Received by the
CON Section

03 JAN 2011 12 : 53

**January 3, 2011 Comments in Opposition
from North State Surgery Center, LLC
Regarding Obesity Management Center of the Carolinas, LLC
CON Application for a Single Specialty Bariatric & General Surgery
Ambulatory Surgical Center (Project I.D. # J-8620-10)
Submitted November 15, 2010 for December 1, 2010 Review**

In accordance with N.C.G.S. Section 131E-185(a1)(1), North State Surgery Center LLC and its member organizations, Foundation Health Systems Corp. and Regional Surgical Associates submit the following comments regarding the CON Application of Obesity Management Center of the Carolinas, LLC for a Bariatric and General Surgery Ambulatory Surgical Center (Project I.D. # J-8620-10).

I. Introduction

The following three CON applications were submitted on November15, 2010 in response to the need determination identified in the *2010 State Medical Facilities Plan* (*2010 SMFP*) for a single-specialty ambulatory surgery center demonstration project with two surgical operating rooms in the Wake-Orange-Durham Service Area:

- J-8616-10: Triangle Orthopaedic Surgery Center, LLC proposes to develop a $2.4 million facility in the Brier Creek area of Raleigh (Wake County) in which to perform outpatient orthopedic surgery.
- J-8520-10: Obesity Management Center of the Carolinas, LLC proposes a $5.9 million surgery in Cary, NC (Wake County).
- J-8621-10: North State Surgery Center, LLC proposes to develop a $5.4 million surgery center in Chapel Hill (Orange County) in which to perform outpatient general surgery.

II. Obesity Management Center of the Carolinas Proposal

A. Three Co-Applicants

There are three co-Applicants:

- Obesity Management Center of the Carolinas, LLC (OMCC, LLC)
- Triangle Area Bariatric Surgeons, LLC (TABS, LLC)
- Rex IV, LLC.

OMCC, LLC is owned jointly by TABS, LLC (60%) and Rex IV, LLC (40%).

Rex IV, LLC is 100% owned by Rex Holdings, LLC. The sole member and 100% owner of Rex Holdings, LLC is Rex Healthcare, Inc.[1]

[1] CON Application J-8620-10 at page 11.

TABS, LLC is a newly formed limited liability company, which is owned by the following five physicians:

- Paul E. Enochs, MD
- Michael A. Tyner, MD
- Jon M. Bruce, MD
- Peter Ng, MD
- Lindsey Sharp, MD.[2]

Drs. Enochs, Tyner, and Bruce are in practice with Bariatric Specialists of North Carolina in Cary.[3] Drs. Ng and Sharp are in practice with Wake Surgical Specialists, which is a physician practice owned by Rex Healthcare.[4] Dr. Ng is the Director of Bariatric Surgery for Rex Surgical Specialists.

Dr. Enochs is identified as the President and Registered Agent of OMCC, LLC. Dr. Bruce is identified as the Secretary/Treasurer of OMCC, LLC. See page 12 of the OMCC CON Application.

For purposes of these Comments, the three co-Applicants are referred to collectively as OMCC.

B. Project Description

Obesity Management Center of the Carolinas ("the proposed ASC") will be located at 1505 SW Cary Parkway, Cary, NC 27511. The land on which the proposed 8,050 square foot surgery center facility will be located is owned by Rex Hospital, Inc. The proposed new building will be adjacent to Rex Surgery Center of Cary and Cary Wellness Center.[5] Rex Surgery Center of Cary is located at 1505 South Cary Parkway, Cary, NC, 27511.

Rex Surgery Center of Cary opened as a hospital-based surgery center in 2003 with 4 operating rooms, and has averaged less than 50% utilization of these four operating rooms during the last four fiscal years as discussed in comments on page 17 of these comments. In 2007 Rex received CON approval to convert the center to freestanding, but has yet to complete this conversion.

The OMCC facility will be developed in a medical office building by Capital Associates Management, Inc., and the building will be leased to Obesity Management Center of the Carolinas, LLC (OMCC, LLC). OMCC, LLC will upfit the leased space for the proposed ASC. Rex Hospital will manage the proposed ASC.[6]

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[2] CON Application J-8620-10 at page 11.

[3] http://www.surgerync.com/index.asp

[4] http://www.wakesurgical.com/our_surgeons.html

[5] CON Application J-8620-10 at page 31.

[6] CON Application J-8620-10 at page 9.

As reflected in Exhibit 10 of the OMCC Application, the entire building is being built just for this project and it is reasonable to assume that it will not be constructed if the project is not approved. The developer of the building is constructing an ambulatory surgery center, not a medical office building. No physician offices are included in the drawings in Exhibit 10. Therefore, the developer should be identified as a co-applicant and construction cost for the building should be included in the total cost of the project.

OMCC projects that the proposed ambulatory surgery demonstration project will become operational on April 1, 2013. Project Years are presented as April 1, 2013 - March 30, 2015.

C. Project Cost and Financing

On page 159 of the Application in response to Question VIII.1, OMCC states: "OMCC will be responsible for all capital costs of the proposed project [...]." That statement does not appear to be accurate in view of applicant's statements made on CON Application pages 161 through 167.

Total capital cost for the OMCC project is $5,911,398 as specified in CON Application Section VIII. Of that total, Rex will contribute from its accumulated reserves the amount of $2,364,599 (40% based on Rex's IV's membership interests in OMCC, LLC).[7]

TABS will contribute $3,546,839 (60% based on TABS membership interests in OMCC, LLC).[8] "Funds from TABS will be its capital contribution to OMCC."[9] The project will be financed from accumulated reserves (from Rex) and cash from TABS via a commercial loan from North State Bank to TABS.[10]

On pages 162 and 166, OMCC incorrectly states that "TABS is not an applicant, and as such, no interest expense is included in the financial statements following Section XII." TABS, LLC is essentially a co-Applicant, since TABS, LLC holds 60% of the membership interests in the new LLC applicant, OMCC.

OMCC projects that total working capital required will be $625,189[11] TABS, LLC will fund $375,113 (or 60%) of the working capital needs of OMCC and Rex will fund $250,076 (or 40%) of the working capital needs of OMCC.

D. Physician Ownership and Physicians Expected to Use the Proposed ASC

On page 21, OMCC states that "Rex boasts the largest number of bariatric surgeons on staff of any hospital in the Triangle – eight." For comparison purposes, The Duke Center for Metabolic and Weight Loss Surgery has six bariatric surgeons.[12]

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[7] CON Application J-8620-10 at page 161.

[8] CON Application J-8620-10 at page 161.

[9] CON Application J-8620-10 at page 162.

[10] CON Application J-8620-10 at page 163.

[11] CON Application J-8620-10 at page 166.

Exhibit 41 contains a two-page document entitled "Obesity Management Center of the Carolinas General Surgery ASC Physician Support." Included in that two-page document are five tables. The following are three of those five tables.

Physician Owners (TABS) Will Utilize the Proposed ASC

Name of Physician	Practice
Jon Bruce, MD	Bariatric Specialists of North Carolina
Paul Enochs, MD	Bariatric Specialists of North Carolina
Michael Tyner, MD	Bariatric Specialists of North Carolina
Peter Ng, MD	Rex Surgical Specialists
Lindsey Sharp, MD	Rex Surgical Specialists

Physicians Who Will Utilize the Proposed ASC

Name of Physician	Practice
Scott Bovard, MD	Bovard Bariatric Center
Peter Henderson, MD	Progress Weight Loss Surgery
Joseph Moran, MD	Raleigh Center for Weight Loss Surgery

Rex Employed General Surgeons Who Support the Proposed ASC

Name of Physician	Practice
Eric DeMaria, MD	Rex Surgical Specialists

It is curious that OMCC would choose to describe Dr. DeMaria as a general surgeon who supports the proposed ASC, but will not utilize the proposed ASC. On pages 109 and 110 of the Application, Dr. DeMaria is included in the category labeled "Rex employed general surgeons*" in a table that reports surgical case volume at Rex for surgeons who will practice at the proposed ASC (page 109) and surgical case volume at non-Rex Facilities for surgeons who will practice at the proposed ASC (page 110). The table on page 109 is reproduced below.

[12] http://www.dukehealth.org/services/weight_loss_surgery/physicians

Rex Surgical Case Volume for Surgeons Who Will Practice at the Proposed ASC

Surgeon	FY 2010
Enochs	185
Bruce	170
Moran	124
Bovard	75
Tyner	40
Henderson	4
Rex employed general surgeons*	**150**
Total	748

Source: Rex internal data.
***Include Drs. Ng, Sharp, and DeMaria.** Please see Exhibit 41 for their letters of support. Please note, these physicians are part, but not all, of Rex's employed surgical group, Rex Surgical Specialists. Drs. Ng and Sharp have ownership interests in OMCC. [**Emphasis** added.]*

Dr. DeMaria is listed on ObesityHelp.com as a bariatric surgeon[13], and was the director of The Duke Center for Metabolic and Weight Loss Surgery until August 1, 2010.[14]

It is possible that OMCC learned about circumstances that would make it difficult for Dr. DeMaria to participate fully in the project, and edited the Application to reduce his involvement to support only.[15] Dr. DeMaria's FY 2010 surgical volume, therefore, should have been eliminated from the Rex employed general surgeon volume, and not included in volume upon which the projections for the proposed ASC are based, given that Dr. DeMaria was associated with Duke until August 1, 2010, which only 15 days before the OMCC CON Application was filed.

Exhibit 41 includes letters from physicians named in the five tables.

It should be noted that in a letter included in Exhibit 41, Dr. Henderson states that he did not have any case volume in FY 2010 because he is new to the area. Dr. Henderson is shown to have performed 4 cases at Rex in FFY 2010, as shown in the previous table.

Ten of the letters from physicians listed in the table entitled "Cary LLC Physicians" are letters that were submitted by Rex with its February 15, 2010 CON Applications (J-8468-10 and J-8469-10), which sought CON-approval for a Rex Healthcare two-OR hospital based surgery center in Holly Springs (Wake County) and to add one new OR at Rex Hospital. These projects were denied by the CON Section and remain in litigation as of the date these comments were filed. Those CON Applications will be discussed in more detail in Subsection E below.

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13 http://www.obesityhelp.com/morbidobesity/bariatric+surgeon+profile+Eric+J+DeMaria+ddh.html

14 http://www.wral.com/news/local/story/8700929/

15 On November 30, 2010, Dr. DeMaria was arrested and charged with stealing $100,000 from Duke University. http://www.wral.com/news/local/story/8700929/

III. CON Review Criteria

The following comments are submitted based upon the CON Review Criteria found at G.S.131E-183. While some issues impact multiple Criteria, they are discussed under the most relevant review Criteria and referenced in others to which they apply.

G.S. 131E-183 (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.

A. SMFP Policy GEN-3 – Basic Principles

The plain language of "SMFP Policy GEN-3: Basic Principles" requires that:

"A certificate of need applicant applying to develop or offer a new institutional health service for with 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 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 the residents in the service area. [Emphasis added]

As discussed in detail in the context of Criterion (3) below, OMCC fails to adequately demonstrate the quantitative and qualitative need for the project, and therefore failed to document how its projected volumes incorporate the Basic Principles in meeting the need identified in the *2010 SMFP* for a single specialty ambulatory surgery demonstration project in the Wake-Durham-Orange Demonstration Project Service Area. Consequently, the Application is not conforming to Policy GEN-3, and does not conform to Criterion (1).

B. Proposed Bariatric Surgery Charity Care Percent Unreasonable

OMCC states that its charity care policies will cover surgical needs for self-pay patients, or almost 25% of all bariatric surgical patients reflected in the Proforma Statements. In Form E for bariatric patients, OMCC projects total net revenue for self-pay patients of only $38,908 or an average of $248 per patient. Another way to analyze the estimated net revenue for the proposed facility in Year 1 is to calculate the number of self-pay patients who will pay the projected average charge for self-pay bariatric patients of $12,392 by dividing total net revenue by the projected charge. In this analysis, only three self-pay patients[16], or approximately 0.5% of total

[16] Calculation: Total net revenue $38,908/Avg Charge $12,392 = 3 cases

bariatric surgical patients pay the full self-pay charge and the remaining 154 patients will be charity care.

However, according to the HealthGrades Fifth Annual Bariatric Surgery Trends in American Hospitals Study May 2010 (includes 19 all-payer states), of all patients, 6.57% of patients paid for their surgery out-of-pocket (self-pay) and did not utilize any type of insurance.[17]

Based upon the HealthGrades study, it is reasonable to assume that 6.57% of OMCC patients would pay the self-pay average charge for the proposed bariatric surgery, resulting in total net revenue in Form E for self-pay bariatric cases of $520,464.[18] In turn, this increases the average reimbursement for self-pay patients and decreases the self-pay variance reflected on page 56 of the application. The net impact of a 6.57% self-pay percent of bariatric surgery patients that do pay the self-pay charge is significant when analyzing total self-pay/Medicaid revenue and reimbursement for the 7.0% requirement. As reflected in the schedule included in Attachment 1, OMCC will fail to meet the 7.0% requirement in the Criteria and Standards for self pay/Medicaid patients if the national average documented by HealthGrades is obtained. In fact the percent for self pay/Medicaid patients decreases to less than 2.0% of total collected revenue. This is shown in Attachment 1, and illustrated in these comments in the section regarding the Criteria and Standards for special demonstration projects.

In addition, it is questionable if OMCC could successfully generate sufficient self-pay patients that would meet the charity care requirements of the OMCC Charity Care Policy in Exhibit 8. In a study[19] published in 2009 regarding the socioeconomics of the morbidly obese patient population and the impact on access to bariatric surgery using two nationally representative databases, the national bariatric eligible population was identified from the 2005-2006 National Health and Nutrition Examination Study, and compared with the adult non-eligible population. The eligible cohort was then compared with patients who had undergone bariatric surgery in the 2006 National Inpatient Sample, and the key socioeconomic disparities were identified and analyzed. More than one third (35%) of bariatric eligible patients were either uninsured or underinsured, and 15% had incomes less than the poverty level. A total of 87,749 bariatric surgical procedures were performed in 2006. Most were performed on white patients (75%) with greater than median incomes (80%) and private insurance (82%). **Less than 1% of bariatric surgical procedures were performed on uninsured patients. Significant disparities associated with a decreased likelihood of undergoing bariatric surgery were noted by race, income, insurance type, and gender. Researchers concluded that socioeconomic factors play a major role in determining who does and does not undergo bariatric surgery, despite medical eligibility.**[20]

Other than stating that they would provide surgical care without charge at the proposed facility, OMCC provided no additional documentation in the application to support the necessary changes in the community to meet the needs of the population at risk as discussed below.

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[17] http://www.healthgrades.com/media/DMS/pdf/HealthGradesBariatricSurgeryTrendsStudy2010.pdf
[18] Calculation: 636 bariatric cases x 6.57% = 42 cases; 42 cases x $12,392 average self pay charge = $520,464
[19] http://www.asmbs.org/Newsite07/resources/Featured_article_6_1.pdf
[20] Ibid.

C. Charity Care Provision of Imaging and Other Necessary Testing Not Addressed

OMCC states that its charity care policies will cover surgical needs. The application also states that this is all that will be covered. Physician services are not covered. The surgeon and the anesthesiologist will bill the patient. On pages 31- 33, OMCC provides an extensive list of other required services necessary to qualify for bariatric surgery. According to the Application, these services will be coordinated and provided at the Rex Wellness Center in Cary. However, no documentation is provided regarding any available charity care for these services.

The Applicant also discusses six months of appointments which must be met to qualify for bariatric surgery. However, the location of the proposed facility is in a very wealthy area of Wake County with limited bus service as illustrated in Attachment 2. OMCC does not discuss transportation needs of the indigent and Medicaid population to be served.

On page 145 of the OMCC Application in response to question VI.6., OMCC describes its strategies and facility policies which will ensure access to its services by indigent and other medically underserved persons, especially those who do not have access to physician services as follows:

> "As discussed in detail in Section II.1., OMCC's services will be accessible to Medicaid recipients, the uninsured, and the underinsured. In particular, OMCC's charity care policies, Exhibit 8, treat Medicaid patients as self-pay/charity care patients for bariatric cases so they are not denied care. OMCC's generous charity care policies provide access to its services to those least able to afford them, but also most in need of the services."

The Applicant does not discuss any proposed relationships with the Wake County Health Department, a primary care provider to the indigent and Medicaid population in Wake County. Nor does the Applicant discuss local transportation alternatives for the poor of Wake County. Furthermore, letters of support from referring physicians do not discuss the referral of indigent patients. Finally, the Applicant does not discuss outreach to regional providers of care to the indigent or Medicaid population in surrounding counties, since over 35% of projected patients are coming from outside of Wake County.

OMCC assumes that 25% of total bariatric surgery cases will be "self-pay" or free care. However, without documentation and support from other providers to remove additional "barriers" to care, OMCC has not documented that it can realistically achieve its projected free care objective.

D. Operating Room Need Methodology – Results in Overstated Surgical Volume

As discussed in detail in the context of Criterion (3) below, surgical volume is overstated. As a result, the projected utilization is unreasonable and unsupported and cannot be used to justify the proposed two single specialty ambulatory operating rooms in Wake County. Therefore, the Application is non-conforming to Criterion (1).

For these reasons, the proposed project is non-conforming to Policy GEN-3: Basic Principles and Basic Assumptions included in the Operating Room Need Methodology.

G.S. 131E-183 (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.

A. The Methodology Used to Project Surgical Volume at the Proposed ASC is Flawed, Unreasonable, and Results in Overstated Volume

1. Methodology - Overview

On pages 109-115, OMCC documents the methodology used to project surgical volume at the proposed ASC. That methodology is based on surgical volume of 1,030 cases that nine surgeons performed at Rex and non-Rex facilities (WakeMed Cary and Duke Raleigh Hospital) in FY 2010. OMCC increases that base volume by an annual growth rate of 12.4% through FY 2016. OMCC converted FY projections to Project Years of April 2013-March 2016.

As discussed in Section II.D above, the nine surgeons who performed 1,030 cases at Rex and non-Rex facilities (WakeMed Cary and Duke Raleigh Hospital) in FY 2010 include Dr. DeMaria. Due to inconsistencies in the Application and Exhibit 41, it is unclear whether Dr. DeMaria will perform surgery at the proposed ASC in Project Years 1-3. Dr. DeMaria's historical surgical case volumes should be excluded from the OMCC base year data for the reasons discussed above in Section II.D of these comments. See also footnote 15 above in these comments. It is not clear whether Dr. DeMaria will be available to perform future bariatric surgical cases at OMCC.

In addition, the five TABS surgeons also previously signed surgeon letters of support included in Exhibit #6 of the Rex Holly Springs Surgery Center CON Application, filed in February 2010, as CON Project I.D. #J-8468-10. These letters of support indicated that these five surgeons intended to practice and shift outpatient surgical cases to Rex's existing and historically underutilized Rex Surgery Center of Cary. These letters are dated Feb.10, 2010. In three of these letters, Drs. Bruce, Enochs, and Tyner each committed: "as a result of my involvement in Rex's Cary surgery center, over the next few months I intend to shift as many of these outpatient cases as possible from non-Rex facilities to Rex's Cary facility, which could be as many as many as 500 cases....In the 12 months ending June 2009, I performed approximately 500 [general surgery &/or bariatric surgery] cases at non-Rex facilities." *See pages 280-282 of the Rex Holly Springs Surgery Center CON Application for these letters.* The letters signed by Drs. Ng and Sharp stated: "The additional [Rex] operating rooms [Cary, Wakefield, & proposed Holly Springs ASCs] will...bring much needed capacity to Rex, enabling me to shift all my remaining cases

from Duke Raleigh to Rex.... *See pages 276 and 279 of the Rex Holly Springs Surgery Center CON Application for these letters.*

It appears these five surgeons are double counting the surgical volume that they propose to perform at either the Rex's ASCs in Cary and Wakefield (Feb. 2010 letters of support) or at Obesity Management Center of the Carolinas proposed in this application, filed on Nov. 15, 2010.

In the Nov. 15, 2010 letters of surgeon support from these five surgeons found in OMCC CON Application Exhibit #41, they state:

- Dr. Bruce projects to perform 372 to 470 outpatient general surgery cases per year at the proposed OMCC
- Dr. Enochs proposes to perform 426 to 528 outpatient general surgery cases per year at the proposed OMCC
- Dr. Tyner proposes to perform 142 to 179 outpatient general surgery cases per year at the proposed OMCC
- Dr. Ng states: "I fully support the Obesity Management Surgery Center of the Carolinas, LLC's proposal."
- Dr. Sharp states: "I fully support the Obesity Management Surgery Center of the Carolinas, LLC's proposal."

See Exhibit #41, pages 449-457.

The same set of outpatient surgical cases from these five surgeons can not be utilized to justify both increased utilization at Rex's existing Cary Surgery Center and to justify the outpatient general surgery/bariatric surgery volumes to support the proposed new 2-OR single specialty demonstration project surgery center, OMCC, to also be located in Cary.

2. OMCC Fails to Document the Growth Rate Used to Project Future Volume at the Proposed ASC

On page 114 of the Application, OMCC states that it "expects that the current percentage of bariatric cases to total cases (41%) will not change in the development of the proposed project. The applicant supplies only one year of data in the Application and Exhibits to document to show the allocation of surgical volume of 1,030 cases in FY 2010 between bariatric and non-bariatric cases. This assumption is not reasonable as it assumes that the rate of growth for non-bariatric cases will be equal to the growth of bariatric cases. Rex and OMCC did not provide any documentation to show that general surgery outpatient cases are increasing at a rate of 12.4% annually, nor did they show that general surgery outpatient cases for the obese population are increasing at a rate of 12.4% annually.

It is reasonable to assume that internal data at Rex could have been utilized to document the number bariatric and non-bariatric cases, respectively, that each surgeon performed in its operating rooms. Surgeons who performed cases at non-Rex facilities (WakeMed Cary and Duke Raleigh Hospital) should have been able to document in each of their letters included in Exhibit 41, at a minimum, the percentage of bariatric and non-bariatric cases performed in the

last several years and the historical growth rates related to those two separate categories of outpatient surgery cases.

Without documentation to show allocation of the base year annual surgical volume of 1,030 cases between bariatric and non-bariatric cases by surgeon, there is no independent means by which to evaluate the reasonableness of the growth rate of combined bariatric and non-bariatric cases used to calculate future volume of the proposed ASC. OMCC should have separated bariatric and non-bariatric cases, and showed a growth rate for each.

On page 111, OMCC assumes that one-fourth of the compound annual growth of 49.5% in bariatric and non-bariatric cases performed between FY 2007 and FY 2010 at Rex by physicians who will use OMCC ("organic growth") is the appropriate growth rate to project volume at OMCC (49.5% / 4 = 12.4%). On pages 112-113, OMCC bases that growth rate on four factors:

- OMCC believes that there is a pent up demand for "bariatric and related surgeries."
  - The market has "historically lacked bariatric surgeons; prior to 2007, Raleigh area was the largest metropolitan area in the U.S. without a bariatric surgeon.
- OMCC has "excluded the growth based on the volumes of three surgeons who have recently begun practicing in this area."
- Bariatric surgery program at FirstHealth Moore Regional in Moore County was recently closed.
- OMCC has projected only for surgeons who will practice at the proposed ASC, and not included any "estimated cases from outside surgeons who can utilize [the proposed ASC] through its open access policy."

Several of those justifications are unsupported and unreasonable.

First, OMCC provides no documentation from patients who would have had surgery but did not because of various obstacles. Letters of support in Exhibit 41 (please see OMCC CON Application pages 514-529 for community support letters) included thirteen patients who have had bariatric surgery. One of those 13 patients had weight loss surgery at WakeMed in September 2003 (please see pages 518-519).

Second, The Raleigh-Durham-Chapel Hill metropolitan area did not lack a bariatric surgeons prior to 2007. Robert Rutledge, MD performed bariatric surgeries at UNC Hospitals. In 1997, while at UNC Hospitals, Dr. Rutledge developed the mini-gastric bypass (MGB), a variation of gastric bypass surgery.[21] After leaving UNC Hospitals, Dr. Rutledge performed bariatric surgeries at Duke University Hospital and Durham Regional Hospital. In Fiscal Year 2004, bariatric surgeons at Durham Regional Hospital performed approximately 350 surgeries.[22]

Dr. Tyner, one of the five physician owners of TABS, LLC, which entity owns 60% of OMCC, LLC, began his professional career with Easley Surgical Associates of Easley, South Carolina in 1988. In 1990, he joined Four Counties Surgical clinic in Henderson, and then Pinehurst

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21 http://www.bariatric.us/mini-gastric-bypass.html

22 www.durhamregional.org/news/pressreleases/20060612084734169

Surgical Associates of Pinehurst in 1992. In 1997, Dr. Tyner joined Executive Surgical Center in Raleigh, where he focused his attention in Cary. He went onto become a founding partner of Cary Surgical Specialists in 2003.[23]

Kenneth Mitchell, MD, a general and bariatric surgeon in practice with Pinehurst Surgical, performed the first bariatric procedure at Moore Regional in March 1999. The Bariatric Center at Moore Regional was first designated a Center of Excellence in 2006 by the Surgical Review Corporation. Moore Regional's program received a Center of Excellence designation from BCBS of North Carolina in 2004, and was recertified as a Blue Center of Distinction in 2009. In March 2010, Moore Regional received a renewal of its designation as a Bariatric Surgery Center of Excellence by the American Society.[24] On page 113, OMCC states that the Bariatric Center at Moore Regional has closed, however, there is nothing on the web site for First Health Moore Regional Hospital to indicate that that the bariatric surgery center program has been closed.

Lastly, it is unreasonable for OMCC to include volume of a surgeon who will not use the proposed ASC in the base volume and in the "organic growth rate" use to project future volume. As discussed in Section II.D above, Dr. DeMaria is listed as a "Rex employed general surgeon" in a note below a table labeled "Rex Surgical Case Volume for Surgeons Who Will Practice at OMCC" on OMCC CON Application page 109. In that note, OMCC stated "*Includes Drs. Ng, Sharp, and DeMaria." In Exhibit 41, Dr. DeMaria is described as a general surgeon who supports the proposed ASC, but will not utilize the proposed ASC. Dr. DeMaria's letter of support in Exhibit 41 does not state that he will use the proposed ASC. Dr. DeMaria was associated with the Duke Health System until 15 days before the OMCC CON application was filed on August 15, 2010.

3. There is no Documentation of the Historical Surgical Volume of Rex Employed General Surgeons

The following table summarizes the historical and projected volume set forth the physician owner letters and letters from physicians who will utilize the proposed ASC (Exhibit 41).

[23] http://www.surgerync.com/bariatric_weight_loss.asp

[24] http://www.thepilot.com/news/2010/jun/09/moore-regional-redesignated-as-bariatric-surgery/

Historical and Projected Volume for Physician Owners (TABS) Will Utilize the Proposed ASC and Physicians Who Will Utilize the Proposed ASC

Name of Physician	Practice	Ownership in TABS, LLC	FY 2010	PY 1: 4/13-3/14	PY2: 4/14-3/15	PY 3: 4/15-3/16
Jon Bruce, MD	Bariatric Specialists of North Carolina	YES	247	372	418	470
Paul Enochs, MD	Bariatric Specialists of North Carolina	YES	283	426	479	538
Michael Tyner, MD	Bariatric Specialists of North Carolina	YES	94	142	159	179
Scott Bovard, MD	Bovard Bariatric Center		75	113	127	143
Peter Henderson, MD	Progress Weight Loss Surgery		0	6	7	8
Joseph Moran, MD	Raleigh Center for Weight Loss Surgery		124	187	210	236
Subtotal			823	1,246	1,400	1,574
Rex Employed Physicians						
Peter Ng, MD	Rex Surgical Specialists	YES	No Data	No Data	No Data	No Data
Lindsey Sharp, MD	Rex Surgical Specialists	YES	No Data	No Data	No Data	No Data
Eric DeMaria, MD	Rex Surgical Specialists		No Data	No Data	No Data	No Data
Subtotal			Cannot be determined	Cannot be determined	Cannot be determined	Cannot be determined
Total			1,030	1,551	1,744	1,959

Source: CON Application

It is unreasonable for OMCC not to have documented in the letters from Drs. Ng, Sharp, and DeMaria, each physician's historical and projected surgical cases. Furthermore, it is unreasonable for OMCC not to have documented in those physician letters the number bariatric and non-bariatric cases, respectively, performed in FY 2010 and that will be performed in Project Years 1-3. Rex fails to explain why this historical information for Drs. Ng and Sharp is not included in the OMCC CON Application. It is reasonable to assume that information is available to Rex, since Drs. Ng and Sharp are physicians employed by the Rex Healthcare system. As discussed earlier, Dr. DeMaria's historical data cannot be counted as part of the Rex Surgical Specialists employed physician group, since Dr. DeMaria was associated with the Duke Health system until two weeks prior to the filing of the OMCC CON Application on August 15, 2010.

In the absence of such documentation, it is impossible to evaluate independently the accuracy and reasonableness of OMCC's projections.

B. Projections for Future Outpatient Utilization of Rex "Related Entities" Are Unreasonable

1. Shifting Outpatient Surgical Volumes

In July 2008, Rex Hospital was approved to relocate 8 of its existing 27 shared surgical operating rooms to the Macon Pond Outpatient Center to become ambulatory surgical operating rooms[25]. The table on page 47 shows 4 rather than the 8 approved ambulatory surgical operating rooms at the Macon Pond Road Outpatient Center as a result of the January 2010 Material Compliance Request submitted to the Agency requesting that it may proceed to re-size the Macon Pond Road Outpatient Center from 8 to 4 surgical operating rooms, and retain the other 4 surgical operating

[25]Project ID #J-8053-08

rooms at Rex Hospital. The Agency response, dated March 22, 2010, approved Rex's request to re-size the Macon Pond Outpatient Center from 8 to 4 surgical operating rooms, with the other four surgical operating rooms to remaining at Rex Hospital in Raleigh.

There are four CON-approved orthopedic ambulatory surgical operating rooms at Orthopaedic Surgery Center of Raleigh (OSCR), which is a joint venture between Rex and Raleigh Orthopaedic Clinic, PA to be located at intersection of Macon Pond Road and Edwards Mill Road in Raleigh, NC 27607.[26] OSCR was awarded four new ORs, based on a need determination in the 2008 SMFP for four new ORs in Wake County. OSCR was projected to be operational in January 2011. On April 14, 2010, OSCR submitted a CON Application for a change of scope and cost-overrun for Project ID # J-8170-08 to change the ownership of the land and to add two minor procedure rooms. The CON Section approved that CON Application, and an appeal is pending.

Both the Macon Pond Road Outpatient Center and OSCR involve Rex Hospital's shifting of ambulatory surgery volume to each of those facilities. In the case of OSCR, the shift will be only orthopedic ambulatory surgical volume. On February 15, 2010, Rex submitted CON Application J-8648-10 to develop two ambulatory surgery operating rooms at Rex Holly Springs ASC[27]. In that February 15, 2010 CON Application (Project I.D. #J-8648-10), Rex proposed to shift of ambulatory surgical volume from Rex Hospital to the proposed new surgery center in Holly Springs, to include orthopedic ambulatory surgical volume, as well as ENT, gynecology, urology, and general surgery ambulatory surgery cases. As discussed in Section II.E above, February 15, 2010 CON Application J-8648-10 was denied, and an appeal is pending. It appears that Rex may be using some of the same counts of historical outpatient cases to be shifted to two separate proposed ASCs, as justification for 2 new ORs at the Rex Holly Springs Surgery Center, OSCR, and at the OMCC proposed in this application. It is not possible for the Agency to discern whether the same set of Rex's outpatient general surgery cases are projected to be relocated to both the Rex Holly Springs Surgery Center and to the proposed OSCC, and even to the 4-OR Macon Pond Road Outpatient Surgery Center.

Each of these CONs were approved based upon shifting outpatient surgical volume from one location to another and increasing outpatient surgical utilization. The following table compares the outpatient surgical growth rate utilized by Rex to justify three additional operating room in a CON application submitted in February of 2010 and the OMCC CON application currently under review.

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[26] Project ID #J-8170-08

[27] CON Application J-8468-10: Rex Hospital, Inc. d/b/a Rex Healthcare for Two Outpatient Surgical Operating Rooms in a Hospital-Based Ambulatory Surgery Center at Rex Healthcare of Holly Springs

Projected Outpatient Surgical Growth for All Rex Related Entities

Surgical Center	Overall Rex Outpatient Growth Rate
Rex Holly Springs Surgery Center - February 2010	3.4%
OMCC - November 2010	9.4%

Source: CON Applications

Overall growth in outpatient volume projected in the current CON application is 9.4% and is inconsistent with projected growth in the previous CON application for the Rex Holly Spring Surgery Center CON filed earlier **in the same year as the OMCC CON application was filed (2010).**

2. Projected Outpatient Growth Rate Unreasonable

The projected 9.4% annual growth rate for outpatient surgical cases at Rex surgical facilities is unreasonable and unsupported. Total outpatient surgical growth (Compound Annual Growth rate for FFY 2007-2009) for Durham, Orange and Wake Counties Surgical providers and for Wake County Surgical providers only is reflected in the following table.

Outpatient Surgical Growth - Durham, Orange and Wake Counties Surgical Providers

Surgical Facilities	Operating Rooms10	2007	2008	2009	CAGR 2007-2009
Durham Regional	14	3,434	3,238	3,234	0.970
Duke	65	18,694	19,055	19,343	1.017
NC Specialty Hospital	4	4,043	5,600	6,285	1.247
Davis Am Surg Center	8	6,232	5,299	4,477	0.848
Chapel Hill Surg Ctr	2	809	849	955	1.086
UNC	40	13,525	13,970	15,138	1.058
WakeMed (Includes North)	30	13,407	12,985	13,177	0.991
WakeMed Cary	9	7,159	6,962	7,273	1.008
Rex (Includes Cary, Wakefield)	31	17,767	23,672	24,567	1.176
Duke Raleigh	15	9,134	9,138	10,817	1.088
Blue Ridge	6	5,296	5,474	5,904	1.056
Southern Eye	2	519	509	515	0.996
Raleigh Plastic	2	397	352	350	0.939
Raleigh Women	0	2,833	2,268	2,170	0.875
Raleigh Orthopaedic	3	0	0	0	0.000
Holly Springs Surgery Center	3	0	0	0	0.000
Total Durham, Orange and Wake Outpatient Surgical Volume	234	103,249	109,371	114,205	1.052
Total Wake Only Wake Outpatient Surgical Volume	101	56,512	61,360	64,773	1.071

Source: LRAs

As shown in the previous table, the CAGR for outpatient surgery in the three-county area was only 5.2% annually from FFY 2007 through FFY 2009. Wake County outpatient surgical growth was only 7.1%. Therefore, an annual outpatient growth rate for total outpatient surgery at Rex over the six-year projected timeframe of 9.4% is unreasonable and unsupported.

Although the following tables reflect a 17.6% growth rate for Rex outpatient surgery from FY 2007 through FFY 2009, the CAGR is skewed by significant growth between 2007 and 2008. The source of this aggressive volume growth from FY 2007 to FY 2008 was 2008 was the first year of Rex's inclusion of surgical cases performed in procedure rooms in their total count of surgical cases as required by the LRA. In addition, total outpatient surgery at Rex decreased from FFY 2009 to FFY 2010 as reflected in the following tables.

Rex Outpatient Surgical Growth
FFY 2007-2010

Surgical Facilities	2007	2008	2009	2010
Rex (Includes Cary, Wakefield)	17,767	23,672	24,567	23,274
Annual Growth		33.2%	3.8%	-5.3%

Source: LRAs; OMCC CON Application

As a result, the three-year CAGR for outpatient surgical volume at Rex surgical facilities was from 2008 through 2010.

Rex 3-Year Compound Annual Growth Rate
FFY 2007-2009 and FFY 2008-2010

	2007	2008	2009	2010	3Yr CAGR
Outpatient Surgical Cases	17,767	23,672	24,567		1.176
Growth Rate		23,672	24,567	23,274	0.992

Source: LRAs; OMCC CON Application

As shown in the previous table, the most current 3-Year CAGR is -0.08%. Therefore, the 9.4% outpatient surgery annual growth projected by OMCC for future utilization of all Rex-related entities is unreasonable. Thus, OMCC fails to show that all existing and approved operating rooms are needed as prescribed by this Certificate of Need Surgical Services Criteria and Standards.

C. *Rex Healthcare System Decrease in Surgical Volume from 2009-2010 and Underutilized Operating Room Capacity in Wake County*

On pages 45- 49 of the Application, OMCC provides surgical volume from existing "related entities" including Rex Hospital, Rex Surgery Center of Cary, and Rex Healthcare of Wakefield.

At the time of this Application, all three facilities operate under the same license, which is the acute care hospital license of Rex Hospital. The following three paragraphs document the decrease in surgical utilization at Rex's three existing hospital-based surgery facilities in the Demonstration Project Service Area (Wake, Durham, and Orange Counties).

1. Rex Hospital – Surgical Case Volumes Declining and Results in a Surplus of Three Operating Rooms

The following table shows a **surplus of 2.8 ORs, which rounds up to 3** shared surgical operating rooms at Rex Hospital, when "Surgical Cases" performed in shared surgical operating rooms are used as the basis for analysis. That is consistent with the requirements of the CON OR Regulation definition of surgical case and the performance standards applicable to the Application. See 10A NCAC 14C. 2103(c) for performance standard and .2101(14) for definition of a "surgical case."[28]

Rex Hospital Surgical Facilities
FFY 2009- 2010 Surgical Case Volumes Performed in ORs
And OR Utilization

Fiscal Year	10/08-9/09	10/09-9/10
Inpatient Cases*	6,867	6,464
Annual Growth		-5.9%
Outpatient Cases	14,678	13,557
Annual Growth		-7.6%
Weighted OR Case Hours	42,618	39,728
ORs Needed at 1,872 Hrs/Yr	22.8	21.2
Licensed ORs**	24	24
Surplus (+)/Deficit (-)	1.2	**2.8**
Capacity 24 ORs @ 2,340 Hrs Per *SMFP****	56,160	56,160
Utilization	75.89%	**70.74%**

Source: CON Application; LRA
**Cases do not include C-Section Cases performed in 3 dedicated C-Section ORs at Rex.*
***Rex Hospital operates 24 shared ORs. It will relocate 4 of these ORs to its Macon Pond Road Outpatient Center. Volumes from Rex Hospital will be shifted to the Macon Pond Location.*
****100% Annual OR Capacity in hours as defined in the SMFP OR Need Method, Chapter 6: 9 hours per day per OR X 260 days per year*
Cases are "Surgical Cases" as that term is defined in 10A NCAC 14C .2101(14)

As shown in the previous table, Rex Hospital's inpatient and outpatient OR case volume has declined during the two most recent federal fiscal years, and utilization of its 24 shared surgical operating rooms has fallen to 70.74% in the most recent fiscal year ending September 30, 2010.

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[28] 10A NCAC 14C.2101(14) defines surgical case as "an individual who receives one or more surgical procedures <u>in an operating room</u> during a single operative encounter. On page 44 of the OMCC CON Application, the applicant states: "*This proposal was developed in accordance with the definitions as stated in 10A NCAC 14C.2101*". This would imply that OMCC would count only historical surgical cases performed in operating and would not include surgical cases performed in a procedure room.

However, as discussed above, Rex Hospital inpatient surgical volume is projected to increase by 1.6% annually through 2016 and outpatient cases are projected to increase 9.4% annually based upon the data reflected on page 49 of the Application. OMCC has not provided sufficient documentation to support this growth rate given the recent decrease in surgical volumes at Rex Hospital. These growth rates in the OSCC CON Application are unreasonable and unsupported.

2. Rex Surgery Center of Cary – Surgical Case Volume Declining and Results in a Surplus of Two Operating Rooms

Rex Surgery Center of Cary opened in 2003 with 4 operating rooms, and has averaged less than 50% utilization of these four operating rooms during the last four fiscal years as reflected in the following table.

Rex Surgery Center of Cary
Historical Utilization

Fiscal Year	10/06-9/07	10/07-9/08	10/08-9/09	10/09-9/10	CAGR 2007-2010	CAGR 2008-2010
Outpatient Cases	3,100	3,193	2,945	2,765	-3.7%	-6.9%
Annual Growth		3.00%	-7.77%	-6.11%		
Weighted Outpatient OR Case Hours	4,650	4,790	4,418	4,148		
ORs Needed at 1,872 Hrs/Yr	2.5	2.6	2.4	2.2		
Licensed ORs	4	4	4	4		
Surplus (+)/Deficit (-)	1.5	1.4	1.6	1.8		
Capacity 4 ORs @ 2,340 Hrs Per *SMFP**	9,360	9,360	9,360	9,360		
Utilization	49.70%	51.20%	47.20%	44.31%		

Source: CON Application and LRAs
Cases are "Surgical Cases" as that term is defined in 10A NCAC 14C .2101(14)
**100% Annual OR Capacity in hours as defined in the SMFP OR Need Method, Chapter 6: 9 hours per day per OR X 260 days per year*

As shown in the previous table, the compound annual growth rate for the Rex Surgery Center of Cary is negative as a result of decreasing ambulatory surgical case utilization. **Case volume and utilization in the most recent fiscal year ending September 30, 2010 is at the lowest since the fiscal year ending September 30, 2007**. The surplus of operating rooms has grown from 1.5 to 1.8, which rounds to a **surplus of 2 operating rooms as of September 30, 2010** at Rex Cary Outpatient Surgery Center.

In 2007, Rex received approval of CON Application Project I.D. # J-7878-07 to convert the Rex Surgery Center of Cary to a freestanding ambulatory surgery center (Rex Cary Surgery Center, LLC) to expand options and to help address the poor utilization of the facility. To date, Rex had not yet converted the facility to freestanding and Rex recently filed a Declaratory Ruling Request proposing yet another change in the ownership structure. There has been no decision from the state yet on this DRR.

It is instructive to review projected utilization of Rex Surgery Center of Cary, as set forth in the Findings dated November 9, 2007 at page 5 for Project ID #J-7878-07.

Rex Surgery Center of Cary
Projected Utilization

	10/06-9/07	10/07-9/08	10/08-9/09	10/09-9/10	10/10-9/11	10/11-9/12
Projected Outpatient Cases	3,140	3,530	3,968	4,460	5,013	5,634
Projected Annual Increase		12.40%	12.40%	12.40%	12.40%	12.40%

Source: CON Application and LRAs

As shown in the previous table, Rex projected outpatient cases through September 2012 at a very aggressive annual growth rate of 12.4% in the 2007 CON. As shown in the following table Rex has completely failed to meet projected growth rates for Rex Surgery Center of Cary.

Comparison of Actual and
Projected Utilization Rex Surgery Center of Cary (Project ID #J-7878-07)

Fiscal Year	10/06-9/07	10/07-9/08	10/08-9/09	10/09-9/10
Actual Historical Outpatient Cases RSSC	3,100	3,193	2,945	2,765
Actual Growth		2.9%	-7.8%	-6.1%
Projected Outpatient Cases	3,140	3,530	3,968	4,460
Projected Growth		12.40%	12.40%	12.40%
Difference	40	337	1,023	1,695
% Difference	-1.3%	-10.6%	-34.7%	-61.3%

Source: CON Application (Project ID #J-7878-07) and LRAs

As shown in the previous table, Rex has not come close to achieving projected outpatient surgical volume at Rex Surgery Center of Cary. In February 15, 2010 CON Applications J-8468-10 and J-8469-10, Rex projects that Rex Surgery Center of Cary will perform 3,663 surgical cases in CY 2014, which would have been the third project year, as shown in the following table.

Projected Utilization Rex Surgery Center of Cary
as per February 15, 2010 CON Applications J-8468-10 and J-8469-10

Calendar Year	2012	2013	2014
Projected Outpatient Cases	3,371	3,514	**3,663**
Weighted Cases	5,066	5,271	5,495
ORs Needed at 1,872 Hrs/Yr	2.7	2.8	2.9
Licensed ORs	4	4	4
Surplus (+)/Deficit (-)	1.3	1.2	1.1

Source: Pages 127-128 of CON Application J-8469-10

As shown in the previous table, Rex projects that there will continue to be a surplus of operating rooms at Rex Surgery Center of Cary through CY 2014.

On page 68 of the OMCC Application, OMCC projects that in Project Year 3 (April 2014-March 2015), Rex Surgery Center of Cary will perform **5,809 outpatient cases**.

In Exhibit 16, OMCC projects that the surgical volume at Rex Surgery Center of Cary will remain constant at 2,765 cases through Project Year 3. OMCC then adds "the projected impact of Cary LLC Physicians," and subtracts volume that will be shifted to the proposed ASC. OMCC believes that "all growth at [Rex Surgery Center of Cary] will be due cases shifted by the physician investors [Cary LLC Physicians]."

On November 12, 2010, Rex submitted a Request for a Declaratory Ruling seeking the Agency's approval, without a CON, an intra-corporate restructuring such that Rex Hospital will transfer its CON rights associated with the four operating rooms at Rex Surgery Center of Cary to its subsidiary Rex Cary Surgery Center, LLC, and to hold the CON rights to the four operating rooms directly, rather than pursuant to a long-term lease from Rex Hospital, its parent. In its Request for a Declaratory Ruling, Rex states that "**it is envisioned** that local physicians **may** own a minority interest in the ASC [Rex Cary Surgery Center, LLC] at some point in the future [...]." [**Emphasis** added.]

At the time that this Application was submitted, there are no "physician investors" for Rex Surgery Center of Cary. It is therefore unreasonable to project that Rex Surgery Center of Cary will perform **5,809 outpatient cases** in Project Year 3 when:

- There is no certainty that there will be any physician investors.
- If there are investors, it is unknown how many physicians will actually invest.
- The number of cases physician investors will perform, if at all, is unknown.
- The impact of shifting surgical volume on other existing providers also is unknown.

OMCC did not disclose or explain the reasons for the inconsistency between projected volume in the February 15, 2010 CON Applications J-8468-10 and J-8469-10 and this Application filed just nine months later in November 2010.

However, as discussed above, outpatient cases are projected to increase 9.0% based upon the data reflected on page 49 of the Application. OMCC has not provided sufficient documentation to support this growth rate given the recent decrease in surgical volumes at Rex Cary Surgical Center.

3. Rex Healthcare of Wakefield – Surgical Case Volume Declining and Results in a Surplus of Two Operating Rooms

On April 27, 2009, three ambulatory surgical operating rooms at Rex Healthcare of Wakefield became operational. The following table shows utilization of that ambulatory surgery center.

Historical Utilization Rex Healthcare of Wakefield

Fiscal Year	4/27/09-9/30/09 Annualized	10/09-9/10
Outpatient Cases	814	1,164
Annual Growth		43.0%
Weighted Outpatient OR Case Hours	1,221	1,746
ORs Needed at 1,872 Hrs/Yr	0.7	0.9
Licensed ORs	3	3
Surplus (+)/Deficit (-)	2.3	**2.1**
Capacity 3 ORs @ 2340 Hrs Per *SMFP**	7,020	7,020
Utilization	17.39%	**24.87%**

Source: CON Application *Cases are "Surgical Cases" as that term is defined in 10A NCAC 14C .2101(14)*
**100% Annual OR Capacity in hours as defined in the SMFP OR Need Method, Chapter 6: 9 hours per day per OR X 260 days per year*

As shown in the previous table, volume is growing as Rex is still in the process of shifting cases to its Rex Healthcare of Wakefield. Shifting cases has reduced the surplus of operating rooms from 2.3 to 2.1, which rounds to a **surplus of 2 operating rooms as of September 30, 2010** at Rex Healthcare of Wakefield.

It is instructive to review projected utilization of Rex Healthcare of Wakefield, as set forth in the Findings dated January 26, 2007 at page 9 for Project ID #J-7657-06.

Rex Healthcare of Wakefield
Projected Utilization

	10/08-9/09	10/09-9/10	10/10-9/11
Outpatient Cases	3,190	3,567	3,977
Projected Annual Increase		11.8%	11.5%

Source: CON Applications

As shown in the previous table, Rex projected outpatient cases through September 2011 at a very aggressive annual growth rate of 11.5%.

The following table compares actual and projected utilization of Rex Healthcare of Wakefield.

Comparison of Actual and Projected Utilization Rex Healthcare of Wakefield

Fiscal Year	4/27/09-9/30/09 Annualized	10/09-9/10
Actual Outpatient Cases RHW	814	1,164
Projected Outpatient Cases RHW	3,190	3,567
Difference-OR Cases	2,376	2,403
% Difference	-291.9%	-206.4%

Source: CON Applications

As shown in the previous table, Rex Healthcare of Wakefield is experiencing actual annual outpatient surgical case volumes that are thousands of cases less than the RHW volumes projected in the CON Application.

In February 15, 2010 CON Applications J-8468-10 and J-8469-10, Rex projects that Rex Healthcare of Wakefield will perform 4,367 surgical cases in CY 2014 (Jan – Dec), which would have been the third project year, as shown in the following table.

Projected Utilization Rex Healthcare of Wakefield as per February 15, 2010 CON Applications J-8468-10 and J-8469-10

Calendar Year	CY 2012	CY 2013	CY 2014
Projected Outpatient Cases	4,019	4,190	**4,367**
Weighted Cases	6,029	6,285	6,551
ORs Needed at 1,872 Hrs/Yr	3.2	3.3	3.5
Licensed ORs	3	3	3
Surplus (+)/Deficit (-)	-0.2	-0.3	-0.5

Source: Pages 127-128 of CON Application J-8469-10

As shown in the previous table, Rex projects that there will be a deficit of operating rooms at Rex Healthcare of Wakefield through CY 2014. This is dramatically different than the analysis above in this section that projects a surplus of 2 ORs (out of 3 ORs) at Rex Healthcare of Wakefield as of 9/30/2010.

It will be quite a feat for Rex Healthcare of Wakefield to achieve those projections when its utilization in the fiscal year ending September 30, 2010 is 1,164 cases. This would require the ORs at Rex Healthcare of Wakefield to increase its OR cases by 3,203 during the period Oct. 1, 2010 through December 31, 2014, which is an increase of 275%[29].

On page 68 of the Application, OMCC projects that in Project Year 3 (April 2014-March 2015), Rex Healthcare of Wakefield will perform **3,775 outpatient cases**. This represents an increase of 2,611 outpatient OR cases at Rex Healthcare of Wakefield, beyond the 1,164 cases performed in FFY 2010 at RHW.

In Exhibit 16, OMCC projects that the surgical volume at Rex Healthcare of Wakefield will grow to **3,977 cases** through Project Year 3. OMCC then subtracts volume that will be shifted to the proposed OMCC to arrive at its projection of **3,775 outpatient cases** in Project Year 3. Those 3,775 cases translate to 5,663 weighted cases, which support a need for 3.0 operating rooms at 1,872 hours per year in Project Year 3.

OMCC did not disclose or explain the reasons for the inconsistency between projected volume in the February 15, 2010 CON Applications J-8468-10 and J-8469-10 and this Application, filed just nine months later in November 2010. Thus, its OMCC volume projections to justify the need for two new ORs are unreasonable and unsupported.

[29]Calculation: (4367 – 1164) = 3202; 3203/1164 = 275% Increase

4. Rex Hospital, Rex Surgery Center of Cary, and Rex Healthcare of Wakefield – Surgical Case Volume Declining and Results in a Surplus of Seven Operating Rooms

The following table shows a **surplus of 6.6, which rounds up to 7 surgical operating rooms** at Rex Healthcare (Rex Hospital, Rex Cary Surgery Center, Rex Healthcare of Wakefield), when "Surgical Cases" performed in shared surgical operating rooms are used as the basis for analysis. That is consistent with the CON OR Regulation performance standards applicable to the Application. See 10A NCAC 14C. 2103(c) (performance standards) and .2101(14) (definition of a "surgical case.").

Historical Utilization
Rex Hospital, Rex Surgery Center of Cary, Rex Healthcare of Wakefield

Fiscal Year	10/08-9/09	10/09-9/10
Inpatient Cases*	6,867	6,464
Annual Growth		-5.9%
Outpatient Cases	18,437	17,486
Annual Growth		-5.2%
Weighted OR Case Hours	48,257	45,621
ORs Needed at 1,872 Hrs/Yr	25.8	24.4
Licensed ORs**	31	31
Surplus (+)/Deficit (-)	5.2	**6.6**
Capacity 31 ORs @ 2,340 Hrs Per *SMFP****	72,540	72,540
Utilization	66.52%	**62.89%**

Source: CON Application **Cases do not include C-Section Cases performed in 3 dedicated C-Section ORs*
***Rex Hospital operates 24 shared ORs. It will relocate 4 of these ORs to its Macon Pond Road Outpatient Center. Rex Surgery Center of Cary operates 4 ORs. Rex Healthcare of Wakefield operates 3 ORs.*
****100% Annual OR Capacity in hours as defined in the SMFP OR Need Method, Chapter 6: 9 hours per day per OR X 260 days per year*
Cases are "Surgical Cases" as that term is defined in 10A NCAC 14C .2101(14)

As shown in the previous table, Rex Healthcare System has lost inpatient and outpatient case volume, and utilization of its 31 surgical operating rooms has fallen to 62.89% in the most recent fiscal year ending September 30, 2010.

D. Projected Service Area is Unsupported by Data Presented in the Application, and Results in Overstated Projections

1. OMCC Did Not Provide Any Historical Patient Origin Data

OMCC has not provided any historical patient origin data for Rex Hospital or for any of the individual surgeons who will perform surgery at the proposed ASC. An absence of historical patient origin data makes it impossible to evaluate whether the projected OMCC patient origin is based on reasonable and supported assumptions.

2. Orange County is Not Included in the Primary Service Area – Orange County is One of the Three Demonstration Project Service Area Counties

It is critical to recognize that Orange County is not included in the primary service area for the OMCC proposal. OMCC claims that "the historic data for the surgeons who will practice at OMCC does not suggest that the county is within its primary service area."[30] OMCC does not, however, provide "historic data for the surgeons who will practice at OMCC."

Projected patient origin from Orange County, one of the three Demonstration Project Service Area counties, is the smallest percentage of all 17 counties in the proposed service area. OMCC failed to explain why OMCC projected that only 0.48% of its patients will be residents of Orange County. A plausible explanation is offered below.

Orange County is the site of UNC Health Care, Rex's parent company. UNC Health Care has a long-standing bariatric surgery program, accredited as a Level 1b facility by the Bariatric Surgery Center Network (BSCN) Accreditation Program of the American College of Surgeons (ACS), named a Blue Distinction Center for Bariatric Surgery by Blue Cross Blue Shield of North Carolina, and accredited by the American College of Surgeons (ACS).[31, 32]

By excluding Orange County from the primary service area, OMCC has acknowledged that the proposed ASC duplicates existing health service resources at UNC Health Care. Further, if it is true as OMCC claims that "the historic data for the surgeons who will practice at OMCC does not suggest that the county is within its primary service area," then is Cary the most efficient and effective site for the proposed ASC?

3. Patient Origin from Durham County, One of the Three Demonstration Project Service Area Counties, is Projected to be Smaller than Johnston and Franklin Counties, and "Other"

Patient origin from Durham County, one of the three Demonstration Project Service Area counties, is projected to be smaller (3.25%) than Johnston (12.88%) and Franklin (4.45%) Counties, respectively and the "Other" category (4.21%). The OMCC CON Application includes no explanation or data to support the projected patient origin for the proposed surgery center.

It is noteworthy that OMCC did not include a larger percentage of patients from Durham County in view of data presented by OMCC on pages 105-107, which data show that Durham County has:

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[30] CON Application J-8620-10, page 122.

[31] http://www.med.unc.edu/gisurgery/patientinfo/Weight-loss%20Surgery

[32] http://www.med.unc.edu/surgery/news/2010-news/BSCN?searchterm=bariatric

- Larger estimated severe and morbid obesity rates than Franklin, Harnett, and Wake Counties, respectively.
- A larger number of morbidly obese population in 2010 (9,707) than Johnston County (8,098)
- Larger estimated severely obese population with diabetes than Franklin, Harnett, and Johnston Counties, respectively.

OMCC is silent about its reasons for projecting such a small percentage of patients who reside in Durham County. OMCC failed to explain why OMCC projected that only 3.25% of its patients will be residents of Durham County. A plausible explanation is offered below.

Durham County is the site of The Duke Center for Metabolic and Weight Loss Surgery, which is recognized by The American Society for Metabolic and Bariatric Surgery, a Blue Cross Blue Shield Blue Distinction Center for Bariatric Surgery, and is Center of Excellence with CIGNA health insurance. The Duke Center Metabolic and Weight Loss Surgery was the first program in the region to receive a Blue Cross Blue Shield Distinction Center for Bariatric Surgery.[33] The Duke Center for Metabolic and Weight Loss Surgery provides weight loss surgery at four locations in the Demonstration Project Service Area: The Health Service Center, Duke Raleigh Hospital, Durham Regional Hospital, and James E. Davis Ambulatory Surgical Center.[34] The Duke Center for Metabolic and Weight Loss Surgery has six surgeons, two psychologists, two nutritionists, a nurse practitioner, three nurses, and an anesthesiologist.[35]

By projecting such a small percentage of patients from Durham County, OMCC has acknowledged that the proposed ASC duplicates existing health service resources for obese in Durham.

4. OMCC's Service Area Negatively Impacts Ability to Meet Charity Projections

The following table shows the proposed service area separated into two categories: (1) the three counties in the Demonstration Project Service Area and (2) the fourteen other counties.

[33] http://www.dukehealth.org/services/weight_loss_surgery/about/program_of_excellence

[34] http://www.dukehealth.org/services/weight_loss_surgery/locations

[35] http://www.dukehealth.org/services/weight_loss_surgery/physicians

Projected Patient Origin
Obesity Management Center of the Carolinas
Project Years 1 and 2

County	PY 1: 4/13-3/14		PY 2: 4/14-3/15	
	% of Total	Patients	% of Total	Patients
Wake	63.66%	988	63.66%	1,110
Durham	3.25%	50	3.25%	57
Orange	0.48%	7	0.48%	8
Subtotal Demonstration Project Service Area	*67.39%*	*1,045*	*67.39%*	*1,175*
Johnston	12.88%	200	12.88%	224
Franklin	4.45%	69	4.45%	78
Harnett	1.93%	30	1.93%	34
Vance	1.32%	21	1.32%	23
Sampson	1.20%	19	1.20%	21
Granville	1.20%	19	1.20%	21
Nash	0.96%	15	0.96%	17
Lee	0.84%	13	0.84%	15
Chatham	0.72%	11	0.72%	13
Wayne	0.60%	9	0.60%	10
Warren	0.60%	9	0.60%	10
Alamance	0.60%	9	0.60%	10
Wilson	0.60%	9	0.60%	10
Cumberland	0.48%	7	0.48%	8
Other*	4.21%	65	4.21%	73
Subtotal Non-Demonstration Project Service Area	*32.59%*	*505*	*32.59%*	*567*
Total	99.98%	1,550	99.98%	1,742

**Other includes Caswell, Columbus, Craven, Dare, Duplin, Edgecombe, Guilford, Halifax, Hertford, Mecklenburg, Moore, New Hanover, Person, Pitt, Randolph, Richmond, Robeson, and Rockingham counties, and other states.*
Source: CON Application

As shown in the previous table, OMCC projects that approximately 33% of the OMCC ambulatory surgery patients in Project Years 1 and 2 are residents of counties outside of the Wake-Durham-Orange Counties Demonstration Project Service Area.

OMCC based its charity care projection on total utilization from the service area. OMCC did not provide any discussion about the need for transportation, support and other ancillary services for patients from outlying areas in need of financial assistance for bariatric surgery. As shown in Cary Transit and the Triangle Transit route maps included Attachment 2 the distance between the OMCC location in Cary. The nearest bus stop is not a walkable distance for the typical bariatric patient. Once again, the charity care projections are based upon unreasonable and unsupported assumptions.

E. The Proposed ASC will have a Negative Impact on Existing Providers

On pages 93-94, OMCC states its belief that the proposed ASC will not have a negative impact on existing providers. OMCC provides only a qualitative discussion of the expected impact on existing providers in the three-county demonstration service area and does not provide a quantitative analysis of the impact of OMCC on existing bariatric surgery programs in Orange and Durham County. As discussed above in these comments, UNC Health Care in Orange County has an established bariatric surgery program, accredited as a Level 1b facility by the Bariatric Surgery Center Network (BSCN) Accreditation Program of the American College of Surgeons (ACS). The Duke Center for Metabolic and Weight Loss Surgery, located in Durham County also is recognized by The American Society for Metabolic and Bariatric Surgery. The Duke Center offers services at four locations in the Demonstration Project Service Area: The Health Service Center, Duke Raleigh Hospital, Durham Regional Hospital, and James E. Davis Ambulatory Surgical Center. OMCC's projected patient origin shows that it proposes to serve some patients from Durham and Orange counties, as well as from Wake County. Thus, further assessment of the impact of the proposed OMCC on existing providers is clearly warranted. OMCC failed to mention these existing bariatric surgery providers in its application.

In addition, the proposed ASC will shift volume from existing surgical providers in Wake County. The following table shows the historical and projected cases that physician owners and users of OMCC will shift to the proposed ASC.

Cases Shifted from WakeMed Cary and Duke Raleigh Hospital
Due to the Proposed ASC

Facility from which Cases Projected to Shift	FY 2010	PY 1: 4/13-3/14	PY 2: 4/14-3/15	PY 3: 4/15-3/16
WakeMed Cary				
Cases	229	345	388	436
Percent of Total Cases at Proposed ASC	22.2%	22.2%	22.2%	22.3%
Weighted Cases	344	518	582	654
% of 1872 Hrs/Yr	18.3%	27.6%	31.1%	34.9%
Duke Raleigh Hospital				
Cases	53	80	90	100
Percent of Total Cases at Proposed ASC	5.1%	5.2%	5.2%	5.1%
Weighted Cases	80	120	135	150
% of 1872 Hrs/Yr	4.2%	6.4%	7.2%	8.0%
Total				
Cases	282	425	478	536
Percent of Total Cases at Proposed ASC	27.4%	27.4%	27.4%	27.4%
Weighted Cases	423	638	717	804
% of 1872 Hrs/Yr	22.6%	34.1%	38.3%	42.9%

Source: CON Application

The previous table shows that in Project Year 3, OMCC projects that 536 cases will no longer be performed at WakeMed Cary and Duke Raleigh Hospital. Those 536 cases translate to 804

weighted cases, which support a need for 0.4 operating rooms at 1,872 hours per year in Project Year 3. That is not inconsequential impact for either facility as discussed below.

1. Duke Raleigh Hospital Lost 17 Surgeons Associated with Raleigh Surgical Group and Wake Surgical Specialists Which Will Impact Future Surgical Volume

According to Rex's February 15, 2010 CON Applications (Project I.D. #s J-8468-10 and J-8469-10), on August 1, 2009, Raleigh Surgical Group and Wake Surgical Specialists joined Rex Healthcare, adding "17 world-class surgeons to Rex Healthcare's employed medical staff. The merged group is called Rex Surgical Specialists and is employed by Rex Physicians, LLC."[36]

According to Rex's February 15, 2010 CON Applications (Project I.D. #s J-8468-10 and J-8469-10), "Wake Surgical Specialists performed 326 inpatient surgical cases and 1,696 outpatient surgical cases from April 2008 to March 2009 at Duke Raleigh Hospital (2,022 cases in total)."[37] Rex provided the following table to show Wake Surgical Specialists cases at DRH.

Wake Surgical Specialists Cases at Duke Raleigh Hospital
April 2007 – March 2009

Time Period	Cases
April 2007 to March 2008	1,397
April 2008- March 2009	2,022
Percent Growth	44.7%

Source: Rex Hospital CON Applications J-8468-10 and J-8469-10, pages 91-92, citing Thomson Reuters

Rex explained that "[t]he impetus behind some of this 44.7 percent growth in cases at Duke Raleigh was the addition of another Wake Surgical Specialists surgeon during this time frame. This group also added another surgeon just prior to joining Rex [...]."[38]

Rex quantified the surgical volume it expects will shift from Wake Surgical Specialists to Rex Hospital and Rex Holly Springs ASC in FY 2010 – FY 2015, as shown in the following table.

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[36] Rex Hospital CON Applications J-8468-10 and J-8469-10, pages 83 & 90-91
[37] Rex Hospital CON Applications J-8468-10 and J-8469-10, page 91
[38] Rex Hospital CON Applications J-8468-10 and J-8469-10, page 91, FN 18

**Projected Future Wake Surgical Specialists
Surgical Cases Shifted from Duke Raleigh Hospital to Rex Hospital
and Rex Holly Springs ASC**

Federal Fiscal Year	Inpatient	Outpatient	Total
2010	326	1,696	2,022
2011	332	1,768	2,100
2012	332	1,843	2,181
2013	338	1,921	2,265
2014	344	2,002	2,352
2015	350	2,087	2,444
CAGR	1.8%	4.2%	3.9%

Source: CON Applications J-8468-10 and J-8469-10, pages 92-94

It is reasonable to assume that the Wake Surgical Specialists surgical volume shown in the previous table would have been performed at Duke Raleigh Hospital, had those surgeons not joined Rex. Those cases therefore represent significant lost surgical volume to Duke Raleigh Hospital.

The magnitude of the loss to Duke Raleigh Hospital of surgeons associated with Wake Surgical Specialists joining Rex as employed surgeons is significant both in terms of current volume on which to base projections and the projections themselves. Consequently, it is reasonable to assume that Duke Raleigh Hospital:

- Surgical volume will decline by at least the number of cases performed annually by the surgeons associated with Wake Surgical Specialists.
- Annual surgical volume will be negatively affected until replacement surgeons are performing surgical cases at DRH.
- Has a lower surgical volume on which to base projections for its proposed inpatient surgery expansion, including the addition of two new operating rooms.
- Has a lower rate of growth for surgical cases, which reflects the extent of lower utilization.
- Projected FY 2010 through FY 2015 annual surgical volume must be adjusted downward to reflect a lower base volume and lower growth rate.

On August 16, 2010, Duke Raleigh Hospital submitted CON Application (CON Project I.D) # J-8567-10) in which it sought approval to transfer two single-specialty ambulatory operating rooms from National Women's Health Organization to DRH where they will become shared surgical operating rooms. This application was approved by the Agency on November 24, 2010.

It is reasonable to assume that the addition of another two shared operating rooms will exacerbate Duke Raleigh Hospital's challenge to utilize fully its expanded operating room inventory. One can also infer that the proposed OMCC is an unnecessary duplication of existing and approved OR capacity at Duke Raleigh Hospital.

2. WakeMed Cary Operating Rooms are not Over Utilized and will be Impacted by a Loss of Surgical Volume to the Proposed ASC

On pages 80 and 83 of February 15, 2010 CON Application CON Project I.D. #J-84 63-10, WakeMed Cary discussed capacity issues and patient satisfaction issues as reasons three additional operating rooms are needed at WakeMed Cary. WakeMed Cary misinterprets the *SMFP* definition of capacity and in fact the operating rooms at WakeMed Cary not operating at 99% of current operating room capacity. Based upon the information included on page 62 of the *SMFP*, capacity of an operating room equals the number of hours the operating room is staffed and available for surgical procedures which according to the *SMFP* is nine hours per day 260 days per year or 2,340 hours per operating room. For planning purposes, the *SMFP* utilizes an 80% planning threshold, or 1,872, to identify future need in a county.

Therefore, based upon the capacity definition in the *SMFP*, the utilization of WakeMed Cary's nine shared operating rooms is considerably less than 99%, when the annual OR capacity of 2,340 OR hours per year is used to calculate capacity. This is shown in the following table.

WakeMed Cary 2009 Surgical Services Utilization

	2009
Operating Rooms	9
Capacity per rooms (Total available staffed hours)	2,340
Total Capacity	21,060
Inpatient Surgery (Less C-Section cases)	1,947
Outpatient Surgery	7,273
Weighted Surgical Hours (3.0 hrs per inpt and 1.5 hrs per outpt)	16,751
Current Surgical Services Utilization	79.5%

Source: SMFP; 2010 LRA

The nine operating rooms at WakeMed Cary are operated at 79.5% of capacity assuming a nine hour day as reflected in the previous table.

OMCC projects that WakeMed Cary will bear the brunt of the cases shifted to the proposed ASC, as shown in the following table.

Cases Shifted from WakeMed Cary and Duke Raleigh Hospital due to the Proposed ASC

Facility from which Cases Projected to Shift	FY 2010	PY 1: 4/13-3/14	PY 2: 4/14-3/15	PY 3: 4/15-3/16
WakeMed Cary				
Cases	229	345	388	436
Percent of Total Cases at Proposed ASC	22.2%	22.2%	22.2%	22.3%
Weighted Cases	344	518	582	654
% of 1872 Hrs/Yr	18.3%	27.6%	31.1%	34.9%
Duke Raleigh Hospital				
Cases	53	80	90	100
Percent of Total Cases at Proposed ASC	5.1%	5.2%	5.2%	5.1%
Weighted Cases	80	120	135	150
% of 1872 Hrs/Yr	4.2%	6.4%	7.2%	8.0%
Total				
Cases	282	425	478	536
Percent of Total Cases at Proposed ASC	27.4%	27.4%	27.4%	27.4%
Weighted Cases	423	638	717	804
% of 1872 Hrs/Yr	22.6%	34.1%	38.3%	42.9%

Source: CON Application

A loss of 436 cases during the first year of OMCC's operation is the equivalent of 35% of total annual hours for one operating room. One can reasonably assume that WakeMed Cary would be negatively impacted by that loss. One can also infer that the proposed OMCC is an unnecessary duplication of existing OR capacity at WakeMed Cary.

F. OMCC Proposes to Shift Bariatric and Non-Bariatric Ambulatory Cases Focused on Obese Patients from Rex and non-Rex Facilities in Wake County

In this Application, OMCC proposes to shift bariatric and non-bariatric ambulatory cases focused on obese patients from Rex Hospital, Rex Surgery Center of Cary, Rex Healthcare of Wakefield, and Rex Macon Pond Road Outpatient Center, respectively, to the proposed ASC. OMCC also proposes to shift bariatric and non-bariatric ambulatory cases focused on obese patients from Rex Holly Springs ASC, which project (February 15, 2010 CON Application J-8648-10) was denied and which remains in litigation, with Rex seeking to overturn the approval of Novant's Holly Springs Surgery Center. Lastly, OMCC proposes that bariatric and non-bariatric ambulatory cases focused on obese patients will shift from WakeMed Cary and Duke Raleigh Hospital to the proposed ASC.

Bariatric and Non-Bariatric Cases Proposed to be Shifted to the Proposed ASC

Facility	PY 1: 4/13-3/14	PY 2: 4/14-3/15	PY 3: 4/15-3/16
Rex Hospital	443	498	559
Rex Surgery Center of Cary	178	200	224
Rex Healthcare of Wakefield	160	179	202
Rex Macon Pond Road Outpatient Center	262	295	331
Rex Holly Springs ASC*	84	95	107
Subtotal	*1,127*	*1,267*	*1,423*
WakeMed Cary	345	388	436
Duke Raleigh Hospital	80	90	100
Subtotal	*425*	*478*	*536*
Total	1,552	1,745	1,959

Source: CON Application
**February 15, 2010 CON Application J-8468-10 was denied and has been appealed.*

The number of cases that OMCC proposes to shift from Rex Holly Springs ASC (February 15, 2010 CON Application J-8468-10 denied) should not be included, and the cases projected at the proposed OMCC should be reduced accordingly. Otherwise, Rex is counting the same set of surgical cases to justify the need for two new ORs at the Rex Holly Springs ASC and for two new ORs at the Rex joint venture ASC, OMCC.

G.S. 131E-183 (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.

On page 128 of the Application, OMCC summarily states that "OMCC maintains that no other existing provider can meet the need identified for the proposed single specialty ASC as effectively as OMCC." OMCC conveniently does not include Rex in that declaration, although Rex owns 40% of the membership interests in the new limited liability company, OMCC. Rex proposes to fund 40% of the capital cost of OMCC. See the Rex funds letter in Exhibit 38 and the Rex audited financial statements in Exhibit 39

In this Application, OMCC proposes to shift bariatric and non-bariatric ambulatory cases focused on obese patients from an existing facility (Rex Hospital including the hospital-based Rex Surgery Center of Cary), an approved facility (Rex Healthcare of Wakefield (2 ORs), and a proposed facility (Rex Holly Springs ASC), respectively, to the proposed OMCC.

Bariatric and Non-Bariatric Cases
Proposed to be Shifted from Rex to the Proposed ASC

Facility	PY 1: 4/13-3/14	PY 2: 4/14-3/15	PY 3: 4/15-3/16
Rex Hospital	443	498	559
Rex Surgery Center of Cary	178	200	224
Rex Healthcare of Wakefield	160	179	202
Rex Macon Pond Road Outpatient Center	262	295	331
Rex Holly Springs ASC*	84	95	107
Total	**1,127**	**1,267**	**1,423**

Source: CON Application
**February 15, 2010 CON Application J-8468-10 was denied and has been appealed and remains in litigation as of the date of these comments.*

The previous table shows that alternative methods of meeting the needs for the proposed project exist today at Rex. It is unclear why Rex would shift patients from an inpatient setting where a procedure is reimbursable to an outpatient setting where the procedure is not reimbursed. This also could impact the amount a patient must pay. Therefore, OMCC and Rex have not documented the proposed project to be the most cost effective alternative.

The following Subsections explore at least four alternatives that were not discussed in the Application. Two of those alternatives use existing and approved operating room inventory at Rex facilities to meet the needs of the proposed OMCC project.

A. Use Existing and Underutilized Operating Rooms at Rex

OMCC could have opted not to submit the Application, and instead to use existing and underutilized operating rooms at Rex Hospital, Rex Cary Surgery Center, and/or Rex Healthcare of Wakefield for general surgery with a focus on obese patients. In fact, the five TABS, LLC surgeons, who own 60% of the membership interests in OMCC (Drs. Enochs, Ng, Tyner, Sharp, and Bruce) signed letters of surgeon support letters dated February 2010 to shift their cases to the existing, but underutilized Rex Cary ASC. See Rex's CON Application filed Feb. 2010, CON Project I.D. # 8468-10, Exhibit #6 for copies of these letters.

If it were necessary to make modifications to the existing facilities/operating rooms at Rex Cary Surgery Center and/or Rex Healthcare of Wakefield, surely such modifications would certainly cost less than the total capital needed to implement the proposed ASC ($6,536,587 = $5,911,398 + $625,189 [start up expense]). Thus, this would be a more cost effective alternative than the proposed OMCC. OMCC/Rex did not discuss this alternative in its application.

B. Modify the Approved Rex Macon Pond Road Outpatient Center

OMCC could have opted not to submit the Application, and instead modified the approved Rex Macon Pond Road Outpatient Center for general surgery with a focus on obese patients.

If it were necessary to make modifications to the approved Rex Macon Pond Road Outpatient Center operating rooms, surely, such modifications would cost less than the total capital needed to implement the proposed ASC ($6,536,587 = $5,911,398 + $625,189 [start up expense]). Thus, this would be a more cost effective alternative than the proposed OMCC. OMCC/Rex did not discuss this alternative in its application.

C. Joint Venture with One or More Existing Provider in Durham and/or Orange County

OMCC rules out locating the proposed ASC in Durham and Orange Counties due to "underutilization of operating rooms in the Durham and Orange counties."[39] It could have, but did not discuss whether it considered a joint venture with one or more existing provider(s) with underutilized operating room inventory in Durham or/and Orange County as less costly and/or more effective alternatives to the proposed ASC called OMCC.

D. Joint Venture with UNC Health Care

OMCC and Rex failed to discuss the existing UNC Health Care bariatric program, which provides an alternative for the proposed project. On September 23, 2010, UNC Health Care announced that the bariatric surgery program received two important distinctions. The program has been accredited as a Level 1b facility by the Bariatric Surgery Center Network (BSCN) Accreditation Program of the American College of Surgeons (ACS). In addition, the bariatric program was named a Blue Distinction Center for Bariatric Surgery by Blue Cross Blue Shield of North Carolina.

> *"These new designations for our established bariatric surgery program are important in the current environment because they demonstrate the UNC Health Care System's continuing commitment to top level bariatric care for the people of North Carolina within the doors of the flagship institution," said Tim Farrell, MD, who co-directs the program with D. Wayne Overby, MD. "Having patients here in the clinical and academic environment of UNC Hospitals helps them receive the best multidisciplinary care, but also exposes our trainees and researchers to the human face of the obesity epidemic. These personal connections will help patients today, but will also pay future dividends in better trained health care providers and research innovations."*
>
> *Overby said, "UNC has a long history of providing weight loss surgery patients with excellent care. Patients and their providers can be even more confident choosing our program knowing we have been objectively reviewed and recognized by both the American College of Surgeons and Blue Cross Blue Shield of North Carolina."*[40]

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[39] CON Application J-8620-10, page 126.

[40] http://news.unchealthcare.org/news/2010/September/unc-bariatric-surgery-program-receives-two-important-distinctions

Also in September 2010, UNC Health Care's bariatric surgery program in the gastrointestinal surgery division was officially accredited by the American College of Surgeons (ACS). That designation is testament to the facility having met the essential criteria that ensure bariatric surgery care capability and institutional performance as outlined by the ACS Bariatric Surgery Center Network.[41]

There is no statement at all in the Application that UNC Health Care and Rex even entertained the possibility of a joint venture as an alternative to the proposed ASC. Rex also did not mention that UNC was a "related entity," as that term is defined in the OR CON regulations.

The burden is on OMCC to demonstrate that the proposed project is the least costly or most effective alternative, which burden it does not carry. As a result, the Application does not conform to Criterion (4).

G.S. 131E-183 (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.

As discussed above in the context of Criterion (3), surgical case volume projections are unreasonable and overstated. OMCC uses those surgical case volume projections as the basis for CON Pro Forma Forms B through E. Therefore, financial projections are unreliable.

In addition, a review of Proforma E for non-bariatric patients reflects an average reimbursement rate for Medicaid which is greater than the average reimbursement for Medicare in each of the first three project years as reflected in the following table. This is most unusual since typically, Medicaid reimbursement is lower than Medicare reimbursement.

Projected Average Reimbursement - Non-Bariatric Cases

Payer	Project Year 1	Project Year 2	Project Year 3
Medicare	$1,447	$1,505	$1,565
Medicaid	$2,015	$2,095	$2,179

Source: OMCC CON Application, Form E, Page 188

The list of top 20 procedures to be provided at the proposed facility reflected on page 53 of the OMCC CON Application includes 11 non-bariatric procedures. The following table provides a comparison of current Medicare and Medicaid reimbursement rates for these procedures.

41 http://www.med.unc.edu/surgery/news/2010-news/BSCN?searchterm=bariatric

Outpatient Medicare and Medicaid Reimbursement Rates - 2010

CPT	YEAR 2010	MEDICARE REIMBURSEMENT	MEDICAID REIMBURSEMENT
11770	PILONIDAL CYST REMOVAL	$ 823.73	$ 524.26
47562	CHOLECTECTOMY - LAPAROSCOPIC	$ 1,874.25	$ 1,644.39
47563	CHOLECTECTOMY - LAPAROSCOPIC	$ 1,874.25	$ 1,644.39
49320	EXPLORATORY LAPAROSCOPY - ABDOMEN	$ 1,263.86	$ 644.22
49505	INGUINAL HERNIA REPAIR	$ 1,109.88	$ 689.17
49560	VENTRAL HERNIA REPAIR	$ 1,109.88	$ 689.17
49585	UMBILICAL HERNIA REPAIR	$ 1,109.88	$ 689.17
49650	INGUINAL HERNIA REPAIR - LAPAROSCOPIC	$ 1,556.19	$ 823.27
49652	OTHER LAPAROSCOPIC HERNIA REPAIR	$ 2,919.34	$ 611.00
49653	OTHER LAPAROSCOPIC HERNIA REPAIR	$ 2,919.34	$ 763.44
49654	OTHER LAPAROSCOPIC HERNIA REPAIR	$ 2,919.34	$ 702.23

Source: CMS

As reflected in the previous table, Medicare reimbursement exceeds Medicaid reimbursement for every non-bariatric case reflected on page 53 of the OMCC CON Application. Therefore, the average reimbursement rates reflected in the previous table and on page 188 of the OMCC CON Application are incorrect. These incorrect rates were utilized by OMCC in the calculation of total revenues projected for the proposed project in the Proforma Income Statements to determine the financial feasibility of the project. Therefore, the CON Agency cannot determine if the proposed project is financially feasible.

These incorrect rates also were used by OMCC in the calculation of total revenues collected for the proposed project and in the determination of projected 7% requirement for the demonstration project set forth in the OR CON regulations specifically applicable to proposed demonstration project surgery centers. Therefore, the CON Agency cannot determine if the proposed project meets the regulatory requirements specific to demonstration projects enumerated in the Criteria and Standards for Surgical Services at 10 NCAC 14C .2102 (d)(3).

For these reasons, the Application does not conform to Criterion (5).

G.S. 131E-183 (6)

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

OMCC and Rex failed to discuss the existing UNC Health Care bariatric program, which provides and alternative for the proposed project. On September 23, 2010, UNC Health Care announced that the bariatric surgery program received two important distinctions. The program has been accredited as a Level 1b facility by the Bariatric Surgery Center Network (BSCN) Accreditation Program of the American College of Surgeons (ACS). In addition, the bariatric program was named a Blue Distinction Center for Bariatric Surgery by Blue Cross Blue Shield of North Carolina.

For the reasons discussed below, OMCC chooses to duplicate the ongoing program at UNC and fails to demonstrate that the proposed project will not result in unnecessary duplication of existing health service capabilities and facilities. Consequently, the Application does not conform to Criterion (6). See the discussion in these comments above regarding Review Criterion (3).

A. Surplus of Existing Operating Room Inventory at Rex

As documented above in the context of Criterion (3), there is a **surplus of 6.6** (rounds up to 7) operating rooms at Rex Hospital, Rex Surgery Center of Cary, and Rex Healthcare of Wakefield. Included in that surplus is a **surplus of 1.8** (rounds up to 2) operating rooms at Rex Surgery Center of Cary, which is located adjacent to the proposed ASC. The proposed project is duplicative of existing operating room inventory at Rex, including the Rex Cary ASC that is only a few hundred yards from the proposed OMCC.

B. Proposed ASC is Duplicative of Existing Bariatric Surgery Programs in the Demonstration Project Service Area

OMCC also fails to present any information about existing bariatric surgery programs in the Demonstration Project Service Area.

Based on information in the Application and publicly available information, there are at least six hospitals (Rex Hospital, UNC Hospitals, Duke Raleigh Hospital, Durham Regional Hospital, and WakeMed Cary) and an ASC (James E. Davis Ambulatory Surgical Center) in the Demonstration Project Service Area that provide bariatric surgery on an outpatient basis.

As discussed in the context of Criteria (3) and (4) above, UNC Health Care has a long-standing bariatric surgery program, which in September 2010 receive two important distinctions. The program has been accredited as a Level 1b facility by the Bariatric Surgery Center Network (BSCN) Accreditation Program of the American College of Surgeons (ACS). This designation means that UNC Hospitals has met the essential criteria that ensure it is fully capable of supporting a bariatric surgery care program and that its institutional performance meets the requirements outlined by the ACS BSCN Accreditation Program. In addition, the program was named a Blue Distinction Center for Bariatric Surgery by Blue Cross Blue Shield of North Carolina.[42] Also in September 2010, UNC Health Care's Bariatric Surgery program in the Gastrointestinal Surgery division was officially accredited by the American College of Surgeons (ACS). That designation is testament to the facility having met the essential criteria that ensure bariatric surgery care capability and institutional performance as outlined by the ACS Bariatric Surgery Center Network.[43]

As discussed in the context of Criterion (3) above, Durham County is the site of The Duke Center for Metabolic and Weight Loss Surgery is recognized by The American Society for

[42] http://www.med.unc.edu/gisurgery/patientinfo/Weight-loss%20Surgery
[43] http://www.med.unc.edu/surgery/news/2010-news/BSCN?searchterm=bariatric

Metabolic and Bariatric Surgery, is a Blue Cross Blue Shield Blue Distinction Center for Bariatric Surgery, and is Center of Excellence with CIGNA health insurance. The Duke Center Metabolic and Weight Loss Surgery was the first program in the region to receive a Blue Cross Blue Shield Distinction Center for Bariatric Surgery.[44] The Duke Center for Metabolic and Weight Loss Surgery provides weight loss surgery at four locations in the Demonstration Project Service Area: The Health Service Center, Duke Raleigh Hospital, Durham Regional Hospital, and James E. Davis Ambulatory Surgical Center.[45] The Duke Center for Metabolic and Weight Loss Surgery has six surgeons, two psychologists, two nutritionists, a nurse practitioner, three nurses, and an anesthesiologist.[46]

OMCC fails to document that its proposed ASC is not duplicative of existing bariatric surgery programs in the Demonstration Project Service Area.

C. OMCC has not Demonstrated that the Proposed ASC is not Duplicative of Existing Bariatric Surgery Programs in the State

OMCC's decision to include 17 counties in its proposed service area leads one to believe that it considers the proposed ASC to be "the first ASC focused on the treatment of the obese patient population in North Carolina, South Carolina, and Virginia."[47] That may or may not be true; OMCC does not provide any information in its application to explain that assertion or by which that statement can be evaluated.

OMCC does not provide a list of the existing facilities in North Carolina, South Carolina, and Virginia that provide bariatric and general surgery to obese patients. Based on information available on ObesityHelp.com, there are 50 hospitals in North Carolina that provide bariatric surgery.[48]

OMCC fails to document that its proposed ASC is not duplicative of existing bariatric surgery programs in State.

E. The Proposed ASC will have a Negative Impact on WakeMed Cary and Duke Raleigh Hospital

On pages 93-94, OMCC states its belief that the proposed ASC will not have a negative impact on existing providers. An evaluation of the veracity and reasonableness of that statement is warranted.

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[44] http://www.dukehealth.org/services/weight_loss_surgery/about/program_of_excellence

[45] http://www.dukehealth.org/services/weight_loss_surgery/locations

[46] http://www.dukehealth.org/services/weight_loss_surgery/physicians

[47] CON Application J-8620-10, page 22.

[48] http://www.obesityhelp.com/morbidobesity/list-hospitals.php - please click on North Carolina to see information about 2 of 50 hospitals in North Carolina which include Duke University and The Presbyterian Hospital. The other 48 hospitals in North Carolina have yet to register with ObesityHelp.com.

The following table shows the historical and projected cases that physician owners and users of OMCC will shift to the proposed ASC.

Cases Shifted from WakeMed Cary and Duke Raleigh Hospital due to the Proposed ASC

Facility from which Cases Projected to Shift	FY 2010	PY 1: 4/13-3/14	PY 2: 4/14-3/15	PY 3: 4/15-3/16
WakeMed Cary				
Cases	229	345	388	436
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Weighted Cases	344	518	582	654
% of 1872 Hrs/Yr	18.3%	27.6%	31.1%	34.9%
Duke Raleigh Hospital				
Cases	53	80	90	100
Percent of Total Cases at Proposed ASC	5.1%	5.2%	5.2%	5.1%
Weighted Cases	80	120	135	150
% of 1872 Hrs/Yr	4.2%	6.4%	7.2%	8.0%
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Weighted Cases	423	638	717	804
% of 1872 Hrs/Yr	22.6%	34.1%	38.3%	42.9%

Source: CON Application

The previous table shows that in Project Year 3, OMCC projects that 536 cases will not be performed at WakeMed Cary and Duke Raleigh Hospital. Those 536 cases translate to 804 weighted cases, which support a need for 0.4 operating rooms at 1,872 hours per year in Project Year 3 of the operation of OMCC. This shift of outpatient surgical case volume to OMCC is not inconsequential to either facility (WakeMed Cary & Duke Raleigh Hospital), as discussed below.

1. Duke Raleigh Hospital Lost 17 Surgeons Associated with Raleigh Surgical Group and Wake Surgical Specialists Which Will Impact Future Surgical Volume

According to Rex's February 15, 2010 CON Applications (CON Project I.D. #s J-8468-10 and J-8469-10), on August 1, 2009, Raleigh Surgical Group and Wake Surgical Specialists joined Rex Healthcare, adding "17 world-class surgeons to Rex Healthcare's employed medical staff. The merged group is called Rex Surgical Specialists and is employed by Rex Physicians, LLC."[49]

According to Rex's February 15, 2010 CON Applications J-8468-10 and J-8469-10, "Wake Surgical Specialists performed 326 inpatient surgical cases and 1,696 outpatient surgical cases

[49] Rex Hospital CON Applications J-8468-10 and J-8469-10, pages 83 & 90-91

from April 2008 to March 2009 at Duke Raleigh Hospital (2,022 cases in total)."[50] Rex provided the following table to show Wake Surgical Specialists cases at DRH.

Wake Surgical Specialists Cases at Duke Raleigh Hospital
April 2007 – March 2009

Time Period	Cases
April 2007 to March 2008	1,397
April 2008- March 2009	2,022
Percent Growth	44.7%

Source: Rex Hospital CON Applications J-8468-10 and J-8469-10, pages 91-92, citing Thomson Reuters

Rex explained that "[t]he impetus behind some of this 44.7 percent growth in cases at Duke Raleigh was the addition of another Wake Surgical Specialists surgeon during this time frame. This group also added another surgeon just prior to joining Rex [...]."[51]

Rex quantified the surgical volume it expects will shift from Wake Surgical Specialists to Rex Hospital and Rex Holly Springs ASC in FY 2010 – FY 2015, as shown in the following table.

Projected Future Wake Surgical Specialists
Surgical Cases Shifted from Duke Raleigh Hospital to Rex Hospital
and Rex Holly Springs ASC

Federal Fiscal Year	Inpatient	Outpatient	Total
2010	326	1,696	2,022
2011	332	1,768	2,100
2012	332	1,843	2,181
2013	338	1,921	2,265
2014	344	2,002	2,352
2015	350	2,087	2,444
CAGR	1.8%	4.2%	3.9%

Source: CON Applications J-8468-10 and J-8469-10, pages 92-94

It is reasonable to assume that the Wake Surgical Specialists surgical volume shown in the previous table would have been performed at Duke Raleigh Hospital, had those surgeons not joined Rex. Those cases therefore represent significant lost surgical volume to Duke Raleigh Hospital.

The magnitude of the loss to Duke Raleigh Hospital of surgeons associated with Wake Surgical Specialists joining Rex as employed surgeons is significant both in terms of current volume on which to base projections, and the projections themselves. Consequently, it is reasonable to assume that Duke Raleigh Hospital:

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[50] Rex Hospital CON Applications J-8468-10 and J-8469-10, page 91

[51] Rex Hospital CON Applications J-8468-10 and J-8469-10, page 91, FN 18

- Surgical volume will decline by at least the number of cases performed annually by the surgeons associated with Wake Surgical Specialists.
- Annual surgical volume will be negatively affected until replacement surgeons are performing surgical cases at DRH.
- Has a lower surgical volume on which to base projections for its proposed inpatient surgery expansion, including the addition of two new operating rooms.
- Has a lower rate of growth for surgical cases, which reflects the extent of lower utilization.
- Projected FY 2010 through FY 2015 annual surgical volume must be adjusted downward to reflect a lower base volume and lower growth rate.

On August 16, 2010, Duke Raleigh Hospital submitted CON Application J-8567-10 in which it sought approval to transfer two single-specialty ambulatory operating rooms from National Women's Health Organization to DRH where they will become shared surgical operating rooms. The CON Section issued a decision on November 24, 2010 approving DRH's CON Application J-8567-10.

It is reasonable to assume that the addition of another two shared operating rooms will exacerbate Duke Raleigh Hospital's challenge to utilize fully its operating room inventory.

2. WakeMed Cary Operating Rooms are not Over-utilized and will be Impacted by a Loss of Surgical Volume to the Proposed ASC

On pages 80 and 83 of February 15, 2010 CON Application J-84 63-10, WakeMed Cary discussed capacity issues and patient satisfaction issues as reasons three additional operating rooms are needed at WakeMed Cary. WakeMed Cary misinterprets the *SMFP* definition of capacity and in fact the operating rooms at WakeMed Cary not operating at 99% of current operating room capacity. Based upon the information included on page 62 of the *SMFP*, capacity of an operating room equals the number of hours the operating room is staffed and available for surgical procedures which according to the *SMFP* is nine hours per day 260 days per year or 2,340 hours per operating room. For planning purposes, the *SMFP* utilizes an 80% planning threshold, or 1,872, to identify future need in a county.

Therefore, based upon the capacity definition in the *SMFP*, the utilization of WakeMed Cary's nine shared operating rooms is considerably less than 99% as shown in the following table.

WakeMed Cary 2009 Surgical Services Utilization

	2009
Operating Rooms	9
Capacity per rooms (Total available staffed hours)	2,340
Total Capacity	21,060
Inpatient Surgery (Less C-Section cases)	1,947
Outpatient Surgery	7,273
Weighted Surgical Hours (3.0 hrs per inpt and 1.5 hrs per outpt)	16,751
Current Surgical Services Utilization	79.5%

Source: SMFP; 2010 LRA

The nine operating rooms at WakeMed Cary are operated at 79.5% of capacity assuming a nine hour day as reflected in the previous table.

OMCC projects that WakeMed Cary will bear the brunt of the cases shifted to the proposed ASC, as shown in the following table.

Cases Shifted from WakeMed Cary and Duke Raleigh Hospital due to the Proposed ASC

Facility from which Cases Projected to Shift	FY 2010	PY 1: 4/13-3/14	PY 2: 4/14-3/15	PY 3: 4/15-3/16
WakeMed Cary				
Cases	229	345	388	436
Percent of Total Cases at Proposed ASC	22.2%	22.2%	22.2%	22.3%
Weighted Cases	344	518	582	654
% of 1872 Hrs/Yr	18.3%	27.6%	31.1%	34.9%
Duke Raleigh Hospital				
Cases	53	80	90	100
Percent of Total Cases at Proposed ASC	5.1%	5.2%	5.2%	5.1%
Weighted Cases	80	120	135	150
% of 1872 Hrs/Yr	4.2%	6.4%	7.2%	8.0%
Total				
Cases	282	425	478	536
Percent of Total Cases at Proposed ASC	27.4%	27.4%	27.4%	27.4%
Weighted Cases	423	638	717	804
% of 1872 Hrs/Yr	22.6%	34.1%	38.3%	42.9%

Source: CON Application

A loss of 436 cases is the equivalent of 35% of total annual hours of one operating room. One can reasonably assume that WakeMed Cary would be negatively impacted by that loss.

G.S. 131E-183 (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.

The OMCC facility will be developed in a medical office building by Capital Associates Management, Inc., and the building will be leased to Obesity Management Center of the Carolinas, LLC (OMCC, LLC). OMCC, LLC will upfit the leased space for the proposed ASC. Rex Hospital will manage the proposed ASC. [52]

As reflected in Exhibit 10 of the OMCC Application, the entire building is being built just for this project and it is reasonable to assume that it will not be constructed if the project is not approved. The developer of the building is constructing an ambulatory surgery center, not a medical office building. No physician offices are included in the drawings in Exhibit 10. Therefore, the developer should be identified as a co-applicant and construction cost for the building should be included in the total cost of the project.

For these reasons, the Application does not conform to Criterion (12).

G.S. 131E-183 (13)

The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and members of the 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 identified in the State Health Plan as deserving of priority.

As previously discussed and further reflected in the following comments on CON Criteria and Standards for Operating Room – 10A NCAC 14C .2100 OMCC understated the self-pay net revenue associated with the project and as a result overstated the commitment to the underinsured and uninsured.

For these reasons, the Application does not conform to Criterion (13).

IV. CON Criteria and Standards for Operating Room – 10A NCAC 14C .2100

The proposed project is non-conforming to the Criteria and Standards for Operating Rooms for the following reasons.

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[52] CON Application J-8620-10 at page 9.

10A NCAC 14C .2102(b)(2)

As discussed in the context of Section II.E. above, the February 15, 2010 CON Applications J-8469-10 to develop one additional operating room at Rex Hospital and J-8468-10 to develop a new multi-specialty ambulatory surgery center, Rex Healthcare of Holly Springs, are neither "concurrent" nor "complementary." Rex assumes that it "will eventually be awarded th[o]se three operating rooms." That is an assumption not supported by fact or law. Those two applications remain in litigation at the time these comments are filed.

At the time of the Application, there are multiple parties appealing the CON Section's decisions on the following five CON applications submitted on February 15, 2010 in response to the need determination identified in the *2010 State Medical Facilities Plan* (*2010 SMFP*) for three surgical operating rooms in Wake County:

- J-8463-10: WakeMed for Three Additional Shared Surgical Operating Rooms at WakeMed Cary Hospital
- J-8468-10: Rex Hospital, Inc. d/b/a Rex Healthcare for Two Outpatient Surgical Operating Rooms in a Hospital-Based Ambulatory Surgery Center at Rex Healthcare of Holly Springs
- J-8469-10: Rex Hospital, Inc. d/b/a Rex Healthcare for One Additional Shared Surgical Operating Room at Rex Hospital
- J-8467-10: Duke University Health System d/b/a Raleigh Hospital for Two Additional Shared Use Surgical Operating Rooms
- J-8471-10: Novant Health's Holly Springs Surgery Center for a Freestanding Ambulatory Surgery Center with Three Outpatient Surgical Operating Rooms

OMCC fails to disclose that the CON Section approved CON Application J-8471-10 Novant Health's Holly Springs Surgery Center for a Freestanding Ambulatory Surgery Center with Three Outpatient Surgical Operating Rooms. Unless and until the CON Section's decision has been overturned, the three operating rooms are not to be included in Novant Health's approved operating room inventory.

The following table shows the surgical operating room inventory of Rex and its "related entities" in Wake County in Project Year 3.

Facility	Proposed ASC	Rex Hospital	Rex Surgery Center of Cary	Rex Healthcare Wakefield	Macon Pond Road Outpatient Center	OSCR	Total
Number of Existing and Approved ORs	2	20	4	3	4	4	37

Source: CON Application

OMCC and Rex failed to identify the operating rooms at UNC Hospitals, Rex's parent organization located in Orange County, which is included in the SMFP defined Triangle Service Area for the proposed project.

10A NCAC 14C .2102(b)(4)(5)

In addition, as discussed above in the context of Criterion (3), surgical case volume projections set forth in the tables provided by OMCC for the proposed ASC, Rex Hospital, Rex Surgery Center of Cary, and Rex Healthcare of Wakefield are overstated and based on unreasonable assumptions. Projected growth rate of 9.4% annually in outpatient surgical cases at Rex surgical facilities is unreasonable and unsupported .

In addition, OMCC and Rex failed to project surgical case volume projections for UNC Hospitals, Rex's parent organization located in Orange County, which is included in the SMFP defined Triangle Service Area for the proposed project.

10A NCAC 14C .2102(d)(3)- (10)

OMCC failed to justify the provision of 7% charity and Medicaid reimbursement as required by these rules.

First, as previously discussed, OMCC states that its charity care policies will cover surgical needs for self-pay patients, or almost 25% of all bariatric surgical patients reflected in the Proforma Statements. In OMCC ProForma Form E for bariatric patients, OMCC projects total net revenue for self-pay patients of only $38,908 or an average of $248 per patient. One way to analyze the estimated net revenue for the proposed facility in Year 1 is to calculate the number of self-pay patients who will pay the projected average charge for self-pay bariatric patients of $12,392 by dividing total net revenue by the projected charge. In this analysis, only three self-pay patients[53], or **approximately 0.5% of total bariatric surgical patients pay the full self-pay charge and the remaining 154 patients will be charity care.**

However, according to the HealthGrades Fifth Annual Bariatric Surgery Trends in American Hospitals Study May 2010 (includes 19 all-payer states), of all patients, 6.57% of patients paid for their surgery out-of-pocket (self-pay) and did not utilize any type of insurance.[54]

Based upon the HealthGrades study, it is reasonable to assume that 6.57% of patients at the proposed OMCC would pay the self-pay average charge for the proposed bariatric surgery, resulting in total net revenue in Form E for self-pay bariatric cases of $520,464.[55] In turn, this increases the average reimbursement for self-pay patients and decreases the self-pay variance reflected on page 56 of the application. The net impact of a 6.57% self-pay percent of bariatric surgery patients that pay the self-pay charge is significant when estimating total self-pay/Medicaid and results in less than 2.0% of total collected revenue as shown in Attachment 1.

[53] Calculation: Total net revenue $38,908/Avg Charge $12,392 = 3 cases

[54] http://www.healthgrades.com/media/DMS/pdf/HealthGradesBariatricSurgeryTrendsStudy2010.pdf

[55] Calculation: 636 bariatric cases x 6.57% = 42 cases; 42 cases x $12,392 average self pay charge = $520,464

Furthermore, if only 3.0% of projected self-pay patients pay the self-pay average charge, less than half of the HealthGrades average, the proposed project would not meet the 7.0% requirement in the Criteria and Standards for demonstration project surgery centers as shown in the following table.

Impact of 3.0% Self-Pay Payments

	Adjusted Self-Pay Variance	Medicaid Variance	Total Variance	Adjusted Total Collected Revenue	Self-Pay/Medicaid Percentage
PY1	$ (387,013.88)	$ (12,597.69)	$ (399,611.57)	$ 6,088,061.36	6.56%
PY2	$ (449,620.92)	$ (14,486.16)	$ (464,107.08)	$ 7,114,636.60	6.52%
PY2	$ (526,256.09)	$ (17,264.84)	$ (543,520.93)	$ 8,313,965.27	6.54%

Source: Attachment 1, Tables 4, 5

In addition, as previously discussed it is questionable if OMCC can successfully generate sufficient self-pay patients that meet the charity care requirements of the OMCC Charity Care Policy in Exhibit 8 based upon a study[56] published in 2009 regarding the socioeconomics of the morbidly obese patient population and the impact on access to bariatric surgery using two nationally representative databases. The national bariatric eligible population was identified from the 2005-2006 National Health and Nutrition Examination Study, and compared with the adult non-eligible population. The eligible cohort was then compared with patients who had undergone bariatric surgery in the 2006 National Inpatient Sample, and the key socioeconomic disparities were identified and analyzed. More than one third (35%) of bariatric eligible patients were either uninsured or underinsured, and 15% had incomes less than the poverty level. A total of 87,749 in-patient bariatric surgical procedures were performed in 2006. Most were performed on white patients (75%) with greater than median incomes (80%) and private insurance (82%). **Less than 1% of bariatric surgical procedures were performed on un-insured patients. Significant disparities associated with a decreased likelihood of undergoing bariatric surgery were noted by race, income, insurance type, and gender. Researchers concluded that socioeconomic factors play a major role in determining who does and does not undergo bariatric surgery, despite medical eligibility.**[57]

OMCC assumes that 25% of total bariatric surgery cases will be "self-pay" or free care. However, without documentation and support from other providers to remove additional "barriers" to care, OMCC has not documented that it can achieve its projected free care objective.

Second, this rule requires the Applicant to calculate the difference between the Medicare allowable expenditure and the amount paid. There is no Medicare allowable expenditure for the outpatient bariatric procedures proposed by OMCC. Therefore, a strict interpretation of the rules results in failure to achieve the 7% self-pay/Medicaid requirement as illustrated in Attachment 4. The schedule included at Attachment 4 reflects the commitment that the Medicare allowable amount ($0.00) for self pay and Medicaid surgical cases minus all revenue collected from self-

[56] http://www.asmbs.org/Newsite07/resources/Featured_article_6_1.pdf
[57] Ibid.

pay and Medicaid surgical cases will be at only 1.2% percent of the total net revenue collected for all surgical cases performed in the proposed facility.

Finally, as previously discussed, a review of Proforma E for non-bariatric patients reflects an average reimbursement rate for Medicaid which is greater than the average reimbursement for Medicare in each of the first three project years as reflected in the following table.

Projected Average Reimbursement - Non-Bariatric Cases

Payer	Project Year 1	Project Year 2	Project Year 3
Medicare	$1,447	$1,505	$1,565
Medicaid	$2,015	$2,095	$2,179

Source: OMCC CON Application, Form E, Page 188

The list of top 20 procedures to be provided at the proposed facility reflected on page 53 of the OMCC CON Application includes 11 non-bariatric procedures. The following table provides a comparison of current actual Medicare and Medicaid reimbursement rates for these procedures.

Outpatient Medicare and Medicaid Reimbursement Rates - 2010

CPT	YEAR 2010	MEDICARE REIMBURSEMENT	MEDICAID REIMBURSEMENT
11770	PILONIDAL CYST REMOVAL	$ 823.73	$ 524.26
47562	CHOLECTECTOMY - LAPAROSCOPIC	$ 1,874.25	$ 1,644.39
47563	CHOLECTECTOMY - LAPAROSCOPIC	$ 1,874.25	$ 1,644.39
49320	EXPLORATORY LAPAROSCOPY - ABDOMEN	$ 1,263.86	$ 644.22
49505	INGUINAL HERNIA REPAIR	$ 1,109.88	$ 689.17
49560	VENTRAL HERNIA REPAIR	$ 1,109.88	$ 689.17
49585	UMBILICAL HERNIA REPAIR	$ 1,109.88	$ 689.17
49650	INGUINAL HERNIA REPAIR - LAPAROSCOPIC	$ 1,556.19	$ 823.27
49652	OTHER LAPAROSCOPIC HERNIA REPAIR	$ 2,919.34	$ 611.00
49653	OTHER LAPAROSCOPIC HERNIA REPAIR	$ 2,919.34	$ 763.44
49654	OTHER LAPAROSCOPIC HERNIA REPAIR	$ 2,919.34	$ 702.23

Source: CMS

As reflected in the previous table, Medicare reimbursement exceeds Medicaid reimbursement for every non-bariatric case reflected on page 53 of the OMCC CON Application. Therefore, the average reimbursement rates reflected in the previous table and on page 188 of the OMCC CON Application are incorrect. These incorrect rates also were used by OMCC in the calculation of total revenues collected for the proposed project and in the determination of projected 7% requirement for this rule. Therefore, the CON Agency cannot determine if the proposed project meets the regulatory requirements specific to 10 NCAC 14C .2102 (d)(3).

10A NCAC 14C .2103(b)(c)

As discussed above in the context of Criterion (3), surgical case volume projections for OMCC and its "related entities" as set forth in the table provided in response to this Rule are unreasonable, unsupported, and overstated. Volume in tables provided in response to this Rule are based on OMCC's assumption that February 15, 2010 CON Applications J-8468-10 and J-8469-10 will be approved on appeal. Instead, OMCC should have projected for the circumstances that existed at the time of the Application, and document inpatient and outpatient surgical case volume at Rex Hospital with twenty shared operating rooms and no cases shifting to Rex Holly Springs ASC.

In addition, as discussed above in the context of Criterion (3), surgical case volume projections set forth in the tables provided by OMCC for the proposed ASC, Rex Hospital, Rex Surgery Center of Cary, and Rex Healthcare of Wakefield are overstated and based on unreasonable assumptions.

Projected growth rate of 9.4% annually in outpatient surgical cases at Rex surgical facilities is unreasonable and unrealistic. Total outpatient surgical growth for Durham, Orange and Wake Counties Surgical providers was only 5.2% and in Wake County outpatient surgical growth was 7.1%.

Therefore, the 9.4% outpatient annual growth projected by OMCC for future utilization of all related entities is unreasonable and OMCC fails to show that all existing and approved operating rooms are needed as prescribed by this rule.

Furthermore, OMCC and Rex failed to project surgical case volume projections for UNC Hospitals, Rex's parent organization located in Orange County, which is included in the SMFP defined Triangle Service Area for the proposed project.

Therefore, the Agency cannot determine if all existing and proposed operating rooms are needed based upon the formula included in this regulation.

V. Conclusion

The CON Application submitted by OMCC fails to conform to key Criterion reflected in N.C.G.S. 131E-183. It fails to document the need for the proposed single specialty ambulatory surgery demonstration project in the Wake-Durham-Orange Service Area. When a CON application is not in conformity with CON Statutory Review Criterion (3), it is also found derivatively non-conforming with CON Statutory Review Criteria (1), (4), (5), (6).(12), and (13).

Furthermore the proposed project submitted by NSSC provides a better alternative to meet the demonstration project for the Triangle Area specified in the 2010 SMFP. Rex has yet to develop its Certificate of Need for operating rooms at Macon Pond Road approved in 2008 which was to include eight operating rooms which has now been decreased to four operating rooms. In addition, Rex and its partner Raleigh Orthopaedic Clinic have four new operating rooms which have been delayed, for which a cost overrun CON is recently approved, but under appeal and

finally, Rex Cary Surgery Center (J-7878-07), approved in November 2007 to convert a hospital-based facility to a freestanding ambulatory surgery center. As illustrated in progress reports included in Attachment 3, these projects have yet to be implemented Rex appears to have a pattern changing the scope and revising the timelines for the implementation of approved operating room projects in the Triangle Area. Adding a new provider to the market may be a better alternative.

Attachment 1

Table 1. **CON Application Pages 59, 186, 188**

Bariatric Only	Medicare Allowable Self Pay	Net Revenue Form E	Self Pay Variance
PY1	$ 500,888.09	$ 38,908.00	$ (461,980.09)
PY2	$ 583,964.48	$ 45,468.00	$ (538,496.48)
PY2	$ 683,238.60	$ 53,134.00	$ (630,104.60)
Non Bariatric	**Medicare Allowable Self Pay**	**Net Revenue Form E**	**Self Pay Variance**
PY1	$ 137,462.15	$ 14,897.00	$ (122,565.15)
PY2	$ 159,513.04	$ 17,409.00	$ (142,104.04)
PY2	$ 186,239.76	$ 20,344.00	$ (165,895.76)
Combined			**Self Pay Variance**
PY1			$ (584,545.24)
PY2			$ (680,600.52)
PY2			$ (796,000.36)

Table 2. **CON Application Pages 59, 188 - Adjustment to Net Revenue on page 186 Assuming 6.57% of self-pay patients pay avg charges**

Bariatric Only	Medicare Allowable Self Pay	Net Revenue Form E	Self Pay Variance
PY1	$ 500,888.09	$ 517,802.20	$ 16,914.11
PY2	$ 583,964.48	$ 605,420.24	$ 21,455.76
PY2	$ 683,238.60	$ 707,103.41	$ 23,864.81
Non Bariatric	**Medicare Allowable Self Pay**	**Net Revenue Form E**	**Self Pay Variance**
PY1	$ 137,462.15	$ 14,897.00	$ (122,565.15)
PY2	$ 159,513.04	$ 17,409.00	$ (142,104.04)
PY2	$ 186,239.76	$ 20,344.00	$ (165,895.76)
Combined			**Self Pay Variance**
PY1			$ (105,651.04)
PY2			$ (120,648.28)
PY2			$ (142,030.95)

Table 3. **CON Application Page 56 reflecting adjusted self-pay variance with 6.57% of self-pay net revenue**

	Adjusted Self-Pay Varience	Medicaid Variance	Total Variance	Adjusted Total Collected Revenue	Self-Pay/Medicaid Percentage
PY1	$ (105,651.04)	$ (12,597.69)	$ (118,248.73)	$ 6,369,424.20	1.86%
PY2	$ (120,648.28)	$ (14,486.16)	$ (135,134.44)	$ 7,443,609.24	1.82%
PY2	$ (142,030.95)	$ (17,264.84)	$ (159,295.79)	$ 8,698,190.41	1.83%

Attachment 1

Table 4. **CON Application Pages 59, 186, 188**

Bariatric Only	Medicare Allowable Self Pay	Net Revenue Form E	Self Pay Variance
PY1	$ 500,888.09	$ 38,908.00	$ (461,980.09)
PY2	$ 583,964.48	$ 45,468.00	$ (538,496.48)
PY2	$ 683,238.60	$ 53,134.00	$ (630,104.60)
Non Bariatric	**Medicare Allowable Self Pay**	**Net Revenue Form E**	**Self Pay Variance**
PY1	$ 137,462.15	$ 14,897.00	$ (122,565.15)
PY2	$ 159,513.04	$ 17,409.00	$ (142,104.04)
PY2	$ 186,239.76	$ 20,344.00	$ (165,895.76)
Combined			**Self Pay Variance**
PY1			$ (584,545.24)
PY2			$ (680,600.52)
PY2			$ (796,000.36)

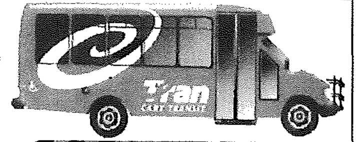
Table 5. **CON Application Pages 59, 188 - Adjustment to Net Revenue on page 186 Assuming 3.0% of self-pay patients pay avg charges**

Bariatric Only	Medicare Allowable Self Pay	Net Revenue Form E	Self Pay Variance
PY1	$ 500,888.09	$ 236,439.36	$ (264,448.73)
PY2	$ 583,964.48	$ 276,447.60	$ (307,516.88)
PY2	$ 683,238.60	$ 322,878.27	$ (360,360.33)
Non Bariatric	**Medicare Allowable Self Pay**	**Net Revenue Form E**	**Self Pay Variance**
PY1	$ 137,462.15	$ 14,897.00	$ (122,565.15)
PY2	$ 159,513.04	$ 17,409.00	$ (142,104.04)
PY2	$ 186,239.76	$ 20,344.00	$ (165,895.76)
Combined			**Self Pay Variance**
PY1			$ (387,013.88)
PY2			$ (449,620.92)
PY2			$ (526,256.09)

Table 6. **CON Application Page 56 reflecting adjusted self-pay variance with 6.57% of self-pay net revenue**

	Adjusted Self-Pay Varience	Medicaid Variance	Total Variance	Adjusted Total Collected Revenue	Self-Pay/Medicaid Percentage
PY1	$ (387,013.88)	$ (12,597.69)	$ (399,611.57)	$ 6,088,061.36	6.56%
PY2	$ (449,620.92)	$ (14,486.16)	$ (464,107.08)	$ 7,114,636.60	6.52%
PY2	$ (526,256.09)	$ (17,264.84)	$ (543,520.93)	$ 8,313,965.27	6.54%

C-Tran CARY TRANSIT



For more information:

(919) 485-RIDE/7433

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MORRISVILLE

CARY

RALEIGH

APEX

To RTP

To Apex

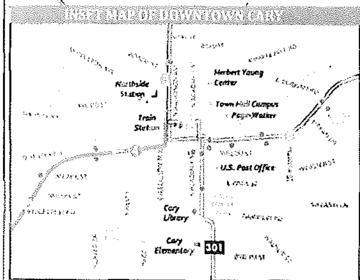
To Cary Train Station

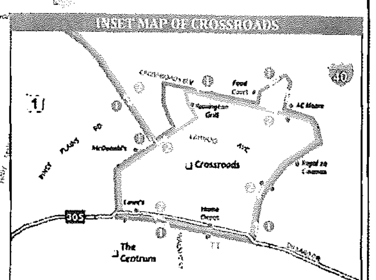
To NC State And Downtown Raleigh

To NC State University

See Inset Map "DOWNTOWN CARY"

See Inset Map "CROSSROADS"





C-TRAN ROUTES

- Route 1 (Maynard Loop)
- Route 2 (Maynard Loop)
- Route 3 (Harrison Ave)
- Route 4 (High House Rd to Hwy 55)
- Route 5 (Kildaire Farm Rd to Crescent Commons)
- Route 6 (E. Chatham St/Cary Towne Mall/ Buck Jones Rd/Raleigh connection)

TRIANGLE TRANSIT ROUTES

- 301 Regional Peak Bus Routes (301, 305, 311)
- 303 Regional Midday Bus Route

CAPITAL AREA TRANSIT ROUTE

- 11c Capital Area Transit Bus Route 11c

TRANSFER POINTS

- cat Transfer Point to Capital Area Transit
- Transfer Point between C-Tran Bus Routes
- Transfer Point Between Triangle Transit and C-Tran Bus Routes

LEGEND

- C-Tran Bus Stop
- Shopping Center
- School
- Wake Medical Center
- Point of Interest
- U.S. Postal Office
- Public Library
- Park and Ride
- Lake
- Park
- Cary Town Limits
- Other Town Limits
- Apartments

Plotted: April 2010

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TOWN of CARY

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SYSTEM MAP

Downtown Durham

VA Hospital
Duke Hospital
Duke Univ
American Tobacco Park-and-Ride
NCCU
Durham Tech
Briggs Ave
Alston Ave
Fayetteville St
Westgate Dr at Target
Old Chapel Hill Rd
New Hope Commons
Woodcroft
Southpoint Mall Park-and-Ride

Hillsborough

Maxway Shopping Ctr
Triangle SportsPlex
Durham Tech CCC Park-and-Ride
Eubanks Rd Park-and-Ride (Rte. CRX)
Homestead Rd Senior Ctr

Chapel Hill

UNC Hospitals

Not to Scale

RTP

RTP employers served by shuttles 42, 46, 47, and 49
Cornwallis Davis Dr
Miami Blvd
Emperor Blvd
Slater Rd
Chapel Hill Rd
Morrisville Outlet Mall
Airport Blvd
Aviation Pkwy
Terminal 2
Terminal 1
RDU Airport
Glenwood Ave

Shelley Lake Park-and-Ride
Millbrook Rd
Pleasant Valley at Gold's Gym
Lynn Rd
North Hills Dr
Exchange Park at Spring Forest Rd Park-and-Ride
Old Neuse Rd
Triangle Town Center Park-and-Ride
Capital Blvd
Millbrook Rd at Target

Wake Forest

White St at Elm Ave Park-and-Ride
Capital Blvd

Raleigh

Blue Ridge Rd
Faircloth St
District Dr Park-and-Ride
Wade Ave
Meredith
Hillsborough St
NCSU
New Bern Ave
Wake Med
Western Blvd
Shaw Univ
Buck Jones Rd
Duke Medical Plaza Park-and-Ride

Knightdale

Village Park Dr. at Rex

Zebulon

Gannon Ave at NC-97 Park-and-Ride

Wendell

4th Ave at Oakwood Ave Park-and-Ride

Garner

Tryon Rd
Forest Hills Shopping Ctr Park-and-Ride
Jones Sausage Rd
White Oak Shopping Ctr

Cary

Harrison Ave
Chatham St
Hillsborough St
Maynard Rd
Kildaire Farm
Big Lots Park-and-Ride
Walnut St
Jones Franklin Rd
Waverly Place Park-and-Ride
Lake Pine Plaza Park-and-Ride
Edinburgh South
High House Rd

Apex

W Williams
Galaxy Food Park-and-Ride

100 (All day)
Raleigh • RDU • RTC

102

201
North Raleigh • RTC

303 305 311
RTC • Apex • Cary • Raleigh

400 (All day)
Durham • Chapel Hill

420
Hillsborough • Chapel Hill
Operated by Orange Public Transportation and Chapel Hill Transit

700 (All day)
Durham • RTC

800 (All day)
Chapel Hill • RTC

CRX
Chapel Hill • Raleigh

DRX

Operated by CAT

WRX
Wake Forest • Raleigh
Operated by CAT

ZWX
Zebulon • Wendell • Raleigh
Operated by CAT

Legend

- Points of Interest
- Transit Center
- Park and Ride Lot
- Bus Route
- Express Route (Limited Stops)

transit

301 • 305 • 311 • 303 Mid-day

RTP • Downtown Raleigh • Cary • Apex

Major stops

Other stops

Transit Center

Park-and-Ride Lot

Plan your trip at gotriangle.org or call 485-RIDE (7433) for assistance. Se habla español.

Attachment 3

CON Application/ Project ID	Applicant(s)	Date of Application	Project Summary	Status	Projected Operational Date
J-7878-07	Rex Hospital, Rex Surgery Center of Cary, LLC, and Rex Cary MOB, LLC	6/14/2007	Reorganize a hospital-based outpatient surgery center with three operating rooms into a separately licensed freestanding ambulatory surgery center	Application approved 11/9/2007; Request for Declaratory Ruling filed 11/22/2010 seeking approval for an intra-corporate restructuring such that Rex Hospital will transfer its CON rights in the four approved operating rooms to its subsidiary Rex Surgery Center of Cary, LLC rather than pursuant to a long-term lease from Rex Hospital	ASC has been operational since 2003; has not converted to freestanding as of 12/31/10
J-8008-07	Rex Hospital	11/17/2007	Rex Healthcare of Panther Creek - Develop hsopital-based outpatient center in Cary with urgent care, x-ray, mammo, lab, ultrasound, bone density	Application denied 4/28/08; Appeal pending	
J-8053-08	Rex Hospital	2/15/2008	Rex Macon Pond Road Outpatient Center - construct a new building adjacent to Rex Hospital campus to house existing hospital-based services to include 8 ambulatory surgery operating rooms, urgent care, diagnostic imaging, lab, outpatient rehabilitation, and pain management	Application approved 7/28/2008; Material Compliance Determination issued on 3/22/10 approving relocation of 4 of 8 operating rooms	1/1/2013
J-8170-08	Orthopaedic Surgery Center of Raleigh, LLC	8/15/2008	Construct a freestanding orthopaedic ambulatory surgery center with four operating rooms	Application approved 1/28/2009; Appeal complete	1/1/2011
J-8263-08	Rex Hospital	11/17/2008	Rex Healthcare of Panther Creek - Develop hsopital-based outpatient center in Cary with urgent care, x-ray, mammo, lab, ultrasound, bone density	Application denied 4/29/2009	
J-8469-10	Rex Hospital	2/15/2010	Develop additional shared operating room at Rex Hospital	Application denied 7/28/10; Appeal pending	1/1/2012
J-8468-10	Rex Hospital	2/15/2010	Rex Healthcare of Holly Springs - Develop two outpatient operating rooms	Application denied 7/28/10; Appeal pending	1/1/2013
J-8496-10	Orthopaedic Surgery Center of Raleigh, LLC	4/14/2010	Change of Scope and Cost-overrun of Project ID #J-8170-08; Change the ownership of the land and to add two minor procedure rooms	Application approved 9/27/10; Appeal pending	8/1/2011

CERTIFICATE OF NEED
PROGRESS REPORT FORM

County: Wake County
Facility: Rex Healthcare
Project I.D. #: J-7878-07
Date of Progress Report: December 1, 2010
Facility I.D. #: 953429
Effective Date of Certificate: November 28, 2007
Project Description: Reorganize an existing hospital-based ambulatory surgery center into a separately licensed, freestanding ASC.

Received by the CON Section
21 DEC 2010 10:14

A. Status of the Project

(a) Describe in detail the current status of the project. If the project is not going to be developed exactly as proposed in the certificate of need application, describe all differences between the project as proposed in the application and the project as currently proposed. Such changes include, but are not limited to, changes in the: 1) design of the facility; 2) number or type of beds to be developed; 3) medical equipment to be acquired; 4) proposed charges; and 5) capital cost of the project. (See the Capital Cost Section of this form for additional questions regarding changes in the total capital cost of the project.)

The project is being developed as it was originally proposed. Rex is in the process of converting the facility into a freestanding ambulatory surgery center. Rex anticipates the conversion will occur in the next 30 days.

(b) Pursuant to G.S. 131E-181(d), the CON Section cannot determine that a project is complete **until** *"the health service or the health service facility for which the certificate of need was issued is licensed and certified and in material compliance with the representations made in the certificate of need application."* To document that new or replacement facilities, new or additional beds, new or replacement equipment or new services have been licensed and certified, provide copies of correspondence from the appropriate section within the Division of Health Service Regulation and the Centers for Medicare and Medicaid Services (CMS).

B. Timetable

1. Complete the following table. The first column **must** include the timetable dates found on the certificate of need. If the CON Section has authorized an extension of the timetable in writing, you may substitute the dates from that letter.

PROJECT MILESTONES	Projected Completion Date from certificate Month/day/year	Actual completion date Month/day/year	Proposed completion date Month/day/year
Obtained Funds for the Project			
Final Drawings and Specifications Sent to DHSR			
Acquisition of land/facility			
Construction Contract Executed			
25% completion of construction			
50% completion of construction			
75% completion of construction			
Completion of construction			
Ordering of medical equipment			
Operation of medical equipment			
Occupancy/offering of services	**January 1, 2009**		**January 1, 2011**
Licensure	**December 30, 2008**		**December 30, 2010**
Certification	**December 30, 2008**		**December 30, 2010**

2. If the project is experiencing significant delays in development:
   a. explain the reasons for the delay; and
   b. provide a revised timetable for the CON Section to consider.

A revised timetable has been provided.

C. Medical Equipment Projects – If the project involves the acquisition of any of the following equipment: 1) major medical equipment as defined in NCGS §131E-176(14f); 2) the specific equipment listed in NCGS §131-176(16); 3) equipment that creates an oncology treatment center as defined in NCGS §131-176(18a); or 4) equipment that creates a diagnostic center as defined in NCGS §131E-176(7a), provide the following information for each piece or unit of equipment: 1) manufacturer; 2) model; 3) serial number; and 4) date acquired.

D. Capital Expenditure

1. Complete the following table.
   a. Include all capital costs that have been paid to date as well as those that the applicant(s) are legally obligated to pay.
   b. If you have not already done so, provide copies of the executed construction contracts, including the one for architect and engineering services, and all final purchase orders for medical equipment costing more than $10,000/unit.
   c. If the project involves renovation or construction, provide copies of the Contractors Application for Payment [AIA G702] with Schedule of Values [AIA G703].

	Capital Expense Since Last Report	Total Cumulative Capital Expenditure
Site Costs		
Purchase price of land		
Closing costs		
Legal Fees		
Site preparation costs		
Landscaping		
Other site costs (identify)		
Subtotal Site Costs		
Construction Costs		
Construction Contract		
Miscellaneous Costs		
Moveable Equipment		
Fixed Equipment		
Furniture		
Consultant Fee		
Financing Costs		
Interest during Construction		
Other Misc. Costs (identify)		
Subtotal Misc. Costs		
Total Capital Cost of the Project		

2. What do you project to be the remaining capital expenditure required to complete the project? $0

3. Will the total actual capital cost of the project exceed 115% of the approved capital expenditure on the certificate of need? If yes, explain the reasons for the difference.

   This project is not expected to exceed 115% of the approved capital expenditure on the certificate of need.

E. **CERTIFICATION** – The undersigned hereby certifies that the responses to the questions in this progress report and the attached documents are correct to the best of his or her knowledge and belief.

Signature of Officer: [signature]
Name and Title of Responsible Officer: Bernadette Spong, CEO
Telephone Number of Responsible Officer: (919) 784-3245

Effective date: 4/24/09

CERTIFICATE OF NEED
PROGRESS REPORT FORM

County: Wake County
Facility: Rex Healthcare
Project I.D. #: J-8007-07
Project Description: Rex Healthcare of Holly Springs

Date of Progress Report: December 1, 2010
Facility I.D. #: 953429
Effective Date of Certificate: August 28, 2008

Received by the CON Section
01 DEC 2010

A. Status of the Project

(a) Describe in **detail** the current status of the project. If the project is not going to be developed exactly as proposed in the certificate of need application, describe all differences between the project as proposed in the application and the project as currently proposed. Such changes include, but are not limited to, changes in the: 1) design of the facility; 2) number or type of beds to be developed; 3) medical equipment to be acquired; 4) proposed charges; and 5) capital cost of the project. (See the Capital Cost Section of this form for additional questions regarding changes in the total capital cost of the project).

A developer for the site has been chosen and the project is moving forward as planned.

(b) Pursuant to G.S. 131E-181(d), the CON Section cannot determine that a project is complete **until** *"the health service or the health service facility for which the certificate of need was issued is licensed and certified and in material compliance with the representations made in the certificate of need application."* To document that new or replacement facilities, new or additional beds, new or replacement equipment or new services have been licensed and certified, provide copies of correspondence from the appropriate section within the Division of Health Service Regulation and the Centers for Medicare and Medicaid Services (CMS).

B. Timetable

1. Complete the following table. The first column **must** include the timetable dates found on the certificate of need. If the CON Section has authorized an extension of the timetable in writing, you may substitute the dates from that letter.

PROJECT MILESTONES	Projected Completion Date from certificate Month/day/year	Actual completion date Month/day/year	Proposed completion date Month/day/year
Obtained Funds for the Project			
Final Drawings and Specifications Sent to DHSR			
Acquisition of land/facility			
Construction Contract Executed	**3/15/2011**		
25% completion of construction	**5/1/2011**		
50% completion of construction	**7/1/2011**		
75% completion of construction	**1/1/2011**		
Completion of construction	**12/1/2011**		
Ordering of medical equipment	**3/1/2011**		
Operation of medical equipment	**12/1/2011**		
Occupancy/offering of services	**1/1/2012**		
Licensure			
Certification			

2. If the project is experiencing significant delays in development:
   a. explain the reasons for the delay; and
   b. provide a revised timetable for the CON Section to consider.

The project has been delayed in order to partner with a developer for the site. The revised time table is noted above.

C. Medical Equipment Projects – If the project involves the acquisition of any of the following equipment: 1) major medical equipment as defined in NCGS §131E-176(14f); 2) the specific equipment listed in NCGS §131-176(16); 3) equipment that creates an oncology treatment center as defined in NCGS §131-176(18a); or 4) equipment that creates a diagnostic center as defined in NCGS §131E-176(7a), provide the following information for each piece or unit of equipment: 1) manufacturer; 2) model; 3) serial number; and 4) date acquired.

D. Capital Expenditure

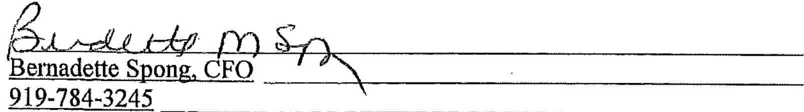
1. Complete the following table.
   a. Include all capital costs that have been paid to date as well as those that the applicant(s) are legally obligated to pay.
   b. If you have not already done so, provide copies of the executed construction contracts, including the one for architect and engineering services, and all final purchase orders for medical equipment costing more than $10,000/unit.
   c. If the project involves renovation or construction, provide copies of the Contractors Application for Payment [AIA G702] with Schedule of Values [AIA G703].

	Capital Expense Since Last Report	Total Cumulative Capital Expenditure
Site Costs		
Purchase price of land		874,447
Closing costs		
Legal Fees		45,534
Site preparation costs		
Landscaping		
Other site costs (identify)		
Subtotal Site Costs		**919,981**
Construction Costs		
Construction Contract		**24,299**
Miscellaneous Costs		
Moveable Equipment		
Fixed Equipment		
Furniture		
Consultant Fee		43,714
Financing Costs		
Interest during Construction		
Other Misc. Costs (identify)		
Subtotal Misc. Costs		**43,714**
Total Capital Cost of the Project		**987,994**

2. What do you project to be the remaining capital expenditure required to complete the project? **4,472,743**

3. Will the total actual capital cost of the project exceed 115% of the approved capital expenditure on the certificate of need? If yes, explain the reasons for the difference.

E. CERTIFICATION – The undersigned hereby certifies that the responses to the questions in this progress report and the attached documents are correct to the best of his or her knowledge and belief.

Signature of Officer: 
Name and Title of Responsible Officer: Bernadette Spong, CFO
Telephone Number of Responsible Officer: 919-784-3245

Effective date: 4/24/09

CERTIFICATE OF NEED
PROGRESS REPORT FORM

Received by the CON Section
01 DEC 2010 10 : 14

County:	Wake County	Date of Progress Report:	December 1, 2010
Facility:	Rex Hospital, Inc.	Facility I.D. #:	080094
Project I.D. #:	J-8053-08	Effective Date of Certificate:	August 28, 2008

Project Description: Rex Outpatient Care Center @ Macon Pond

A. Status of the Project

(a) Describe in **detail** the current status of the project. If the project is not going to be developed exactly as proposed in the certificate of need application, describe all differences between the project as proposed in the application and the project as currently proposed. Such changes include, but are not limited to, changes in the: 1) design of the facility; 2) number or type of beds to be developed; 3) medical equipment to be acquired; 4) proposed charges; and 5) capital cost of the project. (See the Capital Cost Section of this form for additional questions regarding changes in the total capital cost of the project).

The project has been delayed to evaluate the services to be offered at the Outpatient Care Center in relation to changes on the main campus as part of the new Facility Master Plan.

(b) Pursuant to G.S. 131E-181(d), the CON Section cannot determine that a project is complete **until** *"the health service or the health service facility for which the certificate of need was issued is licensed and certified and in material compliance with the representations made in the certificate of need application."* To document that new or replacement facilities, new or additional beds, new or replacement equipment or new services have been licensed and certified, provide copies of correspondence from the appropriate section within the Division of Health Service Regulation and the Centers for Medicare and Medicaid Services (CMS).

B. Timetable

1. Complete the following table. The first column **must** include the timetable dates found on the certificate of need. If the CON Section has authorized an extension of the timetable in writing, you may substitute the dates from that letter.

PROJECT MILESTONES	Projected Completion Date from certificate	Actual completion date	Proposed completion date
	Month/day/year	**Month/day/year**	**Month/day/year**
Obtained Funds for the Project			
Final Drawings and Specifications Sent to DHSR	**1/2/2009**		
Acquisition of land/facility			
Construction Contract Executed			
25% completion of construction	**2/5/2010**		
50% completion of construction	**8/2/2010**		
75% completion of construction	**12/30/2010**		
Completion of construction			
Ordering of medical equipment			
Operation of medical equipment			
Occupancy/offering of services	**7/1/2011**		
Licensure			
Certification			

2. If the project is experiencing significant delays in development:
   a. explain the reasons for the delay; and
   b. provide a revised timetable for the CON Section to consider.

As noted above, the delay is due to verification that the project supports planned changes to the Main Campus. The revised time table has not been established.

C. Medical Equipment Projects – If the project involves the acquisition of any of the following equipment: 1) major medical equipment as defined in NCGS §131E-176(14f); 2) the specific equipment listed in NCGS §131-176(16); 3) equipment that creates an oncology treatment center as defined in NCGS §131-176(18a); or 4) equipment that creates a diagnostic center as defined in NCGS §131E-176(7a), provide the following information for each piece or unit of equipment: 1) manufacturer; 2) model; 3) serial number; and 4) date acquired.

No medical equipment as defined above has been acquired as a part of this project.

D. Capital Expenditure

1. Complete the following table.
   a. Include all capital costs that have been paid to date as well as those that the applicant(s) are legally obligated to pay.
   b. If you have not already done so, provide copies of the executed construction contracts, including the one for architect and engineering services, and all final purchase orders for medical equipment costing more than $10,000/unit.
   c. If the project involves renovation or construction, provide copies of the Contractors Application for Payment [AIA G702] with Schedule of Values [AIA G703].

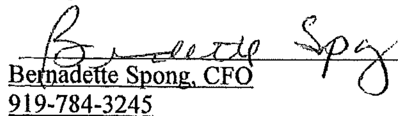
	Capital Expense Since Last Report	Total Cumulative Capital Expenditure
Site Costs		
Purchase price of land		
Closing costs		
Legal Fees		
Site preparation costs		1,000
Landscaping		
Other site costs (identify)		
Subtotal Site Costs		1,000
Construction Costs		
Construction Contract		
Miscellaneous Costs		
Moveable Equipment		
Fixed Equipment		
Furniture		
Consultant Fee		312,204
Financing Costs		
Interest during Construction		
Other Misc. Costs (identify)		
Subtotal Misc. Costs		**312,204**
Total Capital Cost of the Project		**312,204**

2. What do you project to be the remaining capital expenditure required to complete the project? **115,034,796**

3. Will the total actual capital cost of the project exceed 115% of the approved capital expenditure on the certificate of need? If yes, explain the reasons for the difference.

The costs are not expected to exceed 115% of the approved CON budget for this project.

E. **CERTIFICATION** – The undersigned hereby certifies that the responses to the questions in this progress report and the attached documents are correct to the best of his or her knowledge and belief.

Signature of Officer: 
Name and Title of Responsible Officer: Bernadette Spong, CFO
Telephone Number of Responsible Officer: 919-784-3245

Effective date: 4/24/09

CERTIFICATE OF NEED
PROGRESS REPORT FORM

County:	Wake County	Date of Progress Report:	December 1, 2010
Facility:	Orthopaedic Surgery Center of Raleigh	Facility I.D. #:	080609
Project I.D. #:	J-8170-08	Effective Date of Certificate:	October 5,2009

Project Description: Construct an Ambulatory Surgical Facility with [illegible] Surgical Operating Rooms in Wake County

Received by the CON Section
21 DEC 2010 10:8 14

A. Status of the Project

(a) Describe in **detail** the current status of the project. If the project is not going to be developed exactly as proposed in the certificate of need application, describe all differences between the project as proposed in the application and the project as currently proposed. Such changes include, but are not limited to, changes in the: 1) design of the facility; 2) number or type of beds to be developed; 3) medical equipment to be acquired; 4) proposed charges; and 5) capital cost of the project. (See the Capital Cost Section of this form for additional questions regarding changes in the total capital cost of the project).

This project is on hold pending the decision on the supplemental CON (#J-8496) filed April 15, 2010.

(b) Pursuant to G.S. 131E-181(d), the CON Section cannot determine that a project is complete **until** *"the health service or the health service facility for which the certificate of need was issued is licensed and certified and in material compliance with the representations made in the certificate of need application."* To document that new or replacement facilities, new or additional beds, new or replacement equipment or new services have been licensed and certified, provide copies of correspondence from the appropriate section within the Division of Health Service Regulation and the Centers for Medicare and Medicaid Services (CMS).

B. Timetable

1. Complete the following table. The first column **must** include the timetable dates found on the certificate of need. If the CON Section has authorized an extension of the timetable in writing, you may substitute the dates from that letter.

PROJECT MILESTONES	Projected Completion Date from certificate	Actual completion date	Proposed completion date
	Month/day/year	Month/day/year	Month/day/year
Obtained Funds for the Project			
Final Drawings and Specifications Sent to DHSR			
Acquisition of land/facility			
Construction Contract Executed			
25% completion of construction	8/30/2010		
50% completion of construction	12/15/2010		
75% completion of construction	5/15/2011		
Completion of construction			
Ordering of medical equipment			
Operation of medical equipment			
Occupancy/offering of services	8/1/2011		
Licensure			
Certification			

2. If the project is experiencing significant delays in development:
   a. explain the reasons for the delay; and
   b. provide a revised timetable for the CON Section to consider.

C. Medical Equipment Projects – If the project involves the acquisition of any of the following equipment: 1) major medical equipment as defined in NCGS §131E-176(14f); 2) the specific equipment listed in NCGS §131-176(16); 3) equipment that creates an oncology treatment center as defined in NCGS §131-176(18a); or 4) equipment that creates a diagnostic center as defined in NCGS §131E-176(7a), provide the following information for each piece or unit of equipment: 1) manufacturer; 2) model; 3) serial number; and 4) date acquired.

Not Applicable. The project does not involve medical equipment as defined in NCGS 131E-176 (14f), (16), (18a), or (7a).

D. Capital Expenditure

1. Complete the following table.
   a. Include all capital costs that have been paid to date as well as those that the applicant(s) are legally obligated to pay.
   b. If you have not already done so, provide copies of the executed construction contracts, including the one for architect and engineering services, and all final purchase orders for medical equipment costing more than $10,000/unit.
   c. If the project involves renovation or construction, provide copies of the Contractors Application for Payment [AIA G702] with Schedule of Values [AIA G703].

	Capital Expense Since Last Report	Total Cumulative Capital Expenditure
Site Costs		
Purchase price of land		
Closing costs		
Legal Fees		
Site preparation costs		
Landscaping		
Other site costs (identify)		
Subtotal Site Costs		
Construction Costs		
Construction Contract	1,100.00	1,100.00
Miscellaneous Costs		
Moveable Equipment		
Fixed Equipment		
Furniture		
Consultant Fee/Legal Fee	60,491.63	696,941.00
Financing Costs		
Interest during Construction		
Other Misc. Costs (identify)		
Subtotal Misc. Costs		**698,041.00**
Total Capital Cost of the Project		**698,041.00**

2. What do you project to be the remaining capital expenditure required to complete the project? **6,802,127**

3. Will the total actual capital cost of the project exceed 115% of the approved capital expenditure on the certificate of need? If yes, explain the reasons for the difference.

The costs are not expected to exceed 115% of the approved CON budget for this project.

E. CERTIFICATION – The undersigned hereby certifies that the responses to the questions in this progress report and the attached documents are correct to the best of his or her knowledge and belief.

Signature of Officer: Bernadette M Spong
Name and Title of Responsible Officer: Bernadette Spong, CFO
Telephone Number of Responsible Officer: 919-784-3245

Attachment 4

This schedule reflects the commitment that the Medicare allowable amount for self pay and Medicaid surgical cases minus all revenue collected from self-pay and Medicaid surgical cases shall be only 1.2% of the total net revenue collected for all surgical cases performed in the proposed facility

BARIATRIC CASES					
	Self Pay Cases	Medicare Medicare Reimbursement Per Case	Total Projected Medicare Reimbursement	Projected Payments Self Pay	Difference Between Projected Medicare & Self Pay Collected
Year 1	157	$0.00	$0	$38,908	($38,908)
Year 2	176	$0.00	$0	$45,468	($45,468)
Year 3	198	$0.00	$0	$53,134	($53,134)
	Medicaid Cases	Medicare Reimbursement Per Case	Total Medicare Reimbursement	Medicaid Reimbursement	Difference Between Projected Medicare & Medicaid Reimbursement
Year 1	0	$0.00	$0	$0	$0
Year 2	0	$0.00	$0	$0	$0
Year 3	0	$0.00	$0	$0	$0
Combined Bariatric Self Pay and Medicaid					
Year 1	Total Medicaid and Self Pay - Bariatric Cases				($38,908)
Year 2	Total Medicaid and Self Pay - Bariatric Cases				($45,468)
Year 3	Total Medicaid and Self Pay - Bariatric Cases				($53,134)

NON - BARIATRIC CASES					
	Self Pay Cases	Medicare Medicare Reimbursement Per Case	Total Projected Medicare Reimbursement	Projected Payments Self Pay	Difference Between Projected Medicare & Self Pay Collected
Year 1	95	$1,446.97	$137,462	$14,897	$122,565
Year 2	106	$1,504.84	$159,513	$17,409	$142,104
Year 3	119	$1,565.04	$186,240	$20,344	$165,896
	Medicaid Cases	Medicare Reimbursement Per Case	Total Medicare Reimbursement	Medicaid Reimbursement	Difference Between Projected Medicare & Medicaid Reimbursement
Year 1	23	$1,446.97	$33,280	$45,877	($12,597)
Year 2	26	$1,504.84	$39,126	$53,612	($14,486)
Year 3	29	$1,565.04	$45,386	$62,651	($17,265)
Combined Non-Bariatric Self Pay and Medicaid					
Year 1	Total Medicaid and Self Pay - Bariatric Cases				$109,968
Year 2	Total Medicaid and Self Pay - Bariatric Cases				$127,618
Year 3	Total Medicaid and Self Pay - Bariatric Cases				$148,631

Combined					
Year 1	Total Medicaid and Self Pay - Bariatric Cases & Non Bariatric				$71,060
Year 2	Total Medicaid and Self Pay - Bariatric Cases & Non Bariatric				$82,150
Year 3	Total Medicaid and Self Pay - Bariatric Cases & Non Bariatric				$95,497
Year 1	TOTAL NET REVENUE				$5,890,530
Year 2	TOTAL NET REVENUE				$6,883,657
Year 3	TOTAL NET REVENUE				$8,044,221
Year 1	**Surgery Component - Percentage >>>>>>>>>>>>>>>....**				**1.2%**
Year 2	**Surgery Component - Percentage >>>>>>>>>>>>>>>....**				**1.2%**
Year 3	**Surgery Component - Percentage >>>>>>>>>>>>>>>....**				**1.2%**

Fails the commitment that the Medicare allowable amount for self pay and Medicaid surgical cases minus all revenue collected from self-pay and Medicaid surgical cases shall be at least seven percent of the total net revenue collected for all surgical cases performed in the proposed facility. Medicare and Medicaid does not reimburse Bariatric cases.