Competitive Comments Regarding the CON Applications Submitted for the 2021 Need Determinations for Four Operating Rooms and Forty Acute Care Beds in Durham County

In response to the need determinations for additional Operating Rooms (ORs) and Acute Care Beds, the following Certificate of Need applications were submitted:

J-012052-21, FID # 180558, Southpoint Surgery Center - Add four ORs pursuant to the need determination in the 2021 SMFP which is a change of scope to Project ID # J-11626-18

J-012075-21, FID # 180213, Duke Ambulatory Surgery Center Arringdon – Add two ORs which is a change of scope for Project ID #J-11508-18

J-012070-21, FID # 943138, Duke University Hospital – Add two ORs which is a change of scope for Project ID #J-11631-18

J-012069-21, FID # 943138, Duke University Hospital – Develop no more than 40 acute care beds

J-012065-21, FID # 210266, UNC Hospitals-RTP - Construct a new separately licensed hospital by developing 40 acute care beds and two ORs

These comments are submitted by Southpoint in accordance with N.C. Gen. Stat. § 131E-185(a1)(1) to address the representations in the applications, including a comparative analysis and a discussion of the most significant issues regarding the applicants' conformity with the statutory and regulatory review criteria ("the Criteria") in N.C. Gen. Stat. §131E-183(a) and (b). Other non-conformities in the competing applications may exist. Nothing contained in this document should be considered an amendment to the Southpoint Surgery Center application as submitted.

Operating Room Comparative Analysis

The following factors are suggested for the comparative analysis and review of the applications' proposals to develop Operating Rooms:

- Conformity to Statutory and Regulatory Criteria
- Scope of Services
- Geographic Accessibility
- Competition
- Patient Access to Lower Cost Surgical Services
- Access by Service Area Residents
- Access by Underserved Groups
- Projected Average Net Revenue per OR Case
- Projected Average Total Operating Cost per OR Case

Operating Room Comparative Data

Applicants	SouthPoint Surgery Center	Duke Ambulatory Surgery Center Arringdon	Duke University Hospital	UNC Hospitals-RTP
Project ID #	J-012052-21	J-012075-21	J-012070-21	J-012065-21
Operating Rooms Proposed	Add 4 ORs to ASC	Add 2 ORs to ASC	Add 2 Hospital-based ORs	40 Beds, 2 Hospital-based ORs
Conformity to Statutory and Regulatory Criteria	Yes	No	No	No
Change of Scope fpr Previously Approved Project	J-11626-18	J-11508-18	J-11631-18	No
Status of Previously Approved Project	In Construction	Facility Operational	Delayed	NA
Scope of Services (Surgical Specialties)	Orthopaedic (including spine), general surgery, ophthalmology, obstetrics / gynecology, otolaryngology, urology, plastic surgery, podiatry, urology, vascular, and oral surgery	Gynecology, plastic surgery, orthopaedic, ophthalmology	Not listed for specific additional ORs	General surgery, vascular surgery, obstetrics/gynecology, ophthalmology, orthopedics, otolaryngology
Geographic Accessibility (Location within the Service Area)	7810 NC 751 Hwy, Durham, in Triangle Township	5601 Arringdon Park Dr., Suite 500, Morrisville Triangle Township	2301 Erwin Rd., Durham NC, in Durham Township	NC HWY 54 and NC HWY 147 in Morrisville, Triangle Township
Competition	Yes - Expands Access	Not Effective and Not Approvable	Not Effective and Not Approvable	Not Effective and Not Approvable
Patient Access to Lower Cost Surgical Services	Yes - Most Effective	Not Effective and Not Approvable	Not Effective and Not Approvable	Not Effective and Not Approvable
Access by Service Area Residents	36.16% Durham	26.2% Durham	21.8% Durham	90% Durham
Access by Underserved Groups	Ambulatory Surgery 44.32% Medicare 4.12% Medicaid 0.48% Charity	Ambulatory Surgery 42.56% Medicare 5.38% Medicaid 1.72% Charity	Inpatient and Ambulatory Surgery 40.5% Medicare 11.6% Medicaid 1.9% Charity	Ambulatory Surgery 34.7% Medicare 7.0% Medicaid
Projected Average Net Revenue per OR Case	$2,780	$5,130	$17,719	$12,455
Projected Average Total Operating Cost per OR Case	$2,274	$3,412	$24,205	$12,302

Comparative Comments Regarding Applications Proposing Operating Rooms

Conformity to Statutory and Regulatory Criteria

Of the four applications proposing operating rooms in this competitive review, only the Southpoint application is conforming to all of the applicable CON review criteria and regulatory criteria based on reasonable projections. In contrast, the Duke Arringdon application and the Duke University Hospital (DUH) application do not conform to multiple criteria due to inconsistent representations regarding operating room inventory, flawed operational projections, and unreasonable financial pro formas; the applicants' methodologies and assumptions are not credible. The UNC-RTP application is fatally flawed based on its unreliable utilization assumptions that are premised on developing a "hospital of convenience" in Research Triangle Park with a more limited scope of services as compared to all the existing hospitals in Durham County. The UNC-RTP application fails to adequately demonstrate a need for additional hospital-based operating rooms because changes in reimbursement and patient preferences are continuing to drive surgery volumes to the non-hospital facilities. The Southpoint application is comparatively superior for this factor.

Historical Utilization

Generally, the application submitted by the applicant with the highest utilization of its available surgical services is the more effective alternative with regard to this comparative factor. However, not all applicants are existing providers of surgical services in Durham County.

NC Specialty Hospital, the parent of Southpoint Surgery Center, has very high historical utilization based on 1,588 inpatient cases and 4,128 ambulatory cases according to Table 6B of the 2021 SMFP. In its review of Project ID #J-11626-18, the Agency Findings (p. 37) concluded that developing Southpoint Surgery Center with only 2 ORs would not accommodate the volume of ASC cases expected to shift from NC Specialty Hospital and the sizable number of cases reasonably projected based, in part, on proposed surgeon recruitment. The Agency found that developing Southpoint Surgery Center with only 2 ORs would likely result in scheduling constraints and that developing Southpoint Surgery Center with 4 ORs would be the most effective alternative, would provide enhanced access for physicians and patients, cost-effective services and economies of scale.

Duke and UNC facilities have undeveloped approved ORs.

Southpoint is the most effective alternative on this factor.

Scope of Services

Generally, the application proposing to provide the greatest scope of services is the more effective alternative with regard to this comparative factor. Despite differences in the applicants,

Southpoint should be found most effective on this factor because, notwithstanding its proposal to add ORs to an ASC, the Southpoint application demonstrated the greatest scope of services, as explained below.

The Southpoint application proposes to provide the most comprehensive scope of surgical services for its proposed project with eleven surgical specialties. The Duke Arringdon application proposes only four surgical specialties for its ambulatory surgery operating rooms and the DUH application fails to specify what surgical specialties will be performed in its proposed additional operating rooms. UNC-RTP proposes six surgical specialties to be performed in its hospital-based operating rooms. The Southpoint application is the most effective proposal for the scope of services comparative factor.

Geographic Accessibility (Location within the Service Area)

Durham County is divided into six townships: Carr, Durham, Lebanon, Mangum, Oak Grove, and Triangle.

Duke University Hospital (DUH), Duke Regional Hospital, James E. Davis Ambulatory Surgical Center (DASC) and North Carolina Specialty Hospital are located in the city of Durham (Durham Township). Duke has two previously approved ORs at Duke North Pavilion, 2400 Pratt Street, Durham, two blocks north of DUH. Thus, the majority of existing operating rooms and the ORs proposed in the DUH application are located in the Durham Township.

The DUH application is the least effective alternative because it proposes to develop new ORs in the Duke North Pavilion in the City of Durham (Durham Township), the area of Durham County that has the majority of existing ORs.

Both Duke Arringdon and UNC-RTP propose new ORs in Morrisville (Triangle Township) where Duke Arringdon already offers OR capacity.

Duke Arringdon Surgery Center (Project ID #J-11508-18) is now operational at 5601 Arringdon Park Drive, Suite 500, in Morrisville, (Triangle Township. Project ID #J-11508-18 relocated four of the eight DASC ORs to develop a new ASF in the Triangle Township in southern Durham. The Duke Arringdon application proposes the development of 2 additional ORs in space currently used for 2 procedure rooms. After project completion, Duke Arringdon would have 6 ORs and 2 PRs. UNC-RTP also proposes to develop two hospital-based ORs in Morrisville (Triangle Township) at the potential site at NC HWY 54 and NC HWY 147.

Southpoint is developing a new ASF (Project ID #J-11626-18) at 7810 NC 751 Hwy, Durham, in Triangle Township, in southern Durham, that has not yet opened. Southpoint's application will convert previously approved procedure rooms to add 4 ORs to Southpoint Surgery Center for a total of 6 ORs. Southpoint is the only applicant proposing a location that is neither in the Durham Township nor in Morrisville.

All the proposed projects involve additional ORs in regions of Durham County with existing and approved ORs. Therefore, with regard to geographic access, the proposals are equally effective.

Competition

Duke Health System owns and controls the vast majority (93.75 percent) of the existing and approved operating room inventory in Durham County. The combined inventory of operating rooms at North Carolina Specialty Hospital (4 existing ORs) and Southpoint Surgery Center (2 approved ORs) represent a combined 6.25 percent of the total OR inventory.

The Duke Arringdon and the DUH applications propose to increase OR capacity which would increase the total combined OR inventory controlled by Duke Health System to 96 percent of all ORs in Durham County. Southpoint's proposal would increase the combined North Carolina Specialty Hospital / Southpoint Surgery Center inventory to 10 ORs for 10 percent of the total OR inventory of Durham County. The Southpoint application is more effective than the Duke Arringdon and DUH applications on this factor. UNC-RTP proposes to develop 2 ORs that would represent 2 percent of the total Durham County inventory.[1] However, the UNC-RTP proposal is not approvable. Therefore, the Southpoint application is the most effective in terms of improving competition.

Patient Access to Lower Cost Surgical Services

The cost of the same surgical services will often be much higher in a hospital licensed operating room or, conversely, much less expensive if received in a non-hospital licensed operating room or ASF. Considering the relatively high percent of surgical cases in Durham County that are ambulatory cases and the relatively low percent of total OR capacity in Durham County in ASFs, a project proposing ASF ORs would generally be more effective on this factor.

The Southpoint proposal will expand OR capacity in a freestanding ambulatory surgical facility that will improve patient access to cost-effective ambulatory surgery. Although the Duke Arringdon proposal would also add ORs in an ASF, as compared to Southpoint, the Duke Arringdon application proposes ORs with substantially higher costs and charges. The following table provides the comparison of the applicants' average net revenue per case and average cost per case for Year 3:

Applicants	Southpoint Surgery Center	Duke Ambulatory Surgery Center Arringdon	Duke University Hospital	UNC Hospitals-RTP
Projected Average Net Revenue per OR Case	$2,780	$5,130	$17,719	$12,455
Projected Average Total Operating Cost per OR Case	$2,274	$3,412	$24,205	$12,302

[1] UNC-RTP also proposes to develop 2 dedicated C-section operating rooms.

The Southpoint application is the more effective alternative for patient access to lower cost surgical services, as compared to the Duke Arringdon application.

The DUH application proposes new ORs that will be licensed on the DUH License #H0015 as hospital-based ORs at Duke North Pavilion.

The Southpoint application is more effective than the DUH and UNC-RTP applications which each propose additional operating rooms that will be hospital-licensed ORs, not ASF ORs, and would have significantly higher costs and patient charges for outpatients. Consequently, the Southpoint application is the most effective proposal for improving patient access to lower cost surgical services.

Access by Service Area Residents

The Southpoint application projects to serve 36.16 percent of patients from Durham County and 0.72 percent from Caswell County based on reasonable assumptions. The Duke Arringdon projects to serve 26.2 percent from Durham County and an unreported percentage from Caswell County. DUH OR proposal reports 21.8 percent from Durham County and 0.5 percent from Caswell County. The Southpoint application is more effective on this factor as compared to the Duke Arringdon and DUH applications.

UNC-RTP hospital projects to serve 90 percent of patients from Durham County and 0.2 percent from Caswell based on unreasonable assumptions. The UNC-RTP proposal is not approvable. Therefore, the Southpoint application is the most effective in terms of improving access by service area residents.

Access by Underserved Groups

Southpoint projects to serve 44.32% Medicare patients, 4.12% Medicaid patients and 0.48% Charity patients in Year 3. The following table shows Southpoint projects the highest Medicare percentage and the highest number of Medicare patients in Year 3.

	Southpoint Surgery Center	**Duke Ambulatory Surgery Center Arringdon**	**Duke University Hospital**	**UNC Hospitals-RTP**
Access by Underserved Groups	Ambulatory Surgery 44.32% Medicare 4.12% Medicaid 0.48% Charity	Ambulatory Surgery 42.56% Medicare 5.38% Medicaid 1.72% Charity	Inpatient and Ambulatory Surgery 40.5% Medicare 11.6% Medicaid 1.9% Charity	Ambulatory Surgery 34.7% Medicare 7.0% Medicaid
Numbers of Medicare Patients / OR - Year 3	502.5	492.5	261.1	334.2
Numbers of Medicaid Patients / OR - Year 3	46.7	62.3	74.8	67.4

Duke Arringdon projects to serve 42.56 % Medicare patients, 5.38 % Medicaid patients and 1.72% Charity patients in Year 3. However, the Duke Arringdon projections are not based on reasonable assumptions. DUH projects to serve 40.5 % Medicare patients, 11.6 % Medicaid patients and 1.9% Charity patients in Year 3, but the DUH projections are also not based on reasonable assumptions. UNC-RTP projects to serve 34.7 % Medicare patients, 7.0% Medicaid patients and no projections for Charity patients. However, the UNC-RTP projections are not based on reasonable assumptions.

Southpoint projects to serve the highest percentage and numbers of Medicare patients based on reasonable assumptions and is comparatively superior. The Duke Arringdon, DUH and UNC-RTP proposals are not approvable. Therefore, the Southpoint application is the most effective in terms of access by underserved groups.

Projected Average Net Revenue per Case and Average Total Operating Cost per Case

As documented in the 2021 State Medical Facilities Plan, for all North Carolina hospitals and ambulatory surgical facilities, 72.6% of surgical cases were ambulatory and 27.4% were inpatient cases based on the data reported in the 2020 license renewal applications. Therefore, a comparison of financial projections for the Southpoint Surgery Center and the Duke Arringdon applications are relevant and conclusive because both are ASCs that will provide only ambulatory surgery. The applications for DUH and UNC-RTP are not comparable due to the differences in the overall scope of services at these hospitals.

The following table provides the comparison of the projected average net revenue per OR case and the total operating cost per OR case.

Applicants	SouthPoint Surgery Center	Duke Ambulatory Surgery Center Arringdon	Duke University Hospital	UNC Hospitals-RTP
Projected Average Net Revenue per OR Case	$2,780	$5,130	$17,719	$12,455
Projected Average Total Operating Cost Per OR Case	$2,274	$3,412	$24,205	$12,302

Applicants that project lower average net revenue per case and lower average cost per case are more cost effective. Southpoint Surgery Center projects the lowest average net revenue per case and lowest average cost per case based on reasonable assumptions and as compared to the Duke Arringdon application. The Duke Arringdon, DUH and UNC-RTP proposals are not approvable. Therefore, the Southpoint application is the most effective in terms of projected average net revenue per case and average total operating cost per case.

Conformity with CON Conditions

Although the Agency has not typically compared applicants on conformity with CON conditions, this review may present an appropriate opportunity for the Agency to rely on such a comparative factor. As explained below, the Agency approved the development of the Duke Arringdon facility with a condition that charges not be increased by more than 5% without express Agency approval. Notwithstanding that condition and with no documentation of Agency approval, the Duke Arringdon application for a change in scope of its prior-approved project includes a projection for an over 38% increase in gross revenue (charges) per case. An applicant that proposes to violate the conditions on a prior CON approval should be found comparatively less effective on conformity with CON conditions.

The Agency has used "history of project development" in certain reviews in the past where the proposals of the applicants suggested it was appropriate to draw such comparisons to evaluate whether the applicants had conformed to representations in prior CON approvals. The same logic supporting use of a "history of project development" factor would suggest that it would be appropriate to evaluate competing applicants on "conformity with CON conditions."

Acute Care Beds Comparative Analysis

The following factors are suggested for the comparative analysis and review of the applications that include Acute Care Beds:

- Conformity to Statutory and Regulatory Criteria
- Scope of Services
- Geographic Accessibility (Location within the Service Area)
- Historical Utilization
- Competition
- Access by Service Area Residents
- Access by Underserved Groups
- Projected Average Net Revenue
- Projected Average Total Operating Cost

Applicants	**Duke University Hospital**	**UNC Hospitals-RTP**
Project ID #	**J-012069-21**	**J-012065-21**
Acute Care Beds / ORs	Add 40 Beds	40 Beds/ 2 ORs at New Hospital
Conformity to Statutory and Regulatory Criteria	No	No
Scope of Services	Tertiary Hospital - Trauma Center, ICU, Acute Care, Obstetrics, Surgery, Endoscopy, Imaging, Ancillary and Support	Community Hospital - Emergency Services, Acute Care Admissions, Obstetrics, Surgery, Imaging, Ancillary and Support, Laboratory, Pharmacy, Nutritional Services, and Adminstration
Geographic Accessibility (Location within the Service Area)	2301 Erwin Rd. Durham, NC Durham Township	NC HWY 54 and NC HWY 147 in Morrisville, Triangle Township
Competition - New Provider	No	Yes
Access by Service Area Residents	28.1% Durham 0.5% Caswell	90% Durham 0.2% Caswell
Access by Underserved Groups	Total Duke University Hospital 39.7% Medicare 11.2% Medicaid	Total UNC-RTP 24.4% Medicare 12.2% Medicaid
Inpatient Acute Care Discharges (YR 3)	46,182	2,238
Projected Average Net Revenue Inpatient Services	Not comparable	Not comparable
Projected Average Operating Expense	Not comparable	Not comparable

Comparative Comments Regarding Applications Including Acute Care Beds

Conformity to Statutory and Regulatory Criteria

Both the DUH and the UNC-RTP applications fail to conform to multiple CON review criteria due to unreasonable assumptions and projections that are simply not credible. The DUH application fails to adequately demonstrate the need for the proposed project due to unreasonable patient origin projections, overstated admissions and inconsistent representations. UNC-RTP's application fails to demonstrate the need for the proposed hospital because its projections are based on irrational and unsupported assumptions. Neither of these applications merit approval.

Scope of Services

Duke University Hospital (DUH) proposes 40 additional acute care beds for a total of 1,102 licensed acute care beds. Duke reports that it has 102 previously-approved acute care beds including 14 NICU beds that are currently in development. DUH provides the most advanced forms of medical care as a Level 1 trauma center and a quaternary care academic medical center. The proposed UNC-RTP project is a community hospital with 40 acute care beds, 10 observation beds, two operating rooms, two dedicated C-section operating rooms, an emergency department, and imaging and laboratory services. The UNC-RTP project does not involve many of the types of specialized services that are currently provided at Duke University Hospital. Furthermore, all of the services proposed by UNC-RTP are already provided by Duke Regional Hospital and North Carolina Specialty Hospital. The DUH application provides a more comprehensive scope of services as compared to the UNC-RTP application. However, neither application is approvable.

Geographic Accessibility (Location within the Service Area)

DUH proposes to add beds to its main campus location in Durham while UNC-RTP proposes to develop a new hospital facility in Morrisville near the border of Durham and Wake Counties. The DUH proposal adds acute care beds where the majority of beds are already located. The UNC-RTP application fails to demonstrate that there is a need for a community hospital at its proposed location. Therefore, neither application is an effective alternative regarding geographic access.

Competition

As a potential new entrant to the Durham market, UNC-RTP could offer a new hospital service location, but the proposed project lacks a sufficient scope of service to have any positive competitive impact. The DUH proposal fails to demonstrate that its proposal will enhance competition because it already has over 100 acute care beds still in development. Neither application is approvable based on numerous CON non-conformities.

Access by Service Area Residents

DUH projects that 28.1% of its patients served in acute care beds will originate from Durham County based on its historical patient origin data. DUH indicates that in the last full fiscal year, 28.5% of its patients served in acute care beds were residents of Durham County. In connection with adding beds, DUH projects to serve a slightly lower percent of Durham County residents as a percentage of total patients served in its acute care beds. Thus, the project if approved is not expected to improve access by service area residents. And, the DUH application fails to identify the county-specific patient origin for 16% of its projected future patients that are assigned to "Other." The DUH patient origin projections are unreliable because the projected 16% from "Other" is undefined even though it represents the highest projected percentage of patients from outside of Durham County.

UNC-RTP provides the unreasonable forecast that 90% of its patients will originate from Durham County, which is unreasonable given the proposed location near the border of Durham and Wake Counties. The UNC-RTP application also fails to provide the patient origin assumptions or any data to demonstrate the reasonableness of a projection that fully 90% of its patient will originate from Durham with the remaining percentages from Wake, Chatham and Caswell Counties. UNC-RTP omits the assumptions for patient origin in its Form C assumptions. The UNC-RTP application fails to demonstrate that its patient origin and utilization projections are based on reasonable assumptions.

For these reasons, neither application is an effective alternative regarding access by service area residents.

Access by Underserved Groups

DUH projects to serve 37.7 % Medicare patients, and 11.2 % Medicaid patients in Year 3, but the DUH projections are not based on reasonable utilization projections and assumptions. UNC-RTP projects to serve 24.4% Medicare patients and 12.2% Medicaid patients. However, the UNC-RTP projections are not based on reasonable operational projections and payor assumptions.

Projected Average Net Revenue and Projected Average Total Operating Cost

The DUH and UNC-RTP applications differ greatly in terms of the overall scope of services for the inpatient acute care beds. The operational and financial projections are not comparable due to the differences in the patient acuity and the organizational characteristics. The DUH application fails to adequately demonstrate the need for the proposed project due to unreasonable utilization projections. UNC-RTP's application fails to demonstrate the need for the proposed hospital because its projections are based on irrational and unsupported assumptions. While the financial comparison of these applications is not conclusive, neither application should be approved.

Comments Regarding Duke Ambulatory Surgery Center Arringdon, Project ID #J-012075-21, FID # 180213 - Add two ORs which is a change of scope for Project ID #J-11508-18

The Duke Arringdon application proposes to add two operating rooms to its existing facility with 4 licensed ORs in southeastern Durham County. The Duke Arringdon application is non-conforming to multiple CON review criteria as explained in the following comments.

Comments Regarding Criterion 1

Project ID #J-012075-21 is nonconforming to Criterion 1 and Policy GEN-3. The information provided by the applicant is not reasonable and does not adequately support the determination that the applicant's proposal would maximize healthcare value because the applicant does not adequately demonstrate that its projected utilization is based on reasonable and adequately supported assumptions. Therefore, the Duke Arringdon application fails to conform to Policy GEN-3 and Criterion 1.

Comments Regarding Criterion 3

The Duke Arringdon application is non-conforming to Criterion 3 because the utilization projections are not based on reasonable and adequately supported assumptions:

Unreliable Growth Rate Assumptions

The applicant uses unreliable compound annual growth rates on page 118 of the application based on its contrived "2-YR CAGR" that is based on FY2020 annualized data and not actual historical data as reported in its license renewal applications. Furthermore, the applicant's use of a "2-YR CAGR" is not reliable because the surgery volume for Duke Health System fails to demonstrate the long-term growth to support projections through 2025.

The following table provides the 2015 through 2020 historical data for Duke Health System operating rooms that achieved no growth in total surgery utilization. Duke University Hospital shows only **0.52% CAGR** for inpatient cases and **- 2.73% CAGR** for outpatient cases.

Duke Health Durham Facilities	SMFP	2017 SMFP	2018 SMFP	2019 SMFP	2020 SMFP	2021 SMFP	Draft 2022 SMFP	5-YR CAGR
	Data Periods	2015	2016	2017	2018	2019	2020	2015 - 2020
Duke ASC Arringdon	Inpatient	NA	NA	NA	NA	NA	NA	NA
	Ambulatory	0	0	0	0	0	0	0
James E. Davis ASC	Inpatient	NA	NA	NA	NA	NA	NA	NA
	Ambulatory	4,869	5,161	5,277	5,877	6,079	5,911	3.95%
Duke University Hospital	Inpatient	17,344	17,151	17,984	18,300	18,733	17,804	0.52%
	Ambulatory	23,728	22,642	22,575	22,215	22,139	20,659	-2.73%
Duke Regional	Inpatient	3,865	3,765	3,942	4,061	3,991	3,574	-1.55%
	Ambulatory	2,995	2,981	3,352	3,581	3,555	3,468	2.98%
Duke Health System Totals								
Combined for Duke Health System	Inpatient	21,209	20,916	21,926	22,361	22,724	21,378	0.16%
Combined for Duke Health System	Ambulatory	31,592	30,784	31,204	31,673	31,773	30,038	-1.00%

Sources: 2017 to 2021 SMFP and Draft Table 6B 2022 SMFP

The applicant's growth rate assumptions on page 120 of its application are unreasonable because these include higher percentages with up to 5% annual growth as compared to the 5-Year CAGR percentages that are based on the actual License Renewal Data for Duke facilities as published in the State Medical Facilities Plans. The Duke application fails to explain why it is reasonable to project future growth that far exceeds its actual utilization trend over the past five years.

Over the past five years, Duke University Hospital (DUH) has experienced the largest numerical and percentage decline in ambulatory surgery cases for all of the Duke Health System locations.

From 2015 to 2020, ambulatory surgery cases at DUH declined by **3,069 cases or 12.93%.** Therefore, the applicant's projections that it will have a need to shift thousands of future ambulatory cases from DUH to Duke Arringdon are unreasonable.

Duke Arringdon's methodology and assumptions on pages 123 to 140 are based on unsupported assumptions regarding the expected shift of projected outpatient cases from various Duke related facilities. The shift assumptions are not tied to any data for the projected numbers of physicians by specialty that will be practicing at the Duke Arringdon ASC or other facilities. There is no mathematical basis or connection to underlying data to support the applicant's shift percentage assumptions. Furthermore, the application fails to adequately describe (or even list) the "quantitative and qualitative factors" that were considered in projecting the percent of cases by specialty that are expected to shift to the Duke Arringdon ASC.

According to the Duke Arringdon ASC website (visited on May 18, 2021) the current medical staff consists of only one orthopedic surgeon, six ophthalmologists, and three anesthesiologists. No timeline is provided for when additional surgical specialists will begin performing cases at the

ASC. The applicant's projections for the proposed project for 2023 through 2025 are unreliable due to the small size and limited specialties for Duke Arringdon's current medical staff along with the absence of a medical staff recruitment plan to support the future increases in cases.

Other than Duke Arringdon's unsupported shift percentage assumptions, no legitimate data is provided in the application to explain the astronomical growth in ambulatory surgery utilization that is projected in Form C.3a. This form reports 591 ambulatory cases projected for the period 7/1/2020 to 6/30/2021 which is followed by 4,904 ambulatory cases for the period 7/1/2021 to 6/30/2022. The physician support letters included in the Exhibit C.4 do not specify the numbers of surgeons who are joining the Duke Arringdon medical staff or the timeframe. It would require **approximately 34 additional surgeons** (with the current 7 surgeons) to perform 4,904 ambulatory surgery cases based on an average of 100 cases per year per surgeon. The application fails to report the numbers of physicians who intend to join the medical staff in 2021, 2022 and 2023 to support the reasonableness of the utilization projections.

For purposes of comparison, the James E. Davis Ambulatory Surgery Center (DASC) website reports 81 physicians on staff with six of these listed as anesthesiologists or pain management physicians. Therefore, the 75 surgeons at DASC performed 6,079 for an average of 81 annual cases per surgeon. In summary, the Duke Arringdon ASC projections in Form C.3a are not credible.

Inconsistencies in Duke Arringdon Forms C.3a and C.3b and Inconsistencies with Form C.3a included in the Duke University Application Project ID #J-12070-21.

The Duke Arringdon application fails to explain why its Form C.3b reports an adjusted planning inventory of 68 ORs for Duke University Hospital for years 2023 to 2025 which incorrectly reports an increase of 4 ORs from its Form C.3a inventory as seen in the following:

Duke ASC Arringdon Application Project ID #J-12075-21

Form C.3a Historical and Interim OR and GI Endo Room Utilization Duke University Hospital	Interim Full FY* F: 07/01/2020 T: 06/30/2021	Interim Full FY F: 07/01/2021 T: 06/30/2022
Operating Rooms - Number of Rooms by Type		
Open Heart ORs	10	10
Dedicated C-Section ORs	0	0
Other Dedicated Inpatient ORs	0	0
Shared ORs	46	46
Dedicated Ambulatory ORs	9	9
Total # of ORs	65	65
# of Excluded ORs (Trauma/Burn ORs)	1	1
Adjusted Planning Inventory [1]	64	64

Form C.3b Projected OR and GI Endo Room Utilization upon Project Completion Duke University Hospital	1st Full FY* F: 07/01/2022 T: 06/30/2023	2nd Full FY F: 07/01/2023 T: 06/30/2024	3rd Full FY F: 07/01/2024 T: 06/30/2025
Operating Rooms - Number of Rooms by Type			
Open Heart ORs	10	10	10
Dedicated C-Section ORs	0	0	0
Other Dedicated Inpatient ORs	0	0	0
Shared ORs	46	46	46
Dedicated Ambulatory ORs	13	13	13
Total # of ORs	69	69	69
# of Excluded ORs (Trauma/Burn ORs)	1	1	1
Adjusted Planning Inventory [1]	68	68	68

The Duke Arringdon application projects an increase of 4 operating rooms at DUH which is inconsistent with the narrative representations in Section C and the Forms C.3a and C.3b assumptions that report a pending increase for 2 previously-approved ORs.

The Form C.3b included in the Duke Arringdon application is also inconsistent with the current adjusted planning inventory of 66 ORs for 2023 to 2025 that is documented in the DUH application Project ID #J-12070-21 in Form C.3a.

Duke University Hospital Application Project ID #J-12070-21

Form C.3a Historical and Interim OR and GI Endo Room Utilization Duke University Hospital	Interim Full FY* F: 07/01/2020 T: 06/30/2021	Interim Full FY F: 07/01/2021 T: 06/30/2022	Interim Full FY F: 07/01/2022 T: 06/30/2023	Interim Full FY F: 07/01/2023 T: 06/30/2024	Interim Full FY F: 07/01/2024 T: 06/30/2025
Operating Rooms - Number of Rooms by Type					
Open Heart ORs	10	10	10	10	10
Dedicated C-Section ORs					
Other Dedicated Inpatient ORs	0	0	0	0	0
Shared ORs	46	46	46	46	46
Dedicated Ambulatory ORs	9	9	9	9	9
Total # of ORs	65	65	65	65	65
# of Excluded ORs (Trauma/Burn ORs)	1	1	1	1	1
Adjusted Planning Inventory (includes 2 approved but undeveloped ORs) (1)	66	66	66	66	66

The inconsistencies in the OR inventories for these two applications demonstrate that the utilization projections and the assumptions for the projected shift of cases are not based on reasonable assumptions.

Duke Arringdon uses erroneously-reported data in its need methodology, rendering the methodology unreliable and the projections inaccurate and overstated

By way of background, in the 2018 Wake County Operating Room Review, the fundamental problem with the Duke application (Project ID #J-11557-18), *as admitted by Duke and identified by the Agency*, was an overstatement of surgical cases at Duke Raleigh.

In 2018, Duke identified over 12,000 outpatient surgical cases at Duke Raleigh as a starting point for its methodology. The Agency questioned this, concluding Duke should have relied only on data showing the outpatient cases performed in its operating rooms, not the volumes from both operating rooms (ORs) and procedure rooms (PRs). Per the 2019 LRA, Duke's outpatient surgical cases in its ORs were only about 7,400 cases.

The Agency concluded:

The 2019 Hospital LRA was emailed on January 23, 2019 to Martha Frisone, Chief. The applicant's email states, "While total surgical cases continue to increase, in previous years, Duke Raleigh

inadvertently included all cases performed in the surgical suite, including procedures in both licensed ORs and in procedure rooms, in this category. … We apologize for our previous ***reporting errors*** *and greatly regret any difficulties that this causes in the planning process or the review of Wake County certificate of need applications."*

… projected surgical case volumes and growth rates are ***questionable*** *because the applicant reported in its 2019 Hospital License Renewal Application that historical surgical case volume data for Duke Raleigh Hospital has been overstated for an unknown number of years.*

2018 Wake County Operating Room Review, Agency Findings, p. 73.

- As shown above, Duke expressly acknowledged and apologized for an admitted error caused by reporting outpatient surgical case volumes to improperly include procedures performed in procedures rooms.
- And, the Agency has gone on record concluding that using an outpatient case volume number including procedure room volumes renders projections based on those baseline surgical case volumes questionable.

In this 2021 Review, Duke again erroneously combined OR and PR volumes for Duke Raleigh and reported the combined volumes in a chart with the misleading label: "Step 1: Review DUHS Historical ***OR*** Cases." *See,* 2021 Duke Arringdon application, p. 118 and Exhibit Q Supplementary Documentation, p. 1.

This is the very same flaw that resulted in Duke's non-conformity in the 2018 Wake County Operating Room Review where the Analyst identified the use of PR volumes as erroneous and performed a re-calculation of Duke's need methodology substituting OR-only volumes.

In the 2018 Wake County Operating Room Review, the Agency created a chart to show the "extent of overstatement," depicting that Duke used an overstated outpatient case volume count instead of the correct number of **7,474**. *See,* Agency Finding for 2018 Wake County Operating Room Review, p. 73.

In this 2021 Review, as revealed in the Exhibit Q Supplementary Documentation, Duke again used an overstated Outpatient case volume count by combining its **7,474** OR cases with another 3,880 PR cases to identify "Total OP cases" for Duke Raleigh for FY2018. *See* Exhibit Q Supplementary Documentation, p. 1.

In Step 1 of Duke Arringdon's methodology, the overstated number for Duke Raleigh appears with nothing *on that page* to alert the reader that this so-called number of "Historical ***OR*** Cases" is, **once again, the erroneously reported number reflecting both OR and PR cases.**

Although it misleadingly labeled Step 1 as a review of "Historical DUHS OR Cases," per the Exhibit Q Supplementary Documentation (p. 1), Duke admittedly "bumped up" its surgical case volumes

at Duke Raleigh by adding in PR cases, not just for FY2018, but for each year FY2018, FY2019 and annualized FY2020.

For Duke Raleigh, page 1 of Exhibit 12's Supplemental Methodology Information shows:

	FY2018
OP OR Cases	**7,474**
OP PR Cases	3,880
Total OP Cases	11,354

The Agency made it clear in the 2018 Findings for Project ID #J-11557-18 that the correct number is **7,474** for the Duke Raleigh FY2018 baseline surgical volume and that using an overstated number was cause for a non-conformity. But Duke inflated the **7,474** again in this 2021 need methodology for FY2018 for Duke Raleigh.

To calculate a positive CAGR for Duke Raleigh's Outpatient volumes, Duke "threw in" its procedure room cases (although not described on page 118 of the Duke Arringdon application). Adding in the cases performed in procedure rooms inflated the numbers relied on by Duke.

Step 1: Review DUHS Historical OR Cases

	FY2018	FY2019	FY2020 Ann.	2-YR CAGR
OP Cases	11,354	11,540	11,601	1.1%

Source: 2021 Duke Arringdon App., p. 118

To be correct, and based on Outpatient Surgical Cases performed in ORs at Duke Raleigh, the DUHS numbers show a negative CAGR for of **-1.2%** for Duke Raleigh's Outpatient OR surgical cases.

Step 1: Review DUHS Historical OR Cases

	FY2018	FY2019	FY2020 Ann.	2-YR CAGR
OP OR Cases	**7,474**	7,415	7,293	-1.2%

Source: Exhibit Q Supplementary Documentation, p. 1.

In Step 2, Duke used +1.1% as the Growth Rate Assumption for Duke Raleigh Outpatient cases. *See* 2021 Duke Arringdon App., p. 120.

To be correct, in Step 2, Duke should have identified **-1.2%** as the Growth Rate Assumption for Duke Raleigh Outpatient cases.

In Step 3, starting from an FY2020 Annualized total of 11,601 and using a +1.1% Growth Rate Assumption, Duke showed this for Duke Raleigh "OP Cases" as if these were all OR volumes:

Step 3: Projected DUHS Surgical Cases

	FY2021	FY2022	FY2023	FY2024	FY2025	2-YR CAGR
OP Cases	11,727	11,853	11,982	12,111	12,242	+1.1%

Source: 2021 Duke Arringdon App., p. 121.

As explained above, both the FY2020 Annualized total starting point and the CAGR are overstated based on Duke Raleigh's erroneous reporting.

The FY2020 Annualized total starting point should be 7,293 and the CAGR should be -1.2% as reported by Duke on page 1 of its Exhibit 12 Supplemental Methodology Exhibit.

To be correct, for Duke Raleigh, Step 3 should show:

Step 3: Projected DUHS Surgical Cases

	FY2021	FY2022	FY2023	FY2024	FY2025	2-YR CAGR
OP Cases	7,293	7,205	7,119	7,034	6,949	-1.2%

In Step 4, Duke assumes 77.8% of the cases from Duke Raleigh are appropriate to shift to an ASC setting.[2]

In Step 5, for Duke Raleigh, Duke erroneously shows the following:

Step 5: Project Surgical Cases Appropriate for ASC

	FY2021	FY2022	FY2023	FY2024	FY2025
OP Cases	9,125	9,223	9,323	9,424	9,526

To be correct, in Step 5, Duke should have shown the following for Duke Raleigh:

Step 5: Project Surgical Cases Appropriate for ASC

	FY2021	FY2022	FY2023	FY2024	FY2025
OP Cases	5,674	5,606	5,539	5,472	5,406

[2] In 2018, in Duke's Step 4 of its methodology, Duke stated that 73.2% of the total outpatient cases at Duke Raleigh would be ASC-appropriate (2018 Duke App., p. 128).

Steps 6 and 7 show an analysis by specialty of the so-called OR cases at Duke Raleigh, concluding 63.2% of cases would be available to shift to an ASC.

In Step 7, for Duke Raleigh, Duke shows the following:

Step 7: Potential ASC Cases Available to Shift

	FY2021	FY2022	FY2023	FY2024	FY2025
OP Cases	9,125	9,223	9,323	9,424	9,526
Specialty Assumption	63.2%	63.2%	63.2%	63.2%	63.2%
Pre-Shift	5,766	5,828	5,891	5,955	6,019

To be correct, Step 7 should show the following for Duke Raleigh:

Step 7: Potential ASC Cases Available to Shift

	FY2021	FY2022	FY2023	FY2024	FY2025
OP Cases	5,674	5,606	5,539	5,472	5,406
Specialty Assumption	63.2%	63.2%	63.2%	63.2%	63.2%
Pre-Shift	3,586	3,543	3,500	3,458	3,417

In Step 8, Duke accounts for shifts it already assumed in prior applications as shifts to Duke Green Level ASC and Duke Garner ASC.

In Step 8, Duke assumed 1,080 cases would shift from Duke Raleigh to Duke Green Level ASC in FY2025 with no shifts in prior years. Duke assumed 314 cases in FY2024 and 470 cases in FY2025 would shift from Duke Raleigh to Duke Garner ASC. By Duke's calculation, this would leave the following number of potential OP cases available to shift to Arringdon ASC from Duke Raleigh.

Step 8: Shift to Other DUHS ASCs

	FY2023	FY2024	FY2025
OP Cases	5,891	5,955	6,019
Shift to Green Level	0	0	1,080
Shift to Garner	0	314	470
Potential to Shift to Arringdon	5,891	5,641	4,469

To be correct, Step 8 should show the following for Duke Raleigh:

Step 8: Shift to Other DUHS ASCs

	FY2023	FY2024	FY2025
OP Cases	3,500	3,458	3,417
Shift to Green Level	0	0	1,080
Shift to Garner	0	314	470
Potential to Shift to Arringdon	3,500	3,144	1,867

In Step 9, Duke shows specialty and shift assumptions for Duke Raleigh. As summarized in Exhibit 12 (p.2), Duke assumes the following for Duke Raleigh:

Step 9: Percentage of Potential "OR" Cases to Shift to Arringdon

FY2022	FY2023	FY2024	FY2025
7.2%	10.6%	11.0%	10.7%

In Step 10, Duke shows the cases projected to shift to Arringdon. For Duke Raleigh, Duke shows:

Step 10: Shift to Arringdon

FY2022	FY2023	FY2024	FY2025
422	625	653	643

Duke then combines its Duke Raleigh projections with all other projections to forecast utilization for Duke Arringdon ASC:

Shift From:	FY2022	FY2023	FY2024	FY2025
DASC	2,068	2,277	2,502	2,743
DUH	1,571	2,202	2,833	3,443
DRH	33	58	105	114
Duke Raleigh	422	625	653	643
TOTAL	4,094	**5,162**	**6,093**	**6,943**

To be correct, Step 10 should show the following for Duke Raleigh:

Step 10: Shift to Arringdon

FY2022	FY2023	FY2024	FY2025
255	371	380	366

Shift From:	FY2022	FY2023	FY2024	FY2025
DASC	2,068	2,277	2,502	2,743
DUH	1,571	2,202	2,833	3,443
DRH	33	58	105	114
Duke Raleigh	255	371	380	366
TOTAL	3,927	**4,908**	**5,820**	**6,666**

As seen on Form C.3b on page 5 in Section Q, all the Duke Arringdon application projections and assumptions rely on and are driven off projected Surgical Cases of:

1st Full FY 5,162

2nd Full FY 6,093

3rd Full FY 6,943

If corrected solely for the erroneous reliance on Duke Raleigh's combined OR plus PR baseline surgical volume data, the Duke projections and assumptions would be reduced to:

1st Full FY 4,908

2nd Full FY 5,820

3rd Full FY 6,666

Because of the complexity in the assumptions, it would be infeasible for the Agency to restate the Duke Arringdon application projections to account for the error caused by Duke's reliance on the overstated Duke Raleigh baseline surgical volume data. But, as demonstrated above, correcting for that error alone would materially alter the utilization numbers used by Duke to drive its responses to the CON application form questions. As such, the responses provided by Duke are questionable and unreliable. As a result, the Duke Arringdon application fails to demonstrate conformity with Criteria 3, 4, 5, 6 and 18a and cannot be approved.

It is also important to note that in the 2018 Wake County Operating Room Review, in finding Duke non-conforming to Criterion 3, the Analyst also found that Duke's error in baseline surgical

case volume for Duke Raleigh rendered its projected shift of volumes from Duke Raleigh to be questionable.

The Analyst in 2018 performed calculations to show that if the baseline surgical case volumes were corrected, the shift of cases from Duke Raleigh as a percentage of total volume would be such a high number as to be questionable. The Agency relied on this rationale to find Duke non-conforming to Criterion 3 (and other Criteria) in 2018. *See* Agency Findings, 2018 Wake County Operating Room Review, p. 75.

The current Duke Arringdon application shows the following shifts from Duke Raleigh in FY2025:

	FY2025
Shift to Duke Green Level	1,080
Shift to Duke Garner	470
Shift to Arringdon	643
TOTAL	2,193

Based on Duke's Step 3, Duke Raleigh's total "OP" surgical case volume in FY 2025 is projected by Duke to be 12,242 such that the percentage shifts of 2,193 would represent a shift of 17.9% of Duke's Raleigh "OP" surgical case volume in FY 2025. However, as explained above, the 12,242 number is overstated because it is driven off an erroneous baseline and assumes an inaccurate growth rate assumption. Starting from **7,474** and using the actual 2-Year CAGR as the OR historical growth rate assumption for Duke Raleigh, Duke Raleigh should be expected to be providing about 6,949 OR cases in FY 2025 before any shifts.

If Duke shifts a total of 2,193 OR cases from Duke Raleigh in FY 2025, that shift would represent a 31.6% shift of OR cases. In 2018, after the very same type of re-calculation, the Agency determined a shift of 39.3% cases was "questionable." *See* 2018 Wake County Operating Room Review, Agency Findings, p. 75. Just as a 39% shift was questionable in 2018, a shift of nearly 32% is similarly questionable in this Review. To be consistent with its actions in the 2018 Wake County Operating Room Review and based on Duke's written admission of error in reporting OR volumes that mistakenly included cases performed in procedure rooms, the Agency should find Duke's 2021 methodology and the conclusions drawn from it to be questionable and, as a result, a failure to project need based on reasonable and adequately supported assumptions.

An admitted reporting error that inflates surgical volumes by erroneously including PR volumes is not an issue that is erased by the passage of the time. The erroneous numbers cannot be used repeatedly in future Reviews without question when Duke has admitted the error in an e-mail to

Ms. Frisone and the Agency has expressly found Duke non-confirming because it relied on the erroneous data. What was an erroneous number for surgical cases at Duke Raleigh in 2018 is still an erroneous number in the 2021 Duke Arringdon application. Duke's mistake in this Review is that it once again used admittedly erroneous data both as a baseline and to calculate growth rate assumptions. Duke chose to rely on its erroneously reported historical data that includes procedure room cases because it needs to inflate the baseline surgical case volumes and deceptively boost future projections. Projections premised on erroneous data are not projections based on reasonable and adequately supported assumptions.

Comments Regarding Criterion 4

Duke Arringdon does not adequately demonstrate that the alternative proposed in its application is the most effective alternative to meet the identified need because the application is not conforming to all statutory and regulatory review criteria. An application that cannot be approved cannot be the most effective alternative. Therefore, the Duke Arringdon application fails to conform to Criterion 4.

Comments Regarding Criterion 5

The Duke Arrington application is non-conforming to Criterion 5 because the financial projections are not based on reasonable utilization projections as discussed in the Criterion 3 comments. In addition, the Duke Arringdon proposal is based on unsupported increases in gross charges.

Duke's Arringdon ASC was initially approved in September 2018 (Project ID #J-11557-18) with the following condition:

For the first three years of operation following completion of the project, Arringdon Ambulatory Surgical Center 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.

https://info.ncdhhs.gov/dhsr/coneed/decisions/2018/sept/1018_durham_aasc_find.pdf

According to page 25 of the Agency Findings for the Arringdon ASC, Duke proposed the following number of cases and total gross revenues (charges):

Arringdon ASC	FY 2021	FY 2022	**FY 2023**
Total of Cases	2,733	3,737	4,936
Total Gross Revenues (Charges)	$27,139,210	$36,728,189	$48,110,827
Charge per case	$9,930	$9,828	**$9,747**

Duke Arringdon (Project ID #J-012075-21) now projects the following number of cases and total gross revenues (charges):

Form F.2b

Arringdon ASC	**FY 2023**	FY 2024	FY 2025
Total of Cases	5,162	6,093	6,943
Total Gross Revenues (Charges)	$69,498,224	$83,865,699	$96,057,222
Gross Charge per case	**$13,463**	$13,764	$13,835

As shown above, Duke now projects a significant increase in charges at the Arringdon ASC. $13,463 is a **38.1%** increase over $9,747. The applicant fails to adequately explain the basis for the projected increase charges that far exceed the CON condition.

Comments Regarding Criterion 6

The Duke Arringdon application is non-conforming to Criterion 6 because it does not adequately demonstrate that additional operating rooms are needed at the surgery center. *See* the discussion of projected utilization found in Criterion 3 above. Duke Arringdon fails to adequately demonstrate that its proposal would not result in an unnecessary duplication of existing or approved services in the service area.

Comments Regarding Criterion 12

Duke Arringdon is non-conforming to Criterion 12 because the application fails to demonstrate that the proposed design of the facility is an effective alternative due to the proposed conversion of two procedure rooms to become operating rooms because these spaces are substantially smaller than existing Arringdon operating rooms. As seen in the line drawings in Arringdon Exhibit K.2, the applicant fails to demonstrate that any changes will be made to these procedure rooms will enable these rooms to accommodate more complex surgical cases.

Comments Regarding Criterion 18a

Duke does not demonstrate that developing additional ORs at Duke Arringdon ASC will enhance competition or have a positive impact of cost effectiveness and access. The applicant's projected utilization is not based on reasonable and adequately supported assumptions. The discussions regarding analysis of need and projected utilization found in Criterion 3 are incorporated herein by reference. Therefore, the Duke Arringdon application does not conform to Criterion 18a.

Comments Regarding Duke University Hospital, Project ID #J-012070-21, FID # 943138 – Add two ORs which is a change of scope for Project ID #J-11631-18

The Duke University Hospital (DUH) application proposes to add two operating rooms to its existing hospital facility in Durham. The DUH application is non-conforming to multiple CON review criteria as explained in the following comments.

Comments Regarding Criterion 1

Project ID #J-012070-21 is nonconforming to Criterion 1 and Policy GEN-3. The information provided by the applicant is not reasonable and does not adequately support the determination that the applicant's proposal would maximize healthcare value because the applicant does not adequately demonstrate that its projected utilization is based on reasonable and adequately supported assumptions. Therefore, the DUH application fails to conform to Policy GEN-3 and Criterion 1.

Comments Regarding Criterion 3

The DUH application is non-conforming to Criterion 3 because the utilization projections are not based on reasonable and adequately supported assumptions:

Defective Patient Origin Projections

Duke states that it "projected patient origin <u>for both the service line and the facility as a whole</u>" to reflect the existing patient origin for the first six months of FY 2021 which is July through December of 2020. However, the "Entire Facility" projections do not reflect the existing patient origin for the first six months of FY 2021 (July-December 2020). So, contrary to its narrative, Duke did not project patient origin for <u>both the service and the facility as a whole</u> using the first six months of data for Surgical Services. For instance, for the Service Line, patients from Durham are expected to account for 21.8% of total patients but for the facility as a whole, patients from Durham are expected to account for 35.8% of total patients. The numbers for the "facility as whole" appear to generally mirror the entire facility numbers on page 28. It is not clear if these projections are based on the Last Full FY or the first six months of FY 2021 and Duke does not specify.

Patient origin projections for the proposed project are also unreliable because page 29 of the application states that the projections are based on only six months of data (July to December 2021) that occurred during the COVID-19 pandemic. This patient origin assumption lacks adequate support because COVID-19 vaccines were not available to the public in 2020 and DUH

has previous years' patient origin data based on the 12-month reporting period prior to the COVID-19 occurrence.

Historically, the applicant's patient origin for ambulatory surgery cases has reflected higher percentages of ambulatory cases from Durham and Wake Counties as compared to the patient origin for Inpatient cases as seen in the following tables:

	2019 Patient Origin Data	
Duke University Hospital	Ambulatory Surgery	Inpatient Surgery
Durham County	23.51%	19.23%
Wake County	16.63%	14.33%

Source: DHSR 2020 Healthcare Patient Origin by Facility

If the applicant were projecting the same annual rates of growth for both ambulatory surgery and inpatient surgery then the percentages in future years could remain approximately the same. However, Duke unreasonably assumes that its ambulatory cases will increase by 2.0% annually while its inpatient cases will increase by 1.5% annually. These different annual growth rates will be compounded over multiple years causing the percentages of patients from Durham and Wake to inevitably change. Consequently, the DUH patient origin projections for its ORs are mathematically incorrect and unreasonable.

Unreasonable Growth Rate Assumptions

The applicant uses unreliable compound annual growth rates in Section Q, Assumptions for Forms C.3a and C.3b using its manufactured "2-YR CAGR" that is based on FY2020 annualized partial year data and not actual historical data as reported in its license renewal applications. Furthermore, the applicant's use of the "2-YR CAGR" assumptions are unreliable because the surgery volumes for Duke Health System fails to demonstrate the long-term growth to support projections through 2025. Using the current year's annualized data overstates the growth because some short-term rebound in surgery cases in the later months of 2021 is due to cases that had to be deferred in early 2021 due to COVID-19.

The following table provides the 2015 through 2020 historical data for Duke Health System operating rooms. Duke University Hospital shows only **0.52% CAGR** for inpatient cases and **-2.73% CAGR** for ambulatory cases.

Duke Health Durham Facilities	SMFP	2017 SMFP	2018 SMFP	2019 SMFP	2020 SMFP	2021 SMFP	Draft 2022 SMFP	5-YR CAGR
	Data Periods	2015	2016	2017	2018	2019	2020	2015 - 2020
Duke ASC Arringdon	Inpatient	NA	NA	NA	NA	NA	NA	NA
	Ambulatory	0	0	0	0	0	0	0
James E. Davis ASC	Inpatient	NA	NA	NA	NA	NA	NA	NA
	Ambulatory	4,869	5,161	5,277	5,877	6,079	5,911	3.95%
Duke University Hospital	Inpatient	17,344	17,151	17,984	18,300	18,733	17,804	0.52%
	Ambulatory	23,728	22,642	22,575	22,215	22,139	20,659	-2.73%
Duke Regional	Inpatient	3,865	3,765	3,942	4,061	3,991	3,574	-1.55%
	Ambulatory	2,995	2,981	3,352	3,581	3,555	3,468	2.98%
Duke Health System Totals								
Combined for Duke Health System	Inpatient	21,209	20,916	21,926	22,361	22,724	21,378	0.16%
Combined for Duke Health System	Ambulatory	31,592	30,784	31,204	31,673	31,773	30,038	-1.00%

Sources: 2017 to 2021 SMFP and Draft Table 6B 2022 SMFP

The applicant's growth rate assumptions (1.5% inpatients and 2.0% outpatients) on page 96 of its application are unreasonable because these project higher percentages of growth as compared to the 5-Year CAGR percentages that are based on the actual utilization as published in the State Medical Facilities Plans. The Duke application fails to explain why it is reasonable to project future growth that far exceeds its actual utilization trend over the past five years.

From 2015 to 2020, Duke University Hospital (DUH) has experienced the largest numerical and percentage decline in ambulatory surgery cases for all of the Duke Health System locations. During this period, ambulatory surgery cases at DUH **declined by 3,069 cases or 12.93%.** For the same 5-year period total ambulatory surgery for the Duke Health System declined by 1,554 cases and inpatient surgery gained only 169 cases. Therefore, the historical data proves that the Duke Health System fails to demonstrate growth in overall surgery utilization.

The DUH application unreasonably argues that its growth in surgery utilization is restricted by capacity constraints since it has experienced an overall decline in total surgery cases over the past five years. According to the 2019 and 2020 License Renewal applications, DUH has been able to perform higher volumes of both inpatient and ambulatory cases for these prior years. The DUH application fails to document that it is having to continually extend hours of surgery or schedule surgery cases on Saturdays to relieve its alleged capacity constraints.

Inconsistencies in Duke University Application Project ID #J-12070-21 Form C.3a with the Duke Arringdon Project ID #J-012075-21 Form C.3b

The DUH application shows an adjusted planning inventory of 66 ORs for Duke University Hospital for years 2023 to 2025 that is inconsistent with the OR inventory reported in the Duke Arringdon application for the same three-year period.

Duke University Hospital Application Project ID #J-12070-21

Form C.3a Historical and Interim OR and GI Endo Room Utilization Duke University Hospital	Interim Full FY* F: 07/01/2020 T: 06/30/2021	Interim Full FY F: 07/01/2021 T: 06/30/2022	Interim Full FY F: 07/01/2022 T: 06/30/2023	Interim Full FY F: 07/01/2023 T: 06/30/2024	Interim Full FY F: 07/01/2024 T: 06/30/2025
Operating Rooms - Number of Rooms by Type					
Open Heart ORs	10	10	10	10	10
Dedicated C-Section ORs					
Other Dedicated Inpatient ORs	0	0	0	0	0
Shared ORs	46	46	46	46	46
Dedicated Ambulatory ORs	9	9	9	9	9
Total # of ORs	65	65	65	65	65
# of Excluded ORs (Trauma/Burn ORs)	1	1	1	1	1
Adjusted Planning Inventory (includes 2 approved but undeveloped ORs) [1]	66	66	66	66	66

Duke ASC Arringdon Application Project ID #J-12075-21

Form C.3b Projected OR and GI Endo Room Utilization upon Project Completion Duke University Hospital	1st Full FY* F: 07/01/2022 T: 06/30/2023	2nd Full FY F: 07/01/2023 T: 06/30/2024	3rd Full FY F: 07/01/2024 T: 06/30/2025
Operating Rooms - Number of Rooms by Type			
Open Heart ORs	10	10	10
Dedicated C-Section ORs	0	0	0
Other Dedicated Inpatient ORs	0	0	0
Shared ORs	46	46	46
Dedicated Ambulatory ORs	13	13	13
Total # of ORs	69	69	69
# of Excluded ORs (Trauma/Burn ORs)	1	1	1
Adjusted Planning Inventory [1]	68	68	68

The inconsistencies in the OR inventories for these two applications demonstrate that the utilization projections and the assumptions for the projected cases are not based on reasonable assumptions.

Unreliable Projected Shift of Surgery Cases in Section Q, Step 3 of Methodology for Duke University Hospital Application Project ID #J-12070-21

As described on pages 98 and 101 of the DUH application, the methodology and assumptions of the Duke University application Project ID #J-12070-21 are tied to and dependent on the methodology and assumptions of the Duke Arringdon application Project ID #J-012075-21. However, the methodology and assumptions for the Duke Arringdon project are fatally flawed as previously discussed and the DUH application fails to demonstrate that its surgery volume projections are based on reasonable and adequately supported assumptions. In other words, Duke Arringdon has no need for additional surgical capacity and DUH has no real growth in surgery utilization to shift to any other facilities.

Steps 4 and 5 of the DUH methodology and assumptions on pages 98 to 102 are unreliable as follows:

1) It is not credible for DUH to claim it has surgery capacity constraints because it has the capability to obtain additional operating rooms at any time under Policy AC-3. This Policy allows academic medical centers to be exempt from the need determinations in the SMFP. Duke University Hospital previously obtained 16 licensed (ORs) that were approved under Policy AC-3 (Project ID #J-008030-07).
2) DUH has undeveloped operating rooms at Duke North Pavilion that were approved for Project ID #J-011631-18 that are unaccounted for in the assumptions regarding the projected shift of cases for the DUH application Project ID #J-12070-21. Since the development of these ORs has been delayed, the projected shift assumptions depicted on pages 98 to 102 are unreliable. The existing and approved ORs at Duke North Pavilion cannot be utilized for inpatient surgery cases because the facility location is physically separate from the inpatient beds. Thus, the future utilization of these additional ORs at Duke North Pavilion (located at 2400 Pratt Street in Durham) will add capacity to shift outpatient cases from the main DUH hospital ORs.
3) The DUH application fails to demonstrate that its methodology and projections consider the profound impact of the COVID-19 pandemic that accelerated outpatient surgical migration from hospitals toward ASCs.
4) As of December of 2020, the Centers for Medicare and Medicaid Services (CMS) is phasing out its "Inpatient Only List." According to CMS, this transition will occur over a three-year period and will begin by eliminating about 300 services, mostly musculoskeletal procedures such as total joint procedures. The applicant's methodology and assumptions fail to consider changes in reimbursement that will enable more patients to have the freedom of choice to obtain surgery in ASCs. This change in CMS reimbursement was finalized late in 2020 and is likely to diminish overall surgery utilization at DUH, Duke Regional and Duke Raleigh Hospitals as more patients will have the option to obtain surgery at ASCs.

Additional Errors and Inconsistencies in Project ID #J-12070-21

The DUH application contains various inconsistencies. *See, e.g.,* Criterion (6).

Page 16 of the DUH application identifies its total projected capital cost as **$3.5 million**. Elsewhere, Duke describes its project as involving zero additional capital costs beyond the original CON-authorized capital expenditure amount of **$17.8 million**.

The DUH application for 2 ORs lists "2301 Erwin Road" on page 16 in response to the application question asking for the site address of the facility; the Erwin Road address is for Duke University Hospital. Instead, the application describes plans to develop the additional ORs at Duke North Pavilion on Pratt Street.

As seen on page 22, the DUH application indicates that it is filed in response to the Need Determination for 40 acute care beds which is erroneous.

An excerpt of page 31 of the DUH application refers the Agency to the content of its prior application for Project ID No. J-11631-18.

> DUH originally established the need for 4 additional ORs in J-11631-18, which application was originally approved by the CON Section. All of the factors discussed in that application continue to apply, including the high acuity of patients treated at DUH and resulting high surgical case times and the need for capacity across inpatient and outpatient platforms. DUHS refers the Agency to that application for a description of the project and qualitative factors that support this project, and updates the discussion of need below to reflect Duke's current experience.

Each CON application must demonstrate conformity "as submitted" and the 2021 DUH OR application Project ID #J-12070-21 fails to do so. The above reference to the prior DUH project does not suffice, on its own, to remedy the issue. The DUH CON application for Project ID #J-11631-18 clearly did not discuss factors such as the COVID-19 pandemic and the recent CMS changes to eliminate the "Inpatient Only" surgery list. These factors diminished the DUH surgical utilization to far below what was predicted in this previous application. Since this project is not being developed in accordance with its proposed schedule, the overall OR capacity at DUH and the shift assumptions to other facilities contained in this prior application are entirely unreliable.

Comments Regarding Criterion 4

The DUH application to add ORs does not adequately demonstrate that the alternative proposed in its application is the most effective alternative to meet the identified need because the application is not conforming to all statutory and regulatory review criteria. An application that

cannot be approved cannot be the most effective alternative. Therefore, the DUH application fails to conform to Criterion 4.

Comments Regarding Criterion 5

The DUH application Project ID #J-12070-21 is non-conforming to Criterion 5 because the financial projections are not based on reasonable utilization projections as discussed in the Criterion 3 comments.

The DUH application is also non-conforming to Criterion 5 because the application provides inconsistent, incomplete and unreliable information regarding the project capital cost.

In Project ID #J-11631-18, Duke projected capital costs to develop 4 additional ORs. After an appeal, Duke was ultimately approved to develop 2 ORs and 3 procedure rooms in the proposed space for the same capital cost it originally proposed for the development of 4 ORs, adjusted for inflation due to delay:

- Duke's previous CON states that it will offer services on July 1, 2023; its current CON application proposes a change to offer services January 1, 2025.
- Duke did not account for any change in cost projections based on this development delay even though the cost of construction materials has increased dramatically.
- Duke did not account for any additional cost associated with its proposed change in scope.
- Duke did not document the availability of funds for any associated costs.

Although Duke initially identifies a $3.5 million capital cost on page 16, it later presents its proposed project as a zero-capital-cost project. No budget is presented for costs of any kind associated with its plans to change its project from a CON-approved 2 OR / 3 PR project to a 4 OR project. No letter is provided to document the willingness of Duke University Health System, Inc. to commit any cash to change its project.

In Duke's "complementary" application proposing to add ORs instead of PRs at Duke Arringdon, Duke said its OR project would cost $650,000 more because "the cost of equipping a procedure room is less than a cost of equipping an operating room." Duke goes on to project an additional $300,000 per room to upfit the rooms as ORs instead of PRs at Duke Arringdon. Duke Arringdon App., p. 63. Yet, in the DUH application that proposes to develop 4 ORs instead of 2 ORs and 3 PRs at Duke North Pavilion, Duke identifies zero additional costs to develop the procedure rooms as licensed operating rooms.

Form F.1b fails to account for any cost differences associated with building a project to open in 2025 instead of 2023 with the proposed change in scope.

Duke provides an Architect letter in Exhibit F-1 but its wording makes it impossible to read it as a certification that the cost for the 3 PR project is the same to the dollar as the cost for a 2 OR proposal. The letter in Exhibit F-1 states that the Architect "has reviewed the construction cost estimate prepared by Balfour Beatty for the upfit and renovation of the 2nd level of the Duke Pavilion to expand the ambulatory surgery operative room, prep and recover, sterile processing, and staff support space." The Architect letter fails to explain why it is reasonable to project no increases in the total capital costs with the proposed change in scope and delay in project development.

Comments Regarding Criterion 6

The DUH application is non-conforming to Criterion 6 because it does not adequately demonstrate that additional operating rooms are needed at the hospital. *See* the discussion of projected utilization found in Criterion 3 above. DUH has previously-approved ORs (Project ID #J-011631-18) that have not been timely developed. DUH fails to adequately demonstrate that its proposal would not result in an unnecessary duplication of existing or approved services in the service area.

Comments Regarding Criterion 12

The DUH application Project ID #J-12070-21 is non-conforming to Criterion 12 because the architect letter from Julie Risk, AIA with IHR Architecture that is included in Exhibit F omits critical information such as:

- the updated description of the scope of the project to add two operating rooms;
- the timeframe for the development of the project;
- identification of additional costs and contingencies for infection control measures to renovate the existing building and enable existing clinical services to continue to operate;
- And identification of the projected capital cost that is specific to the proposed change of scope project.

Since the development of the project has been delayed, the architect's letter is unreasonable because it "rubber stamps" the same capital cost projections as submitted in Project ID #J-11631-18 without any inflation factors assigned to materials and labor costs.

Comments Regarding Criterion 18a

Developing additional ORs at DUH will not enhance competition or have a positive impact on cost effectiveness and access. Hospital-based ORs at Duke University Hospital have lower productivity

and higher costs and charges as compared to all other existing and proposed facilities. The applicant's utilization projections are not based on reasonable and adequately supported assumptions. The discussions regarding analysis of need and projected utilization found in Criterion 3 are incorporated herein by reference. Therefore, the DUH application does not conform to Criterion 18a.

Comments Regarding Duke University Hospital, Project ID # -012069-21, FID # 943138, – Develop no more than 40 acute care beds

Project ID #J-012069-21 proposes to add 40 acute care beds to the existing Duke Hospital in Durham for a total of 1,102 licensed acute care beds. However, the application is flawed because Duke chooses to continually add bed capacity at Duke University Hospital while maintaining underutilized beds in outdated semi-private patient rooms at Duke Regional Hospital which could have been modernized and replaced on the same campus long ago without CON approval.

The DUH application is non-conforming to multiple CON criteria because the DUH 40-bed application fails to demonstrate the need the population has for the proposed project.

- Patient origin projections are unreasonable due to the applicant's reliance on FY 2021 data that is skewed by the impact of the COVID-19 pandemic.
- Operational and financial projections are flawed and based on unreasonable assumptions.
- The DUH proposal to develop 40 additional acute care beds in Durham County is duplicative of previous projects including projects to add acute care beds that are pending development in Durham County and the proposed 40-bed Duke Green Level Hospital application Project ID #J-12029-21.

Comments Regarding Criterion 1

Project ID #J-012069-21 is non-conforming to Criterion 1 and Policy GEN-3. The applicant does not adequately demonstrate how its projected volumes incorporate the concept of maximum value for resources expended. The applicant does not adequately demonstrate the need to develop 40 beds. Therefore, the applicant fails to adequately demonstrate how the proposed project will maximize healthcare value for resources expended in meeting the need identified in the 2021 SMFP. The discussion regarding analysis of need, including projected utilization, found in Criterion 3 is incorporated herein by reference. Therefore, the application is not consistent with Policy GEN-3 and Criterion 1.

Comments Regarding Criterion 3

The DUH 40-bed application is non-conforming to Criterion 3 because the utilization projections are not based on reasonable and adequately supported assumptions.

Patient origin projections are unreliable because these are based on the applicant's utilization for July to December 2020 which is skewed by the COVID-19 pandemic. Duke's previously-approved CON application for Project ID #J-11426-17 authorized 90 additional acute care beds based on Duke's projected patient origin percentages as follows:

DUH Historical and Projected Patient Origin

	Percent of Total Patients	
County	**FY2017**	**FY2024-2026**
Durham	29.1%	29.1%
Wake	12.3%	12.3%
Person	3.8%	3.8%
Granville	3.7%	3.7%
Orange	3.6%	3.6%
Alamance	3.4%	3.4%
Vance	2.9%	2.9%
Cumberland	2.7%	2.7%
Robeson	1.6%	1.6%
Guilford	1.4%	1.4%
Franklin	1.3%	1.3%
Johnston	1.2%	1.2%
Harnett	1.0%	1.0%
Nash	1.0%	1.0%
Other NC Counties*	19.3%	19.3%
Virginia	6.1%	6.1%
Other States	5.4%	5.4%
Total	100.0%	100.0%

*Other NC counties includes <1% patient origin from each of the remaining counties in NC, including Caswell County.

Patient origin projections provided in Project ID #J-012069-21 (based on July to December 2020 data) report noticeably different percentages that include 28.1% patients for Durham County, 4.0% for Orange County and 16% for Other Counties. It is unreasonable for Duke to ignore the pre-COVID patient origin data (and the prior CON representations) and instead predict the future year's patient origin based on six month's 2020 data that was still being impacted by COVID-19.

The applicant's utilization projections in Section Q, Form C methodology and assumptions are flawed because the applicant fails to reasonably demonstrate that the projected shift of patients to the proposed Duke Green Level facility is included in the projections. In fact, the projected numbers of acute care admissions and days of care to be shifted from DUH to the proposed Duke Green Level facility are not included in the Section Q Form C assumptions and methodology.

The applicant's utilization projections in Section Q, Form C methodology and assumptions wrongly assume that hospital utilization will resume at pre-COVID rates even though major

changes in Medicare reimbursement have been implemented that will shift surgery utilization away from hospitals.[3]

Section Q, Form C-1 assumptions fail to provide adequate explanations for the increases in projected discharges and average length of stay in FY2021, FY 2022 and FY 2023 that inflate the total projected days of care. Most notably, Duke's current average length of stay (ALOS) forecast of 7.58 days is unreasonable because it is 15 percent higher than the ALOS of 6.61 days approved in the prior-filed CON application for Project ID #J-11426-17. Because the ALOS is the overstated multiplier for the applicant's admissions, it causes the projected patient days to also be overstated and unreasonable.

For all of these reasons, the DUH application Project ID #J-012069-21 is non-conforming to Criterion 3.

Comments Regarding Criterion 4

The DUH application to develop 40 additional acute care beds does not adequately demonstrate that the alternative proposed in its application is the most effective alternative to meet the identified need because the application is not conforming to all statutory and regulatory review criteria. An application that cannot be approved cannot be the most effective alternative. Therefore, the DUH application fails to conform to Criterion 4.

Comments Regarding Criterion 5

The operational projections used by Duke in preparation of the pro forma financial statements are not reasonable and adequately supported because the projected utilization is not based on reasonable and adequately supported assumptions. *See* discussion regarding projected utilization found in Criterion 3 above. Therefore, since projected revenues and expenses are based on projected utilization, projected revenues and expenses are not adequately supported. Thus, the application fails to conform to Criterion 5.

Staffing projections and salaries are unreasonable because the application for 40 additional beds (along with the pending addition of 102 previously-approved beds) includes no increases in the nurse manager positions. The applicant's Form H incorrectly shows no increases in the 24.6 FTE nurse manager positions even through DUH is adding a combined total of 142 licensed beds.

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[3] CY 2021 Medicare Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System Final Rule (CMS-1736-FC)
https://www.cms.gov/files/document/12220-opps-final-rule-cms-1736-fc.pdf

Comments Regarding Criterion 6

The DUH application does not adequately demonstrate that the proposed 40 additional acute care beds are needed and is non-conforming to Criterion 6. Duke has 102 previously-approved acute care beds in development in Durham County and 40 proposed acute care beds at the Duke Green Leven Hospital in Wake County. The DUH application fails to demonstrate that its project would not result in an unnecessary duplication of existing or approved services in the proposed service area that includes Durham County and adjoining counties. The applicant's utilization projections are not based on reasonable and adequately supported assumptions. The discussions regarding analysis of need and projected utilization found in Criterion 3 are incorporated herein by reference.

Comments Regarding Criterion 7

The DUH application is non-conforming to Criterion 7 because staffing projections and salaries for the inpatient care service line are unreasonable. Form H unreasonably shows no increases in the number of FTEs for the nurse manager position through June 2028, even though DUH is proposing to add a combined total of 142 licensed beds (including the 102 pending beds plus the 40 proposed additional beds).

As explained below, Form H of the DUH application unreasonably shows no incremental additions in numerous clinical positions that are necessary to support additional inpatient acute care beds.

Form H, DUH Application Project ID #J-012069-21

Form H Staffing	Current Staff			Projected Staff								
	As of 6/30/2021			1st Full FY			2nd Full FY			3rd Full FY		
Include employees, contract employees and temporary employees but not independent contractors	# of FTEs	Average Annual Salary	Total Salary *	# of FTEs	Average Annual	Total Salary *	# of FTEs	Average Annual	Total Salary *	I	Average Annual	Total Salary *
	B	C	D=B*C	E	F	G=E*F	H	I	J=H*I	K	L	M=K*L
Nurse Practitioners	3.9	$103,650	$404,759	4.3	$123,104	$527,624	4.8	$127,412	$608,354	5.4	$131,872	$711,959
Registered Nurses	1,774.80	$75,499	$133,991,381	1,947.90	$89,669	$174,664,512	2,170.00	$92,807	$201,389,643	2,453.70	$96,055	$235,687,002
Licensed Practical Nurses	3.7	$42,044	$155,778	4.1	$49,935	$203,064	4.5	$51,683	$234,135	5.1	$53,492	$274,009
Certified Nurse Aides / Nursing Assistants	457.3	$36,978	$16,908,847	501.9	$43,919	$22,041,533	559.1	$45,456	$25,414,072	632.2	$47,047	$29,742,177
Surgical Technicians	2.4	$54,825	$129,509	2.6	$65,115	$168,821	2.9	$67,394	$194,652	3.3	$69,753	$227,802
Clerical	5.6	$55,980	$315,057	6.2	$66,487	$410,692	6.9	$68,814	$473,531	7.8	$71,223	$554,175
Other (Nurse Manager)	24.6	$109,531	$2,698,677	24.6	$130,088	$3,205,181	24.6	$134,641	$3,317,363	24.6	$139,354	$3,433,470
Other (Physicians)	1	$407,000	$407,000	1.1	$483,388	$530,545	1.2	$500,307	$611,723	1.4	$517,818	$715,901
Total	2,273		$155,011,006	2,493		$201,751,973	2,774		$232,243,473	3,133		$271,346,496
* Exclusive of taxes and benefits												
State the percentage of total salary projected for taxes and benefits: Non-Exempt Employee Average Benefit Rate 23.9%; Exempt Employee Average Benefit Rate-26.9%												
Applicants may delete rows for position types not applicable to the type of facility identified in response to Section A, Question 4.												
Applicants may add rows for position types not listed.												

The staff positions omitted from the above Form H include Social Workers, Dieticians, Pharmacists, Pharmacy Technicians, Lab Technicians, Radiology Technologists, Physical Therapists, Speech Therapists, Occupational Therapists, and Respiratory Therapists. All of these

additional positions were necessary for the additional inpatient beds in the previously-approved CON application for Project ID #J-11426-17 as seen on the following page that lists the incremental additions.

Page 41 of the Agency Findings for CON application Project ID #J-11426-17 to add 96 beds demonstrates that a broad array of additional clinical staff would be required.

Durham County Acute Care Bed Review
Project ID #'s: J-11422-17 and J-11426-17
Page 41

Position	Number of Full-Time Equivalent (FTE) Positions
Physician Assistant	1.90
RN	223.33
Aides/Orderlies	0.32
Cert. Med Assistant	4.20
LPN	0.30
Nurse Practitioner	6.47
Patient Service Associate	8.34
Nursing Assistant	31.53
Social Workers	4.24
Dieticians	3.82
Pharmacists	11.61
Pharmacy Technicians	11.41
Lab Technicians	6.84
Radiology Technologists	27.48
Physical Therapists	5.59
Speech Therapists	1.04
Occupational Therapists	2.24
Respiratory Therapists	15.19
Surgery Technicians	6.48
Surgery CRNA	9.54
Surgery Anes. Tech	3.58
Central Sterile Technicians	8.43
Administrative Manager	10.99
Clerical	15.86
Patient Services	43.49
IT	0.08
Other*	35.72
	500.03

*Includes various positions from different departments
Totals may not sum due to rounding
Source: Form H in Section Q of the application

The DUH application Project ID #J-012069-21 fails to demonstrate adequate clinical staff to support the proposed expansion of 40 inpatient beds for the quaternary academic medical center.

Comments Regarding Criterion 18a

DUH already has 102 previously-approved acute care beds that are in development in Durham County plus a proposed 40 bed hospital at Duke Green Level in Wake County. The DUH proposal to add 40 beds is non-conforming to Criterion 18 because the utilization projections are not based on reasonable and adequately supported assumptions. The discussions regarding analysis of need and projected utilization found in Criterion 3 are incorporated herein by reference.

Comments Regarding UNC Hospitals-RTP (UNC-RTP), Project ID #J-012065-21, FID # 210266, - Construct a new separately licensed hospital by developing 40 acute care beds and two ORs

Project ID #J-012065-21 proposes to establish a new freestanding 40-bed hospital near the southeastern border of Durham County to steer patients and resources away from nearby existing hospitals. While the CON application claims that this proposal merely shifts patients that would otherwise utilize existing UNC Hospitals, this contention is false for several reasons:

- No health system would be willing to spend over $252 million to build a new hospital unless it would gain market share and provide substantial return on investment.
- Other than alleged geographic accessibility, the application fails to demonstrate that the proposed new hospital will offer greater depth of services, improved cost savings or any other benefit to patients.
- The applicant's contrived utilization projections and assumptions are contrary to historical data and pretend that COVID-19 has no impact by "normalizing" the current year's data for UNC facilities.

The application is non-conforming to multiple CON criteria because UNC-RTP fails to demonstrate the need the population has for the proposed project.

- Patient origin projections are unreasonable due to the absence of any data, methodology and assumptions.
- Operational and financial projections are flawed and based on unreasonable assumptions.
- The proposed new hospital would unnecessarily duplicate existing services.
- UNC-RTP's proposal to develop a new project fails to enhance competition or promote cost effectiveness.

Comments Regarding Criterion 1

Project ID #J-012065-21 is non-conforming to Criterion 1 and Policy GEN-3. The applicant does not adequately demonstrate how its projected volumes incorporate the concept of maximum value for resources expended. The applicant does not adequately demonstrate the need to develop a new hospital facility with 40 beds and 2 ORs. Therefore, the applicant fails to adequately demonstrate how the proposed project will maximize healthcare value for resources expended in meeting the need identified in the 2021 SMFP. The discussion regarding analysis of need, including projected utilization, found in Criterion 3 is incorporated herein by reference. Therefore, the application is not consistent with Policy GEN-3 and Criterion 1.

Comments Regarding Criterion 3

The UNC-RTP application is non-conforming to Criterion 3 because the utilization projections are not based on reasonable and adequately supported assumptions. The most glaring deficiencies in this proposal include unsupported patient origin projections, unreasonable utilization projections for the proposed acute care beds and operating rooms, and inadequate justification for the projections for emergency department and imaging services.

Unsupported Patient Origin Projections

Pages 38 to 41 of the application provide the UNC-RTP patient origin projections that have no assumptions and methodology. On page 38, UNC-RTP states, "As detailed in the Form C Assumptions and Methodology, Durham County residents are expected to comprise 90 percent of projected UNC Hospitals-RTP utilization and the remaining 10 percent of patients are assumed to originate from outside of the county as inmigration." However, the Form C Assumptions and Methodology provides no data or any methodology and assumptions to explain the 90 percent Durham and 10 percent inmigration projections.

The proposed hospital location in Research Triangle Park at the intersection of North Carolina Highway 54 and North Carolina Highway 147 is in southeastern Durham County. The proposed new facility is approximately 2 miles from the border with Wake County and within 3 miles of Chatham County. Based on the geographic location of the proposed facility so near the border of Wake and Chatham Counties, UNC-RTP's projection to serve 90 percent of patients from Durham County is unreliable.

For purposes of comparison, Chatham Hospital (an existing UNC hospital with 25 licensed beds and 2 ORs) is located in Siler City in the western region of the county near Randolph and Alamance Counties. The 2020 patient origin data for Chatham Hospital is approximately 71% Chatham County patients, with patients from Randolph and Alamance Counties representing more than 21 percent of total acute care admissions.[4]

Unreasonable Utilization Projections

The UNC-RTP proposal involves a new community hospital that supposedly offers geographical convenience to a speculative subset of patients. The application fails to demonstrate that the proposed new hospital will offer greater depth of services, improved cost savings or any other benefit to patients. The flaws with the proposed project include unreasonable assumptions and overstated utilization projections.

The applicant's Form C assumptions and methodology report that UNC Health's CY 2019 market share of the UNC Hospitals-RTP potential days of care in Durham County is 10.1 percent. However, this market share is being achieved by physician practices based in Orange County, not

[4] https://info.ncdhhs.gov/dhsr/mfp/pdf/por/2020/02-Facility_Acute-2020.pdf

Durham County. UNC-RTP fails to demonstrate the availability of physician practices and resources to be located and available in Durham County to support the development of the proposed project. Page 53 of the application documents that UNC Hospitals has a current deficit of 22.4 family medicine FTEs and 3.6 general surgery FTEs in Durham County. But in spite of this shortcoming, the proposed project fails to document a project specific physician recruitment plan. Without a physician recruitment plan to support the proposed new UNC-RTP hospital, the market share projections and the utilization assumptions are unsupported.

The application attempts to argue that the proposed project will serve low-acuity patients that would otherwise be served by UNC Hospitals but the application fails to quantify the expected shift in utilization. At the same time, the applicant also states that the proposed project is not expected to impact other hospitals that currently serve Durham residents. The UNC-RTP utilization projections are not based on reasonable and adequately supported assumptions because to achieve the stated utilization, Durham County residents historically receiving care in the selected services at UNC Medical Center, UNC Hillsborough and UNC Rex would have to make a wholesale "shift" to the proposed UNC-RTP facility which is an unsupported assumption.

The Form C projections for the UNC - RTP acute care beds provides the projected patient discharges, patient days, and average length of stay. These projections are unreasonable and inconsistent with the historical utilization data. On page 6 of Section Q, the applicant determines that on any given day in CY 2019, counting all Durham County residents in acute care beds in the UNC facilities in Chapel Hill, Hillsborough and Raleigh <u>combined</u>, the total number of such patients being served was only 24.4 patients. Yet, in the first year of UNC-RTP, the applicant expects that half that number, or about 12.3 patients, will choose care at UNC-RTP instead of at the UNC facilities in Chapel Hill, Hillsborough, and Raleigh. By the third year, FY27, UNC expects that 26.5 -- a number higher than the **entire** CY 2019 population of Durham County residents receiving care in the selected services in all the UNC hospitals <u>combined</u> -- will be served at UNC-RTP.

UNC-RTP assumes its utilization will be drawn exclusively from growth in acute care utilization for Durham County residents and will come only from patients that would have otherwise been served by UNC facilities in Orange and Wake Counties. There is no support for the assumption that the Durham County residents to be served by UNC-RTP will be comprised entirely of residents that would have otherwise chosen a UNC facility.

For the projected acute care bed utilization, UNC begins with the total days of care provided to Durham County residents, narrows that total by removing days associated with higher acuity services, grows the total by a growth factor, and then applies a market share assumption to determine days of care to be provided by UNC-RTP. The UNC-RTP location is expected to capture 75% of UNC's market share by the third year. To this, UNC adds a number to project those expected to use the UNC-RTP acute care beds who are residents of Counties other than Durham (*i.e.,* inmigration). However, none of these mathematical contrivances are adequately supported.

The only hospital within the UNC Health System that is similar to the proposed project is Chatham Hospital in Siler City with 25 licensed acute care beds and 2 operating rooms. According to the 2021 SMFP, Chatham Hospital had an average daily census of 6 patients with a total of 2,127 acute care days of care. According to the 2020 patient origin data, Chatham Hospital served a total of 477 acute care patients from Chatham County. In contrast, UNC Hospitals reported a total of 2,516 acute care admissions from Chatham County. Thus, of the total 3,570 acute care patients from Chatham County choosing between Chatham Hospital and UNC Hospitals, **less than 14 percent** of Chatham patients utilized their community hospital in their home county. This data demonstrates the unreasonableness of the applicant's assumption in the Section Q, Form C Utilization – Methodology and Assumptions.

The applicant's projected average lengths of stay also lack adequate support in terms of historical data for similar facilities such as Chatham Hospital or other community hospitals with 40 or fewer acute care beds. The proposed services to be offered at UNC-RTP are described as lower acuity, yet the average lengths of stay associated with the services are over 5 days for Medicine and Surgery patients and 2.7 days for obstetrics patients. Any admissions necessitating an inpatient stay in a hospital of over 5 days is likely viewed as quite serious for most patients and families. Patients with care needs associated with an inpatient hospital stay of 5 or 6 days (or 2 to 3 days for obstetrics) are patients who are more likely to choose a hospital with more comprehensive services than those offered by UNC-RTP.

Inadequate Justification for the Emergency Department and Imaging Services Projections

UNC worked off its overstated assumptions about the number of patients expected to be admitted to UNC-RTP to project Emergency Department (ED) visits for UNC-RTP. In other words, because the UNC admission assumptions are overstated, its ED visit projections, which are mathematically driven off those admission assumptions, are likewise overstated. The same is true for imaging services, all of which are projected using a ratio to acute care days. Because the acute care day projections are not based on reasonable assumptions, the imaging utilization projections are likewise questionable.

Comments Regarding Criterion 4

UNC-RTP does not adequately demonstrate that the alternative proposed in its application is the most effective alternative to meet the identified need because the application is not conforming to all statutory and regulatory review criteria. An application that cannot be approved cannot be the most effective alternative. Therefore, the application is non-conforming to Criterion 4.

Comments Regarding Criterion 5

In response to questions requiring documentation of available cash and cash equivalents, UNC supplies what appears to be a corrupted file that is unreadable. On **Page 10 of Exhibit A-1** of the UNC Hospitals at Chapel Hill Statement of Net Position for June 30. 2020, the figures cannot be deciphered and appear to contain letters combined with numbers. On page 22, under Note 2, the figures are likewise unreadable. Other figures that do appear readable are not the cash and cash equivalents figures.

The letter from CFO Will Bryant refers the reader to the "cash and cash equivalents" line item in the financial statements as the verification of available funds but that line item is not readable. The burden is on an applicant to document available funds in its application as submitted. The UNC-RTP application, as submitted, fails to adequately document the availability of funds for the proposed project. Therefore, the application is non-conforming to Criterion 5.

The assumptions used by UNC-RTP in preparation of the pro forma financial statements are not reasonable and adequately supported because projected utilization is not based on reasonable and adequately supported assumptions. *See* discussion regarding projected utilization found in Criterion 3 above. Therefore, since projected revenues and expenses are based on projected utilization, projected revenues and expenses are not adequately supported. Thus, the application fails to conform to Criterion 5.

Comments Regarding Criterion 6

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

If the North Carolina Legislature had intended to narrowly define Criterion 6 to only include health services capabilities or facilities within the SMFP defined service area or other geographic area, the language in the CON Law would specifically reflect that intent. Similar to the demonstration that is required for CON Review Criterion 20, the applicant's burden to demonstrate conformity to Criterion 6 should not be so narrowly focused as to obviate the fact that healthcare providers routinely serve patients from outside their home counties and that some providers may also have facilities in adjoining counties.

The UNC-RTP application does not adequately demonstrate that the proposed acute care beds and operating rooms are needed at the proposed hospital and is non-conforming to Criterion 6. *See* the discussion of projected utilization found in Criterion 3 above. The UNC-RTP application fails to demonstrate that its project would not result in an unnecessary duplication of existing or approved services in the proposed service area that completely overlaps with the applicant's proposed services area for previously-approved UNC projects. The UNC Healthcare System

already has 114 previously-approved acute care beds pending completion for UNC Hospitals in Orange County and 50 previously-approved acute care beds pending completion for Rex Hospital in Wake County that will serve patients from Wake and Chatham Counties that would also be served by the proposed UNC-RTP hospital. Section G of the UNC-RTP application fails to discuss the pending UNC and Rex projects in Wake and Orange Counties even though the service areas of these projects overlap with the proposed UNC-RTP hospital.

Comments Regarding Criterion 18a

UNC-RTP's proposal to develop a new community hospital in Durham County will not have a positive impact on cost effectiveness and access. The UNC Healthcare System already has 114 previously-approved acute care beds for UNC Hospitals in Orange County and 50 previously-approved acute care beds for Rex Hospital in Wake County that will draw patients from the specific zip codes that would also be served by the proposed UNC-RTP hospital.

The applicant's utilizations are not based on reasonable and adequately supported assumptions. The discussions regarding analysis of need and projected utilization found in Criterion 3 are incorporated herein by reference. Therefore, the DUH application does not conform to Criterion 18a.