

January 2, 2018

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 New Hanover County OR CON Applications

Dear Mr. Yakaboski:

Enclosed please find comments prepared by New Hanover Surgical Center, LLC regarding the competing CON applications to develop one new operating room in New Hanover County to meet the need identified in the *2017 State Medical Facilities Plan*. 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 910.332.3800. I look forward to seeing you at the public hearing.

Sincerely,

Steve DeBiasi

Stephen L. DeBiasi, FACHE, CMPE
New Hanover Surgical Center

COMMENTS ABOUT COMPETING CERTIFICATE OF NEED APPLICATIONS NEW HANOVER COUNTY OPERATING ROOMS

Submitted by New Hanover Surgical Center, LLC
January 2, 2018

Four applicants submitted Certificate of Need (CON) applications in response to the need identified in the *2017 State Medical Facilities Plan (SMFP)* for one new operating room (OR) in New Hanover County. In accordance with N.C.G.S. §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 their applications complies with the relevant review criteria, plans, and standards. These comments also address the determination of which of the competing proposals represents the most effective alternative for development of one new OR in New Hanover County.

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 in New Hanover County;
- (2) Maximizes healthcare value in the delivery of health care services, and represents the most cost-effective alternative for development of the need determined OR, with competitive charges and costs;
- (3) Reasonably demonstrates the need the population has for the proposed services;
- (4) Does not represent unnecessary duplication of existing services; and
- (5) 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 is to identify the proposal that would bring the greatest overall benefit to the community. The table on the following page summarizes 10 objective metrics that the Agency should use for comparing the four applications in this New Hanover County OR batch review.

**New Hanover County OR Batch Review
 Applicant Comparative Analysis**

Metrics				
Comparative	New Hanover Surgical Center	Wilmington SurgCare	Wilmington ASC	NHRMC
Enhance Market Competition	Yes	No	No	No
Improve Geographic Access	No Change	No Change	No Change	No Change
Operational Date	1/1/2020	1/1/2021	1/1/2020	10/1/2019
PY2 Gross Revenue/Case	\$4,988	\$11,070	\$9,441	\$30,211
PY2 Net Revenue/Case	\$2,353	\$1,560	\$3,993	\$7,642
PY2 Operating Cost/Case	\$1,959	\$1,426	\$2,576	\$3,933
Self-Pay/Charity Care %	3.40%	1.24%	2.00%	3.60%
Medicare %	12.90%	51.26%	49.00%	46.00%
Medicaid %	10.50%	7.78%	4.00%	6.90%
New Hanover Co. Patient Origin %	74.50%	42.62%	43.00%	42.60%

Rankings				
Comparative	New Hanover Surgical Center	Wilmington SurgCare	Wilmington ASC	NHRMC
Enhance Market Competition	1	2	2	2
Improve Geographic Access	1	1	1	1
Operational Date	2	3	2	1
PY2 Gross Revenue/Case	1	3	2	4
PY2 Net Revenue/Case	2	1	3	4
PY2 Operating Cost/Case	2	1	3	4
Self-Pay/Charity Care %	2	4	3	1
Medicare %	4	1	2	3
Medicaid %	1	2	4	3
New Hanover Co. Patient Origin %	1	3	2	3
Average	1.7	2.1	2.4	2.6
Total	17	21	24	26

Based on this comparative analysis which shows NHSC ranks more favorably on the overall head-to-head comparisons, and considering that the NHSC application conforms to the Review Criteria and best achieves the Basic Principles of the 2017 SMFP (Policy Gen-3), NHSC represents the most effective alternative for development of the need determined operating room.

Comparative Analysis

Geographic Accessibility

The 2017 SMFP identifies a need for one additional OR in the New Hanover County OR Service Area. All four applications propose to develop a new OR in Wilmington, New Hanover County. Therefore, with regard to geographic accessibility the four proposed projects are comparable.

Patient Access to Alternative Providers/Enhance Market Competition

In New Hanover County there are currently only two licensed facilities with ORs: New Hanover Regional Medical Center (NHRMC) and Wilmington SurgCare. NHRMC is a hospital with multiple campuses, and Wilmington SurgCare is a freestanding ambulatory surgical center. Both NHRMC and Wilmington SurgCare are proposing to add one new OR to their respective existing facilities. Just last year, Wilmington SurgCare received CON approval to develop three additional ORs in the 2016 New Hanover County OR Review (CON Project ID #O-11272-16). The proposal by Wilmington ASC involves development of one new OR, three new procedure rooms, and the relocation of three GI endoscopy procedure rooms from an existing ASC in New Hanover County. Thus, the proposal by Wilmington ASC represents relocation and expansion of an existing ASC in New Hanover County. Therefore, the proposals by NHRMC, Wilmington SurgCare, and Wilmington ASC will not introduce a new entrant into the healthcare licensed facility marketplace in New Hanover County.

NHSC is owned by 15 physician members of EmergeOrtho. Neither EmergeOrtho, nor any of the 15 physician members of NHSC currently own any existing ORs in New Hanover County. NHSC's proposal would introduce a new provider in the surgical marketplace in New Hanover County. Therefore, with regard to improving accessibility to an increased number of providers of surgical services located in New Hanover County, the NHSC proposal is the most 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 and Medicaid recipients in the second project year. Generally, the application proposing to serve the higher numbers of Self-Pay/Charity Care and Medicaid patients is the more effective alternative with regard to this comparative factor. The following tables reflect OR cases only, not non-surgical procedures.

Projected OR Payor Mix

	New Hanover Surgical Center	Wilmington SurgCare	Wilmington ASC	NHRMC*
Self-Pay/Charity/Indigent	3.40%	1.24%	2.00%	3.60%
Medicaid	10.50%	7.78%	4.00%	6.90%

*Reflects outpatient payor mix

As shown in the tables above, NHSC projects the highest percentage of cases to be provided to Charity Care and Medicaid combined. Therefore, the application submitted by NHSC is the most effective alternative with regard to access by medically underserved groups.

Patient Origin

NHSC projects the highest patient origin for residents from New Hanover County of the four competing proposals, as shown on the table below.

Projected Patient Origin, Year Two

	New Hanover Surgical Center	Wilmington SurgCare	Wilmington ASC	NHRMC
New Hanover	74.50%	42.62%	43.00%	42.60%
Brunswick	0.00%	24.76%	24.00%	19.90%
Onslow	12.00%	9.38%	9.00%	9.60%
Pender	13.60%	8.10%	9.00%	11.50%
Other	0.00%	15.00%	15.00%	16.00%
Total	100.00%	100.00%	100.00%	100.00%

Source: CON Applications

The NHSC proposal is the most effective alternative for expanding access to surgical services for local residents in the SMFP-defined service area of New Hanover County.

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 outpatient 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 New Hanover County batch review, NHSC projects competitive charges and costs, with the lowest gross charges, second lowest average reimbursement per surgical case, and second lowest average costs of the competing proposals. Please see the following tables.

Projected Average Charge per Surgical Case*

Project Year	New Hanover Surgical Center (NHSC)	Wilmington SurgCare	Wilmington ASC	NHRMC
1	\$4,912	\$10,544	\$9,322	\$29,392
2	\$4,988	\$11,070	\$9,441	\$30,211
3	\$5,071	\$11,623	\$9,584	\$31,064

Source: CON Applications

*Reflects only technical charges. For surgical cases only, not non-surgical procedures.

Projected Average Reimbursement per Surgical Case*

Project Year	New Hanover Surgical Center (NHSC)	Wilmington SurgCare	Wilmington ASC	NHRMC
1	\$2,317	\$1,549	\$4,014	\$7,658
2	\$2,353	\$1,560	\$3,993	\$7,642
3	\$2,392	\$1,569	\$3,994	\$7,627

Source: CON Applications

*Reflects only technical charges. For surgical cases only, not non-surgical procedures.

Projected Average Cost per Case*

Project Year	New Hanover Surgical Center (NHSC)	Wilmington SurgCare	Wilmington ASC	NHRMC
1	\$2,091	\$1,438	\$3,084	\$3,858
2	\$1,959	\$1,426	\$2,576	\$3,933
3	\$1,860	\$1,418	\$2,583	\$4,011

Source: CON Applications

*Reflects total project expenses for all surgical cases and non-surgical procedures.

The other OR applicants, who propose a multi-specialty OR, may contend that comparing the costs and charges of a multi-specialty OR to a single-specialty ASC is like comparing apples and oranges. However, considering that orthopaedic surgical cases are typically more complex, and thus costlier than many other specialties, NHSC’s projection of comparatively lower costs and charges per surgical case is noteworthy. Therefore, the comparison of charges and costs between the applicants is relevant in this batch review.

This comparative analysis demonstrates NHSC’s commitment to competitive pricing and greater cost-effectiveness. Clearly, NHSC most effectively satisfies the value requirement of Policy GEN-3, and is a comparatively superior application because it is cost effective and enhances competition with the addition of a new market entrant in New Hanover County.

Specific comments regarding the Wilmington SurgCare application CON Project I.D. #O-11437-17

Comments specific to Criterion 3

Wilmington SurgCare recently received CON approval to develop three additional ORs in the 2016 New Hanover County batch review (CON Project ID #O-11272-16). Addition of yet another operating room at Wilmington SurgCare is certainly premature considering the three additional rooms were just recently approved. Indeed, Wilmington SurgCare did not adequately demonstrate the need it has to develop another OR in addition to its existing and approved ORs. Specifically, the methodology used to project ambulatory surgical cases is unreasonable and not supported.

Step 3 of Wilmington SurgCare’s methodology (page 46) incorrectly calculates a compound annual growth rate (CAGR) for the inpatient and ambulatory utilization in New Hanover County during FY2013 through FY2016. Page 47 of the Wilmington SurgCare application incorrectly states the FY2013-FY2016 CAGR for New Hanover inpatient cases was 6.81% and the FY2013-FY2016 CAGR for New Hanover outpatient cases was 6.67%. The following summarizes the correct CAGRs for inpatient and ambulatory surgical utilization.

	FY2013	FY2014	FY2015	FY2016	
New Hanover County Facility Totals	2012-13	2013-14	2014-15	2015-16	CAGR
New Hanover IP Cases (Exc C-Section)	9,506	10,625	10,932	11,716	7.2%
New Hanover OP Cases	29,139	30,859	31,666	33,276	4.5%
Total New Hanover Cases (IP + OP)	38,645	41,484	42,598	44,992	5.2%

Source: FY2013 – FY2016 data obtained from page 47 of Wilmington SurgCare application

The FY2013-FY2016 CAGR for inpatient and ambulatory surgery utilization in New Hanover County based on the information provided in Wilmington SurgCare’s methodology is actually 7.2% and 4.5%, respectively. The actual ambulatory surgery CAGR is considerably lower compared to the erroneous CAGR provided in Wilmington SurgCare’s methodology (page 47). This is significant because the applicant uses the FY2013-FY2016 CAGR to support its projected utilization. Specifically, Step 4 of the methodology states *[h]aving confirmed that the CAGR exceeds 6 percent for both inpatient and ambulatory operating room utilization, the applicant*

projects future years' ambulatory surgery cases using a 5.5 [sic] percent annual growth assumption that is more conservative than the CAGR. As demonstrated by the previous table, the FY2013-FY2016 CAGR for ambulatory surgery utilization in New Hanover County did not exceed 6 percent, nor did it exceed the applicant's projected growth rate of 5 percent¹. First and foremost, it is not reasonable to project that ambulatory surgery utilization will grow by 5 percent annually for the next seven years when the CAGR has only been 4.5 percent during the most recent three years. Secondly, the applicant failed to consider the impact that the 2016 SMFP need determination for one OR in Brunswick County will have on future ambulatory surgery utilization in New Hanover County. Brunswick Surgery Center (BSC) received CON approval to develop a one-room ASC in Brunswick County (CON Project ID # O-11282-16). As described in its CON application, BSC's approved ASC will greatly improve geographic access to ambulatory surgery services for residents of Brunswick County. Therefore, some patients who currently travel to New Hanover County for orthopaedic ambulatory surgical services are projected to be served in Brunswick County. Wilmington SurgCare failed to consider this factor when projecting future ambulatory surgery utilization in New Hanover County. For these reasons, the projected growth rate of 5 percent for New Hanover County surgery utilization is not reasonable.

Wilmington SurgCare's methodology also projects unreasonable market share assumptions. Step 8 of the applicant's methodology (page 48) assumes that its 2017 New Hanover County ambulatory surgery market share (24.4%) will remain constant through 2019; however, Wilmington SurgCare failed to provide information regarding its historical ambulatory surgery market share to support this assumption. Indeed, Wilmington SurgCare's ambulatory surgery market share in New Hanover County has experienced a decreasing trend during recent years as shown in the following table.

	FY2013	FY2014	FY2015	FY2016	FY2017
	2012-13	2013-14	2014-15	2015-16	2016-17
Wilmington SurgCare OP Cases	8,378	7,935	8,463	8,589	8,531
New Hanover OP Cases	29,139	30,859	31,666	33,276	34,940
Wilmington SurgCare OP Market Share	28.8%	25.7%	26.7%	25.8%	24.4%

Source: FY2013 – FY2017 data obtained from page 47 of Wilmington SurgCare application

¹ Wilmington SurgCare provides conflicting information about its projected growth rate. Step 4 of its methodology states a 5.5 percent growth rate was used, while the table on page 47 shows a 5 percent growth rate was used.

As shown in the previous table, Wilmington SurgCare's ambulatory surgery market share in New Hanover County has steadily declined during recent years from 28.8% in FY2013 to 24.4% in FY2017. Wilmington SurgCare failed to describe the rationale for its diminishing market share in New Hanover County and why it is realistic to assume this trend will immediately cease, given there will be no change to the ASC until 2020 when the three approved ORs become operational. Therefore, the projected market shares are not supported by Wilmington SurgCare's historical utilization.

While NHSC does not dispute the approval of Wilmington SurgCare's recent CON approval to develop three additional ORs (CON Project ID #O-11272-16), Wilmington SurgCare does not adequately demonstrate the need to develop an eleventh OR. In order to satisfy the 10A NCAC 14C .2103(b)(1) Performance Standard, the applicant must rely on unreasonable assumptions that are not supported by either the local market or by the applicant's historical utilization. Therefore, the application is non-conforming to Criterion 3.

Comments specific to Criterion 4

As described previously, Wilmington SurgCare does not demonstrate that projected surgical utilization is based on reasonable and supported assumptions. Therefore, the application is not conforming to Criterion 4.

Comments specific to Criterion 5

As described previously, Wilmington SurgCare does not demonstrate that projected surgical utilization is based on reasonable and supported assumptions. Because Wilmington SurgCare does not reasonably project utilization of its facility, it does not demonstrate the financial feasibility of the proposal. Therefore, the application is not conforming to Criterion 5.

Comments specific to Criterion 6

Wilmington SurgCare did not adequately demonstrate that its proposal would not result in the unnecessary duplication of surgical services in New Hanover County. Specifically, Wilmington SurgCare did not adequately demonstrate in its application that the new OR it proposes to develop is needed, and that it will not unnecessarily duplicate the ORs that Wilmington SurgCare already owns and is approved to develop in New Hanover County. See discussion regarding projected

utilization in Criterion 3. Therefore, the Wilmington SurgCare application is non-conforming to Review Criterion 6.

Comments specific to Criterion 18a

Because the Wilmington SurgCare application is non-conforming with Criteria (3), (4), (5), and (6), it should also be found non-conforming with Criterion (18a). Wilmington SurgCare did not adequately demonstrate the need the population projected to be served has for the proposed project, and did not adequately demonstrate that its proposal would not result in the unnecessary duplication of surgical services in New Hanover County. Wilmington SurgCare did not adequately demonstrated the financial feasibility of the proposal. Thus, the proposed Wilmington SurgCare project will not have a positive impact on competition.

10A NCAC 14C .2103(b)(1) Performance Standard

The Wilmington SurgCare application does not conform to 10A NCAC 14C .2103(b)(1) because the Wilmington SurgCare surgical case projections are not based on reasonable and supported assumptions. Please see discussion regarding Criterion 3.

10A NCAC 14C .2103(c)(1) Performance Standard

The Wilmington SurgCare application does not conform to 10A NCAC 14C .2103(c)(1) because the Wilmington SurgCare surgical case projections are not based on reasonable and supported assumptions. Please see discussion regarding Criterion 3.

10A NCAC 14C .2103(f) Performance Standard

The Wilmington SurgCare application does not conform to 10A NCAC 14C .2103(f) because the Wilmington SurgCare volume projections are not based on reasonable and supported assumptions. Please see discussion regarding Criterion 6.

Specific comments regarding the New Hanover Regional Medical Center application

CON Project I.D. #O-11434-17

General Comments

NHRMC controls 38 of the 45 currently licensed operating rooms in New Hanover County, or 84%. NHRMC has 26 ORs at its main hospital, another 8 at its Orthopedic Hospital, and another 4 at its Atlantic Surgicenter. NHRMC states that over the past 15 years it has never been awarded a CON for additional ORs in a competitive review. However, NHRMC has nonetheless increased its OR inventory during that time by 27%, from 30 to 38 ORs. This includes acquisition of 4 ORs in 2014 that were an independent ASC but now are hospital based (Atlantic Surgicenter), and 2 ORs in 2015 that were originally CON approved to be a Novant ASC but are now based in the main hospital at NHRMC.

Addition of one OR at NHRMC will increase the NHRMC inventory by just 2.6%, and is not the most effective alternative in terms of community benefit or competition. NHRMC claims the project will foster competition because NHRMC competes with other hospitals in the service area. However, NHRMC's 38 ORs is 58% more than the combined total of 24 ORs operated by all other providers in the five-county area of Brunswick, Columbus, New Hanover, Onslow, and Pender counties. NHRMC states it is also competing "with much larger systems both inside and outside of North Carolina". However, NHRMC's own surgical utilization data shows that its outpatient volume is increasing. NHRMC, thus, has been able to compete successfully with local providers for the outpatient surgery business, and is doing just fine from a competitive standpoint. NHRMC has not demonstrated that it has lost business as a result of out-of-market competition.

New Hanover County is the 8th most populous county in North Carolina, yet has only one ASC, and currently just 7 of 45 ORs in New Hanover County are billed at non-hospital rates. Value is one of the three Basic Principles in the State Medical Facilities Plan. The State Health Coordinating Council defines health care value as maximum health care benefit per dollar expended. With regard to hospital-based versus ASC surgeries, typically an ASC has a lower cost setting than a hospital, reflected in lower co-pays, lower charges to insurers, and lower operational costs. The U.S. healthcare system could reduce costs by more than \$38 billion per year by performing all appropriate cases in the ASC setting, according to a report authored by Healthcare Bluebook, ASCA and HealthSmart. The report estimates ASCs could reduce Medicare costs by \$2.3 billion per year. Thus, the NHRMC proposal is not the most effective alternative from a value perspective.

Other benefits of ASC versus hospital setting for surgery:

- ASCs offer greater convenience than hospital outpatient departments, including quick surgical scheduling.
- The ASC scheduling and room turnover is typically more efficient than a hospital setting, allowing physicians to perform a higher volume of procedures in ASCs than hospital outpatient departments. Also, scheduled surgical cases in an ASC are less likely to get bumped for other cases, such as in a hospital setting.

Thus, the NHRMC proposal for another hospital-based OR is not the most effective alternative in this competitive batch review.

Comments specific to Criterion 5

The NHRMC Form C total expenses do not include an allocation of general and administrative hospital expenses that are necessary to support the surgical services. Thus, the operating cost per surgical case is not an accurate representation of the entire cost of surgical cases at NHRMC.

Comments specific to Criterion 8

NHRMC states there are over 550 physicians on hospital medical staff, yet its CON application included only four MD letters of support.

Specific comments regarding the Wilmington ASC application CON Project I.D. #O-11441-17

General Comments

It is highly questionable that one OR can reasonably be shared by the physicians of at least nine different surgical specialties as is proposed by WASC. Given the limited available block time for a 1-OR ASC, it is highly unlikely that the spectrum of specialties identified on page 29 of WASC's application can effectively be made accessible to the prospective physicians and patients in a meaningful way. Furthermore, OR turnover time between cases of different specialties is likely to be longer compared to OR turnover time between cases of the same specialty because of the different equipment and set up that may be needed for the various types of specialties proposed. Indeed, page 82 of WASC's application describes the specialized equipment needed for neurosurgery and ophthalmology. WASC's prospective limited OR capacity (i.e. 1 OR) coupled with the number of surgical specialties results in a less-efficient ASC with less available capacity compared to a single-specialty ASC. Thus, the WASC proposal is not the most effective alternative in this competitive batch review.

Comments specific to Criterion 5

The net patient revenue in Form C -- OR services does not match the net revenue shown in Form E for OR services.

The payor mix projection listed in Table VI.5 on page 158 does not match the payor percentages portrayed in the financial proformas, including Form C and the Form C assumptions.

The proforma assumptions state a 4% management fee expense; the management services agreement in Exhibit 3 indicates a 5% fee on page 6.

All these financial inconsistencies indicate that WASC did not demonstrate the financial feasibility of the proposal based upon reasonable projections of the costs and charges for providing health services, and is therefore non-conforming to Criterion 5.

Comments specific to Criterion 12

Exhibit 7 of the WASC application includes only a site plan, and not a line drawing of the ASC. Therefore, WASC is not able to demonstrate that the cost, design and means of construction represent the most reasonable alternative and that the project will not unduly increase the cost of providing services, and is non-conforming to Criterion 12.

Comments specific to Criterion 13c

The WASC payor mix projection is not reasonable, because as shown in Section VI of the application, it is estimated based on payor mix data from SCA's seven North Carolina facilities, which are located in Wake, Mecklenburg, Cumberland, Guilford, Moore and Wilson counties. None of those counties are within the service area of New Hanover County proposed in the WASC application. Therefore, WASC did not reasonably identify the medically underserved groups and the extent to which they will utilize the proposed service, and is non-conforming to Criterion 13c.

CONCLUSION

For all of the foregoing reasons, the competing applications should be disapproved. They fail to satisfy multiple CON criteria, and are also comparatively inferior to the New Hanover Surgery Center application. The NHSC application should be approved because it satisfies all the applicable CON criteria and is comparatively superior to the competing applications.