



Surgical Care Affiliates



Via Hand Delivery and Electronic Mail (DHSR.CON.Comments@dhhs.nc.gov)

Ms. Lisa Pittman, Assistant Section Chief
Celia C. Inman, Project Analyst
Healthcare Planning and Certificate of Need Section
Division of Health Service Regulation
809 Ruggles Drive
Edgerton Building
Raleigh, NC 27603

Dear Ms. Pittman and Ms. Inman,

On behalf of Surgical Care Affiliates, LLC ("SCA"), please find enclosed comments prepared by SCA regarding the competing applications for operating rooms in Forsyth County to meet the need identified in the 2018 State Medical Facilities Plan. SCA's comments are submitted in accordance with N.C. Gen. Stat. § 131E-185(a1)(1). I trust that you will consider the comments presented herein during your review of all of the applications.

Thank you very much for your time and for your consideration of this information. Please do not hesitate to call me if you have any questions.

Sincerely,

Kelli Collins
Vice President of Operations
Surgical Care Affiliates

INTRODUCTORY COMMENTS

Surgical Care Affiliates (“SCA”) is an experienced provider of ambulatory surgical services and is one of the largest national providers of specialty surgical services. SCA operates over 210 ambulatory surgery centers (“ASCs”) and surgical hospitals in thirty-five states, and it performs one million procedures annually in partnership with more than 7,500 physician partners. The Clemmons Baptist-SCA ASC represents a joint venture between SCA and Wake Forest Baptist Health.

The following five Certificate of Need (“CON”) applications were submitted on May 15, 2018 in response to the need determination identified in the 2018 *State Medical Facilities Plan* (“2018 SMFP”) for four operating rooms (“ORs”) in the Forsyth Operating Room Service Area:

- **Project ID G-011513-18:** Triad Center for Surgery, LLC filed a CON application to develop a new ASC with 2 ORs and 3 procedure rooms in Forsyth County;
- **Project ID G-011516-18:** MC Kernersville, LLC and The Moses H. Cone Memorial Hospital filed a CON application to develop a new ASC (Triad Surgery Center) in Kernersville with 2 ORs, 1 GI endoscopy room, and 1 procedure room in Forsyth County;
- **Project ID G-011517-18:** Forsyth Memorial Hospital, Inc. and Novant Health, Inc. filed a CON application to add 2 ORs for a total of 35 ORs on the hospital license upon completion of this project in Forsyth County;
- **Project ID G-011518-18:** Novant Health Clemmons Outpatient Surgery, LLC and Novant Health, Inc. filed a CON application to add 2 ORs to the previously-approved ASC for a total of 4 ORs upon completion of this project and project ID G-11300-17 (relocate 2 ORs from Novant Health Winston Salem) in Forsyth County; and
- **Project ID G-011519-18:** North Carolina Baptist Hospital filed a CON application add 4 ORs for a total of 51 ORs upon completion of this project and project ID G-846010-17 (add 7 dedicated outpatient ORs pursuant to Policy AC-3) in Forsyth County.

In accordance with N.C. Gen. Stat. § 131E-185(a1)(1), SCA’s comments include discussion concerning whether, in light of the material contained in the respective applications and other factual material, the applications comply with the relevant review criteria, plans, and standards. These comments also address which of the competing proposals represents the most effective alternative for development of four new operating rooms in the Forsyth Operating Room Service Area. For ease of review, SCA has organized its comments by applicant.

For the reasons set forth herein, SCA opposes Project ID Nos. G-011513-18, G-011516-18, G-011517-18, and G-011518-18, and supports the approval of Project ID No. G-011519-18. SCA's specific comments are below.

**SCA'S COMMENTS REGARDING TRIAD CENTER FOR SURGERY CON APPLICATION
(PROJECT ID G-011513-18)**

I. Project Description

Triad Center for Surgery, LLC ("TCS") proposes to develop a new ambulatory surgery center ("ASC") with two operating rooms, and three procedure rooms in Forsyth County (the "Project"). TCS Application, pp. 5, 7. There are two parties who have an ownership interest in TCS: Orthopaedic Specialists Surgical Properties, LLC and Compass Surgical Partners Holdings of Triad, LLC. TCS Application, p. 5. Orthopaedic Specialists Surgical Properties, LLC is owned by OrthoCarolina and individual physicians. Compass Surgical Partners Holdings of Triad, LLC is wholly owned by Compass Surgical Partners, LLC. TCS Application, p. 5. The Project's total proposed capital expenditure is \$7,158,685.

II. CON Review Criteria

The TCS Application fails to conform to Review Criteria 3, 4, 5, 6, and 18a, and fails to comply with the administrative rules.

A. Criterion 3

(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.*

The TCS Application is nonconforming to Criterion 3 because TCS failed to demonstrate need. On page 26 of the TCS Application, TCS listed the following factors to demonstrate the need that the population has for its proposed ASC:

- The projected growth and aging of the population generating increased need for ambulatory surgery facilities;
- Increased demand for ambulatory surgeries due to advances in surgical technologies and anesthesia services;
- Lower reimbursement rates for ASCs as compared to hospital based facilities;
- The historical and projected growth of ambulatory surgery in Forsyth County and the projected utilization for the TCS ASC based on physician support letters; and
- The purported slowness of Novant Health and North Carolina Baptist Hospital in developing free-standing ASCs and the benefits associated with increased competition and additional choice of providers.

However, TCS failed in its application to provide reasonable or adequate support for the above assertions.

Additional ASCs in Forsyth County are Not Needed.

The TCS Application failed to demonstrate the need for a new ASC with additional ORs in Forsyth County since there is a recent saturation of ASCs in the Forsyth market that provides adequate incremental capacity for patients seeking outpatient surgical care in an ASC setting. Between February 2018 and July 2019, three ASCs have been developed and/or are opened and operational for patients seeking outpatient surgical care. See North Carolina Baptist Hospital (“NCBH”) Application, pp. 29-30.

In February 2018, Wake Forest Baptist Hospital Outpatient Surgery (“WFBOS”) opened a three-OR ASC in Clemmons, and in June 2018, Novant Health opened Novant Health Kernersville Outpatient Surgery (“NHKOS”), a two OR multispecialty ASC in Kernersville. NCBH Application, pp. 29-30. Both WFBOS and NHKOS are ASCs in Forsyth County. In addition, Novant Health received a CON to develop a second multi-specialty ASC in Forsyth County by relocating two ORs from the Novant Health Winston Salem campus and developing a new procedure room on the Novant Health Clemmons Medical Center campus (Project ID G-11300-17). Novant Health Clemmons Outpatient Surgery (“NHCOS”) Application, pp. 1, 2, 12. This Novant Health facility, NHCOS, is currently under construction in Forsyth County. NHCOS Application, p. 12. The addition of yet another ASC with two ORs in Forsyth County is unnecessary considering that WFBOS and NHKOS both recently opened, and that NHCOS is scheduled to open in July 2019 with two ORs, all of which will create additional incremental ASC capacity. Given that two new ASCs providing similar services just opened and another one is scheduled to open in July 2019, TCS has not adequately demonstrated the need for its proposed ASC.

Forsyth County OR Need was Driven by North Carolina Baptist Hospital: TCS has no Experience in the Service Area and Fails to Demonstrate how Increased Competition in the Forsyth County Service Area would Address this Need.

The TCS Application states that there is an unmet need in Forsyth County for non-hospital-managed ORs that are not associated with NCBH or Novant Health. TCS Application, p. 40. However, per Table 6B in the Forsyth County OR Service Area in the 2018 SMFP, the Novant Health system has a total projected surplus of 6.81 ORs while NCBH has a total projected deficit of 6.65 ORs. See 2018 SMFP, Table 6B, pp. 73-74. This indicates that the need for additional OR capacity in Forsyth County is attributable to patients choosing NCBH for surgical care. The need for additional ORs at NCBH is also demonstrated by the physician letters of support submitted for each project. TCS submitted approximately 28 physician letters of support with its Application. TCS Application, Exhibit C.4-3. By contrast, the NCBH Application contains 326 physician support letters. NCBH Application, Exhibit H.4.2.

TCS has no experience in the applicable service area and failed to demonstrate the need for additional service providers generally, or for its proposed ASC specifically. TCS relies on the 2018 SMFP OR methodology when it benefits them to demonstrate the need for at least two additional ORs, but ignores that the need for four ORs in the Forsyth OR Service Area in the 2018 SMFP was generated by patients choosing to have surgery at NCBH.

TCS' Need Methodology is Unreasonable and Unsupported.

The TCS Application's methodology used to project ambulatory surgical cases is unreasonable and not supported. TCS states that its volume projections "are based on OrthoCarolina physicians' historical data combined with projections for new participating surgeons." TCS Application, p. 16. In addition, TCS states that it projects patient origin for the project based on the historical origin of patients associated with the participating OrthoCarolina physicians. TCS Application, p. 25. However, TCS fails to document any historical volume to justify physician projections regarding referrals. Rather, its projected volume is based on unreasonable assumptions regarding referrals derived solely from physician support letters. In the absence of historical volume, there is nothing to document that the projected volume provided in the physician support letters is reasonable. In its methodology and assumptions, TCS seems to acknowledge the inherent unreliability of the projections in the support letters when it discounts the volumes projected by the physicians by as much as 70% in certain cases. TCS Application, p. 102. Further, there is nothing to document where the projected physician referrals would be shifting from, and whether or how much such a shift would duplicate volume projections of the approved Novant Health Forsyth and Wake Forest Baptist projects or adversely impact existing facilities. Finally, as TCS acknowledges in its own application, "there is a concern that some physicians could choose to withdraw their letters of support after the CON application is submitted. Absent these letters of support, the resulting lower utilization could drop below the threshold necessary to support the . . . ORs." TCS Application, p. 58. The projected utilization for the ORs and procedure rooms is unreliable as the physician support letters do not support the projected levels of utilization.

TCS' own projections in its Application are, at times, internally inconsistent. On page 39 of its Application, TCS projects that its year two and year three procedure room utilization will be 877 and 1,035 cases, respectively. However, on Page 48 of the Application, in response to the performance standards, TCS states that the year two and year three procedure room utilization will be 856 and 1,010 cases, respectively. The TCS Application should be found nonconforming with Criterion 3 and the rules located at 10A NCAC 14C.2103(a) and (b).

In addition to the TCS Application's projections regarding the initial volume or OR and procedure room cases, TCS relies on unreliable projections of the growth rate for surgical cases at the proposed facility. The 2018 SMFP calls for a growth factor of 4.02% from 2016 to 2020, which is calculated using the change in the general population in the operating room service area based on the figures available from the North Carolina Office of State Budget and Management ("NCOBM"). Note that the 4.02% growth factor applied by the SMFP is the cumulative growth

rate, not the CAGR. Using the Forsyth County population data provided by the NCOBM, the CAGR for Forsyth County's population between 2016 and 2020 is projected to be 0.99%. Although TCS is not required to use the 2018 SMFP growth factor to project need, the actual growth rate projected in the TCS Application is without merit and unreliable. TCS projects a 24.4% growth rate in total OR and procedure room volumes between year one and year two, and a 19.7% increase in those volumes between year two and year three. TCS Application, p. 36. This reflects a projected CAGR of 22.09%. This growth rate is unsupported other than the assumptions made in the physician support letters, which have no basis of support based on any historical data.

In addition to the foregoing, the assumptions and methodology that TCS sets forth on pages 101 through 105 of the Application are flawed for the reasons set forth below.

- *Step One: Physician Support Letters Related to TCS Volume Projections.* TCS Application p. 101.
 - There are discrepancies in the numbers of patients projected by the physicians in their letters of support and those that are projected by TCS in the table on page 101. These differences raise questions to the accuracy of the physician support letters.
 - TCS acknowledges that “there is a concern that some physicians could choose to withdraw their letters of support after the CON application is submitted. Absent these letters of support, the resulting lower utilization could drop below the threshold necessary to support the . . . ORs.” TCS Application, p. 58.

- *Step Two: Assumptions Regarding Volume Based on Physician Letters.* TCS Application p. 102.
 - TCS failed to provide any historical data related to referrals by the physicians who wrote letters of support, failed to document the locations of the practices who provided those letters, and relied on speculative utilization projections because the volume estimates provided in the letters of support are unreliable.

- *Step Three: Allocation of Volumes to ORs versus Procedure Rooms.* TCS Application p. 103.
 - TCS failed to provide any description or documentation of the “internal discussions and calls” that support its assertion that 90% of orthopaedic cases will be performed in an OR, including who was involved in those discussions and the names of the other ASCs consulted. TCS also failed to provide any support for the ratio of cases performed in ORs versus procedure rooms for ophthalmology cases. These unsupported assumptions are not reliable.

- *Steps Four and Five: Projecting Case Times per OR and Determining Need.* TCS Application pp. 104-105.
 - Because TCS' volume estimates are unreliable, the calculations related to average case time and need for additional ORs are likewise unreliable.

TCS Fails to Demonstrate how it will Meet the Unmet Need for ORs to Support a Broad Base of Surgical Specialties in Forsyth County.

The TCS Application fails to demonstrate how it will meet the unmet need for ORs to support a broad base of surgical specialties in Forsyth County. Of the 3,057 combined OR and procedure room cases that TCS projects in its first year, 2,702 (88%) are orthopaedic and ophthalmological cases, 9% are for neurosurgery, and the remaining cases are related to pain management (18 cases), oral and facial surgery (25 cases) and plastic surgery (12 cases). TCS Application, p. 36. TCS further fails to provide any support for its assumed percentages concerning cases that can be performed in ORs versus procedure rooms. See TCS Application, p. 103. For instance, the TCS Application provides an assumption that 60% of the projected ophthalmology cases would require an OR and 40% would be performed in a procedure room. TCS Application, p. 103. While TCS states that physicians prefer to use ORs for cataract cases and that procedure rooms can be safely used for YAG laser and other procedures, it implies without support that cataract cases will constitute 60% of the total ophthalmology cases referred to the proposed facility. TCS Application p. 103.

Moreover, the TCS Application fails to provide support for its contention that the need for ORs in Forsyth County could be adequately met by the provision of what amounts to a two-specialty ASC. While the TCS Application states “the population has a need for improved access to a broad range of surgical specialties[,]” the TCS Application projects 88% (2,702/3,057) of its cases in year one to be orthopaedic and ophthalmological cases, 89% (3,384/3,807) in year two, and 89% (4,065/4,557) in year three. See TCS Application, p. 102. Only the NCBH application addresses the need of the service area population for improved access to a broad range or surgical specialties.

TCS Fails to Provide Substantial Charity Care or Access to Services by Medicaid Patients.

The TCS Application fails to demonstrate that it will provide access to its proposed services to all area residents, including low income persons. According to TCS’ own projections, charity care will account for 0.76% of gross revenue for procedure room cases, and 0.78% of gross revenue for OR cases in each of project years one through three. TCS Application, pp. 112-113. By contrast, NCBH projects that deductions in gross revenue for charity care will account for 2.7% in fiscal year 2018, 2.9% in fiscal year 2019, and over 6% in each of fiscal years 2020-2027. NCBH Application, Section Q, p. 142. Similarly, TCS projects that Medicaid patients will account for 2.88% of total procedures and 3.82% of surgeries in project years one through three. TCS Application pp. 112-113. NCBH projects that Medicaid patients will account for 30.1% of cases in fiscal year 2019 and will remain over 20% through fiscal year 2027. NCBH Application, Section Q, p. 142. The TCS facility therefore fails to provide access to its proposed services to all area residents, including low income persons.

For all of the foregoing reasons, the TCS Application is nonconforming to Criterion 3 because TCS failed to demonstrate need.

B. Criterion 4

- (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.*

As described in Section II.A. of these comments, TCS does not demonstrate that projected surgical utilization at TCS is based on reasonable and supported assumptions. Furthermore, as discussed in Section II.A. of these comments, the opening of WFBMC (a three OR ASC), NHKOS (a two OR ASC) and NHCOS (a two OR ASC) between February 2018 and July 2019 provides adequate incremental ASC capacity in Forsyth County. NHCOS Application, p. 53; NCBH Application, pp. 29-30. Therefore, TCS' proposal to develop a new ASC in an already ASC-saturated market is not the most effective alternative. For these reasons, the TCS application is nonconforming to Criterion 4.

C. Criterion 5

- (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.*

The TCS Application's financial projections for the project reflect that TCS will not own the building or land on which the project will be situated, but rather will lease the building from MMAC HT I NC Portfolio LP through a sublandlord, OCRE HOLDINGS, LLC. TCS Application, p. 9. The owner of the building does not have joint or common ownership with TCS. TCS Application, p. 10. For this reason, TCS states in Form F.1a of the application that the building purchase price and purchase price of the land are zero dollars, and projects that the renovation costs for the leased space will be \$4,100,000. TCS Application, Form F.1a, p. 107. However, in its balance sheet for the facility TCS states that the leasehold improvement for the facility is an asset valued at \$4,829,880. TCS Application, Form F.2, p. 109. TCS provides no support for its projection that the value of the leasehold will exceed the renovation costs by \$729,000 in all three years of its financial projections ($\$4,829,880 - \$4,100,000 = \$729,000$).

Further, the TCS Application provides no explanation for why the leasehold improvement should be considered an asset on TCS' balance sheet in the first instance, since TCS does not own the building or the property and is not in joint or common ownership of these assets with the landlord or sublandlord. The Sublease Agreement between TCS and OCRE HOLDINGS, LLC provided with the TCS Application states that TCS must accept the premises in "as is" condition, and that any structural alterations to the premises are conditioned on the sublandlord's prior written consent, which may be granted, withheld, or conditioned in the sublandlord's sole discretion. The sublease further states that all alterations to the facility are to be made at TCS'

sole expense. TCS Application, Exhibit A9(b), pp. 25-26. From the terms of the lease, it is clear that TCS will incur the expenses of renovating the facility, which is borne out by TCS' capital cost projections in Form F.1a. There is nothing in the lease, however, supporting TCS' assertion that the leasehold improvement for the facility, which it arbitrarily values at \$4,829,880, should: 1) exceed in value the cost of the renovation itself; or 2) be considered an asset on TCS' balance sheet in the first place. TCS provides no further support for either of those assertions.

TCS also asserts that it will incur no expenses for non-medical equipment associated with the proposed facility. See TCS Application, Form F.1a p. 107. However, it is unreasonable to assume that TCS will not have expenditures related to non-medical equipment, including computers and information technology infrastructure and services, communications technology, and audio-visual equipment, among others.

As described above in Section II.B. of these comments, the financial projections in the TCS Application are based on unreasonable and overstated utilization projections. These utilization projections form the basis for TCS' projections of revenue and expenses, as set forth in Forms F.3, F.4, and F.5. Since TCS does not reasonably project utilization of its facility, it fails demonstrate the financial feasibility of the project.

For the reasons herein and for the same reasons that the TCS Application is nonconforming to Criterion 3, the TCS Application is non-conforming to Criterion 5.

D. Criterion 6

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

The TCS Application is nonconforming to Criterion 6 for the same reasons it is nonconforming with Criterion 3, and because it is an unnecessary duplication of existing or approved health service capabilities and facilities. As discussed in detail in Section II.A of these comments, there are three ASCs with a total of seven ORs in Forsyth County that either already have opened or will be open by July 2019. Furthermore, of the total existing and approved facilities in Forsyth County OR service area that provide the same services, one of those facilities is in Kernersville, NHKOS (2 ORs), and three of those facilities are located in the Clemmons area, NHCMC (5 ORs), NHCOS (2 ORs), and WFBOS (3 ORs), and each of which are approximately only 10 miles from Winston Salem where TCS proposes to develop its new ASC. NHCOS Application, p. 53; NCBH Application, pp. 29-30; TCS Application, p. 9. Given the 12 total existing and approved ORs in the Kernersville and Clemmons areas in Forsyth County, which are only ten miles from Winston Salem, TCS has not adequately demonstrated the need for the new ASC with two ORs that it proposes to develop, and as a result, has not demonstrated that its proposal will not unnecessarily duplicate the ORs in the Kernersville, Clemmons, and Forsyth County OR service

area. For the reasons herein and for the same reasons that the TCS Application is nonconforming to Criterion 3, the TCS Application is non-conforming to Criterion 6.

E. Criterion 18a

(18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

The TCS Application is nonconforming to Criterion 18a for the same reasons it is nonconforming with Criteria 3, 4, 5, and 6, and because it will not enhance competition so as to have a positive impact on the cost effectiveness, quality, and access to the services proposed. TCS did not adequately demonstrate the need that the population projected to be served has for the proposed project, and did not adequately demonstrate that its Project would not result in the unnecessary duplication of surgical services in the Kernersville, Clemmons, and Forsyth County areas. TCS further did not demonstrate the financial feasibility of its proposal. Therefore, TCS' Project will not have a positive impact on competition. For all these reasons, the TCS Application is nonconforming to Criterion 18a.

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

The TCS Application is nonconforming to 10A NCAC 14C.2103(a)(1) because the TCS surgical case projections are not based on reasonable and supported assumptions. For the same reasons that the TCS Application is nonconforming to Criterion 3, the TCS Application is also nonconforming with 10A NCAC 14C.2103(a)(1).

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

The TCS Application is nonconforming to 10A NCAC 14C.2103(b)(1) because the TCS surgical case projections are not based on reasonable and supported assumptions. For the same reasons that the TCS Application is nonconforming to Criterion 3, the TCS Application is also nonconforming with 10A NCAC 14C.2103(b)(1).

**SCA'S COMMENTS REGARDING TRIAD SURGERY CENTER CON APPLICATION
(PROJECT ID G-011516-18)**

I. Project Description

MC Kernersville, LLC and The Moses H. Cone Memorial Hospital (collectively, "Cone Health") propose to develop Triad Surgery Center, a new ambulatory surgery center ("ASC") to be located adjacent to Cone Health's existing MedCenter Kernersville campus with two operating rooms, one GI endoscopy room, and one procedure room in Forsyth County (the "Project"). Cone Health Application, pp. 8, 11, 13, 21. The proposed capital expenditure for the Project is \$12,713,263.

II. CON Review Criteria

The Cone Health Application fails to conform to Review Criteria 3, 4, 5, 6, and 18a, and fails to comply with the administrative rules.

A. Criterion 3

(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.*

The Cone Health Application is nonconforming to Criterion 3 because Cone Health failed to demonstrate need.

Cone Health's Need Methodology is Unreasonable and Unsupported.

Cone Health's methodology used to project ambulatory surgical cases is unreasonable and not supported. Cone Health states in its application that the need for the Project is based on the following factors: 1) demand for ambulatory surgery services; 2) need for additional freestanding ASC capacity in Forsyth County, particularly in Kernersville; and 3) need for a Cone Health ASC. Cone Health Application, p. 26. As is demonstrated below, Cone Health's need methodology and utilization projections are unreasonable and unsupported.

Additional ASCs in Forsyth County are Not Needed.

Contrary to Cone Health's assertions regarding factors one and two cited above, Cone Health failed to demonstrate the need for a new ASCs with additional ORs in Forsyth County because there is a recent saturation of ASCs in the Forsyth market that provides adequate

incremental capacity for patients seeking outpatient surgical care in an ASC setting. Between February 2018 and July 2019, three ASCs have been developed and/or are opened and operational for patients seeking outpatient surgical care. See North Carolina Baptist Hospital (“NCBH”) Application, pp. 29-30.

In February 2018, Wake Forest Baptist Hospital Outpatient Surgery (“WFBOS”) opened a three-OR ASC in Clemmons, and in June 2018, Novant Health opened Novant Health Kernersville Outpatient Surgery (“NHKOS”), a two OR multispecialty ASC in Kernersville (Project ID G-11150-16). NCBH Application, pp. 29-30. Both WFBOS and NHKOS are ASCs in Forsyth County. In addition, Novant Health received a CON to develop a second multi-specialty ASC in Forsyth County by relocating two ORs from the Novant Health Winston Salem campus and developing a new procedure room on the Novant Health Clemmons Medical Center campus (Project ID G-11300-17). See Novant Health Clemmons Outpatient Surgery (“NHCOS”) Application, pp. 1, 2, 12. This Novant Health facility, NHCOS, is currently under construction in Forsyth County. NHCOS Application, p. 12. The addition of yet another ASC with two ORs in Forsyth County is unnecessary considering that WFBOS and NHKOS both recently opened, and NHCOS is scheduled to open in July 2019 with two ORs, all of which will create additional incremental ASC capacity. Given that two new ASCs providing similar services in Forsyth County have just opened and another one is scheduled to open in July 2019, Cone Health has not adequately demonstrated the need it has to develop its new proposed ASC.

Additional ASCs in Kernersville are Not Needed.

Cone Health as not adequately demonstrated the need for a new ASC in Kernersville. Novant Health added two ORs to Novant Health Kernersville Outpatient Surgery (“NHKOS”) in June 2018 (Project ID G-11150-16), and patients in Kernersville can also readily access surgical facilities in Winston Salem and Clemmons as well as those available in Greensboro and Highpoint. In fact, within 18 miles of Kernersville there are eight surgical programs with six different owners, including both hospital-based ORs and freestanding ASCs. See NHCOS Application at p. 28. Consequently, residents of Kernersville have ample choice of providers. Indeed, Cone Health projects that 59.8% of its surgical referrals will be from practices located in Guilford County. See Cone Health Application, Form C, p. 3 (Of the 3,428 total referrals from the four primary care practices that Cone Health assumes will result in surgery, 2,050 are referrals from practices in High Point and Oak Ridge, respectively, which is 59.8% ($2,050/3,428 = 59.8\%$)). However, there are 96 ORs currently located in Guilford County, including 43 ambulatory ORs, and the 2018 SMFP projected no need for additional ORs in Guilford County. See 2018 SMFP, Table 6A, pp. 66, 74. Cone Health failed to provide reasonable support for its claim that additional ASC ORs are needed in Kernersville.

Forsyth County OR Need was Driven by North Carolina Baptist Hospital.

Cone Health's third factor in support of its proposed Project was an assertion that there is a need for a Cone Health ASC in Forsyth County. However, Cone Health failed to demonstrate the need for a Cone Health ASC in Forsyth County since the need for four ORs in the Forsyth OR Service Area in the 2018 SMFP was generated by patients choosing to have surgery at NCBH. Pursuant to Table 6B in the Forsyth County OR Service Area in the 2018 SMFP, the Novant Health system has a total projected surplus of 6.81 ORs while NCBH has a total projected deficit of 6.65 ORs. See 2018 SMFP, Table 6B, pp. 73-74. This data indicates that the need for additional OR capacity in Forsyth County is attributable to patients choosing NCBH for surgical care. The need for additional ORs at NCBH is also demonstrated by the physician letters of support submitted for each project. Cone Health submitted 47 physician letters of support with its Application. Cone Health Application, Exhibit C.4-3. By contrast, the NCBH Application contains 326 physician support letters. NCBH Application, Exhibit H.4.2.

Cone Health Failed to Respond to the Rules Located at 10A NCAC 14C.2103(b) and 10A NCAC 14C.3903(d)(1) and (d)(2).

Cone Health failed in its Application to respond to the rule located at 10A NCAC 14C.2103(b) related to the need for additional ORs in addition to the existing and approved ORs in Cone Health's health system. The rule located at 10A NCAC 14C.2103(b) states:

A proposal to increase the number of operating rooms (excluding dedicated C-section operating rooms) in a service area shall demonstrate the need for the number of proposed operating rooms **in addition to the existing and approved operating rooms in the applicant's health system** in the third operating year of the proposed project based on the Operating Room Need Methodology set forth in the 2018 State Medical Facilities Plan. The application is not required to use the population growth factor.

(Emphasis added). Cone Health should have responded to this rule because it is proposing to "increase the number of operating rooms (excluding dedicated C-section operating rooms) in a service area". As such, and as required by the rule, Cone Health needed to demonstrate "the need for the number of proposed operating rooms in addition to the existing and approved operating rooms in the applicant's health system...." It was incorrect for Cone Health to respond that this rule is "not applicable." Cone Health Application, p. 47. Accordingly, the Cone Health Application should be found nonconforming to the rule located at 10A NCAC 14C.2103(b) and to Criterion 3.

Likewise, Cone Health also failed to respond to the rule located at 10A NCAC 14C.3903(d)(1) and (d)(2), regarding the demonstration of need for GI endoscopy procedure rooms. Cone Health should have responded to this performance standard rule, because "service area" is defined more broadly than is stated in Cone Health's response. The GI endoscopy

procedure room rules define “service area” to mean “the geographical area, as defined by the applicant using county lines, from which the applicant projects to serve patients.” See 10A NCAC 14C.3901(6). Cone Health incorrectly responded to subparts (d)(1) and (d)(2) by stating each was “not applicable” because “Cone Health does not own operating rooms in the proposed service area of Forsyth County as defined in the Operating Room Need Methodology set forth in the 2018 SMFP.” Cone Application, pp. 49-50. The proposed “service area” as defined by 10A NCAC 14C.3901(6), however, includes Guilford County where Cone Health owns 54 operating rooms. Accordingly, Cone Health was required to demonstrate whether it would meet the criteria in subpart (d)(1) or (d)(2). Due to its failure to respond to this rule and demonstrate that it would meet either subpart (d)(1) or (d)(2), the Cone Health Application is nonconforming to the rule located at 10A NCAC 14C.3903(d)(1) and (d)(2) and to Criterion 3.

Cone Health’s Projection of Utilization is Unreliable.

Cone Health projected the utilization for its proposed facility by performing an internal analysis of the 2017 referral volumes of four primary care practices, two of which are located in Kernersville and two of which are located on High Point and Oak Ridge, respectively. See Cone Health Application, Form C, pp. 1-2. However, Cone Health failed to provide a copy of its internal analysis. Further, throughout Cone Health’s utilization projections, Cone Health assumes percentages to calculate the projected number of patients who would result in a surgical case at the proposed facility. Most, if not all of, these percentages used by Cone Health are “based on its experience and discussions with referring physicians and surgeons.” See Cone Health Application, Form C, pp. 2,3. Cone Health provides no other support for its percentages.

For instance, Cone Health provides no documented basis in Table 2 (located on Application, Form C, p. 3) for the estimated percentage of referrals from the identified primary care practices that would result in surgeries for each specialty. Further, Cone Health assumes, without providing adequate justification, that 70% of these referred patients would result in surgery at the proposed ASC. See Cone Health Application, p. 3. However, there are no projected volumes provided in the Letters of Support accompanying the Application for patients to be referred to the proposed facility for surgical services or GI endoscopy procedures.

Cone Health even resorts to using 100% assumptions to project utilization, which is unreasonably as referral patterns to one facility are unlikely to be 100%, even if the facilities are close and within the same health system:

- “... Cone Health assumes that 100 percent of the patients referred from those practices to orthopedists would result in a surgical case...” Cone Health Application, Form C, p. 3.
- “... Cone Health assumes that 100 percent of those surgical referrals from Cone Health Primary Care at MC Kernersville and Piedmont Triad Family Medicine will choose to have their surgery at the proposed ASC...” Cone Health Application, Form C, p. 4.

Cone Health failed to provide any documented basis for these estimated percentages of referrals, such as prior historical utilization patterns. The Cone Health Application provides no information concerning where these four practices have historically referred their surgical patients. There is nothing to justify the assumption that there will be a 100% shift in surgical referrals from Cone Health Primary Care at MC Kernersville and Piedmont Triad Family Medicine to the proposed facility. Yet, Cone Health is making such an assumption when it states that “100 percent of those surgical referrals from [those two facilities] will choose to have their surgery at the proposed ASC.” Cone Health Application, Form C, p. 4.

In addition, Cone Health’s projection of utilization is unreliable for the reasons set forth below:

- Cone Health did not address how its proposed facility would improve access to healthcare services for patients in the projected service area given that it anticipates that all cases will originate from the four primary care practices. Cone Health’s proposal is not improving access to surgical services and GI endoscopy procedures for patients outside of the Cone Health system.
- Cone Health uses the 3.5% compound annual growth rate (“CAGR”) for outpatient surgeries in Forsyth County to project utilization of its proposed facility through Fiscal Year 2023. See Cone Health Application, Form C, pp. 5-6. However, the CAGR for Forsyth County outpatient surgeries is not indicative of the growth of surgical referrals from the practices that Cone Health projects will refer surgical cases to the proposed facility, particularly given that two of them are located outside Forsyth County.
- Cone Health fails to provide any documentation supporting its reliance on projects by The Advisory Board with respect to the annual growth rate for outpatient surgeries in Forsyth County. See Cone Health Application, Form C, p. 6.
- Cone Health’s reliance on data from the Piedmont Outpatient Surgery Center (“POSC”) is not relevant because POSC is a single-specialty demonstration project. See Cone Health Application, Form C, p. 9.
- Cone Health provides no documentation or support for its assertion that 80% of the referrals to gastroenterologists would result in GI Endoscopy procedures, and that 90% of those endoscopy procedures would be ASC-appropriate. In addition, Cone Health assumes, without justification, that 100% of the GI endoscopy procedures performed at Cone Health Primary Care at MC Kernersville and at Piedmont Triad Family Medicine, and 60% of those referred by LeBauer High Point and LeBauer Oak Ridge will be performed at its proposed ASC. See Cone Health Application, Form C, p. 10. These assumptions are without support and Cone Health failed to demonstrate the reasonableness of the projections. As referenced above with surgical projections, a projection of 100% without supporting documentation (such as historical referral trends) is particularly unreasonable and unreliable.
- As with the surgical projections in the proposed ORs, the Cone Health Application fails to document where the GI endoscopy procedures have been historically performed. Consider the high projected percentages of these procedures projected to the referred to the proposed facility (100% and 60%, as noted above), the Cone Health

Application should have included the historical referral pattern to demonstrate the reasonable of the projected percentage shifts.

- Cone Health unreasonably projects that GI endoscopy utilization at the proposed facility will match the GI endoscopy utilization growth rate of all Forsyth County facilities. See Cone Health Application, Form C, p. 11. The Cone Health Application failed to show why these rates of growth would be identical. The proposed service area is from only a few zip codes of Forsyth County, not the entire County. Further, the projected referrals are from four primary care facilities, two of which are located in Guilford County. Accordingly, it is unreasonable to project GI endoscopy utilization at the proposed facility based upon historical GI endoscopy utilization growth rate of Forsyth County facilities.
- Cone Health asserts that, based on its discussions with the physicians who expect to practice at the proposed facility and documented in letters of support, that the referring physicians will perform 695 non-surgical procedures at the facility. See Cone Health Application, Form C, p. 12. However, the referenced letters of support provide no projected volumes, and Cone Health provides no basis of support for these projections. As result, the projected utilization of the procedure room is unreliable.

TCS Fails to Provide Substantial Charity Care or Access to Services by Medicaid Patients.

The Cone Health Application fails to demonstrate that it will provide access to its proposed services to all area residents, including low income persons. According to Cone Health's own projections, charity care will account for 0.25% of gross revenue in each of project years one through three. Cone Health Application, Form F.3. By contrast, NCBH projects that deductions in gross revenue for charity care will account for 2.7% in fiscal year 2018, 2.9% in fiscal year 2019, and over 6% in each of fiscal years 2020-2027. NCBH Application, Section Q, p. 142. Similarly, Cone Health projects that Medicaid patients will account for 0.95% of revenue in project years one through three. Cone Health Application Form F.3. NCBH projects that Medicaid patients will account for 30.1% of cases in fiscal year 2019 and will remain over 20% through fiscal year 2027. NCBH Application, Section Q, p. 142. Cone Health therefore fails to provide access to its proposed services to all area residents, including low income persons.

For all of the foregoing reasons, the Cone Health Application is nonconforming to Criterion 3.

B. Criterion 4

- (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.*

As described in Section II.A. of these comments, Cone Health does not demonstrate that projected surgical utilization at Triad Surgery Center is based on reasonable and supported assumptions. Furthermore, as discussed in Section II.A. of these comments, the opening of

WFBMC (a three OR ASC), NHKOS (a two OR ASC) and NHCOS (a two OR ASC) between February 2018 and July 2019 provides adequate incremental ASC capacity in Forsyth County. NHCOS Application, p. 53; NCBH Application, pp. 29-30. Therefore, Cone Health's proposal to develop a new ASC in an already ASC-saturated market is not the most effective alternative. For these reasons, the Cone Health application is nonconforming to Criterion 4.

C. Criterion 5

- (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 described above in Section II.B. of these comments, the financial projections in the Application are based on unreasonable and unreliable utilization projections. These utilization projections form the basis for Cone Health's projections of revenue and expenses, as set forth in Forms F.2, F.3, F.4, and F.5. Since Cone Health does not reasonably project utilization of its facility, it fails demonstrate the financial feasibility of the project. For the reasons herein and for the same reasons that the Cone Health Application is nonconforming to Criterion 3, Cone Health's Application is non-conforming to Criterion 5.

D. Criterion 6

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

The Cone Health Application is nonconforming to Criterion 6 for the same reasons it is nonconforming with Criterion 3, and because it is an unnecessary duplication of existing or approved health service capabilities and facilities. As discussed in detail in Section II.A of these comments, there are three ASCs with a total of seven ORs in Forsyth County that either already have opened or will be open by July 2019. Furthermore, of the total existing and approved facilities in Forsyth County OR service area that provide the same services, one of those facilities is already in Kernersville, NHKOS (2 ORs), where Triad Surgery Center is proposed to be located, and three of those facilities are located in the Clemmons area approximately 20 miles away from Kernersville: NHCMC (5 ORs), NHCOS (2 ORs), and WFBOS (3 ORs). NHCOS Application, p. 53; NCBH Application, pp. 29-30; Cone Health Application, p. 12. Given the two existing ORs in Kernersville, and twelve total existing and approved ORs in the Kernersville and Clemmons area in Forsyth County, Cone Health has not adequately demonstrated the need for the new ASC with two ORs it proposes to develop at Triad Surgery Center, and as a result, has not demonstrated that its proposal will not unnecessarily duplicate the ORs in the Kernersville, Clemmons, and Forsyth County OR service area. For the reasons herein and for the same reasons that the Cone

Health Application is nonconforming to Criterion 3, the Cone Health Application is nonconforming to Criterion 6.

E. Criterion 18a

(18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

The Cone Health Application is nonconforming to Criterion 18a for the same reasons it is nonconforming with Criteria 3, 4, 5, and 6, and because it will not enhance competition so as to have a positive impact on the cost effectiveness, quality, and access to the services proposed. Cone Health did not adequately demonstrate the need that the population projected to be served has for the proposed project, and did not adequately demonstrate that its Project would not result in the unnecessary duplication of surgical services in the Kernersville, Clemmons, and Forsyth County areas. Cone Health further did not demonstrate the financial feasibility of its proposal because it relies on inherently unreliable and unsupported utilization projections. Therefore, Cone Health's Project will not have a positive impact on competition.

F. Performance Standard 10A NCAC 14C.2103(a)

The Cone Health Application is nonconforming to 10A NCAC 14C.2103(a) because the Cone Health surgical case projections are not based on reasonable and supported assumptions. For the same reasons that the Cone Health Application is nonconforming to Criterion 3, the Cone Health Application is also nonconforming with 10A NCAC 14C.2103(a).

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

The Cone Health Application is nonconforming to 10A NCAC 14C.2103(b) because this rule is applicable to the Cone Health Project and the Cone Health Application failed to provide the information requested by this rule. Cone Health should have responded to this rule because it is proposing to "increase the number of operating rooms (excluding dedicated C-section operating rooms) in a service area". As such, and as required by the rule, Cone Health needed to demonstrate "the need for the number of proposed operating rooms in addition to the existing and approved operating rooms in the applicant's health system...." It was incorrect for Cone Health to respond that this rule is "not applicable." See Cone Health Application, p. 47. Accordingly, the Cone Health Application is nonconforming to the rule located at 10A NCAC 14C.2103(b).

H. Performance Standard 10A NCAC 14C.3903(d)(1) and (d)(2)

The Cone Health Application is nonconforming to 10A NCAC 14C.3903(d)(1) and (d)(2) because this rule is applicable to the Cone Health Project and the Cone Health Application failed to provide the information requested by this rule. Cone Health should have responded to this performance standard rule, because “service area” is defined more broadly than is stated in Cone Health’s response. The GI endoscopy procedure room rules define “service area” to mean “the geographical area, as defined by the applicant using county lines, from which the applicant projects to serve patients.” *See* 10A NCAC 14C.3901(6). Cone Health incorrectly responded to subparts (d)(1) and (d)(2) by stating each was “not applicable” because “Cone Health does not own operating rooms in the proposed service area of Forsyth County as defined in the Operating Room Need Methodology set forth in the 2018 SMFP.” Cone Application, pp. 49-50. The proposed “service area” as defined by 10A NCAC 14C.3901(6), however, includes Guilford County where Cone Health owns 54 operating rooms. Accordingly, Cone Health was required to demonstrate whether it would meet the criteria in subpart (d)(1) or (d)(2). Due to its failure to respond to this rule and demonstrate that it would meet either subpart (d)(1) or (d)(2), the Cone Health Application is nonconforming to the rule located at 10A NCAC 14C.3903(d)(1) and (d)(2).

**SCA'S COMMENTS REGARDING NOVANT HEALTH FORSYTH MEDICAL CON APPLICATION
(PROJECT ID G-011517-18)**

I. Project Description

Forsyth Memorial Hospital, Inc. d/b/a Novant Health Forsyth Medical Center (“NHFMC”) and Novant Health, Inc. (collectively, “Novant”) propose to add two new ORs to the first-floor operating suite at NHFMC Main Campus in Winston-Salem (the “Project”). NHFMC Application, p. 12.

Novant was originally approved in June 2017 to develop a freestanding ASC with two ORs in Clemmons, North Carolina, Novant Health Clemmons Outpatient Surgery (“NHCOS”), Project ID G-11300-17, which is scheduled to open in July 2019. Concurrent with the NHFMC CON Application, Novant filed a separate application seeking to add two additional ORs to NHCOS. NHFMC Application, p. 16-17. SCA’s comments regarding the NHCOS CON application (Project ID G-011518-18) will be addressed separately.

II. CON Review Criteria

The NHFMC Application fails to conform to Review Criteria 1, 3, 4, 5, 6, and 18a, and fails to comply with the applicable policies and administrative rules.

A. Policy GEN-4 and Criterion 1

- (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, ORs, or home health offices that may be approved.*

The NHFMC application is nonconforming to Criterion 1 and Policy GEN-4 since it is inconsistent with Policy GEN-4. Section B.2 of the Application requires the applicant to demonstrate conformity with the policies in Chapter 4 of the SMFP that are applicable to the OR review. On page 7 of the NHFMC application, Novant confirms that Policy GEN-4 applies to its Project. The first portion of Policy GEN-4, for projects such as Novant’s Project that exceed \$2 million, requires applicants to include a written statement describing “the project’s plan to assure improved (a) [e]nergy efficiency, and (b) [w]ater conservation.” While Novant asserts in response to Question B.4 that it includes the requisite written statement describing such plan based on Novant Health’s 2018 Sustainable Energy Management Plan (“SEMP”), it merely notes that its written statement “is articulated in the broader framework of the 2018 SEMP” and directs the reader to a copy of the SEMP at Exhibit B-4. NHFMC Application, pp. 10-11. A review of the SEMP evidences information about Novant’s goals for energy consumption across the entire Novant

Health system, but nothing that relates to an actual plan for energy efficiency and water conservation for the NHFMC Project. Since the NHFMC application provides no plan for the proposed Project related to energy efficiency and water conservation, as required, the NHFMC application is not in compliance with Policy GEN-4, and for the same reasons is also non-conforming with Criterion 1.

B. Criterion 3

- (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.*

The NHFMC application is nonconforming to Criterion 3 because Novant failed to demonstrate need.

The Novant Health System, including NHFMC, has Surplus OR Capacity.

Novant has not demonstrated the need for two additional ORs at NHFMC since it has capacity not only across its system in Forsyth County, but at NHFMC itself. Pursuant to Table 6B in the Forsyth County OR Service Area in the 2018 SMFP, the Novant Health system has a total projected surplus of 6.81 ORs. See 2018 SMFP, Table 6B, pp. 73-74. Such surplus includes: a projected surplus of 3.47 ORs at NHFMC, a projected surplus of 2 ORs at NHCOS, a projected surplus of 2 ORs at Novant Health Kernersville Outpatient Surgery, and a projected OR deficit of 0.66 ORs Novant Health Medical Park Hospital. See 2018 SMFP, Table 6B, pp. 73-74. This data demonstrates that Novant Health has sufficient capacity in both acute care hospital and ASC facilities such that Novant has not demonstrated the need for either the two additional ORs at NHFMC, or for the total of four additional ORs in Forsyth County between its two applications (Project ID Nos. G-011518-18 and G-011517-18).

Forsyth County OR Need was Driven by North Carolina Baptist Hospital.

Novant failed to demonstrate the need for ORs in Forsyth County since the need for four ORs in the Forsyth OR Service Area in the 2018 SMFP was generated by patients choosing to have surgery at NCBH. Pursuant to Table 6B in the Forsyth County OR Service Area in the 2018 SMFP, the Novant Health system has a total projected surplus of 6.81 ORs, 3.47 of which are at NHFMC, while NCBH has a total projected deficit of 6.65 ORs. See 2018 SMFP, Table 6B, pp. 73-74. This data indicates that the need for additional OR capacity in Forsyth County is attributable to patients choosing NCBH for surgical care. The need for additional ORs at NCBH is also demonstrated by the physician letters of support submitted for each project. NHFMC submitted approximately 32 physician letters of support with its Application. NHFMC Application, Exhibit H-

Letters. By contrast, the NCBH Application contains 326 physician support letters. NCBH Application, Exhibit H.4.2.

Novant's Need Methodology is Unreasonable and Unsupported.

Novant's methodology used to project surgical cases is unreasonable and not supported. The 2018 SMFP calls for a growth factor of 4.02% from 2016 to 2020, which is calculated using the change in the general population in the operating room service area based on the figures available from the North Carolina Office of State Budget and Management ("NCOBM"). Note that the 4.02% growth factor applied by the SMFP is the cumulative growth rate, not the CAGR. Using the Forsyth County population data provided by the NCOBM, the CAGR for Forsyth County's population between 2016 and 2020 is projected to be 0.99%. Instead of applying the 2018 SMFP growth factor to project need, the NHFMC application applies a 3.4% compound annual growth rate ("CAGR")— derived from the total increase in all inpatient and outpatient surgical services from 2015 to 2017 — to project future growth. Novant uses this 3.4% CAGR to project future growth in both inpatient and outpatient surgical cases. NHFMC Application, pp. 18-19. Although not required to use the SMFP population growth factor, Novant used its own CAGR rather than the SMFP growth factor because Novant could not demonstrate need at NHFMC using the 2018 SMFP; indeed, applying the SMFP growth factor results in Novant having a surplus of ORs at NHFMC. NHFMC Application, p. 21.

Novant's use of an assumed 3.4% CAGR for total surgical growth rate across all Novant surgical locations from 2015 -2017 is unreasonable for another reason: Novant states that the additional ORs are needed because of surgeon recruitment, yet the dates and data used to calculate the CAGR are inconsistent with the data used to determine the percentage growth in active surgical specialists. First, in calculating its CAGR, Novant uses surgical volumes across all of its inpatient and outpatient facilities in Forsyth County. NHFMC Application, p. 20. By contrast, in determining its total percentage growth in active surgical specialists, Novant only uses data from NHFMC. Second, to calculate the 3.4% CAGR, Novant uses a fiscal year period, from FFY2015 to FFY2016 and from FFY2016 to FFY 2017, whereas it uses calendar years from 2013 through 2017 to show its annual percentage growth in active surgical specialists. NHFMC Application, p. 20. Thus, Novant is not comparing apples to apples when computing its surgical volumes and percentage growth for its utilization projections.

More fundamentally, however, Novant mischaracterized the total percentage growth in active surgical specialists during this time. The increase from 182 total surgeons to 226 total surgeons, which occurred between 2013 and 2017, reflects a total percentage growth of 24%, not 35% as stated on page 20 of the NHFMC Application. NHFMC Application, p. 20. Rather, the 35% figure appears to reflect the growth between 2012 and 2017 (by subtracting the 2013 net surgeon growth from the number of total surgeons in 2013, it appears that Novant had 168 total surgeons in 2012). Further, while Novant asserts that the new ORs are needed because of its surgeon recruitment efforts, Novant fails to articulate why such an aggressive recruitment strategy is necessary or appropriate in the first place. Between 2013 and 2017, the CAGR for Novant's surgical staff was 5.56% (the figure rises to 6.11% when factoring in the 2012 data), well

in excess of the historical growth in population and surgical volumes. In other words, Novant is growing its population of surgical specialists faster than its growth in surgical volume or in the general population, yet it argues that more ORs are needed precisely because of its growing number of surgeons.

But even assuming that Novant's recruitment strategy is reasonable, Novant's use of two growth periods — 2015 to 2016, and 2016 to 2017 — to calculate the 3.4% CAGR is itself grossly misleading because nearly all of the growth in surgical volume occurred in year two (*i.e.* between FFY2016 and FFY2017). In fact, the total number of surgical cases for the Novant Health System as a whole increased by only 30 cases between FFY2015 and FFY2016, an increase of less than one-tenth of one percent (0.08%). By contrast, the increase in the number of total surgical cases for Novant Health System between FFY2016 and FFY2017 was 2,496 cases, an increase of 6.8%. This overall trend was also seen at NHFMH, which in 2016 experienced a 0.01% increase in combined inpatient and outpatient surgeries and in 2017 saw an 8.5% increase in total surgical cases. However, the 2017 increase may have been an outlier, and the 3.4% CAGR used by Novant as the historical growth rate does not reflect any sort of growth "trend". In addition, whereas Novant used only two growth periods, NCBH based its utilization projections for surgical cases on twelve years of historical data from FFY 2005 through FFY 2017. NCBH Application, pp. 27-29. For these reasons, the NHFMC Application is nonconforming to Criterion 3.

C. Criterion 4

(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.*

As described in Section II.B. of these comments, Novant does not demonstrate that projected surgical utilization at NHFMC is based on reasonable and supported assumptions. For the same reasons that the NHFMC Application is nonconforming with Criterion 3, the NHFMC Application is nonconforming to Criterion 4.

D. Criterion 5

(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.*

On page 50 of the NCFMC application, in response to Question 2(d), Novant states that "no additional start-up expenses, initial operating expenses, or working capital will be required." However, it is unreasonable to assume that Novant will incur no additional start-up or capital expenses in developing two additional ORs since Novant will need to hire additional staff and

train that staff for purposes of performing surgeries in the two ORs, and acquire additional inventory to use in those two ORs.

More fundamentally, however, and as described above in Section II.B. of these comments, the financial projections in the NHFMC application are based on unreasonable and unreliable utilization projections. These utilization projections form the basis for Novant's projections of revenue and expenses, as set forth in Forms F.3, F.4, and F.5. Since Novant does not reasonably project utilization of its facility, it fails demonstrate the financial feasibility of the Project. For the reasons herein and for the same reasons that the NHFMC Application is nonconforming to Criterion 3, Novant's NHFMC Application is non-conforming to Criterion 5.

E. Criterion 6

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

The NHFMC Application is nonconforming to Criterion 6 for the same reasons it is nonconforming with Criterion 3, and because it is an unnecessary duplication of existing or approved health service capabilities or facilities. Given the surplus of ORs across Novant facilities in Forsyth County, Novant has not adequately demonstrated the need for the two new ORs it proposes to develop at NHFMC, and as a result, has not demonstrated that its proposal will not unnecessarily duplicate the ORs in the Forsyth County OR service area. NHCOS Application, p. 53; NCBH Application, pp. 29-30. For the reasons herein and for the same reasons that the NHFMC Application is nonconforming to Criterion 3, Novant's NHFMC Application is non-conforming to Criterion 6.

F. Criterion 18a

(18a) *The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.*

The NHFMC Application is nonconforming to Criterion 18a for the same reasons it is nonconforming with Criteria 3, 4, 5, and 6, and because it will not enhance competition so as to have a positive impact on the cost effectiveness, quality, and access to the services proposed. Novant did not adequately demonstrate the need that the population projected to be served has for the proposed project, and did not adequately demonstrate that its Project would not result in the unnecessary duplication of surgical services in the Forsyth County OR service area. Novant

further did not demonstrate the financial feasibility of its proposal. Therefore, Novant's Project will not have a positive impact on competition.

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

The NHFMC Application is nonconforming to 10A NCAC 14C.2103(a)(1) because the NHFMC surgical case projections are not based on reasonable and supported assumptions. For the same reasons that the NHFMC Application is nonconforming to Criterion 3, the NHFMC Application is also nonconforming with 10A NCAC 14C.2103(a)(1).

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

The NHFMC Application is nonconforming to 10A NCAC 14C.2103(b)(1) because the NHFMC surgical case projections are not based on reasonable and supported assumptions. For the same reasons that the NHFMC Application is nonconforming to Criterion 3, the NHFMC Application is also nonconforming with 10A NCAC 14C.2103(b)(1).

**SCA’S COMMENTS REGARDING NOVANT HEALTH CLEMMONS OUTPATIENT SURGERY CON
APPLICATION (PROJECT ID G-011518-18)**

I. Project Description

Novant Health Clemmons Outpatient Surgery, LLC (“NHCOS”) and Novant Health, Inc. (collectively, “Novant”) propose to add two ORs to Novant Health Clemmons Outpatient Surgery, its freestanding ambulatory surgery center (“ASC”) currently under development in Clemmons, North Carolina, for a total of four ORs at NHCOS (the “Project”). NHCOS Application, pp. 1, 3-4, 12.

Novant was originally approved in June 2017 to develop NHCOS with two ORs, Project ID G-11300-17, which ASC is scheduled to open in July 2019. Thus, Novant’s current Project, which would develop a total of four ORs at NHCOS, although in response to the 2018 SMFP need determination, represents a change in scope from Project ID No. G-11300-17. NHCOS Application, pp. 1, 3.

Concurrent with the NHCOS CON application, Novant filed a separate application seeking to add two ORs to Novant Health Forsyth Medical Center’s (“NHFMC”) Main Campus. SCA’s comments regarding the NHFMC CON application (Project ID G-011517-18) will be addressed separately.

II. CON Review Criteria

The NHCOS application fails to conform to Review Criteria 1, 3, 4, 5, 6, and 18a, and fails to comply with the applicable policies and administrative rules.

A. Policy GEN-4 and Criterion 1

- (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, ORs, or home health offices that may be approved.*

The NHCOS application is nonconforming to Criterion 1 and Policy GEN-4 since it is inconsistent with Policy GEN-4. Section B.2 of the Application requires the applicant to demonstrate conformity with the policies in Chapter 4 of the SMFP that are applicable to the OR review. On page 7 of the NHCOS application, Novant confirms that Policy GEN-4 applies to its Project. The first portion of Policy GEN-4, for projects such as Novant’s Project that exceed \$2 million, requires applicants to include a written statement describing “the project’s plan to assure

improved (a) [e]nergy efficiency, and (b) [w]ater conservation.” While Novant asserts in response to Question B.4 that it includes the requisite written statement describing such plan based on Novant Health’s 2018 Sustainable Energy Management Plan (“SEMP”), it merely notes that its written statement “is articulated in the broader framework of the 2018 SEMP” and directs the reader to a copy of the SEMP at Exhibit B-4. NHCOS Application, pp. 10-11. A review of the SEMP evidences information about Novant’s goals for energy consumption across the entire Novant Health system, but nothing that relates to an actual plan for energy efficiency and water conservation for the NHCOS Project. Since the NHCOS application provides no plan for the proposed Project related to energy efficiency and water conservation, as required, the NHCOS application is not in compliance with Policy GEN-4, and therefore, is non-conforming with Criterion 1.

B. Criterion 3

- (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.*

The NHCOS application is nonconforming to Criterion 3 because Novant failed to demonstrate need.

Additional ORs at ASCs in Forsyth County are Not Needed.

Novant failed to demonstrate the need for additional ORs at ASCs in Forsyth County since there is a recent saturation of ASCs in the Forsyth market that provides adequate incremental capacity for patients seeking outpatient surgical care in an ASC setting. Between February 2018 and July 2019, three ASCs have been developed and/or are opened and operational for patients seeking outpatient surgical care. North Carolina Baptist Hospital (“NCBH”) Application, pp. 29-30.

In February 2018, Wake Forest Baptist Hospital Outpatient Surgery (“WFBOS”) opened a three-OR ASC in Clemmons, and in June 2018, Novant Health opened Health Kernersville Outpatient Surgery (“NHKOS”), a two OR multispecialty ASC in Kernersville. NCBH Application, pp. 29-30. Both WFBOS and NHKOS are ASCs in Forsyth County. In addition, Novant received a CON to develop a second multi-specialty ASC in Forsyth County by relocating two ORs from the Novant Health Winston Salem campus and developing a new procedure room on the Novant Health Clemmons Medical Center campus (Project ID G-11300-17). NHCOS Application, pp. 1, 2, 12. This facility is NHCOS that is currently under construction in Forsyth County. NHCOS Application, p. 12. The addition of yet another two ORs at NHCOS, for a total of four ORs at that facility, is premature considering that WFBOS and NHKOS both recently opened, and NHCOS is

scheduled to open in July 2019 with two ORs, all of which will create additional incremental ASC capacity. Given that two new ASCs providing similar services just opened and another one is scheduled to open in July 2019, Novant has not adequately demonstrated the need it has to develop two additional ORs at NHCOS.

The Novant Health System, including NHCOS, has Surplus OR Capacity.

Novant has not demonstrated the need for two additional ORs at NHCOS since it has capacity not only across its system in Forsyth County, but at NHCOS itself. Pursuant to Table 6B in the Forsyth County OR Service Area in the 2018 SMFP, the Novant Health system has a total projected surplus of 6.81 ORs. See 2018 SMFP, Table 6B, pp. 73-74. Such surplus includes: a projected surplus of 2 ORs at NHCOS, a projected surplus of 2 ORs at NHKOS, a projected surplus of 3.47 ORs at NHFMC, and a projected OR deficit of 0.66 ORs Novant Health Medical Park Hospital. See 2018 SMFP, Table 6B, pp. 73-74. This data demonstrates that Novant Health has sufficient capacity in both ASC and acute care hospital facilities such that Novant has not demonstrated the need for either the two additional ORs at NHCOS, or for the total of four additional ORs in Forsyth County between its two applications (Project ID Nos. G-011518-18 and G-011517-18).

Likewise, of the total existing and approved facilities in the Forsyth County OR Service Area that provide the same services proposed to be provided by Novant, three of those facilities are located in the Clemmons area: NHCOS (5 ORs), NHCOS (2 ORs), and WFBOS (3 ORs)¹. NHCOS Application, p. 53; NCBH Application, pp. 29-30. Although Novant asserts on page 53 of its Application that “the Novant Health CON for NHCOS showed it would meet the utilization standard based on shifting existing Novant Health patients from FMC Main and NHOOS”, Novant failed to attach any supporting documentation as required by Question 3(b). NHCOS Application, pp. 53-54. Given the ten existing and approved ORs in the Clemmons area, and lack of documentation provided by Novant to support its utilization projections, Novant has failed to adequately demonstrate the need for two additional ORs at NHCOS.

Forsyth County OR Need was Driven by North Carolina Baptist Hospital.

Novant failed to demonstrate the need for ORs in Forsyth County since the need for four ORs in the Forsyth OR Service Area in the 2018 SMFP was generated by patients choosing to have surgery at NCBH. Pursuant to Table 6B in the Forsyth County OR Service Area in the 2018 SMFP, the Novant Health system has a total projected surplus of 6.81 ORs while NCBH has a total projected deficit of 6.65 ORs. See 2018 SMFP, Table 6B, pp. 73-74. This data indicates that the need for additional OR capacity in Forsyth County is attributable to patients choosing NCBH for surgical care. The need for additional ORs at NCBH is also demonstrated by the physician letters

¹ The NHCOS Application states that WFBOS has two ORs, but the NCBH Application states that WFBOS has three ORs.

of support submitted for each project. NHCOS submitted approximately 20 physician letters of support with its Application. NHCOS Application, Exhibit H-Letters. By contrast, the NCBH Application contains 326 physician support letters. NCBH Application, Exhibit H.4.2.

Novant's Need Methodology is Unreasonable and Unsupported.

Novant's methodology used to project ambulatory surgical cases is unreasonable and not supported. The 2018 SMFP calls for a growth factor of 4.02% from 2016 to 2020, which is calculated using the change in the general population in the operating room service area based on the figures available from the North Carolina Office of State Budget and Management ("NCOBM"). Note that the 4.02% growth factor applied by the SMFP is the cumulative growth rate, not the CAGR. Using the Forsyth County population data provided by the NCOBM, the CAGR for Forsyth County's population between 2016 and 2020 is projected to be 0.99%. Instead of applying the 2018 SMFP growth factor to project need, the NHCOS application applies a 3.4% compound annual growth rate ("CAGR") — derived from the total increase in all inpatient and outpatient surgical services from 2015 to 2017 — to project future growth. Novant uses this 3.4% CAGR to project future growth in both inpatient and outpatient surgical cases. NHCOS Application, pp. 16-18. Although not required to use the SMFP population growth factor, Novant used its own CAGR rather than the SMFP growth factor because Novant could not demonstrate need at NHCOS using the 2018 SMFP; indeed, applying the SMFP growth factor results in Novant having a surplus of ORs at NHCOS.

Novant's use and application of its 3.4% CAGR to the NHCOS application is unreasonable since NHCOS is an ASC dedicated to providing outpatient surgical services, which outpatient services Novant acknowledges had a 2.9% CAGR between 2015 and 2017. NHCOS Application, pp. 16 and 26. Novant's own data evidences that Novant should have, at most, applied a 2.9% CAGR to the NHCOS Application, which makes the use of a 3.4% CAGR in its utilization projections unreasonable.

Novant's use of an assumed 3.4% CAGR for total surgical growth rate across all Novant surgical locations from 2015 -2017 is unreasonable for another reason: Novant states that the additional ORs are needed because of surgeon recruitment, yet the dates and data used to calculate the CAGR are inconsistent with the data used to determine the percentage growth in active surgical specialists. First, in calculating its CAGR, Novant uses surgical volumes across all of its inpatient and outpatient facilities in Forsyth County. NHCOS Application, p. 17. By contrast, in determining its total percentage growth in active surgical specialists, Novant only uses data from Novant Health Forsyth Medical Center ("NHFMC"). Second, to calculate the 3.4% CAGR, Novant uses a fiscal year period, from FFY2015 to FFY2016 and from FFY2016 to FFY 2017, whereas it uses calendar years from 2013 through 2017 to show its annual percentage growth in active surgical specialists. NHCOS Application, p. 17. Thus, Novant is not comparing apples to apples when computing its surgical volumes and percentage growth for its utilization projections.

More fundamentally, however, Novant mischaracterized the total percentage growth in active surgical specialists during this time. The increase from 182 total surgeons to 226 total

surgeons, which occurred between 2013 and 2017, reflects a total percentage growth of 24%, not 35% as stated on page 17 of the NHCOS Application. NHCOS Application, p. 17. Rather, the 35% figure appears to reflect the growth between 2012 and 2017 (by subtracting the 2013 net surgeon growth from the number of total surgeons in 2013, it appears that Novant had 168 total surgeons in 2012). Further, while Novant asserts that the new ORs are needed because of its surgeon recruitment efforts, Novant fails to articulate why such an aggressive recruitment strategy is necessary or appropriate in the first place. Between 2013 and 2017, the CAGR for Novant's surgical staff was 5.56% (the figure rises to 6.11% when factoring in the 2012 data), well in excess of the historical growth in population and surgical volumes. In other words, Novant is growing its population of surgical specialists faster than its growth in surgical volume or in the general population, yet it argues that more ORs are needed precisely because of its growing number of surgeons.

But even assuming that Novant's recruitment strategy is reasonable, Novant's use of two growth periods —2015 to 2016, and 2016 to 2017 — to calculate the 3.4% CAGR is itself grossly misleading because nearly all of the growth in surgical volume occurred in year two (*i.e.* between FFY2016 and FFY2017). In fact, the total number of surgical cases for the Novant Health System as a whole increased by only 30 cases between FFY2015 and FFY2016, an increase of less than one-tenth of one percent (0.08%). By contrast, the increase in the number of total surgical cases for Novant Health System between FFY2016 and FFY2017 was 2,496 cases, an increase of 6.8%. However, the 2017 increase may have been an outlier, and the 3.4% CAGR used by Novant as the historical does not reflect any sort of growth "trend", much less a linear annual growth rate. In addition, whereas Novant used only two growth periods, NCBH based its utilization projections for surgical cases on twelve years of historical data from FFY 2005 through FFY 2017. NCBH Application, pp. 27-29.

Further, the use of both inpatient and outpatient surgical cases to calculate the 3.4% CAGR was particularly misleading in the NHCOS Application. Between FFY2016 and FFY2017, Novant's inpatient surgical volume increased by 12.7%, while its outpatient surgical volume increased by only 4.5%. In other words, the overall increase of 6.8% in total surgical volume in from 2016-2017 was skewed by the growth in inpatient cases, making it particularly inappropriate to use a 3.4% CAGR to project future growth for outpatient facilities such as NHCOS. In sum, the 3.4% CAGR used by Novant to project inpatient and outpatient future growth in surgical cases is unreasonable because it is supported by only one year of growth and because the growth in inpatient cases far outpaced the growth in outpatient cases, making it particularly inappropriate to use as a growth factor for outpatient facilities such as NHCOS. For these reasons, the NHCOS application is nonconforming to Criterion 3.

C. Criterion 4

- (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.*

As described in Section II.B. of these comments, Novant does not demonstrate that projected surgical utilization at NHCOS is based on reasonable and supported assumptions. Furthermore, as discussed in Section II.B. of these comments, the opening of WFBMC (a three OR ASC), NHKOS (a two OR ASC) and NHCOS (a two OR ASC) between February 2018 and July 2019 provides adequate incremental ASC capacity in Forsyth County. NHCOS Application, p. 53; NCBH Application, pp. 29-30. Therefore, Novant's proposal to add two additional ORs to an ASC in an already ASC-saturated market and when Novant has a surplus of ORs at its Forsyth County ASCs is not the most effective alternative. For these reasons, the NHCOS application is nonconforming to Criterion 4.

D. Criterion 5

(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.*

Novant states on page 46 of the NCHOS application that, because the proposed project is both a change in scope for Project I.D. # G-11300-17 and a response to a need determination in the 2018 SMFP, that Novant would respond to all of the questions in Section F, not only the Change of Scope Questions beginning with Question 5. To this end, Novant states in Question 1(a) that Form F.1a is located in Section Q of the Application. However, Novant failed to provide a form F.1a in Section Q.

Novant Understates the Expenses to Develop Two Additional ORs.

On page 48 of the NCHOS application, in response to Question 2(d), Novant states that "no additional start-up expenses, initial expenses, or working capital will be required beyond what was contained in Project I.D. #G-11300-17." If Novant is adding two additional ORs to NHCOS, it is unreasonable to assume that Novant will have no additional start-up or other expenses. In adding two ORs to NHCOS to the previously approved ORs, Novant will need to hire additional staff and train that staff for purposes of performing surgeries in the two additional ORs, and acquire additional inventory to use in those two additional ORs. In addition, Column D of form F.1b states that Novant will incur additional capital costs of \$3,106,882, bringing the New Total Capital Costs for Project I.D. G-11300-17 to \$16,277,774. Novant unreasonably asserts that it will incur no additional expenses, even while its own projections in Form F.1b state otherwise.

More fundamentally, however, and as described above in Section II.B. of these comments, the financial projections in the NHCOS application are based on unreasonable and overstated utilization projections. These utilization projections form the basis for Novant's projections of revenue and expenses, as set forth in Forms F.3, F.4, and F.5. Since Novant does not reasonably project utilization of its facility, it fails demonstrate the financial feasibility of the

Project. For the reasons herein and for the same reasons that the NHCOS Application is nonconforming to Criterion 3, Novant's NHCOS application is non-conforming to Criterion 5.

E. Criterion 6

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

The NHCOS application is nonconforming to Criterion 6 for the same reasons it is nonconforming with Criterion 3, and because it is an unnecessary duplication of existing or approved health service capabilities and facilities. As discussed in detail in Section II.B of these comments, there are three ASCs with a total of seven ORs in Forsyth County that either already have opened or will be open by July 2019. Furthermore, of the total existing and approved facilities in Forsyth County OR service area that provide the same services, three of those facilities are located in the Clemmons area: NHCMC (5 ORs), NHCOS (2 ORs), and WFBOS (3 ORs). NHCOS Application, p. 53; NCBH Application, pp. 29-30. Given the surplus of ORs across Novant facilities in Forsyth County and the ten existing and approved ORs in the Clemmons area alone, Novant has not adequately demonstrated the need for the two new ORs it proposes to develop at NHCOS, and as a result, has not demonstrated that its proposal will not unnecessarily duplicate the ORs in the Clemmons and Forsyth County OR service area. For the reasons herein and for the same reasons that the NHCOS Application is nonconforming to Criterion 3, Novant's NHCOS application is non-conforming to Criterion 6.

F. Criterion 18a

(18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

The NHCOS application is nonconforming to Criterion 18a for the same reasons it is nonconforming with Criteria 3, 4, 5, and 6, and because it will not enhance competition so as to have a positive impact on the cost effectiveness, quality, and access to the services proposed. Novant did not adequately demonstrate the need that the population projected to be served has for the proposed project, and did not adequately demonstrate that its Project would not result in the unnecessary duplication of surgical services in the Clemmons and Forsyth County areas. Novant further did not demonstrate the financial feasibility of its proposal. Therefore, Novant's Project will not have a positive impact on competition.

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

The NHCOS application is nonconforming to 10A NCAC 14C.2103(a)(1) because the NHCOS surgical case projections are not based on reasonable and supported assumptions. For the same reasons that the NHCOS Application is nonconforming to Criterion 3, the NHCOS Application is also nonconforming with 10A NCAC 14C.2103(a)(1).

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

The NHCOS application is nonconforming to 10A NCAC 14C.2103(b)(1) because the NHCOS surgical case projections are not based on reasonable and supported assumptions. For the same reasons that the NHCOS Application is nonconforming to Criterion 3, the NHCOS Application is also nonconforming with 10A NCAC 14C.2103(b)(1).