Comments on Competing Applications for Additional Operating Rooms in Wake County

submitted by

University of North Carolina Hospitals at Chapel Hill, Rex Hospital, Inc. and Rex Surgery Center of Garner, LLC

In accordance with N.C. GEN. STAT. § 131E-185(a1)(1), University of North Carolina Hospitals at Chapel Hill, Rex Hospital, Inc. d/b/a UNC REX Hospital, and Rex Surgery Center of Garner, LLC (collectively, "UNC Health Care System" or "UNC HCS") submit the following comments related to competing applications to develop additional operating rooms in Wake County. UNC HCS's comments on these competing applications 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). To facilitate the Agency's review of these comments, UNC HCS 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 on the following applications:

- **RAC Surgery Center ("RAC"), Project ID # J-11551-18**
- **Green Level Ambulatory Surgical Center ("Green Level"), Project ID # J-11557-18**
- **Duke Raleigh Hospital ("DRAH"), Project ID # J-11558-18**
- **WakeMed Surgery Center-North Raleigh ("WMSCNR"), Project ID # J-11564-18**
- **WakeMed Surgery Center-Cary ("WMSCC"), Project ID # J-11565-18**

General Comments

Among the nine applications, none proposed to develop all six operating rooms allocated in the *2018 SMFP*. As such, more than one application can be approved. The most recent allocation of operating rooms in the Wake County service area was in the *2010 SMFP*, which resulted in the approval of an ambulatory surgery center ("ASC") in Holly Springs. UNC HCS believes there are unique benefits to operating rooms in freestanding ASCs and different, but equally unique, benefits to operating rooms in hospital-based settings. For instance, ASCs provide outpatient surgery to lower acuity patients in a lower cost setting, and, ideally, can expand geographic access to patients through a location in an area of the county with insufficient access to surgical services. The tradeoff for ASCs, however, compared to hospital-based settings, is their shorter operating hours (both in terms of per day and number of days per week), inability to care for inpatients and emergency patients, and the exclusion of certain types of cases from reimbursement in an ASC. Hospital-based operating rooms, therefore, provide broader access to surgical services, with higher capacity per room based on typically longer hours of operation each day and more days of operation each week and greater ability to care for more highly acute patients. Given these factors and the circumstances of this review, UNC HCS believes that its proposed projects, which include some operating rooms in a hospital-based setting and some in an ASC setting should be approved. The comments below include substantial issues that UNC HCS believes renders the applications listed above non-conforming with applicable statutory and regulatory criteria. However, as presented at the end of these comments, even if all applications were conforming, the applications filed by UNC HCS are comparatively superior to the others and represent the most effective alternatives for expanding access to surgical services in Wake County.

COMMENTS ON RAC SURGERY CENTER

General Comments

RAC proposes to develop a newly licensed ASC with one operating room for the performance of vascular access procedures. Over the past couple years, there have been multiple *SMFP* petitions regarding the need for such ASCs; all have been denied. There have been many reasons for the denials, some of which are mirrored in the comments on the application below. Of note, neither the petitioners nor RAC has chosen to adopt any of the approaches recommended by the Agency in its reports on the petitions. UNC HCS believes the RAC application should be denied, based on the reasons cited in the Agency's report on the petitions, as well as the specific issues outlined below.

Issue-Specific Comments

1. RAC fails to demonstrate a reasonable basis for or need for the project.

   The foundation of the need argument in the application is the idea that the vascular access cases should be provided in a licensed ASC rather than a hospital because of improved access, lower costs and better outcomes. While it may be true that many patients with outpatient surgical needs that can be provided in a non-hospital setting benefit from access to an ambulatory surgical facility, the RAC application fails to demonstrate the need for its project based on these factors, for several reasons.

   First, the vast majority of the patient population proposed to be served at the RAC facility already has access to care in a non-hospital setting. As demonstrated on pages 31 and 32 of the application, RAC is already performing over 5,700 cases/procedures annually in its existing vascular access centers in Raleigh and Cary. These patients already have access to the office-based setting, which RAC presumably believes to be safe for these patients. The application fails to demonstrate why these patients need to be treated in an ASC, which would actually increase the cost of care, including expenses and actual charge to the patient, by adding a facility fee and costs for the development of the ASC that do not currently exist. Moreover, the application fails to demonstrate that any attempts were made to join the medical staff of the existing ASCs in the county, as suggested by the Agency in its analysis of the *SMFP* petitions, which would allow any cases that had to be performed in an ASC setting (as opposed to office-based), if any, to be performed there without necessitating the development of the proposed project.

   Second, the only cases that apparently cannot currently be provided in the office-based setting are the fistula creations, which total only 246 projected cases in Year 3. This represents less than 10 percent of the total cases/procedures projected in the ASC[1]. Thus, the only cases that arguably need to be performed in a licensed facility are these 246 cases. The application fails to demonstrate that there is insufficient capacity in an existing licensed facility in Wake County or elsewhere to accommodate this small number of cases. To wit, the proposed RAC facility is located near WakeMed's Capital City Surgery Center, which has capacity for these cases.

[1] See discussion below regarding the inconsistent utilization projections.

Third, the application uses contradictory language regarding the enhanced access it would provide. On page 12, the application states that it will provide "coordinated care for patients in that their dialysis therapy is available within minutes of the ASC." However, the patient origin projections and service area definition show that RAC expects patients to travel from up to several counties away, as far as Sampson and Halifax counties, to access services at the ASC. Given the need for dialysis treatment three times per week, the amount of time to be dialyzed during each treatment and the availability of outpatient dialysis service in each of the service area counties, it is simply unreasonable to believe that patients will travel to dialysis facilities near RAC for care. While the physicians involved in the proposed project may have office locations in these counties serving patients in their home county at a dialysis facility that treats them every other day, those patients certainly do not receive their treatment "within minutes" of the proposed ASC.

Fourth, the application asserts that no existing ASCs are equipped to treat the proposed patient population. However, the application fails to demonstrate that the physicians that would use the RAC facility have had any barriers in attempting to access existing ASCs, including the nearby Capital City Surgery Center, which has at least two operating rooms of available capacity in its operating rooms[2]. Moreover, according to the application, the vast majority (more than 90 percent) of the proposed cases/procedures can be performed in procedure rooms. The application fails to document any attempts to obtain access to procedure rooms at existing ASCs, which might include the ability to use a procedure room dedicated to these cases.

Fifth, the application provides no discussion regarding the fate of patients currently receiving these treatments in an office-based setting, but who would be subject to higher costs and charges in the proposed ASC. Given the high percentage of Medicare and dually-eligible Medicaid dialysis patients who this change would likely disproportionally impact, the application fails to show that these patients would not have diminished access following the development of the proposed project.

Sixth, the application fails to demonstrate that it can be developed as proposed. While the application notes that it has a transfer agreement with UNC REX Hospital, it does not demonstrate that its nephrologists or surgeon have or will have privileges at UNC REX Hospital, as required by the Division of Health Service Regulation through its licensure rules. Specifically, the licensure rule for ambulatory surgical facilities at 10A NCAC 13C .0402(a) states:

> *The governing authority shall delineate surgical privileges for each physician and dentist performing surgery in accordance with criteria which it has established provided, however, that no physician or dentist may be given privileges to perform surgical procedures for which he or she does not have privileges to perform at the hospital with which the facility has a transfer agreement as provided in Paragraph (a) in Rule .0403 of this Section.*

[2] See discussion below regarding the utilization of WakeMed's Capital City Surgery Center.

(emphasis added)

Thus, while UNC REX Hospital will accept transfers in accordance with the transfer agreement, RAC cannot meet licensure rules unless the physicians performing cases at the ASC also obtain privileges to perform the same cases at UNC REX Hospital. They do not currently have these privileges, nor is UNC REX aware of any application for privileges or any attempt to obtain or discussion regarding privileges for these physicians.

Based on these issues, the application should be found non-conforming with Criteria 1, 3, 3a, 4, 5, 6, 8 and 18a, as well as the performance standards at 10A NCAC 14C .2103.

2. The application fails to provide reasonable and supported utilization projections.

The application states that the utilization assumptions are based on the historical utilization at the Raleigh and Cary office-based centers and the letters from physicians who would practice at the proposed ASC. According to the table on page 31, the Raleigh and Cary centers performed 1,218 operating room-appropriate cases and 4,490 procedure room-appropriate cases in annualized FY 2018. The methodology then projects these cases to grow each year as a baseline volume, with additional assumptions for shifts and additional cases. Of note, the methodology does not project to capture 100 percent of the cases historically performed at the Cary facility.

At first glance, the net growth in cases and procedures appears to be fairly minimal, as the application projects 1,329 OR cases and 4,491 procedure room cases in the first year. However, when examined in light of the letters from physicians who will actually be performing these cases, the projected growth is substantial and not supported by the assumptions in the application. According to the support letters in Exhibit C-4, which are consistent with the totality of the physicians projected to utilize the facility in Section H, those physicians performed only 665 OR-appropriate cases and 2,897 procedure room-appropriate cases historically. Thus, the application projects the number of cases and procedures performed by these physicians to increase by 100 percent and 55 percent, respectively, which is clearly not supported by any assumptions, including the annual growth rates used in the application. Even if the addition of 246 fistula creation cases is included, the utilization projections are unreasonable, as shown in the table below.

Physician	***Historical OR Cases***	***Historical Procedure Room Cases***	***Total***
Adam Stern, MD	91	481	572
Byron Abels, MD	5	21	26
James Godwin, MD	103	482	585
Jeffrey Hoggard, MD	263	734	997
Karn Gupta, MD	81	614	695
Sejan Patel, MD	122	565	687
Total	**665**	**2,897**	**3,562**

Source: RAC Application, Exhibit C-4, pages 144-151

When compared with the projected utilization in the application, the actual projected growth rate in cases performed by these physicians is unreasonable and unsupported, as shown below.

Total Historical Cases	*Total Projected Cases- Year 3 (excluding new fistula creation cases)*	*Total Projected Case Growth*	*Total Projected Percentage Growth*
3,562	6,448	2,886	81%

Even factoring out the fistula cases that the application states cannot currently be performed in an office-based setting, the utilization projections assume that the historical cases will nearly double, growing over 80 percent by the third project year. While the physician support letters do claim that they expect their cases to grow significantly following development of the proposed project, there is simply no reasonable basis for the tremendous amount of growth projected in the application and support letters. In particular, the application provides no analysis of growth in the number of patients, disease incidence, market share, or any other factors that would support the growth in the number of cases projected to be performed by the six physicians involved in the project.

Based on these issues, the application should be found non-conforming with Criteria 1, 3, 5, 6, and 18a, as well as the performance standards at 10A NCAC 14C .2103.

3. The financial information and statements in the application contain multiple errors, omissions and inconsistencies.

Please note that many of the errors explained below are based on statements in the application that relate to the management services agreement (MSA) included in the application. While that may be the purported basis of the assumptions, it should be noted that the MSA is signed by Stephen Loehr, MD, who is not identified in the application as having a role in the project or authority to sign on behalf of an applicant. Therefore, it is unclear whether the included MSA is a valid and binding document.

a. No start-up costs/initial operating expenses. Although stating on page 51 that there will be "activities prior to the initiation of services" on the part of one of the applicants, the application provides no start-up or initial operating expenses showing the cost of these activities and how they will be funded. While it may be possible for an existing facility to cover the cost of such expenses, RAC is not an existing licensed entity, nor has it or the co-applicant demonstrated that they have other sources of revenue that will cover these expenses. Moreover, the application states clearly that these activities will be covered by the MSA; however, the cost of the MSA to cover these pre-initiation activities is not provided, either as a start-up cost or as an expense prior to operating the facility. Therefore, the application has understated its expenses and has failed to provide documentation of funding for these expenses.

b. No documentation of revenue for professional fees. The application states on page 53 that the facility will bill professional fees. The application form directs applicants

to separately list professional fees separate from other revenue and expenses. While the application shows the expense for professional fees, it fails to provide separate revenue for the professional fees, as directed. The assumption for the expense on the Fresenius Vascular Care Raleigh MSO, LLC ("MSO") income statement states "N/A," providing additional inconsistency. Thus, the reasonableness of the revenue assumptions cannot be determined.

c. Inconsistent and unreasonable assumptions regarding management fees. In Exhibit A-10.2, page 138, the MSA states that the management fee would be a fixed fee. However, the assumptions for Form F.3 for the MSO show management fees as 8.0 percent of revenue, which therefore varies with revenue and is not fixed. Further, the expense for the management fee appears on the income statement for MSO; however, it is clear from the MSA in Exhibit A-10.2 that MSO would be providing the services to the facility (RAC), and therefore, the expense should appear on Form F.3 for RAC, not the MSO. The pro forma for RAC therefore understates its expenses.

d. Understated capital costs. The architect letter provided in Exhibit K-4 states that the projected construction costs are $900,000; however, Form F.1a shows only $875,443 in construction/renovation costs. The application therefore understates the total capital cost by approximately $25,000. As a result, the applicant also failed to pay sufficient application fees based on correct capital costs.

e. Understated expenses/overstated net income. Form F.3 for the MSO on page 88 shows zero net income in Year 1. However, the total expenses ($7,571,934) clearly exceed the total revenue ($7,411,934) by $160,000, the amount of interest expense. In addition, the application fails to project any interest expense for Years 2 and 3, which is clearly inconsistent with the terms of the loan in Exhibit F.2-2 on page 184.

f. Balance sheet issues. The application contains a balance sheet, Form F.2, but it does not state which applicant entity's position it represents. In particular, it includes assets for both applicant entities, such as receivables for RAC and inventory for MSO, and similarly shows liabilities for MSO, such as salaries payable, but a fund balance (although technically equity) which presumably is for the RAC entity. This unconventional method of displaying balance sheet data does not provide a clear picture of the financial position of either applicant. Moreover, notably missing from the balance sheet is the $2 million liability proposed to be incurred by MSO for the capital costs of the project.

g. Inconsistent procedure room utilization projections. Form F.4 for the procedure rooms projects $18.6 million in gross revenue in Year 3, based on 1,625 cases with an average charge of $11,448. Form F.5 for the procedure rooms projects $6.2 million in net revenue in Year 3, based on 5,069 cases and an average reimbursement of $1,231 per case. Similar inconsistencies exist in Years 1 and 2. These gross and net revenue totals combined with those for the operating room provide the total revenue on Form F.3 for RAC. However, given the inconsistency in the number of cases projected on Form F.4 and F.5, it is impossible to determine which number of cases is accurate. Whichever is the correct case number, it is clear that the revenue projected for the inaccurate case number is also inaccurate, since it's based on the number of cases

times the average charge. As such, the financial statements are not based on reasonable projections of charges.

Based on these numerous issues, the application has failed to demonstrate the availability of funds and the immediate and long-term feasibility of the project, nor has it demonstrated that the projections of costs and charges are reasonable. As such, the application should be found non-conforming with Criteria 1, 5, 12 and 18a.

4. The application provides no documentation of accommodation of health professional training programs.

On page 72, the application makes clear that the physicians involved in the proposed project do not have existing relationships with health professional training programs. While the application states that the facility will be "open" to discussions regarding such relationships, it fails to demonstrate that the clinical needs of these training programs will be accommodated, as required. Moreover, the application provides no evidence of any attempts to establish such relationships. As an existing office-based provider performing thousands of these cases each year, the physicians have had ample opportunity to provide access to training programs already, or at a minimum, to establish relationships with such programs and offer access to the office-based center.

This issue is particularly important given the shortage of trained health professionals—locally, regionally and nationally. As healthcare utilization increases with population growth and aging—at least in some settings—the shortage of healthcare professionals will continue to be an issue unless the number being trained can be increased. The availability of training sites is an essential part of the solution to this problem.

The application fails to demonstrate that the facility will accommodate the clinical needs of health professional training programs. As such, it should be found non-conforming with Criterion 14.

COMMENTS ON GREEN LEVEL AMBULATORY SURGERY CENTER

General Comments

The application states multiple times that the Duke Health System is the only one in Wake County without a freestanding ASC in the county. While that statement might be true, that fact is a direct result of Duke's choice. In contrast, the other health systems in the county, particularly UNC REX, were proactive in recognizing the need for freestanding ASCs and used existing operating rooms to create better access for patients. Duke Raleigh Hospital continues to have that option as well.

Issue-Specific Comments

1. <u>The application fails to reasonably identify the patient population to be served.</u>

   On pages 18 and 19, the application provides projected patient origin, stating that it expects it to reflect the patient origin at Duke Raleigh Hospital. However, while the methodology does assume that many of the cases at the ASC will shift from DRAH, it is not reasonable to assume that the patient origin at a facility in Apex will be the same as the hospital in North Raleigh, for several reasons. First, the application provides as one of its supporting factors for the utilization projections the "reduced travel burden" and "convenient location" of the ASC (page 134). However, for patients that would be closer to DRAH, such as residents north or east of DRAH, the proposed location will not reduce their travel burden. In addition, Duke University Health System previously proposed to develop an ASC in Morrisville in Durham County, Arringdon ASC (Project ID # J-11508-18) which would be a more convenient location for patients from areas north and west of DRAH than would Green Level. In fact, as shown on page 132 of the Green Level application, patients are projected to be shifted from Duke Raleigh Hospital to the Arringdon ASC. Given its location, it is more reasonable that the patients north or west of DRAH would shift to Arringdon as opposed to a more distant location in Apex in southern Wake County. Second, the methodology assumes that more than 800 patients at the proposed ASC would shift from Duke University Hospital, which has a different patient origin than Duke Raleigh Hospital; the patient origin assumptions fail to account for the impact of these shifts. Third, given the specificity with which the application attempts to quantify the volume shifts by specialty, the data regarding patient origin for the cases to be shifted were surely available to allow the application to exclude patients who would more likely be treated at another facility, including Arringdon.

   Since it is unlikely that patients, especially those outside Wake County, would bypass other ASCs, particularly other Duke-owned ASCs, to access care at the proposed facility, the application's utilization projections based on this patient population are similarly unreasonable**. For these reasons, the application should be found non-conforming with Criterion 3 and the performance standards at 10A NCAC 14C .2103**.

2. <u>The application fails to demonstrate that its utilization projections are based on reasonable assumptions</u>.

   In Section Q, Form C, the application presents the methodology for projecting utilization for the proposed operating rooms. In Step 4, the methodology starts with total surgical

cases (12,604) and calculates the percentage that would be ASC-appropriate using several criteria, including the exclusion of pediatric cases, and arrives at a total of 7,664 cases, or 60.8 percent of DRAH's total surgical cases. In Step 5, the methodology applies the percentage, 60.8 percent, to the total projected outpatient cases for DRAH, to determine the percentage of cases that could be treated in an ASC. In Step 6, the methodology again starts with total surgical cases (12,604) and calculates the number of cases by specialty and the corresponding percentages represented by each specialty. In other words, both Steps 4 and 6 begin with the same number of cases and end with different subsets of that total. Thus, the number of cases by specialty shown in Step 6 have not had the criteria from Step 4 applied, and therefore include cases that would not be ASC-appropriate.

In Step 7, the methodology calculates the number of cases that it states could be shifted to an ASC based on the specialties expected to be performed at the ASC. This step starts with the total number of cases calculated in Step 5, then applies the percentages by specialty calculated in Step 6. This approach is unreasonable, however, since the percentage of total cases represented by each specialty calculated in Step 6 includes cases that would not be appropriate for an ASC. Thus, the percentage of each specialty that is ASC-appropriate cannot and should not be derived from the percentage of specialties that includes non-ASC appropriate cases.

For example, the application states that 1,027 Otolaryngology (ENT) cases, or 8.1 percent of the total, were performed at DRAH in FY 2018. While that may be factual, it does not follow that 8.1 percent of ASC-appropriate cases are ENT cases. In particular, as noted above, the methodology states in Step 4 that pediatric cases should be excluded. ENT is a specialty that typically includes many pediatric cases. As such, it is incorrect to assume that the percentage of total ENT cases (including pediatrics) would equal the percentage of ENT cases not including pediatrics. This is a single example, but the same problem exists with other exclusionary criteria, such as Medicare approval and ASA level.

To prevent this error, Step 6 of the methodology should have started with the ASC-appropriate cases, then determined their volume by specialty. The results of this revised step would then include the percentage of ASC-appropriate cases by specialty, not total cases by specialty, which cannot be accurately applied to a subset of the total cases, as was erroneously done in Step 7 of the application's methodology.

These errors flow through the remainder of the methodology, causing multiple issues with the projected utilization that cannot be resolved. First, the number of cases by specialty projected at the ASC are not based on reasonable assumptions. Using the ENT example from above, it is not reasonable to assume, nor can it be calculated from the information in the application that the number of ENT cases projected to be performed at the ASC do not include pediatric cases, as the percentage of cases by specialty flows from the calculation in Step 6, a step which does not exclude pediatric cases. Second, the total number of projected cases is therefore unreasonable, and the application fails to demonstrate that the application can reasonably achieve the required volume. Third, the financial projections, which are based on the volume by specialty projected in the application, also are not based on reasonable assumptions and the financial feasibility and reasonableness of the costs and charges has not been demonstrated.

The application also contains letters of support from pediatric surgeons, particularly pediatric urologists, who state their intention to perform cases at the proposed ASC. These letters are inconsistent with the representations in the application, including the utilization projections, which purportedly exclude pediatric cases as the applicant does not intend to perform these cases at the ASC. This inconsistency further undermines the reasonableness of the utilization projections.

Based on these errors, the application should be found non-conforming with Criteria 3 and 5, and the performance standards at 10A NCAC 14C .2103.

3. <u>The application fails to demonstrate that its projected payor mix is based on reasonable assumptions.</u>

In Section L.3.(b), the application provides its payor mix projections and refers to the methodology shown in Exhibit 12. In that exhibit, the application provides payor mix by specialty for outpatient cases at DRAH and Duke University Hospitals. The application then applies these percentages to the shift by specialty projected from each of the facilities. This methodology is not a reasonable approach to determining the projected payor mix at the ASC, based on similar flaws noted in #2 above. Specifically, the methodology assumes that the payor mix for each specialty, based on the total number of cases, will be the same for each specialty after the exclusionary criteria for the ASC are applied. This assumption is simply unreasonable. Using the application's own language from pages 103 and 104:

> *"For example, 43.5% of surgical cases at Blue Ridge Surgery Center (BRSC) were ENT, which typically includes a large number of pediatric patients. Many pediatric patients have Medicaid coverage, and this is reflected by the 9.0 percent Medicaid payor mix at BRSC. (Green Level ASC will provide ambulatory surgical services primarily to adults age 18 and older.)"*

By its own admission, ENT surgery includes a large number of pediatric cases, and pediatric patients are often covered by Medicaid. Indeed, this fact is reflected in the payor mix shown in Exhibit 12 for both DRAH and DUH, for which the largest percentage of Medicaid—by far—is for ENT. In fact, for DRAH, ENT is 14 percent Medicaid, and the next highest percentage of Medicaid is 5.0 percent for general surgery. Clearly the ENT payor mix for DRAH and DUH include "a large number of pediatric patients" with Medicaid coverage. As such, it is unreasonable to assume that the Medicaid percentage at the ASC—which will not serve pediatric patients—will be the same as the hospitals which do serve these patients.

This error also applies to other specialties, such as ophthalmology or other specialties with high percentages of older patients, most of whom are covered by Medicare. Older patients are more likely to be sicker with more co-morbidities than younger patients, which increases the likelihood that they may have an ASA classification of III (and therefore have a 50-50 chance of being ASC-appropriate in the DRAH methodology) or IV, in which case they would not qualify for surgery in the ASC according to the methodology.

These erroneous assumptions impact the payor mix projections as well as the financial assumptions that use those payor mix projections. They also impact the comparative analysis, as both Medicare and Medicaid are typically favored in that portion of the review. **As such, the application should be found non-conforming with Criteria 5 and 13(c), and the Medicare and Medicaid percentages should not be given any weight in the comparative analysis.**

COMMENTS ON DUKE RALEIGH HOSPITAL

Issue-Specific Comments

1. The application fails to reasonably define the patient population to be served.

   The application projects future patient origin at DRAH to be identical to its historical patient origin. While this assumption might seem reasonable, DRAH is projecting to shift a considerable portion of its surgical cases—nearly 4,000 in the third project year—to a new ASC in Apex in southern Wake County. As noted in the comments for that project, it is unreasonable to assume that a new ASC located approximately 25 miles away near the border of Durham County will have the same patient origin as DRAH. The application for the Green Level ASC even cites reduced travel time for patients as a basis for the need for the ASC; as such, it asserts its belief that the facility would provide better access for patients living closer to the proposed ASC. Similarly, the proposed location would be farther away from other patients, who would be more likely to choose another facility, including either DRAH or the previously-proposed Arringdon ASC in Morrisville.

   Because the application fails to adjust its projected patient origin to account for these projected shifts of thousands of cases to Morrisville and to Apex, the application fails to adequately and reasonably identify the patient population to be served, and it should be found non-conforming with Criterion 3.

2. The application fails to demonstrate that its projected payor mix is based on reasonable assumptions.

   In Section L, page 87, the application projects its payor mix to change from the historical percentages by increasing the percentage of Medicare patients and decreasing its percentage of Commercial patients. The application states that the change is based on the aging of the population and assumes a 1.8 percent shift in 2020, then 1.7 percent shifts annually in 2021 through 2023 for both inpatients and outpatients. As shown in the financial statements in the application, however, the actual changes used in the pro forma is inconsistent with what is stated in Section L, and also differs for inpatient and outpatients, without explanation. The table below shows these inconsistencies.

Payor	*2019*	*2020*	*2021*	*2022*	*2023*	*Total Change*
Medicare-IP	57.6%	58.6%	59.6%	60.6%	61.6%	4.0%
Medicare-OP	43.4%	44.2%	44.9%	45.7%	46.5%	3.1%
Commercial-IP	32.9%	31.9%	30.9%	29.9%	28.8%	-4.1%
Commercial-OP	44.8%	44.0%	43.3%	42.5%	41.7%	-3.1%

As shown, the projected change in payor mix differs between inpatient (4.0%) and outpatient (3.1%), which is inconsistent with the statements in the application[3]. Moreover, the percentage change assumed in the application is not based on reasonable assumptions. If the aging of the population is assumed to increase the percentage of Medicare patients, then the largest change one could expect would mirror the growth in patients over age 65. As shown in the table below, however, the application projects on page 30 that the 65 and older population will increase by a much smaller percentage over the same time frame:

	2018	***2023***	***Total Change***
Age 65 and older	11.5%	13.6%	2.1%

Thus, the actual growth in 65 and older population projected in the DRAH application is approximately one-half of the projected growth in Medicare projected in the application. The basis for the assumed change in payor mix in the application is therefore unfounded and unreasonable.

These erroneous assumptions impact the payor mix projections as well as the financial assumptions that use those payor mix projections. They also impact the comparative analysis, as Medicare is typically favored in that portion of the review. **As such, the application should be found non-conforming with Criteria 5 and 13(c), and the Medicare and Medicaid percentages should not be given any weight in the comparative analysis.**

[3] Please note that the difference of 0.1% in the inpatient change between Medicare and Commercial appears to be only a rounding error, not a material issue.

COMMENTS ON WAKEMED SURGERY CENTER-NORTH RALEIGH

General Comments

Please note that while the comments regarding WMSCNR are similar to those for WMSCC, they apply equally to both applications. The need analysis and methodology contained in each are similar, in fact identical in some places, necessitating the similarity of the comments on each.

Issue-Specific Comments

1. The application's need arguments are not based on reasonable assumptions.

   In Section C.4, page 25, the application states that there are no freestanding ASCs in northern Wake County, citing that fact as a basis for its projected need for the North Raleigh ASC it proposes. However, that statement ignores the existing Rex Surgery Center of Wakefield, which completed its conversion from hospital-based to freestanding in July 2018, before the WMSCNR application was filed. Thus, it is not accurate to say that there is a lack of a freestanding ASC in the service area. Further, the application makes the same statement in Section G in attempting to demonstrate why its proposed facility will not unnecessarily duplicate existing or approved facilities. As such, the application fails to explain why it will not be unnecessarily duplicating the existing freestanding Rex Surgery Center of Wakefield.

   The application also asserts that its proposed location near an existing hospital is reasonable because of the proximity to physician practices and emergency services. Both arguments are not reasonable bases for its proposed location, however, for several reasons. First, emergencies requiring transport from an ASC to a hospital are extraordinarily rare, particularly given appropriate patient selection processes, quality policies and staff training. It is also concerning that the application states that the location will allow for higher acuity cases to be performed in the ASC—even with the proximity to a hospital, the proposed ASC will not be a hospital, and the implication that the patient selection criteria would be less rigorous for the ASC is troubling. Next, while the existing physician practices are logically close to existing healthcare facilities, like the hospital, locating an outpatient facility like an ASC close to existing facilities for that reason completely ignores the need for improved geographic access, an important consideration in the CON process. It also implies that WMSCNR has not worked with its potential surgeon partners to identify locations that would expand geographic access for patients as well as physician practices, by giving them the potential to develop new office locations. In contrast, UNC HCS has worked with its physician partners to identify sites that would be beneficial to both patients and physicians and is in the process of developing physician office buildings to provide clinic space for its physicians.

   The application also fails to demonstrate that the proposed development of two new operating rooms to create a new ASC is the most effective or least costly alternative. In particular, the availability of operating rooms at WakeMed North and in the WakeMed System (described in detail below), as well as the proposed shift of cases from WakeMed North to the proposed ASC on the same campus, indicate that a more effective (and potentially less costly) alternative would be to relocate existing operating rooms on the

same campus, rather than proposing new operating rooms and increasing the surplus of operating rooms in the WakeMed System.

The application projects volume for the proposed ASC based on shifts of cases from its existing facilities. As such, the volume for WMSCNR is based on the underlying assumptions of growth for each facility in the system from which cases are projected to shift. As described in the sections to follow, the assumptions regarding the projected utilization for these facilities are unreasonable, rendering the projections for WMSCNR unreasonable as they are supported by the unreasonable growth projections at other facilities.

The application proposes to develop procedure rooms in the new ASC. While procedure rooms may not be regulated as operating rooms are, the application contains statements regarding the procedure rooms that render the assumptions for the operating rooms unreasonable. Specifically, on page 131, the application states that the procedure rooms will be used for "non-surgical procedures." However, the list of "non-surgical procedures" includes surgery cases, such as cataract implants [sic], carpal tunnel release and others. Since the cases on that list are often performed in surgical operating rooms, and would therefore be legitimately counted as surgical cases, it is likely that they are in the surgical case volume at the various WakeMed System facilities that the application projects to grow and shift to the proposed ASC. On that basis, they would already be included in the projected surgical case volume to be performed in operating rooms, and to include them in the procedure rooms would be "double counting" the cases, which is unreasonable.

For these reasons, the application should be found non-conforming with Criteria 3, 4 and 6.

2. <u>The application's utilization projections for WakeMed Cary are not based on reasonable assumptions.</u>

In Section Q, Form C, the application provides its utilization projections. These projections include inconsistent and unreasonable data and assumptions, however, and are therefore unreliable, as discussed below.

The data for WakeMed Cary include non-surgical cases and cases not performed in operating rooms. Despite the language used in the application referring repeatedly to "surgical case volumes," the data clearly include cases that do not comport with this definition. As shown in the tables below, it is clear that the application includes cases from the Hospital License Renewal Application ("HLRA") that are in the "non-surgical" table, 9f. This is also clear from Tables Q.2A, Q.2B, and Q.2C, which show surgical cases performed in operating rooms from each facility's license renewal application—with the exception of WakeMed Cary's which includes more cases than reported in the HLRA.

Year	*Inpatient Cases-Table Q.5*	*Inpatient Cases-HLRA**	*Outpatient Cases-Table Q.5*	*Outpatient Cases-HLRA*
2015	2,769	2,560	4,815	4,228
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2017	3,162	3,041	5,242	4,663

*Excludes C-Section cases.

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The number of surgical cases shown in the HLRAs match the number of patients shown in the patient origin tables for the HLRAs, indicating that the surgical case numbers in Table 9d in the HLRA appear to be accurate. Thus, the surgical cases reported in the application are overstated, inaccurate, and include non-surgical cases. The inclusion of non-surgical cases and cases (even surgical ones) not performed in operating rooms is problematic, for several reasons. First, only the cases reported in Table 9d are used in the *SMFP* to determine the need for additional operating rooms; therefore, WMSCNR's inclusion of these cases as part of its projections to show need for an *SMFP* allocation is improper. Second, while non-surgical cases may be performed in an operating room, the application does not demonstrate the need to use an operating room for these cases, particularly when WakeMed Cary has procedure rooms in which these cases can be performed, without necessitating the use of operating rooms. Third, the application does not project that these cases will in the future become surgical cases or be performed in an operating room, and thus cannot be used to demonstrate the need for or the utilization of operating rooms. Finally, the Agency has previously determined that non-surgical cases cannot be included in demonstrating conformity with the performance standards for operating rooms. In a contested case hearing conducted in January 2018 (17-DHR-06745 and 17-DHR-06576), Ms. Martha Frisone testified that the inclusion of non-surgical cases (in that case, GI endoscopy cases) performed in operating rooms was not permitted for demonstrating conformity with the operating room performance standards. The following excerpt includes Ms. Frisone's testimony in that case (see responses preceded with "A" below):

SCW v. NCDHHS_DHSR_HPCON and SurgCare - Vol. 6, (Pages 1208:22 to 1210:10)

1208

Q Okay.
A While you can't do--GI endoscopy rooms are limited to GI endoscopy procedures by definition. Operating rooms-- you can do nonsurgical cases in an operating room.

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Q And you would consider a GI endoscopy procedure done in an operating room to be a nonsurgical case?
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when you back out those GI endo cases, yes, they still show a need for three additional ORs.

Q Okay. So the number that was for the performance standard that you believe--because the Agency's decision included the performance standard calculation including the GI endoscopy room or GI endoscopy cases as OR cases. And then there was a second analysis that removed those. Do you remember that from the decision?

A I wouldn't call it a second analysis. I would call it a continuation of the analysis, that if you look at the total procedures to be done in the ORs, this is the result you get. But backing the GI endo cases out, you still show a need for three additional ORs.

Q So let me restate that, then. There was a chart included in the decision that showed the performance standard calculated with the GI endoscopy procedures included.

A Correct.

Q And then there was a second chart that showed the performance standard without the GI endoscopy procedures included.

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A Correct.

Q And so it's the Agency's position in terms of SurgCare meeting or not meeting the performance standard that the one that they viewed, the one that the Agency views, is the one that did not include the GI endoscopy procedures?

A In order to meet the rule you have to back out the GI endoscopy cases.

Q So the answer to my question is yes, it's the one without the GI endoscopy procedures?

A Well, I didn't really--yes.

(Emphasis added.) As applied to the WakeMed data, in order to be conforming with the rule, the non-surgical cases must be "backed out."

In order to be consistent with the Agency's position regarding non-surgical cases, the following tables show the result of removing the non-surgical and non-operating room cases shown above from the 2017 surgery cases in the methodology for WakeMed Cary. Please note that this change is only for the base year—2017—and no changes to the projected growth rate are made.

Table Q.7 Adjusted for Consistency with Agency Position by Removing Non-Surgical/Non-OR Cases

Patient Surgical Category	*2017 Actual**	*CAGR Growth Rate*	*2018*	*2019*	*2020*	*2021*	*2022*	*2023*
Hospital Surgical Inpatients	3,041	3.76%	3,155	3,274	3,397	3,525	3,657	3,795

Hospital Surgical Outpatients	4,663	2.43%	4,776	4,892	5,011	5,133	5,258	5,386
Total	**7,704**		**7,932**	**8,166**	**8,408**	**8,658**	**8,915**	**9,180**

*Reflects total surgical cases, less C-Sections, from Table 9f of WakeMed Cary's 2018 HLRA.

To calculate the final total of projected outpatient surgical cases for WakeMed Cary after removing the inappropriate cases, the projected shift of cases to the two proposed surgery centers were subtracted from the total above. The shifted cases shown below are identical to the cases projected in Table Q.11 of the application.

	2018	***2019***	***2020***	***2021***	***2022***	***2023***
Projected Outpatient Cases	4,776	4,892	5,011	5,133	5,258	5,386
Less Cases shifted to ASCs				-981	-1,005	-1,029
Total	**4,776**	**4,892**	**5,011**	**4,152**	**4,253**	**4,357**

To determine the need for operating rooms based on projected surgical cases performed in operating rooms, the table below shows the adjusted inpatient and outpatient cases from the calculations above, multiplied by the case times and standard hours per operating room from Table Q.18 of the application:

	2018	***2019***	***2020***	***2021***	***2022***	***2023***
Projected Inpatient Cases	3,155	3,274	3,397	3,525	3,657	3,795
Projected Outpatient Cases	4,776	4,892	5,011	4,152	4,253	4,357
Projected Inpatient Hours (115.3 mins/case)	6,064	6,292	6,528	6,774	7,028	7,292
Projected Outpatient Hours (73.3 mins/case)	5,835	5,977	6,122	5,072	5,195	5,322
Total Hours	**11,899**	**12,268**	**12,650**	**11,846**	**12,224**	**12,615**
OR Need (Hours/1500 hours per OR)	**7.9**	**8.2**	**8.4**	**7.9**	**8.1**	**8.4**
OR Surplus (Deficit)	**1.1**	**0.8**	**1.6**	**2.1**	**1.9**	**1.6**

As shown, WakeMed Cary will have a surplus of nearly two operating rooms in the project years when these cases are removed.

Finally, and most critically, the application uses improper case time assumptions, which results in grossly overstated utilization projections for its facilities, including WakeMed Cary and the WakeMed System. Specifically, the application inexplicably uses the average group case times for inpatient and outpatient cases, not the actual case times for the facility from Table 6B in the *2018 SMFP*, as required. For WakeMed Cary in particular, this difference is significant: the application uses an inpatient case time of 115.3 minutes instead of the correct 84.7 minutes (a difference of 36 percent) and an outpatient case time of 73.3 minutes instead of the correct 41.8 minutes (a difference of

75 percent). On page 129, the application calculates the projected operating room hours and need based on its projected utilization. Even without adjusting for the non-surgical/non-operating room cases as shown above (i.e. using the same volume projections presented in the application), when using the correct case times as required by the performance standards and as noted in the application form, WakeMed Cary has a surplus of 4.0 operating rooms, as shown below. Please see the discussion below for a calculation of the surplus for the WakeMed System.

WakeMed Cary	*2018*	*2019*	*2020*	*2021*	*2022*	*2023*
Inpatient Cases (Table Q.7)	3,281	3,404	3,532	3,665	3,803	3,946
Outpatient Cases (Table Q.11)	5,369	5,499	5,633	4,789	4,905	5,025
Projected Inpatient Hours (84.7 mins/case per SMFP Table 6B)	4,593	4,766	4,945	5,131	5,324	5,524
Projected Outpatient Hours (41.8 mins/case per SMFP Table 6B)	3,669	3,758	3,849	3,272	3,352	3,434
Total Hours	**8,262**	**8,523**	**8,794**	**8,403**	**8,676**	**8,958**
OR Need (Hours/1500 hours per OR)	**5.5**	**5.7**	**5.9**	**5.6**	**5.8**	**6.0**
Operating Rooms	9	9	10	10	10	10
OR Surplus (Deficit)	**3.5**	**3.3**	**4.1**	**4.4**	**4.2**	**4.0**

Based on these errors and unreasonable assumptions, the application fails to demonstrate the need for the additional operating rooms proposed for WMSCNR based on the availability (surplus) of operating rooms in the system. As such, the application should be found non-conforming with Criterion 3 and the performance standards at 10A NCAC 14C .2103.

3. The application's utilization projections for WakeMed North are not based on reasonable assumptions.

First, the application assumes a 10.0 percent growth rate for inpatient cases, which is unreasonably high. Even though the historical CAGR may be higher, the total number of inpatient cases is low and the historical growth period includes its first year of operation as an inpatient facility, FY 2015. This growth rate is also unreasonable in light of the most recent historical period, 2016-2017, in which inpatient surgical cases decreased from 88 to 63, a decline of more than 28 percent. The projected growth rate is therefore unreasonable and unsupported.

Next, the application's projected shift of cases from WakeMed North to the proposed WMSCNR facility are unreasonable. In Step 5, the application assumes that only 15 percent of total outpatient cases will shift to the ASC, compared with 20 percent of outpatient cases from WakeMed Raleigh. Prior to becoming an inpatient facility, in FY 2014, nearly 2,000 outpatient surgical cases were performed at the hospital-based, outpatient-only facility. Given the proximity of the proposed WNSCNR facility to WakeMed North (on the same campus), the relative lower acuity of surgical cases at WakeMed North compared to WakeMed Raleigh, and the historical number of outpatient cases performed on the campus prior to the initiation of inpatient cases, it is more

reasonable to assume that more cases would shift to the proposed ASC than are projected in the application. In addition, the application provides no assumption for the projected shifts or how they were determined, particularly given the difference in shifts from the various WakeMed facilities. As such, the projected utilization for the ASC and for WakeMed North are not reasonable.

Next, WakeMed North is projected to have a surplus of operating rooms. Although not shown separately in the utilization projections, using the assumptions in the application and applying them to the projected operating room utilization at WakeMed North, the total surplus of operating rooms can be determined, as shown in the table below.

WakeMed North	***2018***	***2019***	***2020***	***2021***	***2022***	***2023***
Inpatient Cases (Table Q.9)	69	76	84	92	101	111
Outpatient Cases (Table Q.13)	2,403	2,461	2,521	2,143	2,195	2,249
Projected Inpatient Hours (191.6 mins/case per SMFP Table 6B)	220	243	268	294	323	354
Projected Outpatient Hours (123 mins/case per SMFP Table 6B)	4,926	5,045	5,168	4,393	4,500	4,610
Total Hours	**5,146**	**5,288**	**5,436**	**4,687**	**4,822**	**4,965**
OR Need (Hours/1950 hours per OR)	**2.6**	**2.7**	**2.8**	**2.4**	**2.5**	**2.5**
Operating Rooms	4	4	4	4	4	4
OR Surplus (Deficit)	**1.4**	**1.3**	**1.2**	**1.6**	**1.5**	**1.5**

Please note that the actual surplus of operating rooms will be higher, as the operating rooms at WakeMed North do not have the longer cases times reported for the combined WakeMed/WakeMed North. While the two facilities are operated on the same license and are therefore assumed to have the same case time in the *SMFP* methodology, from a practical perspective, the inpatient case times at WakeMed North are much shorter (105 minutes versus 194 minutes, on average), as are the outpatient cases times (65 minutes versus 129), as shown in the 2018 HLRA for WakeMed. Given the more realistic actual case times, WakeMed North has a surplus of two operating rooms or more, which could be more reasonably used to create the proposed ASC, rather than developing two additional operating rooms.

Based on these errors and unreasonable assumptions, the application fails to demonstrate the need for the additional operating rooms proposed for WMSCNR based on the availability (surplus) of operating rooms in the system, particularly on the same campus. As such, the application should be found non-conforming with Criterion 3 and the performance standards at 10A NCAC 14C .2103.

4. <u>The application's utilization projections for Capital City Surgery Center are not based on reasonable assumptions</u>.

The application projects utilization at Capital City Surgery Center (CCSC) by applying the countywide freestanding ASC growth rate to FY 2017 volume. The application makes no

attempt to explain why this assumption is reasonable. In fact, the volume trend at CCSC has been negative in the past three years, as shown in Table Q.2C of the application:

Capital City Surgery Center	*2015*	*2016*	*2017*	*CAGR*
Outpatient Cases	6,647	6,123	5,388	-10%

Over the past three years, CCSC volume has declined more than 1,200 cases, with a CAGR of negative 10 percent (-10%). Therefore, the projected increase of 3.93 percent per year through 2023, which equates to a growth of more than 1,400 cases, is completely unsupported and unreasonable.

Notwithstanding the incredible volume projections, the application erroneously fails to apply the correct assumption for case times from Table 6B, which is the same error in the methodology for the other facilities. When this error is corrected, even using the unreasonable volume projections in the application, the following surplus of operating rooms is projected at Capital City:

Capital City Surgery Center	*2018*	*2019*	*2020*	*2021*	*2022*	*2023*
Outpatient Cases (Table Q.14)	5,600	5,820	6,049	5,847	6,076	6,315
Projected Outpatient Hours (67.9 mins/case per SMFP Table 6B)	6,337	6,586	6,845	6,617	6,876	7,146
Total Hours	**6,337**	**6,586**	**6,845**	**6,617**	**6,876**	**7,146**
OR Need (Hours/1312.5 hours per OR)	**4.8**	**5.0**	**5.2**	**5.0**	**5.2**	**5.4**
Operating Rooms	8	8	8	8	8	8
OR Surplus (Deficit)	**3.2**	**3.0**	**2.8**	**3.0**	**2.8**	**2.6**

As shown, CCSC has a surplus of more than two operating rooms, which could be used to develop the proposed ASC in North Raleigh.

5. <u>The application's utilization projections for the WakeMed System are not based on reasonable assumptions.</u>

As noted in the preceding sections, the application erroneously used the group average case times to show conformity with the performance standards and with Criterion 3. The performance standards and the application form refer to the methodology in the *SMFP*, which clearly bases the deficit or surplus of operating rooms for each facility on its own case time. The service area need is then the sum of all the facility needs and is therefore also based on the case time for each facility. When the correct case times from Table 6B are used for each facility, <u>the WakeMed System has a projected surplus of 2.7 operating rooms</u>, as shown below. Please note that the table below shows the projected deficit for WakeMed Raleigh/North from the application. Since those facilities are combined on one license, both are credited with the same case times, even though the times at WakeMed North are much shorter, as noted above. In addition, the inpatient case times were overstated, as they were for the other facilities; however, the outpatient case times were understated. The corrected case times result in approximately the same number of

operating hours and similar operating room deficit as projected in the application; therefore, for this analysis, they are unchanged from the application in the table below.

WakeMed System	*2021*	*2022*	*2023*
WakeMed Surgery Center-North Raleigh	(0.13)	(0.48)	(0.75)
WakeMed Surgery Center-Cary	0.14	(0.10)	(0.45)
WakeMed Cary	4.40	4.22	4.03
WakeMed Raleigh/North	(2.55)	(2.60)	(2.64)
Capital City Surgery Center	2.96	2.76	2.56
Total System OR Surplus (Deficit)	**4.81**	**3.79**	**2.74**

Although the operating room methodology in the *2018 SMFP* is new, the assumptions regarding the case time for existing facilities is simple, straightforward and provided in Table 6B. Moreover, even if there were any question as to the appropriate case time to use, an applicant's methodology must be reasonable and sensible. The methodologies presented for the WakeMed facilities in the application use case times that, in most cases, far exceed the actual case time for the WakeMed facility. Even if the applicant had felt compelled to use an incorrect case time, it must still demonstrate the need for the project using reasonable assumptions. To base operating room need on case times that are, in some cases, nearly twice the actual case times is simply unreasonable under any standard. Moreover, the application makes no attempt to explain why these case times are more accurate. **Clearly the assumed case times are simply erroneous, and they demonstrate that the proposed project is non-conforming with Criteria 3, 6 and the performance standards at 10A NCAC 14C .2103 and should not be approved.**

COMMENTS ON WAKEMED SURGERY CENTER-CARY

General Comments

Please note that while the comments regarding WMSCC are similar to those for WMSCNR, they apply equally to both applications. The need analysis and methodology contained in each are similar, in fact identical in some places, necessitating the similarity of the comments on each.

Issue-Specific Comments

1. The application's need arguments are not based on reasonable assumptions.

   In Section C.4, page 25, the application discusses other facilities that are located in its service area. Included among these is Holly Springs Surgery Center, a freestanding ASC in which WakeMed, the parent company of the applicant, has an ownership interest, and which has the same manager as the proposed WMSCC. Table C.2 shows several high population and high growth ZIP codes in the WMSCC service area that are generally closer to the Holly Springs Surgery Center, such as Holly Springs, Fuquay-Varina, Willow Spring and the southwest Raleigh ZIPs. Other than mentioning this facility, however, the application fails to demonstrate why it would not be appropriate for patients from at least a portion of the service area to utilize Holly Springs Surgery Center. While the facility may not be considered part of the WakeMed System in the operating room need methodology in the *SMFP*, given WakeMed's ownership stake in and the management company's oversight of the facility, it is reasonable to assume that it would be a valid and reasonable alternative for WakeMed's patients. Further, the facility is currently underutilized, as shown in Table Q.2C. In 2017, only 478 cases were performed in its three operating rooms, and the *Proposed 2019 SMFP* shows it as having a surplus of 2.54 operating rooms. Thus, the application has not shown the need for another WakeMed-owned and Compass Surgical Partners-managed freestanding ASC in the service area. Further, the application asserts in Section G that WakeMed has no freestanding facility in southern Wake County in which its surgeons can practice, which is not accurate. As such, the application fails to explain why it will not be unnecessarily duplicating the existing freestanding Holly Springs Surgery Center.

   The application also asserts that its proposed location near an existing hospital is reasonable because of the proximity to physician practices and emergency services. Both arguments are not reasonable bases for its proposed location, however, for several reasons. First, emergencies requiring transport from an ASC to a hospital are extraordinarily rare, particularly given appropriate patient selection processes, quality policies and staff training. It is also concerning that the application states that the location will allow for higher acuity cases to be performed in the ASC—even with the proximity to a hospital, the proposed ASC will not be a hospital, and the suggestion that the patient selection criteria would be less rigorous for the ASC is troubling. Next, while the existing physician practices are logically close to existing healthcare facilities, like the hospital, locating an outpatient facility like an ASC close to existing facilities for that reason completely ignores the need for improved geographic access, an important consideration in the CON process. It also implies that WMSCC has not worked with its potential surgeon partners to identify locations that would expand geographic access for patients as well as

physician practices, by giving them the potential to develop new office locations. In contrast, UNC HCS has worked with its physician partners to identify sites that would be beneficial to both patients and physicians and is in the process of developing physician office buildings to provide clinic space for its physicians.

The application also fails to demonstrate that the proposed development of two new operating rooms to create a new ASC is the most effective or least costly alternative. In particular, the availability of operating rooms at WakeMed Cary and in the WakeMed System (described in detail below), as well as the proposed shift of cases from WakeMed Cary to the proposed ASC only one-quarter mile away, indicate that a more effective (and potentially less costly) alternative would be to relocate existing operating rooms to create the proposed ASC, rather than proposing new operating rooms and increasing the surplus of operating rooms in the WakeMed System.

The application projects volume for the proposed ASC based on shifts of cases from its existing facilities. As such, the volume for WMSCC is based on the underlying assumptions of growth for each facility in the system from which cases are projected to shift. As described in the sections to follow, the assumptions regarding the projected utilization for these facilities are unreasonable, rendering the projections for WMSCC unreasonable as they are supported by the growth at other facilities.

The application proposes to develop procedure rooms in the new ASC. While procedure rooms may not be regulated as operating rooms are, the application contains statements regarding the procedure rooms that render the assumptions for the operating rooms unreasonable. Specifically, on page 129, the application states that the procedure rooms will be used for "non-surgical procedures." However, the list of "non-surgical procedures" includes surgery cases, such as cataract implants [sic], carpal tunnel release and others. Since the cases on that list are often performed in surgical operating rooms, and would therefore be legitimately counted as surgical cases, it is likely that they are in the surgical case volume at the various WakeMed System facilities that the application projects to grow and shift to the proposed ASC. On that basis, they would already be included in the projected surgical case volume to be performed in operating rooms, and to include them in the procedure rooms would be "double counting" the cases, which is unreasonable.

For these reasons, the application should be found non-conforming with Criteria 3, 4 and 6.

2. <u>The application's utilization projections for WakeMed Cary are not based on reasonable assumptions.</u>

In Section Q, Form C, the application provides its utilization projections. These projections include inconsistent and unreasonable data and assumptions, however, and are therefore unreliable, as discussed below.

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from the Hospital License Renewal Application ("HLRA") that are in the "non-surgical" table, 9f. This is also clear from Tables Q.2A, Q.2B, and Q.2C, which show surgical cases performed in operating rooms from each facility's license renewal application—with the exception of WakeMed Cary's which includes more cases than reported in the HLRA.

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The number of surgical cases shown in the HLRAs match the number of patients shown in the patient origin tables for the HLRAs, indicating that the surgical case numbers in Table 9d in the HLRA are accurate. Thus, the surgical cases reported in the application are overstated, inaccurate, and include non-surgical cases. The inclusion of non-surgical cases and cases (even surgical ones) not performed in operating rooms is problematic, for several reasons. First, only the cases reported in Table 9d are used in the *SMFP* to determine the need for additional operating rooms; therefore, WMSCNR's inclusion of these cases as part of its projections to show need for an *SMFP* need determination is improper. Second, while non-surgical cases may be performed in an operating room, the application does not demonstrate the need to use an operating room for these cases, particularly when WakeMed Cary has procedure rooms in which these cases can be performed, without necessitating the use of operating rooms. Third, the application does not project that these cases will in the future become surgical cases or be performed in an operating room, and thus cannot be used to demonstrate the need for or the utilization of operating rooms. Finally, the Agency has previously determined that non-surgical cases cannot be included in demonstrating conformity with the performance standards for operating rooms. In a contested case hearing conducted in January 2018 (17-DHR-06745 and 17-DHR-06576), Ms. Martha Frisone testified that the inclusion of non-surgical cases (in that case, GI endoscopy cases) performed in operating rooms was not permitted for demonstrating conformity with the operating room performance standards. The following excerpt includes Ms. Frisone's testimony in that case (see responses preceded with "A" below):

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Q And you would consider a GI endoscopy procedure done in an operating room to be a nonsurgical case?

A Yes. That's why we backed it out when we looked at the--whether SurgCare demonstrated the need for three additional ORs. And we mathematically showed that yes, even when you back out those GI endo cases, yes, they still show a need for three additional ORs.

Q Okay. So the number that was for the performance standard that you believe--because the Agency's decision included the performance standard calculation including the GI endoscopy room or GI endoscopy cases as OR cases. And then there was a second analysis that removed those. Do you remember that from the decision?

A I wouldn't call it a second analysis. I would call it a continuation of the analysis, that if you look at the total procedures to be done in the ORs, this is the result you get. But backing the GI endo cases out, you still show a need for three additional ORs.

Q So let me restate that, then. There was a chart included in the decision that showed the performance standard calculated with the GI endoscopy procedures included.

A Correct.

Q And then there was a second chart that showed the performance standard without the GI endoscopy procedures included.

1210

A Correct.

Q And so it's the Agency's position in terms of SurgCare meeting or not meeting the performance standard that the one that they viewed, the one that the Agency views, is the one that did not include the GI endoscopy procedures?

A In order to meet the rule you have to back out the GI endoscopy cases.

Q So the answer to my question is yes, it's the one without the GI endoscopy procedures?

A Well, I didn't really--yes.

(Emphasis added.) As applied to the WakeMed data, in order to be conforming with the rule, the non-surgical cases must be "backed out."

In order to be consistent with the Agency's position regarding non-surgical cases, the following tables show the result of removing the non-surgical and non-operating room cases shown above from the 2017 surgery cases in the methodology for WakeMed Cary.

Please note that this change is only for the base year—2017—and no changes to the projected growth rate are made.

Table Q.7 Adjusted for Consistency with Agency Position by Removing Non-Surgical/Non-OR Cases

Patient Surgical Category	*2017 Actual**	*CAGR Growth Rate*	*2018*	*2019*	*2020*	*2021*	*2022*	*2023*
Hospital Surgical Inpatients	3,041	3.76%	3,155	3,274	3,397	3,525	3,657	3,795
Hospital Surgical Outpatients	4,663	2.43%	4,776	4,892	5,011	5,133	5,258	5,386
Total	**7,704**		**7,932**	**8,166**	**8,408**	**8,658**	**8,915**	**9,180**

*Reflects total surgical cases, less C-Sections, from Table 9f of WakeMed Cary's 2018 HLRA.

To calculate the final total of projected outpatient surgical cases for WakeMed Cary, the projected shift of cases to the two proposed surgery centers were subtracted from the total above. The shifted cases shown below are identical to the cases projected in Table Q.11 of the application.

	2018	*2019*	*2020*	*2021*	*2022*	*2023*
Projected Outpatient Cases	4,776	4,892	5,011	5,133	5,258	5,386
Less Cases shifted to ASCs				-981	-1,005	-1,029
Total	**4,776**	**4,892**	**5,011**	**4,152**	**4,253**	**4,357**

To determine the need for operating rooms based on projected surgical cases performed in operating rooms, the table below shows the adjusted inpatient and outpatient cases from the calculations above, multiplied by the case times and standard hours per operating room from Table Q.18 of the application:

	2018	*2019*	*2020*	*2021*	*2022*	*2023*
Projected Inpatient Cases	3,155	3,274	3,397	3,525	3,657	3,795
Projected Outpatient Cases	4,776	4,892	5,011	4,152	4,253	4,357
Projected Inpatient Hours (115.3 mins/case)	6,064	6,292	6,528	6,774	7,028	7,292
Projected Outpatient Hours (73.3 mins/case)	5,835	5,977	6,122	5,072	5,195	5,322
Total Hours	**11,899**	**12,268**	**12,650**	**11,846**	**12,224**	**12,615**
OR Need (Hours/1500 hours per OR)	**7.9**	**8.2**	**8.4**	**7.9**	**8.1**	**8.4**
OR Surplus (Deficit)	**1.1**	**0.8**	**1.6**	**2.1**	**1.9**	**1.6**

As shown, WakeMed Cary will have a surplus of nearly two operating rooms in the project years when these cases are removed.

Finally, and most critically, the application uses improper case time assumptions, which results in grossly overstated utilization projections for its facilities, including WakeMed Cary and the WakeMed System. Specifically, the application inexplicably uses the average group case times for inpatient and outpatient cases, not the actual case times for the facility from Table 6B in the *2018 SMFP*, as required. For WakeMed Cary in particular, this difference is significant: the application uses an inpatient case time of 115.3 minutes instead of the correct 84.7 minutes (a difference of 36 percent) and an outpatient case time of 73.3 minutes instead of the correct 41.8 minutes (a difference of 75 percent). On page 127, the application calculates the projected operating room hours and need based on its projected utilization. Even without adjusting for the non-surgical/non-operating room cases as shown above (i.e. using the same volume projections presented in the application), when using the correct case times as required by the performance standards and as noted in the application form, WakeMed Cary has a surplus of 4.0 operating rooms, as shown below. Please see the discussion below for a calculation of the surplus for the WakeMed System.

WakeMed Cary	***2018***	***2019***	***2020***	***2021***	***2022***	***2023***
Inpatient Cases (Table Q.7)	3,281	3,404	3,532	3,665	3,803	3,946
Outpatient Cases (Table Q.11)	5,369	5,499	5,633	4,789	4,905	5,025
Projected Inpatient Hours (84.7 mins/case per SMFP Table 6B)	4,593	4,766	4,945	5,131	5,324	5,524
Projected Outpatient Hours (41.8 mins/case per SMFP Table 6B)	3,669	3,758	3,849	3,272	3,352	3,434
Total Hours	**8,262**	**8,523**	**8,794**	**8,403**	**8,676**	**8,958**
OR Need (Hours/1500 hours per OR)	**5.5**	**5.7**	**5.9**	**5.6**	**5.8**	**6.0**
Operating Rooms	9	9	10	10	10	10
OR Surplus (Deficit)	**3.5**	**3.3**	**4.1**	**4.4**	**4.2**	**4.0**

Based on these errors and unreasonable assumptions, the application fails to demonstrate the need for the additional operating rooms proposed for WMSCC based on the availability (surplus) of operating rooms in the system, particularly at a facility located only one-quarter of a mile from the proposed ASC. As such, the application should be found non-conforming with Criterion 3 and the performance standards at 10A NCAC 14C .2103.

3. The application's utilization projections for WakeMed North are not based on reasonable assumptions.

First, the application assumes a 10.0 percent growth rate for inpatient cases, which is unreasonably high. Even though the historical CAGR may be higher, the total number of inpatient cases is low and the historical growth period includes its first year of operation as an inpatient facility, FY 2015. This growth rate is also unreasonable in light of the most recent historical period, 2016-2017, in which inpatient surgical cases decreased from 88 to 63, a decline of more than 28 percent. The projected growth rate is therefore unreasonably high and unsupported.

Next, the application's projected shift of cases from WakeMed North to the WMSCNR facility are unreasonable. In Step 5, the application assumes that only 15 percent of total outpatient cases will shift to the ASC, compared with 20 percent of outpatient cases from WakeMed Raleigh. Prior to becoming an inpatient facility, in FY 2014, nearly 2,000 outpatient surgical cases were performed at the hospital-based, outpatient-only facility. Given the proximity of the proposed WNSCNR facility to WakeMed North (on the same campus), the relative lower acuity of surgical cases at WakeMed North compared to WakeMed Raleigh, and the historical number of outpatient cases performed on the campus prior to the initiation of inpatient cases, it is more reasonable to assume that more cases would shift to the proposed ASC than are projected in the application. In addition, the application provides no assumption for the projected shifts or how they were determined, particularly given the difference in shifts from the various WakeMed facilities. As such, the projected utilization for WMSCNR and for WakeMed North are not reasonable.

Next, WakeMed North is projected to have a surplus of operating rooms. Although not shown separately in the utilization projections, using the assumptions in the application and applying them to the projected operating room utilization at WakeMed North, the total surplus of operating rooms can be determined, as shown in the table below.

WakeMed North	***2018***	***2019***	***2020***	***2021***	***2022***	***2023***
Inpatient Cases (Table Q.9)	69	76	84	92	101	111
Outpatient Cases (Table Q.13)	2,403	2,461	2,521	2,143	2,195	2,249
Projected Inpatient Hours (191.6 mins/case per SMFP Table 6B)	220	243	268	294	323	354
Projected Outpatient Hours (123 mins/case per SMFP Table 6B)	4,926	5,045	5,168	4,393	4,500	4,610
Total Hours	**5,146**	**5,288**	**5,436**	**4,687**	**4,822**	**4,965**
OR Need (Hours/1950 hours per OR)	**2.6**	**2.7**	**2.8**	**2.4**	**2.5**	**2.5**
Operating Rooms	4	4	4	4	4	4
OR Surplus (Deficit)	**1.4**	**1.3**	**1.2**	**1.6**	**1.5**	**1.5**

Please note that the actual surplus of operating rooms will be higher, as the operating rooms at WakeMed North do not have the longer cases times reported for the combined WakeMed/WakeMed North. While the two facilities are operated on the same license and are therefore assumed to have the same case time in the *SMFP* methodology, from a practical perspective, the inpatient case times at WakeMed North are much shorter (105 minutes versus 194 minutes, on average), as are the outpatient cases times (65 minutes versus 129), as shown in the 2018 HLRA for WakeMed. Given the more realistic actual case times, WakeMed North has a surplus of two operating rooms or more, which could be more reasonably used to create the proposed ASC, rather than developing two additional operating rooms.

Based on these errors and unreasonable assumptions, the application fails to demonstrate the need for the additional operating rooms proposed for WMSCC based on the availability (surplus) of operating rooms in the system. As such, the application

should be found non-conforming with Criterion 3 and the performance standards at 10A NCAC 14C .2103.

4. The application's utilization projections for Capital City Surgery Center are not based on reasonable assumptions.

The application projects utilization at Capital City Surgery Center (CCSC) by applying the countywide freestanding ASC growth rate to FY 2017 volume. The application makes no attempt to explain why this assumption is reasonable. In fact, the volume trend at CCSC has been negative in the past three years, as shown in Table Q.2C of the application:

Capital City Surgery Center	*2015*	*2016*	*2017*
Outpatient Cases	6,647	6,123	5,388

Over the past three years, CCSC volume has declined more than 1,200 cases, with a CAGR of negative 10 percent (-10%). Therefore, the projected increase of 3.93 percent per year through 2023, which equates to a growth of more than 1,400 cases, is completely unsupported and unreasonable.

Notwithstanding the incredible volume projections, the application erroneously fails to apply the correct assumption for case times from Table 6B, which is the same error in the methodology for the other facilities. When this error is corrected, even using the unreasonable volume projections in the application, the following surplus of operating rooms is projected at Capital City:

Capital City Surgery Center	*2018*	*2019*	*2020*	*2021*	*2022*	*2023*
Outpatient Cases (Table Q.14)	5,600	5,820	6,049	5,847	6,076	6,315
Projected Outpatient Hours (67.9 mins/case per SMFP Table 6B)	6,337	6,586	6,845	6,617	6,876	7,146
Total Hours	**6,337**	**6,586**	**6,845**	**6,617**	**6,876**	**7,146**
OR Need (Hours/1312.5 hours per OR)	**4.8**	**5.0**	**5.2**	**5.0**	**5.2**	**5.4**
Operating Rooms	8	8	8	8	8	8
OR Surplus (Deficit)	**3.2**	**3.0**	**2.8**	**3.0**	**2.8**	**2.6**

As shown, CCSC has a surplus of more than two operating rooms, which could be used to develop the proposed ASC in Cary.

5. The application's utilization projections for the WakeMed System are not based on reasonable assumptions.

As noted in the preceding sections, the application erroneously used the group average case times to show conformity with the performance standards and with Criterion 3. The performance standards and the application form refer to the methodology in the *SMFP*, which clearly bases the deficit or surplus of operating rooms for each facility on its own case time. The service area need is then the sum of all the facility needs and is therefore

also based on the case time for each facility. When the correct case times from Table 6B are used for each facility, the WakeMed System has a projected surplus of 2.7 operating rooms, as shown below.

WakeMed System	*2021*	*2022*	*2023*
WakeMed Surgery Center-North Raleigh	(0.13)	(0.48)	(0.75)
WakeMed Surgery Center-Cary	0.14	(0.10)	(0.45)
WakeMed Cary	4.40	4.22	4.03
WakeMed Raleigh/North	(2.55)	(2.60)	(2.64)
Capital City Surgery Center	2.96	2.76	2.56
Total System OR Surplus (Deficit)	**4.81**	**3.79**	**2.74**

Although the operating room methodology in the *2018 SMFP* is new, the assumptions regarding the case time for existing facilities is simple, straightforward and provided in Table 6B. Moreover, even if there were any question as to the appropriate case time to use, an applicant's methodology must be reasonable and sensible. The methodologies presented for the WakeMed facilities in the application use case times that, in most cases, far exceed the actual case time for the WakeMed facility. Even if the applicant had felt compelled to use an incorrect case time, it must still demonstrate the need for the project using reasonable assumptions. To base operating room need on case times that are, in some cases, nearly twice the actual case times is simply unreasonable under any standard. Moreover, the application makes no attempt to explain why these case times are more accurate. **Clearly the assumed case times are simply erroneous, and they demonstrate that the proposed project is non-conforming with Criteria 3, 6 and the performance standards at 10A NCAC 14C .2103 and should not be approved.**

COMPARATIVE ANALYSIS

Given that a total of nine applicants propose to meet all or part of the need for the six new operating rooms in Wake County, not all can be approved as proposed. To determine the comparative factors that are applicable in this review, UNC HCS examined recent Agency findings for competitive OR reviews, including the 2017 New Hanover County OR review, the 2017 Union County OR review, and the 2017 Brunswick County OR review. Based on that examination and the facts and circumstances of the competing applications in this review, UNC HCS compared the applications on the following factors:

- Conformity with Rules and Criteria
- Geographic Accessibility
- Documentation of Physician Support
- Patient Access to Low Cost Outpatient Surgical Services
- Patient Access to Surgical Specialties
- Access by Underserved Groups
- Projected Average Revenue per Case
- Projected Average Operating Expense per Case

Conformity with Applicable Statutory and Regulatory Review Criteria

As discussed in the application-specific comments above, the two Duke Health applications (Green Level and DRAH), the two WakeMed applications (WMSCNR and WMSCC), and the RAC application are non-conforming with multiple statutory and regulatory review criteria. In contrast, the UNC REX, Rex Surgery Center of Garner and UNC Hospitals applications are conforming with all applicable statutory and regulatory review criteria. Therefore, with regard to statutory and regulatory review criteria, the three UNC Health System applications are the most effective alternatives.

Geographic Accessibility

The *2018 SMFP* identifies a need for six additional operating rooms in the Wake County OR Service Area. Rex Surgery Center of Garner proposes to develop two operating rooms in a freestanding ASC in Garner. UNC Hospitals proposes to develop two operating rooms in a freestanding ASC in the Panther Creek area of west Cary. Green Level Surgery Center proposes to develop four operating rooms in a freestanding ASC in Apex. The other applicants propose to develop operating rooms either in existing facilities or on or near existing surgical facilities. Only UNC Hospitals, Rex Surgery Center of Garner and Green Level Surgery Center propose to develop operating rooms in areas of high growth without existing local access to surgical facilities. Both the UNC Hospitals and Rex Surgery Center of Garner applications present data and analysis regarding the need for additional operating room capacity in the Garner and Panther Creek areas. Therefore, with regard to geographic accessibility, UNC Hospitals, Rex Surgery Center of Garner and Green Level Surgery Center are the most effective alternatives.

Documentation of Physician Support

The applications from UNC HCS, Duke/Green Level and WakeMed all contain 40 or more letters from surgeons and referring physicians. Therefore, all seven applicants have a comparable demonstration of physician support. However, the Green Level application includes multiple

letters of support from pediatric specialties, which is inconsistent with representations in the application that the utilization projections exclude pediatric cases. Those letters should therefore be excluded from documenting support for the Green Level project. Further, the UNC HCS applications are the only ones that are conforming with all applicable statutory and regulatory review criteria. Therefore, the UNC HCS applications are the most effective alternatives with regard to physician support.

Patient Access to Low Cost Outpatient Surgical Services

As noted in the 2017 New Hanover County Operating Review (see Attachment 1), "*many, but not all outpatient surgical services can either be performed in a hospital licensed operating room (either a shared OR or a dedicated outpatient OR) or in a non-hospital licensed operating room (ASC) however, the cost for that same service will often be much higher in a hospital licensed operating room or, conversely much less expensive if received in a non-hospital licensed operating room*." DRAH and UNC REX are existing hospitals that offer hospital licensed operating rooms. The remaining applicants would offer non-hospital licensed operating rooms. However, Green Level, RAC, WMSCC and WMSCNR are not conforming with statutory and regulatory review criteria. Therefore, they cannot be effective alternatives with regard to patient access to low cost outpatient surgical services.

Patient Access to Surgical Specialties

Among the nine applications, all but two propose to provide surgical services representing multiple specialties. Among the three UNC HCS applications, support letters from as many as 10 specialties are represented. Similarly, the Duke/Green Level applications contain support letters from up to 10 different specialties; however, at least one of those specialties includes letters from pediatric specialists, which is inconsistent with the representations in the application that the projected utilization does not include pediatric cases. As such, they should not be considered in the count of surgical specialties for Green Level. The WMSCC application includes support letters from eight specialties and the WMSCNR from seven. However, as explained above, among these applicants, the UNC HSC applications are only ones that are conforming with all applicable statutory and regulatory review criteria. Moreover, among all the providers in the review, UNC REX Hospital provides the most diverse and comprehensive surgical specialties. Therefore, the UNC HCS applications are the most effective alternatives with regard to providing Wake County patients with access to multiple surgical specialties.

Access by Underserved Groups

The following tables show each applicant's projected operating room cases to be provided to Self Pay/Indigent/Charity Care, Medicare, and Medicaid recipients in the third project year following completion of the project, based on the information provided in the applicants' pro forma financial statements (Forms D and E). Consistent with previous Agency findings, the percentages below are based on operating room cases only.

Self Pay/Indigent/Charity, Medicare, and Medicaid Surgical Cases – Project Year 3

Applicant	*Self Pay/ Indigent/Charity as % of Total*	*Medicare % of Total*	*Medicaid % of Total*
UNC REX Hospital	2.3%	41.0%	3.4%
Rex Garner ASC	3.4%	29.6%	6.0%
UNC Panther Creek ASC	3.9%	13.2%	13.2%
DRAH	0.5%	50.4%	3.8%
Green Level	1.7%	42.9%	5.1%
OrthoNC ASC	1.7%	25.2%	6.2%
RAC	2.3%	56.9%	6.1%
WMSCNR	1.6%	14.5%	8.4%
WMSCC	3.0%	17.1%	4.1%

Source: Each applicant's Forms D and E

As shown in the table above, comparing all applicants, UNC Health Care Panther Creek ASC projects the highest percentage of Self Pay/Indigent/Charity and the highest percentage of Medicaid patients. RAC projects the highest percentage of Medicare patients. However, as noted above, the DRAH, Green Level, RAC, WMSCNR and WMSCC applications have errors that relate to utilization and payor mix, and therefore are not appropriate for comparison. Therefore, the three UNC HCS applications are more effective alternatives with regard to access by underserved groups.

Projected Average Revenue per Case

The following tables show the projected gross revenue per operating room case in the third year of operation based on the information provided in each applicant's pro forma financial statements (Forms D and E). Consistent with previous Agency findings, the per case statistics below are based on operating room cases only.

Gross Revenue per Operating Room Case - Project Year 3

Applicant	*Gross Revenue*	*Cases*	*Gross Revenue per Case*
WMSCNR	$14,942,616	3,152	$4,741
WMSCC	$16,058,985	2,812	$5,711
UNC Panther Creek ASC	$14,972,019	1,875	$7,985
Rex Garner ASC	$16,185,006	1,990	$8,133
OrthoNC ASC	$10,253,712	1,230	$8,336
Green Level	$44,979,034	4,770	$9,430
RAC	$22,448,253	1,625	$13,814
UNC REX Hospital	$699,144,711	20,528	$34,058
DRAH	$631,663,439	17,079	$36,985

Source: Each applicant's Forms D and E

As shown above, among all applicants, WMSCNR and WNSCC project the two lowest average gross revenue per operating room case in the third project year. However, as noted in the application-specific comments above, WMSCC's and WMSCNR's projected utilization is unsupported and unreasonable, rendering their revenue per case unreasonable. Among the remaining applicants, UNC Health Care Panther Creek ASC and Rex Garner ASC project the next lowest gross revenue per case and are the most effective alternatives.

As noted above and in the UNC HCS applications, adequate access to hospital-based operating rooms is an important consideration in this review. Between the two hospital-based applicants, UNC REX projects the lower gross revenue per case and is a more effective alternative.

The following table shows the projected net revenue per operating room case in the third year of operation based on the information provided in each applicant's pro forma financial statements (Form B). Consistent with previous Agency findings, the percentages below are based on operating room cases only.

Net Revenue per Operating Room Case – Project Year 3

Applicant	*Net Revenue*	*Cases*	*Net Revenue per Case*
WMSCNR	$8,288,066	3,152	$2,629
Rex Garner ASC	$6,244,482	1,990	$3,138
WMSCC	$8,878,134	2,812	$3,157
OrthoNC ASC	$3,938,349	1,230	$3,202
UNC Panther Creek ASC	$6,116,410	1,875	$3,262
Green Level	$15,978,168	4,770	$3,350
RAC	$7,530,602	1,625	$4,634
DRAH	$182,614,355	17,079	$10,692
UNC REX Hospital	$255,397,563	20,528	$12,441

Source: Each applicant's Form B

As shown above, among all applicants, WMSCNR projects the lowest average net revenue per operating room case. As noted above, WMSCNR's and WMSCC's projected utilization is unsupported and unreasonable, rendering their revenue per case unreasonable. Among the remaining applicants, Rex Surgery Center of Garner projects the lowest average net revenue per operating room case, followed by OrthoNC ASC and UNC Health Care Panther Creek ASC.

Between the two hospital applicants, DRAH projects lower net revenue per case; however, it should be noted that UNC REX Hospital is a tertiary facility, providing surgical services that are more complex, resource intensive and therefore are more highly reimbursed, such as open heart surgery, while DRAH does not provide the same level of services. As such, a direct comparison of surgical net revenue per case is not relevant or informative.

Further, the DRAH, Green Level, RAC, WMSCNR and WMSCC applications are not conforming with all applicable statutory and regulatory review criteria. Therefore, the UNC HCS applications and OrthoNC ASC are the most effective alternatives with regard to patient revenue.

Projected Average Operating Expense per Case

The following table shows the projected average operating expense per case/procedure in the third year of operating for each of the applicants, based on the information provided in applicants' pro forma financial statements (Form B). Consistent with previous Agency findings, the per case expenses below include both operating room cases and procedure room procedures.

Operating Expenses per Case – Project Year 3

Applicant	*Total Operating Expenses*	*Cases*	*Operating Expense per Case*
OrthoNC ASC	$3,467,036	1,230	$1,100
WMSCNR	$6,807,703	3,152	$1,536
WMSCC	$6,768,025	2,812	$1,638
UNC Panther Creek ASC	$5,521,460	1,875	$2,335
RAC	$8,194,479	1,625	$2,521
Rex Garner ASC	$6,183,235	1,990	$2,809
Green Level	$13,804,670	4,770	$3,080
UNC REX Hospital	$182,498,940	20,528	$8,890
DRAH	$168,378,020	17,079	$9,859

Source: Each applicant's Financials Form B & C

As shown in the table above, OrthoNC ASC projects the lowest average operating expense per case in the third project year. While WMSCNR and WMSCC project the second and third lowest average operating expenses per case, both contain unreasonable utilization projections, rendering their expenses per case unreliable. Among the remaining applicants, UNC Health Care Panther Creek ASC projects the second lowest operating expenses, followed by Rex Healthcare of Garner ASC (the RAC proposal has unreliable and inconsistent volume projections). Therefore, with regard to operating expenses, OrthoNC ASC, UNC Panther Creek ASC and Rex Garner ASC are the most effective alternatives.

Between the two hospital applicants, UNC REX projects the lower operating expenses per case and is therefore a more effective alternative.

SUMMARY

In summary, among the nine applications, none applied for all six operating rooms. As such, more than one applicant can be approved. UNC HCS believes that some of the operating rooms should be approved for a hospital setting, where they can provide care to both inpatients and outpatients, as well as emergency patients, and provide access to more specialties and patients of all acuities. It is also important to expand access to lower cost surgical services in an ASC, which can (and should) also expand geographic access to residents of a large, growing and crowded county like Wake. To assess the most effective alternatives for these operating rooms, the following table summarizes the comparative analysis shown above.

Factors	*UNC REX Hospital*	*Rex Garner ASC*	*UNC Panther Creek ASC*	*DRAH*	*Green Level*	*Ortho NC ASC*	*RAC*	*WMSCNR*	*WMSCC*
Expands Geographic Access		X	X		X				
Physician Support	X	X	X	X	X			X	X
Access to Low Cost Surgical Svcs		X	X		X	X	X	X	X
Access to Surgical Specialties	X	X	X	X	X			X	X
Access by Underserved	X	X	X						
Projected Revenue/Case	X	X	X						
Projected Operating Exp/Case	X	X	X			X			
Ability to Meet Complete Need Determination	X	X	X						

The bottom row indicates that because of the number of operating rooms proposed by the UNC HCS, all can be approved, and the entire need determination will be met. Please note that the table above does not imply that all of the applications are approvable; as noted above, the DRAH, Green Level, RAC, WMSCNR and WMSCC applications are non-conforming. However, even assuming that all the applications were conforming, the UNC HCS applications are the most effective alternatives for the following reasons:

<u>UNC Rex Hospital</u>:

- Provides essential access to hospital-based surgery;
- Provides the greatest depth of services (tertiary facility);
- Between the hospital-based applications, provides the highest percentage of care to self-pay/indigent/charity and Medicaid patients;
- Between the hospital-based applications, projects the lowest gross revenue and expenses per case;
- With two proposed operating rooms, effectively "matches" with other approvable applications.

<u>UNC Health Care Panther Creek ASC</u>:

- Expands geographic access to a multispecialty ASC;
- Has numerous provider support from multiple specialties;
- Provides access to low-cost surgical services;

- Projects the highest percentage of care to self-pay/indigent/charity and Medicaid patients;
- Projects among the lowest revenue and expenses per case;
- With two proposed operating rooms, effectively "matches" with other approvable applications.

Rex Healthcare of Garner:

- Expands geographic access to a multispecialty ASC;
- Has numerous provider support from multiple specialties;
- Provides access to low-cost surgical services;
- Projects the second highest percentage of care to self-pay/indigent/charity patients;
- Projects among the lowest revenue and expenses per case;
- With two proposed operating rooms, effectively "matches" with other approvable applications.

In summary, UNC HCS believes that its three complementary applications are clearly the most effective alternatives for six additional operating rooms needed in Wake County. They are also fully conforming to all applicable statutory and regulatory review criteria and comparatively superior on the relevant factors in this review. As such, the proposals by UNC REX Hospital, UNC Health Care Panther Creek ASC and Rex Healthcare of Garner should be approved.

Attachment 1

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS
C = Conforming
CA = Conditional
NC = Nonconforming
NA = Not Applicable

Decision Date: April 27, 2018
Findings Date: May 4, 2018

Project Analyst: Gregory F. Yakaboski
Co-Signer: Fatimah Wilson

COMPETITIVE REVIEW

Project ID #:	O-11434-17
Facility:	New Hanover Regional Medical Center
FID #:	943372
County:	New Hanover
Applicant:	New Hanover Regional Medical Center
Project:	Develop one new OR pursuant to the need determination in the 2017 SMFP for a total of 39 ORs at NHRMC upon project completion

Project ID #:	O-11437-17
Facility:	Wilmington SurgCare
FID #:	923566
County:	New Hanover
Applicant:	Wilmington Surgery Center, L.P.
Project:	Develop one new OR pursuant to the need determination in the 2017 SMFP for a total of 11 ORs upon completion of this project and Project ID #O-11272-16 (add 3 ORs and one procedure room)

Project ID #:	O-11441-17
Facility:	Wilmington ASC
FID #:	170523
County:	New Hanover
Applicant:	Wilmington ASC, LLC
Project:	Develop a new multispecialty ambulatory surgical facility by developing one new OR pursuant to the need determination in the 2017 SMFP, developing three procedure rooms, and relocating three existing multispecialty GI endoscopy rooms from Wilmington Health

Project ID #:	O-11444-17
Facility:	New Hanover Surgical Center
FID #:	170529
County:	New Hanover

Applicants: New Hanover Surgical Center, LLC
OWP4, LLC
Project: Develop a new ambulatory surgical facility with one new OR pursuant to the need determination in the 2017 SMFP and two procedure rooms

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REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

N.C. Gen. Stat. §131E-183(a) The Agency shall review all applications utilizing the criteria outlined in this subsection and shall determine that an application is either consistent with or not in conflict with these criteria before a certificate of need for the proposed project shall be issued.

(1) The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service, health service facility, health service facility beds, dialysis stations, operating rooms, or home health offices that may be approved.

C
NHRMC
WASC
NHSC

NC
Wilmington SurgCare

Need Determination

Chapter 6 of the 2017 State Medical Facilities Plan (SMFP) includes a methodology for determining the need for additional operating rooms (ORs) by service area. Application of the standard need methodology in the 2017 SMFP identifies a need for one additional OR in the New Hanover County operating room service area. Four applications were submitted to the Healthcare Planning and Certificate of Need Section (Agency), each proposing to develop one new OR in the New Hanover County operating room service area. The four applicants each applied for one OR, for a combined total of four additional ORs. Pursuant to the need determination in Table 6C, page 82 of the 2017 SMFP, only one new OR may be approved in this review for the New Hanover County operating room service area.

Policies

The following policy is applicable to all four applications in this review:

- POLICY GEN-3: BASIC PRINCIPLES

The following policy is applicable to only two of the four applications in this review:

- POLICY GEN-4: ENERGY EFFICIENCY AND SUSTAINABILITY FOR HEALTH SERVICE FACILITIES

POLICY GEN-3: BASIC PRINCIPLES states:

> *"A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area."*

POLICY GEN-4: ENERGY EFFICIENCY AND SUSTAINABILITY FOR HEALTH SERVICE FACILITIES states:

> *"Any person proposing a capital expenditure greater than $2 million to develop, replace, renovate, or add to a health service facility pursuant to G.S. 131E-178 shall include in its certificate of need application a written statement describing the project's plan to assure improved energy efficiency and water conservation.*
>
> *In approving a certificate of need proposing an expenditure greater than $5 million to develop, replace, renovate, or add to a health service facility pursuant to G.S. 131E-178, Certificate of Need shall impose a condition requiring the applicant to develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. The plan must be consistent with the applicant's representation in the written statement as described in paragraph one of Policy GEN 4.*
>
> *Any person awarded a certificate of need for a project or an exemption from review pursuant to G.S. 131E-184 are required to submit a plan for energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation. The plan must be consistent with the applicant's representation in the written statement as described in paragraph one of Policy-GEN 4. The plan shall not adversely affect patient or resident health, safety, or infection control."*

New Hanover Regional Medical Center (NHRMC) proposes to develop one new OR pursuant to the need determination in the 2017 SMFP for a total of 39 operating rooms (ORs) at NHRMC upon project completion.

Need Determination. The applicant does not propose to develop more ORs than are determined to be needed in the New Hanover County Operating Room service area.

Policy GEN-3. The applicant addresses Policy GEN-3 as follows:

Promote Safety and Quality - The applicant describes how it believes the proposed project would promote safety and quality in Section II.8, pages 18-19, Section III.4, pages 62-64 and Exhibit 7. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would promote safety and quality.

Promote Equitable Access - The applicant describes how it believes the proposed project would promote equitable access in Section V.7, pages 66-67, and Exhibits 7 and 13-14. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would promote equitable access.

Maximize Healthcare Value - The applicant describes how it believes the proposed project would maximize health care value in Section V.7, pages 68-69, Section X, pages 95-97 and the applicant's pro forma financial statements, pages 105-123. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal will maximize health care value.

The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would maximize healthcare value and that the applicant's projected volumes incorporate the concepts of quality, equitable access and maximum value for resources expended in meeting the need identified in the 2017 SMFP. Therefore, the application is consistent with Policy GEN-3.

Policy GEN-4. The proposed capital expenditure for this projected is less than $2.0 million, therefore, Policy GEN-4 is not applicable to the review of this application.

Conclusion. The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant does not propose to develop more ORs than are determined to be needed in the 2017 SMFP for the New Hanover County operating room service area.
- The applicant adequately demonstrates that the proposal is consistent with Policy GEN-3 for the following reasons:

- The applicant uses existing policies, historical data and verifiable sources to project utilization, and
- The applicant adequately demonstrates how the projected volumes incorporated the concepts of quality, equitable access and maximum value for resources expended in meeting the identified need.

Wilmington Surgery Center, L.P. (Wilmington SurgCare) proposes to develop one new OR pursuant to the need determination in the 2017 SMFP for a total of 11 ORs upon completion of this project and Project ID #O-11272-16 (add 3 ORs and one procedure room).

Need Determination. The applicant does not propose to develop more ORs than are determined to be needed in the New Hanover County operating room service area.

Policy GEN-3. The applicant addresses Policy GEN-3 as follows:

Promote Safety and Quality - The applicant describes how it believes the proposed project would promote safety and quality in Section II.8, pages 14-15, Section III.4, pages 53-54 and Exhibits 8, 14, 15 and 17. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would promote safety and quality.

Promote Equitable Access - The applicant describes how it believes the proposed project would promote equitable access in Section III.4, pages 53-55, Section VI, pages 78-85 and Exhibits 12, 25, 26, 33 and 34. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would promote equitable access.

Maximize Healthcare Value - The applicant describes how it believes the proposed project would maximize health care value in Section III.4, pages 53-55, Section X, pages 102-104 and the applicant's pro forma financial statements, pages 115-131.

However, the applicant does not adequately demonstrate how its projected volumes incorporate the concept of maximum value for resources expended. The applicant does not adequately demonstrate the need to add one OR to its facility in New Hanover County. Therefore, the applicant fails to adequately demonstrate how the proposed project will maximize healthcare value for resources expended in meeting the need identified in the 2017 SMFP. The discussion regarding analysis of need, including projected utilization, found in Criterion (3) is incorporated herein by reference. Therefore, the application is not consistent with Policy GEN-3.

Policy GEN-4. The proposed capital expenditure for this projected is less than $2.0 million, therefore, Policy GEN-4 is not applicable to the review of this application.

Conclusion. The Agency reviewed the:

- Application
- Exhibits to the application

- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is not conforming to this criterion for the following reasons:

- The applicant does not adequately demonstrate that the proposal is consistent with Policy GEN-3 for the following reasons:

    - The applicant does not adequately demonstrate how its projected volumes incorporate the concept of maximum value for resources expended. The applicant does not adequately demonstrate the need to add one OR to its existing facility in New Hanover County.

Wilmington ASC, LLC (WASC) proposes to develop a new multispecialty ambulatory surgical facility by developing one new OR pursuant to the need determination in the 2017 SMFP, developing three procedure rooms, and relocating three existing multispecialty GI endoscopy rooms from Wilmington Health.

Need Determination. The applicant does not propose to develop more ORs than are determined to be needed in the New Hanover County operating room service area.

Policy GEN-3. The applicant addresses Policy GEN-3 as follows:

Promote Safety and Quality - The applicant describes how it believes the proposed project would promote safety and quality in Section II.8, page 50, Section III.4, page 101 and Exhibit 12. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would promote safety and quality.

Promote Equitable Access - The applicant describes how it believes the proposed project would promote equitable access in Section III.4, pages 101-102, Section VI, pages 140-158, and Exhibits 12. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would promote equitable access.

Maximize Healthcare Value - The applicant describes how it believes the proposed project would maximize health care value in Section III.4, pages 102-103, Section X, pages 187-190 and the applicant's pro forma financial statements in Section XIII. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal will maximize health care value.

The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would maximize healthcare value and that the applicant's projected volumes incorporate the concepts of quality, equitable access and

maximum value for resources expended in meeting the need identified in the 2017 SMFP. Therefore, the application is consistent with Policy GEN-3.

Policy GEN-4. The proposed capital expenditure for this project is greater than $5.0 million therefore Policy GEN-4 is applicable to the review of this application. In Section III, page 104, Section XI.8, page 203 and Exhibit 22, the applicant explains why it believes its application is consistent with Policy GEN-4. On pages 104 the applicant states, *"WASC understands and agrees to submit a plan for energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of DHSR. The plan will include a written statement describing the project's plan to assure improved energy efficiency and water conservation in a way that does not affect patient or resident health, safety or infection control."*

Conclusion. The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant does not propose to develop more ORs than are determined to be needed in the 2017 SMFP for the New Hanover County operating room service area.
- The applicant adequately demonstrates that the proposal is consistent with Policy GEN-3 for the following reasons:
    - The applicant uses existing policies, historical data and verifiable sources to project utilization, and
    - The applicant adequately demonstrates how the projected volumes incorporated the concepts of quality, equitable access and maximum value for resources expended in meeting the identified need.
- The applicant provides a written statement describing the project's plan to assure improved energy efficiency and water conservation.

New Hanover Surgical Center, LLC (NHSC, LLC) and OWP4, LLC (OWP4), known collectively as NHSC proposes to develop a new ambulatory surgical facility with one new OR pursuant to the need determination in the 2017 SMFP and two procedure rooms.

Need Determination. The applicant does not propose to develop more ORs than are determined to be needed in the New Hanover County operating room service area.

Policy GEN-3. The applicant addresses Policy GEN-3 as follows:

Promote Safety and Quality - The applicants describes how the proposed project would promote safety and quality in Section II.8, page 22, Section III.4, pages 57-59 and Exhibit 7 and13. The information provided by the applicants is reasonable and adequately supports the determination that the applicants proposal would promote safety and quality.

Promote Equitable Access - The applicants describes how the proposed project would promote equitable access in Section III.4, pages 57-59, Section VI, pages 76-87, and Exhibits 4. The information provided by the applicants is reasonable and adequately supports the determination that the applicants proposal would promote equitable access.

Maximize Healthcare Value - The applicants describes how the proposed project would maximize health care value in Section III.4, pages 56-57, Section X, pages 106-108 and the applicants pro forma financial statements in Section XIII of the application. The information provided by the applicants is reasonable and adequately supports the determination that the applicant's proposal will maximize health care value.

The information provided by the applicants is reasonable and adequately supports the determination that the applicants proposal would maximize healthcare value and that the applicants projected volumes incorporate the concepts of quality, equitable access and maximum value for resources expended in meeting the need identified in the 2017 SMFP. Therefore, the application is consistent with Policy GEN-3.

Policy GEN-4. The proposed capital expenditure for this project is greater than $5.0 million therefore Policy GEN-4 is applicable to the review of this application. In Section XI.8, page 117, the applicants explain why the application is consistent with Policy GEN-4. On page 117, the applicant states, *"NHSC will work with experienced architects and engineers to ensure energy efficient systems and water conservation are an inherent part of the planned facility project."*

Conclusion. The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicants do not propose to develop more ORs than are determined to be needed in the service area.
- The applicants adequately demonstrate that the proposal is consistent with Policy GEN-3 for the following reasons:

  - The applicants use existing policies, historical data and verifiable sources to project utilization, and
  - The applicants adequately demonstrates how the projected volumes incorporated the concepts of quality, equitable access and maximum value for resources expended in meeting the identified need.
- The applicants provide a written statement describing the project's plan to assure improved energy efficiency and water conservation.

Decision

The applications submitted by NHRMC, Wilmington SurgCare, WASC and NHSC are conforming to the need determination in the 2017 SMFP, which identifies a need for one OR in the New Hanover County operating room service area. However, the limit on the number of ORs that can be approved is one. Collectively, the applicants propose a total of four ORs. Therefore, all of the applications cannot be approved even if all are conforming to all statutory and regulatory review criteria.

The applications submitted by NHRMC, WASC and NHSC are consistent with Policy GEN-3.

The application submitted by Wilmington SurgCare is not consistent with Policy GEN-3.

The applications submitted by WASC and NHSC are consistent with Policy GEN-4. As stated above, Policy GEN-4 is not applicable to the applications submitted by NHRMC and Wilmington SurgCare.

See the Conclusion following the Comparative Analysis for the decision.

(2) Repealed effective July 1, 1987.

(3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C
NHRMC
WASC
NHSC

NC
Wilmington SurgCare

NHRMC. The applicant proposes to develop one new OR pursuant to the need determination in the 2017 SMFP in the New Hanover operating room service area for a total of 39 operating

rooms (ORs) at NHRMC upon project completion. The applicant proposes to develop the new OR as a shared OR in NHRMCs existing surgical pavilion.

Patient Origin

On page 57, the 2017 SMFP defines the service area for ORs as *"the operating room planning area in which the operating room is located. The operating room planning areas are the single and multicounty groupings shown in Figure 6-1* [on page 60]*."* Figure 6-1 shows New Hanover County as a single county OR service area. Thus, the service area for this facility consists of New Hanover County. Facilities may also serve residents of counties not included in their service area.

In Section III.6, page 40, the applicant provides NRMC's historical patient origin for inpatient (IP) and outpatient (OP) surgical cases for fiscal year (FY) 2017 and the projected patient origin for the first two operating years (OY) FY2021 and FY2022 as shown in the table below.

County	**Current: FY2017 10/1/16 to 9/30/17**	**Projected: OY1(FY2020)**	**Projected: OY2(FY2021)**
New Hanover	42.6%	42.6%	42.6%
Brunswick	19.9%	19.9%	19.9%
Pender	11.5%	11.5%	11.5%
Onslow	9.6%	9.6%	9.6%
Columbus	5.1%	5.1%	5.1%
Other	11.4%	11.4%	11.4%
Total	100.0%	100.0%	100.0%

Source: Table page 40 of the application.

In Section III.6, page 40, the applicant provides the assumptions and methodology used to project its patient origin. The applicant's assumptions are reasonable and adequately supported.

Analysis of Need

In Section III.1, pages 27-34, the applicant describes the need for the proposed project and states that the need for an additional OR at NHRMC is supported by the factors as listed below and discussed thereafter:

- *Surgery Utilization*- NHRMC has operated at over 100.0 percent of OR capacity since FY2014. Since FY2016 NHRMC has had a facility need for three (3) ORs. (See pages 32-34 and Exhibit 8.)
- *Population Growth Trends*- The population of New Hanover County, from 2012-2017, grew by 8.3 percent. New Hanover County is projected to grow another 8.0 percent from 2017-2022 with the elderly segment of the population (65+ years old) projected to grow at 18.5% during that time. Further, NHRMC's primary service area of New Hanover Brunswick, Columbus, Onslow and Pender counties is projected to grow an additional 7.6 percent from 2017 -2022 on top of 7.4 percent growth from 2012-2017 with the elderly segment of the population projected to grow at 19.4% during that time (See pages 28-29)

- *New NHRMC Services*- Focusing on market capture, both current and future, in January 2014, NHRMC began operating and Accountable Care Organization (ACO) called Physician Quality Partners. An ACO is a set of health care providers, including primary care physicians, specialists and hospitals that work together collaboratively… *"ACOs may be the most promising mechanism to control costs and improve quality and access in the American healthcare system"*. (See pages 31-32)
- *NHRMC Physician Group Growth*- NHRMC's medical staff has increased by 80 physicians over the last 10 years, from 470 to 550. In addition, 20 additional physicians are scheduled to be added to NHRMC's physician's network over the next three years.

The information is reasonable and adequately supported for the following reasons:

- There is a need determination for one OR in the New Hanover County Operating Room Service Area in the 2017 SMFP. The applicant is applying to develop one OR in the New Hanover County operating room service area in accordance with the OR need determination in the 2017 SMFP.

- NHRMC's current OR utilization shows a need in excess of one OR.

- The applicant uses historical data that is clearly cited and reasonable demographical data to make the assumptions with regard to identifying the population to be served.

- The applicant uses Agency accepted methodologies and reasonable assumptions to demonstrate the need the population projected to be served has for the proposed services.

Projected Utilization

In Section IV.1, pages 44-45, the applicant provides historical and projected utilization as illustrated in the following tables.

Historical: Total NHRMC Surgical Cases <u>with</u> Exclusions

NHRMC: Total Historical Surgical Cases- Inpatient/Outpatient

	FY2012	FY2013	FY2014	FY2015	FY2016	FY2017
OP Cases*	15,928	19,526	21,666	21,944	23,421	25,574
IP Cases**	8,341	8,688	9,717	9,299	9,936	9,273
Total Cases	24,269	28,214	31,383	31,243	33,357	34,847

Source: Tables on pages 44-45 of the application.
*The number of OP Cases for FY2012 and FY2013 reflect corrections NHRMC made to the License Renewal Applications (LRA) to adjust for dental cases being mistakenly included in the OR OP cases for those respective LRAs.
**The number of IP surgical cases does not include any Open-Heart, C-Section or Trauma cases. Under the OR rules for calculating utilization and need Open-Heart, C-Section and Trauma cases are excluded.

Projected NHRMC Surgical Cases based on Historical Cases excluding Open-Hear, C-Section and Trauma cases.

NHRMC: Projected Surgical Cases Inpatient/Outpatient

	FY2018 (Interim)	FY2019 (Interim)	FY2020 (OY1)	FY2021 (OY2)	FY2022 (OY3)
OP Cases	27,027	28,564	30,187	31,903	33,716
IP Cases	8,930	8,777	8,626	8,478	8,330
Total Cases	35,957	37,341	38,813	40,380	42,046

Source: Table page 44 of the application.

In Section IV, pages 45-51, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

Step 1. Historical Analysis: NHRMC identified its historical IP and OP cases for the years FY2012-FY2017. The applicant then subtracted out all Open-Heart, C-Section and Trauma cases from the IP Case total. The applicant then subtracted out all dental cases from the total OP cases. (See page 45.)

	FY2012	FY2013	FY2014	FY2015	FY2016	FY2017
OP Cases	17,204	20,761	21,666	21,944	23,421	25,574
Dental Cases*	(1,276)	(1,235)	na	na	na	na
OP Cases with corrections	15,928*	19,526*	21,666	21,944	23,421	25,574
IP Cases*	10,686	11,167	12,289	11,978	12,815	12,389
Open Heart	(563)	(594)	(554)	(619)	(679)	(710)
C-Section	(1,120)	(1,067)	(1,110)	(1,046)	(1,099)	(1,122)
Trauma	(662)	(818)	(908)	(1,014)	(1,101)	(1,284)
IP Cases with exclusions	8,341	8,688	9,717	9,299	9,936	9,273
Total Cases**	24,269	28,214	31,383	31,243	33,357	34,847

Source: Table on page 45 of application
*The number of OP Cases for FY2012 and FY2013 reflect corrections NHRMC made to the License Renewal Applications (LRA) to adjust for dental cases being mistakenly included in the OR OP cases for those respective LRAs. The LRAs for FY2014 through FY2017 did not include dental cases in the OP OR case totals for which a correction had to be made.
**Total Cases equals OP Cases with corrections + IP Cases with exclusions

Step 2. Calculate Historical CAGR: NHRMC calculated the 2 year, 3 year, 4 year and 5 year historical CAGR for its surgical cases (IP and OP) for FY2012 to FY2017. The lowest historical CAGR was the 3 year CAGR: -1.5% for IP Cases and 5.7% for OP Cases. (See page 46.)

Historical Growth CAGR

	2yr	3yr	4yr	5yr
OP Cases	8.0%	5.7%	7.0%	9.9%
IP Cases	-0.1%	-1.5%	1.6%	2.1%

Source: Table on page 46.

Step 3. Project IP and OP Utilization through OY3 utilizing 3 year CAGR (See page 46.)

	CAGR applied	FY2017	FY2018	FY2019	FY2020	FY2021	FY2022
OP Cases	5.7%	25,574	27,027	28,564	30,187	31,903	33,716
IP Cases	-1.5%	9,273	9,130	8,988	8,849	8,712	8,578
Total Cases		34,847	36,157	37,552	39,036	40,615	42,294

Source: Table on page 46.

Step 4. Adjust or "Back Out" IP Surgical Cases Projected to Shift to Wilmington SurgCare (See page 47.)

	FY2018	FY2019	FY2020	FY2021	FY2022
Projected NHRMC IP Cases	9,130	8,988	8,849	8,712	8,578
Total Projected Case shift to Wilmington SurgCare	(200)	(211)	(223)	(235)	(248
Projected NHRMC IP Cases after shift	8,930	8,777	8,626	8,478`	8,330

Source: Table on page 47.

Step 5. Consolidate Projected IP and OP Cases – Table below reflects the adjustments calculated in Step 4. (See pages 48-49.)

	FY2017 (Historical)	FY2018 (Interim)	FY2019 (Interim)	FY2020 (OY1)	FY2021 (OY2)	FY2022 (OY3)
OP Cases	25,574	27,027	28,564	30,187	31,903	33,716
IP Cases	9,273	8,930	8,777	8,626	8,478	8,330
Total Cases	34,847	35,957	37,341	38,813	40,381	42,046

Source: Table page 48 of the application.

Step 6. OY3: Calculate OR Need at NRHMC in OY3 (See pages 50-51.)

OR Cases	OY3 (FY2022)	Hours/Case	OR Hours
OP Cases	33,716	1.5	50,574
IP Cases	8,330	3.0	24,989
Total OR Hours			75,563
OR Need (hours/1872)			40.36
# of Existing OR *			32
OR Need (ORs Needed – Existing ORs)			8.36
NHRMC OR Need			8

**NHRMC's # of ORs is based on a current total of 38 ORs minus 2 dedicated open heart surgery ORs = 36 ORs; 36 ORs minus 3 dedicated C-Section ORs = 33 ORs; 33 ORs minus 1 OR for Level II trauma = 32 ORs.
Source: Tables on pages 50-51.

As shown in the table above, in OY 3 (FY 2022), the applicant projects that 75,563 surgical hours will be performed at NHRMC, which documents a need for eight ORs consistent with the OR Performance Standard promulgated in 10A NCAC 14C .2103(b), as illustrated in the table below:

	Total Surgical Hours	Total Hours/ 1,872 Hours / OR / Year	# of existing ORs	# of ORs Needed
OY3	75,563	40.36	32	8

Furthermore, based on NHRMC's historical data from FY2017, NHRMC demonstrates a need for 3 ORs in FY2017. If NHRMC had projected no growth from FY2017 through OY3(FY2022), NHRMC's OR utilization would have shown a need for 3 ORs as shown on the table below.

OR Cases	FY2017	Hours/Case	OR Hours
OP Cases	25,574	1.5	38,361
IP Cases	9,273	3.0	27,819
Total OR Hours			66,180
OR Need (hours/1872)			35.4
# of Existing OR *			32
NHRMC OR Need (ORs Needed – Existing ORs)			3

**NHRMC's # of ORs is based on a current total of 38 ORs minus 2 dedicated open heart surgery ORs = 36 ORs; 36 ORs minus 3 dedicated C-Section ORs = 33 ORs; 33 ORs minus 1 OR for Level II trauma = 32 ORs.

Projected utilization is reasonable and adequately supported for the following reasons:

- NHRMC's historic and current OR utilization shows a need in excess of one OR, even with no OR utilization growth going forward.
- The applicant applied conservative CAGR growth rates in its projections.
- The applicant, again conservatively, backed out certain OP OR cases that, in a different application, are projected to shift from NHRMC to another facility.
- The methodology and assumptions are reasonable and adequately supported.

Access

In Section VI.4, page 72, the applicant states, *"It is the policy of all departments within NHRMC to admit and to treat all patients without regard to race, color, religion, creed, national origin, sex, sexual preference, disability, age, or ability to pay."* In Section VI. 14, page 78, and in Form D, pages 115 and 117 of the proformas, the applicant projects the following payor mix during the second full fiscal year of operation following completion of the project, as shown in the table below.

OR Services at NHRMC:
OY2 10/1/20 to 9/30/21 IP and OP Combined

Payor Category	Services as Percent of Total Surgical (IP + OP combined)	Actual Cases (Combined IP and OP)
Self Pay/Charity	4.6%	1,539
Medicare/Medicare Managed Care	50.6%	18,965
Medicaid	11.2%	3,151
Managed Care/Commercial Insurance	27.6%	14,304
Other	6.0%	2,423
Total	**100.0%**	**40,381**

Source: Page 78 of the application and Proformas Form D, pages 115 &117

The projected payor mix is reasonable and adequately supported.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately identifies the population to be served.
- The applicant adequately explains why the population to be served needs the services proposed in this application.
- Projected utilization is reasonable and adequately supported.
- The applicant projects the extent to which all residents, including underserved groups, will have access to the proposed services (payor mix) and adequately supports its assumptions.

Wilmington SurgCare. The applicant proposes to develop one new OR pursuant to the need determination in the 2017 SMFP in the New Hanover County operating room service area for a total of 11 ORs upon completion of this project and Project ID #O-11272-16 (add 3 ORs and a procedure room). Wilmington SurgCare is an existing multispecialty ambulatory surgical center (ASC) that is currently licensed with seven ORs. On April 28, 2017, the facility was approved to develop three additional ORs, however, that project is currently under appeal and no certificate of need (CON) has been issued.

Patient Origin

On page 57, the 2017 SMFP defines the service area for ORs as, *"the operating room planning area in which the operating room is located. The operating room planning areas are the single and multicounty groupings shown in Figure 6-1* [on page 60]*."* Figure 6-1 shows New Hanover County as a single county OR service area. Thus, the service area for this facility consists of New Hanover County. Facilities may also serve residents of counties not included in their service area.

In Section III, pages 58 and 61, the applicant provides Wilmington SurgCare's historical patient origin for OP surgical cases for FY2017 and the projected patient origin for the second operating year CY2022 as shown in the table below.

OR Surgery Cases: Historical and Projected Patient Origin

County	Current (October 1, 2016 to September 30, 2017)		Second Full FY of Operation following Project Completion (1/1/2022 to 12/30/2022)	
	Patients	% of Total	Patients	% of Total
New Hanover	3,638	42.64%	5,515	42.64%
Brunswick	2,112	24.76%	3,202	24.76%
Pender	691	8.10%	1,047	8.10%
Onslow	800	9.38%	1,213	9.38%
Columbus	426	4.99%	646	4.99%
Duplin	276	3.24%	418	3.24%
Sampson	73	0.86%	111	0.86%
Bladen	104	1.22%	158	1.22%
Carteret	91	1.07%	138	1.07%
Craven	57	0.67%	86	0.67%
Jones	29	0.34%	44	0.34%
Robeson	13	0.15%	20	0.15%
Wake	8	0.09%	12	0.09%
Pitt	6	0.07%	9	0.07%
Pamlico	5	0.06%	8	0.06%
Wayne	5	0.06%	8	0.06%
Halifax	4	0.05%	6	0.05%
Cumberland	4	0.05%	6	0.05%
Guilford	3	0.04%	5	0.04%
Mecklenburg	3	0.04%	5	0.04%
Harnett	2	0.02%	3	0.02%
Hyde	2	0.02%	3	0.02%
Lenoir	2	0.02%	3	0.02%
Randolph	2	0.02%	3	0.02%
Other NC Counties	22	0.26%	33	0.26%
South Carolina	118	1.38%	179	1.38%
Georgia	2	0.02%	3	0.02%
Tennessee	1	0.01%	2	0.01%
Virginia	6	0.07%	9	0.07%
Other States	26	0.30%	39	0.30%
Totals	8,531	100.00%	12,932	100.00%

Source: Pages 58 and 61 of the Application.
Note: Wilmington SurgCare currently has a GI endo room which they will be delicensing as part of Project ID# O-11272-16 (add 3 ORs and a procedure room). In Project ID# O-11272-16 the applicant projects the cases that were being performed in the GI endo room would be performed in an OR upon project completion.

In Section III.6, page 59, the applicant provides the assumptions and methodology used to project its patient origin for surgical services. The applicant's assumptions are reasonable and adequately supported.

In Section III, page 60, the applicant provides Wilmington SurgCare's projected patient origin for procedure room for the first two operating years (CY2021 and CY2022) as shown in the table below.

Procedure Room Cases- Wilmington SurgCare

County	OY1-Patients (CY 2021)	OY2-Patients (CY 2022)	% of Total Patients
New Hanover	141	144	42.64%
Brunswick	82	84	24.76%
Pender	27	27	8.10%
Onslow	31	32	9.38%
Columbus	17	17	4.99%
Duplin	11	11	3.24%
Sampson	3	3	0.86%
Bladen	4	4	1.22%
Carteret	4	4	1.07%
Craven	2	2	0.67%
Jones	1	1	0.34%
Robeson	1	1	0.15%
Other Counties	4	4	1.21%
South Carolina	5	5	1.38%
Total	331	338	100.0%

*Other North Carolina Counties include: Alamance, Ashe,, Beaufort, Burke, Cabarrus, Camden, Catawba, Dare, Davie, Edgecombe, Forsyth, Franklin, Lee, Lincoln, Montgomery, Moore, Nash, Rockingham, Stanly, Watauga and Wilson counties.

In Section III.6, page 60, the applicant provides the assumptions and methodology used to project its patient origin for the procedure room. The applicant's assumptions are reasonable and adequately supported.

Analysis of Need

In Section III.1, pages 25-51, the applicant describes the need for the proposed project and states that the need for an additional OR at Wilmington SurgCare is supported by the factors as listed below and discussed thereafter:

- *Population Factors (Aging and Growth).* The populations of New Hanover, Pender, Onslow and Brunswick counties are projected to grow by a combined 50,280 residents from 2018 to 2023. The segment of the population that is over 60 years old is projected to grow by a combined 27,071 residents for New Hanover, Brunswick, Pender, Onslow, Columbus, Duplin and Bladen counties from 2016 to 2021. (See application pages 26-28)
- *Advances in anesthesia and surgical techniques for ambulatory surgery*. A continued shift of surgical procedures to an ambulatory setting is being supported by changes in surgical and anesthesia techniques. (See application page 29)
- *Utilization trends in ASCs.* The number of surgical procedures in freestanding ambulatory centers has increased. (See application pages 30-31)

- *Reimbursement changes incentivizing separately licensed ASC use*. The Centers for Medicaid Services (CMS) has expanded its lists of procedures that can be reimbursed when performed in an ASC. (See application pages 31-33)
- *Need to expand physician access to multi-specialty ASC.* There are a limited number of ORs in freestanding ASC's in New Hanover County while the number of ambulatory surgery cases continues to increase. (See application page 33-34)
- *Additional capacity needed at Wilmington SurgCare.* Based on historic utilization. (See application pages 33-51)
- *Need to support physician recruitment and productivity.* Need additional OR to permit effective OR scheduling and physician productivity. (See application pages 36-51)
- *Need to add an OR consistent with the 2017 SMFP OR need determination*. Based on the need determination in the 2017 SMFP for an OR in the New Hanover County operating room service area. (See application pages 34-35)

The information is reasonable and adequately supported for the following reasons:

- There is a need determination for one OR in the New Hanover County Operating Room Service Area in the 2017 SMFP. The applicant is applying to develop one OR in the New Hanover County Operating Room Service Area in compliance with the OR need determination in the 2017 SMFP
- The applicant uses historical data that is clearly cited and reasonable demographical data to make the assumptions with regard to identifying the population to be served.
- The population (current and future) of the service area identified by the applicant, and especially the elderly population, has grown the last five years and is projected to grow at over 8.0% for the next five years.
- Patients have lower costs for the same services when those surgical services are received at a separately licensed ASC as opposed to OP surgery in ORs that operate under a hospital license.
- The list of surgical procedures received at an ASC which are reimbursable under Centers for Medicaid Services (CMS), Medicare and commercial insurance companies has expanded.
- Overall trends demonstrate increased utilization of ASC's.

Projected Utilization

In Section IV.1, page 68, the applicant provides historical utilization for FY2016 through CY2017 as illustrated in the following table.

Wilmington SurgCare: Historical Utilization

	2016**	2017 **	Actual Utilization 10/1/2016 to 9/30/2017 (will be 2018 LRA)	Current* 1/1/2017 to 12/31/2017
OP OR cases	8,463	8,589	8,531	8,531
# of OR rooms	7	7	7	7
GI Endoscopy Cases**	240	231	233	233
# of GI/Endoscopy Rooms	3	3	3	3
# of Procedures	212	226	223	223
# of Procedure Rooms	0	0	0	0

*Procedure Cases were performed in the GI/Endoscopy Rooms
**Based on 2016 and 2017 LRA
Note: The applicant is switching from a FY of October 1st through September 30th to a calendar year as of CY2017.

In Section IV.1, page 68, the applicant provides interim and projected utilization for CY2018 through CY2023(OY3) as illustrated in the following table.

Wilmington SurgCare: Interim and Projected Utilization

	Interim CY2018	Interim CY2019	Interim CY2020	OY1 CY2021	OY2 CY2022	OY3 CY2023
OP OR cases	8,958	9,405	10,921	11,891	12,932	13,813
# of OR rooms	7	7	10	10	10	11
Annual Growth Rate- OR Cases	na	5.0%	16.12%	8.9%	8.76%	6.8%
GI Endoscopy Cases*	224	215	0	0	0	0
# of GI/Endoscopy Rooms	3	3	0	0	0	0
Procedure Room Cases	234	246	285	311	338	361
# of Procedure Rooms	0	0	1	1	1	1

**The applicant has 3 existing GI/endoscopy rooms which it is delicensing as part of Project ID #: O-11272-16 and shifting the GI/endoscopy cases to the ORs.
Source: Table on page 68 of the application.

In Section III, pages 46-52, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

Steps 1-2. Historical IP and OP OR cases for the last four federal fiscal years (FFY2013 through FFY2016) from all the facilities in New Hanover County with licensed ORs. (See page 46.)

Licensed Facilities with ORs in New Hanover County	FY2013	FY2014	FY2015	FY2016
NHRMC-OP Cases Only	20,761	22,924	23,203	24,687
Wilmington SurgCare Cases	8,378	7,935	8,463	8,589
Total OP OR Cases	29,139	30,859	31,666	33,276

*Source: Tables on p.47 of the application.

Steps 3-4. Calculate the CAGR for the IP and OP OR cases from FFY2013 through FFY2016. (See page 46.)

Licensed Facilities with ORs in New Hanover County	**FY2013**	**FY2014**	**FY2015**	**FY2016**	**3-YR CAGR**
NHRMC-OP Cases Only	20,761	22,924	23,203	24,687	
Wilmington SurgCare	8,378	7,935	8,463	8,589	
Total OP OR Cases	29,139	30,859	31,666	33,276	6.67%

*Source: Tables on p.47 of the application.

Steps 4-7. Project total combined future OP OR utilization for all licensed OR facilities in New Hanover County that perform OP surgery in ORs by applying a CAGR of 5.5%, which is below the historical CAGR of 6.67% for OP OR cases in New Hanover County. (See page 46-48)

	CY2016	**CY2017**	**CY2018 (Interim)**	**CY2019 (Interim)**	**CY2020 (Interim)**	**OY1 (CY2021)**	**OY2 (CY2022)**	**OY3 (CY2023)**
Annual Growth Rate*	na	5.0%	5.0%	5.0%	5.0%	5.0%	5.0%	5.0%
Projected combined OP OR cases from NHRMC and Wilmington SurgCare	33,276	34,940	36,687	38,521	40,447	42,470	44,593	46,823

*Note: In Step 4 on page 46 the applicant states that to project future ambulatory surgery cases a 5.5% CAGR was used. However, the Table on p.47 refers to both a 5.5% CAGR and a 5.0% CAGR. The calculations utilized a 5.0% CAGR as reflected in the table above.

Source: Table on page 47 of the application.

Step 8-9. Calculate Wilmington SurgCare's OP OR market share for CY2017 through CY2023 and projected OR Utilization (See pages 48-49)

The applicant calculated Wilmington SurgCare's market share of by dividing the most recent 12 months actual annual utilization of 8,531 by the total OP OR cases in performed New Hanover County for CY2017 (34,940) [Market Share CY2017: 8,531/ 34,940 = .24416 or 24.4%.]

The market share, 24.4%, is used to project OR utilization for Wilmington SurgCare for CY2017, CY2018 and CY2019 during which time Wilmington SurgCare has seven ORs.

	CY2017	**CY2018**	**CY2019**
# of ORs	7	7	7
Total OP OR cases in New Hanover County Facilities	34,940	36,687	38,521
Market Share Assumption	24.4%	24.4%	24.4%
Wilmington SurgCare Cases	8,531	8,958	9,405

Source: Table on page 47 of the application.

Based on the approval of Project ID# O-11272-16 (add 3 ORs and one procedure room), Wilmington SurgCare is proposed to have 10 ORs in CY2020. With the approval of this project, Wilmington SurgCare assumes they will have 11 ORs in CY2021, CY2022 and CY2023. The first three Operating Years for this project are CY2021-CY2023. Wilmington SurgCare projects a market share of 27.0%, 28.0%, 29.0% and 29.5% for CY2020 through CY2023 based on the projected increase in the number of ORs at Wilmington SurgCare and the recruitment of new physicians. See both Exhibit 35 regarding the recruitment of new physicians and Exhibit 48 for additional information regarding projected market share and utilization projections as illustrated in the table below. (See page 48-49.)

	CY2020 (Interim)	**OY1 (CY2021)**	**OY2 (CY2022)**	**OY3 (CY2023)**
Total OP OR cases in New Hanover County Facilities (NHRMC and Wilmington SurgCare)	40,447	42,470	44,593	46,823
Market Share Assumption	27.0%	28.0%	29.0%	29.5%
Wilmington SurgCare Cases	10,921	11,891	12,932	13,813

Source: Table on page 47 of the application.

Steps 10-11. Calculate annual OR surgical case hours for Wilmington SurgCare for OY1-OY3 and the number of ORs needed at Wilmington SurgCare (See page 47 and 49)

	CY2020 (Interim)	**OY1 (CY2021)**	**OY2 (CY2022)**	**OY3 (CY2023)**
# of ORs*	10	11	11	11
Wilmington SurgCare Cases	10,921	11,891	12,932	13,813
Surgical Hours (OP Cases x 1.5 hrs)	16,381	17,837	19,398	20,719
# of ORs needed (Surgical Hours/1,872)	8.75	9.53	10.36	11.07
# of ORs needed per Rule**	9.0	10.0	10.0	11.0

*Wilmington SurgCare
**In Operating Room Service Areas with more than 10 ORs 0.5 is rounded up and 0.4 is rounded down.
Source: Table on page 47.

As shown in the table above, in OY 3 (CY 2022), the applicant projects that 20,719 outpatient surgical cases will be performed in the 11 ORs (7 existing, 3 approved, one proposed) at the Wilmington SurgCare facility, which documents a need for one ORs consistent with the OR Performance Standard promulgated in 10A NCAC 14C .2103(b), as illustrated in the table below:

	Outpatient Cases	**Total Hours (OP Cases x 1.5 Hours / Case)**	**Total Hours/ 1,872 Hours / OR / Year**	**# of Existing ORs***	**# of ORs Needed**
OY 3	13,813	20,719	11.07	10.0	1.0

*7 existing and 3 approved. See Project ID#O-11272-16
Source: Table on page 47 of the application.

However, projected OR utilization is not reasonable and adequately supported for the following reasons:

First: *An inaccurate CAGR Calculation was used in Steps 3-4 of the methodology to project overall OP OR cases in New Hanover through OY3*

As shown in the table below from page 47 of the application, the applicant calculated a CAGR of 6.67% for the last four historical years of OR OP cases in New Hanover County facilities.

Licensed Facilities with ORs in New Hanover County	**FY2013**	**FY2014**	**FY2015**	**FY2016**	**CAGR**
NHRMC-OP Cases Only	20,761	22,924	23,203	24,687	
Wilmington SurgCare Cases	8,378	7,935	8,463	8,589	
Total OP OR Cases	29,139	30,859	31,666	33,276	6.67%
CORRECTED CAGR					**4.52%**

*Source: Tables on p.47 of the application.

However, the mathematical calculation showing a CAGR of 6.67% is incorrect. The correct CAGR is 4.52%. The incorrect CAGR of 6.67% was "reduced" by the applicant to 5.0% and then applied in Steps 4-7 to project total overall OP OR cases for New Hanover County in OY3(CY2023) from all facilities with ORs (NHRMC and Wilmington SurgCare).

Using the correct CAGR of 4.52%, the table below projects overall OP OR cases for New Hanover County in OY3(CY2023) from all facilities with ORs (NHRMC and Wilmington SurgCare).

	CY2016	**CY2017**	**CY2018**	**CY2019**	**CY2020**	**OY1 (CY2021)**	**OY2 (CY2022)**	**OY3 (CY2023)**
Annual Growth Rate*	na	5.0%	5.0%	5.0%	5.0%	5.0%	5.0%	5.0%
Projected combined OP OR cases from NHRMC and Wilmington SurgCare	33,276	34,940	36,687	38,521	40,447	42,470	44,593	46,823
CORRECTED CAGR	**na**	**4.52%**	**4.52%**	**4.52%**	**4.52%**	**4.52%**	**4.52%**	**4.52%**
CORRECTED combined OP OR cases from NHRMC and Wilmington SurgCare	**33,276**	**34,780**	**36,352**	**37,995**	**39,712**	**41,507**	**43,383**	**45,344**

*Note: In Step 4 on page 46 the applicant states that to project future ambulatory surgery cases a 5.5% CAGR was used. However, the Table on p.47 refers to both a 5.5% CAGR and a 5.0% CAGR. The calculations utilized a 5.0% CAGR as reflected in the table above.

If a CAGR of 4.52% is utilized instead of a CAGR of 5.0% total projected OP OR cases in OY3 (CY2023) would be 45,343 not 46,823. The reason this is important is that to calculate projected OP OR cases in the OY3 Wilmington SurgCare utilized a methodology of projecting

total OP OR cases in New Hanover County for OY3(CY2023) and then multiplying that number by a projected market share assumption for Wilmington SurgCare. As shown above, Wilmington SurgCare's projected total of OP OR cases in New Hanover County for OY3(CY2023) was not reasonable. Furthermore, as discussed below, the projected market share assumption (the second part of the critical equation) utilized by Wilmington SurgCare was also not reasonable.

Second: *The Market Share Assumptions and Projections in Step 8 of the methodology are unsupported and not reasonable:*

The applicant utilizes its market share of OP OR cases in New Hanover County as part of its methodology to project utilization. See Step 8 above and on page 48 of the application. For CY2017 Wilmington SurgCare' market share is calculated by dividing its OP OR cases for CY2017 (8,531 cases) by the total OP OR cases for New Hanover County (34,940) to arrive at 24.4% market share assumption [8,531 / 34,940 = .2442 or 24.4%]. The applicant applies that market share percentage for CY2017 through CY2019 before starting to apply a higher market share assumption. However, as shown below, the applicant has declined in market share by -3.53% from FY2013 through FY2016.

	FY2013	FY2014	FY2015	FY2016	Change in Market Share OR CAGR
Total New Hanover OP OR Cases	29,139	30,859	31,666	33,276	
Wilmington SurgCare OP OR Cases	8,378	7,935	8,463	8,589	
Wilmington SurgCare OP OR Market Share	28.75%	25.71%	26.73%	25.81%	**(-3.53%)**
Average Change in Market Share from FY2013 to CY2016					(-1.18**)

*Under the applicant's method of converting FY to CY the years above are analogous.
** -3.53 / 3 years = -1.176 or -1.18% per year

Based on the historical decline in market share for Wilmington SurgCare from FY2013 to FY2016 it was not reasonable for Wilmington SurgCare to hold projected market share for CY2017 to CY2019 steady at 24.4%. Rather, based on the historical trend, the applicant should have reasonably applied a decreasing market share percentage for CY2017, CY2018 and CY2019 which would have lowered the projected market share for the first three operating years of the project.

Using the average yearly change in market share (or CAGR) for Wilmington SurgCare of (-1.18%) calculated in the table above the table below reflects the corrected market share assumptions for CY2017 through CY2023(OY3).

Projected Market Share CY2017: 25.81% (FY2016) - 1.18% = 24.63%
Projected Market Share CY2018: 24.63% - 1.18% = 23.45%
Projected Market Share CY2019: 23.45% - 1.18% = 22.27%

The applicant projected a 2.6% increase in Market Share in CY2020 based on three additional ORs being placed in service at Wilmington SurgCare pursuant to CON Project ID #O-11272-16. For CY2021 (OY1) and CY2022 (OY2) the applicant projected consecutive 1.0% increases in projected market share and for CY2023 (OY3) the applicant projected a 0.5% increase in market share. The projected market share for CY2021- CY2023 is calculated below keeping those same projected market share increases

Projected Market Share CY2020: 22.27% + 2.6% = 24.87%
Projected Market Share CY2021: 24.87 + 1.0% = 25.87%
Projected Market Share CY 2022: 25.87% + 1.0% = 26.87%
Projected Market Share CY2023: 26.87% + 0.5% = 27.37%

The table below shows both the applicants original market share assumptions for CY2017 to CY2023(OY3) and the corrected market share assumptions calculated above which factor in the historical decline in market share for Wilmington SurgCare from FY2013 to FY2016.

	CY2016	**CY2017**	**CY2018 (Interim)**	**CY2019 (Interim)**	**CY2020 (Interim)**	**OY1 (CY2021)**	**OY2 (CY2022)**	**OY3 (CY2023)**
# of ORs*	7	7	7	7	10	11	11	11
Applicants Market Share Assumption		24.4%	24.4%	24.4%	27.0%	28.0%	29.0%	29.5%
CORRECTED Market Share Assumption	25.81%	24.63%	23.45%	22.27%	24.87%	25.87%	26.87%	27.37%
Change in Market Share	na	-1.085%	-1.085%	-1.085%	2.6%	1.0%	1.0%	0.5%

Projected OP OR cases for Wilmington SurgCare through OY3(CY2023) utilizing the corrected projected OP OR cases for New Hanover County from all facilities (NHRMC and Wilmington SurgCare) and the corrected market share percentage.

	CY2017	CY2018	CY2019	CY2020 (Interim)	OY1 (CY2021)	OY2 (CY2022)	OY3 (CY2023)
# of ORs*	7	7	7	10	11	11	11
	34,780	**36,352**	**37,995**	**39,712**	**41,507**	**43,383**	**45,344**
CORRECTED Market Share Assumption (-1.085)	24.63%	23.45%	22.27%	24.87%	25.87%	26.87%	27.37%
Total Projected OP OR Cases from New Hanover County Facilities							12,411
X 1.5 hours							18,617
Divided by 1,872							9.95
Total ORs Needed (round up if .5 or higher)							**10.0**
Total number of Existing or Approved ORs							**10.00**
Total ORs needed at Wilmington SurgCare							**0.00**

Based on the corrected projected total OP OR cases in New Hanover County OY3 (CY2023) and the corrected projected market share of Wilmington SurgCare the projected utilization at Wilmington SurgCare in OY3 shows a need for 10 ORs. Wilmington SurgCare already has 10 ORs (7 existing and 3 approved). Therefore, there is no need for an additional OR as Wilmington SurgCare.

Third: *Unreasonable Time Frame:* As part of its utilization projections for this project the applicant relies on having developed three new ORs with the first operating year for the three new ORs being CY2020. See CON Project ID #O-11272-17. In Steps 8-11 above, the applicant utilizes a percent of market share to calculate projected utilization. The applicant increases market share based on the number of ORs the applicant anticipates being in service at Wilmington SurgCare. However, that approval is currently under appeal. By the time the appeal is fully resolved the project, at a minimum, will have been significantly delayed. The approval could also potentially be overturned. A delay in the three new ORs being developed by Wilmington SurgCare negatively impacts projected utilization. The applicant did not address this issue in its application, but rather kept the original projected project completion date. Adding the 3 approved ORs to Wilmington SurgCare even just one year later in CY2021 would have negatively impacted the market percentage in OY3 (CY2023) such that the total ORs needed at Wilmington SurgCare would have been less than 10 ORs based on the market share utilization methodology in this application.

GI/Endoscopy Room and Procedure Room Utilization

In Section IV.1, page 68, and Section III, pages 50-52, the applicant provides historical and projected utilization as summarized in the following table(s).

Wilmington SurgCare: Historical GI Endoscopy and Procedure Room Cases

	2016**	2017 **	Actual Utilization 10/1/2016 to 9/30/2017 (will be 2018 LRA)	Current* 1/1/2017 to 12/31/2017
GI Endoscopy Cases**	240	231	233	233
# of GI/Endoscopy Rooms	3	3	3	3
Procedure Room Cases*	212	226	223	223
# of Procedure Rooms	0	0	0	0

*Procedure Cases were performed in the GI Endoscopy Rooms
**Based on LRA

Wilmington SurgCare: Interim and Projected GI Endoscopy and Procedure Room Cases

	Interim CY2018	Interim CY2019	Interim CY2020	OY1 CY2021	OY2 CY2022	OY3 CY2023
GI Endoscopy Cases*	224	215	0	0	0	0
# of GI/Endoscopy Rooms	3	3	0	0	0	0
Procedure Room Cases (from Minor Procedure Room)	234	246	285	311	338	361
# of Procedure Rooms	0	0	1	1	1	1

**The applicant has 3 existing GI endoscopy rooms which it is delicensing as part of Project ID#O-11272-16 and shifting the GI endoscopy cases to the ORs.

Wilmington SurgCare had a ratio of OP OR Cases to procedure room cases of .026 for the last 12 months ending September 30, 2017. To project procedure room cases the applicant applied this historic ratio to projected OP OR cases at Wilmington SurgCare to project procedure room cases.

	Interim CY2018	Interim CY2019	Interim CY2020	OY1	OY2	OY3
OR Cases	8,958	9,405	10,921	11,891	12,932	13,813
Ratio	0.026	0.026	0.026	0.026	0.026	0.026
Procedure Room Cases	234	246	285	311	338	361

Projected Utilization of GI Endoscopy room cases and procedure room cases is reasonable and supported.

Access

In Section VI.2, page 78, the applicant states, *""The facility will not discriminate against anyone due to age, race, color, religion, ethnicity, gender, disability or ability to pay. Wilmington SurgCare provides language translation services at no cost to patients. The facility holds Medicare and Medicaid certification and accreditation in support of expanded patient access."*

In Section VI.14, page 85, the applicant projects the following payor mix during the second full fiscal year of operation following completion of the project, as illustrated in the following table.

Payor Category	Services as Percent of Total
Self Pay/Indigent	1.24%
Commercial Insurance	0.41%
Medicare/Medicare Managed Care	51.26%
Medicaid	7.78%
Managed Care	32.65%
Other	6.65%
Total	**100.0%**

Source: Table page 85 of application.

The projected payor mix is reasonable and adequately supported.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is not conforming to this criterion for the following reasons:

- Projected utilization is not reasonable and is not adequately supported.
- The applicant was previously approved to develop 3 ORs (See Project ID#O-11272-16). The applicant does not adequately address why the surgical services proposed in this application are needed in addition to the approved capacity surgical services pursuant to Project ID #O-11272-17.

WASC. The applicant proposes to develop a new multispecialty ambulatory surgical facility by developing one new OR pursuant to the need determination in the 2017 SMFP in the New Hanover County operating room service area, developing three procedure rooms, and relocating three existing multispecialty GI endoscopy rooms from Wilmington Health.

Patient Origin

On page 57, the 2017 SMFP defines the service area for ORs as *"the operating room planning area in which the operating room is located. The operating room planning areas are the single and multicounty groupings shown in Figure 6-1* [on page 60]*."* Figure 6-1 shows New

Hanover County as a single county OR service area. Thus, the service area for this facility consists of New Hanover County. Facilities may also serve residents of counties not included in their service area.

In Section III, page 106, the applicant provides WASC's projected patient origin for the first and second operating years CY2020 and CY2021, as shown in the table below.

County	First Full FY of Operation following Project Completion (1/1/2020 to 12/30/2020)		Second Full FY of Operation following Project Completion (1/1/2021 to 12/30/2021)	
	Patients	% of Total	Patients	% of Total
New Hanover	3,335	43.0%	5,900	43.0%
Brunswick	1,833	24.0%	3,243	24.0%
Pender	713	9.0%	1,261	9.0%
Onslow	694	9.0%	1,227	9.0%
Columbus	405	5.0%	717	5.0%
Other NC	432	6.0%	765	6.0%
Duplin	237	3.0%	419	3.0%
Other States	118	2.0%	208	2.0%
Totals	7,766	100.0%	13,740	100.0%

Source: Page 106 of the Application.

In Section III.6, pages 106-107, the applicant provides the assumptions and methodology used to project its patient origin for surgical services. The applicant's assumptions are reasonable and adequately supported.

Analysis of Need

In Section III.1, pages 64-96, the applicant describes the need for the proposed project and states that the need for an OR at WASC is supported by the factors as listed below and discussed thereafter:

- *Growth, aging, and health status of the population and a need for new multi-specialty* ASC that is organized around the needs of a moderate-income community that has a diversified population and substantial pockets of poverty of the population of the proposed service area (See application pages 66-68 and Exhibit 36)
- *Growth in ambulatory surgical cases in New Hanover County.* (See application pages 69-72)
- *Historical development of ORs in New Hanover County (See application pages 73-75)*
- *Need for more ASC capacity in New Hanover County not under a hospital license.* (See application pages 76-78)
- *Need for an OR to complement Wilmington Health's procedure rooms. (See application page 79)*
- *Need to reduce the cost of spine surgeries, and other more common surgeries like cataract, which are extremely expensive in a hospital-based environment.* (See application pages 80-81)
- *Need for specialized equipment.* (See application page 82)

- *Need for standardized pre and post-surgical processes for neurosurgery cases.* (See application page 83)
- *Need for increased patient convenience.* (See application page 84)
- *Need to increase physician capacity to treat more patients in Southeastern North Carolina.* (See application pages 85-86)
- *Need for extended stay short stay recovery beds.* (See application page 84)

The information is reasonable and adequately supported for the following reasons:

- There is a need determination for one OR in the New Hanover County Operating Room Service Area in the 2017 SMFP. The applicant is applying to develop a new ASC with one OR in the New Hanover County Operating Room Service Area in compliance with the OR need determination in the 2017 SMFP.
- The applicant uses historical data that is clearly cited and reasonable demographical data to make the assumptions with regard to identifying the population to be served.
- The applicant uses Agency accepted methodologies and reasonable assumptions to demonstrate the need the population projected to be served has for the proposed services.
- The population (future patient base for WASC) of the service area identified by the applicant is projected to increase by 57,145 residents over the next five years with the elderly population projected to increase by 22,597 people or a growth rate of 18.1%.
- Patients have lower costs for the same services when those surgical services are received at a separately licensed ASC as opposed to OP surgery in ORs that operate under a hospital license.
- The list of surgical procedures received at an ASC which are reimbursable under Centers for Medicaid Services (CMS), Medicare and commercial insurance companies has expanded.
- Overall trends demonstrate increased utilization of ASC's.

Projected Utilization

In Section IV.1, pages 117-118, the applicant provides projected utilization as illustrated in the following table(s).

WASC: Projected Utilization

	OY 1 (CY 2020)	**OY 2 (CY 2021)**	**OY 3 (CY 2022)**
# of ORs	1	1	1
Total OR OP Cases	795	1,337	1,357
# of GI/Endoscopy Rooms	3	3	3
Total GI/Endoscopy Procedures	4,915	4,915	4,990
# of Procedure Rooms	3	3	3
Total Procedure Room Cases	8,744	12,331	12,518

Source: Tables IV.1 and IV.2 on pages 117-118.

In Section IV, pages 119-128, the applicant provides the assumptions and methodology used to project utilization, which is summarized below:

The applicant projected OR Cases by specialty as illustrated in the table below.

Specialties	**OY1 (CY2020)**	**OY2 (CY2021)**	**OY3 (CY2022)**
General Surgery	250	439	446
Neurosurgery	232	372	378
Ophthalmology	0	0	0
Oral Surgery	15	29	29
Orthopedics	135	228	231
Plastic Surgery	146	240	244
Urology	0	0	0
Vascular	16	29	29
Podiatry	0	0	0
Gastroenterology	0	0	0
Total	795	1,337	1,357

Source: Table page 127 of the application.

To develop the table above, the applicant first projected total cases for OY2, then OY1 and then OY3 utilizing the following steps. The applicant first applied all appropriate cases to OY2 and then calculated a "start-up lag" for OY1 and reduced the cases in OY2 by the startup lag to project cases for OY1.

Step 1. Determined that the proposed WASC facility would be completed an offering services by January 1, 2020. Therefore OY1 through OY3 are CY2020 through CY2022, respectively. (See page 119)

Step 2. Utilized physician support letters by specialty found in Exhibit 18 which includes the number of cases expected to be performed by each physician. See also Exhibit 25. The cases, by specialty, match the overall table in Exhibit 25. The applicant states that the physician practices evaluated the number of outpatient surgical cases that would be appropriate for WASC. (See page 119)

Step 3. Eliminated referral cases that were not deemed appropriate for the proposed services at WASC. (See page 120)

Step 4. OY2 projected utilization: Identified the appropriate cases identified in the physician referral letters for WASC and assigned them, by specialty, to OY2. (See page 120 and Exhibit 25).

Step 5. By specialty, estimated the Medicaid and Medicare percentage of each specialty based on payor mix data and assumptions from Table VI.3 on page 156 of the application. (See page 121 and 156)

Specialties	% Medicare	% Medicaid	% Medicare/Medicaid Combined
General Surgery	40.7%	8.5%	49.3%
Neurosurgery	15.5%	0.0%	15.5%
Ophthalmology	71.8%	2.5%	74.3%
Oral Surgery	0.6%	73.7%	74.63%
Orthopedics	29.8%	4.8%	34.6%
Plastic Surgery	24.0%	2.0%	26.0%
Urology	34.0%	12.0%	46.0%
Vascular	55.0%	5.0%	60.0%
Podiatry	38.8%	6.3%	45.1%
Gastroenterology	35.0%	2.0%	37.0%

Step 6. OY1 projected utilization: Calculated a "Start-up Lag" for WASC and applied the "Start-up Lag" to the projected cases for OY2 to calculate projected cases for OY1. The "start-up lag" was based on a two-step process: first, the applicant applied a 35% reduction in all the cases listed by specialty, except for GI endo cases, to "allow time for all proposed WASC physicians to become comfortable with scheduling in the new facility"; and then, on top of the 35% reduction, the applicant applied a 25% reduction to all cases by specialty, except for GI endo cases, to allow for a three month delay associated with Medicare and Medicaid certification. Furthermore, the applicant assumed that all GI endo cases from Wilmington Health would transfer immediately upon WASC opening. See Table IV.4 and assumptions on pages 122-123 of the application.

Projected % Medicare & Medicaid	Specialty	WASC Cases OY2 (CY2021)	Start-up Lag (35%)	Medicare/Medicaid Certification Delay (25%)	WASC Cases OY1 (CY2020)
A	B	C	D	E	F
49.3%	General Surgery	732	256	59	417
15.5%	Neurosurgery	372	130	9	232
74.3%	Ophthalmology	5,112	1,789	617	2,706
74.63%	Oral Surgery	48	17	6	25
34.6%	Orthopedics	432	151	24	257
26.0%	Plastic Surgery	480	168	20	292
46.0%	Urology	684	239	51	393
60.0%	Vascular	288	101	28	159
45.1%	Podiatry	1,092	382	80	630
37.0%	Gastroenterology	4,428	na	na	4,428
	Total	13,688	3,234	895	9,539

Step 7. OY3 projected utilization: In Table III.4, page 89 of the application, the applicant calculated, for 2017 through 2022, the five year CAGR (1.5%) for projected population growth for the counties consisting of the proposed service area. The applicant projected OY3 cases by multiplying OY2 projected cases by the 1.5% CAGR. (See Table IV.5 and methodology on page 124.)

Specialties	OY2 (CY2021)	Population Growth Rate*	OY3 (CY2022)
General Surgery	732	1.50%	743
Neurosurgery	372	1.50%	378
Ophthalmology	5,112	1.50%	5,189
Oral Surgery	48	1.50%	49
Orthopedics	432	1.50%	439
Plastic Surgery	480	1.50%	487
Urology	684	1.50%	694
Vascular	288	1.50%	292
Podiatry	1,092	1.50%	1,109
Gastroenterology	4,428	1.50%	4,495
Total	13,688	1.50%	13,876

*Based on CAGR calculated in Table III.14, page 89.

The project analyst notes that the CAGR of 1.5% in Table III.14 on page 89 of the application is incorrect. The correct CAGR is 1.27% based on a starting population of 731,346 (2017), and ending population of 778,971 (2022) and a 5 year period. In the table below the CAGR of 1.27% is applied. The specialties in bold are the specialties the applicant projects performing in the proposed OR. Utilizing the corrected CAGR only reduced the projected number of OR cases in OY3 by 6 cases for a total of 1,351 OR cases in OY3 [1,357-6 = 1,351].

Specialties	OY2 (CY2021)	Population Growth Rate*	OY3 (CY2022)	Difference
General Surgery	**732**	**1.27%**	**741**	**-2**
Neurosurgery	**372**	**1.27%**	**377**	**-1**
Ophthalmology	5,112	1.27%	5,177	-12
Oral Surgery	**48**	**1.27%**	**49**	**0**
Orthopedics	**432**	**1.27%**	**438**	**-1**
Plastic Surgery	**480**	**1.27%**	**486**	**-1**
Urology	684	1.27%	693	-1
Vascular	**288**	**1.27%**	**292**	**0**
Podiatry	1,092	1.27%	1,106	-3
Gastroenterology	4,428	1.27%	4,484	-11
Total	13,688	1.27%	13,843	

*Based on CAGR calculated in Table III.14, page 89.
Source: Table IV.5 on page 124 and Table III.14 on page 89.

Furthermore, note that for OY2 (CY2021) the applicant projected 1,337 OR cases and for OY3 (CY2022) the applicant projects 1,357 OR cases, or an increase from OY2 to OY3 of only 20 OR cases, which is a very conservative increase. The 0.23 difference in the CAGR [1.50 – 1.27 = 0.23] had no significant effect.

Step 8: Calculated WASC overall combined cases: OR and Procedure Room, by specialty, for OY1-OY3. (See page 125.)

Specialties	OY1 (CY2020)	OY2 (CY2021)	OY3 (CY2022)
General Surgery	417	732	743
Neurosurgery	232	372	378
Ophthalmology	2,706	5,112	5,190
Oral Surgery	25	48	49
Orthopedics	257	432	439
Plastic Surgery	292	480	487
Urology	393	684	694
Vascular	159	288	292
Podiatry	630	1,092	1,109
Gastroenterology	4,428	4,428	4,495
Total*	9,539	13,688	13,876

Source: Table page 125 of the application.
*Note: the totals for OY1- OY3 in Table IV.6 on page 125 are incorrect. They were not totaled correctly. In addition, for OY1 there was a typographical error for gastroenterology. The number of cases of OY1 should have been 4,428 based on the rest of the application, not 2,612. The mathematical error was corrected and the total cases for OY1-OY3 are correct.

Step 9. Categorize WASC's projected cases, by specialty, as OR cases or Procedure Room cases. (See page 126.)

On page 126, the applicant states, *"Staff of Wilmington Health and SCA reviewed case history provided by the professionals who proposed to become members of the WASC medical staff. Using their combined experience managing ambulatory facilities, assembling ASA code surgical data for ACO and other reports, consulting with the professionals, these staff members estimated cases appropriate for the operating room or procedure rooms, by specialty. The process involved assigning a percentage operating room and procedure room to each physician and multiplying the proposed cases for project year 2. See Tables IV.4 and IV.5 for the result of this analysis. See Exhibit 24 for a breakdown of project year two, 2021, cases for operating room procedure rooms, by specialty."*

Steps 10-11. Projected WASC OR Cases and WASC Procedure Room Cases, By Specialty for OY1-OY3. The applicant applied the results of Step 9 to the table in Step 8 which resulted in the following tables. (See pages 126-128)

Projected OR Cases at WASC for OY1-OY3

Specialties	OY1 (CY2020)	OY2 (CY2021)	OY3 (CY2022)
General Surgery	250	439	446
Neurosurgery	232	372	378
Ophthalmology	0	0	0
Oral Surgery	15	29	29
Orthopedics	135	228	231
Plastic Surgery	146	240	244
Urology	0	0	0
Vascular	16	29	29
Podiatry	0	0	0
Gastroenterology	0	0	0
Total	795	1,337	1,357
Percent Increase	na	68.2%	1.5%
Case Increase	na	542	20

Source: Table page 127 of the application.

Projected Procedure Room Cases at WASC for OY1-OY3

Specialties	OY1 (CY2020)	OY2 (CY2021)	OY3 (CY2022)
General Surgery	167	293	297
Neurosurgery	0	0	0
Ophthalmology	2,706	5,112	5,190
Oral Surgery	10	19	19
Orthopedics	121	204	207
Plastic Surgery	146	240	244
Urology	393	684	694
Vascular	143	259	263
Podiatry	630	1,092	1,109
Gastroenterology	4,428	4,428	4,495
Total	8,744	12,331	12,518

Source: Table page 127 of the application.

The number of ORs needed at WASC, based on projected utilization, is calculated in the table below:

ORs Needed based on Projected Utilization

	CY 2020 (OY1)	CY 2021 (OY2)	CY 2022 (OY3)
Total OR Cases	795	1,337	1,357
Total OR Hours Based on 1.5 Hrs per Case* (OP Cases x 1.5 hrs per case)	1,192.5	2,005.5	2,035.5
Annual Hrs Per OR	1,872	1,872	1,872
Total ORs Needed at WASC (Total OR Hours/Annual Hrs (1,872) per OR)	0.64	1.07	1.09
Existing ORs	0	0	0
Additional ORs needed	0	1.0	1.0
Year 3 Rounded up to Whole Number			1.0

Source: Table on page 58 of the application.
*In Chapter 6 "*Operating Rooms*" of the 2016 SMFP there is a section on page 64 entitled "*The Methodology for Projecting Operating Room Need"* which states: *"For purposes of the State Medical Facilities Plan, the average operating rooms is anticipated to be staffed nine hours a day, for 260 days per year, and utilized at least 80 percent of the available time. The standard number of hours per operating room per year based on these assumptions is 1,872 hours. (Column K: 9 hours x 260 days x 0.8 – 1,872 hours per operating room per year)."* (See page 64, Step 3, Section f, of the 2016 SMFP)

As shown in the table above, in OY 3 (CY 2022), the applicant projects that 2,035.5 outpatient surgical hours will be performed in the proposed OR at the WASC facility, which documents a need for one ORs consistent with the OR Performance Standard promulgated in 10A NCAC 14C .2103(b), as illustrated in the table below:

	Inpatient Cases	Outpatient Cases	Total Hours (OP Cases x 1.5 Hours / Case)	Total Hours/ 1,872 Hours / OR / Year	# of ORs Needed
OY 3	----	1,357	2,035.5	1.09	1.0

Based on the analysis stated in Step 7 above, the applicant over projected OR cases by 6 cases. In the table below the OR need for WASC is projected based on 6 less OR cases than the applicant predicted. As shown in the table above, in OY 3 (CY 2022), the revised OR case projection results in 2,026.5 outpatient surgical hours to be performed in the proposed OR at the WASC facility, which documents a need for one ORs consistent with the OR Performance Standard promulgated in 10A NCAC 14C .2103(b), as illustrated in the table below:

	Inpatient Cases	Outpatient Cases	Total Hours (OP Cases x 1.5 Hours / Case)	Total Hours/ 1,872 Hours / OR / Year	# of ORs Needed
OY 3	----	1,351	2,026.5	1.082	1.0

Projected Utilization: GI Endoscopy Procedures

Step 12. Project GI Endoscopy Procedures at WASC for OY1-OY3. (See page 128.)

	OY1 (CY2020)	OY2 (CY2021)	OY3 (CY2022)
GI/Endoscopy Cases	4,428	4,428	4,495
Procedures per Case	1.11	1.11	1.11
GI/Endoscopy Procedures	4,915	4,915	4,990

Source: Table IV.9, page 128.

On page 128, the applicant states that the number of GI endo cases is conservatively estimated to start in 2021 *"at the level estimated by the physicians."* See Exhibits 18 and 25.

Projected utilization is reasonable and adequately supported for the following reasons:

- The methodology and assumptions are reasonable and adequately supported.
- The applicant documents a need for one ORs consistent with the OR Performance Standard promulgated in 10A NCAC 14C .2103(b),

Access

In Section VI.2, page 141, the applicant states, *"WASC will not discriminate on the basis of age, race, national, or ethnic origin, disability, sex, income, or ability to pay."*

In Form D of the proformas, the applicant projects the following payor mix for the proposed OR surgical services during the second full fiscal year of operation following completion of the project, as shown in the table below.

Payor Category	OR Services as Percent of Total OR Services:	OR Cases
Self Pay	5.94%	70
Medicare/Medicare Managed Care	28.31%	378
Medicaid	5.67%	76
Commercial Insurance	54.86%	733
Other (Military, Workers Comp)	5.21%	70
Total	**100.0%**	**1,337***

Source: Form D, Proformas of the application.
*Totals as 1,336. Appears to be a rounding issue.

Note: Table VI.1, page 153 of the application appears to be a typographical error and is incorrect. The information in the table above is consistent with the information in the proformas and the rest of the application.

The projected payor mix is reasonable and adequately supported.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately identifies the population to be served.
- The applicant adequately explains why the population to be served needs the services proposed in this application.
- Projected utilization is reasonable and adequately supported.
- The applicant projects the extent to which all residents, including underserved groups, will have access to the proposed services (payor mix) and adequately supports its assumptions.

NHSC. The applicants propose to develop a new single specialty ambulatory surgical facility with one new OR pursuant to the need determination in the 2017 SMFP in the New Hanover operating room service area for a total of one OR and two procedure rooms upon project completion.

Patient Origin

On page 57, the 2017 SMFP defines the service area for ORs as *"the operating room planning area in which the operating room is located. The operating room planning areas are the single and multicounty groupings shown in Figure 6-1* [on page 60]*."* Figure 6-1 shows New Hanover County as a single county OR service area. Thus, the service area for this facility consists of New Hanover County. Facilities may also serve residents of counties not included in their service area.

In Section III, page 61, the applicants provide NHSC's projected patient origin for the first and second operating years (CY2020 and CY2021) as shown in the table below.

NHSC: Projected Patient Origin- OY1 and OY2

County	**CY2020**	**CY2021**
New Hanover	76.2%	74.5%
Onslow	11.1%	12.0%
Pender	12.6%	13.6%
Total	100.0%	100.0%

Source: Table on page 61 of the application.

In Section III.6, page 61, the applicants provide the assumptions and methodology used to project its patient origin. The applicants assumptions are reasonable and adequately supported.

Analysis of Need

In Section III.1, pages 31-47, the applicants explains describes the need for the proposed project and states that the need for an OR as NHSC is supported by the factors listed below and discussed thereafter:

In identifying the need, the applicants reviewed:

- *Service Area Demographics and Growth Trends.* The population of New Hanover County is projected to increase by 18,283 residents from 2017 to 2022. The young adult segment of the population, ages 18-44, is expected to comprise approximately 40% of the population of New Hanover County by 2020 and due to participation in all levels of sports and recreation activities, with the accompanying prevalence of injuries, the proposed ASC specializing exclusively in orthopedics would benefit this population. (See application pages 42-47)

- *Physician Support*. Exhibit 10 includes letters from 12 orthopedic surgeons, in addition to letters of support from physicians who perform pain management procedures. (See application page 47 and Exhibit 10)

- *Ambulatory Surgery Centers.* There is increased demand for ASC's based on convenience, high levels of quality, cost savings and efficient physician practice. (See application pages 32-36)

- *Ambulatory Surgery for New Hanover County Residents*. There is a high ambulatory surgery usage rate in New Hanover County over 74% of those cases being performed in hospital-based surgical ORs. (See application pages 37-39)

- *Orthopaedic Surgery*. Orthopedic surgeries represent over 22.0% of the outpatient surgical cases in New Hanover County with musculoskeletal symptoms and disorders projected to continue to increase. (See application pages 39-42)

- *Ambulatory Surgery Growth Trends*. Ambulatory surgery cases account for approximately 72% of all surgical utilization in North Carolina and this trend is projected to continue. (See application pages 31-32)

The information is reasonable and adequately supported for the following reasons:

- There is a need determination for one OR in the New Hanover County operating room service area in the 2017 SMFP. The applicants are applying to develop a new ASC with one OR in the New Hanover County operating room service area in compliance with the OR need determination in the 2017 SMFP.

- The applicants use historical data that is clearly cited and reasonable demographical data to make the assumptions with regard to identifying the population to be served.

- The applicants use Agency accepted methodologies and reasonable assumptions to demonstrate the need the population projected to be served has for the proposed services.

- The population (future patient base for NHSC) of New Hanover County, identified by the applicants as the prime county of its three county service area, and especially the elderly population, has a projected 5 year CAGR growth rate of 1.6% which equates to an additional 18,238 residents.

- Patients have lower costs for the same services when those surgical services are received at a separately licensed ASC as opposed to OP surgery in ORs that operate under a hospital license.

- Overall trends demonstrate increased utilization of ASC's.

Projected Utilization

In Section IV.1, pages 66-67, the applicants provide projected utilization as illustrated in the following table.

NHSC: Projected Utilization

	OY 1 (CY 2020)	**OY 2 (CY 2021)**	**OY 3 (CY 2022)**
# of ORs	1	1	12
Total OR OP Cases	1,335	1,515	1,704
# of Procedure Rooms	2	2	2
Total Procedure Room Cases	306	311	316

In Section III, pages 48-55, the applicants provide the assumptions and methodology used to project utilization, which is summarized below.

OR Utilization

Step 1. Historical Utilization and Background Information (pages 48-50)

- Identified the proposed service area as being New Hanover, Onslow and Pender counties.

- State that, only Orthopaedic Surgeons are projected to use the proposed NHSC facility.

- State that, *"Based on recent data, orthopaedic ambulatory surgery cases from New Hanover, Onslow and Pender counties have increase by a CAGR of 6.5%"*

- Identified twelve individual Orthopaedic Surgeons (NHSC User Surgeons) projected to utilize the NHSC facility (See page 48). These NHSC User Surgeons provided letters of support which also include the specific number of projected case referrals to the proposed NHSC facility. See Table on page 53 and Exhibit 10.

- Historical OP OR cases of NHSC User Surgeons: Identified historical OP OR cases, for CY2015-CY2017, for the NHSC User Surgeons for the three county service area as illustrated below.

NHSC User Surgeons: Historic Orthopaedic OP OR Cases**

County	CY2015	CY2016	CY2017*
New Hanover	1,046	1,079	1,212
Onslow	293	253	281
Pender	263	303	323
Total	1,602	1,635	1,816

*Annualized based on data from January-September, 2017.
**Does not included any OP Surgical Case volume performed at Wilmington SurgCare. See application page 49.
Source: NHSC member surgeons (this does not necessarily mean from the 12 identified docs)

Step 2. Projected Utilization at all OR facilities for NHSC User Surgeons through CY2022 (pages 50-51)

First calculated the three year CAGR for all OP OR cases (including, but not limited to, orthopaedic cases) performed on residents from the three county service area, as shown below

All OP OR Cases Performed on Service Area Residents, 2013-2016

County	2013	2014	2015	2016	3 yr CAGR
New Hanover	10,068	14,857	15,197	15,490	15.4%
Onslow	8,807	9,067	9,471	10,368	5.6%
Pender	3,715	3,853	3,916	4,235	4.5%

Source: Table on page 50.

Second: Calculate a 3 yr CAGR for only orthopaedic OP OR cases

To project orthopaedic OP OR cases for New Hanover County the applicant applied a CAGR of 3.9%. The 3.9% was determined by calculating one-fourth or 25% of the 3 year CAGR for New Hanover County identified in the table above [15.4% x .25 = 3.85 or 3.9%]

To project orthopaedic OP OR cases for Onslow County the applicant applied a CAGR of 1.9%. The 1.9% was determined by calculating one-third or 33% of the 3 year CAGR for Onslow County identified in the table above [5.6% x .33 = 1.848 or 1.9%].

To project orthopaedic OP OR cases for Pender County the applicant applied a CAGR of 1.5%. The 1.5% was determined by calculating one-third or 33% of

the 3 year CAGR for Pender County identified in the table above [4.5% x .33 = 1.485 or 1.5%]

Third: Utilizing the identified CAGR's the applicant projected utilization for the NHSC User Surgeons from CY2018 to CY2022 as shown in the table below.

NHSC User Surgeons: Projected ORTHO OP OR Cases OY1-OY3**

County	**Growth Rate**	**CY2017 (Historic)**	**CY2018 (Interim)**	**CY2019 (Interim)**	**CY2020 (OY1)**	**CY2021 (OY2)**	**CY2022 (OY3)**
New Hanover	3.9%	1,212	1,259	1,307	1,358	1,410	1,465
Onslow	1.9%	281	287	292	297	303	309
Pender	1.5%	323	327	332	337	342	347
Total		1,816	1,873	1,932	1,993	2,055	2,121
Yearly Growth Rate		na	3.13%	3.15%	3.16%	3.11%	3.21%

*Annualized based on data from January-September 2017
**Does not included any OP Surgical Case volume performed at Wilmington SurgCare.
Source: NHSC member surgeons (this does not necessarily mean from the 12 identified docs)

Step 3. Projected Utilization at NHSC for NHSC User Surgeons through CY2022 (pages 51-54)

To project the number of OP OR cases of the NHSC User Surgeons that would be performed at the proposed NHSC facility the applicant projects that:

- During OY1(2020) 75% of the New Hanover Cases and 50% of the Onslow and Pender Cases identified in the table above would be performed at the proposed NHSC facility.

- During OY2(2021) 80% of the New Hanover Cases and 60% of the Onslow and Pender Cases identified in the table above would be performed at the proposed NHSC facility.

- During OY3(2022) 85% of the New Hanover Cases and 70% of the Onslow and Pender Cases identified in the table above would be performed at the proposed NHSC facility.

NHSC: Projected ORTHO OP OR Cases for OY1-OY2 for NHSC User Surgeons at NHSC

County	**CY2020**	**CY2021**	**CY2022**
New Hanover	1,018	1,128	1,245
Onslow	149	182	216
Pender	169	205	243
Total	1,336	1,515	1,704

Source: Table on page 52.

In support of the percentages applied the applicant states:

- Anecdotal Feedback from patients that most of the hospital-based OP OR cases would utilize the new proposed NHSC facility.

- Benefits of access to OP OR Surgical Services that are not hospital-based such as: lower cost/charges.

- Epidemiological and demographic data support the continued growth of orthopaedic OP OR services in the service area.

- Letters of Support from the twelve NHSC User Surgeons each projecting the number of OP OR cases they anticipate performing at the proposed NHSC. The projected number of cases totals 2,210. See Table on page 53 and Exhibit 10.

The table shows the calculation of the number of ORs needed at NHSC, based on projected utilization, for OY3.

ORs Needed based on Projected Utilization

	CY2020(OY1)	CY 2021 (OY2)	CY 2022 (OY3)
Total OR Cases	1,336	1,515	1,704
Total OR Hours Based on 1.5 Hrs per Case* (OP Cases x 1.5 hrs per case)	2,004	2,272.5	2,556
Annual Hrs Per OR	1,872	1,872	1,872
Total ORs Needed at NHSC (Total OR Hours/Annual Hrs (1,872) per OR)	1.07	1.21	1.37
Existing ORs	0	0	0
Additional ORs needed	1.0	1.0	1.0
Year 3 Rounded to Whole Number			1.0

Source: Table on page 58 of the application.
*In Chapter 6 "*Operating Rooms*" of the 2016 SMFP there is a section on page 64 entitled "*The Methodology for Projecting Operating Room Need"* which states: *"For purposes of the State Medical Facilities Plan, the average operating rooms is anticipated to be staffed nine hours a day, for 260 days per year, and utilized at least 80 percent of the available time. The standard number of hours per operating room per year based on these assumptions is 1,872 hours. (Column K: 9 hours x 260 days x 0.8 – 1,872 hours per operating room per year)."* (See page 64, Step 3, Section f, of the 2016 SMFP)

As shown in the table above, in OY 3 (CY 2022), the applicants project that 2,035.5 outpatient surgical cases will be performed in the one projected OR at the NHSC facility, which documents a need for one ORs consistent with the OR Performance Standard promulgated in 10A NCAC 14C .2103(b), as illustrated in the table below:

	Inpatient Cases	Outpatient Cases	Total Hours (OP Cases x 1.5 Hours / Case)	Total Hours/ 1,872 Hours / OR / Year	# of ORs Needed
OY 3	----	1,704	2,556	1.37	1.0

Projected utilization is reasonable and adequately supported for the following reasons:

- These NHSC User Surgeons provide letters of support which letters also include specific numbers of projected case referrals to the proposed NHSC facility. See Table on page 53 and Exhibit 10. The applicants project 1,336 orthopaedic OR cases at the proposed NHSC facility in OY1 and 1,704 orthopaedic OR cases in OY3. The twelve NHSC User Surgeons, per their letters of support, anticipate referring 2,210 orthopaedic OR cases to the proposed NHSC facility in OY1.
- The projected utilizations were conservative given the twelve NHSC User Surgeons anticipated OR case referrals in OY1

- NOTE: The projected OR methodology, without the above referenced letters of support with specific anticipated OR case referrals, was not reasonable and adequately supported for the following reasons:
  - The statement set forth in Step 1 *"Based on recent data, orthopaedic ambulatory surgery cases from New Hanover, Onslow and Pender counties have increase by a CAGR of 6.5%"* was not documented or supported.
  - The basis for the assumptions in Step 2 utilized to calculate the 3yr CAGR for New Hanover, Onslow and Pender were not adequately documented, explained or supported.
  - The basis for the assumptions in Step 3 utilized to calculate the number of the NHSC user surgeon cases that would be performed at NHSC was not documented, explained or supported.

Procedure Room Utilization

	OY1 (CY2020)	**OY2 (CY2021)**	**OY3 (CY2022)**
# of Procedure Rooms	2	2	2
# of Procedures (non-surgical)	306	311	318

As illustrated in the table below the applicants identified the non-surgical procedures performed by NHSC members on residents of New Hanover, Onslow and Pender counties at all facilities. To project utilization the applicant applied the New Hanover County population growth rate of 1.6%. The applicants then projected that approximately 10.0% of the projected procedures would be performed at NHSC based on historical analysis of the types of procedures performed on residents from the three county service area. Three physicians provided letters of support which included anticipated procedure case referrals. See pages 54-55 and Exhibit 10.

NHSC Pain Management Specialists: Procedures (non-surgical)

	Historical (CY2016)	**Annualized (CY2017)**	**Interim (CY2018)**	**Interim (CY2019)**	**OY1 (CY2020)**	**OY2 (CY2021)**	**OY3 (CY2022)**
Procedures (non-surgical): All facilities	2,171	2,970	3,016	3,016	3,111	3,160	3,209
NHSC					306	311	316

Projected utilization is reasonable and adequately supported for the following reasons:

- The methodology is reasonable, based on historic data and a reasonable growth rate and backed by physician letters of support with specific numbers of anticipated referrals that supports the applicants projections.

Access

In Section VI.2, page 76, the applicants state *"NHSC will not discriminate against anyone, and will provide medical services without regard to race, ethnicity, creed, color, age, religion, national origin, gender or handicap."* In Section VI.14, page 85, the applicants project the following payor mix during the second full fiscal year of operation following completion of the project, as illustrated in the following table.

Payor Category	& Services as Percent of Total:
Self Pay/ Indigent	3.4%
Medicare/Medicare Managed Care	12.9%
Medicaid	10.5%
Managed Care and Commercial Care	23.8%
BCBS	39.7%
Other (Workers Comp, TRICARE, VA)	9.7%
Total	**100.0%**

Source: Table on page 85 of application.

The projected payor mix is reasonable and adequately supported.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicants adequately identified the population to be served.
- The applicants adequately explain why the population to be served needs the services proposed in this application.
- Projected utilization is reasonable and adequately supported.
- The applicants project the extent to which all residents, including underserved groups, will have access to the proposed services (payor mix) and adequately supports its assumptions.

(3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

C
WASC

NA
NHRMC
Wilmington SurgCare
NHSC

NHRMC. The applicant does not propose to reduce, eliminate or relocate a facility or service in this review. Therefore, Criterion (3a) is not applicable to the review of this application.

Wilmington SurgCare. The applicant does not propose to reduce, eliminate or relocate a facility or service in this review. Therefore, Criterion (3a) is not applicable to the review of this application.

WASC. The applicant proposes to develop a new multispecialty ambulatory surgical facility by developing one new OR pursuant to the need determination in the 2017 SMFP, developing three procedure rooms, and relocating three existing multispecialty GI endoscopy rooms from Wilmington Health.

The applicant proposes to relocate three multispecialty GI/Endoscopy rooms from Wilmington Health Endoscopy Center (a licensed and existing ambulatory center owned and operated by Wilmington Health) to the proposed WASC facility. Both the existing Wilmington Health Endoscopy Center and the proposed WASC facility are located within Wilmington, in New Hanover County. According to Map Quest, the proposed WASC facility will be located approximately 3.9 miles (a seven minute drive) from the existing Wilmington Health Endoscopy Center facility. Therefore, the three multispecialty GI/Endoscopy rooms would be geographically accessible to the same population (including underserved groups) presently served by Wilmington Health Endoscopy Center.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments

- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the applicant adequately demonstrates that:

- The needs of the population currently using the services to be reduced, eliminated or relocated will be adequately met following project completion.
- The project will not adversely impact the ability of underserved groups to access these services following project completion.

NHSC. The applicants do not propose to reduce, eliminate or relocate a facility or service in this review. Therefore, Criterion (3a) is not applicable to the review of this application.

(4) Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

C
NHRMC
WASC
NHSC

NC
Wilmington SurgCare

NHRMC proposes to develop one new OR pursuant to the need determination in the 2017 SMFP for a total of 39 operating rooms (ORs) at NHRMC upon project completion. The project does not include any gastrointestinal endoscopy (GI/endoscopy) rooms.

In Section III.8, page 41-42, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

> Maintain the Status Quo- The applicant states that NHRMC is the ultimate safety-net provider of surgical services in the New Hanover County operating room service area and must treat all patients even as its capacity constraints are threatening its ability to meet the community's need. NHRMC has shown an internal need for 3 ORs since FY2016. Maintaining the status quo is not the most effective alternative to meet the need for additional ORs at NHRMC.
>
> Joint Venture- The applicant states that, because the project will be internal to NHRMC, a joint venture is impractical. Therefore, a joint venture to develop one new OR is not the most effective alternative.

On page 42, the applicant states that its proposal is the most effective alternative because there are not expensive renovation or equipment costs associated with the new OR, NHRMC has had an internal facility need for at least one additional OR since FY2014 and three ORs since FY2016 and the additional OR will meet the demand for surgical services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the applicant demonstrates that this proposal is its least costly or most effective alternative to meet the identified need for one additional OR in the New Hanover County operating room service area. Therefore, the application is conforming to this criterion.

Wilmington SurgCare proposes to develop one new OR pursuant to the need determination in the 2017 SMFP for a total of 11 ORs upon completion of this project and Project ID #O-11272-16 (add 3 ORs and one procedure room.)

In Section III.8, pages 62-63, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

Maintain the Status Quo- The applicant states that due to the growth and aging of the population in the service area the patients and physicians in New Hanover County will continue to need access to high quality, cost-effective ambulatory surgery services. Increasing demand for ambulatory surgical services is also being driven by changes in surgical technology and high demand for services. The most significant limiting factor Wilmington SurgCare has faced in the past has been the capacity of its operating rooms. The applicant states that despite the three additional ORs that will be developed at Wilmington SurgCare (CON Project ID# O-11272-16) it is not an effective alternative for Wilmington SurgCare not to seek to develop an additional OR when the opportunity arises.

Developing a New ASC at an Alternate Location- The applicant states that the current location of Wilmington SurgCare is in a highly effective location, can be expanded, and offers high quality services and a broad scope of services. Developing a new ASC in a new location in New Hanover County would necessitate incurring site, equipment and facility costs and be duplicative of what already exists at the Wilmington SurgCare facility. A new ASC would be more financially susceptible to changes in physicians or primary care referral patterns. Developing a new ASC at an alternate location would not be the least costly or most effective alternative.

On page 63, the applicant states that its proposal is the most effective alternative because the project avoids duplicative costs such as overall site development. Adding on to the existing project takes advantage of economies of scale, existing clinical and administrative services, agreements for professional services, support services and coordination with existing healthcare providers.

However, the applicant does not adequately demonstrate that the alternative proposed in this application is the most effective alternative to meet the need for the following reasons:

- The application is not conforming to all statutory and regulatory review criteria. An application that cannot be approved cannot be the most effective alternative.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is not conforming to this criterion for the reasons stated above. Therefore, the application is denied.

WASC proposes to develop a new multispecialty ambulatory surgical facility by developing one new OR pursuant to the need determination in the 2017 SMFP, developing three procedure rooms, and relocating three existing multispecialty GI endoscopy rooms from Wilmington Health.

In Section III.8, pages 108-109, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

Maintain the Status Quo – The applicant states that per the 2017 North Carolina license renewal applications (LRAs) for hospitals and ASCs utilization of ORs in New Hanover County is high. The New Hanover County operating room service area had need determination in the 2016 SMFP for three new ORs and the 2017 SMFP had a need determination for one new OR. Delays for surgery could occur with surgery demand exceeding available OR time in New Hanover County. Maintaining the status quo by not seeking to develop a new OR pursuant to the 2017 SMFP OR need determination for the New Hanover County operating room service area is not the most effective alternative.

Develop More Operating Rooms at New Hanover Regional Medical Center or Wilmington SurgCare- The applicant states that NHRMC and Wilmington SurgCare currently are the only two OR providers in New Hanover County. Simply adding OR capacity to one of the only two existing providers of OR surgical services in the New Hanover County operating room service area denies the patients in the proposed counties to be served the benefits of competition, the encouragement of lower cost and higher quality surgical services. Therefore, adding OR capacity to one of the only two existing providers of OR services and not adding a new provider in the New Hanover operating room service area is not the most effective alternative.

Joint Venture with Other Providers and/or include other Specialties- The applicant states that it has established a membership structure that will allow joint ventures with specialists who practice at the proposed facility. The proposed project is structured such as to permit ownership by participating specialties and accommodate interest from providers in those specialties.

Choose a Different Location- The applicant states that currently, NHRMC operates a surgery center, Atlantic SurgiCenter, in the northern part of New Hanover County, north of Wilmington. The proposed WASC facility would be south of Wilmington and south of NHRMC in a growing part of the county and accessible to both patients from New Hanover County, north of New Hanover County and from such counties as Brunswick and Columbus via major traffic corridors. Therefore, choosing a different location is not the most effective alternative.

On page 108, the applicant states that its proposal is the most effective alternative because it would add a new provider to the New Hanover County operating room service area, is structured in a flexible manner such as to permit ownership by participating specialties and makes joint ventures a possibility, and will be located in a growing area of the New Hanover County which is accessible to patients both from New Hanover County and surrounding counties.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the applicant demonstrates that this proposal is its least costly or most effective alternative to meet the identified need for one additional OR

in the New Hanover County operating room service area. Therefore, the application is conforming to this criterion.

NHSC proposes to develop a new ambulatory surgical facility with one new OR pursuant to the need determination in the 2017 SMFP and two procedure rooms.

In Section III.8, pages 62-64, the applicants describe the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

Maintain the Status Quo- The applicants state that there is a need for ambulatory surgery services in New Hanover County that is both cost effective and offered in the comfort and convenience of a dedicated outpatient ambulatory surgery facility. Currently there is only one freestanding, non-hospital based ASC in New Hanover County. The applicant states that the number of New Hanover County residents receiving ambulatory surgery has increased as well as the number of residents from Onslow and Pender counties traveling to New Hanover County for surgery. The applicants state that in 2017 NHSC's physicians will perform over 1,200 ambulatory surgery cases in hospital-based operating rooms. Therefore, maintaining the status quo by not developing a new OR pursuant to the need determination in the 2017 SMFP is not the most effective alternative.

Develop the Proposed ASC in Another Location- The applicants state that the proposed location will be centrally located in New Hanover County in Wilmington in a new medical office building near EmergOrtho's clinic. Wilmington is the major population center for New Hanover County and the county's medical infrastructure. The applicants state that local residents are accustomed to and familiar with Wilmington as the destination for their healthcare services in New Hanover County. The proposed location will be in close proximity to referring physician offices and accessible to primary traffic corridors. Therefore, developing the proposed ASC in another location is not the most effective alternative.

Develop an ASC Without Procedure Rooms- The applicants state that the combination of one OR and two procedure rooms maximizes economies of scale in terms of resources and facility staff. Further, pain management specialists are able to rotate procedures between each procedure room while the other room is being cleaned. Therefore, developing an ASC without procedure rooms is not the most effective alternative.

Develop a Multi-Specialty ASC with Procedure Rooms- The applicants state that developing a multi-specialty ASC could potentially increase OR turn over time because of the need to prepare the OR for different specialties and increase capital costs because of the different equipment needed for different surgical specialties. Staff training would also be less efficient. Therefore, developing a multi-specialty ASC with procedure rooms was not the most effective alternative.

On pages 62-64, the applicants state that its proposal is the most effective alternative because a new ASC with two procedure rooms will provide an additional provider of needed

ambulatory surgery services in a dedicated, free-standing ASC, centrally located and accessible by major traffic corridors and efficiently organized and focused.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the applicants demonstrate that this proposal is its least costly or most effective alternative to meet the identified need for one additional OR in the New Hanover County operating room service area. Therefore, the application is conforming to this criterion.

(5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C
NHRMC
WASC
NHSC

NC
Wilmington SurgCare

NHRMC proposes to develop one new OR pursuant to the need determination in the 2017 SMFP for a total of 39 operating rooms (ORs) at NHRMC upon project completion.

Capital and Working Capital Costs

In Section VIII, page 90, the applicant projects the total capital cost of the project as shown in the table below.

Construction Costs	$450,000
Miscellaneous Costs	$850,000
Total	**$1,300,000**

In Section XI, the applicant provides the assumptions used to project the capital cost.

In Section IX, page 94, the applicant projects that there will be no working capital costs as NHRMC is an existing facility.

Availability of Funds

In Section VIII, page 91, the applicant states that the capital cost will be funded as shown in the table below.

Sources of Capital Cost Financing

Type	Total
Accumulated reserves	$1.300,000
Total Financing	$1,300,000

Financial Feasibility

The applicant provided pro forma financial statements for the first three full fiscal years of operation following completion of the project. In Form C, the applicant projects that revenues will exceed operating expenses in the first three operating years of the project, as shown in the table below.

	1st Full Fiscal Year	2nd Full Fiscal Year	3rd Full Fiscal Year
Total Cases (Combined IP and OP cases)	38,813	40,381	42,046
Total Gross Revenues (Charges)	$1,140,795,430	$1,219,933,548	$1,306,078,005
Total Net Revenue	$297,213,754	$308,601,171	$320,674,149
Average Net Revenue per case	7,657.58	7,642.24	7,626.75
Total Operating Expenses (Costs)	$149,722,638	$158,825,455	$168,647,184
Average Operating Expense per case	3,857.54	3,933.17	4,011.02
Net Income	$147,491,116	$149,775,716	$152,026,965

Source: Source: Form C and Form D in the proformas, pages 109-117.

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section XIII of the application for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions.
- The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal.
- The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

Wilmington SurgCare proposes to develop one new OR pursuant to the need determination in the 2017 SMFP for a total of 11 ORs upon completion of this project and Project ID #O-11272-16 (add 3 ORs and a procedure room).

Capital and Working Capital Costs

In Section VIII, page 96, the applicant projects the total capital cost of the project as shown in the table below.

Site Costs	$64,419
Construction Costs	$673,092
Miscellaneous Costs	$360,000
Total	**$1,097,511**

In Section XI, the applicant provides the assumptions used to project the capital cost.

In Section IX, page 101, the applicant projects that there will be no working capital costs as NHRMC is an existing facility.

Availability of Funds

In Section VIII, page 98, the applicant states that the capital cost will be funded as shown in the table below.

Sources of Capital Cost Financing

Type	Total
Cash of Surgery Partners	$1.097,511
Total Financing	$1,097,511

Financial Feasibility

The applicant provided pro forma financial statements for the first three full fiscal years of operation following completion of the project. In Forms B & C, the applicant projects that revenues will exceed operating expenses in the first three operating years of the project, as shown in the table below.

	1st Full Fiscal Year	2nd Full Fiscal Year	3rd Full Fiscal Year
Total Cases*	12,202	13,270	14,174
Total Gross Revenues (Charges)	$125,999,345	$143,879,026	$161,364,610
Total Net Revenue	$18,659,651	$20,443,693	$21,959,413
Average Net Revenue per case	$1,529.23	$1,540.59	$1,549.27
Total Operating Expenses (Costs)	$17,099,589	$18,442,832	$19,587,318
Average Operating Expense per case	$1,401.38	$1,389.81	$1,381.92
Net Income	$1,560,062	$2,000,861	$2,372,095

*Total Cases includes: OR cases and pain cases
Source: Forms C, B and D in the proformas, pages 116-123.

However, the assumptions used by the applicant in preparation of the pro forma financial statements are not reasonable and adequately supported for the following reasons:

- Projected utilization is questionable. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference. Therefore, since projected revenues and expenses are based at least in part on projected utilization, projected revenues and expenses are also questionable.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is not conforming to this criterion because the applicant does not adequately demonstrate that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

WASC proposes to develop a new multispecialty ambulatory surgical facility by developing one new OR pursuant to the need determination in the 2017 SMFP, developing three procedure rooms, and relocating three existing multispecialty GI endoscopy rooms from Wilmington Health.

Capital and Working Capital Costs

In Section VIII, pages 173-174, the applicant projects the total capital cost of the project as shown in the table below.

Construction Costs	$5,176,441
Miscellaneous Costs	$8,211,510
Total	**$13,387,950**

In Section XI, the applicant provides the assumptions used to project the capital cost.

In Section IX, page 185, the applicant projects that start-up costs will be $1,408,067 and initial operating expenses will be $1,921,355 for a total working capital of $3,329,422. On page 186 and in Exhibit 31, the applicant provides the assumptions and methodology used to project the working capital needs of the project.

Availability of Funds

In Section VIII, page 98, the applicant states that the capital cost will be funded as shown in the table below.

Sources of Capital Cost Financing

Type	Total
Bank Loan from Sun Trust Bank	$13,387,950
Total Financing	$13,387,950

In Section IX, page 186, the applicant states that the working capital needs of the project will be funded as shown in the table below.

	Sources of Financing for Working Capital	Amount
(a)	Bank Loan from Sun Trust Bank	$3,329,422
(e)	**Total**	$3,329,422

Financial Feasibility

The applicant provided pro forma financial statements for the first three full fiscal years of operation following completion of the project. In Form B, the applicant projects that revenues will exceed operating expenses in the second and third operating years of the project, as shown in the table below.

	1st Full Fiscal Year	2nd Full Fiscal Year	3rd Full Fiscal Year
Total Cases*	9,539	13,668	13,875
Total Gross Revenues (Charges)	$43,615,351	$64,493,886	$66,453,729
Total Net Revenue	$10,121,953	$17,540,960	$17,808,655
Average Net Revenue per case	$1,061.11	$1,283.36	$1,283.51
Total Operating Expenses (Costs)	$11,321,950	$15,593,580	$15,852,772
Average Operating Expense per case	$1,186.91	$1,140.88	$1,142.54
Net Income	(-$1,199,998)	$1,947,380	$1,955,884

*Total Cases includes both OR cases and procedure room cases.
Source: Proformas in Section XIII.

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See the proformas of the application for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately demonstrates that the capital and working capital costs are based on reasonable and adequately supported assumptions.
- The applicant adequately demonstrates availability of sufficient funds for the capital and working capital needs of the proposal.
- The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

NHSC proposes to develop a new ambulatory surgical facility with one new OR pursuant to the need determination in the 2017 SMFP and two procedure rooms.

Capital and Working Capital Costs

In Section VIII, pages 98-99, the applicants project the total capital cost of the project as shown in the table below.

OWP4

Site Costs	$725,325
Construction Costs	$3,947,088
Miscellaneous Costs	$295,895
Total	**$4,968,308**

Note: OWP4 will include the development and construction costs of the building where the new ASC will be located.

New Hanover Surgical Center

Site Costs	$0.00
Construction Costs	$0.00
Miscellaneous Costs	$1,218,957
Total	$1,218,957

In Section VIII, page 96 and in Section XI, the applicants provide the assumptions used to project the capital cost.

In Section IX, page 104, the applicants project that start-up costs will be $160,000 and initial operating expenses will be $360,000 for a total working capital of $520,000. On page 104, the applicants provide the assumptions and methodology used to project the working capital needs of the project.

Availability of Funds

In Section VIII, page 98, the applicants state that the capital cost will be funded as shown in the table below.

Sources of Capital Cost Financing

Type	OWP4	New Hanover Surgical Center	Total
Total Financing: Loans	$4,968,308	$1,218,957	$ 6,187,265

In Section IX, page 186, the applicants state that the working capital needs of the project will be funded as shown in the table below.

Sources of Financing for Working Capital		Amount
(a)	Bank Loan from Sun Trust Bank	$520,000
(e)	**Total**	$520,000

Financial Feasibility

The applicants provide pro forma financial statements for the first three full fiscal years of operation following completion of the project. In Form B, the applicants project that revenues will exceed operating expenses in the first, second and third operating years of the project, as shown in the table below.

	1st Full Fiscal Year	2nd Full Fiscal Year	3rd Full Fiscal Year
Total Cases*	1,642	1,826	2,020
Total Gross Revenues (Charges)	$6,840,545	$7,843,333	$8,921,297
Total Net Revenue	$3,153,158	$3,618,377	$4,118,507
Average Net Revenue per case	$1,920.32	$1,981.59	$2,038.86
Total Operating Expenses (Costs)	$2,793,853	2,968,566	$3,163,185
Average Operating Expense per case	$1,701.49	$1,625.72	$1,565.93
Net Income	$359,304	$649,811	$955,322

*Total Cases includes both OR cases and procedure room cases.
Source: Proformas in Section XIII.

The assumptions used by the applicants in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See the proformas of the application for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicants adequately demonstrate that the capital and working capital costs are based on reasonable and adequately supported assumptions.
- The applicants adequately demonstrate availability of sufficient funds for the capital and working capital needs of the proposal.
- The applicants adequately demonstrate sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

(6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

C
NHRMC
WASC
NHSC

NC
Wilmington SurgCare

The 2017 State Medical Facilities Plan (2017 SMFP) includes an Operating Room Need Determination for one operating room in the New Hanover County operating room service area.

On page 57, the 2017 SMFP defines the service area for ORs as *"the operating room planning area in which the operating room is located. The operating room planning areas are the single and multicounty groupings shown in Figure 6-1* [on page 60]*."* Figure 6-1 shows New Hanover County as a single county OR service area. Thus, the service area for this proposal is New Hanover County. Facilities may also serve residents of counties not included in their service area.

According to Table 6A, on page 75 of the 2017 SMFP, there are 45 ORs in New Hanover County located in two facilities: Wilmington SurgCare (7 ORs) and NHRMC (38 ORs). In addition, the 2016 SMFP Need Determination contained a Need Determination for three ORs in the New Hanover County operating room service area. See table below. The decision

awarding the three ORs from the 2016 SMFP OR Need Determination, increasing the number of ORs to 48, is currently under appeal.

Operating Room Inventory for the New Hanover County Operating Room Service Area

	Inpatient ORs	Ambulatory ORs	Shared ORs	CON Adjustments	Total
2016 SMFP Need Determination*	0	0	0	3	3
Wilmington SurgCare	0	7	0	0	7
New Hanover Regional Medical Center	5	4	29	0	38
Total**	5	11	29	3	48

* The 3 ORs in the 2016 SMFP were awarded to Wilmington SurgCare. That decision is under appeal.
**Does not include CON adjustments for C-Section ORs.

NHRMC proposes to develop one new OR pursuant to the need determination in the 2017 SMFP for a total of 39 operating rooms (ORs) at NHRMC upon project completion. The applicant adequately demonstrates the need to develop one additional OR at NHRMC in Wilmington, New Hanover County, based on the number of projected patients it proposes to serve.

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area for the following reasons:

- There is a need determination in the 2017 SMFP for the proposed OR.
- The applicant adequately demonstrates the need the population proposed to be served has for the OR in addition to the existing and approved ORs.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

Wilmington SurgCare proposes to develop one new OR pursuant to the need determination in the 2017 SMFP for a total of 11 ORs upon completion of this project and Project ID #O-11272-16 (add 3 ORs and one procedure room).

In Section III.1, pages 25-51, the applicant explains why it believes the population projected to utilize the proposed OR services needs the proposed services.

However, the applicant does not adequately demonstrate that the proposal would not result in an unnecessary duplication of existing or approved services in the service area for the following reasons:

- Wilmington SurgCare's projected utilization is not reasonable and adequately supported. The discussion regarding analysis of need, including projected utilization, found in Criterion (3) is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is not conforming to this criterion for the reasons stated above.

WASC proposes to develop a new multispecialty ambulatory surgical facility by developing one new OR pursuant to the need determination in the 2017 SMFP, developing three procedure rooms, and relocating three existing multispecialty GI endoscopy rooms from Wilmington Health. The applicant adequately demonstrates the need to develop one OR at the proposed WASC facility in Wilmington, New Hanover County, based on the number of projected patients it proposes to serve.

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area for the following reasons:

- There is a need determination in the 2017 SMFP for the proposed OR.
- The applicant adequately demonstrates the need the population proposed to be served has for the existing and approved ORs.

Conclusion

The Agency reviewed the:

- Application

- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

NHSC proposes to develop a new ambulatory surgical facility with one new OR pursuant to the need determination in the 2017 SMFP and two procedure rooms. The applicant adequately demonstrates the need to develop one additional OR at the proposed NHSC facility in Wilmington, New Hanover County, based on the number of projected patients it proposes to serve.

The applicants adequately demonstrate that the proposal would not result in an unnecessary duplication of existing or approved services in the service area for the following reasons:

- There is a need determination in the 2017 SMFP for the proposed OR.
- The applicant adequately demonstrates the need the population proposed to be served has for the existing and approved ORs.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

(7) The applicant shall show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided.

C
NHRMC
Wilmington SurgCare

WASC
NHSC

NHRMC. In Section VII, Table VII.1 and Table VII.2, pages 79-80, the applicant provides current and projected staffing for the proposed services as illustrated in the following table.

Position	**Current FTEs* FY2017**	**Projected FTEs OY2(FY2021)**
Nursing Anesthetist	63.02	64.68
Staff Nurse	94.44	96.94
RN First Assistant	3.20	3.20
RN Specialty Nurse	7.56	7.56
Lead Intervention Rad Technician	1.09	1.09
Special Procedures Technician	4.27	4.27
Surgical Technician	10.28	10.53
Surgical Technology Extern	1.23	1.23
Certified Surgical Technologist	47.40	48.65
Nurse Aide II	0.98	0.98
Endoscopy Technician	0.97	0.97
OR Assistant I	4.84	4.84
OR Assistant II	21.46	21.96
Manager	1.00	1.00
Assistant Manager	1.94	1.94
Nurse Manager	1.00	1.00
Nursing Coordinator	2.65	2.65
Administrative Nursing Coordinator	1.00	1.00
Nurse Assessment	0.99	0.99
Schedule Facilitator	2.33	2.33
OR Charges Specialist- RN	1.00	1.00
Schedule Facilitator- WOW	0.65	0.65
Central Sterile Technician	1.41	1.41
Support Associate II	0.56	0.56
Support Associate III	5.73	5.73
Patient Liaison	1.03	1.03
Total	282.02	288.18

Source: Table VII.1 and Table VII.2, page 80 of the application.
*Full-Time Equivalent (FTE)

The assumptions and methodology used to project staffing are provided in Section XIII, pages 111-113. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form C, which is found in Section XIII, page 109. In Section VII, pages 81, 84-85 and Exhibit 16, the applicant describes the methods used to recruit or fill new positions and its existing (or proposed) training and continuing education programs. In Section VII.9, page 87, the applicant identifies the current medical director. In Exhibit 12, the applicant provides a letter from the proposed medical director indicating an interest in serving as medical director for the proposed services. In Section VII.7, pages 85-87, the applicant describes its physician recruitment plans. In Exhibit 11 and 17, the applicant provides supporting documentation.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

Wilmington SurgCare. In Section VII, pages 86-87, the applicant provides current and projected staffing for the proposed services as illustrated in the following table.

Position	**Current FTEs FY 2017**	**Projected FTEs OY2(FY2022)**
Administration	3.25	3.25
Medical Records/Billing	10.75	15.50
Materials Management	1.00	1.00
Clinical-Supervisors-RNs	2.00	2.00
Clinical-Infection/Quality Coordinator	1.00	1.00
Registered Nurses (RN)	21.75	30.50
Certified Nursing Assistants II	4.25	7.00
Certified Sterile Processing Technicians	2.75	3.50
Surgical Technicians	8.00	11.50
Clinical-Preadmission RN	2.00	2.50
Radiological Technologists	0.50	0.75
TOTAL	57.25	78.50

Source: Table VII.2 on pages 86-87 of the application.

The assumptions and methodology used to project staffing are provided in the financials section of the application pages 118 and 127-128. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in the proformas pages 127-128, which is found in the Financials Section of the application. In Section VII.3-4, pages 88-89, and Section VII.7, page 92, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. In Section VII.9, page 93, the applicant identifies the current medical director. In Exhibit 30, the applicant provides a letter from the proposed medical director indicating an interest in serving as medical director for the proposed services. In Section VII.7, page 92, the applicant describes its physician recruitment plans. In Exhibit 35, the applicant provides supporting documentation.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

WASC. WASC is not an existing facility, therefore it has no current staffing to report. In Section VII, page 160, the applicant provides projected staffing for the proposed services for the second full operating year (CY2021) as illustrated in the following table.

Position	Projected FTEs
Professional Health Care Administrators	1.00
Director of Nursing	1.00
Business Office Lead	1.00
RN	23.85
LPN	5.83
Surgical Technician	8.48
Radiology Technician	1.59
OR Attendant	2.00
Sterile Processing Coordinator	1.06
Medical Records Tech	1.00
All "non-health professionals" and "technical" personnel*	18.12
TOTAL	**64.93**

Source: Table VII.2, page 160 of the application.
*Includes Business Office Clerks, Purchasing Coordinators, Sterile Processing Clerk and Maintenance.

The assumptions and methodology used to project staffing are provided in Section XIII. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in the proformas, which are found in Section XIII. In Section VII, pages 161-162, the applicant describes the methods to be used to recruit or fill new positions and its proposed training and continuing education programs. In Section VII, page 168, the applicant identifies the proposed medical director. In Exhibit 6, the applicant provides a letter from the proposed medical director indicating an interest in serving as medical director for the proposed services. In Section VII, pages 165-168, the applicant describes its physician recruitment plans. In Exhibit 12, the applicant provides supporting documentation.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

NHSC. NHSC is not an existing facility, therefore it has no current staffing to report. In Section VII, page 89, the applicant provides projected staffing for the proposed services for the second full operating year (CY2021) as illustrated in the following table.

Position	Projected FTEs
Professional Health Care Administrator/Nurse Manager	1.0
Registered Nurses- Operating Room	2.0
Registered Nurses- Pre-admission, Pre-op, Post-op	3.0
Surgical Technicians/ Central Sterile	2.0
Medical Record Technician/Coder	0.5
Radiological Technologists and /or Technicians	1.0
All "non-health professionals" and "technical" personnel	2.5
TOTAL	**12.0**

Source: Table on page 89 of the application.

The assumptions and methodology used to project staffing are provided in Section XIII. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form B/C, which is found in Section XIII. In Section VII, pages 90-91 and 93, the applicants describe the methods to be used to recruit or fill new positions and its proposed training and continuing education programs. In Section VII, page 94, the applicants identified the proposed medical director. In Exhibit 5, the applicants provide a letter from the proposed medical director indicating an interest in serving as medical director for the proposed services. In Section VII, page 93, the applicants describe its physician recruitment plans. In Exhibit 8, the applicants provide supporting documentation.

The applicants adequately demonstrate the availability of sufficient health manpower and management personnel to provide the proposed services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

(8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

C
NHRMC
Wilmington SurgCare
WASC
NHSC

NHRMC. NHRMC is an existing hospital. In Section II, page 15, the applicant identifies the ancillary and support services necessary for the proposed project.

On page 15, and in Section XI, page 99, and Exhibit 22, the applicant adequately explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibit 5.

In Section V, pages 52-53, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibits 5, 9 and 10.

The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments

- Remarks made at the public hearing
- Responses to comments
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion.

Wilmington SurgCare. Wilmington SurgCare is an existing ASC. In Section II, page 10, the applicant identifies the ancillary and support services necessary for the proposed project.

On pages 10-12, the applicant adequately explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibits 9-12 and 49.

In Section V, pages 69-70, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibits 9-12, 23 and 49.

The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion.

WASC. In Section II, pages 43-44, the applicant identifies the ancillary and support services necessary for the proposed project.

On pages 43-44, the applicant adequately explains how each ancillary and support service will be made available and provides supporting documentation in Exhibits 9-10.

In Section V, pages 130-133, the applicant describes its efforts to develop relationships with other local health care and social service providers and provides supporting documentation in Exhibit 11, 18 and 19.

The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion.

NHSC. In Section II, pages 14-15, the applicants identified the ancillary and support services necessary for the proposed project.

On page15, the applicants adequately explain how each ancillary and support service will be made available and provides supporting documentation in Exhibit 18.

In Section V, pages 68-71, the applicants describe the efforts to develop relationships with other local health care and social service providers and provides supporting documentation in Exhibit 5, 6, 8, 10 and 11.

The applicants adequately demonstrate that the proposed services will be coordinated with the existing health care system.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion.

(9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA- All Applications

None of the applicants project to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which the services will be offered. Furthermore, none of the applicants project to provide the proposed services to a substantial number of persons residing in other states that are not adjacent to the North Carolina county in which the services will be offered. Therefore, Criterion (9) is not applicable to this review.

(10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:

(i) would be available under a contract of at least 5 years duration;
(ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
(iii) would cost no more than if the services were provided by the HMO; and
(iv) would be available in a manner which is administratively feasible to the HMO.

NA- All Applications

None of the applicants are an HMO. Therefore, Criterion (10) is not applicable to this review.

(11) Repealed effective July 1, 1987.

(12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

C
Wilmington SurgCare
WASC
NHSC

NA
NHRMC

NHRMC. The applicant does not propose to make more than minor renovations to existing space. Therefore, Criterion (12) is not applicable to the review of this application.

Wilmington SurgCare. In Section XI, page 107, the applicant states that the project involves constructing 804 square feet of new space. Line drawings are provided in Exhibit 44.

On page 112, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal and provides supporting documentation in Exhibit 37.

On page 102, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services and provides supporting documentation in Exhibits 37, 44 and 46.

On pages 55-56 and pages 112-113, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans and provides supporting documentation in Exhibit 37.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion.

WASC. In Section XI, page 200, the applicant states that the project involves constructing 18,875 square feet of new space. Line drawings are provided in Exhibit7.

On page 202, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal and provides supporting documentation in Exhibit 22.

On page 187, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services and provides supporting documentation in Exhibit 22.

On pages 104 and 203, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans and provides supporting documentation in Exhibit 22.

On page191-192 and Exhibit 22, the applicant identifies the proposed site and provides information about the current owner, zoning and special use permits for the site, and the availability of water, sewer and waste disposal and power at the site.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion.

NHSC. In Section XI, page 114, the applicants state that the project involves up fitting 15,034 square feet of leased space. Line drawings are provided in Exhibit 12.

On page 116, the applicants adequately explain how the cost, design and means of construction represent the most reasonable alternative for the proposal and provides supporting documentation in Exhibit 12.

On page 106, the applicants adequately explain why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services.

On page 117, the applicants identified any applicable energy and water saving features that will be incorporated into the construction plans.

On page 110, the applicants identified the proposed site and provides information about the current owner, zoning and special use permits for the site, and the availability of water, sewer and waste disposal and power at the site.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments

- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion.

(13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:

(a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C
NHRMC
Wilmington SurgCare

NA
WASC
NHSC

NHRMC. In Section VI.13, page 77, the applicant provides the historical payor mix for the last full operating year for the proposed services during 10/1/2016 – 9/30/2017, as shown in the table below.

Surgical Services- NHRMC: 10/1/2016 to 9/30/2017
Current Patient Days/ Procedures as Percent of Total Utilization

	IP	**OP**
Self Pay/ Charity	4.6%	3.6%
Medicare/Medicare Managed Care	50.6%	46.0%
Medicaid	11.2%	6.9%
Managed Care/Commercial Insurance	27.6%	`37.5%
Other	6.0%	6.0%
Total*	100.0%	100.0%

Source: Table on page 77 of application.

The United States Census Bureau provides demographic data for North Carolina and all counties in North Carolina. The following table contains relevant demographic statistics for the applicants service area.

Percent of Population						
County	**% 65+**	**% Female**	**% Racial & Ethnic Minority***	**% Persons in Poverty****	**% < Age 65 with a Disability**	**% < Age 65 without Health Insurance****
	2016 Estimate	2016 Estimate	2016 Estimate	2015 Estimate	2011-2015	2015 Estimate
New Hanover	17%	52%	23%	17%	9%	12%
Brunswick	29%	51%	18%	14%	12%	15%
Pender	18%	50%	25%	15%	13%	14%
Onslow	9%	16%	33%	15%	12%	10%
Columbus	19%	51%	41%	24%	15%	15%
Statewide	16%	51%	37%	16%	10%	13%

Source: http://www.census.gov/quickfacts/table Latest Data 7/1/16 as of 8/22/17
*Excludes *"White alone"* who are *"not Hispanic or Latino"*
***"This geographic level of poverty and health estimates are not comparable to other geographic levels of these estimates. Some estimates presented here come from sample data, and thus have sampling errors that may render some apparent differences between geographies statistically indistinguishable…The vintage year (e.g., V2016) refers to the final year of the series (2010 thru 2016). Different vintage years of estimates are not comparable."*

However, a direct comparison to the applicant's current payor mix would be of little value. The population data by age, race or gender does not include information on the number of elderly, minorities, women or handicapped persons utilizing health services.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the applicant's adequately documents the extent to which medically underserved populations currently use the applicants existing services in comparison to the percentage of the population in the applicants service area which is medically underserved. Therefore, the application is conforming to this criterion.

Wilmington SurgCare. In Section VI.13, pages 84, the applicant provides the historical payor mix for the last full operating year for the proposed surgical services during 1/1/2016 – 12/31/2016, as shown in the table below:

Wilmington SurgCare Payor Mix FY 2016 (1/1/16-12/31/16)	
Payor	**Cases as % of Total Cases**
Self-Pay / Indigent	1.24%
Medicare / Medicare Managed Care	51.26%
Medicaid	7.78%
Commercial Insurance	0.41%
Managed Care	32.65%
Other (Workers Comp, TriCare and Other)	6.65%
Total	100.00%

Source: Application page 84. Tables may not foot due to rounding.

The United States Census Bureau provides demographic data for North Carolina and all counties in North Carolina. The following table contains relevant demographic statistics for the applicants service area.

Percent of Population						
County	**% 65+**	**% Female**	**% Racial & Ethnic Minority***	**% Persons in Poverty****	**% < Age 65 with a Disability**	**% < Age 65 without Health Insurance****
	2016 Estimate	2016 Estimate	2016 Estimate	2015 Estimate	2011-2015	2015 Estimate
New Hanover	17%	52%	23%	17%	9%	12%
Brunswick	29%	51%	18%	14%	12%	15%
Pender	18%	50%	25%	15%	13%	14%
Onslow	9%	16%	33%	15%	12%	10%
Columbus	19%	51%	41%	24%	15%	15%
Duplin	17%	51%	48%	25%	12%	21%
Statewide	16%	51%	37%	16%	10%	13%

Source: http://www.census.gov/quickfacts/table Latest Data 7/1/16 as of 8/22/17
*Excludes *"White alone"* who are *"not Hispanic or Latino"*
***"This geographic level of poverty and health estimates are not comparable to other geographic levels of these estimates. Some estimates presented here come from sample data, and thus have sampling errors that may render some apparent differences between geographies statistically indistinguishable…The vintage year (e.g., V2016) refers to the final year of the series (2010 thru 2016). Different vintage years of estimates are not comparable."*

However, a direct comparison to the applicant's current payor mix would be of little value. The population data by age, race or gender does not include information on the number of elderly, minorities, women or handicapped persons utilizing health services.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments

- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the applicants adequately document the extent to which medically underserved populations currently use the applicants existing services in comparison to the percentage of the population in the applicants service area which is medically underserved. Therefore, the application is conforming to this criterion.

WASC. Neither the applicant nor any related entity owns, operates, or manages an existing facility in the service area. Therefore, Criterion (13a) is not applicable to the review of this application.

NHSC. Neither the applicants nor any related entity owns, operates, or manages an existing facility in the service area. Therefore, Criterion (13a) is not applicable to the review of this application.

(b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C
NHRMC
Wilmington SurgCare

NA
WASC
NHSC

NHRMC. Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section VI.11, page 76, the applicant states, *"NHRMC fulfilled its Hill-Burton obligation and does not have any related obligation under any applicable federal regulations to provide uncompensated care, community service, or access by minorities and the handicapped."*

In Section VI.10, page 76, the applicant states that during the last five years no patient civil rights access complaints have been filed against NHRMC**.**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments

- Remarks made at the public hearing
- Responses to comments
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion.

Wilmington SurgCare. Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section VI, page 83, the applicant states, *"Wilmington SurgCare has no obligations to provide uncompensated care."*

In Section VI, page 83, the applicant states that during the last five years no patient civil rights access complaints exist.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion.

WASC. Neither the applicant nor any related entity owns, operates or manages an existing facility located in the service area. Therefore, Criterion (13b) is not applicable to the review of this application.

NHSC. Neither the applicants nor any related entity owns, operates or manages an existing facility located in the service area. Therefore, Criterion (13b) is not applicable to the review of this application.

(c) That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services; and

C
NHRMC
Wilmington SurgCare
WASC

NHSC

NHRMC. In Section VI. 14, page 78, and in Form D, pages 115 and 117 of the proformas, the applicant projects the following payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as shown in the table below.

Surgical Services at NHRMC
OY2 10/1/20 to 9/30/21 IP and OP Combined

Payor Category	Services as Percent of Total Surgical (IP + OP combined)	Actual Cases (Combined IP and OP)
Self Pay/Charity	4.6%	1,539
Medicare/Medicare Managed Care	50.6%	18,965
Medicaid	11.2%	3,151
Managed Care/Commercial Insurance	27.6%	14,304
Other	6.0%	2,423
Total	**100.0%**	**40,381**

Source: Proformas Form D, pages 115 & 117 of the application.
Note: NHRMC surgical services does not include any procedure rooms.

As shown in the table above, during the second full fiscal year of operation, the applicant projects that for IP OR Services 4.6% of total services will be provided to self-pay/charity patients, 50.6% to Medicare patients and 11.2% to Medicaid patients and that for OP OR Services 3.6% of total services will be provided to self-pay/charity patients, 46.0% to Medicare patients and 6.9% to Medicaid patients.

On page 78, the applicant provides the assumptions and methodology used to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported for the following reasons:

- The projected payor mix is based on historical payor mix of NHRMC.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion.

Wilmington SurgCare. In Section VI. 14, page 85, the applicant projects the following payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as shown in the table below.

Payor Category	OR Services as Percent of Total OR Services	OR Cases
Self Pay/Indigent	1.24%	160
Commercial Insurance	0.41%	53
Medicare/Medicare Managed Care	51.26%	6,629
Medicaid	7.79%	1,007
Managed Care	32.65%	4,222
Other	6.65%	860
Total	**100.0%**	**12,932**

Source: Table page 85 of application and Proformas- Form D, page 121.

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 1.24% of total services will be provided to self-pay/indigent patients, 7.78% to Medicare patients and 51.26% to Medicaid patients.

On page 85, the applicant provides the assumptions and methodology used to project payor mix during the second full fiscal year of operation following completion of the project. In the proformas, pages 124-126, the applicant projects the same payor mix for just the OR cases and the combination of OR and procedure room cases. The projected payor mix is reasonable and adequately supported for the following reasons:

- The projected payor mix is based on historical payor mix of Wilmington SurgCare for the entire facility, including ORs and GI procedure rooms.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion.

WASC. In Form D of the proformas, the applicant projects the following payor mix for the proposed OR surgical services during the second full fiscal year of operation following completion of the project, as shown in the table below.

Payor Category	OR Services as Percent of Total OR Services:	OR Cases
Self Pay	5.94%	70
Medicare/Medicare Managed Care	28.31%	378
Medicaid	5.67%	76
Commercial Insurance	54.86%	733
Other (Military, Workers Comp)	5.21%	70
Total	**100.0%**	**1,337***

Source: Form D, Proformas of the application.
*Totals as 1,336. Appears to be a rounding issue.

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 5.94% of total services will be provided to self-pay patients, 28.31% to Medicare patients and 5.67% to Medicaid patients.

Note: [Table VI.1, page 153 of the application the percentages for each payor category appear to be a typographical error and are incorrect.

Payor Category	OR Services as Percent of Total OR Services:
Self Pay	2.0%
Medicare/Medicare Managed Care	49.0%
Medicaid	4.0%
Commercial Insurance	43.0%
Other (Military, Workers Comp)	3.0%
Total	**100.0%**

In its response to comments WASC acknowledged the typos and stated that the payor mix projections in the proformas match the entire facility payor mix projections in Table VI.5 and that the data in the proformas is consistent with the pro forma assumptions, utilization assumptions and income statements.] The information in the table above, not the table in the Note, is consistent with the information in the proformas and the rest of the application.

On pages 153-158, the applicant provides the assumptions and methodology used to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported for the following reasons:

- The projected payor mix is based on historical payor mix of existing ASC facilities in North Carolina.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion.

NHSC. In Section VI. 14, page 85, the applicants project the following payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as shown in the table below.

Payor Category	OR Services as Percent of Total OR Services:	OR Cases
Self Pay/ Indigent (p. 85) (Just Self Pay in Form D)	3.4%	52
Medicare/Medicare Managed Care (p.85)…(Just Medicare in Form D)	12.9%	195
Medicaid	10.5%	159
Managed Care and Commercial Care	23.8%	360
BCBS	39.7%	601
Other (Workers Comp, TRICARE, VA)	9.7%	148
Total	**100.0%**	**1,515**

Source: Table on page 85 of application and Proformas Form D

As shown in the table above, during the second full fiscal year of operation, the applicants project that 3.4% of total services will be provided to self-pay/indigent patients, 12.9% to Medicare patients and 10.5% to Medicaid patients.

On pages 86-87, the applicants provide the assumptions and methodology used to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported for the following reasons:

- The projected payor mix is based on the historical payor mix of residents from New Hanover, Onslow and Pender County who obtained outpatient surgery from NHSC physicians during 2016.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion.

(d) That the applicant offers a range of means by which a person will have access to its services. Examples of a range of means are outpatient services, admission by house staff, and admission by personal physicians.

C
NHRMC
Wilmington SurgCare
WASC
NHSC

NHRMC. In Section VI.9, page 75, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion.

Wilmington SurgCare. In Section VI.9, page 83, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion.

WASC. In Section VI.9, page 150, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion.

NHSC. In Section VI.9, page 82-83, the applicants adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion.

(14) The applicant shall demonstrate that the proposed health services accommodate the clinical needs of health professional training programs in the area, as applicable.

C
NHRMC
Wilmington SurgCare
WASC
NHSC

NHRMC. In Section V, pages 52-53, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibits 9 and 10.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the applicant adequately demonstrates that the proposed services will accommodate the clinical needs of area health professional training programs, and therefore, the application is conforming to this criterion.

Wilmington SurgCare. In Section V, page 69, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit 27.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the applicant adequately demonstrates that the proposed services will accommodate the clinical needs of area health professional training programs, and therefore, the application is conforming to this criterion.

WASC. In Section V, page 129, the applicant describes the extent to which health professional training programs in the area will have access to the facility for training purposes and provides supporting documentation in Exhibit 23.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the applicant adequately demonstrates that the proposed services will accommodate the clinical needs of area health professional training programs, and therefore, the application is conforming to this criterion.

NHSC. In Section V, page 68, the applicants describes the extent to which health professional training programs in the area will have access to the facility for training purposes and provides supporting documentation in Exhibit 11.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the applicants adequately demonstrate that the proposed services will accommodate the clinical needs of area health professional training programs, and therefore, the application is conforming to this criterion.

(15) Repealed effective July 1, 1987.
(16) Repealed effective July 1, 1987.
(17) Repealed effective July 1, 1987.
(18) Repealed effective July 1, 1987.

(18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

WASC
NHSC

NC
Wilmington SurgCare

The 2017 SMFP includes an Operating Room Need Determination for one operating room in the New Hanover County operating room service area.

On page 57, the 2017 SMFP defines the service area for ORs as *"the operating room planning area in which the operating room is located. The operating room planning areas are the single and multicounty groupings shown in Figure 6-1* [on page 60]*."* Figure 6-1 shows New Hanover County as a single county OR service area. Thus, the service area for this proposal is New Hanover County. Facilities may also serve residents of counties not included in their service area.

According to Table 6A, on page 75 of the 2017 SMFP, there are 45 ORs in New Hanover County located in two facilities: Wilmington SurgCare (7 ORs) and NHRMC (38 ORs). In addition, the 2016 SMFP Need Determination contained a Need Determination for three ORs in the New Hanover County operating room service area. See table below. The decision awarding the three ORs from the 2016 SMFP OR Need Determination, increasing the number of ORs to 48, is currently under appeal.

Operating Room Inventory for the New Hanover County Operating Room Service Area

	Inpatient ORs	Ambulatory ORs	Shared ORs	CON Adjustments	Total
2016 SMFP Need Determination*	0	0	0	3	3
Wilmington SurgCare	0	7	0	0	7
New Hanover Regional Medical Center	5	4	29	0	38
Total**	5	11	29	0	48

* The 3 ORs in the 2016 SMFP were awarded to Wilmington SurgCare. That decision is under appeal.
**Does not include CON adjustments for C-Section ORs.

NHRMC. The applicant proposes to develop one new OR pursuant to the need determination in the 2017 SMFP in the New Hanover operating room service area for a total of 39 operating rooms (ORs) at NHRMC upon project completion. The applicant proposes to develop the new OR as a shared OR in NHRMCs existing surgical pavilion.

In Section V.7, pages 58-69, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services. On page 58, the applicant states, *"This project will foster competition. NHRMC competes not only with other hospitals in the service area, but also with much larger systems both inside and outside of North Carolina. NHRMC recognizes that patients have a choice of where to receive their care and it strives to earn the loyalty of its patients every day."*

See also Sections II, III, V, VI and VII where the applicant discusses the impact of the project on cost-effectiveness, quality and access to the proposed services.

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates:

- The cost-effectiveness of the proposal. The discussions regarding analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.
- Quality services will be provided. The discussions regarding quality found in Criteria (1) and (20) are incorporated herein by reference.
- Access will be provided to underserved groups. The discussions regarding access found in Criteria (3) and (13) are incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

Wilmington SurgCare. The applicant proposes to develop one new OR pursuant to the need determination in the 2017 SMFP for a total of 11 ORs upon completion of this project and Project ID #O-11272-16 (add 3 ORs and one procedure room).

In Section V.7, pages 73-77, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services. On page 77, the applicant states, *"Wilmington SurgCare's proposal to add one operating room promotes competition because it best responds to the need determination in the 2017 SMFP for the New Hanover County service area."*

See also Sections II, III, V, VI and VII where the applicant discusses the impact of the project on cost-effectiveness, quality and access to the proposed services.

The applicant does not adequately describe the expected effects of the proposed services on competition in the service area and does not adequately demonstrate:

- The cost-effectiveness of the proposal. The discussion regarding analysis of need and projected utilization found in Criterion (3) and alternatives found in Criterion (4) is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is not conforming to this criterion for the reasons stated above.

WASC. The applicant proposes to develop a new multispecialty ambulatory surgical facility by developing one new OR pursuant to the need determination in the 2017 SMFP, developing three procedure rooms, and relocating three existing multispecialty GI endoscopy rooms from Wilmington Health.

In Section V.7, pages 137-139, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services. On page 137, the applicant states, *"This project will increase the number of competing surgical providers in New Hanover County from two to three; this is a 50 percent increase in competitive options….WASC will provide a critical element in fostering competition."*

See also Sections II, III, V, VI and VII where the applicant discusses the impact of the project on cost-effectiveness, quality and access to the proposed services.

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates:

- The cost-effectiveness of the proposal. The discussions regarding analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.
- Quality services will be provided. The discussions regarding quality found in Criteria (1) and (20) are incorporated herein by reference.
- Access will be provided to underserved groups. The discussions regarding access found in Criteria (3) and (13) are incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

NHSC proposes to develop a new ambulatory surgical facility with one new OR pursuant to the need determination in the 2017 SMFP and two procedure rooms.

In Section V.7, pages 72-75, the applicants describe the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services. On pages 73-74, the applicant states, *"NHSC's proposal offers a cost-effective alternative in terms of cost to the patient compared to a hospital-based facility…the proposed project will increase access to cost-effective surgical services for the underserved population of the service area. NHSC's physician members have an excellent track record of providing care to persons covered by government insurance, and to persons dependent upon charity care….NHSC will utilize the quality measures to monitor quality of care and patient safety relevant to the proposed project."*

See also Sections II, III, V, VI and VII where the applicants discuss the impact of the project on cost-effectiveness, quality and access to the proposed services.

The applicants adequately describe the expected effects of the proposed services on competition in the service area and adequately demonstrates:

- The cost-effectiveness of the proposal. The discussions regarding analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.
- Quality services will be provided. The discussions regarding quality found in Criteria (1) and (20) are incorporated herein by reference.
- Access will be provided to underserved groups. The discussions regarding access found in Criteria (3) and (13) are incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments

- Remarks made at the public hearing
- Responses to comments
- Information publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

(19) Repealed effective July 1, 1987.

(20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C
NHRMC
Wilmington SurgCare
WASC

NA
NHSC

NHRMC. In Section I, page 8, the applicant identifies the health care facilities operated or managed by the applicant or a related entity.

In Section II.12, page 26, the application states that none of the facilities listed on page 8 of the application has ever had its license revoked or had its Medicare or Medicaid provider agreement terminated. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, during the 18 months immediately preceding the date of this decision incidents related to quality of care occurred in none of these facilities. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at all the facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

Wilmington SurgCare. In Section I, pages 5-6, the applicant identifies the facilities located in North Carolina owned, operated or managed by the applicant or a related entity.

In Section II.12, page 24, the application states that none of the facilities listed on pages 5-6 of the application has ever had its license revoked or had its Medicare or Medicaid provider agreement or certification revoked or terminated. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, during the 18 months immediately preceding the date of this decision, incidents related to quality of care occurred in none of these facilities. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at all the facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

WASC. In Section I, pages 15-66, the applicant identifies the facilities located in North Carolina owned, operated or managed by the applicant or a related entity.

In Section II.12, page 63, the application states that none of the facilities listed on pages 15-16 of the application has ever had its license revoked or had its Medicare or Medicaid provider agreement or certification revoked or terminated. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, during the 18 months immediately preceding the date of this decision, incidents related to quality of care occurred in four of these facilities. The problems have been corrected at three of the facilities. At the fourth facility a survey was conducted on February 2, 2018 which resulted in an immediate jeopardy. The immediate jeopardy issue was found to be have been abated in a follow up survey conducted on March 9, 2018. The survey on March 9, 2018 found a different issue which has not yet been confirmed to have been brought back into compliance. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure and Certification Section, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

NHSC. Neither the applicant nor any related entity owns, operates, or manages an existing facility in the service area. Therefore, Criterion (13a) is not applicable to the review of this application.

(21) Repealed effective July 1, 1987.

(b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C
NHRMC
WASC
NHSC

NC
Wilmington SurgCare

NHRMC. The application is conforming with all applicable Criteria and Standards for Surgical Services and Operating Rooms promulgated in 10A NCAC 14C .2100. The specific criteria are discussed below.

Wilmington SurgCare. The application is not conforming with all applicable Criteria and Standards for Surgical Services and Operating Rooms promulgated in 10A NCAC 14C .2100. The specific criteria are discussed below.

WASC. The application is conforming with all applicable Criteria and Standards for Surgical Services and Operating Rooms promulgated in 10A NCAC 14C .2100. The specific criteria are discussed below.

NHSC. The application is conforming with all applicable Criteria and Standards for Surgical Services and Operating Rooms promulgated in 10A NCAC 14C .2100. The specific criteria are discussed below.

SECTION .2100 – CRITERIA AND STANDARDS FOR SURGICAL SERVICES AND OPERATING ROOMS

10A NCAC 14C .2103 PERFORMANCE STANDARDS

(a) In projecting utilization, the operating rooms shall be considered to be available for use five days per week and 52 weeks a year.

-C- **NHRMC.** In Section II, page 22, the applicant states that the ORs at NHRMC facility are considered to be available for use five days per week and 52 weeks a year**.**

-C- **Wilmington SurgCare.** In Section II, page 19, the applicant states that the ORs at Wilmington SurgCare are considered to be available for use five days per week and 52 weeks a year.

-C- **WASC.** In Section II, page 54, the applicant states that the OR at the proposed WASC facility are considered to be available for use five days per week and 52 weeks a year.

-C- **NHSC.** In Section II, pages 24-25, the applicants state that the OR at the proposed NHSC facility are considered to be available for use five days per week and 52 weeks a year.

(b) A proposal to establish a new ambulatory surgical facility, to establish a new campus of an existing facility, to establish a new hospital, to increase the number of operating rooms in an existing facility (excluding dedicated C-section operating rooms), to convert a specialty ambulatory surgical program to a multispecialty ambulatory surgical program or to add a specialty to a specialty ambulatory surgical program shall:

(1) demonstrate the need for the number of proposed operating rooms in the facility which is proposed to be developed or expanded in the third operating year of the project based on the following formula: {[(Number of facility's projected inpatient cases, excluding trauma cases reported by Level I or II trauma centers, cases reported by designated burn intensive care units and cases performed in dedicated open heart and C-section rooms, times 3.0 hours) plus (Number of facility's projected outpatient cases times 1.5 hours)] divided by 1872 hours} minus the facility's total number of existing and approved operating rooms and operating rooms proposed in another pending

application, excluding one operating room for Level I or II trauma centers, one operating room for facilities with designated burn intensive care units, and all dedicated open heart and C-section operating rooms or demonstrate conformance of the proposed project to Policy AC-3 in the State Medical Facilities Plan titled "Exemption From Plan Provisions for Certain Academic Medical Center Teaching Hospital Projects;" and

(2) The number of rooms needed is determined as follows:

(A) in a service area which has more than 10 operating rooms, if the difference is a positive number greater than or equal to 0.5, then the need is the next highest whole number for fractions of 0.5 or greater and the next lowest whole number for fractions less than 0.5; and if the difference is a negative number or a positive number less than 0.5, then the need is zero;

(B) in a service area which has 6 to 10 operating rooms, if the difference is a positive number greater than or equal to 0.3, then the need is the next highest whole number for fractions of 0.3 or greater and the next lowest whole number for fractions less than 0.3, and if the difference is a negative number or a positive number less than 0.3, then the need is zero; and

(C) in a service area which has five or fewer operating rooms, if the difference is a positive number greater than or equal to 0.2, then the need is the next highest whole number for fractions of 0.2 or greater and the next lowest whole number for fractions less than 0.2; and if the difference is a negative number or a positive number less than 0.2, then the need is zero.

-C- **NHRMC.** The proposed project is in New Hanover County which has more than 10 ORs.

NHRMC is an existing facility with 38 ORs. Based on this rule NHRMC calculates projected OR need based on 32 ORs [*NHRMC's # of ORs is based on a current total of 38 ORs minus 2 dedicated open heart surgery ORs = 36 ORs; 36 ORs minus 3 dedicated C-Section ORs = 33 ORs; 33 ORs minus 1 OR for Level II trauma = 32 ORs.] On page 23 of the application, the applicant projects the 32 ORs at NHRMC will perform 8,330 inpatient surgical cases and 33,716 outpatient surgical cases in the third year of operation (FY2022) which demonstrates a need for 8 ORs at the facility [8,330 IP cases x 3.0 hours per case = 24,989 hours + 33,716 OP cases x 1.5 hours per case = 50,574 hours totals to 75,562 hours; 75,562 hours/ 1,872 hours = 40.4 ORs needed. 40.4 ORs needed – 32 existing ORs = 8.4 OR deficit or 8.0 ORs needed]. The discussion regarding analysis of need, including projected utilization, found in Criterion (3) is incorporated herein by reference. Thus, the application is conforming with this rule.

-NC- **Wilmington SurgCare**. The proposed project is in New Hanover County which has more than 10 ORs.

Wilmington SurgCare is an existing facility with 10 ORs (7 existing and 3 approved). On page 23 of the application, the applicant projects the 10 ORs (7 existing and 3 approved) at the Wilmington SurgCare facility will perform 20,719 outpatient surgical

cases in the third year of operation (CY2023) which demonstrates a need for 11 ORs at the facility [13,813 cases x 1.5 hours per case = 20,719 hours; 20,719 hours/ 1,872 hours = 11.07 ORs needed - 10 ORs (existing and approved) = 1.07 or 1.0 ORs needed]**.** However, Wilmington SurgCare's projected utilization is not reasonable and adequately supported. The discussion regarding analysis of need, including projected utilization, found in Criterion (3) is incorporated herein by reference. Thus, the application is not conforming with this rule.

-C- **WASC**. The proposed project is in New Hanover County which has more than 10 ORs.

WASC is not an existing facility. WASC proposes to develop one OR in an ASC. On page 55 of the application, the applicants project the proposed OR at the proposed WASC facility will perform 1,337 outpatient surgical cases in the third year of operation which demonstrates a need for one OR at the proposed facility [1,337 cases x 1.5 hours per case = 2,006 hours; 2,006 hours/ 1,872 hours = 1.07 or 1 OR needed]. The discussion regarding analysis of need, including projected utilization, found in Criterion (3) is incorporated herein by reference. Thus, the application is conforming with this rule.

-C- **NHSC**. The proposed project is in New Hanover County which has more than 10 ORs.

NHSC is not an existing facility. NHSC proposes to develop one OR in an ASC. On pages 52 and 66 of the application, the applicants project the proposed OR at the proposed NHSC facility will perform 1,704 outpatient surgical cases in the third year of operation which demonstrates a need for one OR at the proposed facility [1,704 cases x 1.5 hours per case = 2,556 hours; 2,556 hours/ 1,872 hours = 1.365 or 1 OR needed]. The discussion regarding analysis of need, including projected utilization, found in Criterion (3) is incorporated herein by reference. Thus, the application is conforming with this rule.

(c) A proposal to increase the number of operating rooms (excluding dedicated C-section operating rooms) in a service area shall:

(1) demonstrate the need for the number of proposed operating rooms in addition to the rooms in all of the licensed facilities identified in response to 10A NCAC 14C .2102(b)(2) in the third operating year of the proposed project based on the following formula: {[(Number of projected inpatient cases for all the applicant's or related entities' facilities, excluding trauma cases reported by Level I or II trauma centers, cases reported by designated burn intensive care units and cases performed in dedicated open heart and C-section rooms, times 3.0 hours) plus (Number of projected outpatient cases for all the applicant's or related entities' facilities times 1.5 hours)] divided by 1872 hours} minus the total number of existing and approved operating rooms and operating rooms proposed in another pending application, excluding one operating room for Level I or II trauma centers, one operating room for facilities with designated burn intensive care units, and all dedicated open heart and C-Section

operating rooms in all of the applicant's or related entities' licensed facilities in the service area; and

(2) The number of rooms needed is determined as follows:

(A) in a service area which has more than 10 operating rooms, if the difference is a positive number greater than or equal to 0.5, then the need is the next highest whole number for fractions of 0.5 or greater and the next lowest whole number for fractions less than 0.5; and if the difference is a negative number or a positive number less than 0.5, then the need is zero;

(B) in a service area which has 6 to 10 operating rooms, if the difference is a positive number greater than or equal to 0.3, then the need is the next highest whole number for fractions of 0.3 or greater and the next lowest whole number for fractions less than 0.3, and if the difference is a negative number or a positive number less than 0.3, then the need is zero; and

(C) in a service area which has five or fewer operating rooms, if the difference is a positive number greater than or equal to 0.2, then the need is the next highest whole number for fractions of 0.2 or greater and the next lowest whole number for fractions less than 0.2; and if the difference is a negative number or a positive number less than 0.2, then the need is zero.

-C- **NHRMC.** In Section IV, pages 45-51, the applicant demonstrates the need for the number of proposed operating rooms in all of its facilities in the New Hanover County operating room service area in the third operating year of the proposed project as illustrated in the table below

Projected OR Utilization at NHRMC: ORs Needed

OR Cases	**OY3 (FY2022)**	**Hours/Case**	**OR Hours**
IP Cases	8,330	3.0	24,989
OP Cases	33,716	1.5	50,574
Total OR Hours			75,563
OR Need (hours/1872)			40.36
# of Existing OR*			32*
OR Need (ORs Needed – Existing ORs)			8.36
NHRMC OR Need			8

*NHRMC's # of ORs is based on a current total of 38 ORs minus 2 dedicated open heart surgery ORs = 36 ORs; 36 ORs minus 3 dedicated C-Section ORs = 33 ORs; 33 ORs minus 1 OR for Level II trauma = 32 ORs.

-NA- **Wilmington SurgCare.** Neither Wilmington SurgCare nor a related entity has a controlling interest in any other ORs in the service area.

-NA- **WASC.** Neither WASC nor a related entity has a controlling interest in any other ORs in the service area.

-NA- **NHSC.** Neither NHSC nor a related entity has a controlling interest in any other ORs in the service area.

(d) An applicant that has one or more existing or approved dedicated C-section operating rooms and is proposing to develop an additional dedicated C-section operating room in the same facility shall demonstrate that an average of at least 365 C-sections per room were performed in the facility's existing dedicated C-section operating rooms in the previous 12 months and are projected to be performed in the facility's existing, approved and proposed dedicated C-section rooms during the third year of operation following completion of the project.

-NA- **NHRMC**. In Section II, page 25, the applicant states that it is not proposing to develop an additional dedicated C-Section OR.

-NA- **Wilmington SurgCare** does not have an existing or approved dedicated C-section ORs and is not proposing to develop an additional dedicated C-Section OR.

-NA- **WASC** does not have an existing or approved dedicated C-section ORs and is not proposing to develop an additional dedicated C-Section OR. WASC is not an existing facility.

-NA- **NHSC** does not have an existing or approved dedicated C-section ORs and is not proposing to develop an additional dedicated C-Section OR.is not an existing facility. NHSC is not an existing facility.

e) An applicant proposing to convert a specialty ambulatory surgical program to a multispecialty ambulatory surgical program or to add a specialty to a specialty ambulatory surgical program shall:

(1) provide documentation to show that each existing ambulatory surgery program in the service area that performs ambulatory surgery in the same specialty area as proposed in the application is currently utilized an average of at least 1,872 hours per operating room per year, excluding dedicated open heart and C-Section operating rooms. The hours utilized per operating room shall be calculated as follows: [(Number of projected inpatient cases, excluding open heart and C-sections performed in dedicated rooms, times 3.0 hours) plus (Number of projected outpatient cases times 1.5 hours)] divided by the number of operating rooms, excluding dedicated open heart and C-Section operating rooms; and

(2) demonstrate the need in the third operating year of the project based on the following formula: [(Total number of projected outpatient cases for all ambulatory surgery programs in the service area times 1.5 hours) divided by 1872 hours] minus the total number of existing, approved and proposed outpatient or ambulatory surgical operating rooms and shared operating rooms in the service area. The need is demonstrated if the difference is a positive number greater than or equal to one, after the number is rounded to the next highest number for fractions of 0.50 or greater.

-NA- **NHRMC** is not proposing to convert a specialty ambulatory surgical program to a multispecialty ambulatory surgical program or to add a specialty to a specialty ambulatory surgical program.

-NA- **Wilmington SurgCare** is not proposing to convert a specialty ambulatory surgical program to a multispecialty ambulatory surgical program or to add a specialty to a specialty ambulatory surgical program.

-NA- **WASC** is not proposing to convert a specialty ambulatory surgical program to a multispecialty ambulatory surgical program or to add a specialty to a specialty ambulatory surgical program. WASC is not an existing facility.

-NA- **NHSC** is not proposing to convert a specialty ambulatory surgical program to a multispecialty ambulatory surgical program or to add a specialty to a specialty ambulatory surgical program. NHSC is not an existing facility.

(f) The applicant shall document the assumptions and provide data supporting the methodology used for each projection in this Rule.

-C- **NHRMC**. In Section III, pages 27-34 and Exhibit 8, the applicant documents the assumptions and provides data supporting the methodology used for each projection in this Rule. The discussion regarding analysis of need, including projected utilization, found in Criterion (3) is incorporated herein by reference.

-NC- **Wilmington SurgCare.** In Section III, pages 46-5, the applicant documents the assumptions and provides data supporting the methodology used for each projection in this Rule. However, Wilmington SurgCare's projected utilization is not reasonable and adequately supported. The discussion regarding analysis of need, including projected utilization, found in Criterion (3) is incorporated herein by reference. Thus, the application is not conforming with this rule.

-C- **WASC.** In Section III, pages 87-96 and Section IV, pages 119-128, the applicant documents the assumptions and provides data supporting the methodology used for each projection in this Rule. The discussion regarding analysis of need, including projected utilization, found in Criterion (3) is incorporated herein by reference.

-C- **NHSC.** In Section III, pages 48-55 and Exhibits 10, the applicant document the assumptions and provides data supporting the methodology used for each projection in this Rule. The discussion regarding analysis of need, including projected utilization, found in Criterion (3) is incorporated herein by reference.

COMPARATIVE ANALYSIS

Pursuant to N.C. Gen. Stat. §131E-183(a) (1) and the 2017 State Medical Facilities Plan, no more than one new or additional OR may be approved in this review for New Hanover County. Because the four applications in this review collectively propose four new ORs (one OR each), only one of the applications can be approved to develop the new OR. Therefore, after considering all of the information in each application and reviewing each application individually against all applicable review criteria, the Project Analyst conducted a comparative analysis of the proposals to decide which proposal should be approved to develop the new OR. For the reasons set forth below and in the rest of the findings, the application submitted by **WASC** is approved. The applications submitted by **NHRMC, Wilmington SurgCare and NHSC** are denied.

Conformity with Applicable Statutory and Regulatory Review Criteria

Wilmington SurgCare is not conforming with all applicable statutory and regulatory review criteria as discussed throughout the Findings. Therefore, the application of Wilmington SurgCare is not approvable.

NHRMC, WASC and NHSC are conforming with all applicable statutory and regulatory review criteria as discussed throughout the Findings.

Therefore, the applications submitted by **NHRMC**, **WASC** and **NHSC** are equally effective alternatives with respect to conformity with statutory and regulatory review criteria.

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 one new OR in Wilmington, New Hanover County.

Therefore, with regard to geographic accessibility the proposed projects of NHRMC, WASC and NHSC are equally effective alternatives.

Physician Support

NHRMC is an existing hospital. Exhibit 24 contains letters of support from 3 surgeons and the medical director. In its comments NHRMC states that over 100 surgeons currently utilize the ORs in the Surgical Pavilion.

Wilmington SurgCare is an existing ASC. Exhibit 23 contains letters of support from 28 surgeons who have performed OR cases at Wilmington SurgCare have expressed their intent to utilize the facility.

WASC- The applicant is proposing to develop a new ASC in Wilmington. Exhibit 18 contains letters of support from 30 physicians projecting to refer a total of 1,337 OP OR cases annually to the proposed WASC facility.

NHSC- The applicant is proposing to develop a new ASC in Wilmington. Exhibit 10 contains letters from twelve physicians who historically have provided OP OR surgical services to residents of NHSC's proposed three county service area projecting to refer a total of 2,210 orthopaedic cases annually to the NHSC facility.

Therefore, with regard to physician support the four proposed projects are equally effective.

Patient Access to Alternative Providers

In New Hanover County there are only two facilities with ORs: New Hanover Regional Medical Center and Wilmington SurgCare. NHRMC is a hospital and Wilmington SurgCare is a freestanding ambulatory surgical center. There are currently 48 ORs in the New Hanover County operating room service area (45 existing and 3 approved). NHRMC currently has 38 ORs and Wilmington SurgCare has 10 ORs (7 existing and 3 approved.) NHRMC is proposing to develop one new OR by converting a storage room at its Surgical Pavilion and Wilmington SurgCare is proposing to add one new OR to its existing ambulatory surgery center.

If Wilmington SurgCare's application is approved, Wilmington SurgCare would be the only provider of ORs in an ASC facility in New Hanover County.

Approval of WASC, which is ultimately owned by Surgical Care Affiliates, and NHSC, would introduce an alternative provider of OR services and, introduce an alternative ASC for OR services in New Hanover County.

Therefore, with regard to providing New Hanover County patients with access to an alternative provider of outpatient OR services the proposals submitted by **WASC** and **NHSC** are the most effective alternatives.

Patient Access to Low Cost Outpatient Surgical Services

There are currently 48 ORs in the New Hanover County operating room service area (45 existing and 3 approved). NHRMC currently has 38 ORs and Wilmington SurgCare has 10 ORs (7 existing and 3 approved.) Operating rooms can be licensed either under a hospital license or an ASC that does not operate under a hospital license. Based on the applications, written comments and response to comments and statements made at the public hearing, many, but not all outpatient surgical services can be either be performed in a hospital licensed operating room (either a shared OR or a dedicated outpatient OR) or in a non-hospital licensed operating room (ASC) however, the cost for that same service will often be much higher in a hospital licensed operating room or, conversely, much less expensive if received in a non-hospital licensed operating room.

NHRMC is an existing hospital that offers both inpatient and outpatient OR surgical services.

Wilmington SurgCare is an existing ASC offering outpatient OR surgical services.

WASC is a proposed ASC which would offer outpatient OR surgical services.

NHSC is a proposed ASC which would offer outpatient OR surgical services.

Therefore, as to patient access to low cost outpatient surgical services **NHRMC** is the least effective alternative and **Wilmington SurgCare**, **WASC** and **NHSC** are all equally effective alternatives.

Patient Access to Multiple Surgical Specialties

NHRMC provides access to all surgical specialties.

Wilmington SurgCare is a multispecialty facility providing gastroenterology, general surgery, vascular surgery, gynecology, neurology, ophthalmology, orthopedic surgery, otolaryngology, plastic surgery, podiatry and urology services, which equals eleven specialties.

WASC proposes a multispecialty ASC providing general surgery, neurosurgery, ophthalmology, oral surgery, orthopedics, plastic surgery, urology, vascular, podiatry and gastroenterology services, which equals ten specialties.

NHSC projects only orthopaedic cases, which equals one specialty.

Therefore, with regard to providing New Hanover County patients with access to more multiple surgical specialties **NHRMC**, **Wilmington SurgCare** and **WASC** are the most effective alternative and **NHSC** is the least effective alternative.

Access by Underserved Groups

Charity Care

The following table shows each applicant's projected Charity Care to be provided in the second operating year of each applicant's proposed project in terms of projected dollars. Generally, the application proposing to serve the highest number of Charity Care cases is the most effective alternative with regard to this comparative factor.

Charity Care
Operating Year 2

Applicant	Projected Charity Cases	Projected Charity Care Dollars	Basis of Projected Charity Care
NHRMC	1,597	$48,500,000	4.00% of Gross Revenue
Wilmington SurgCare	171	$112,226	0.55% of Net Revenue
WASC	81	$644,939	1.00% of Gross Revenue
NHSC	59	$54,903	0.70% of Gross Revenue

Note: Charity Care Cases come from the cases listed under the payor category of Self Pay/ Indigent/Charity Care.
Source: NHRMC: Section VI.8, page 74.

Source: Wilmington SurgCare: Section VI.8, page 82.
Source: WASC: Section VI.8, page 148.
Source: NHSC: Section VI.8, page 81.

As shown in the table above, NHRMC projects the highest amount of charity care in terms of cases. However, due to significant differences in how each applicant defines charity care, the fact that Wilmington SurgCare's projected charity care is provided as a percentage of net revenue and the other three applications project charity care as a percentage of gross revenue and the fact that WASC's projected charity care is derived from across all payor categories in contrast to the other applications it is not possible to make conclusive comparisons with regard to projected charity care. Thus, this comparative factor may be of little value.

Medicare/Medicaid

The following tables show each applicant's projected total number of cases to be provided to Medicare/Medicaid recipients in the third operating year (OY3) following completion of each of the proposed project , based on the information provided in the applicants' pro forma financial statements. Generally, the application proposing to serve the higher percentage of Medicare/Medicaid patients is the more effective alternative with regard to this comparative factor.

Medicare/Medicaid Cases
Operating Year 3

	Projected Total Cases	Projected Total Medicare Cases	Projected Total Medicaid Cases	Projected Total Medicare/Medicaid Cases	Percent of Total Cases Provided to Medicare/Medicaid Recipients
NHRMC	42,046	19,724	3,259	22,983	54.66%
Wilmington SurgCare	14,174	7,266	1,104	8,370	59.05%
WASC	13,875	6,734	517	7,251	52.26%
NHSC	2,020	268	330	598	29.60%

Source: Proformas of each application.

As shown in the in the table above, Wilmington SurgCare projects the highest percentage of cases to Medicare/Medicaid recipients. However, Wilmington SurgCare's projected utilization is not reasonable and adequately supported. The discussion regarding analysis of need, including projected utilization, found in Criterion (3) is incorporated herein by reference. Therefore, Wilmington SurgCare's application is not approvable. Furthermore, due to significant differences in the types of surgical services proposed by the applicants, it is not possible to make conclusive comparisons with regard to percentage of Medicare/Medicaid cases. Therefore, this comparative factor may be of little value.

Projected Average Net Revenue per Facility

The following table shows the projected net revenue per OR case in the third year of operation for each of the applicants, based on the information provided in the applicants' pro forma financial

statements. Generally, the application proposing the lowest average net revenue per case is the more effective alternative with regard to this comparative factor.

Operating Year 3	NHRMC	Wilmington SurgCare	WASC	NHSC
Net Revenue	$359,856,489	$21,945,588	$17,808,655	$4,118,507
Total Cases including procedure room cases	42,046*	14,174**	13,875	2,020
Net Revenue/Case	$8,559	$1,548	$1,284	$2,039

*IP and OP Cases for NHRMC Combined (No procedure room cases of any type)
**13,813 + 361 Procedure Cases=$14,174

As shown in the table above, WASC projects the lowest average net revenue per case in the third operating year. However, due to differences in the types of surgical services proposed by each of the facilities, it is not possible to make conclusive comparisons with regard to net revenue per surgical case. Thus, this comparative factor may be of little value.

Projected Average Operating Expense per Case (Total Facility)

The following table shows the projected average operating expense per case in the third year of operation for each of the applicants, based on the information provided in the applicants' pro forma financial statements. Generally, the application proposing the lowest average operating expense per case is the more effective alternative with regard to this comparative factor.

Third Operating Year	NHRMC	Wilmington SurgCare	WASC	NHSC
Total Operating Expenses	$168,647,184	$19,587,318	$15,852,772	$3,163,185
Cases*	42,046	14,174	13,875	2,020
Operating Expense/Case	$4,011	$1,382	$1,143	$1,566

*Cases is for the entire facility including both OR cases, GI endo cases and procedure room cases. (except not for NHRMC and NHSC)

As shown in the table above, WASC projects the lowest average operating expense per case in the third operating year. However, due to differences in the types of surgical services proposed by each of the facilities, it is not possible to make conclusive comparisons with regard to operating expense per case. Thus, this comparative factor may be of little value.

SUMMARY

Comparative Factor	NHRMC	Wilmington SurgCare	WASC	NHSC
Conformity with Rules and Criterion	Equally Effective	**Least Effective**	Equally Effective	Equally Effective
Geographic Accessibility	Equally Effective			
Physician Support	Equally Effective			
Patient Access to Alternative Providers	**Least Effective**	**Least Effective**	Equally Effective	Equally Effective
Patient Access to Low Cost Outpatient Surgical Services	**Least Effective**	Equally Effective	Equally Effective	Equally Effective
Patient Access to Surgical Specialties	Equally Effective			**Least Effective**
Access by Underserved Groups	Inconclusive Comparison			
Projected Average Net Revenue per Case	Inconclusive Comparison			
Projected Average Operating Expense per Case	Inconclusive Comparison			

For each of the comparative factors listed below, all four applications were determined to be **equally** effective:

- Geographic Accessibility
- Physician Support
- Access by Underserved Groups
- Projected Average Net Revenue per Case
- Projected Average Operating Expense per Case

For each of the comparative factors listed below, **WASC** was determined to be **equally** effective alternative:

- Conformity with Rules and Criterion
- Patient Access to Alternative Providers
- Patient Access to Low Cost Outpatient Surgical Services
- Patient Access to Surgical Specialties

As demonstrated in the table above, **WASC** was <u>not</u> the least effective alternative for any of the comparative factors.

For each of the comparative factors listed below, **NHRMC** was determined to be the **least** effective alternative:

- Patient Access to Alternative Providers
- Patient Access to Low Cost Outpatient Surgical Services

For each of the comparative factors listed below, **Wilmington SurgCare** was determined to be the **least** effective alternative:

- Conformity with Rules and Criterion
- Patient Access to Alternative Providers

For each of the comparative factors listed below, **NHSC** was determined to be the **least** effective alternative:

- Patient Access to Surgical Specialties

CONCLUSION

All four applications are conforming to the need determination in the 2017 SMFP for one new OR in the New Hanover Operating Room Service Area. N.C. Gen. Stat. §131E-183(a) (1) states that the need determination in the SMFP is the determinative limit on the number of ORs that can be approved in this review. The Agency determined that the application submitted by **Wilmington ASC, LLC, Project I.D. #O-11441-17** is the most effective proposed in this review for the development of one new OR in the New Hanover County operating room service area to meet the 2017 OR Need Determination for the New Hanover OR service area and that application is approved as conditioned below. Approval of either the NHRMC, Wilmington SurgCare or the NHSC applications for development of a new OR in the New Hanover OR service area would result in the approval of new ORs in New Hanover County operating room service area in excess of the operating room need determination in the 2017 SMFP and therefore, the applications of **NHRMC**, **Wilmington SurgCare** and **NHSC** are all denied.

The application submitted by Wilmington ASC, LLC is approved subject to the following conditions.

1. **Wilmington ASC, LLC shall materially comply with all representations made in the certificate of need application.**

2. **Wilmington ASC, LLC shall develop a new multispecialty ambulatory surgical facility by developing one new OR, developing three procedure rooms, and relocating three existing multispecialty gastrointestinal endoscopy rooms from Wilmington Health.**

3. **Upon completion of the project, Wilmington ASC shall be licensed for no more than one OR, 3 multispecialty gastrointestinal endoscopy rooms and 3 procedure rooms.**

4. **Wilmington ASC, LLC shall not acquire as part of this project any equipment that is not included in the project's proposed capital expenditures in Section VIII of the application and that would otherwise require a certificate of need.**

5. **Wilmington ASC, LLC shall receive accreditation from the Joint Commission for the Accreditation of Healthcare Organizations, the Accreditation Association for Ambulatory Health Care or a comparable accreditation authority within two years following licensure of the facility.**

6. **For the first three years of operation following completion of the project, Wilmington ASC, LLC shall not increase charges more than 5% of the charges projected in Section X and Section XIII of the application without first obtaining a determination from the Healthcare Planning and Certificate of Need Section that the proposed increase is in material compliance with the representations in the certificate of need application.**

7. **The procedure rooms shall not be used for procedures that should be performed only in an operating room based on current standards of practice.**

8. **The procedure rooms shall not be used for procedures that should be performed only in a gastrointestinal endoscopy room based on current standards of practice.**

9. **Procedures performed in the procedure rooms shall not be reported for billing purposes as having been performed in an operating room and shall not be reported on the facility's license renewal application as procedures performed in an operating room.**

10. **Procedures performed in the procedure rooms shall not be reported for billing purposed as having been performed in a gastrointestinal endoscopy room and shall not be reported on the facility's license renewal application as procedures performed in a gastrointestinal endoscopy room.**

11. **Upon project completion, Wilmington ASC, LLC and Wilmington Health, PLLC, shall take the steps necessary to delicense the three existing multispecialty gastrointestinal endoscopy rooms at Wilmington Health such that Wilmington Health a/k/a Wilmington Health Endoscopy Center (License # AS0045) shall no longer be licensed as an ambulatory surgical facility.**

12. **Wilmington ASC, LLC shall develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes.**

13. **No later than three months after the last day of each of the first three full years of operation following initiation of the services authorized by this certificate of need, Wilmington ASC, LLC shall submit, on the form provided by the Healthcare Planning and Certificate of Need Section, an annual report containing the:**

    a. **Payor mix for the services authorized in this certificate of need.**
    b. **Utilization of the services authorized in this certificate of need.**
    c. **Revenues and operating costs for the services authorized in this certificate of need.**

d. Average gross revenue per unit of service.
e. Average net revenue per unit of service.
f. Average operating cost per unit of service.

14. Wilmington ASC, LLC shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.