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May 30, 2019

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 April 15, 2019, Duke University Health System (DUHS) submitted a CON application (CON Project ID# J-11692-19) to develop a new ambulatory surgery center (ASC) in response to the need determination in the *2019 State Medical Facilities Plan (SMFP)* for three (3) new operating rooms (ORs) in Orange County.

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

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COMMENTS ABOUT COMPETING CERTIFICATE OF NEED APPLICATION ORANGE COUNTY OPERATING ROOMS

Submitted by Duke University Health System
May 31, 2019

DUHS submits the following comments regarding the competing Certificate of Need (CON) application for the 2019 Orange County OR batch review.

Two providers submitted CON applications in response to the need identified in the *2019 State Medical Facilities Plan (SMFP)* for three new operating rooms (ORs) in Orange County. DUHS submitted CON Project ID# J-11692-19 and University of North Carolina Hospitals (UNC) submitted CON Project ID# J-11695-19.

In accordance with N.C. Gen. Stat. § 131E-185(a.1)(1), this document includes comments relating to the representations made by the competing application, and a discussion about whether the material in the application 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 competition for surgical services with a new provider of multi-specialty surgery in Orange County;
- (2) Enhances access to surgical services for residents of Orange County;
- (3) Provides local patients with a non-hospital facility option for multi-specialty outpatient surgery in Orange County;
- (4) Maximizes healthcare value in the delivery of health care services for development of the need-determined ORs, with competitive charges and costs;
- (5) Provides greatest ASC access to lower cost, multi-specialty ORs for medically underserved patients;
- (6) Demonstrates that projected surgical utilization is based on reasonable and adequately supported assumptions; and
- (7) 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 two applications in this OR batch review.

**2019 Orange County OR Batch Review
 Applicant Comparative Analysis**

	Duke Health Orange ASC	UNC Hospitals
Conformity with Review Criteria	Yes	No
Geographic Accessibility	Equally Effective	
Physician Support	Equally Effective	
Competition	Most effective	Least Effective
Patient Access to Lower Cost Surgical Services	Most effective	Least Effective
Access by Underserved Groups	Inconclusive Comparison	
Projected Average Net Revenue per Case	Inconclusive Comparison	
Projected Average Operating Expense per Case	Inconclusive Comparison	

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 2019 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

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

However, the application process is not limited to the provider (or providers) that show a deficit and create the need for additional ORs. Any provider can apply to develop the three ORs in Orange County. However, it is necessary that an applicant adequately demonstrate the need to develop its project as proposed.

For the reasons discussed later in this document, UNC is non-conforming with Criteria 1, 3, 4, 5, 6, & 18a. Therefore, the UNC application is a less effective alternative with respect to this comparative factor.

Geographic Accessibility

Duke Health Orange ASC proposes to develop a two-OR ASC in Chapel Hill and UNC Hospitals proposes to develop three additional ORs at its main hospital facility in Chapel Hill. Therefore, the applications are equally effective with respect to geographic access.

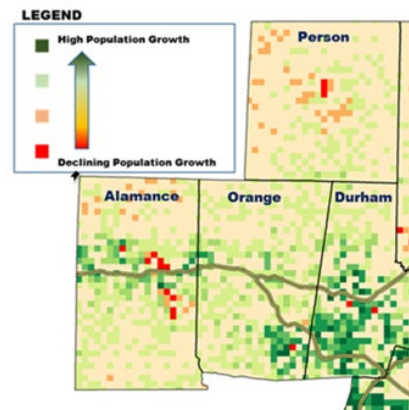
Orange County’s population is heavily concentrated in the southeastern portion of the county, with most county residents (68%) living in Chapel Hill. The southeastern portion is also projected to experience the most rapid population growth.

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
Grand Total	149,522

Source: Truven

Population Growth Heat Map (2017-22)



Source: Truven

Based on population distribution and growth, the proposed Duke Health site is an optimal location for patients 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 66 Vilcom Center Drive 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 86 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, regarding the demonstration of physician support, the proposals are equally effective. However, the UNC 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 three additional operating rooms in the service area represents a rare opportunity to establish a new licensed healthcare facility. Orange County is the 20th most populous county in North Carolina, yet has no non-hospital licensed operating rooms. Further, there is only one existing health service facility located in Orange County with ORs and that is UNC Hospitals. 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, UNC is simply proposing to add new ORs at its existing Chapel Hill facility, so it represents no fundamental change to the local service area offerings.

By contrast, DUHS does not own or operate any existing surgical facilities in Orange County. The Duke Health Orange ASC project will enhance competition via 1) creation of a new licensed ASC facility within Orange County and 2) serving as a new provider of surgical services within Orange County. Local residents will have access to an alternative surgical provider conveniently located in a freestanding ASC in Orange

County. This proposed 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.

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

Patient Access to Lower Cost Surgical Services

The Orange County OR service area currently has 41 ORs, and all are hospital-based. 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 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 proposes to add three ORs at its existing hospital in Chapel Hill (UNC-Main Campus). Duke Health Orange ASC proposes to develop a new freestanding ASC. Therefore, as to patient access to lower cost outpatient surgical services, Duke Health Orange ASC is the more effective alternative.

Access by 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.

Projected OR Payor Mix

Payor Type	Duke Health Orange ASC	UNC
Self-Pay/Charity/ Indigent	1.1%	7.9%
Medicare	41.5%	25.8%
Medicaid	4.2%	23.0%
Total	46.8%	56.7%

Both providers project substantive access to services for medically underserved groups, including self-pay/indigent/charity care, Medicare, and Medicaid patients. However, due to differences in the types of facilities (ASC and Academic Medical Center Teaching Hospital) and the number and types of surgical services proposed by each applicant, there is little value in comparing the numbers in the table above for determining which application to approve in this review. Thus, the result of this analysis is inconclusive.

Projected Average Net Revenue & Average Operating Expense per Case

The following table shows the projected average net surgical revenue per OR and per surgical case in the third fiscal year.

Projected Average Net Charge per Surgical Case

Project Year	Duke Health Orange ASC	UNC
3	\$3,297	\$10,039

Source: CON Applications

Projected Average Cost per Case

Project Year	Duke Health Orange ASC	UNC
3	\$3,393	\$7,552

Source: CON Applications

As shown in the two tables, Duke Health Orange ASC projects both the lowest average net charge per surgical case, and the lowest average cost per case. However, due to differences in the types of facilities (ASC and Academic Medical Center Teaching Hospital) and the number and types of surgical services proposed by each applicant, there is little value in comparing the numbers in the tables above for determining which applications to approve in this review. Thus, the result of this analysis is inconclusive.

Comments regarding the UNC Hospitals application/CON Project I.D. #J-11695-19

General Comments

UNC gratuitously and incorrectly states multiple times throughout its application (p. 30; Form C, page 1) that Chapter 6 of the 2019 SMFP, Table 6B assumes that UNC Hospitals is awarded all six operating rooms from the 2018 OR batch review. Table 6B of the 2019 SMFP makes no such assumption. Rather, per Step 6 of the Methodology for Projecting OR Need, Column L reflects the Adjusted Planning Inventory of ORs in each county. Specific to Orange County, Column L reflects 1) the adjusted planning inventory of ORs for UNC and 2) the 2018 need determination for six (6) additional ORs in Orange County. Column M subtracts the 2018 SMFP need determination (i.e., 6) from UNC's projected OR deficit. UNC is the ONLY provider of surgical services in Orange County; thus, the 2018 SMFP need determination (i.e., 6) is subtracted from UNC's adjusted planning inventory to determine a need for 3 additional ORs in Orange County in the 2019 SMFP. In other words, there was no other provider from which to subtract the 2018 SMFP need determination. The 2018 Orange County batch review was still under review at the time the 2019 SMFP was finalized, thus, there were no assumptions made regarding the Orange County competing applications in Table 6B of the 2019 SMFP.

For comparison purposes, the 2018 SMFP need determination for six (6) ORs in Wake County is subtracted from the total deficit of ORs generated by both UNC and DUHS, i.e. $\text{UNC Health Care Total OR Deficit } 1.78 + \text{Duke Raleigh Hospital OR Deficit } 6.56 = 8.34 \text{ Total OR Deficit} - 2019 \text{ SMFP Need determination } 6 = 2.34$ (See also Table 6B, "Wake Total"). The 2018 Wake County batch review was still under review at the time the 2019 SMFP was finalized, thus, there were no assumptions made regarding the Wake County competing applications in Table 6B of the 2019 SMFP.

The proposed Duke Health Orange ASC project will represent a new opportunity for Orange County residents to access ambulatory surgical services within Orange County at a new ASC and with a trusted surgery provider. The proposed project will provide residents with more convenient access to care, in a lower cost freestanding facility.

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

Comments specific to Criterion 1

UNC does not adequately demonstrate that the projected utilization is based on reasonable and adequately supported assumptions. See discussion regarding Criterion 3. Therefore, UNC 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

UNC failed to demonstrate that its projected surgical utilization is based on reasonable and supported assumptions. UNC relies on unreasonable growth rates that are not supported by recent historical utilization. Specifically,

- UNC’s annualized inpatient and outpatient surgical utilization during SFY2019 (based on July 2018 through January 2019 data and adjusted for seasonal utilization) is projected to be much lower compared to that which UNC previously projected for SFY2019 in its 2018 Orange County CON application (CON Project I.D. #J-11644-18). In CON Project I.D. #J-11644-18 (submitted just 5 months prior to its current CON Project I.D. #J-11695-19 application), UNC projected total inpatient cases to increase 3.1 percent annually through SFY24 and total outpatient cases to increase 4.4 percent annually through SFY24. The following table compares UNC’s projected SFY19 inpatient and outpatient cases in CON Project I.D. #J-11644-18 and annualized SFY19 inpatient and outpatient cases CON Project I.D. #J-11695-19 application.

Projected UNC Health Care Operating Room Cases Prior to Any Shifts

	2018 Batch Review (November 18)	2019 Batch Review (April 19)	Difference Between Projected and Actual/Annualized
	SFY19	SFY19	
Total Inpatient Cases SFY19	14,645	14,223	-2.9%
Total Outpatient Cases SFY19	17,905	17,049	-4.8%

Source: CON Project I.D. #J-11644-18 (Form C, page 3) and CON Project I.D. #J-11695-19 (Form C Methodology and Assumptions, page 2)

UNC therefore significantly overestimated its projected SFY19 inpatient and outpatient surgical cases in CON Project I.D. #J-11644-18. Based on actual data, UNC’s SFY inpatient and outpatient cases are projected to be much lower than the expected growth of 3.1 percent and 4.4 percent, respectively. DUHS acknowledges that UNC is entitled to update its SFY19 inpatient and outpatient case volume in the current CON Project I.D. #J-11695-19 application under review. Indeed, DUHS agrees that it is appropriate to utilize the most recent data available. However, upon review of the most recent data available, it is apparent that UNC perpetuates its practice of utilizing unreasonable growth rates for projecting surgical cases in its 2019 Orange County OR application.

UNC provides the following table in Section Q, Form C Methodology and Assumptions, page 2 summarizing its historical inpatient and outpatient OR cases.

UNC Hospitals Historical Operating Room Cases

	SFY16	SFY17	SFY18	SFY19	3-YR CAGR
UNC Hospitals Main Campus Inpatient Cases	12,513	12,796	12,974	12,831	0.8%
UNC Hospitals Main Campus Outpatient Cases	13,949	13,582	14,197	13,805	-0.3%
UNC Hospitals Hillsborough Campus Inpatient Cases	842	1,150	1,228	1,393	18.3%
UNC Hospitals Hillsborough Campus Outpatient Cases	1,797	2,361	2,957	3,244	21.8%
Total Inpatient Cases	13,355	13,946	14,202	14,223	2.1%
Total Outpatient Cases	15,746	15,943	17,154	17,049	2.7%

Source: CON Project I.D. #J-11695-19 (Form C Methodology and Assumptions, page 2)

As described previously, SFY19 inpatient and outpatient OR cases are much lower than initially projected in CON Project I.D. #J-11644-18. As a result, the SFY16-SFY19 compound annual growth rates (CAGR) for inpatient and outpatient OR cases are also much lower compared to the respective SFY16-SFY18 CAGRs. In fact, the most recent 3-year CAGR, 2-year CAGR, and one-year annual change are rapidly declining for inpatient OR cases (see following table).

UNC Hospitals Historical Operating Room Cases

	SFY16	SFY17	SFY18	SFY19	3-YR CAGR	2-YR CAGR	1-YR Change
Total Inpatient Cases	13,355	13,946	14,202	14,223	2.1%	1.0%	0.1%

Source: CON Project I.D. #J-11695-19 (Form C Methodology and Assumptions, page 2)

As observed by the declining growth of the most recent 3-year CAGR, 2-year CAGR, and one-year annual change, an annual inpatient OR case growth rate of 2.1 percent through SFY26 is doubtful. However, UNC does not project inpatient OR cases to increase annually by 2.1 percent. UNC projects inpatient OR cases to increase by 3.4 percent annually.

UNC contrives a historical 3-year CAGR of 3.4 percent for inpatient OR cases by adding hundreds of speculative OR cases utilized in the methodology of its Wake County OR CON application (which was denied). Specifically, in CON Project I.D. #J-11555-18, UNC projected to shift 1,050 inpatient surgical cases to UNC Rex Hospital by SFY2021. UNC assumed that this shift would ramp up over three years from 50 to 75 to 100 percent and that it would remain constant in future years, as shown in the following table.

Shift of Cases from UNC Hospital to UNC Rex Hospital

	SFY19	SFY20	SFY21	SFY22	SFY23	SFY24
Ramp Up Percentage	50%	75%	100%	100%	100%	100%
Inpatient Cases Shifted to UNC Rex Hospital	525	788	1,050	1,050	1,050	1,050

Source: CON Project I.D. #J-11695-19 (Form C Methodology and Assumptions, page 4)

As described on page 4 of Form C Methodology and Assumptions (CON Project I.D. #J-11695-19), “UNC Health Care added the 525 operating room cases expected to be shifted to UNC Rex over the course of the entirety of SFY 2019 to UNC Hospitals’ annualized SFY 2019 operating room utilization to determine what the historical growth rate would be without the shift to UNC Rex Hospital.” While UNC represents that this shift is undertaken as part of an ongoing effort to redirect utilization to UNC Rex, it does not provide any

basis for this estimate. Considering that actual SFY19 utilization for inpatient OR cases at UNC is much lower compared to the previously projected volume in its 2018 CON applications, the reasonableness for the number of cases projected to shift to UNC Rex Hospital is not substantiated in the current UNC Orange County CON application (CON Project I.D. #J-11695-19). Therefore, there is no basis for UNC to artificially add 525 inpatient OR cases back into its SFY2019 annualized utilization. The resulting "historical" inpatient OR growth rate of 3.4 percent is not supported, and therefore neither is the projected inpatient OR growth rate of 3.4 percent.

The applicant bears the burden to demonstrate the reasonableness of its assumptions and methodology, and UNC application does not meet that obligation. Consequently, the UNC 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

UNC 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

UNC does not adequately demonstrate that projected utilization is based on reasonable and adequately supported assumptions. See discussion regarding Criterion 3. Therefore, UNC 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

UNC did not adequately demonstrate that its proposal would not result in unnecessary duplication of surgical services in Orange County. Specifically,

UNC 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. See discussion regarding projected utilization in Criterion 3. Therefore, the UNC application is non-conforming to Review Criterion 6.

Comments specific to Criterion 18a

For the same reasons that the UNC application is non-conforming with Review Criteria 3, 4, 5, and 6, it should also be found non-conforming with Criterion 18a. 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 health 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.

CONCLUSION

For the foregoing reasons, the competing UNC application should be disapproved. It fails to satisfy multiple CON criteria and is also comparatively inferior to the Duke Health Orange ASC application. The Duke Health Orange ASC application should be approved because it satisfies all the applicable CON criteria and is comparatively superior to the competing UNC application.