generally, the application projecting the lowest average net revenue per surgical case is the more effective alternative with regard to this comparative factor to the extent the average reflects a lower cost to the patient or third-party payor.

Projected Average Net Revenue Per Surgical Case – 3rd Full FY			
Applicant	Total # of Surgical Cases	Net Revenue for Surgical Services	Average Net Revenue per Surgical Cases
DUH	43,857	$865,679,841	$19,739
Arringdon	6,943	$35,614,388	$5,130
SSC	6,803	$18,909,333	$2,780

Source: Form F.2 for each applicant

Projected Average Net Revenue Entire Facility – 3rd Full FY	
UNC-RTP	$77,551,406

Source: Form F.2. the applicant did not provide a Form F.2 for OR services alone

As shown in the table above, **Southpoint Surgical Center** projects the lowest net revenue per surgical case in the third full fiscal year following project completion. **UNC Hospitals-RTP** did not provide a Form F.2 for surgical services alone; thus, it cannot be compared to the other three projects. Therefore, the unapprovable application submitted by **Southpoint Surgical Center** is the more effective alternative with respect to net revenue per surgical case, and the applications submitted by **Duke University Hospital** and **Duke Ambulatory Surgery Center Arringdon** are less effective alternatives. However, differences in the acuity level of patients at each facility, the level of care (community hospital, tertiary care hospital, quaternary care hospital, etc.) at each facility, and the number and types of surgical services proposed by each of the facilities may impact the averages shown in the table above. Thus, the result of this analysis is inconclusive.

Projected Average Operating Expense per Surgical Case/Patient

The following table shows the projected average operating expense per surgical in the third full fiscal

year following project completion for each facility. Generally, the application projecting the lowest average operating expense per surgical case 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 Operating Expense Per Surgical Case – 3rd Full FY			
Applicant	**Total # of Surgical Cases**	**Operating Expenses for Surgical Services**	**Operating Expense per Surgical Cases**
DUH	43,857	$1,182,568,353	$26,964
Arringdon	6,943	$23,686,740	$3,412
SSC	6,803	$15,467,192	$2,274

Source: Form F.2 for each applicant

Projected Operating Expense Entire Facility – 3rd Full FY	
UNC-RTP	$77,551,406

Source: Form F.2. the applicant did not provide a Form F.2 for OR services alone

As shown in the table above, **Southpoint Surgical Center** projects the lowest operating expense per surgical case in the third full fiscal year following project completion. **UNC Hospitals-RTP** did not provide a Form F.2 for surgical services alone; thus, it cannot be compared to the other three projects. Therefore, the unapprovable application submitted by **Southpoint Surgical Center** is the more effective alternative with respect to operating expense per surgical case, and the applications submitted by **Duke University Hospital** and **Duke Ambulatory Surgery Center Arringdon** are less effective alternatives. However, differences in the acuity level of patients at each facility, the level of care (community hospital, tertiary / quaternary care hospital, inpatient / ambulatory surgical services, etc.) at each facility, and the number and types of surgical services proposed by each of the facilities may impact the averages shown in the table above. Thus, the result of this analysis is inconclusive.

SUMMARY

The following table lists the comparative factors and states which application is the more effective alternative with regard to that particular comparative factor. Note: 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	DUH	Arringdon	SSC	UNC-RTP
Conformity with Review Criteria	Yes	Yes	No	Yes
Scope of Services	**More Effective**	Less Effective	Not Approvable	**More Effective**
Geographic Accessibility	Less Effective	**More Effective**	Not Approvable	**More Effective**
Patient Access to Lower Cost Surgical Services	Less Effective	**More Effective**	Not Approvable	Less Effective
Historical Utilization	Inconclusive	Inconclusive	Not Approvable	Inconclusive
Competition/Access to New Provider	Less Effective	Less Effective	Not Approvable	**More Effective**
Access by Service Area Residents	Inconclusive	Inconclusive	Inconclusive	Inconclusive
Access by Underserved Groups				
Projected Charity Care	Inconclusive	Inconclusive	Inconclusive	Inconclusive
Projected Medicare	Inconclusive	Inconclusive	Inconclusive	Inconclusive
Projected Medicaid	Inconclusive	Inconclusive	Inconclusive	Inconclusive
Projected Average Net Revenue per Case	Inconclusive	Inconclusive	Inconclusive	Inconclusive
Projected Average Operating Expense per Case	Inconclusive	Inconclusive	Inconclusive	Inconclusive

The **Southpoint Surgery Center** application is not an effective alternative with respect to Conformity with Review Criteria; therefore, it is not approvable and will not be further discussed in the comparative evaluation below:

- With respect to Conformity with Review Criteria, of the approvable applications, **Duke University Hospital, Duke Ambulatory Surgery Center Arringdon, and UNC Hospitals-RTP** offer equally effective alternatives. See Comparative Analysis for discussion.

- With respect to Scope of Services, the full-service hospitals offer a broader scope of services: Duke University Hospital is a large facility providing tertiary and quaternary care with many specialists, and UNC Hospitals-RTP proposes offering both inpatient and outpatient surgical services in its proposed ORs. Thus, **Duke University Hospital and UNC Hospitals-RTP** offer the more effective alternatives. See Comparative Analysis for discussion.

- With respect to Geographic Accessibility **Duke Ambulatory Surgery Center Arringdon** and **UNC Hospitals-RTP** offer the more effective alternatives. See Comparative Analysis for discussion.

- With respect to Patient Access to Lower Cost Surgical Services, **Duke Ambulatory Surgery Center Arringdon** offers the more effective alternative. See Comparative Analysis for discussion.

- With respect to Competition/Access to New Provider, **UNC Hospitals-RTP** offers the more effective alternative. See Comparative Analysis for discussion.

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. Approval of all applications submitted during this review would result in ORs in excess of the need determination for Durham County.

Three of the four applications submitted to develop ORs in Durham County are conforming to all applicable statutory and regulatory review criteria and are approvable standing alone: **Duke University Hospital, Duke Ambulatory Surgery Center Arringdon, and UNC Hospitals-RTP**. However, collectively they propose six ORs while the need determination is for four ORs; therefore, only four ORs can be approved.

As discussed above, **UNC Hospitals-RTP** was determined to be a more effective alternative for three factors:

- Scope of Services
- Geographic Accessibility
- Competition/Access to a New Provider

As discussed above, **Duke Ambulatory Surgery Center Arringdon** was determined to be a more effective alternative for two factors:

- Geographic Accessibility
- Patient Access to Lower Cost Surgical Services

As discussed above, **Duke University Hospital** was determined to be a more effective alternative for only one factor: Scope of Services.

Thus, the application submitted by **UNC Hospitals-RTP** is the most effective alternative and the application submitted by **Duke Ambulatory Surgery Center Arringdon** is more effective than the application submitted by **Duke University Hospital.**

It is possible to approve the application for **UNC Hospitals-RTP** to develop a new hospital with two ORs while approving the application for **Duke Ambulatory Surgery Center Arringdon** to develop two additional ORs.

Based upon the independent review of each application and the Comparative Analysis, the following applications are approved as submitted:

- **Project ID #J-12065-21 / UNC Hospitals-RTP / Construct a new separately licensed 40-bed hospital by developing 40 acute care beds and two ORs pursuant to the need determination in the 2021 SMFP**

- **Project ID #J-12075-21 / Duke Ambulatory Surgery Center Arringdon / Develop no more than two ORs pursuant to the need determination in the 2021 SMFP which is a change of scope for Project ID #J-11508-18 (relocate 4 ORs) for a total of no more than 6 ORs and two procedure rooms upon completion of both projects**

Project ID #J-12065-21 is approved subject to the following conditions.

1. University of North Carolina Hospitals at Chapel Hill and University of North Carolina Health Care System (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.

2. The certificate holder shall develop a new, separately licensed hospital, with no more than 40 acute care beds and no more than two shared ORs pursuant to the need determinations in the 2021 SMFP.

3. The certificate holder shall also develop no more than two dedicated C-Section ORs, no more than two procedure rooms, no more than 10 observation beds and four LDR beds, and acquire no more than one CT scanner for the new, separately licensed hospital, to be named UNC Hospitals-RTP.

4. Upon completion of the project, UNC Hospitals-RTP shall be licensed for no more than 40 acute care beds and no more than two shared ORs and two dedicated C-Section ORs.

5. Progress Reports:
   a. Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: https://info.ncdhhs.gov/dhsr/coneed/progressreport.html.
   b. The certificate holder shall complete all sections of the Progress Report form.
   c. The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.
   d. Progress reports shall be due on the first day of every third month. The first progress report shall be due on December 1, 2021. The second progress report shall be due on March 1, 2022 and so forth.

6. The certificate holder shall not acquire as part of this project any equipment that is not included in the project's proposed capital expenditures in Section Q of the application and that would otherwise require a certificate of need.

7. The certificate holder shall 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.

8. 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.

9. 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.

Project ID #J-12075-21 is approved subject to the following conditions.

1. Duke University Health System, Inc. and Associated Health Services, Inc. (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.

2. The certificate holder shall develop no more than two ORs pursuant to the need determinations in the 2021 SMFP for a total of no more than six ORs and two procedure rooms at Duke Ambulatory Surgery Center Arringdon.

3. Upon completion of the project and Project ID #J-11508-18, Duke Ambulatory Surgery Center Arringdon will be licensed for no more than six ORs.

4. Progress Reports:
   a. Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: https://info.ncdhhs.gov/dhsr/coneed/progressreport.html.
   b. The certificate holder shall complete all sections of the Progress Report form.
   c. The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.
   d. Progress reports shall be due on the first day of every third month. The first progress report shall be due on December 1, 2021. The second progress report shall be due on March 1, 2022 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. 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.

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