

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: September 25, 2019

Findings Date: October 2, 2019

Project Analyst: Gregory F. Yakaboski

Team Leader: Fatimah Wilson

COMPETITIVE REVIEW

Project ID #: J-11692-19
Facility: Duke Health Orange Ambulatory Surgical Center
FID #: 190164
County: Orange
Applicant: Duke University Health System, Inc.
Project: Develop a new ambulatory surgical center in Chapel Hill with no more than two operating rooms and two procedure rooms pursuant to the need determination in the 2019 SMFP

Project ID #: J-11695-19
Facility: University of North Carolina Hospitals
FID #: 923517
County: Orange
Applicant: University of North Carolina Hospitals at Chapel Hill
Project: Develop 3 additional operating rooms pursuant to the need determination in the 2019 SMFP for a total of 44 operating rooms on the Chapel Hill Campus

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

Both Applications

Need Determination

Chapter 6 of the 2019 State Medical Facilities Plan (SMFP) includes a methodology for determining the need for additional operating rooms (ORs) in North Carolina by service area. Application of the need methodology in the 2019 SMFP identifies a need for three additional ORs in the Orange County OR service area. Two applications were submitted to the Healthcare Planning and Certificate of Need Section (Agency) proposing to develop a total of five ORs. However, pursuant to the need determination, only three ORs may be approved in this review for Orange County. See the Conclusion following the Comparative Analysis for the decision.

Policies

There are two policies applicable to the review for the two applications submitted in response to the need determination in the 2019 SMFP for the Orange County service area.

Policy GEN-3: Basic Principles, on page 31 of the 2019 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 31 of the 2019 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 are required to submit a plan of energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation. The plan must be consistent with the applicant's representation in the written statement as described in paragraph one of Policy GEN-4. The plan shall not adversely affect patient or resident health, safety or infection control."

J-11692-19/Duke Health Orange ASC/Develop Two ORs

The applicant, Duke University Health System, Inc. (**DUHS**) proposes to develop Duke Health Orange Ambulatory Surgery Center (**Duke Health Orange ASC**), a new multi-specialty ambulatory surgery center (ASC) in Chapel Hill with two ORs and two procedure rooms.

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

Policy GEN-3. In Section B.3, page 12, the applicant adequately explains why it believes the application is consistent with Policy GEN-3.

Policy GEN-4. The proposed capital expenditure for this project is greater than \$5 million. In Section B.4, pages 13-14, the applicant adequately 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 for the following reasons:

- The applicant does not propose to develop more ORs than are determined to be needed in Orange County.
- The applicant adequately demonstrates that the proposal is consistent with Policy GEN-3.
- The applicant adequately demonstrates that the proposal is consistent with Policy GEN-4.

J-11695-19/UNC-Main Campus/Develop Three ORs

The applicant, University of North Carolina Hospitals at Chapel Hill (**UNC Hospitals-CH**) proposes to develop three additional ORs at the existing hospital's main campus in Chapel Hill (**UNC-Main Campus**) for a total of 44 ORs upon project completion.

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

Policy GEN-3. In Section B.3, pages 15-19, the applicant adequately explains why it believes the application is consistent with Policy GEN-3.

Policy GEN-4. The proposed capital expenditure for this project is greater than \$5 million. In Sections B.3 and B.4, pages 19-20, the applicant adequately 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 for the following reasons:

- The applicant does not propose to develop more ORs than are determined to be needed in Orange County.
- The applicant adequately demonstrates that the proposal is consistent with Policy GEN-3.
- The applicant adequately demonstrates that the proposal is consistent with Policy GEN-4.

(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.

C Both Applications

Background

There was a need determination in the 2018 SMFP for six additional ORs in the Orange County OR Service Area. Both applicants in this review also submitted applications pursuant to the 2018 SMFP OR need determination.

DUHS submitted an application, Project I.D.# J-11632-18 to develop a new multi-specialty ambulatory surgical center, Duke Health Orange ASC, in Chapel Hill with two operating rooms and two procedure rooms.

UNC Hospitals-CH submitted three applications:

#1) J-11644-18/ UNC-Main Campus-develop two additional ORs at the existing hospital's main campus in Chapel Hill for a total of 42 ORs upon project completion

#2) J-11645-18/North Chapel Hill ASC-develop North Chapel Hill Surgery Center (North Chapel Hill ASC), a new multi-specialty ASC in Chapel Hill with two ORs and two procedure rooms

#3) J-11646-18/UNC-Hillsborough Campus-develop two additional ORs at the existing hospital's Hillsborough campus for a total of 8 ORs upon project completion

On April 29, 2019 the following applications were conditionally approved:

- The Duke Health Orange ASC application, Project I.D.# J-11632-18 Develop a new ASC in Chapel Hill with two ORs and two procedure rooms. That decision is currently under appeal.
- The North Chapel Hill ASC application, Project I.D. #J-11645-18 Develop a new ASC in Chapel Hill with two ORs and two procedure rooms. That decision was not appealed. A certificate of need (CON) was issued and effective as of May 30, 2019.
- The UNC-Main Campus application, Project I.D. #J-11644-18 Develop no more than one OR at UNC-Main Campus. That decision is currently under appeal.
- The UNC-Hillsborough application, Project I.D. #J-11646-18 Develop no more than one OR at UNC-Hillsborough Campus. That decision is currently under appeal.

The two applications currently under review were submitted on April 15, 2019, prior to a decision being rendered in the 2018 Orange County OR Review on April 29, 2019.

J-11692-19/Duke Health Orange ASC/Develop Two ORs

The applicant proposes to develop a new multi-specialty ASC, Duke Health Orange ASC, in Chapel Hill with two ORs and two procedure rooms.

DUHS, in Section Q, page 101, states,

“Please note that while DUHS has an application under review at the time of the filing of this application for an ASC in Orange County (Project I.D. #J-11632-18), this application would not create a second, additional, ASC. Rather, this application reiterates and restates the need for the development by Duke of a 2-OR ASC in Orange County in the even that DUHS is not awarded a CON pursuant to its 2018 application. Upon approval of this project, it would be the only surgery facility operated by DUHS in Orange County.”

Patient Origin – On page 55, the 2019 SMFP states, “An operating room’s service area is the operating room planning area in which the operating room is located. The operating room planning areas are the single and multicounty groupings shown in Figure 6.1.” In Figure 6.1, page 60 of the 2019 SMFP, Orange County is shown as a single-county OR service area. Thus,

the service area for this review consists of Orange County. Facilities may also serve residents of counties not included in the service area.

The following table illustrates projected patient origin.

County	Projected Patient Origin	
	3 rd Full Fiscal Year (FY) SFY2024	
	Patients	% of Total
Orange	1,327	37.4%
Alamance	1,759	49.5%
Chatham	466	13.1%
Total	3,552	100.0%

Source: Section C.3, page 17.

Note: The applicant states that the total number of surgical cases is equivalent to the total number of patients.

In Section Q, pages 101-111, the applicant provides the assumptions and methodology used to project its patient origin. The applicant’s assumptions are reasonable and adequately supported.

Analysis of Need - In Section C.4, pages 18-37, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, summarized as follows:

- Projected growth and aging of the populations in Orange, Alamance and Chatham counties.
- The trend of more surgical cases being performed on an outpatient basis due to technological advancements, improvements in anesthesia and pain management, the development of minimally invasive procedures, and the financial pressure to reduce the cost of healthcare by shifting patients to the outpatient setting.
- Historical utilization of surgical services at DUHS facilities located in Durham County by residents of Orange County.
- Historical growth in outpatient surgery volumes at DUHS facilities.

There are two types of health service facilities that can have licensed ORs in North Carolina: hospitals and ASCs. There are 41 ORs (less exclusions) located in Orange County and all 41 are currently hospital-based. Based on the applications, written comments and response to comments and statements made at the public hearing, many, but not all outpatient surgical services can be appropriately performed either in a hospital-based OR or in an ASC OR. However, the cost to the patient and a third party payor will be lower if the service is provided in an ASC OR than the cost for the same service provided in a hospital-based OR on an outpatient basis.

Orange County residents wanting to take advantage of the lower costs associated with non-hospital-based ORs must utilize an ASC located in another county. In federal fiscal year (FFY) 2017, 6,158 Orange County residents had outpatient surgery, as shown in the table below.

FY 2017	Residents of Orange County Utilized Facilities Located in					
	Orange	Durham	Alamance	Chatham	Other	Total
# of Outpatient Surgical Cases	2,450	3,100	144	12	464	6,158
% of the Total	39.79%	50.34%	2.34%	0.19%	7.53%	100.00%

As shown in the table above, 3,100 Orange County residents utilized a facility located in Durham County which is 50.34% of the total. Only 2,450 or 39.8% Orange County residents utilized the hospital in Orange County for outpatient surgery services. Of the 3,100 Orange County residents that had their outpatient surgery performed at a facility located in Durham County, 2,685 had the surgery performed at a DUHS facility which is 43.6% of the total (2,685 / 6,158 = 0.436).

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

- There is a need determination in the 2019 SMFP for three additional ORs in the Orange County OR Service Area.
- The applicant provides information to support its assertion that the historical trend is toward moving surgical cases to outpatient settings.
- The applicant provides information and data to support its assertions regarding the growth in surgical case volumes for the residents of the service area.
- The applicant provides information and data to support its assertions regarding surgical volumes at DUHS facilities and utilization by Orange County residents.

Projected Utilization - In Section Q, Form C, the applicant provides projected surgical utilization, as illustrated in the following table.

Projected Utilization			
Operating Rooms	1 st Full FY SFY2022	2 nd Full FY SFY2023	3 rd Full FY SFY2024
Dedicated Ambulatory ORs	2	2	2
Outpatient Surgical Cases	2,427	3,181	3,552
Outpatient Surgical Case Time	40.6	40.6	40.6
Outpatient Surgical Hours	1,642	2,152	2,404
Group Assignment	5	5	5
Standard Hours per OR per Year	1,312.0	1,312.0	1,312.0
Total Surgical Hours/Standard Hours Per OR per Year	1.3	1.6	1.8

Source: Section Q, Form C.

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

Surgical Cases

Step 1. Duke Health Orange ASC projects to serve residents of Orange, Alamance and Chatham counties. The applicant obtained projected population data for Orange, Alamance and Chatham counties from 2018 through the third full FY of operation following completion of the project (3rd Full FY) from the North Carolina Office of State Budget and Management (NCOSBM). The growth rates for Orange, Alamance and Chatham counties for this time period were 1.0%, 1.4%

and 1.9% respectively. The Orange County growth rate is comparable to the projected statewide growth rate of 1.1% during the same time period. The Alamance and Chatham county growth rates are projected to exceed the statewide growth rate.

Step 2. The applicant calculated the statewide ambulatory surgery use rate per 1,000 population for 2014-2017 using data from the NCOSBM, 2015-2019 SMFPs. The state-wide ambulatory surgery use rate per 1,000 people was 64.1, 65.0, 64.8 and 64.9 respectively for 2014-2017. These rates were based on the North Carolina population and the annual number of ambulatory surgery cases performed statewide. The application states that the basis for this assumption is the March 2018 MedPAC report to Congress: Medicare Payment Policy which cites studies that suggest that the presence of ASCs might increase overall surgical volume, particularly when introducing ASCs into service areas that had one ASC or none at all. The applicant states that this contextual information combined with projected population growth for individuals age 65+ in the applicant’s service area, statistical data in Section C regarding ambulatory surgery utilization and the qualitative impact of the proposed project for local residents supports the applicant’s use of a statewide use rate.

Step 3. The applicant calculated total projected ambulatory surgery cases for Orange, Alamance and Chatham counties for 2018 through 2024, as shown in the table below.

Projected Ambulatory Surgery Cases

County	CY2018	CY2019	CY2020	CY2021	CY2022	CY2023	CY2024	CAGR
Orange	9,296	9,394	9,491	9,588	9,685	9,782	9,879	1.0%
Alamance	10,535	10,680	10,829	10,977	11,125	11,273	11,421	1.4%
Chatham	4,935	5,035	5,136	5,236	5,336	5,436	5,536	1.9%
Total	24,767	25,110	25,455	25,801	26,146	26,491	26,837	1.3%

Formula: The applicant states that the growth in the 65+ age cohort will have a direct impact on the demand for ophthalmic surgery, which is anticipated to comprise approximately 50% of the projected surgical cases performed at the proposed ASC. Thus, the applicant states that projected demand for outpatient surgical cases is probably conservative.

Step 4. DUHS projected ambulatory surgery market share for Duke Health Orange ASC for CY2021 through CY2024 for Orange, Alamance and Chatham counties, as illustrated in the table below.

Projected Market Share

	Interim CY2021	CY2022	CY2023	CY2024
Orange	8.0%	11.0%	13.5%	13.5%
Alamance	10.0%	13.0%	15.5%	15.5%
Chatham	3.0%	6.0%	8.5%	8.5%

The applicant states that the projected market shares in the table above are incremental or in addition to existing DUHS ambulatory surgery market share for residents of these three counties. Projected utilization assumes no shift of existing market share to the proposed Duke Health Orange ASC.

When projecting market share, the applicant states it considered:

- DUHS market presence;
- Brand awareness DUHS currently maintains for each identified county;
- The number and type of surgeons who will have privileges at the facility;
- Ongoing planned physician recruitment efforts; and
- Confirmation from the clinical and administrative leadership at DUHS that the projected incremental market share percentages are reasonable and achievable.

On pages 105-108, the applicant provides additional factors to support why the projected annual market shares are reasonable and adequately supported.

Step 5. The applicant projects outpatient surgical cases at Duke Health Orange ASC by multiplying market share from Step 4 by projected ambulatory surgery cases from Step 3, as illustrated in the table below.

Projected Ambulatory Surgery Cases

	Interim CY2021	CY2022	CY2023	CY2024
Orange	639	1,065	1,321	1,334
Alamance	913	1,446	1,747	1,770
Chatham	131	320	462	471
Total	1,683	2,832	3,530	3,575

DUHS operates on a fiscal year of July 1st – June 30th (SFY). Therefore, DUHS converted the projected ambulatory surgery cases for Duke Health Orange ASC to its fiscal year, as shown in the table below.

Projected Ambulatory Surgery Cases

	Interim Full FY SFY2021	1st Full FY SFY2022	2nd Full FY SFY2023	3rd Full FY SFY2024
Orange	256	916	1,193	1,327
Alamance	366	1,272	1,597	1,759
Chatham	53	239	391	466
Total	675	2,427	3,181	3,552

*Duke Health Orange ASC is projected to be licensed and operational 1/1/2021.
 Conversion Formula Example: SFY2022 = (0.5 x 767) + (0.5 x 1,065) = 916.

Procedure Room Cases

In Section Q, Form C, the applicant provides projected procedure room utilization, as illustrated in the following table.

Projected Utilization

Procedure Rooms	1st Full FY SFY2022	2nd Full FY SFY2023	3rd Full FY SFY2024
# of Procedure Rooms	2	2	2
Total Procedures	485	636	710

Source: Section Q, Form C.

DUHS bases projected procedure room utilization on its ASC experience in Durham County during FY2017 and FY2018 which was 20% of surgical cases and on physician letters of support (See Exhibit C-4).

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

- Currently, the only operational ORs located in Orange County are hospital-based. [Note: This was correct at time of application being filed. See comments under Background at the beginning of Criterion #3])
- Patients and third-party payors pay less for the same procedure performed at an ASC than one done on an outpatient basis in a hospital-based OR.
- On-going physician recruitment efforts together with existing DUHS physician presence.
- Projected surgical case growth is supported by projected population growth.
- The methodology and assumptions are reasonable and adequately supported.
- DUHS will be a new provider in Orange County.
- Neither Alamance nor Chatham counties has a multi-specialty ASC.

Access - In Section C.8, page 41, the applicant states it is committed to providing services to all patients, and will not discriminate against anyone based on race, age, gender, ethnicity, disability, or the patient’s ability to pay. In Section L.3, page 85, the applicant projects the following payor mix during the 2nd full FY (SFY2023) of operation following completion of the project, as illustrated in the following table.

Payor Category	Operating Room Services as Percent of Total	Procedure Room Services as Percent of Total
Self-Pay/Charity	1.1%	1.8%
Medicare *	41.5%	46.7%
Medicaid *	4.2%	6.2%
Insurance *	51.6%	44.0%
Workers Comp, VA, TRICARE	1.6%	1.3%
Total	100.0%	100.0%

Source: Table on page 85 of the application.

* Including any managed care plans

The projected payor mix is reasonable and adequately supported.

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 identifies the population to be served.
- The applicant adequately explains why the population to be served needs the services proposed in this application.
- Projected utilization is based on reasonable and adequately supported assumptions.
- The applicant projects the extent to which all residents, including underserved groups, will have access to the proposed services (payor mix) and adequately supports its assumptions.

J-11695-19/UNC-Main Campus/Develop Three ORs

The applicant proposes to develop three additional ORs for a total of 44 ORs at UNC Hospitals-CH Main Campus.

Patient Origin – On page 55, the 2019 SMFP states, “An operating room’s service area is the operating room planning area in which the operating room is located. The operating room planning areas are the single and multicounty groupings shown in Figure 6.1.” In Figure 6.1, page 60 of the 2019 SMFP, Orange County is shown as a single-county OR service area. Thus, the service area for this review consists of Orange County. Facilities may also serve residents of counties not included in the service area.

The following table illustrates current and projected patient origin.

County	Current SFY2018		3 rd Full FY SFY2025	
	Patients	% of Total	Patients	% of Total
Wake	3,800	14.0%	3,090	10.8%
Orange	2,939	10.8%	3,202	11.2%
Other*	20,432	75.2%	22,262	78.0%
Total	27,171	100.0	28,554	100.0%

Source: Table on pages 23-29

*The applicant lists the counties and other states included in this category on pages 23-29.

In Section C.3, page 29, 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.4, pages 30-40, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below:

- The combination of a growing and aging population in the Orange County OR service area.
- Demand for surgical services overall in North Carolina and specifically in Orange County.
- The need determination in the 2019 SMFP for three ORs in Orange County.
- The growth in inpatient surgical case volume in Orange County.

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

- There is a need determination in the 2019 SMFP for three additional ORs in the Orange County OR service area.
- The applicant provides information and data to support its assertion regarding the growth in surgical case volumes in North Carolina and Orange County.
- The applicant provides information to support its assertion that inpatient surgical volume in Orange County has increased at a CAGR of 3.5% from FY2012 to FY2017.
- The applicant provides population growth projections for the proposed service area based on data from the NCOSBM.
- The applicant provides information that the combination of the complexity of surgical intervention based on advanced inpatient surgical techniques and higher acuity patients results in greater case time and thus more demand for OR capacity.

Projected Utilization - UNC Main Campus

UNC-Hospitals- CH, in its projected utilization, assumes that all three of its applications were approved.

In Form C, the applicant provides historical, interim and projected utilization, as illustrated in the following tables.

UNC-Main Campus Historical and Interim OR Utilization	SFY2016	SFY2017	SFY2018	SFY2019	Interim SFY2020
Inpatient Surgical Cases	12,513	12,796	12,974	12,831	12,982
Outpatient Surgical Case	13,949	13,582	14,197	13,805	14,093
Total Surgical Cases	26,462	26,378	27,171	26,635	27,075
Inpatient Surgical Case Times	234	234	234	234	234
Outpatient Surgical Case Times	137	137	137	143	143
Inpatient Surgical Hours	48,801	49,904	50,599	50,040	50,631
Outpatient Surgical Hours	31,850	31,012	32,416	32,901	33,588
Total Surgical Hours	80,651	80,917	83,015	82,941	84,220
Group Assignment	1	1	1	1	1
Standard Hours per OR per Year	1,950	1,950	1,950	1,950	1,950
Total Surgical Hours/Standard Hours Per OR per Year	41.4	41.5	42.6	42.5	43.2
Adjusted Planning Inventory - UNC Main Campus	35.0	35.0	35.0	35.0	35.0
OR Deficit	6.4	6.5	7.6	7.5	8.2

Source: Section Q, Form C.

UNC-Main Campus Projected OR Utilization	Interim SFY 2021	Interim SFY2022	Interim SFY2023
Inpatient Surgical Cases	13,163	13,561	13,891
Outpatient Surgical Case	14,292	13,623	13,397
Total Surgical Cases	27,455	27,184	27,288
Inpatient Surgical Case Times	234	234	234
Outpatient Surgical Case Times	143	143	143
Inpatient Surgical Hours	51,336	52,889	54,175
Outpatient Surgical Hours	34,062	32,469	31,930
Total Surgical Hours	85,397	85,357	86,105
Group Assignment	1	1	1
Standard Hours per OR per Year	1,950	1,950	1,950
Total Surgical Hours/Standard Hours Per OR per Year	43.8	43.8	44.2
Adjusted Planning Inventory - UNC Main Campus	35.0	35.0	35.0
OR Deficit	8.8	8.8	9.2
# of ORs from Project I.D. #J-11644-18*	2	2	2

Source: Section Q, Form C.

*In the application, Project I.D. #J-11644-18, UNC Hospitals-CH sought to develop 2 new ORs at UNC-Main Campus. That project was only conditionally approved for 1 new OR at UNC-Main Campus. The application was pending when this application was submitted, and a decision was subsequently rendered on April 29, 2019. That decision is currently under appeal. UNC Hospitals-CH notes that even if the appeal is successful and it is permitted to develop 2 new ORs at UNC-Main Campus there would still be an OR deficit at UNC-Main Campus and UNC Hospitals-CH overall.

UNC-Main Campus Projected OR Utilization	1 st Full FY SFY 2024	2 nd Full FY SFY2025	3 rd Full FY SFY2026
Inpatient Surgical Cases	14,389	14,904	15,437
Outpatient Surgical Case	13,320	13,649	13,987
Total Surgical Cases	27,709	28,554	29,423
Inpatient Surgical Case Times	234	234	234
Outpatient Surgical Case Times	143	143	143
Inpatient Surgical Hours	56,118	58,127	60,203
Outpatient Surgical Hours	31,746	32,531	33,345
Total Surgical Hours	87,864	90,658	93,538
Group Assignment	1	1	1
Standard Hours per OR per Year	1,950	1,950	1,950
Total Surgical Hours/Standard Hours Per OR per Year	45.1	46.5	48.0
Adjusted Planning Inventory - UNC Main Campus	35.0	35.0	35.0
OR Deficit	10.1	11.5	13.0
# of ORs from Project I.D. #J-11644-18*	2	2	2
# of Proposed New ORs	3.0	3.0	3.0

Source: Section Q, Form C.

*In the application, Project I.D. #J-11644-18, UNC Hospitals-CH sought to develop 2 new ORs at UNC-Main Campus. That project was only conditionally approved for 1 new OR at UNC-Main Campus. The application was pending when this application was submitted, and a decision was subsequently rendered on April 29, 2019. That decision is currently under appeal. UNC Hospitals-CH notes that even if the appeal is successful and it is permitted to develop 2 new ORs at UNC-Main Campus there would still be an OR deficit at UNC-Main Campus and UNC Hospitals-CH overall.

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

- UNC Hospitals-CH is currently the only provider of surgical services in Orange County. UNC Hospitals has two campuses: UNC-Main Campus in Chapel Hill and UNC-Hillsborough Campus in Hillsborough. Both campuses operate under the same license.
- UNC-Main Campus currently has an adjusted planning inventory of 35 ORs (not including 3 dedicated C-Section ORs, 1 trauma OR and 1 burn OR).
- UNC-Hillsborough Campus currently has an adjusted planning inventory of six ORs.
- UNC Hospitals-CH (UNC-Main Campus and UNC-Hillsborough Campus) has an adjusted planning inventory of 41 ORs (not including 3 dedicated C-Section ORs, 1 trauma OR and 1 burn OR).
- The 2019 SMFP identified a need for three additional ORs in the Orange County OR service area.
- UNC Hospitals-CH operates under the State Fiscal Year (SFY) which runs from July 1st to June 30th.
- UNC Hospitals-CH calculated its CAGR for inpatient and outpatient surgical cases for SFY2016 – SFY2019. The inpatient CAGR was 3.4% and the outpatient CAGR was 2.7%.
- Using the inpatient and outpatient CAGRs, UNC Hospitals-CH projected its inpatient and outpatient surgical cases through to SFY2026.

- UNC Hospitals-CH also factored in the application it had pending at the time this current application was submitted to develop a new ASC (North Chapel Hill Surgery Center) with two ORs and treated that application as an approval for purposes of this application. Therefore, UNC Health System in Orange County would consist of UNC-Main Campus, UNC-Hillsborough Campus and North Chapel Hill Surgery Center.
- UNC-Hospitals-CH, to calculate the surgical cases at UNC-Main Campus, as illustrated in the table below, backed out the following surgical cases from the overall surgical cases performed or projected to be performed by UNC Hospitals-CH in Orange County:
 - backed out a projected “shift” of inpatient surgical cases from UNC Hospitals-CH to UNC Rex Hospital in Wake County pursuant to Project ID #J-11555-18 (add two ORs) for SFY2019 to SFY2024.
 - Backed out surgical cases that would be performed at the UNC-Hillsborough Campus
 - Identified and backed out cases from UNC-Main Campus that could be performed at the approved North Chapel Hill ASC and accounted for that shift based on a ramp up of 50% in SFY2022, 75% in SFY2023 and 100% in SFY2024.

UNC-Main Campus: Total Surgical Cases to Be Performed

	SFY2024	SFY2025	SFY2026
Total Projected Cases	36,866	37,974	39,115
Less Projected “Shift” of IP Cases to UNC Rex Hospital	1,050	1,050	1,050
	35,816	36,924	38,065
Less Projected OP Cases to be Performed at North Chapel Hill ASC	2,166	2,260	2,359
	33,650	34,664	35,706
Less Surgical Cases to be Performed at UNC-Hillsborough Campus	5,941	6,110	6,283
Surgical Cases Projected to be Performed at UNC-Main Campus	27,709	28,554	29,423

Historical, interim and projected utilization at UNC-Main Campus, UNC-Hillsborough Campus (UNC Hospitals) and the approved North Chapel Hill ASC are shown in the tables below.

UNC Hospitals Health System Historical and Interim OR Utilization	SFY2016	SFY2017	SFY2018	SFY2019	SFY2020
Inpatient (IP) Surgical Cases					
UNC-Main Campus	12,513	12,796	12,974	12,831	12,982
UNC-Hillsborough Campus	842	1,150	1,228	1,393	1,475
Total Projected IP Cases	13,355	13,946	14,202	14,223	14,457
Percent Change	NA	4.4%	1.84%	.0015%	1.65%
Outpatient (OP) Surgical Cases					
UNC-Main Campus	13,949	13,582	14,197	13,805	14,903
UNC-Hillsborough Campus	1,797	2,361	2,957	3,244	3,414
North Chapel Hill ASC	NA	NA	NA	NA	NA
Total Projected OP Cases	15,746	15,943	17,154	17,049	17,507
Percent Change	NA	1.30%	7.60%	<.006%>	2.7%
Total Surgical Cases					
UNC-Main Campus	26,462	26,378	27,171	26,635	27,075
UNC-Hillsborough Campus	2,639	3,511	4,185	4,637	4,888
North Chapel Hill Campus	NA	NA	NA	NA	NA
Total Projected Cases	29,101	29,889	31,356	31,272	31,963
Percent Change	NA	2.70%	4.9%	<.0027%>	2.2%

Source: Section Q, Form C.

UNC Hospitals Health System Interim OR Utilization	1st Full FY SFY2021	2nd Full FY SFY2022	3rd Full FY SFY2023
Inpatient (IP) Surgical Cases			
UNC-Main Campus	13,163	13,561	13,891
UNC-Hillsborough Campus	1,544	1,676	1,894
Total Projected IP Cases	14,707	15,237	15,785
Percent Change	1.73%	3.6%	3.6%
Outpatient (OP) Surgical Cases			
UNC-Main Campus	14,292	13,623	13,397
UNC-Hillsborough Campus	3,685	3,842	4,002
North Chapel Hill ASC	NA	994	1,556
Total Projected OP Cases	17,977	18,459	18,955
Percent Change	2.7%	2.7%	2.7%
Total Surgical Cases			
UNC-Main Campus	27,455	27,184	27,288
UNC-Hillsborough Campus	5,230	5,519	5,896
North Chapel Hill ASC	NA	994	1,556
Total Cases	32,685	33,697	34,740
Percent Change	2.3%	3.0%	3.0%

Source: Section Q, Form C.

Note: the projected shift of inpatient cases from UNC Hospitals-CH to UNC Rex Hospital Wake County projected in Project ID #J-11555-18 for SFY2019 to SFY2024 has already been factored in and is not shown in the table above.

UNC Hospitals Health System Projected OR Utilization	1 st Full FY SFY2024	2 nd Full FY SFY2025	3 rd Full FY SFY2026
Inpatient (IP) Surgical Cases			
UNC-Main Campus	14,389	14,904	15,437
UNC-Hillsborough Campus	1,962	2,032	2,105
Total Projected IP Cases	16,351	16,937	17,542
Percent Change	3.6%	3.6%	3.6%
Outpatient (OP) Surgical Cases			
UNC-Main Campus	13,320	13,649	13,987
UNC-Hillsborough Campus	3,979	4,077	4,178
North Chapel Hill ASC	2,166	2,260	2,359
Total Projected OP Cases	19,465	19,986	20,524
Percent Change	2.7%	2.7%	2.7%
Total Surgical Cases			
UNC-Main Campus	27,709	28,554	29,423
UNC-Hillsborough Campus	5,941	6,110	6,283
North Chapel Hill ASC	2,166	2,260	2,359
Total Cases	35,816	36,924	38,065
Percent Change	3.1%	3.1%	3.1%

Source: Section Q, Form C.

Note: the projected shift of inpatient cases from UNC Hospitals-CH to UNC Rex Hospital Wake County projected in Project ID #J-11555-18 for SFY2019 to SFY2024 has already been factored in.

The following tables illustrate the number of ORs needed at UNC-Main Campus, UNC Hospitals and the proposed ASC, respectively.

Table 1 UNC-Main Campus Projected ORs Needed	1 st Full FY SFY2024	2 nd Full FY SFY2025	3 rd Full FY SFY2026
Inpatient Surgical Cases	14,389	14,904	15,437
Outpatient Surgical Case	13,320	13,649	13,987
Total Surgical Cases	27,709	28,554	29,423
Inpatient Surgical Case Times	234	234	234
Outpatient Surgical Case Times	143	143	143
Inpatient Surgical Hours	56,118	58,127	60,203
Outpatient Surgical Hours	31,746	32,531	33,345
Total Surgical Hours	87,864	90,658	93,538
Group Assignment	1	1	1
Standard Hours per OR per Year	1,950	1,950	1,950
Total Surgical Hours/Standard Hours Per OR per Year	45.1	46.5	48.0
Adjusted Planning Inventory (1)	40.0	40.0	40.0
OR Deficit	5.1	6.5	8.0

Source: Section Q, Form C.

*In the application, Project I.D. #J-11644-18, UNC Hospitals-CH sought to develop 2 new ORs at UNC-Main Campus. That project was only conditionally approved for 1 new OR at UNC-Main Campus. The application was pending when this application was submitted, and a decision was subsequently rendered on April 29, 2019. That decision is currently under appeal. UNC Hospitals-CH notes that even if the appeal is successful and it is permitted to develop 2 new ORs at UNC-Main Campus there would still be an OR deficit at UNC-Main Campus and UNC Hospitals-CH overall.

(1) Includes the existing (40) and proposed (3) from this application and the proposed (2) from application Project I.D.#J-11644-18 [under appeal] less exclusions (5).

Table 2 UNC Hospitals Projected ORs Needed	1st Full FY SFY2024	2nd Full FY SFY2025	3rd Full FY SFY2026
Group Assignment	1	1	1
Standard Hours per OR per Year (1)	1,950	1,950	1,950
Inpatient Surgical Cases	16,351	16,937	17,542
Final Inpatient Case Time (2)	234	234	234
Inpatient Surgical Hours (3)	63,771	66,053	68,413
Ambulatory Surgical Cases	17,299	17,727	18,164
Final Ambulatory Case Time (2)	143	143	143
Ambulatory Surgical Hours (3)	41,228	42,248	43,292
Total Surgical Hours (4)	104,999	108,302	111,705
# of ORs Needed (5)	53.9	55.5	57.3
Adjusted Planning Inventory (6)	48.0	48.0	48.0
OR Deficit	5.9	7.5	9.3

- (1) From Table 6A in the 2019 SMFP.
- (2) From Table 6B in the 2019 SMFP.
- (3) Surgical Hours equals Surgical Cases multiplied by the Final Case Time.
- (4) Total Surgical Hours equals Inpatient Surgical Hours plus Ambulatory Surgical Hours.
- (5) # of ORs Needed equals Total Surgical Hours divided by the Standard Hours per OR per Year.
- (6) Includes the existing (46) and proposed (3) from this application, the proposed (2) from application Project I.D.#J-11644-18 [under appeal], the proposed (2) from application Project I.D.#J-11646-18 [under appeal] less exclusions (5).

Table 3 North Chapel Hill ASC Projected ORs Needed	1st Full FY SFY2024	2nd Full FY SFY2025	3rd Full FY SFY2026
Group Assignment	6	6	6
Standard Hours per OR per Year (1)	1,312.0	1,312.0	1,312.0
Ambulatory Surgical Cases	2,166	2,260	2,359
Average Ambulatory Case Time (2)	76.6	76.6	76.6
Ambulatory Surgical Hours (3)	2,765	2,866	3,012
Total Surgical Hours (4)	2,765	2,866	3,012
Adjusted Planning Inventory (5)	0	0	0
# of ORs Needed (6)	2.1	2.2	2.3
Approved ORs	2.0	2.0	2.0
OR Deficit	0.1	0.2	0.3

- (1) From Table 6A in the 2019 SMFP.
- (2) From Table 6B in the 2019 SMFP.
- (3) Surgical Hours equals Surgical Cases multiplied by the Final Case Time.
- (4) Total Surgical Hours equals Inpatient Surgical Hours plus Ambulatory Surgical Hours.
- (5) Includes the proposed ORs.
- (6) # of ORs Needed equals Total Surgical Hours divided by the Standard Hours per OR per Year.

- As shown in Table 1 above, in the third full FY of the main campus project (SFY2026), the main campus is projected to need eight additional ORs even with the addition of three ORs in this review cycle.
- As shown in Table 2 above, in the third full FY of the main campus project (SFY2026), the UNC Hospitals Health System is projected to need nine additional ORs even with the addition of three ORs in this review cycle.

- As shown in Table 3 above, in the third full FY of the main campus project (SFY2026), the proposed ASC is projected to need no ORs.

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

- The applicant based projected inpatient and outpatient surgical case growth on historical inpatient and outpatient growth rates.
- The applicant accounted for projected shifts of certain outpatient cases to the proposed North Chapel Hill ASC.
- The applicant accounted for the projected shift of inpatient cases from UNC Hospitals to UNC REX Hospital in Wake County (Project ID# J-11555-18).
- The applicant accounted for surgical cases to be performed at UNC-Hillsborough Campus
- Projected growth is supported by projected population growth and the expected recruitment of additional surgeons.
- The methodology and assumptions are reasonable and adequately supported.
- Current OR utilization, based solely on surgical cases performed in FFY 2018 and with no growth, UNC Hospitals shows a need for seven additional ORs. Based on historical and annualized surgical cases for FFY2019, UNC Hospitals shows a need for eight additional ORs. See the table below.

UNC Hospitals Historical OR Utilization	Last Full FY FY2018	SFY2019*
Group Assignment	1	1
Standard Hours per OR per Year (1)	1,950	1,950
Inpatient Surgical Cases	14,226	14,223
Final Inpatient Case Time (2)	234	234
Inpatient Surgical Hours (3)	55,481	55,471
Ambulatory Surgical Cases	16,267	17,049
Final Ambulatory Case Time (2)	143	143
Ambulatory Surgical Hours (3)	38,770	40,633
Total Surgical Hours (4)	94,251	96,105
Adjusted Planning Inventory (5)	41.0	41
# of ORs Needed (6)	48.0	49.3
OR Deficit	7.0	8.3

Source: 2018 License Renewal Application for UNC Hospitals

*SFY 2019 annualized based on year-to-date utilization (July 2018 through January 2019) and historical seasonal utilization. Source: UNC Hospitals Internal Data, 2019 SMFP.

Access - In Section C.8, page 45, the applicant states, “As North Carolina’s only state-owned, comprehensive, full service hospital system, UNC Health Care System, including 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.”

In Section L, page 81, the applicant projects the following payor mix during the 2nd full FY (SFY2025), as illustrated in the table below.

Payor Category	Operating Room Services as Percent of Total
Self-Pay	7.9%
Medicare *	25.8%
Medicaid *	23.0%
Insurance *	35.2%
Other Government, Workers Compensation	8.1%
Total	100.0%

Source: Table on page 81 of the application.

* Including any managed care plans

The projected payor mix is reasonable and adequately supported.

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 identifies the population to be served.
- The applicant adequately explains why the population to be served needs the services proposed in this application.
- Projected utilization is reasonable and adequately supported.
- The applicant projects the extent to which all residents, including underserved groups, will have access to the proposed services (payor mix) and adequately supports the assumptions.

- (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.

NA
Both Applications

Neither of the applicants in this review propose to reduce or eliminate a service, or to relocate a facility or service. Therefore, Criterion (3a) is not applicable to this review.

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

C
Both Applications

J-11692-19/Duke Health Orange ASC/Develop Two ORs

The applicant proposes to develop a new multi-specialty ASC, Duke Health Orange ASC, in Chapel Hill with two ORs and two procedure rooms.

In Section E, pages 50-52, 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:

- Maintain the status quo
- Develop the ASC in another location
- Develop a different number of ORs at the proposed Chapel Hill site
- Develop the project as proposed

On pages 50-52, the applicant states its proposal is the most effective alternative because,

“Over 60% of all Orange County residents leave Orange County for ambulatory surgery. ... ASCs offer high quality surgical and procedural services at a lower cost when compared to hospital services for the same services. ... Based on population distribution and growth, the proposed site is an optimal location for patient [sic] from Orange and neighboring counties in terms of geographic access. ... DUHS determined the complement of two ORs for the proposed project is the most appropriate size, supported by several factors including, but not limited to:

- *the growing ambulatory surgical demand at DUHS facilities,*
- *historical outmigration of Orange County ambulatory surgery cases to DUHS facilities,*
- *the initial and incremental surgical specialties that will be served at Duke Health Orange ASC, and*
- *the projected population in Orange County and surrounding areas.”*

The applicant provides supporting documentation in Section C.4, pages 18-37.

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

- Meets the need identified in the 2019 SMFP for additional ORs in Orange County.
- Growing ambulatory surgical demand at DUHS facilities.
- Capacity constraints across DUHS’s existing facilities.
- Historical outmigration of Orange County ambulatory surgical cases to DUHS.
- Projected population in Orange County and surrounding areas.

- Orange County population is heavily concentrated in southeastern portion of the county and the proposed location is in the southeastern portion of Orange County.
- Proposed location is less than half a mile from the interchange of NC 86 and Interstate 40
- The surgical specialties that will be provided at the proposed facility.

Conclusion - The Agency reviewed the:

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

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

J-11695-19/UNC-Main Campus/Develop Three ORs

The applicant proposes to develop three additional ORs for a total of 44 ORs at UNC Hospitals-CH Main Campus.

In Section E, pages 54-55, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- Maintain the status quo
- Develop a different number of ORs
- Develop the ORs in a different location
- Develop the project as proposed

On page 55, the applicant states its proposal is the most effective alternative because,

“Compared to these alternatives, UNC Hospitals believes that the proposed project to add three operating rooms on the UNC Hospitals Main Campus is the least costly and most effective alternative to meet the need for additional operating rooms in Orange County.”

The applicant provides supporting documentation in Section C.4, pages 30-41 and Exhibit C-4.

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

- Developing less than three ORs at UNC-Main Campus would not meet the need for additional hospital-based capacity for the growing surgical volume at UNC-Main Campus.
- Developing the ORs in a different location would not meet the need for additional hospital based OR capacity for the growing surgical volume at UNC-Main Campus.

- Maintaining the status quo would not be responsive to the need for three additional ORs in Orange County identified in the 2019 SMFP.
- Maintaining the status quo would not be responsive to the current and projected need for additional OR capacity at UNC Hospitals.

Conclusion - The Agency reviewed the:

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

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

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

C
Both Applications

J-11692-19/Duke Health Orange ASC/ Develop Two ORs

The applicant proposes to develop a new multi-specialty ASC, Duke Health Orange ASC, in Chapel Hill with two ORs and two procedure rooms.

Capital and Working Capital Costs

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

Construction Costs	\$7,194,000
Miscellaneous Costs	\$4,890,000
Total Capital Cost	\$12,084,000

In Section Q, the applicant provides the assumptions used to project the capital cost.

In Section F.3, pages 55-56, the applicant projects that start-up costs will be \$405,592 and initial operating expenses will be \$360,000 for a total working capital of \$765,592. On pages 55-56 and in Section Q the applicant provides the assumptions and methodology used to project the working capital needs of the project.

Availability of Funds

In Section F.2, page 54, the applicant states that the capital cost will be funded as shown in the table below.

Sources of Capital Cost Financing	Amount
Accumulated reserves of DUHS	\$12,084,000
Total Financing	\$12,084,000

In Section F.3, page 57, the applicant states that the working capital needs of the project will be funded as shown in the table below.

Sources of Financing for Working Capital	Amount
Accumulated Reserves of DUHS	\$765,592
Total Financing	\$765,592

Exhibit F.2 contains a letter from the Chief Financial Officer for DUHS documenting that the funds will be made available for the capital and working capital needs of the project. Exhibit F.2 also contains the audited financial statements for DUHS which indicates the health system had \$277 million in cash and cash equivalents as of June 30, 2018.

Financial Feasibility

The applicant provided pro forma financial statements for the first three full fiscal years of operation following completion of the project. In Form F.3, the applicant projects that revenues will exceed operating expenses in the second and third operating years of the project, as shown in the table below.

	1st Full FY FY2022	2nd Full FY FY2023	3rd Full FY FY2024
Total Cases (Surgical and Procedure)	2,912	3,817	4,262
Total Gross OR Revenues (Charges)	\$19,680,218	\$25,795,468	\$28,807,292
Total Net OR Revenue	\$8,149,638	\$10,799,360	\$12,189,933
Average Net Revenue per Case	\$2,799	\$2,829	\$2,860
Total Operating Expenses (Costs)	\$8,472,010	\$10,773,840	\$12,052,137
Average Operating Expense per Case	\$2,909	\$2,823	\$2,828
Net Income	(\$322,372)	\$25,521	\$137,796

Totals may not sum due to rounding

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

Conclusion - The Agency reviewed the:

- Application
- Exhibits to the application

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

- The applicant adequately demonstrates that the capital 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-11695-19/UNC-Main Campus/Develop Three ORs

The applicant proposes to develop three additional ORs for a total of 44 ORs at UNC Hospitals-CH Main Campus.

Capital and Working Capital Costs

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

Construction Costs	\$4,140,000
Miscellaneous Costs	\$2,596,595
Total Capital Cost	\$6,736,595

In Section Q, the applicant provides the assumptions used to project the capital cost.

In Section F.3, pages 58-59, the applicant states there will be no start-up costs or initial operating expenses because the project does not involve a new service.

Availability of Funds

In Section F.2, page 57, the applicant states that the capital cost will be funded as shown in the table below.

Sources of Capital Cost Financing	Amount
Accumulated reserves of UNC Hospitals	\$6,736,595
Total Financing	\$6,736,595

Exhibit F.2-1 contains a letter from the Executive Vice President and Chief Financial Officer for UNC Hospitals documenting that the funds will be made available for the capital costs of the project. Exhibit F.2-2 contains the most recent audited financial statements for UNC Hospitals at Chapel Hill which indicate the hospital had \$49.8 million in cash and cash equivalents as of June 30, 2018.

Financial Feasibility

The applicant provided pro forma financial statements for the first three full fiscal years of operation following completion of the project. In Form F.3, the applicant projects that revenues will exceed operating expenses in the first three full operating years of the project, as shown in the table below.

	1st Full FY SFY2021	2nd Full FY SFY2022	3rd Full FY SFY2023
Total Surgical Cases	27,709	28,554	29,423
Total Gross Revenues (Charges)	\$630,640,219	\$669,358,277	\$710,434,045
Total Net Revenue	\$262,195,893	\$278,293,369	\$295,371,090
Average Net Revenue per Case	\$9,462	\$9,746	\$10,038
Total Operating Expenses (Costs)	\$200,266,743	\$211,298,991	\$222,204,983
Average Operating Expense per Case	\$7,227	\$7,399	\$7,552
Net Income	\$61,929,150	\$66,994,378	\$73,166,107

Totals may not sum due to rounding

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

Conclusion - The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C
Both Applications

On page 55, the 2019 SMFP states, “An operating room’s service area is the operating room planning area in which the operating room is located. The operating room planning areas are

the single and multicounty groupings shown in Figure 6.1.” In Figure 6.1, page 60 of the 2019 SMFP, Orange County is shown as a single-county OR service area. Thus, the service area for this review consists of Orange County. Facilities may also serve residents of counties not included in the service area.

The following table identifies the existing and approved inpatient (IP), outpatient (OP), and shared ORs located in Orange County, and the inpatient and outpatient case volumes for each provider, from pages 68 and 80 of the 2019 SMFP.

Orange County	IP ORs	OP ORs	Shared ORs	Excluded C-Section, Trauma, Burn ORs	CON Adjustments	IP Surgery Cases	OP Surgery Cases
UNC Hospitals	6	11	29	-5	0	14,226	16,267
2018 SMFP Need Determination					6		
Total	6	11	29	-5	6	14,226	16,267

Source: 2019 SMFP

Note: On April 29, 2019 the following applications were conditionally approved:

The Duke Health Orange ASC application, Project I.D.# J-11632-18 (Develop a new ASC in Chapel Hill with 2 ORs and 2 procedure rooms) was approved. That decision is currently under appeal.

The North Chapel Hill Surgery Center application, Project I.D. #J-11645-18 (Develop a new ASC in Chapel Hill with 2 ORs and 2 procedure rooms) was approved. That decision was not appealed. A certificate of need was issued for that project and effective as of May 30, 2019.

The UNC-Main Campus application, Project I.D. #J-11644-18 (Develop 2 ORs at UNC-Main Campus) was conditionally approved to develop one OR at UNC -Main Campus. That decision is currently under appeal.

The UNC-Hillsborough application, Project I.D. #J-11646-18 (Develop 2 ORs at UNC-Hillsborough campus) was conditionally approved for one OR only. That decision is currently under appeal.

As the table above indicates, there is only one existing health service provider located in Orange County with ORs and that is UNC Hospitals with 6 inpatient, 11 outpatient and 29 shared ORs. Five of those ORs are excluded from the Adjusted Planning Inventory pursuant to the OR Need Methodology in the 2019 SMFP. The new ASC, North Chapel Hill Surgery Center (Project I.D. #J-11645-19 is also part of the UNC Hospitals health care system.

The 2019 SMFP shows a need for three additional ORs in the Orange County service area based on the utilization of UNC Hospitals. See Table 6B: Projected Operating Room Need for 2021, on page 80. However, anyone can apply to meet the need.

J-11692-19/Duke Health Orange ASC/Develop Two ORs

The applicant proposes to develop a new multi-specialty ASC, Duke Health Orange ASC, in Chapel Hill with two ORs and two procedure rooms.

In Section G.3, pages 62, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved ORs in Orange County. The applicant states,

“The proposed project will not result in unnecessary duplication of existing or approved facilities that provide the surgical services in Orange County. ... Orange County is unique in

that it has only one provider of surgical services and no local access to a freestanding ASC. ... The six dedicated ambulatory ORs are located in UNC's ambulatory surgery center ... however the facility is hospital-based and does not offer patients an alternative charge structure to UNC's HOPD pricing. Therefore, Orange County residents will greatly benefit from access to a new surgical provider in Orange County, especially one that proposes to develop a freestanding, non-hospital-based ASC. "

The applicant 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:

- There is a need determination in the 2019 SMFP for three additional ORs in the Orange County service area and the applicant proposes to develop two ORs.
- The applicant adequately demonstrates that the proposed ORs are needed in addition to the existing or approved ORs in Orange County.

The Agency reviewed the:

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

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

J-11695-19/UNC-Main Campus/Develop Three ORs

The applicant proposes to develop three additional ORs for a total of 44 ORs at UNC Hospitals-CH Main Campus.

In Section G.3, page 63, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved ORs in Orange County. The applicant states,

"The 2019 SMFP includes a need determination for three additional operating rooms in Orange County, based solely on the surgical utilization at UNC Hospitals. The identified need can best be met by the proposed application to add three operating rooms at UNC Hospitals Main Campus. As the sole provider of surgical services in Orange County, and with the need determination based solely on its utilization, the proposed project by UNC Hospitals will provide much-needed additional capacity to serve a growing patient population."

The applicant 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:

- There is a need determination in the 2019 SMFP for three additional ORs in the Orange County service area and the applicant proposes to develop three ORs.
- The applicant adequately demonstrates that the proposed ORs are needed in addition to the existing or approved ORs in Orange County.

The Agency reviewed the:

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

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons 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
Both Applications

J-11692-19/Duke Health Orange ASC/Develop Two ORs

In Section Q, Form H, the applicant provides projected staffing for the proposed services through the first three operating years of the project.

The assumptions and methodology used to project staffing are provided in Section H, page 64 and Section Q. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.3, which is found in Section Q. In Sections H.2 and H.3, pages 65-66, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. In Section H.4, page 71, the applicant identifies the proposed medical directors. In Exhibit H.4, the applicant provides letters from the proposed medical directors indicating an interest in serving as medical directors for the proposed ASC. In Section H.4, pages 66-67, the applicant describes its physician recruitment plans.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide 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 for all the reasons stated above.

J-11695-19/UNC-Main Campus/Develop Three ORs

In Section Q, Form H, the applicant provides projected staffing for the proposed services through the first three operating years of the project.

The assumptions and methodology used to project staffing are provided in Section Q. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.3, which is found in Section Q. In Sections H.2 and H.3, pages 65-66, the applicant describes the methods to be used to recruit or fill new positions and its existing training and continuing education programs. In Section H.4, page 66, the applicant identifies the directors of the major programs involved in the proposed project. In Exhibit I.2, the applicant provides letters from them endorsing the proposed project. In Section H.4, page 67, the applicant describes its physician recruitment plans. In Exhibit I.2, the applicant provides supporting documentation.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide 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 for all 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
Both Applications

J-11692-19/Duke Health Orange ASC/Develop Two ORs

In Section I.1, pages 69-70, the applicant states that the following ancillary and support services are necessary for the proposed services:

- Pathology
- Pharmacy
- Human Resources
- Quality and Performance Improvement
- Accounting/ Billing
- Infection Control
- Anesthesiology
- Medical Supplies
- Dietary
- Medical records
- Reception/Business office
- Housekeeping/Maintenance
- Administration

- Laundry
- Information Technology
- Staff Education
- Surgical Services

On pages 69-70, the applicant adequately explains how each ancillary and support service will be made available.

In Section I.2, page 70, the applicant describes its efforts to develop relationships with other local health care and social service providers. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system.

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-11695-19/UNC-Main Campus/Develop Three ORs

In Section I.1, page 69, the applicant states that, *“as an existing full-service academic medical center, UNC Hospitals has all ancillary and support services in place to support hospital operations, including the existing surgical services at its Main Campus.”* On page 69, the applicant adequately explains how each ancillary and support service will be made available and provides supporting documentation in Exhibit I.1.

In Section I.2, page 69, the applicant describes its efforts to develop 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.

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.

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

NA
Both Applications

Neither of the applicants project to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which the services will be offered. Furthermore, none of the applicants project to provide the proposed services to a substantial number of persons residing in other states that are not adjacent to the North Carolina county in which the services will be offered. Therefore, Criterion (9) is not applicable to this review.

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:
- (i) would be available under a contract of at least 5 years duration;
 - (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
 - (iii) would cost no more than if the services were provided by the HMO; and
 - (iv) would be available in a manner which is administratively feasible to the HMO.

NA
Both Applications

Neither of the applicants is an HMO. Therefore, Criterion (10) is not applicable to this review.

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

C
Both Applications

J-11692-19/Duke Health Orange ASC/Develop Two ORs

The applicant proposes to develop a new multi-specialty ASC in Chapel Hill, Duke Health Orange ASC, with two ORs and two procedure rooms.

In Section K, page 73, the applicant states that the project involves up fitting 18,500 square feet of leased space. The facility will be located at 66 Vilcom Center Drive in Chapel Hill. Line drawings are provided in Exhibit K-3.

On pages 74-75, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal and provides supporting documentation in Exhibit F.1.

On pages 74-75, 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.

On page 75, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans and provides supporting documentation in Exhibit F.1.

On pages 76-79, 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.

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-11695-19/UNC Main Campus/Develop Three ORs

The applicant proposes to develop three additional ORs for a total of 44 ORs at UNC Hospitals-CH Main Campus in Chapel Hill.

In Section K, page 72, the applicant states that the project involves the renovation of 4,648 square feet of existing space located at 101 Manning Drive in Chapel Hill. Line drawings are provided in Exhibit C-1.

On page 73, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal.

On page 73, 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.

On page 74, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

Conclusion - The Agency reviewed the:

- Application
- Exhibits to the application

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

- (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;

C
 Both Applications

J-11692-19/Duke Health Orange ASC/Develop Two ORs

In Section L, pages 81, the applicant states there is no historical payor source data because Duke Health Orange ASC is not an existing facility. For informational purposes, on page 82, the applicant provides the following comparison based on the combined outpatient surgery payor mix for DUHS at all of its facilities during FY2018.

	Percentage of Outpatient Surgery Patients Served by all DUHS facilities during FY 2018	Percentage of the Population of the Service Area
Female	56.3%	52.3%
Male	43.6%	47.7%
Unknown	0.1%	0.0%
64 and Younger	63.3%	86.6%
65 and Older	36.7%	13.4%
American Indian	0.5%	0.6%
Asian	2.1%	8.2%
Black or African-American	21.8%	11.9%
Native Hawaiian or Pacific Islander	0.1%	0.1%
White or Caucasian	68.5%	70.7%
Other Race	3.9%	8.5%
Declined / Unavailable	3.2%	0.0%

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-11695-19/UNC-Main Campus/Develop Three ORs

In Section L, page 79, the applicant provides the historical payor mix for UNC Hospital’s Main Campus ORs for FY2018, as shown in the table below.

Payor Category	Operating Room Services as Percent of Total
Self Pay	7.9%
Medicare*	25.8%
Medicaid*	23.0%
Insurance*	35.2%
Other (Government, Workers Comp, TRICARE)	8.1%
Total	100.0%

Source: Table on page 79 of the application.

*Including any managed care plans.

In Section L, pages 78-79, the applicant provides the following comparison.

	Percentage of Total Patients Served by UNC Hospitals during FY2018	Percentage of the Population of Orange County
Female	58.3%	52.2%
Male	41.7%	47.8%
Unknown	0.0%	0.0%
64 and Younger	71.8%	82.7%
65 and Older	28.2%	17.3%
American Indian	0.6%	0.0%
Asian	1.8%	8.5%
Black or African-American	22.4%	10.9%
Native Hawaiian or Pacific Islander	0.1%	0.8%
White or Caucasian	60.9%	77.0%
Other Race	9.0%	2.8%
Declined / Unavailable	5.1%	0.0%

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities

and handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C
Both Applications

J-11692-19/Duke Health Orange ASC/Develop Two ORs

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, pages 82-83, the applicant states it has no obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, but that DUHS provides services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, ability to pay or any other factor.

In Section L, page 84, the applicant states that during the last five years, three patient civil rights access complaints have been filed against DUHS. The applicant reports that two of the complaints have been closed without further investigation and one complaint is pending. The applicant also states that “*one additional complaint was filed and voluntarily dismissed.*”

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-11695-19/UNC Main Campus/Develop Two ORs

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 80, the applicant states UNC Hospitals has no obligations to provide uncompensated care, community service or access by minorities and persons with disabilities, but that that they provide access to healthcare services to all patients needing care, regardless of their ability to pay.

In Section L, page 80, the applicant states that during the last five years no patient civil rights access complaints have been filed against UNC Hospitals or any related entities.

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
Both Applications

J-11692-19/Duke Health Orange ASC/Develop Two ORs

In Section L, page 85, the applicant projects the following payor mix for the proposed services during the second full fiscal year of operation (FY2023) following completion of the project, as shown in the table below.

Payor Category	Operating Room Services as Percent of Total	Procedure Room Services as Percent of Total
Self-Pay/Charity	1.1%	1.8%
Medicare *	41.5%	46.7%
Medicaid *	4.2%	6.2%
Insurance *	51.6%	44.0%
Workers Comp, VA, TRICARE	1.6%	1.3%
Total	100.0%	100.0%

Source: Table on page 85 of the application.

* Including any managed care plans

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 1.1% of surgical services will be provided to self-pay/charity patients, 41.5% to Medicare patients and 4.2% to Medicaid patients.

On pages 85-86, the applicant provides the assumptions and methodology used to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported because it is based on the applicant's historical outpatient surgical encounters across all DUHS facilities for patients from Orange, Alamance and Chatham counties and the surgical specialties and types of cases and procedures projected for the proposed ASC.

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-11695-19/UNC-Main Campus/Develop Three ORs

In Section L, page 81, the applicant projects the following payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as shown in the table below.

Payor Category	Operating Room Services as Percent of Total
Self-Pay	7.9%
Medicare *	25.8%
Medicaid *	23.0%
Insurance *	35.2%
Other Government, Workers Compensation	8.1%
Total	100.0%

Source: Table on page 81 of the application.

* Including any managed care plans

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 7.9% of total services will be provided to self-pay patients, 25.8% to Medicare patients and 23.0% to Medicaid patients.

On page 81, the applicant provides the assumptions and methodology used to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported because it is based on the applicant's historical experience.

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
Both Applications

J-11692-19/Duke Health Orange ASC/Develop Two ORs

In Section L.5, page 87, 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-11695-19/UNC Main Campus/Develop Three ORs

In Section L.5, page 82, the applicant adequately describe 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
Both Applications

Both Applications. In Section M, the applicants describe the extent to which health professional training programs in the area have or will have access to the facility for training purposes and provide supporting documentation in the referenced exhibits.

The Agency reviewed:

- Each application
- Exhibits to each application

Based on that review, the Agency concludes that all of the applicants adequately demonstrate that the proposed services will accommodate the clinical needs of area health professional training programs, and therefore, all of the applications are conforming to this criterion.

- (15) Repealed effective July 1, 1987.
(16) Repealed effective July 1, 1987.
(17) Repealed effective July 1, 1987.
(18) Repealed effective July 1, 1987.
- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

C
Both Applications

On page 55, the 2019 SMFP states, “An operating room’s service area is the operating room planning area in which the operating room is located. The operating room planning areas are the single and multicounty groupings shown in Figure 6.1.” In Figure 6.1, page 60 of the 2019 SMFP, Orange County is shown as a single-county OR service area. Thus, the service area for

this review consists of Orange County. Facilities may also serve residents of counties not included in the service area.

The following table identifies the existing and approved inpatient (IP), outpatient (OP), and shared ORs located in Orange County, and the inpatient and outpatient case volumes for each provider, from pages 68 and 80 of the 2019 SMFP.

Orange County	IP ORs	OP ORs	Shared ORs	Excluded C-Section, Trauma, Burn ORs	CON Adjustments	IP Surgery Cases	OP Surgery Cases
UNC Hospitals	6	11	29	-5	0	14,226	16,267
2018 SMFP Need Determination					6		
Total	6	11	29	-5	6	14,226	16,267

Source: 2019 SMFP

Note: On April 29, 2019 the following applications were conditionally approved:

The DUHS application, Project I.D.# J-11632-18 (Develop a new ASC in Chapel Hill with 2 ORs and 2 procedure rooms) was approved. That decision is currently under appeal.

The UNC HealthCare System application, Project I.D. #J-11645-18 (Develop a new ASC in Chapel Hill with 2 ORs and 2 procedure rooms) was approved. That decision was not appealed. A certificate of need was issued for this project on May 30, 2019.

The UNC-Main Campus application, Project I.D. #J-11644-18 (Develop 2 new ORs at UNC-Main Campus) was conditionally approved to develop one OR at UNC -Main Campus. That decision is currently under appeal.

The UNC-Hillsborough application, Project I.D. #J-11646-18 (Develop 2 new ORs at UNC-Hillsborough campus) was conditionally approved for one OR only. That decision is currently under appeal.

As the table above indicates, there is only one existing health service facility located in Orange County with ORs and that is UNC Hospitals with 6 inpatient, 11 outpatient and 29 shared ORs. Five of those ORs are excluded from the Adjusted Planning Inventory pursuant to the OR Need Methodology in the 2019 SMFP. The new ASC, North Chapel Hill Surgery Center (Project I.D. #J-11645-19 is also part of the UNC Hospitals health care system.

The 2019 SMFP shows a need for three additional ORs in the Orange County service area based on the utilization of UNC Hospitals. See Table 6B: Projected Operating Room Need for 2021, on page 80. However, anyone can apply to meet the need.

J-11692-19/Duke Health Orange ASC/Develop Two ORs

The applicant proposes to develop a new multi-specialty ASC, Duke Health Orange ASC, in Chapel Hill with two ORs and two procedure rooms.

In Section N, pages 89-92, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services. On page 89, the applicant states,

“Orange County does not currently host a freestanding licensed ambulatory surgery center. The proposed project will represent a new opportunity for residents of Orange

County and surrounding communities to access Duke outpatient surgical services at a non-hospital, freestanding charge structure. The proposed new operating rooms will promote cost-effectiveness, quality, and access to services via 1) creation of a new ASC within Orange County and 2) a new provider of surgical services in Orange County.

This will therefore better serve local residents and will promote competition in the Orange County service area. Competition is healthy for providers, as it spurs continuous quality improvement, and serves as motivation for seeking maximum cost effectiveness. And local residents will have access to an alternative ASC provider conveniently located in Orange County.”

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates:

- The cost-effectiveness of the proposal (see Sections F and Q of the application and any exhibits)
- Quality services will be provided (see Section O of the application and any exhibits)
- Access will be provided to underserved groups (see Section L of the application and any exhibits)

Conclusion - The Agency reviewed the:

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

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

J-11695-19/UNC-Main Campus/Develop Three ORs

The applicant proposes to develop three additional ORs for a total of 44 ORs at UNC Hospitals-CH Main Campus.

In Section N, pages 86-89, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services. On page 86, the applicant states,

“...The proposed project will enhance competition by expanding the capacity of surgical services at UNC Hospitals, which will improve its ability to compete with other providers. The proposed project will enhance the provision of timely, quality patient care and will assist UNC Hospitals in meeting its four-fold mission of patient care, teaching, research, and community service. UNC Hospitals maintains that the development of additional surgical capacity in Orange County will promote cost-effectiveness, quality, and access to services in the proposed service area...”

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates:

- The cost-effectiveness of the proposal (see Sections F and Q of the application and any exhibits)
- Quality services will be provided (see Section O of the application and any exhibits)
- Access will be provided to underserved groups (see Section L of the application and any exhibits)

Conclusion - The Agency reviewed the:

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

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

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

C
Both Applications

J-11692-19/Duke Health Orange ASC/Develop Two ORs

In Section O, the applicant identifies one ASF, the James E. Davis Ambulatory Surgery Center, that is owned or managed by DUHS. In addition, DUHS owns or manages three hospitals, Duke University Hospital, Duke Regional Hospital, and Duke Raleigh Hospital.

In Section O, page 97, the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents related to quality of care did not occur at the James E. Davis Ambulatory Surgery Center. 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 none of these facilities. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure and Certification Section, Section and considering the quality of care provided at all four facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

J-11695-19/UNC-Main Campus/Develop Three ORs

In Section O, page 92, the applicant identifies the health care facilities providing surgical services located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of twelve of this type of facility located in North Carolina.

In Section O, pages 92-95, the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents related to quality of care occurred in five of these facilities. The applicant states that all the problems have been corrected. 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 four of these facilities.

Furthermore, the Acute and Home Care Licensure and Certification Section, DHSR forwarded a letter dated September 5, 2019 from the Chief Operating Officer and Chief Nurse Executive of the Joint Commission to Gary Park, President, UNC Hospitals regarding accreditation which stated,

“This letter confirms that your July 08, 2019 – July 17, 2019 unannounced full resurvey was conducted for the purposes of assessing compliance with the Medicare conditions for hospitals through The Joint Commission’s deemed status survey process.

Based upon the submission of your Plan of Correction on August 19, 2019 and the successful on-site unannounced Evidence of Standards Compliance Follow-up event conducted on August 30, 2019 and the successful on-site unannounced Medicare Deficiency Follow-up event conducted on August 29, 2019, the areas of deficiency listed below have been removed. The Joint Commission is granting your organization an accreditation decision of Accredited with an effective date of August 30, 2019. We congratulate you on your effective resolution of these deficiencies.

*§482.13 Patient’s Rights
§482.23 Nursing Services
§482.41 Physical Environment
§482.42 Infection Control
§482.51 Surgical Services*

The Joint Commission is also recommending your organization for continued Medicare certification effective August 30, 2019.”

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 twelve 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.

C

Both Applications

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

10A NCAC 14C .2103 PERFORMANCE STANDARDS

- (a) *An applicant proposing to increase the number of operating rooms (excluding dedicated C-section operating rooms) in a service area shall demonstrate the need for the number of proposed operating rooms in addition to the existing and approved operating rooms in the applicant's health system in the applicant's third full fiscal year following completion of the proposed project based on the Operating Room Need Methodology set forth in the 2018 State Medical Facilities Plan. The applicant is not required to use the population growth factor.*
- C- **Duke Health Orange ASC** proposes to develop a new ASC with two ORs. The proposed ASC would be the only health service facility in the health system. The applicant projects sufficient surgical cases and hours to demonstrate the need for two ORs in the third full fiscal year of the proposed project based on the Operating Room Need Methodology in the 2019 SMFP. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.
- C- **UNC-Main Campus** proposes to develop three additional ORs on the main hospital campus in Chapel Hill which is part of the UNC Hospitals health system. The applicant projects sufficient surgical cases and hours to demonstrate the need for three additional ORs in the applicant's health system in the third operating year of the project based on the Operating Room Need Methodology in the 2019 SMFP. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.
- (b) *The applicant shall document the assumptions and provide data supporting the methodology used for each projection in this Rule.*
- C- **Duke Health Orange ASC.** In Section Q, pages 101-111 and Form C, the applicant provides the assumptions and methodology used in the development of the projections required by this Rule. The discussion regarding analysis of need, including projected utilization, found in Criterion (3) is incorporated herein by reference.

- C- **UNC-Main Campus.** In Section Q, Form C, and Section Q, Form C, pages 1-19, the applicant provides the assumptions and methodology used in the development of the projections required by this Rule. The discussion regarding analysis of need, including projected utilization, found in Criterion (3) is incorporated herein by reference.

COMPARATIVE ANALYSIS

Pursuant to G.S. 131E-183(a)(1) and the 2019 State Medical Facilities Plan, no more than three additional ORs may be approved for Orange County in this review. Because the two applications in this review collectively propose to develop five additional ORs to be located in Orange County, not all of the applications can be approved for the total number of ORs proposed. Therefore, after considering all of 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.

The following provides a brief description of each of the proposed projects being addressed in the comparative analysis:

- **J-11692-19/Duke Health Orange ASC/**Develop a new multi-specialty ASC, Duke Health Orange Ambulatory Surgery Center, in Chapel Hill with two ORs and two procedure rooms.
- **J-11695-19/UNC-Main Campus/** Develop three additional ORs for a total of 44 ORs at UNC-Main Campus in Chapel Hill.

One application proposes a new multi-specialty ASC with two ORs and one application proposes to develop three additional ORs at an academic medical center teaching hospital.

Conformity with Review Criteria

Table 6C, page 85, of the 2019 SMFP identifies a need for three additional ORs in Orange County. As shown in Table 6B, page 80, the UNC Hospitals shows a projected deficit of 3.38 ORs in 2021, which results in the Orange County need determination for three 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 three ORs in Orange 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.

Each applicant adequately demonstrates the need for their respective proposal and is conforming to all applicable statutory and regulatory review criteria.

Therefore, each application is an equally effective alternative with respect to this comparative factor.

Geographic Accessibility

The 2019 SMFP identifies a need for three additional ORs in the Orange County OR Service Area. Both applications propose to develop new ORs in Chapel Hill. The two locations are approximately 5 miles or an 11 minute drive apart.

Therefore, with regard to geographic accessibility each application is an equally effective alternative.

Physician Support

Each applicant documents physician support for its proposed project. Therefore, with regard to physician support, each application is an equally effective alternative.

Competition

The following table identifies the existing and approved inpatient (IP), outpatient (OP), and shared ORs located in Orange County, and the inpatient and outpatient case volumes for each provider, from pages 68 and 80 of the 2019 SMFP.

Orange County	IP ORs	OP ORs	Shared ORs	Excluded C-Section, Trauma, Burn ORs	CON Adjustments	IP Surgery Cases	OP Surgery Cases
UNC Hospitals	6	11	29	-5	0	14,226	16,267
2018 SMFP Need Determination					6		
Total	6	11	29	-5	6	14,226	16,267

Source: 2019 SMFP

Note: On April 29, 2019 the following applications were conditionally approved:

The DUHS application, Project I.D.# J-11632-18 (Develop a new ASC in Chapel Hill with 2 ORs and 2 procedure rooms) was approved. That decision is currently under appeal.

The UNC HealthCare System application, Project I.D. #J-11645-18 (Develop a new ASC in Chapel Hill with 2 ORs and 2 procedure rooms) was approved. That decision was not appealed. A certificate of need was issued for this project on May 30, 2019.

The UNC-Main Campus application, Project I.D. #J-11644-18 (Develop 2 new ORs at UNC-Main Campus) was conditionally approved to develop one OR at UNC -Main Campus. That decision is currently under appeal.

The UNC-Hillsborough application, Project I.D. #J-11646-18 (Develop 2 new ORs at UNC-Hillsborough campus) was conditionally approved for one OR only. That decision is currently under appeal.

As the table above indicates, there is only one existing health service facility located in Orange County with ORs and that is UNC Hospitals with 6 inpatient, 11 outpatient and 29 shared ORs. Five of those ORs are excluded from the Adjusted Planning Inventory pursuant to the OR Need Methodology in the 2019 SMFP. While a new ASC, North Chapel Hill Surgery Center (Project I.D. #J-11645-19), was approved on April 29, 2019 for which a certificate of need was issued on May 30, 2019, however, North Chapel Hill Surgery Center is also part of the UNC Health Care System in Orange County.

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

Duke Health Orange ASC. In Section O, page 103, the applicant states that it does not own or operate any existing surgical facilities located in the Orange County OR service area. Therefore, this proposed facility would be a new provider of surgical services located in Orange County. Note: The DUHS application, Project I.D.# J-11632-18 (Develop a new ASC in Chapel Hill with 2 ORs and 2 procedure rooms) was approved. That decision is currently under appeal.

DUHS, in Section Q, page 101, states,

“Please note that while DUHS has an application under review at the time of the filing of this application for an ASC in Orange County (Project I.D. #J-11632-18), this application would not create a second, additional, ASC. Rather, this application reiterates and restates the need for the development by Duke of a 2-OR ASC in Orange County in the even that DUHS is not awarded a CON pursuant to its 2018 application. Upon approval of this project, it would be the only surgery facility operated by DUHS in Orange County.”

UNC-Main Campus. The UNC Health Care System currently serves Orange County residents by providing surgical services at the following existing campuses located in Orange County:

- UNC Hospitals Main Campus- Chapel Hill
- UNC Hospitals Hillsborough Campus- Hillsborough

Subsequent to the submittal of this application a new ASC, North Chapel Hill Surgery Center (Project I.D. #J-11645-19), was approved on April 29, 2019 for which a certificate of need was issued on May 30, 2019, however, North Chapel Hill Surgery Center is also part of the UNC Health Care System in Orange County.

Therefore, with regard to introducing a new provider of surgical services located in Orange County, the application submitted by **Duke Health Orange ASC** is the more effective alternative.

Service to Residents of the Service Area

On page 55, the 2019 SMFP states, “An operating room’s service area is the operating room planning area in which the operating room is located. The operating room planning areas are the single and multicounty groupings shown in Figure 6.1.” In Figure 6.1, page 60 of the 2019 SMFP, Orange County is shown as a single-county OR service area. Thus, the service area for this review consists of Orange County. Facilities may also serve residents of counties not included in the service area. Generally, the application projecting to serve the highest percentage of Orange County residents is the more effective alternative with regard to this comparative factor since the need determination is for three additional ORs in Orange County.

3 rd Full FY	
Application	% Orange County Residents
Duke Health Orange ASC	37.4%
UNC-Main Campus	11.2%

Source: Section C.3 (both applications)

As shown in the table above, **Duke Health Orange ASC** projects to serve the highest percentage of Orange County residents during the 3rd Full FY. Therefore, with regard to projected service to Orange County residents, **Duke Health Orange ASC** is the most effective alternative with respect to this comparative factor.

Patient Access to Lower Cost Surgical Services

There are two types of health service facility that can have licensed ORs in North Carolina: hospitals and ASCs. Based on the applications, written comments and response to comments and statements made at the public hearing, many, but not all outpatient surgical services can be appropriately performed either in a hospital-based OR or in an ASC OR. However, the cost to the patient and a third party payor will be lower if the service is provided in an ASC OR than the cost for the same service provided in a hospital-based OR on an outpatient basis. Nonetheless, there are some outpatient surgical services that must be performed in a hospital setting and there are some patients that need to have their outpatient surgery performed in a hospital. Moreover, hospital-based ORs are necessary for inpatients requiring surgery during their admission.

UNC-Main Campus will continue to offer hospital-based outpatient surgical services. **Duke Health Orange ASC** proposes to develop a new ASC and would offer outpatient surgical services in non-hospital-based ORs. The cost to patients and third-party payors would be lower in this ASC as compared to the cost for same service provided in a hospital-based OR on an outpatient basis. Therefore, with respect to this factor, the application submitted by **Duke Health Orange ASC** is more effective than the **UNC-Main Campus** application.

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 each applicant’s projected charity care to be provided in the project’s third full fiscal year. Generally, the application proposing to provide more charity care is the more effective alternative with regard to this comparative factor.

CHARITY CARE				
APPLICANT	Projected Total Charity Care	# of Surgical Cases	Charity Care per Surgical Case	% of Net Revenue
Duke Health Orange ASC *	\$238,949	4,262	\$56	111.3%
UNC-Main Campus	\$55,665,463	29,423	\$1,892	76.1%

Source: Forms F.3, F.4 and F.5 in each application

* For Duke Health Orange ASC the number of cases includes cases performed in both the ORs and the procedure rooms. Charity care is not provided separately for the ORs and the procedure rooms in Form F.3.

As shown in the table above, **UNC-Main Campus** projects the most charity care in dollars. Therefore, the application submitted by **UNC-Main Campus** appears to be more effective alternative with regard to access to charity care. However, due to differences in the types of facilities (an ASC and a hospital campus) and the number and types of surgical services proposed by each applicant, there is little value in comparing the numbers in the table above for determining which applications to approve in this

review. Thus, the result of this analysis is inconclusive.

Projected Medicare

The following table shows each applicant’s total number of projected surgical cases and the number of cases projected to be provided to Medicare patients in the applicant’s third fiscal year. Generally, the application proposing to serve more Medicare patients is the more effective alternative with regard to this comparative factor.

Medicare			
	Projected Total OR Cases	Projected Medicare OR Cases	% of Total OR Cases Provided to Medicare Recipients
Duke Health Orange ASC	3,552	1,474	41.5%
UNC-Main Campus	29,423	7,786	25.8%

Source: Form F.4 in each application

As shown in the table above, **Duke Health Orange ASC** projects to serve 1,474 Medicare patients or 41.5% of total surgical cases. **UNC-Main Campus** projects to serve 7,786 Medicare patients or 25.8% of total surgical cases. The application submitted by **Duke Health Orange ASC** appears to be a more effective alternative based on the percentage of the total and **UNC-Main Campus** appears to be a more effective alternative based on the number of Medicare patients. However, due to differences in the types of facilities (an ASC and a hospital campus) and the number and types of surgical services proposed by each applicant, there is little value in comparing the numbers in the table above for determining which applications to approve in this review. Thus, the result of this analysis is inconclusive.

Projected Medicaid

The following table shows each applicant’s total number of projected surgical cases and the number of cases projected to be provided to Medicaid patients in the applicant’s third fiscal year. Generally, the application proposing to serve more Medicaid patients is the more effective alternative with regard to this comparative factor.

Medicaid			
	Projected Total OR Cases	Projected Medicaid OR Cases	% of Total OR Cases Provided to Medicaid Recipients
Duke Health Orange ASC	3,552	149	4.2%
UNC-Main Campus	29,423	6,772	23.0%

Source: Form F.4 in each application

As shown in the table above, **UNC-Main Campus** projects to serve 6,772 Medicaid patients or 23% of total surgical cases. The application submitted by **UNC-Main Campus** appears to be a more effective alternative with regard to serving Medicaid recipients based on the percentage of the total and **UNC-Main Campus** appears to be a more effective alternative based on the number of Medicaid patients. However, due to differences in the types of facilities (an ASC and a hospital campus) and the number and types of

surgical services proposed by each applicant, there is little value in comparing the numbers in the table above for determining which applications to approve in this review. Thus, the result of this analysis is inconclusive.

Projected Average Net Revenue per Case

The following table shows the projected average net surgical revenue per OR and per surgical case in the third fiscal year. Generally, the application proposing a lower average net revenue per 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.

	Net Revenue	# of OR Cases	Average Net Revenue/Case
Duke Health Orange ASC	\$12,189,933	3,552	\$3,431
UNC-Main Campus (surgical services)	\$295,371,090	29,423	\$10,038

Source: Forms F.3 in each application

As shown in the table above, **Duke Health Orange ASC** projects the lowest average net revenue per case in the third fiscal year. Therefore, the application submitted by **Duke Health Orange ASC** appears to be a more effective alternative with respect to the average net revenue per case. However, due to differences in the types of facilities (an ASC and a hospital campus) and the number and types of surgical services proposed by each applicant, there is little value in comparing the numbers in the table above for determining which applications to approve in this review. Thus, the result of this analysis is inconclusive.

Projected Average Operating Expense per Case

The following table compares the projected average operating expense in the third fiscal year.

Generally, the application proposing a lower average operating expense per 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.

	Total Operating Expenses*	# of OR Cases	Average Operating Expense/Case
Duke Health Orange ASC	\$12,052,137	3,552	\$3,393
UNC-Main Campus	\$222,204,983	29,423	\$7,552

Source: Form F.3 in each application.

*Operating expenses for the ASC applications include expenses for both the ORs and procedure rooms.

As shown in the table above, **Duke Health Orange ASC** projects the lowest average operating expense per case in the third fiscal year. Therefore, the application submitted by **Duke Health Orange ASC** appears to be a more effective alternative with respect to the average operating expense per case. However, due to differences in the types of facilities (an ASC and a hospital campus) and the number and types of surgical services proposed by each applicant, there is little value in comparing the numbers in the table above for determining which applications to approve in this review. Thus, the result of this analysis is inconclusive.

SUMMARY

The following table summarizes the ranking of the applications for each comparative factor. The rankings are: more effective, equally effective and less effective.

Because of the significant differences in types of facilities, numbers of ORs, numbers of projected surgeries, types of proposed surgical services offered and the differences in how the pro forma financial statements were prepared, some of the comparative factors are of less value in determining which applications to approve than if all applications were for like facilities of like size proposing like services and reporting in like formats.

Comparative Factor	Duke Health Orange ASC	UNC- Main Campus
Conformity with Review Criteria	Equally Effective	Equally Effective
Geographic Accessibility	Equally Effective	Equally Effective
Physician Support	Equally Effective	Equally Effective
Competition	More Effective	Less Effective
Service to Residents of Orange County	More Effective	Less Effective
Patient Access to Lower Cost Surgical Services	More Effective	Less Effective
Access by Underserved Groups: Charity Care	Inconclusive	Inconclusive
Access by Underserved Groups: Medicare	Inconclusive	Inconclusive
Access by Underserved Groups: Medicaid	Inconclusive	Inconclusive
Projected Average Net Revenue per Case	Inconclusive	Inconclusive
Projected Average Operating Expense per Case	Inconclusive	Inconclusive

Based on the comparative analysis:

Duke Health Orange ASC is determined to be the most effective alternative in this review. Duke Health Orange ASC is the only proposal that would introduce a new provider located in Orange County, Duke Health Orange ASC proposes to serve the highest percentage of Orange County residents and Duke Health Orange ASC would provide patients access to lower cost outpatient surgical services.

DECISION

Each application is individually conforming to the need determination in the 2019 SMFP for three additional ORs in Orange County as well as individually conforming to all review criteria. However, G.S. 131E-183(a)(1) states that the need determination in the SMFP is the determinative limit on the number of ORs that can be approved by the Healthcare Planning and Certificate of Need Section. Collectively, the applicants propose a total of five ORs.

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

- **Project I.D. #J-11692-19 / Duke University Health System, Inc. / Develop a new multi-specialty ASC in Chapel Hill with two ORs and two procedure rooms**

As that leaves only one OR left to approve, **Project I.D. #F-11695-19** / University of North Carolina Hospitals at Chapel Hill / Develop three ORs on the Main Campus is approved to develop only one of the three ORs it proposed at its Chapel Hill campus.

The application submitted by Duke University Health System, Inc., **Project I.D. #J-11692-19** is approved subject to the following conditions.

1. Duke University Health System, Inc. shall materially comply with all representations made in the certificate of need application.
2. Duke University Health System, Inc. shall develop a new multi-specialty ambulatory surgical facility by developing no more than two operating rooms and two procedure rooms.
3. Upon project completion, Duke Health Orange Ambulatory Surgery Center shall be licensed for no more than two operating rooms and two procedure rooms.
4. Duke University Health System, Inc. 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.
5. Duke University Health System, Inc. shall receive accreditation from the Joint Commission for the Accreditation of Healthcare Organizations, the Accreditation Association for Ambulatory Health Care or a comparable accreditation authority within two years following licensure of the facility.
6. For the first three years of operation following completion of the project, Duke University Health System, Inc. shall not increase charges more than 5% of the charges projected in Section Q of the application without first obtaining a determination from the Healthcare Planning and Certificate of Need Section that the proposed increase is in material compliance with the representations in the certificate of need application.
7. The procedure rooms shall not be used for procedures that should be performed only in an operating room based on current standards of practice.
8. Procedures performed in the procedure rooms shall not be reported for billing purposes as having been performed in an operating room and shall not be reported on the facility's license renewal application as procedures performed in an operating room.
9. Duke University Health System, Inc. 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.
10. Prior to issuing a certificate of need for this project (Project I.D.#J-11692-19), Duke University Health System, Inc. shall either:
 - a. surrender the certificate of need issued for Project I.D.#J-11632-18, if one has been issued, by submitting a letter to the Healthcare Planning and Certificate of Need Section which states that the certificate of need is being surrendered and returning the certificate of need; or
 - b. withdraw the application identified as Project I.D. #J-11632-18, if no certificate of need has been issued for that project, by submitting a letter to the Healthcare Planning and Certificate of Need Section which states that the application identified as Project I.D. #J-11632-18 is being withdrawn.
11. 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, Duke University Health

System, Inc. 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.

12. Duke University Health System, Inc. 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.

The application submitted by the University of North Carolina Hospitals at Chapel Hill, **Project ID# J-11695-19**, is approved subject to the following conditions.

1. University of North Carolina Hospitals at Chapel Hill shall materially comply with all representations made in the certificate of need application.
2. University of North Carolina Hospitals at Chapel Hill shall develop one additional operating room on the Chapel Hill Campus for a total of 42 operating rooms on the Chapel Hill campus and 7 operating rooms on the Hillsborough campus upon completion of this project, Project I.D. # J-11644-18 (add one OR) and Project I.D. # J-11646-18 (add one OR).
3. Upon completion of this project, Project I.D. #J-11644-18 and Project I.D. # J-11646-18 University of North Carolina Hospitals at Chapel Hill shall be licensed for no more than 49 operating rooms (42 on the Chapel Hill campus and 7 on the Hillsborough campus).
4. University of North Carolina Hospitals at Chapel Hill 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.
5. University of North Carolina Hospitals at Chapel Hill 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.
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, University of North Carolina Hospitals at Chapel Hill 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. University of North Carolina Hospitals at Chapel Hill 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.