



**Catharine W. Cummer**  
Regulatory Counsel, Strategic Planning

December 28, 2018

*Via Electronic Mail*

Greg Yakaboski, Project Analyst  
Healthcare Planning and Certificate of Need Section  
Division of Health Service Regulation  
North Carolina Department of Health and Human Services  
809 Ruggles Drive  
Raleigh, North Carolina 27603

RE: Comments on Orange County Operating Room CON Applications

Dear Mr. Yakaboski:

On November 15, 2018, Duke University Health System (DUHS) submitted a CON application (CON Project ID# J-11632-18) to develop a new ambulatory surgery center (ASC) in response to the need determination in the *2018 State Medical Facilities Plan (SMFP)* for six (6) new operating rooms (ORs) in Orange County.

Enclosed please find comments prepared by DUHS regarding the competing CON applications to develop the need determined ORs in Orange County. We trust that you will take these comments into consideration during your review of all the applications.

If you have any questions about the information presented here, please feel free to contact me at (919) 668-0857. I look forward to seeing you at the public hearing.

Sincerely,

*Catharine W. Cummer*

Catharine W. Cummer

## COMMENTS ABOUT COMPETING CERTIFICATE OF NEED APPLICATIONS ORANGE COUNTY OPERATING ROOMS

**Submitted by Duke University Health System  
December 31, 2018**

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Two providers submitted four Certificate of Need (CON) applications in response to the need identified in the *2018 State Medical Facilities Plan (SMFP)* for six new operating rooms (ORs) in Orange County. DUHS submitted CON Project ID# J-11632-18. UNC submitted three CON applications in this batch review: CON Project ID# J-11644-18 University of North Carolina Hospitals, CON Project ID# J-11645-18 North Chapel Hill Surgery Center (NCHSC), and CON Project ID# J-11646-18 University of North Carolina Hospitals-Hillsborough.

In accordance with N.C. Gen. Stat. § 131E-185(a.1)(1), this document includes comments relating to the representations made by the competing applications, and a discussion about whether the material in the respective applications complies with the relevant review criteria, plans, and standards. These comments also address the determination of which of the competing proposals represents the comparatively most effective alternative for development of new ORs in the Orange County service area.

Specifically, the Healthcare Planning and Certificate of Need Section, in making the decision, should consider several key issues, including the extent to which each proposed project:

- (1) Enhances market competition for surgical services with a new provider of multi-specialty surgery in Orange County;
- (2) Provides local patients with a non-hospital facility option for multi-specialty outpatient surgery in Orange County;
- (3) Maximizes healthcare value in the delivery of health care services for development of the need-determined ORs, with competitive charges and costs;
- (4) Provides greatest ASC access to lower cost, multi-specialty ORs for medically underserved patients;
- (5) Demonstrates that projected surgical utilization is based on reasonable and adequately supported assumptions; and
- (6) Demonstrates conformity with applicable review criteria and standards.

The Agency typically performs a comparative analysis when evaluating all applications in a competitive batch review. The purpose of the comparative analysis is to identify the proposal(s) that would bring the greatest overall benefit to the community. The table below summarizes comparative metrics that the Agency should use for comparing the four applications in this OR batch review.

**Orange County OR Batch Review  
 Applicant Comparative Analysis**

	<b>Duke Health Orange ASC</b>	<b>North Chapel Hill Surgery Center</b>	<b>UNC Hospitals</b>	<b>UNC Hospitals-Hillsborough</b>
Conformity with Rules & Criteria	Yes	No	Yes	Yes
Geographic Accessibility	Equally Effective	Not approvable	Equally Effective	Equally Effective
Physician Support	Equally Effective			
Patient Access to Alternative Providers	<b>Most effective</b>	Not approvable	Least Effective	Least Effective
Patient Access to Low Cost Outpatient Surgical Services	<b>Most effective</b>	Not approvable	Least Effective	Least Effective
Patient Access to Surgical Specialties	Effective	Not approvable	Most effective	Most effective
Access by Medically Underserved Groups	Effective	Not approvable	Most effective	Most effective
Projected Average Gross/Net Revenue per Case	<b>Most effective</b>	Not approvable	Least Effective	Least Effective
Projected Average Operating Expense per Case	<b>Most effective</b>	Not approvable	Least Effective	Least Effective

Based on this comparative analysis, which shows Duke Health Orange ASC ranks most favorably on the comparative metrics, and considering that the Duke Health Orange ASC application conforms to the Review Criteria and best achieves the Basic Principles of the 2018 SMFP (Policy GEN-3), Duke Health Orange ASC is the most effective alternative for development of new operating rooms in Orange County.

## Comparative Analysis

### Conformity with Review Criteria

Without establishing conformity with all applicable statutory and regulatory review criteria, an application cannot be approved. For the reasons discussed later in this document, NCHSC is non-conforming with Criteria 1, 3, 4, 5, 6, 13c & 18a.

### Geographic Accessibility

NCHSC and Duke Health Orange ASC each propose to develop a two-OR ASC in Chapel Hill, while UNC Hospitals proposes to develop two additional ORs at each of its hospital facilities in Chapel Hill and in Hillsborough. Chapel Hill and Hillsborough are already host to existing ORs, therefore, the applications are equally effective with respect to geographic access.

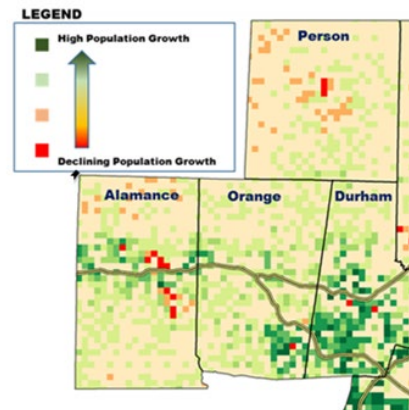
Orange County’s population is heavily concentrated in the southeastern portion of the county, with most county residents (68%) living in Chapel Hill. The southeastern portion is also projected to experience the most rapid population growth.

**Orange County Population by Town (2017)**

Town	Population (2017)
Chapel Hill	101,691
Hillsborough	26,828
Carrboro	14,614
Efland	4,286
Cedar Grove	2,103
<b>Grand Total</b>	<b>149,522</b>

Source: Truven

**Population Growth Heat Map (2017-22)**



Based on population distribution and growth, the proposed Duke Health site is an optimal location for patient from Orange and nearby communities in terms of geographic access.

The proposed project will create a new point of access to DUHS surgical services for patients in a populous and growing area of Orange County. Duke Health Orange ASC will be developed at 201 Sage Road in Chapel Hill. This location is in the southeastern portion of Orange County. Additionally, the facility is located less than half a mile from the interchange at NC 501 and Interstate 40. Therefore, the proposed new ASC will offer convenient access for patients from throughout Orange County as well as surrounding communities.

## **Physician Support**

Each application documents adequate physician support of the proposed projects. Therefore, with regard to the demonstration of physician support, the proposals are equally effective. However, the NCHSC proposal cannot be approved because it does not conform to applicable Review Criteria and administrative rules.

## **Enhances Competition/Patient Access to New Provider**

Aside from Conformity with Review Criteria, this is the most important comparative factor in this batch review. The need determination for six additional operating rooms in the service area represents a rare opportunity to establish a new licensed healthcare facility. Orange County is the 20<sup>th</sup> most populous county in North Carolina, yet has no non-hospital licensed operating rooms. Further, UNC Health Care controls 100% of the OR inventory in Orange County, providing surgical services at the following facilities in Orange County:

- UNC Hospitals
- UNC Hospitals-Hillsborough

In this OR batch review, the two UNC hospital applications are simply proposing to add new ORs at existing facilities, so they represent no fundamental change to the local service area offerings.

As documented on page 10 of NCHSC's CON application, NCHSC is a joint venture between UNC Hospitals and Rex Hospital, Inc., the ultimate parent company of each being the University of North Carolina Health Care System (Applicant 2). This merely creates a new corporate entity within UNC Healthcare, not a new provider in the service area. Thus, the member, parent company, and co-applicant currently provides surgical services in Orange County. Therefore, the NCHSC project will not introduce a new entrant into the healthcare licensed facility marketplace in Orange County, and will not enhance competition in Orange County.

By contrast, the Duke Health Orange ASC project will enhance competition via 1) creation of a new licensed ASC facility within Orange County and 2) a new provider of surgical services in Orange County. Local competition is healthy for providers, as it spurs continuous quality improvement, and serves as motivation for seeking maximum cost effectiveness. Local residents will have access to an alternative surgical provider conveniently located in a freestanding ASC in Orange County. This facility will enable DUHS to better meet the needs of the Orange County patient population by enabling timely provision of and convenient local access to cost-effective, high quality outpatient surgical services.

In summary, approval of only UNC Health Care applications in this review would preclude the opportunity to increase competition and expand local access to care with a new licensed ASC facility. The Duke Health Orange ASC is the most effective alternative with respect to the significant matter of providing access to an alternative provider in Orange County.

### **Patient Access to Lower Cost Outpatient Surgical Specialties**

The Orange County OR service area currently has 46 existing and approved ORs (3 inpatient + 3 dedicated C-section + 34 shared + 6 ambulatory = 46). Operating rooms can be licensed either under a hospital license or as a licensed ASC (non-hospital license). Many, but not all, outpatient surgical services can be performed in a hospital licensed operating room or in a non-hospital licensed operating room (ASC); however, the cost for that same service is typically lower when received in a non-hospital licensed operating room.

ASCs typically offer valuable surgical and procedural services at a lower cost when compared to hospital charges for the same outpatient services. Medicare payments to ASCs are lower than or equal to Medicare payments to hospital outpatient departments (HOPD) for comparable services for 100 percent of procedures.

In this review, UNC Hospitals propose to add two ORs at its two existing hospitals: UNC Hospitals and UNC Hospitals-Hillsborough. Duke Health Orange ASC and NCHSC each propose to develop a new freestanding ASC. Therefore, as to patient access to lower cost outpatient surgical services, Duke Health Orange ASC and NCHSC are equally effective alternatives; however, NCHSC does not conform to all statutory review criteria and cannot be approved.

### **Patient Access to Multiple Surgical Specialties**

UNC Hospitals and UNC Hospitals-Hillsborough each provide access to a wide array of surgical specialties.

DUHS's proposed Duke Health Orange ASC will be a multi-specialty surgical facility providing general surgery, ophthalmology, orthopaedic, otolaryngology, neurology, and plastic surgery (**six specialties**).

NCHSC proposes a multi-specialty surgical facility providing orthopaedic, otolaryngology, urologic surgery, general surgery, surgical oncology, and plastic surgery (**six specialties**).

Therefore, with regard to providing Orange County patients with access to multiple surgical specialties, UNC Hospitals and UNC Hospitals-Hillsborough are the most effective alternatives, while Duke Health Orange ASC and NCHSC are equally effective ASC alternatives. However, NCHSC does not conform to all statutory review criteria and cannot be approved.

**Access by Medically Underserved Groups**

The following table shows each applicant’s projected OR cases to be provided to Self-Pay/Indigent/Charity Care, Medicare and Medicaid recipients in the second project year. Generally, the application proposing to serve the higher numbers of Self-Pay/Charity Care, Medicare and Medicaid patients is the more effective alternative with regard to this comparative factor.

**Projected OR Payor Mix**

<b>Payor Type</b>	<b>Duke Health Orange ASC</b>	<b>NCHSC</b>	<b>UNC Hospitals</b>	<b>UNC Hospitals Hillsborough</b>
Self-Pay/Charity/Indigent	1.1%	6.9%	7.9%	11.0%
Medicare	41.5%	11.3%	25.8%	29.8%
Medicaid	4.2%	25.8%	23.0%	9.9%
<b>Total</b>	<b>46.8%</b>	<b>44.0%</b>	<b>56.7%</b>	<b>50.7%</b>

As shown in the tables above, of the two proposed freestanding ASCs, Duke Health Orange ASC projects the highest percentage of cases to be provided to Charity Care, Medicare and Medicaid combined patients. Therefore, the application submitted by Duke Health Orange ASC is the more effective ASC alternative with regard to access by medically underserved groups.

**Maximize Healthcare Value**

*Average Charges, Reimbursement and Cost per Case*

An essential issue to consider when evaluating the competing applications is the extent to which each proposed project represents a cost-effective alternative for provision of surgical services. In the current healthcare marketplace, where cost of care is a major concern with payors and

consumers, the projected average charges, average reimbursement and average cost per surgical case are all important measures of healthcare value. In this OR batch review, Duke Health Orange ASC projects competitive charges and costs, with the lowest gross charges, the second lowest average reimbursement per surgical case, and the second lowest average costs of the competing proposals. Please see the following tables which compare the charge and cost data for the third project year.

**Projected Average Charge per Surgical Case**

<b>Project Year</b>	<b>Duke Health Orange ASC</b>	<b>NCHSC</b>	<b>UNC Hospitals</b>	<b>UNC Hospitals Hillsborough</b>
<b>3</b>	\$8,110	\$10,153	\$22,096	\$31,221

Source: CON Applications

**Projected Average Reimbursement per Surgical Case**

<b>Project Year</b>	<b>Duke Health Orange ASC</b>	<b>NCHSC</b>	<b>UNC Hospitals</b>	<b>UNC Hospitals Hillsborough</b>
<b>3</b>	\$3,425	\$3,054	\$9,187	\$12,562

Source: CON Applications

**Projected Average Cost per Case**

<b>Project Year</b>	<b>Duke Health Orange ASC</b>	<b>NCHSC</b>	<b>UNC Hospitals</b>	<b>UNC Hospitals Hillsborough</b>
<b>3</b>	\$3,388	\$2,796	\$6,775	\$9,633

Source: CON Applications

As has been pointed out, the two UNC Hospitals are existing facilities, so approval of those two applications to expand hospital OR capacity is less effective in furthering the objective of expanding access to cost-effective surgical care. Additionally, the hospital charges are significantly higher compared to the proposed ASCs. Duke Health Orange ASC is a more cost-effective alternative for Orange County residents in need of local surgical services.



**Comments regarding North Chapel Hill Surgery Center, LLC  
 CON Project I.D. #J-11645-18**

**General Comments**

NCHSC states on page 42 of its CON application it “*believes that both hospital-based and freestanding (ASC) operating rooms should be approved in this review.*” **Currently, there is a monopoly of ORs in Orange County, with UNC Health Care controlling 100% of the OR inventory.** Thus, the need determination in the 2018 SMFP for six new ORs provides an optimal opportunity to expand patient choice in the Orange County service area. As described previously, NCHSC is a joint venture between UNC Hospitals and Rex Hospital, Inc., the ultimate parent company of each being University of North Carolina Health Care System (Applicant 2). Thus, the member, parent company, and co-applicant currently provide surgical services in Orange County. Therefore, the NCHSC project will not enhance competition in Orange County.

It is striking to note that over 60% of all Orange County residents leave Orange County for ambulatory surgery. During FY2017, more Orange County residents received their ambulatory surgery in Durham County than any other county (50.3%). Of the 3,100 Orange County residents travelling to Durham County, the vast majority (86.6%) are utilizing DUHS surgical services.

**Ambulatory Surgery Patients from Orange County, FY2017**

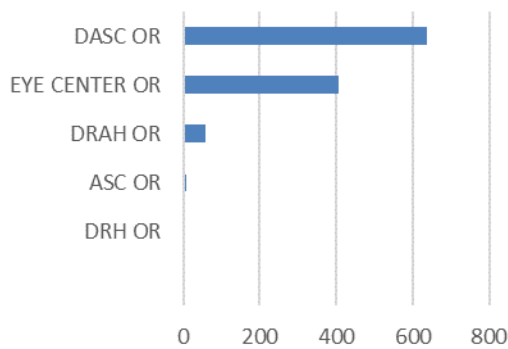
Service Location	Number of Patients	% of Total
Duke University Hospital	1,426	46.0%
Duke Regional Hospital	249	8.0%
Davis Ambulatory Surgery Center	1,010	32.6%
NC Specialty Hospital	415	13.4%
<b>Total</b>	<b>3,100</b>	<b>100.0%</b>

Source: Healthcare Planning & Certificate of Need Section Patient Origin Report, FY2017 data; Patient origin obtained from 2018 License Renewal Applications

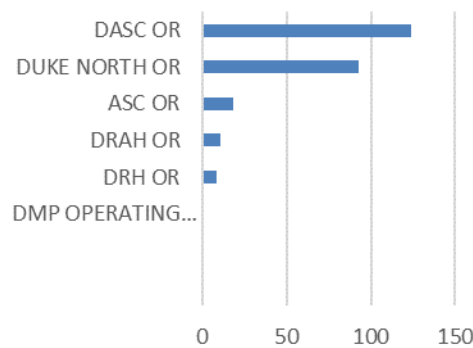
Additionally, of the 357 Orange County residents travelling to Wake County for ambulatory surgery, more than one-third utilize Duke Raleigh Hospital (131 ÷ 357 = 36.7%).

It is obvious by reviewing the historical patient origin, that Orange County residents are familiar with and utilize DUHS surgical services. Many Orange County residents are, in fact, already seeking lower acuity surgery at DUHS facilities. For example, according to internal data for ambulatory surgery across all DUHS surgical sites, approximately nine percent of DUHS’s lower acuity ophthalmology surgeries and seven percent of ENT surgeries are performed on Orange County residents. The majority of these lower acuity patients are served at DASC, DUHS’s freestanding ASC.

**Lower acuity Ophthalmology Surgery by Location – Orange Co. Patients, FY17; ASA Classifications 1-3**



**Lower acuity Otolaryngology, Head, and Neck Surgery by Location – Orange Co. Patients, FY2017**



In addition to this data specific to ambulatory surgery, there is additional evidence that Orange County residents utilize DUHS for healthcare services. DUHS analyzed its FY2018 internal data (Epic) to identify the number of lives touched by any Duke Health specialty/service. During FY2018, 40,363 Orange County residents received some form of healthcare from Duke Health, or approximately 28 percent of the total Orange County population (40,363 Orange County lives touched by Duke Health ÷ 143,873 Orange County population).

The proposed DUHS Orange ASC project will represent a new opportunity for Orange County residents and DUHS patients to access ambulatory surgical services within Orange County at a new ASC and with a trusted surgery provider. The proposed project will also expand DUHS's geographic footprint, providing local residents with more convenient access to care, expanding DUHS surgical capacity, and enabling more efficient utilization and access of system resources.

For these reasons and the reasons previously described in this document, the NCHSC application is comparatively inferior to the Duke Health Orange ASC application.

### **Comments specific to Criterion 1**

NCHSC does not adequately demonstrate that the projected utilization is based on reasonable and adequately supported assumptions. See discussion regarding Criterion 3. Therefore, NCHSC does not adequately demonstrate its proposal would maximize healthcare value. Consequently, the application is not consistent with Policy GEN-3 and is not conforming to Criterion 1.

### **Comments specific to Criterion 3 and Rules**

NCHSC failed to demonstrate that its projected surgical utilization is based on reasonable and supported assumptions. Specifically, NCHSC failed to provide any information or assumptions regarding the projected number of outpatient surgical cases it projects to shift from UNC Hospitals Main Campus. Page 5 of Form C Methodology and Assumptions states, "*North Chapel Hill Surgery Center estimates that 1,675 operating room cases would be appropriate for its proposed facility.*" No further information is provided regarding the number of cases anticipated for NCHSC. In other words, the applicant failed to describe any of the criteria it used to identify the operating room cases that would be appropriate for its proposed facility. This is critical information needed to evaluate the reasonableness of NCHSC's assumptions. Absent this essential information, NCHSC does not demonstrate its projected surgical utilization is based on reasonable and supported assumptions. Consequently, the NCHSC application does not conform to Criterion (3).

DUHS acknowledges it may be appropriate to shift ASC-appropriate cases from a hospital-based setting to a freestanding ASC. In fact, DUHS projects a shift of ASC-appropriate cases from its hospital-based facilities to its approved Arrington ASC (CON Project ID #J-11508-18) and proposed Green Level ASC (CON Project ID #J-11557-18). However, unlike NCHSC, DUHS provided a detailed description of the assumptions it utilized to identify ASC-appropriate cases that could shift from its hospital-based facilities to the approved Arrington ASC and proposed Green Level ASC, including ASA levels, proposed physician clinic locations, and physician input, for example. In

fact, the Agency considered DUHS's specific assumptions and criteria used to identify ASC-appropriate cases in its analysis and subsequent decision of conformity to Criterion (3) for Arrington ASC. (Green Level ASC is still under review as of December 31, 2018.) The applicant owns the burden to demonstrate the reasonableness of its assumptions and methodology, and NCHSC does not meet that obligation. Consequently, the NCHSC application does not conform to Criterion 3 and 10A NCAC 14C .2103(a) because projected surgical utilization is not based on reasonable and adequately supported assumptions.

#### **Comments specific to Criterion 4**

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

#### **Comments specific to Criterion 5**

NCHSC does not adequately demonstrate that projected utilization is based on reasonable and adequately supported assumptions. See discussion regarding Criterion 3. Therefore, NCHSC does not adequately demonstrate its proposal is based upon reasonable projections of the costs of and charges for providing health services. Consequently, the application is not conforming to Criterion 5.

#### **Comments specific to Criterion 6**

NCHSC did not adequately demonstrate that its proposal would not result in unnecessary duplication of surgical services in Orange County. Specifically, NCHSC did not adequately demonstrate in its application that the new ORs it proposes to develop are needed, and that it will not unnecessarily duplicate the ORs that UNC Health Care already owns in Orange County and that demonstrate a surplus of capacity. See discussion regarding projected utilization in Criterion 3. Therefore, the NCHSC application is non-conforming to Review Criterion 6.

#### **Comments specific to Criterion 13c**

The NCHSC payor mix projection is not reasonable. As stated in Section L.3 of its application, NCHSC *“assumes that its proposed payor mix for operating rooms and procedure rooms will reflect the historical payor mix of UNC Hospitals Main Campus”* for the “selected patients” who could be served at the new facility. However, NCHSC

did not identify the selection criteria for these patients (see discussion above regarding Criterion 3), nor the existing payor mix for this unidentified group. Therefore NCHSC did not reasonably identify the medically underserved groups and the extent to which such patients will utilize the proposed service, and is non-conforming to Review Criterion 13c.

### **Comments specific to Criterion 18a**

For the same reasons that the NCHSC application is non-conforming with Review Criteria 3, 4, 5, 6, and 13c, it should also be found non-conforming with Criterion 18a. In simply adding to an existing surplus within the UNC Health Care system, this project would not enhance competition and the project will not have a positive impact on the cost effectiveness, quality and access to the proposed services. UNC Health Care did not adequately demonstrate the financial feasibility of the proposal and did not reasonably identify the need the population has for the proposed service.

### **Comments regarding the UNC Hospitals application/CON Project I.D. #J-11555-18 and UNC Hospitals – Hillsborough Campus /CON Project I.D. #J-11646-18**

#### **General Comments**

UNC states in both its hospital CON applications it “*believes that both hospital-based and freestanding (ASC) operating rooms should be approved in this review.*” **Currently, there is a monopoly of ORs in Orange County with UNC Health Care controlling 100% of the OR inventory.** Thus, the need determination in the 2018 SMFP for six new ORs provides an optimal opportunity to enhance competition in Orange County. Both UNC Hospitals facilities currently provide surgical services in Orange County. Therefore, the proposed UNC Hospitals-Main Campus project and the proposed UNC Hospitals-Hillsborough project will not enhance competition in Orange County.

For these reasons and the reasons previously described in this document, the UNC Hospitals-Main Campus and the UNC Hospitals-Hillsborough applications are comparatively inferior to the Duke Health Orange ASC application. Approval of these UNC applications would result in a missed opportunity to increase competition and expand local access to care with a new licensed facility from a new county provider.

## **CONCLUSION**

For the foregoing reasons, the competing NCHSC application should be disapproved. It fails to satisfy multiple CON criteria and is also comparatively inferior to the Duke Health Orange ASC application. The two UNC Hospitals applications to add ORs are less effective alternatives than Duke Health Orange ASC. The Duke Health Orange ASC application should be approved because it satisfies all the applicable CON criteria and is comparatively superior to the competing applications.