Comments on New Hanover County Operating Room CON Applications

submitted by

Cape Fear Surgical Center, LLC

In accordance with N.C. GEN. STAT. § 131E-185(a1)(1), Cape Fear Surgical Center, LLC (CFSC) submits the following comments related to competing applications to develop three additional surgical operating rooms in New Hanover County. CFSC's comments include "*discussion and argument regarding whether, in light of the material contained in the application and other relevant factual material, the application complies with the relevant review criteria, plans and standards*." *See* N.C. GEN. STAT. § 131E-185(a1)(1)(c). In order to facilitate the Agency's review of these comments, CFSC has organized its discussion by issue, noting some of the general CON statutory review criteria and specific regulatory criteria and standards creating the non-conformity relative to each issue, as they relate to the following projects:

O-11272-16 Wilmington SurgCare (SurgCare)

O-11277-16 Surgery Center of Wilmington (SCW)

GENERAL COMMENTS

All three applicants propose to develop all three of the allocated operating rooms in a dedicated ambulatory surgical setting. All recognize the growth in outpatient surgery cases and the need for this additional capacity in the service area. However, CFSC believes that it has presented the most compelling application to develop these three operating rooms. In addition to the many reasons included in the CFSC application, the following factors show that CFSC is the most effective applicant for the operating rooms:

- Cape Fear Surgery Center is the only applicant that has the specialty support to develop a new multispecialty ambulatory surgical facility;
- Cape Fear Surgery Center is the only applicant to propose a new joint venture of the largest provider groups in the county that will bring together referring physicians, surgeons, and the local provider of emergency and inpatient services;
- Cape Fear Surgery Center is the only applicant to bring together the two Accountable Care Organizations (ACO) in the area, which serve thousands of covered lives across the region;
- Cape Fear Surgery Center is the only applicant with the ability to expand the available capacity of dedicated outpatient surgery in the county by converting existing hospital-based shared operating rooms and shifting cases from the hospital to a lower cost, high quality setting;
- Cape Fear Surgery Center is the only applicant that proposes an approach with the ability to align the incentives of each of its partners to coordinate and provide an unparalleled collaborative approach that achieves the Triple Aim: improving the patient experience of care (including quality and satisfaction); improving the health of populations; and, reducing the per capita cost of healthcare;
- Cape Fear Surgery Center is the only applicant that proposes the capability to share health information data by leveraging the regional health information exchange and its own reporting systems to provide a seamless continuum of care for patients; and,

- Cape Fear Surgery Center is the only applicant that addresses the core need in the SMFP: additional surgery capacity based on surgical volume growth and a deficit of operating rooms at New Hanover Regional Medical Center.

With regard to the last point, CFSC recognizes that the way in which the need determination was generated does not guarantee that the entity that generated the need will be awarded the CON; in fact, New Hanover Regional Medical Center, whose volume generated the need, has not proposed to develop the three new operating rooms. However, as explained in the CFSC application, NHRMC is the only existing provider to show a current and projected deficit of operating rooms; Wilmington SurgCare has a current and projected surplus of operating rooms. As such, the project proposed by CFSC will more effectively meet the need at NHRMC by allowing cases at the highly-utilized medical center to shift to the proposed ASC, where outpatient cases can be performed more efficiently and at a lower cost. As detailed in the CFSC application, both the current and projected deficit of operating rooms at NHRMC and the current and projected surplus of operating rooms at SurgCare are clear from the methodology in the 2016 SMFP. It is only through extraordinary and incredible growth projections that the other applicants project a need for three operating rooms. In contrast, CFSC's project will accommodate the growth at NHRMC through the shifting of appropriate outpatient surgical cases from a hospital setting to the proposed ASC.

CFSC also believes that it is the only applicant that has demonstrated conformity with the statutory and regulatory review criteria, and is therefore the only applicant that should be approved. The following sections provide the detailed comments on each competing application.

APPLICATION-SPECIFIC COMMENTS

Surgery Center of Wilmington (SCW)

SCW proposes to develop a three-OR, one procedure room ASC in Wilmington. Although the application projects to perform neurosurgery, ophthalmology and dental cases in the ASC, it is clear from the lack of support from other specialties that the proposal is essentially a single specialty neurosurgery ASC, with the other specialties added in an attempt to have the necessary volume for all three allocated ORs and to make the application more competitive. As detailed below, CFSC does not believe that SCW has adequately demonstrated the need for its project and should not be approved.

Unreasonable Utilization Projections

As noted above, the majority of the support for the application as well as the programmatic discussion (e.g. Spine Center designation, etc.) is around the neurosurgery component of the project. However, more than two-thirds of the operating room utilization projected in the application is for ophthalmology, as shown in the following table.

Specialty	*Projected Cases in Year 3*	*Percent of Total*
Neurosurgery	1,048	31.5%
Ophthalmology	2,274	68.5%
Total	**3,321**	**100.0%**

Source: Application, page 40

Clearly, without the proposed ophthalmology volume, there is no need for the proposed three operating rooms.

Ophthalmology

With regard to ophthalmology, the application fails to demonstrate that the projected number of cases is reasonable, based on several factors. First, while ophthalmology surgical cases have grown in New Hanover County facilities in recent years, the vast majority of those cases (over 80 percent) are already performed in dedicated ambulatory settings, as shown below.

Facility	*OP Cases (2015)*	*Percent of Total*
Wilmington SurgCare	4,500	50.7%
Atlantic Surgicenter	2,540	28.6%
NHRMC	1,833	20.7%
Total	**8,873**	**100.0%**

Source: 2016 License Renewal Applications

According to the Wilmington SurgCare License Renewal Application, 18 ophthalmologists have privileges there, and the New Hanover Regional Medical Center website lists 23 ophthalmologists with privileges.

Thus, it appears that ophthalmologists have sufficient access to operating rooms in New Hanover County.

It is also commonly understood that ophthalmic surgery cases times are generally much shorter than other specialties, taking as little as 15 to 20 minutes per case, significantly less than the 1.5 hours recognized by the SMFP methodology for ambulatory surgery cases. Thus, from a practical perspective, although ophthalmology cases are numerous, their short case times mitigate their impact on operating room capacity. Further, many of these low acuity cases, particularly cataract surgeries, are expected to migrate to an office-based setting in the future, as payment reform encourages providers to utilize lower cost settings where appropriate. CMS is currently considering paying facility fees for in-office cataract surgery, as documented in numerous articles[1], including one from the American Academy of Ophthalmology, which will encourage this transition.

Most importantly, the application fails to demonstrate that its utilization projections for ophthalmology are reasonable. **The application contains no letters of support from local ophthalmologists who support the project or who intend to do surgery there**. The only support from an ophthalmologist is from Carolina Eye Associates and Dr. Mincey, whose closest office appears to be in Pinehurst, more than two hours' drive time from Wilmington. There is no indication that Dr. Mincey is familiar with the Wilmington market, the capacity of local ophthalmologists or the need for additional ophthalmologists in the area. Dr. Mincey's letter does not provide any estimates of the number of cases the surgeons in his practice typically perform, the number of years a new surgeon must practice before achieving that average number of cases, or any other statistics to support the utilization projections in the application. To support its projected 2,274 ophthalmology cases, SCW provides the following explanation under the table on the first page of Exhibit 20:

> *"Based on data from SCA facilities in which Carolina Eye Associates physicians perform surgery, it is common for ophthalmologists to perform anywhere from 500 to 2500 cases annually. As a result, SCW conservatively interprets 'substantial' to include one provider with 200 and one provider with 500+ cases."*

No evidence is presented to support SCW's interpretation of the term "substantial." Even assuming that there were a need for additional ophthalmologists in New Hanover County, and assuming that they would practice at SCW's proposed facility, SCW's interpretation appears to sum to only 700 cases; thus, the source of the balance of the 2,274 cases is unclear. The assumptions provided on pages 95 and 96 of the application are also unreasonable. The application assumes that SCW can achieve a market share of 18 percent of ophthalmic surgeries by 2021 with only one surgeon. However, based on the documentation from the License Renewal Applications shown in the table above, it would appear that the 8,873 cases performed in New Hanover County in 2015 were performed by at least 23 surgeons (assuming all of those privileged at Wilmington SurgCare also have privileges at NHRMC), equating to an average of 386 cases per surgeon—not 2,274—which is 4.3 percent market share per surgeon. Thus, the projection that one (or even two) new surgeon(s) in the area could grow the market share of a new practice from zero to 18 percent or higher in year three, with no documented support of local surgeons is not reasonable.

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[1] See, e.g., http://www.healio.com/ophthalmology/practice-management/news/print/ocular-surgery-news/%7B04bf9725-e0f6-42d7-bc18-b5345aaf3335%7D/cms-assesses-office-based-cataract-surgery; http://ophthalmologytimes.modernmedicine.com/ophthalmologytimes/news/office-based-surgery-coming-sooner-you-think; https://www.aao.org/eyenet/article/office-based-cataract-surgery

If Carolina Eye Associates did expand into New Hanover County, it is doubtful that they would be successful in generating the volume projected by SCW. Using a physician planning model, the population of New Hanover County supports the need for 13.1 FTE ophthalmologists. Based on information from the North Carolina Medical Board, there are 29 licensed ophthalmologists who reside in New Hanover County. Even under a conservative assumption that these ophthalmologists care for residents of New Hanover County only one-half of their practice time, the equivalent of 14.5 FTE ophthalmologists would remain to care for the New Hanover County population, more than sufficient to meet the need, limiting the potential for Carolina Eye Associates to be successful in this market.

In circumstances in which applicants have projected services that require physicians in a specialty for which they have little to no local support, the Agency has historically found that the applicant failed to demonstrate need. For example, in the 2011 Wake County Acute Care Bed review, the Agency determined that one of the applicants, Novant Health, did not demonstrate that its projected obstetrical service was reasonable, given the lack of physician support in the same county as the proposed facility, even though (unlike SCW's application) there was support from a physician in that specialty in a contiguous county:

> *"However, the applicant did not provide sufficient documentation from obstetricians practicing in Wake County and surrounding areas to support the reasonableness of its utilization projections for obstetrical services. The applicant states it* 'will achieve a market share of 40% of total births in the Primary Service Area' *by the second and third years of operation (2016 and 2017). However, Exhibit 14 does not contain any letters of support from obstetricians practicing in applicant's proposed service area, or from any other Wake County obstetricians. Exhibit 14 contains only one letter an obstetrician in the local area expressing support for the proposed hospital, and that obstetrician practices in Durham. Exhibit 14 also contains a letter of support from the obstetrician who the applicant identifies as the medical director for obstetrical services, however that physician practices in Winston-Salem. In Section V.3(b), page 228, the applicant provides a list of physicians by medical and surgical specialty that support the proposed hospital, but the list does not include obstetricians."*
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> See Agency findings for Project ID # J-8673-11 at page 130.

Similarly, without support from the surgeons who would actually perform the 2,274 cases projected by SCW, and without any support from local ophthalmologists, the utilization projections are not reasonable.

Dental Surgery

The application fails to demonstrate the need for the dental cases it proposes to perform in the ASC. It should be noted that in 2015, the State Health Coordinating Council discussed at length the need for operating room capacity for dental cases; the result of that discussion was a need determination for four ASCs across the state to be part of a demonstration project for dental ambulatory surgical facilities. The CON reviews for those proposals are complete, and none were submitted or approved for New Hanover County. In addition, the approved application for Health Service Area V was approved in Fayetteville. The service area for that approved application includes counties that SCW included in its patient origin on page 80, including Duplin and Columbus counties (an aggregate of 8.1 percent), and counties that it also included as sources of patients (Brunswick and Pender, up to 2.0 percent). See Project ID # M-

11176-16 at pages 118 through 121. The SCW application assumes that 39.28 percent of its patients will originate from these four counties, which equates to 117 patients (297 x 39.28% = 117) in counties that are part of the service area for an approved dental-only ASC in Fayetteville and unlikely to seek care at the proposed facility in Wilmington. It should also be noted that while the projected patient origin for the application is based on the historical patient origin at SurgCare because it "provides all of the specialties proposed by the applicant[2]," SurgCare does not report that any dental or oral surgery cases have been performed there, nor that any dentists or oral surgeons have applied for privileges. Thus, both the projected volume and the patient origin for dental cases are not based on reasonable assumptions.

Moreover, the application projects that none of these cases require a licensed operating room, but that all will be performed in the proposed procedure room. The application fails to demonstrate why existing procedure rooms in the county cannot accommodate this low number of cases (297 in year three), nor does it indicate that the dentists and oral surgeons cannot access these rooms. While the application states that "Wilmington SurgCare does not offer oral surgery" (page 96), it provides no evidence of barriers to oral surgeons at that facility or others.

The application also fails to provide sufficient staffing for this service. As shown on the staffing table in Section VII, there are no RNs listed for the procedure room. Given the nature of the patient population, particularly pediatric patients, and the proposed use of anesthesia, the procedure room would require at least a 1:1 nurse to patient ratio. The support letters from the dental practitioners indicate no intent to provide nurses or other clinical personnel for the project.

Finally, given that all of the dental "surgery" cases are proposed to be performed in the procedure room, not an operating room, these cases do not support the utilization of the three operating rooms that are the central focus of the SCW project. The letter from the pediatric dental group with the highest number of referrals (the last page of Exhibit 20) indicates support for "dedicated operating room space" for these cases; thus, this letter does not support the provision of these cases in the proposed procedure room, and it is therefore unclear whether the dentist would be willing to be limited to using the procedure room as proposed in the application.

Neurosurgery

As stated above, neurosurgery is really the only specialty for which there is any significant support from the surgeons practicing in the community. However, even with regard for neurosurgery, CFSC believes that SCW has overstated its utilization projections. Specifically, the letters of support from the surgeons provide estimates of the number of cases per month they believe they will perform there. Using the higher number of the range of estimates, the five supporting neurosurgeons project a total of 72 cases per month, which equates to 864 per year.

The application provides a list of surgeries by CPT code performed by the supporting neurosurgeons (Exhibit 19). This list equates to 818 cases per year. Thus, based on the actual cases performed by the neurosurgeons that are appropriate for an ASC (818) and the number projected to be performed in the ASC by the surgeons in their letters (up to 864), the maximum number of ASC-appropriate cases is between 818 and 864 per year. In addition, it should be noted that this number is truly a maximum,

[2] SCW application, page 80.

since the list of surgeries by CPT code does not exclude cases which should be performed in a hospital setting, due to the patients' ASA classifications, which are not shown in the list in Exhibit 19.

Since all of the neurosurgeons practicing in the county provided support letters with projected numbers of cases, the best approximation for the number of cases to be performed is the estimate from these physicians, which is a maximum of 864 cases. There simply is no reasonable basis for the application's projection of 1,048 neurosurgery cases.

Based on the issues described above, CFSC believes that the SCW application is non-conforming with Criteria 3, 5, 7, and 8 and the related CON rules.

SCW's Proposed Project Cannot Be Developed as an ASC

While stating its intention to do so, the application does not demonstrate that it will develop a multispecialty ambulatory surgical facility. The application projects that its operating rooms will provide two specialties, neurosurgery and ophthalmology, and that the procedure room will provide oral surgery. Even assuming that the proposed facility would provide any ophthalmology cases (see discussion above), ophthalmology and oral surgery are, at best, two of the three specialties needed to be considered a multispecialty ambulatory surgical program. According to NCGS 131E-176(15a) a multispecialty ambulatory surgical program is:

> *"a formal program for providing on a same-day basis surgical procedures for at least three of the following specialty areas: gynecology, otolaryngology, plastic surgery, general surgery, ophthalmology, orthopedic, or oral surgery."* (emphasis added)

As shown in the table below, excerpted from page 98 of the application, SCW projects cases in three specialty areas: neurosurgery (which is not included in the statutory definition), ophthalmology and oral surgery.

Table IV. 8 – SCW Projected Case Volumes by Specialty

Year	2019	2020	2021
Neurosurgery	766	934	1,048
Ophthalmology	1,138	1,681	2,274
Oral Surgery	190	262	297
Total	2,094	2,877	3,619

Numbers in these tables may not foot exactly because of rounding

Thus, based on its own projections by specialty, the application does not propose a multispecialty surgical program. According to NCGS 131E-176(1b), an "ambulatory surgical facility," which SCW proposes to develop, is "*a facility designed for the provision of a specialty ambulatory surgical program or a multispecialty ambulatory surgical program*." Thus, since SCW does not propose a multispecialty ambulatory surgical program, it must be a specialty ambulatory surgical program in order to be licensed as an ASC. However, according to NCGS 131E-176(24f) a "specialty ambulatory surgical program" is *"… a formal program for providing on a same-day basis surgical procedures for only the specialty areas*

identified on the ambulatory surgical facility's 1993 Application for Licensure as an Ambulatory Surgical Center and authorized by its certificate of need…." Since SCW was not licensed in 1993, it cannot be a specialty ambulatory surgical program. With neither a specialty nor multispecialty ambulatory surgical program, the proposed facility cannot be developed as a licensed ambulatory surgical facility.

Moreover, even if the proposed facility could be developed as a specialty ASC, it would require another certificate of need in order to add a specialty, per NCGS 131E-176(16r). Thus, SCW is, at best, limited to the three specialties it listed, and cannot add others without a CON. Given the issues with its utilization projections and lack of support from local surgeons (other than neurosurgeons), this limitation will further hinder SCW's ability to fully utilize its operating rooms.

Since the application states its intention to develop a multispecialty ambulatory surgical facility but has not demonstrated that it can meet the requirements of the statute, or that it can be developed as a licensed ASC, the application should be found non-conforming with Criterion 3.

Capital Cost, Applicant and Fee Issues

The application has multiple issues with regard to the projected capital cost, the applicants for the proposal and the CON fee, all of which make the application unable to be approved.

CON Fee

In order to be reviewed, the application must be submitted with a fee check that corresponds with the capital cost of the project. Specifically, 10A NCAC 14C .0203(c)(1) requires that the requisite fee be submitted in order for the application to be deemed complete, and 10A NCAC 14C .0203(e) requires applicants to provide that information prior to the beginning of the review period. According to the fee sheet submitted with the application, the total fee due is $30,936. However, the scanned check copy included with the application is for $30,929, indicating that the fee check is less than what is required to deem the application complete.

Further, as explained in more detail below, the application improperly excluded the capital cost for the lessor's portion of the project ($4,710,882), and as such, the proper fee should have been $45,068. In either case, the application did not include the requisite fees and should not be reviewed or approved.

Applicants and Capital Costs

The application includes a sole applicant, Surgery Center of Wilmington, LLC, which will lease the ASC from a related lessor, Surgery Center of Wilmington Properties, LLC. The application states on page 13 that CON analysts provided guidance that the lessor did not need to be an applicant; however, there is no evidence that the applicant provided all necessary information to the analysts, nor is there information regarding the statutory basis for the analysts' position. Page 15 of the application makes it clear that the proposed building *"will be constructed as a shell building suitable for healthcare purposes such as an ambulatory surgical facility or a medical office building."* However, it is clear from the CON statute that such construction is a new institutional health service, which requires a CON.

With regard to the notion that the construction will be for a medical office building, the application provides evidence that the building does not constitute a medical office building, nor is its construction

exempt from review. The line drawings in Exhibit 6 distinctly show that the building will not house physician offices, but will be developed for and house only the ASC. The application states on page 31 that the "*entire building design will meet appropriate building codes from* [sic] *ambulatory surgical facility*." Moreover, even if it were a physician office building, it would not be exempt from review. Specifically, NCGS 131E-184(9) discusses the exemption of a physician office building stating that it is exempt regardless of cost "*unless a new institutional health service other than defined in G.S. 131E-176(16)b. is offered or developed in the building.*" The proposal is to develop an ambulatory surgical facility, which is a new institutional health service per NCGS 131E-176(16)(a). Thus, the building cannot be exempt as a physician office building, and its cost, which exceeds the $2 million capital threshold, is a new institutional health service.

Since the lessor is not proposing a medical office building, it is proposing to construct an ambulatory surgical facility, which is a new health service facility. New health service facilities are new institutional health services and require a CON, per NCGS 131E-176(16)(a). Moreover, given that the lessor and lessee are related entities, the need to include all of the capital costs associated with the development of the ambulatory surgical facility is more evident.

Given the understated capital costs and the lack of a necessary applicant, the application should be found non-conforming with Criteria 3 and 5 and should be denied.

Wilmington SurgCare (SurgCare)

SurgCare proposes to develop three new operating rooms and one procedure room in its existing facility in Wilmington, as well as to close its existing GI endoscopy rooms and renovate the facility. Based on the discussion below, CFSC believes that the SurgCare application is non-conforming with several review criteria and should not be approved.

Unreasonable Utilization Projections

Unreasonable Growth Rates

On page 55 of the application, SurgCare states that it assumes a 5.5 percent annual growth assumption, based on several factors that it lists there and in Exhibit 48. However, this assumption is unreasonable for several reasons. First, all of these listed components have existed historically, yet SurgCare's historical volume trend has been lower than 5.5 percent. The application does not explain why these trends will result in more growth in the future than they have historically. Second, although the application states that the 5.5 percent rate is lower than its historical compound annual growth rate (CAGR) of 7.03 percent, that CAGR was measured over 20 years…a much longer period than the applicant's forecast period, and is therefore an unreliable estimate of growth through the third project year. Third, the application states that the 5.5 percent is lower than the CAGR of 11.2 percent for the historical growth in its medical staff; however, that growth rate did not result in a corresponding growth in surgical cases, and is thus also an unreliable proxy for surgical case growth. In fact, based on the experience of CFSC physicians, it is not uncommon for surgeons to obtain privileges at SurgCare but not perform a single case there. This lack of connection between the growth in the medical staff and the growth in surgical volumes is most apparent for gastroenterologists, which, according to the table on page 39, grew from one to four physicians from 2013 to 2016, a growth of 400 percent, while GI endoscopy procedures declined from 435 in 2014 to 213 in 2016, a CAGR of -27 percent. Fourth, the applicant compares the projected growth rate to one historical year—2014 to 2015—to support its projections; however, the most recent year of growth—2015 to 2016—shows a much smaller increase of only 1.87 percent, as noted on page 53. Fifth, as shown in the table below, the applicant's historical volumes have been inconsistent over the past four years; therefore, its projected high and steady growth rate is even more unreasonable. Finally, as shown on page 63 of the CFSC application and duplicated below, a more reasonable four-year timeframe shows that SurgCare has experienced much lower growth rates in recent years. Thus, the 5.5 percent annual growth rate is simply unsupported and unreasonable, based on much lower historical growth.

New Hanover County Operating Room Utilization

	FFY12	*FFY13*	*FFY14*	*FFY15*	*CAGR*
New Hanover Regional Medical Center					
NHRMC Inpatient Cases	9,003	9,506	10,625	10,932	**6.7%**
NHRMC Outpatient Cases	17,204	20,761	22,924	23,203	**10.5%**
Total Surgical Hours*	52,815	59,660	66,261	67,601	**8.6%**
Wilmington SurgCare					
Wilmington SurgCare Outpatient Cases	7,728	8,378	7,935	8,463	**3.1%**
Total Surgical Hours*	11,592	12,567	11,903	12,695	**3.1%**

Source: *2014 to Proposed 2017 SMFP*s.

If the most recent year of data included in the application were added to the table above (8,621 cases in annualized 2016 per page 53 of the application), the outpatient surgical CAGR for SurgCare would decrease to 2.8 percent. Clearly a sustained 5.5 percent growth rate through 2022 is not supported.

It is also unclear whether the applicant could meet the projections during the interim years. On page 58, the application projects a total of 15,185 surgical hours in 2019, the last interim year. Based on the 1,872 hours per operating room per year cited on page 58 of the application, SurgCare would need 8.1 operating rooms in order to reasonably perform those cases. The application fails to describe how it would accomplish this; therefore, the project year volumes, which are predicated on the interim case volumes, are unreasonable.

Unreasonable Need Analysis

In addition to these issues, the application contains several other assumptions that do not support its proposed project.

- On page 43, the application discusses the average case time at SurgCare, which is 48 minutes. This short case time is likely due to the high number of ophthalmology cases, as the application discusses. Whatever the reason, with an average case time just under one-half the SMFP methodology assumption for outpatient cases (1.5 hours), the need for additional capacity at SurgCare is less than it appears.
- Although the application discusses “physician recruitment” on page 100, SurgCare does not recruit physicians in the traditional sense. That is, SurgCare may look for physicians who are in the area or are moving to the area and ask them to join its medical staff; however, it does not

recruit, incentivize or employ physicians like a hospital or physician practice. As such, it does not drive organic growth of physicians in the area.

- The application projects to increase the number of patients it serves from Brunswick County by hundreds of cases, based on no projected change in patient origin. Given the need determination for an operating room in Brunswick County, it is reasonable to assume that some of the historical volume coming to New Hanover County from Brunswick will shift there. Thus, the application should have accounted for this likelihood.
- On page 32, the application discusses the increase in joint replacement surgeries being performed in ASCs instead of hospitals. CFSC agrees that this is not only a trend, but of benefit to patients and payors. However, unlike CFSC, SurgCare, does not propose to actually perform these cases in its ASC.
- On page 42, the application argues that its proposal is more effective than the development of a new ASC since new providers will have to negotiate new contracts with insurers and seek certification from the Centers for Medicaid and Medicare Services. CFSC believes that this factor is actually an argument in favor of a new provider, as CFSC proposes, in that it will bring additional competition from a new ASC provider in the area. As noted below in the comparative analysis, CFSC's proposed revenues are lower than SurgCare's, a fact that supports the need for an alternative provider in the area.

The SurgCare Project Does Not Require a CON

SurgCare's proposed project involves extensive renovation and expansion of the existing facility, as described on pages 45 through 47, all of which can be accomplished through an exemption notification to the CON Section, per NCGS § 131E-184(g), including the proposed addition of a minor procedure room. The only component of the project which would require a CON is the development of three new operating rooms. However, as described above, SurgCare does not reasonably project the need for these operating rooms, based on either quantitative or qualitative factors.

Even assuming for the sake of argument that SurgCare's utilization projections are reasonable, the facility still does not demonstrate the need for the three additional operating rooms. The majority of SurgCare's surgical cases are appropriate for procedure rooms. The application stresses its ability to add procedure rooms without adherence to "CON regulatory criteria or performance standards" on page 60 and refers to a letter from the former Director of DHSR regarding its ability as a licensed facility to add procedure rooms without a CON. Moreover, the facility already operates three GI endoscopy procedure rooms, which can be renovated, expanded or otherwise made capable of performing surgical cases (assuming they are not already constructed as such)—all without a CON.

CFSC is not suggesting that procedure rooms are completely interchangeable with operating rooms; however, SurgCare's specific circumstances warrant this consideration. In particular, several unique factors make the use of procedure rooms for SurgCare's high volume, low acuity surgical cases a more effective and a less costly alternative:

1. SurgCare has three existing procedure rooms, which are severely underutilized and all of which it intends to delicense (i.e. using them for other types of cases would not impair the current use of those rooms);
2. While GI endoscopy procedures may not be performed in non-GI procedure rooms, nothing precludes the use of GI endoscopy procedure rooms for non-GI cases (particularly given the low utilization of these procedure rooms at SurgCare);

3. The majority of SurgCare's surgical cases are ophthalmology cases, which (particularly in an ASC setting) are generally low acuity and can easily be performed in smaller rooms.
    a. On page 52, SurgCare provides a table showing 4,586 of its 8,621 surgical cases (or 53.2 percent) were ophthalmology in the year ending August 31, 2016.
    b. The SurgCare application projected a single growth rate for all its surgical cases, without any difference by specialty; thus, notwithstanding its unreasonable growth rate, ophthalmology cases will remain 53.2 percent of its projected total cases.
    c. Assuming for this analysis that its projected 11,887 surgical cases in year three were reasonable, SurgCare would perform 6,324 ophthalmology cases in year three (53.2 percent of the total).
    d. Given this level of volume, SurgCare could use these procedure rooms exclusively for ophthalmology and other minor surgical and non-surgical cases (the latter two of which it proposed in its application), without needing to perform any other types of cases in these rooms. While some ophthalmology cases might still need to be performed in the operating rooms, none of the larger, higher acuity surgical cases would need to be performed in the procedure rooms, due to the high percentage of ophthalmology cases at SurgCare.
    e. Since ophthalmology cases typically require less time than the average case, it is reasonable to assume that the procedure rooms would be able to accommodate most of these cases. However, even if SurgCare shifted only one-half of these cases to procedure rooms, the remaining surgical cases could be performed in its existing seven operating rooms, without any additional OR capacity, as shown below.

	SurgCare Year 3
Projected Total Surgical Cases	11,887
Less ½ of Ophthalmology Cases	-3,162
Remaining Surgical Cases	8,725
Hours for Remaining Cases (1.5/case)	13,088
Annual Hours/OR	1,872
Total ORs Needed	**7.0**
Existing ORs at SurgCare	**7.0**
Additional ORs Needed	**0.0**

4. SurgCare's application recognizes both the clinical appropriateness and the regulatory ability to use its proposed procedure room for surgical cases, stating on page 60, *"…SurgCare may choose to utilize the minor procedure room for other surgical specialties, including ophthalmology…."* Thus, SurgCare recognizes the utility of procedure rooms for these ophthalmology cases, at a minimum.
5. Thousands of ophthalmology cases are currently performed in procedure rooms in licensed facilities in North Carolina, indicating that SurgCare's position regarding these cases is neither unusual nor inappropriate.

Given SurgCare's ability to pursue the proposed renovation and expansion without a CON, and with the unique opportunity that it has to better utilize its existing procedure rooms for its highest volume surgical cases, the application does not demonstrate the need for the three additional operating rooms, nor that its proposal is the most effective or least costly alternative.

Improper Calculation of Surgical Volume

As noted above, the application proposes to close its GI endoscopy procedure rooms and move that volume into its surgical operating rooms. While there is nothing to prohibit SurgCare from proposing this change, the application contains a critical error by including the GI endoscopy procedure volume with its calculation of surgical volume and demonstration of need. Since the GI endoscopy procedures are not surgical cases, they cannot be counted towards the demonstration of utilization to meet the CON rules or to demonstrate the need for operating rooms under Criterion 3. Even assuming that they could be counted as surgical cases, the assumption of 1.5 hours per case is incorrect, as the CON rules for GI endoscopy assign only 1.0 hours per procedure. In addition to the negative impact of this error on its projected surgical hours and operating room utilization, the majority of SurgCare's projected utilization is ophthalmology cases, as described in detail above, which can be performed in its existing procedure rooms. With the exclusion of the GI endoscopy cases from its surgical volume, and the more effective use of its procedure rooms for ophthalmology cases, SurgCare has failed to demonstrate a need for any of the proposed additional operating rooms.

Based on the above factors, CFSC believes that SurgCare should be found non-conforming with Criteria 1, 3, 4, 5, 6, and the applicable CON rules.

COMPARATIVE COMMENTS

Given that all of the applications propose to meet the need for all three new operating rooms, only one of the applications can be approved as proposed. In reviewing the comparative factors that are applicable to this review, CFSC compared the applications on the following factors:

- Geographic Access
- Alternative Provider of Ambulatory Surgical Services
- Documentation of Physician Support
- Access by Underserved Groups
- Revenue
- Operating Expenses

Geographic Access

New Hanover County is relatively small in terms of square miles compared to other counties in the state; however, it has the 8th highest population among the 100 counties in the state. As a result, the density of the population is high, and traffic congestion creates issues in getting around the county. The county really has only one city that could support an ASC—Wilmington—with the other population centers in the smaller towns along the beach. Thus, all three applicants propose a location in Wilmington. However, CFSC does believe that it is important to consider that both CFSC and SCW propose new locations for ASCs, which will expand access to patients in a heavily-populated community. In such a comparison, CFSC and SCW would be comparatively superior to SurgCare.

Alternative Provider of Ambulatory Surgical Services

Currently, there are two existing providers of ambulatory surgical services in the county: New Hanover Regional Medical Center and Wilmington SurgCare; however, Wilmington SurgCare is the only existing freestanding (non-hospital based) provider of ambulatory surgical services. Both SCW and CFSC would create a new provider of ambulatory surgical services in New Hanover County. Although NHRMC is a member of CFSC, CFSC would nonetheless be a new provider: separately licensed and accredited, with independent negotiations with managed care payors, and not managed by the hospital. In every key aspect, CFSC will be a new competitor with both NHRMC and SurgCare. Thus, both SCW and CFSC are comparatively superior to SurgCare as alternative providers of ambulatory surgical services.

Documentation of Physician Support

Physician support for the project is important, particular given the proposed increase of three operating rooms in the county. While all of the applications include letters of support from physicians, the amount of support from physicians that can drive the success of the project—specifically referring physicians and surgeons—is different among the applications, as shown in the following table:

Applicant	*Referring Physician and Surgeon Letters*
Surgery Center of Wilmington	8*
Wilmington SurgCare	35
Cape Fear Surgery Center	71

*Includes the letter from the pediatric dentist

Clearly, the applicant with the comparatively superior documentation of physician support is CFSC.

Access by Underserved Groups

The tables below show the relevant comparisons of projected care to the underserved:

Applicant	*Charity Care (Percent of Gross Revenue)*
Surgery Center of Wilmington	1.0%
Wilmington SurgCare	0.1%
Cape Fear Surgery Center	2.1%

Source: Form B, Year 3; detailed notes in the assumptions for SurgCare to extract Charity Care figures.

Applicant	*Medicaid (Percent of Revenue)*
Surgery Center of Wilmington	5.5%
Wilmington SurgCare	6.0%
Cape Fear Surgery Center	8.5%

Source: Form B, Year 3.

In terms of both charity care and Medicaid percentages, CFSC is the most effective applicant to expand access to the underserved. While CFSC may appear less effective with regard to Medicare percentages, the higher level of Medicare projected by the other applicants is driven by higher percentages of ophthalmology cases performed/projected by SCW and SurgCare (more than 50 percent of their respective volumes), not by a lack of access at CFSC.

Projected Revenue per Case

The following table shows the gross and net revenue per case for each applicant in year three.

Applicant	*Gross Revenue per Case*	*Net Revenue per Case*
Surgery Center of Wilmington	$8,176	$3,215
Wilmington SurgCare	$10,789	$1,619
Cape Fear Surgery Center	$4,527	$1,593

Source: Form B, Year 3.

Although all of the applicants propose a different mix of specialties, none are dedicated to a single specialty. Moreover, both SCW (projected) and SurgCare (historically) provide a significant amount of ophthalmology cases (more than one-half their respective volumes), which are typically lower revenue cases. Nonetheless, for both gross and net revenue, CFSC is clearly the most effective applicant, with much lower revenue than its competitors.

Projected Expenses per Case

The following table shows the projected expenses per case for the three applicants in year three.

Applicant	*Projected Expenses per Case*
Surgery Center of Wilmington	$2,466
Wilmington SurgCare	$1,391
Cape Fear Surgery Center	$1,463

Both SurgCare and CFSC are more effective than SCW. Although SurgCare projects slightly lower expenses per case than CFSC, considering the depreciation expense of a new, large ASC, CFSC believes that its expenses per case are reasonable and comparable to (within five percent of) SurgCare's expenses.

SUMMARY

In summary, CFSC believes that it is clearly the most effective alternative for the proposed three new operating rooms in New Hanover County. It is the only applicant that conforms to all the statutory and regulatory review criteria. It is comparatively superior on more relevant factors, including:

- Geographic Access
- Alternative Provider
- Documentation of Physician Support
- Access by Underserved Groups
- Projected Gross Revenue per Case
- Projected Net Revenue per Case

CFSC's projected expenses per case are also comparable with SurgCare and superior to SCW.

Based on these numerous factors, CFSC believes its proposal should be approved.