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Via Electronic Mail

Celia Inman, 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 Durham County OR CON Applications

Dear Ms. Inman:

On November 15, 2018, Duke University Health System (DUHS) submitted a CON application in response to the need determination in the 2018 SMFP for four (4) new operating rooms (ORs) in Durham County (CON Project ID# J-11631-18).

Enclosed please find comments prepared by DUHS regarding the CON application by Southpoint Surgery Center (CON Project ID# J-11626-18) to develop the need determined ORs in Durham County. We trust that you will take these comments into consideration during your review.

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 SUBMITTED CERTIFICATE OF NEED APPLICATIONS DURHAM COUNTY OPERATING ROOMS

Submitted by Duke University Health System
December 31, 2018

Two providers submitted Certificate of Need (CON) applications in response to the need identified in the *2018 State Medical Facilities Plan (SMFP)* for four new operating rooms (ORs) in Durham County. DUHS submitted CON Project ID# J-11631-18, and Southpoint Surgery Center (SSC) submitted CON Project ID# J-11626-18.

As documented in Agency correspondence dated December 6, 2018, SSC did not satisfy all of the procedural requirements of the statutory CON review process. As stated in N.C. Gen. Stat. § 131E-182(c), “*an application fee is imposed on an applicant for a certificate of need. An applicant must submit the fee with the application.*” **Having failed to submit the required application fee prior to the commencement of the review period, SSC did not timely fulfill its obligations in connection with its CON application, and its application cannot be approved.**

Even if this fatal procedural flaw were disregarded, however, the SSC application is not conforming with the applicable statutory and regulatory criteria and should not be approved as a result of material substantive issues. In accordance with N.C. Gen. Stat. § 131E-185(a.1)(1), this document includes DUHS’s comments relating to the representations made by SSC, and a discussion about whether the material in its application complies with the relevant review criteria, plans, and standards. These comments also address the determination of which of the proposals would represent the most effective alternative for development of four new ORs in the service area.

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

- (1) Demonstrates conformity with applicable review criteria and standards;
- (2) Represents the most effective alternative for meeting the county need for additional ORs;
- (3) Provides comprehensive access for surgery patients to new ORs, including inpatient, outpatient, and emergency surgery services across a wide-ranging spectrum of surgical specialties;
- (4) Demonstrates that projected surgical utilization is based on reasonable and adequately supported assumptions; and
- (5) Maximizes healthcare value in the delivery of health care services for development of the need-determined ORs, with competitive charges and costs.

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

that would bring the greatest overall benefit to the community. The table below summarizes comparative metrics that the Agency should use for comparing applications in this OR review.

**Durham County OR Review
 Applicant Comparative Analysis**

	DUH	SSC
Conformity with Rules & Criteria	Yes	No
Geographic Accessibility	Equally Effective	Not approvable
Physician Support	Equally Effective	Not approvable
Patient Access to New Provider	Equally Effective	Not approvable
Patient Access to Lower Cost Surgical Services	Equally Effective	Not approvable
Patient Access to Multiple Services	Most Effective	Least Effective
Access by Underserved Groups		
Projected Charity Care	Most Effective	Least Effective
Projected Medicare		Least Effective
Projected Medicaid		Least Effective
Projected Average Net Revenue per Case	Inconclusive Comparison	
Projected Average Operating Expense per Case	Inconclusive Comparison	

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

Comparative Analysis

Conformity with Administrative Rules & Review Criteria

The DUH application adequately demonstrates the need for its proposal and is conforming with all applicable statutory and regulatory review criteria. The SSC application did not adequately demonstrate the need for its respective proposal and is nonconforming to numerous applicable statutory and regulatory review criteria. Indeed, the SSC application was not filed in accordance with the Filing Applications rules in 10A NCAC 14C .0203, and cannot be included in the review cycle.

Without establishing conformity with all applicable statutory and regulatory review criteria, an application cannot be approved. For the reasons discussed later in this document, SSC is non-conforming with several criteria, including Criteria 1, 3, 4, 5, 6, 12, and 18a.

Therefore, the DUH proposal is the most effective alternative with respect to this comparative and the application submitted by SSC is not an effective alternative with respect to this comparative.

Geographic Access

DUH proposes to develop four additional ORs at its existing North Pavilion facility in Durham. SSC proposes to develop four ORs in a new freestanding ASC on NC 751 Highway in Durham. Both applicants propose to develop ORs in Durham; therefore, the applicants are equally effective with respect to this comparative factor.

In its CON application, SSC provided a geographic analysis of OR distribution by Township in Durham County. SSC proposes to locate new ORs in Triangle Township, which is the same Township where DUHS has already been approved to develop a new ambulatory surgery center (CON Project ID# J-11508-18). Upon development of Arrington ASC, Triangle Township will host four ORs and four procedure rooms. Therefore, SSC's proposal to develop four additional ORs in Triangle Township will not improve geographic access to ambulatory surgical services in Durham County.

Physician Support

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

Patient Access to New Provider

Both applicants already provide surgical services in Durham County.

DUHS serves Durham County residents by providing surgical services at the following existing and approved facilities in Durham County:

- Duke University Hospital
- Durham Regional Hospital
- James E. Davis Ambulatory Surgery Center (operated by a DUHS-controlled affiliate)
- Arrington Ambulatory Surgery Center (Approved, CON Project I.D. #J-11508-18; to be operated by a DUHS-controlled affiliate)

As documented on page 4 of SSC's exhibit book (Exhibit A.1), North Carolina Specialty Hospital, LLC (NCSH) is a member of SSC. NCSH currently provides surgical services at its existing hospital in Durham. Therefore, the proposal by SSC would not provide patient access to a new provider because NCSH already provides surgical services in Durham County.

Patient Access to Lower Cost Surgical Services

Operating rooms can be licensed either under a hospital license or a freestanding ASC that does not operate under a hospital license. DUH proposes to develop four additional ORs at DUH North Pavilion under the hospital license. SSC proposes to develop four new ORs in a freestanding ASC.

The Durham County OR service area (excluding the federal Durham VAMC) has 92 existing and approved ORs (8 inpatient, 17 ambulatory, 67 shared; excluding C-section and dedicated trauma/burn ORs). Durham County is unique in that 71 percent of the county's ORs are located at DUH, which is a full-service tertiary and quaternary care hospital and Academic Medical Center. Accordingly, DUH serves a unique purpose and different patient population compared

to other licensed facilities in Durham County. Patients from throughout North Carolina and beyond come to DUH for surgical services, both inpatient and outpatient. During FY2017, DUH performed approximately 66% ($22,642 \div 34,393 = .658$) of the ambulatory surgical cases performed in Durham County. DUH has and will continue to exhibit a need for access to surgical services. This OR need cannot be met by any of the existing or approved facilities in Durham County.

It is important to note that DUHS currently provides ambulatory surgical services in Durham County in a freestanding ASC setting. Specifically, James E. Davis Ambulatory Surgery Center (DASC) is a freestanding ASC currently licensed for eight (8) ORs owned by a DUHS-controlled affiliate, Associated Health Services, Inc. Additionally, access to lower cost surgical services will soon be enhanced in Durham County via the Agency's approval of CON Project I.D. #J-11508-18. Upon completion of that project, four ORs will be relocated from DASC to the new Arrington ASC in southern Durham County. Therefore, the Agency's approval of Arrington ASC enables DUHS to enhance local access to lower cost surgical services by 1) developing a new ASC in southern Durham County and 2) maximizing utilization of existing DUHS licensed resources. While Arrington ASC (CON Project I.D. #J-11508-18) is already approved and is not part of the competitive OR batch review, it is relevant in evaluating the kinds of surgical services that are available and which are needed in the service area.

Patient Access to Multiple Surgical Specialties

As described previously, DUH is a full-service tertiary and quaternary care hospital and Academic Medical Center. DUH provides access to a wide array of surgical specialties.

While SSC proposes to develop a multi-specialty ASC, the effective scope of services is actually quite limited because the vast majority (67.8%) of projected surgical cases will be orthopaedic cases.

The following table illustrates the surgical specialties (as defined on the North Carolina Hospital License Renewal Application) that the two CON applicants propose to provide:

Specialty and Related Sub-specialties	DUH (IP and OP)	SSC* (OP only)
Cardiothoracic, excluding Open Heart	√	-
Open Heart	√	-
General Surgery	√	7.3%
Neurosurgery, including Spine Surgery	√	-
Obstetrics and Gynecology, excluding C-Section	√	2.6%
Ophthalmology	√	9.5%
Oral Surgery /Dental	√	0.9%
Orthopedic, including Spine Surgery	√	67.8%
Otolaryngology (ENT)	√	2.8%
Plastic Surgery	√	3.5%
Podiatry	√	0.2%
Urology	√	3.4%
Vascular	√	0.8%
Other:	√	-
Pain Management	√	1.3%
Dermatology	√	-
Colorectal Surgery	√	-

*Specialty OR cases as a percent of total OR cases (outpatient only) during project years 2 and 3.

Source: SSC CON application, Section Q, page 108

As a full-service tertiary and quaternary care hospital and Academic Medical Center, DUH offers a full continuum of emergency, medical and surgical services. Therefore, DUH proposes access to a much broader range of specialties than SSC.

As described previously, the vast majority of SSC’s projected surgical cases will be orthopaedic cases (67.8%). Each of the remaining proposed surgical specialties comprises less than 10 percent of projected surgical cases. With regard to providing access to more multiple surgical specialties, DUH is the most effective alternative, while SSC is the least effective alternative.

Access by Underserved Groups

Projected Charity Care Cases

The following table shows each applicant’s projected charity care to be provided in the project’s second full operating year. Generally, the application proposing to provide the most charity care is the more effective alternative with regard to this comparative factor.

Surgical Charity Care Cases, PY2

Applicant	Projected Total Charity Care	Charity Care per OR	Charity Care per Surgical Case	Percent of Total Net Surgical Revenue
DUH	\$57,139,014	\$828,102	\$1,391	6.45%
SSC	\$175,726	\$43,932	\$41	1.06%

Source: Forms F.3, F.4 and F.5 for each applicant.

As shown in the table above, DUH projects not only the most charity care in dollars, but also the highest charity care to be provided to patients per OR, per surgical case, and as a percent of net revenue. Therefore, the application submitted by DUH is the most effective alternative with regard to access to charity care.

Projected Medicare Cases

The following table shows each applicant’s total number of projected outpatient surgical cases and the number of outpatient cases projected to be provided to Medicare patients in the applicant’s second full year of operation following completion of their projects, based on the information provided in the applicants’ pro forma financial statements in Section Q.

Surgical Medicare Cases, PY2

	Projected Total Outpatient Cases	Projected Outpatient Medicare Cases	% of Total Cases Provided to Medicare Recipients
DUH	20,628	7,346	35.6%
SSC	4,189	1,969	47.0%

Source: Forms F.3, F.4 and F.5 for each applicant.

As shown in the table above, DUH projects to serve 7,346 Medicare cases during its second project year. Therefore, the application submitted by DUH is the most effective application with regard to serving Medicare recipients.

Projected Medicaid Cases

The following table shows each applicant’s total number of projected surgical cases and the number of cases projected to be provided to Medicaid patients in the applicant’s second full year of operation following completion of their projects, based on the information provided in the applicants’ pro forma financial statements in Section Q.

Surgical Medicaid Cases, PY2

	Projected Total Outpatient Cases	Projected Outpatient Medicaid Cases	% of Total Cases Provided to Medicaid Recipients
DUH	20,628	2,003	9.7%
SSC	4,189	126	3.0%

Source: Forms F.3, F.4 and F.5 for each applicant.

As shown in the table above, DUH projects to serve both the greatest percentage and largest number of Medicaid patients. DUH projects to serve 2,003 Medicaid cases during its second project year. Therefore, the application submitted by DUH is the most effective application with regard to serving Medicaid recipients.

Projected Average Gross and Net Revenue per Case

As described previously, DUH is a full-service tertiary and quaternary care hospital and Academic Medical Center. SSC proposes to develop a freestanding ASC serving predominately orthopaedic surgical patients. Due to significant differences in the types of surgical services proposed by each applicant, which have a widely varying spectrum of services and thus revenues and reimbursements, it is not possible to make conclusive comparisons with regard to gross and net revenue per surgical case.

Projected Average Operating Expense per Case

As described previously, DUH is a full-service tertiary and quaternary care hospital and Academic Medical Center providing a full range of inpatient and outpatient surgeries. SSC proposes to develop a freestanding ASC serving predominately orthopaedic surgical patients. Due to significant differences in the types of surgical services proposed by each applicant, which have a widely varying spectrum of services and thus costs, it is not possible to make conclusive comparisons with regard to operative expense per surgical case.

Quality in Delivery of Services

Clinical Staff Salaries

In recruitment and retention of high-quality clinical personnel, salaries are a significant factor. Both applicants provided salary information in Form H. As shown on the table below, DUH demonstrates that its proposed salaries for RNs and Surgical Technicians are the most competitive, with a corresponding positive impact on quality of care.

RN & Surgical Tech Salaries, PY 2

	DUH	SSC
Registered Nurse	\$102,301	\$79,968
Surgical Tech	\$55,500	\$47,772

Source: CON Applications

Comments regarding Southpoint Surgery Center, LLC /CON Project I.D. #J-11626-18

General Comments

As documented in the attached Agency letter dated December 6, 2018, SSC did not satisfy the requirements for timely submitting its CON application for Durham County operating rooms. As stated in N.C. Gen. Stat. § 131E-182(c), “*an application fee is imposed on an applicant for a certificate of need. An applicant must submit the fee with the application.*” **Therefore, SSC did not timely submit its CON application, and its application cannot not be approved.**

Comments specific to Criterion 1

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

SSC failed to demonstrate that its projected surgical utilization is based on reasonable and supported assumptions.

The SSC methodology for projecting surgical utilization at the new ASC is based on three fundamental assumptions:

1. Projected growth of ambulatory surgical cases at NCSH,
2. Projected shift of ambulatory surgical cases from NCSH to SSC, and
3. Planned recruitment of 25 additional surgeons

Growth of ambulatory surgical cases at NCSH

Step 1 of the NCSH and SSC methodology and assumptions in Section Q (page 103) states NCSH OR utilization is based on the “*assumption of 2 percent annual growth due to population growth, high patient satisfaction, physician recruitment, the implementation of the hospital’s emergency department.*” While it is not explicitly described, the projected two percent growth rate is assumedly applied to both inpatient and outpatient surgical cases.

Upon review of NCSH’s historical inpatient and outpatient surgical cases, the projected growth rate of two percent is inconsistent with its historical inpatient and outpatient surgical growth rates. The following table summarizes inpatient and outpatient surgical cases performed at NCSH during FY2015-FY208.

**North Carolina Specialty Hospital
 Inpatient & Outpatient Surgical Cases, FY2015-FY2018**

	FY2015	FY2016	FY2017	FY2018	2-YR CAGR	3-YR CAGR
Inpatient	1,597	1,629	1,649	1,528	-3.1%	-1.5%
Outpatient	3,737	3,606	3,724	3,344	-3.7%	-3.6%
Total	5,334	5,235	5,373	4,872	-3.5%	-3.0%

Source: Hospital License Renewal Applications, CON Project ID #J-11626-18

Inpatient and outpatient surgical utilization at NCSH has been unstable during recent years. Both the 2-year and 3-year compound annual growth rates (CAGR) each reflect negative growth rates.

On page 35 of its CON application SSC states, *“the most recent 12 months’ data shows a short-term decrease in OR utilization that is attributed to two physicians who have left the hospital medical staff.... Physicians have been recruited to replace both departures, but their volumes have not fully rebounded in the current year. Some ambulatory surgery volume decrease is attributed to a shift to ambulatory surgery centers that have been developed in other counties.”* SSC does not differentiate the extent to which the physician departures and shifts to ASCs each impacted surgical utilization in FY2018. Moreover, a significant decrease in outpatient utilization also occurred from FY2015 to FY2016, apparently unrelated to the departure of the two physicians from NCSH’s staff, such that outpatient volumes in FY2017 were lower than in FY2015, and total volumes were essentially flat during that period, even before the additional loss in volume in FY2018.

Finally, shifts to ASCs will continue to negatively impact surgical utilization at NCSH, including during the identified interim project years of SSC’s proposal, and may be exacerbated with the potential development in new ambulatory surgery centers in adjacent counties proposed in recent reviews in Wake and Orange Counties.

Projected shift of ambulatory surgical cases from NCSH to SSC

DUHS acknowledges it is theoretically reasonable to project a shift of ambulatory surgical cases from a hospital-based setting to a new freestanding ASC. Indeed, DUHS

projects a shift of ASC-appropriate cases from its existing hospital-based facilities to the approved Arrington ASC in Durham County and the proposed Green Level ASC in Wake County. DUHS notes the factors supporting SSC’s projected shift of utilization from NCSH to the proposed SSC are similar to several of the factors supporting methodology assumptions in the approved Arrington ASC and proposed Green Level ASC CON projects. However, the projected shifts are based on unrealistic overall growth projections as previously described and do not support the utilization projected at the existing and proposed facilities.

Planned recruitment of 25 additional surgeons

A critical assumption of the SSC methodology is based on the recruitment of 25 additional surgeons to the physician practices that are supportive of the SSC project. On page 40 of its CON application SSC states, “*Over the next three years, NCSH and physician practices that are supportive of the Southpoint project are expected to add 25 surgeons.*” What’s most significant is that these 25 surgeons are responsible for performing nearly 44 percent of SSC’s surgical cases during the third project year. At the same time, only 7 of these recruits are projected to be in orthopedics, which makes up 67.8% of the projected surgical cases performed at the SSC facility (see Section Q, page 108).

**Southpoint Surgery Center
 Projected Surgical Cases, Project Year 1 - 3**

	Year 1	Year 2	Year 3
OP Cases shifted from NCSH to SSC	2,129	2,353	2,400
OP Cases from new surgeons to be recruited	1,800	1,836	1,873
Total Cases at SSC	3,929	4,189	4,273

Source: CON Project ID #J-11626-18, Section Q, page 104

Little information is provided regarding the assumptions and methodology used to project the number of surgical cases for the 25 surgeons who are not identified and have yet to be recruited for the proposed project. Page 42 of SSC’s application simply states, “*these new surgeons are projected to perform an average of 72 OR cases and 32 procedure room cases at Southpoint Surgery Center in Year 1 with 2 percent annual growth projected in the following years. These volume projections are reasonable and conservative based on comparison to the volume projections for current physicians and also the EmergeOrtho recruitment letter provided in Exhibit C.4.(a).*” DUHS would note that there is no apparent documentation from other physician practices regarding their intention to recruit any additional physicians in specialties besides orthopaedics.

Furthermore, the application lacks any analysis and/or explanation of how the applicant arrived at 72 OR cases per newly recruited physician in Year 1, regardless of specialty. This unsupported assumption is critical to SSC's utilization projections because it is used to project nearly 44 percent of SSC's surgical cases during the third project year. Section Q does not contain any information regarding the assumptions or methodology used to project OR cases for each new physician to be recruited and who will utilize the proposed new ASC. Therefore, the applicant's utilization projections for SSC are not reasonably and adequately supported.

Based on the reasons previously described, the SSC 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

SSC 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

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

The Form F.3 assumptions state that Management Services expenses are based on 5% of the total net revenue. However, the management agreement included in Exhibit A.9 (Section 5.1) projects the management fee at 6 percent of net revenues, resulting in an expense discrepancy ranging from \$144,925 in PY1 to \$165,689 in PY2.

SSC's project capital cost includes \$20,000 in financing costs, and \$50,000 interest during construction. Both of these estimates appear to be underestimated. Typically, a loan financing cost is 1% of the loan value, which in this case would be \$120,666 ($\$12,066,630 \times .01$), which is much more than the \$20,000. To calculate the construction interest, one would typically take the project construction cost of \$5,500,000 and apply the interest loan rate of 5.5% over the 12-month construction period, assuming various draws. Using two draws, the interest during construction expense is \$151,250, and using four draws, the interest during construction expense is \$75,625. Both of these erroneous

calculations result in a project capital cost that exceeds the loan amount of \$12,066,630 specified in the First Citizen's Bank letter in Exhibit F.2.

These financial inconsistencies and inadequacies indicate that SSC did not demonstrate the financial feasibility of the proposal based upon demonstrating the availability of funds, and also reasonable projections of the costs and charges for providing health services and is therefore non-conforming to Criterion 5.

Comments specific to Criterion 6

SSC did not adequately demonstrate that its proposal would not result in unnecessary duplication of surgical services in Durham County. Specifically, SSC 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 NCSH already owns in Durham County. See discussion regarding projected utilization in Criterion 3. Therefore, the SSC application is non-conforming to Review Criterion 6.

Comments specific to Criterion 12

The applicant SSC is related to SPSC 751, LLC, the legal entity represented to be the developer of the medical office building in which the ASC is proposed to be located. However, SPSC 751 does not currently own the proposed site and the SSC application did not include any documentation that the site is available for acquisition by purchase, lease, donation or other comparable arrangement, as requested in the CON application form. Therefore, the SSC application is non-conforming to Review Criterion 12.

Comments specific to Criterion 18a

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

As set forth above, the SSC application cannot not be approved due to the applicant's failure timely to submit the required application fee. In the scenario that the Agency includes the SSC application in the Durham County ASC review, the SSC application should be disapproved. NCSH fails to satisfy multiple CON criteria and is also comparatively inferior to the DUH

application. The DUH application should be approved because it satisfies all the applicable CON criteria and is comparatively superior to the SSC application.