

**Competitive Comments on Forsyth County
2018 Operating Room Need Determination
Submitted by Triad Center for Surgery**



Five applications were submitted in response to the need determination in the 2018 State Medical Facilities Plan for four additional operating rooms in the Forsyth County service area identified. These include:

1. North Carolina Baptist Hospital (“NC Baptist”) (Project ID No. G-11519-18) proposes to add four shared operating rooms at the main hospital for a total of 51 total operating rooms in Winston-Salem.
2. Novant Health Clemmons Outpatient Surgery Center (“Novant Clemmons”) (Project ID No. G-11517-18) proposes to add two ambulatory operating rooms to its previously-approved Project G-11300-17 that relocates ORs from Novant Health Forsyth Medical Center to a new ambulatory surgical facility in Clemmons.¹
3. Novant Health Forsyth Medical Center (“Novant FMC”) (Project ID No. G-11517-18) proposes to add two shared operating rooms at the Novant Health Forsyth Medical Center in Winston Salem.
4. Triad Surgery Center / Cone Health (“Cone”) (Project ID No. G-11516-18) proposes to develop a new ambulatory surgical facility with two operating rooms, one GI endoscopy procedure room and one procedure room in Kernersville.
5. Triad Center for Surgery (“Triad Center for Surgery”) (Project ID No. G-11513-18) proposes to develop a new ambulatory surgical facility with two operating rooms and three procedure rooms in Winston-Salem.

The following comments are submitted in accordance with N.C. Gen. Stat. § 131E-185(a1) (1) and address the representations in the project applications, including a comparative analysis and discussion as to whether the applications comply with the Certificate of Need (“CON”) review criteria.

¹ Novant filed two CON applications in this batch. The first proposes to add two operating rooms to its freestanding ASC that is “under development” in Clemmons, and the second proposes to add two shared operating rooms to Novant Health Forsyth Medical Center.



Comparative Comments

Geographic Accessibility

According to the two Novant applications, the two existing outpatient operating rooms (licensed under Novant Forsyth Medical Center) that are currently located in Orthopedic Outpatient Surgery at Kimel Park Drive in Winston-Salem will be relocated to Novant Clemmons Outpatient Surgery in 2019. Novant Clemmons proposes to add two operating rooms to the previously approved ambulatory surgical facility in southwest Forsyth County which will be distant from most residents of Forsyth County. Cone proposes develop a new ASF in Kernersville, in the far eastern area of the county that also will be distant from most of the Forsyth residents. The remaining three project applications propose to locate their operating rooms in the largest municipality, Winston-Salem, that is centrally located.

The following table provides comparative demographic statistics obtained from the US Census Bureau:

	Forsyth County	Winston-Salem	Clemmons	Kernersville
Population	371,511	242,203	20,079	24,066
Median Household Income	\$46,283	\$40,898	\$67,783	\$48,383
Persons in Poverty %	17.50%	24.30%	9.70%	15.50%

Clemmons and Kernersville are ineffective locations due to

- Significantly lower populations
- Low percentages and numbers of medically underserved / low income
- Distant from the low-income population in Winston-Salem.

The projects proposed by NC Baptist, Novant FMC and Triad Center for Surgery would improve access for low income residents. Of the three proposals to add operating rooms in Winston-Salem, Triad Center for Surgery is the only proposal that offers a new location option; therefore, the Triad Center for Surgery proposal is the most effective project regarding geographic access.

Percentages of Patients from Forsyth County

The following table compares the project applications based on the percentages of OR patients that originate from Forsyth County:

	OR Forsyth % Patients	
	Inpatient	Oupatient
NC Baptist	25.90%	
Novant Clemmons	NA	57.20%
Novant FMC	46.90%	49.90%
Cone	NA	46.60%
Triad Center for Surgery	NA	56.20%

NC Baptist projects to serve the lowest percentages of Forsyth patients (25.9%) and is the least effective project related to this factor. The Cone patient origin is not reasonable because the participating physicians and most of the referring primary care physicians have practice locations outside of the Forsyth County service area.

The two most effective applications for this comparative factor are Novant Clemmons (57.2%) and Triad Center for Surgery (56.2%) with the highest projected percentages of patients from Forsyth County.

Conformity to CON Review Criteria

The NC Baptist application is nonconforming with Criteria 1, 3, 4, 5, 6, 13c, 18a, 20 and the Performance Standard, 10A NCAC.2103. The Novant Clemmons application is nonconforming with Criteria 1, 3, 4, 5, 6, 13c, 18a, and the Performance Standard, 10A NCAC.2103. The Novant FMC application is nonconforming with Criteria 1, 3, 4, 5, 6, 13c, 18a, and the Performance Standard, 10A NCAC.2103. The Cone application is nonconforming with Criteria 1, 3, 4, 5, 6, 13c, 18a, 20 and the Performance Standards, 10A NCAC.2103 and 10A NCAC.3903.

The Triad Center for Surgery application conforms to all Criteria and the Performance Standard and is comparatively superior to the other proposals.

Adequacy of Physician Support

The existing hospital providers, NC Baptist and Novant FMC, have very large medical staffs with broad ranges of surgical specialties. The NC Baptist application includes extensive physician support. In contrast, the Novant FMC application lacks support from gynecologists, oral surgeons, otolaryngologists, plastic surgeons, podiatrists and urologists. Letters of support included in the Cone proposal are inadequate because most are from physicians outside of Forsyth County; the projected number of cases in the physician letters are hundreds less than the projections for operating rooms in Year 2. The Novant Clemmons application includes generic support letters from Novant-employed physicians with no estimates of the surgical cases. In contrast, the majority of the letters of support for the Triad Center for Surgery include projections for the estimated numbers of surgical cases.

The Novant FMC, Novant Clemmons and Cone applications are less effective proposals regarding physician support. NC Baptist and Triad Center for Surgery provide adequate physician support letters and are equally effective proposals.

Patient Access to Surgical Specialties

The NC Baptist and Novant FMC applications provide access to an extensive scope of services and approximately eleven or more surgical specialties. The projects involving ambulatory surgical facilities -Novant Clemmons and Triad Center for Surgery- both include seven specialties and Cone includes eight specialties. Multispecialty ambulatory surgical facilities can add surgical specialties in the future. Therefore, with regard to providing Forsyth County patients with access to multiple surgical specialties, all the proposed projects are effective.

Patient Access to Low Cost Alternative Ambulatory Surgical Facilities

Forsyth County currently has a total of 99 operating rooms (92 existing and 7 approved). NC Baptist has 43 existing and 7 approved operating rooms and Novant Health (including Clemmons Outpatient Surgery Center and Forsyth Medical Center) has a total of 47 operating rooms. NC Baptist recently opened a new freestanding ambulatory surgical facility, Wake Forest Health Outpatient Surgery Center, in Clemmons. Novant Health also has obtained CON approval for a freestanding center in Clemmons (Project G-11300-17.) The only freestanding ambulatory surgical facility that is not owned by a hospital in Forsyth County is Piedmont Outpatient Surgery Center, a single-specialty ambulatory surgical facility with two dedicated ambulatory operating rooms, located in Winston-Salem.

Many outpatient surgical procedures that are currently being performed in hospitals can be performed at much lower cost (to both patients and payors) in ambulatory surgical facilities. The NC Baptist and Novant FMC applications propose to add operating rooms that are hospital-licensed and would not increase patient access to low cost ambulatory surgical facilities.

The three projects that involve ambulatory surgical facilities--Novant Clemmons, Cone and Triad Center for Surgery--each would provide increased access to low cost ambulatory surgery. Consequently, the NC Baptist and the Novant FMC applications are the least effective proposals, and the Novant Clemmons, Cone and Triad Center for Surgery applications are the most effective projects.

Patient Access to New Provider in the Service Area

Unlike most counties of comparable size, the population of Forsyth County lacks access to a multispecialty ambulatory surgical facility because the NC Baptist/Novant oligopoly has limited competition and delayed the entry of a new provider in the market. The project applications by NC Baptist and Novant FMC to add operating rooms to the existing

hospitals are ineffective at improving patient choice. The Novant Clemmons application is simply shifting OR capacity to a more affluent community to maximize earnings. Only two applications, Cone and the Triad Center for Surgery, have the potential to improve patient access and choice by offering a new provider in the service area.

Access by Underserved Groups

The following table compares the project applications based on the percentages of Medicare and Medicaid patients to be served by the proposed operating rooms:

	Inpatient		Oupatient	
	Medicare	Medicaid	Medicare	Medicaid
NC Baptist	33.84%	19.83%	33.84%	19.83%
Novant Clemmons	NA	NA	44.20%	5.30%
Novant FMC	58.40%	8.60%	34.90%	10.40%
Triad Surgery Center / Cone	NA	NA	31.10%	1.00%
Triad Center for Surgery	NA	NA	46.59%	3.82%

The NC Baptist application provides misleading payor percentages for the combined volumes of inpatient and outpatient surgery cases instead of data specific to each category; this causes the application to be the least effective proposal because it is not comparable to the other proposals.

The next table compares the project applications based on the Medicare and Medicaid cases per operating room.

	Cases	OR #	Cases per OR
NC Baptist			
Medicare	11671	51	229
Medicaid	6841	51	134
Combined	18512	51	363
Novant FMC			
Medicare	8229	35	235
Medicaid	1552	35	44
Combined	9781	35	279
Novant Clemmons			
Medicare	2032	4	508
Medicaid	244	4	61
Combined	2276	4	569
Triad Center for Surgery			
Medicare	1365	2	683
Medicaid	112	2	56
Combined	1477	2	739
Cone			
Medicare	675	2	338
Medicaid	21	2	11
Combined	696	2	348

Based on the projected volumes for Year 2, the NC Baptist application has the lowest Medicare cases per OR and the highest Medicaid number of cases per OR. For Medicare and Medicaid combined, NC Baptist ranks second lowest with 363 cases.

Novant FMC has the second lowest Medicare cases and the second lowest Medicaid cases; Novant FMC combined Medicare and Medicaid is the lowest of applicants with 279 cases.

Novant Clemmons has the second highest Medicare cases and the second highest Medicaid; Novant Clemmons Medicare and Medicaid combined totals 569 cases per OR.

Cone projects the third highest Medicare cases and lowest Medicaid of all applicants; Medicare and Medicaid combined totals 348 cases per OR.

Triad Center for Surgery has the highest Medicare cases and the third highest Medicaid; Medicare and Medicaid combined totals 739 cases per OR. Triad Center for Surgery projects the highest cases per OR to serve the medically underserved and is the most effective proposal.

Charity Care

It is not possible to make conclusive comparisons of the applications regarding charity care due to the differences in the way the charity care information is provided in the applications. Also, NC Baptist, Novant Clemmons and Novant FMC modified the payor mix tables in the CON application forms.

Projected Gross Revenue per OR Cases

As seen in the following table, the average gross revenue per case for the NC Baptist and Novant FMC applications demonstrate that hospital-based surgery for both inpatients and outpatients is extraordinarily expensive.

Gross Revenue Comparison	Average Gross Revenue	
	Inpatient	Ambulatory
Year 2		
NC Baptist	\$98,781	\$98,781
Novant Clemmons	NA	\$11,259
Novant FMC	\$71,419	\$23,942
Cone	NA	\$7,336
Triad Center for Surgery	NA	\$4,307

Although the proposed hospital-based projects involve differences in the scope of services from the ambulatory surgery facilities, the NC Baptist and Novant FMC proposals

are so outrageously expensive that these applications are the least effective proposals. The three project applications that involve multispecialty ambulatory surgery operating rooms are all categorized as Group 6 and are sufficiently similar to allow a conclusive comparison of projected gross revenue for the proposed operating room cases. The Triad Center for Surgery is the most effective proposal with the lowest average gross revenue.

Projected Net Revenue per OR Cases

As seen in the next table, the average net revenue per case for the NC Baptist and Novant FMC applications reinforce the high cost of hospital-based surgery.

Net Revenue Comparison	Average Net Revenue	
	Inpatient	Ambulatory
Year 2		
NC Baptist	\$21,541	\$21,541
Novant Clemmons	NA	\$4,189
Novant FMC	\$21,549	\$10,138
Cone	NA	\$3,746
Triad Center for Surgery	NA	\$2,152

The three project applications that involve multispecialty ambulatory surgery operating rooms are sufficiently similar to allow a conclusive comparison of projected net revenue for the proposed operating room cases. The Triad Center for Surgery is the most effective proposal with the lowest average net revenue per case.

Projected Expense per Total Cases and Procedures

The following table compares the average cost per total combined cases:

	YR 2 Average Cost per Total Combined Cases
NC Baptist	\$16,466
Novant Clemmons	\$2,855
Novant FMC	\$6,981
Cone	\$1,395
Triad Center for Surgery	\$1,594

As expected, the NC Baptist and Novant FMC proposals have higher costs as compared to the applications for ambulatory surgery facilities. The Cone application has the lowest and the Triad Center for Surgery has the second lowest average cost per total case, which makes these two proposals the two most cost-effective.

History of Project Development

NC Baptist has failed to develop CON project # G-8460-10 for so long that its Certificate of Need approval should be withdrawn. Setting that aside, with a proposed operational date of July 1, 2024 for its current proposal, the NC Baptist timetable is not credible or compelling.

Novant Health has a truly dismal track record of failing to develop ambulatory surgery centers, with abandoned projects in New Hanover and Franklin Counties and the Presbyterian Same Day Surgery Center – Monroe (Union County) that remains closed. Therefore, the NC Baptist application and the two Novant proposals are the least effective based on the applicants' inability (or unwillingness) to successfully complete approved projects. Hawthorne Surgical Center in Forsyth County was previously licensed as an ambulatory surgical facility but was converted by Novant to hospital licensed operating rooms in 2007.

Cone Health has not established a track record of success in developing and operating freestanding ambulatory surgery centers in Guilford County. According to the database of the Acute and Home Care Licensure Section, the Wesley Long Surgery Center and Moses Cone Surgery Center were licensed as ambulatory surgical facilities through 12/31/2007. Now these operating rooms are licensed as hospital operating rooms under Cone Health (HO159). Therefore, patients and payors are billed at the higher hospital rates for outpatient surgery at the Wesley Long and Moses Cone Surgery centers. In 2011, Moses Cone Health System and Triad Surgery Center submitted a noncompetitive project, CON ID # G-8657-11, to relocate three operating rooms to a freestanding ambulatory surgical facility. This proposal was denied. Cone Health's penchant for maximizing surgery revenues for its Guilford County operating rooms undermines the merit of Cone's proposal.

The Triad Center for Surgery involves Compass Surgery Partners, OrthoCarolina physicians, and community physicians. Pages 10 through 13 of the Triad Center for Surgery application document the experience of the key participants in successfully developing and managing ambulatory surgery projects in North Carolina. Based on this track record of success, the Triad Center for Surgery is the most effective application.

Quality of Care

According to the report of the Centers for Medicare and Medicaid Services (CMS) survey on February 5-8, 2018, erroneous pathology tests at NC Baptist Hospital resulted in incorrect cancer diagnoses. As a result, CMS placed the hospital on "immediate jeopardy" status. The CMS [*State Operations Manual*](#) defines Immediate Jeopardy (IJ) as "a situation in which the provider's noncompliance with one or more requirements of participation has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident."

On April 9, CMS removed Baptist's immediate jeopardy status. CMS notified the health system that it had until June 12, 2018 to satisfy government inspectors that it had fixed

the problems in its pathology labs. According to the report, the problems included shortcomings in training, equipment maintenance and lab supply problems as well as missing or incomplete documentation.

Novant Health has existing healthcare facilities; none of which are reported to have CMS surveys with Immediate Jeopardy status within the past 18 months. Cone Health has existing facilities including hospitals and ambulatory surgery centers. The Cone application failed to provide quality of care information for its hospitals as required under Criterion 20.

Triad Center for Surgery has no existing healthcare facilities. None of the ambulatory surgery centers managed by Compass Surgical Partners or OrthoCarolina's University Surgery Center are reported to have CMS surveys with Immediate Jeopardy status within the past 18 months.

Therefore, with regard to quality of care, the NC Baptist and the Cone proposals are the least effective and the other applications are equally effective.

Medical Staff Composition

The five project applications show significant variation on the composition of their proposed medical staffs. The NC Baptist project requires the prospective members of the medical staff to be either full-time or part-time members of the faculty; this means that the proposed NC Baptist ORs will be closed to non-faculty surgeons. The Novant applications indicate medical staffs that are dominated by Novant-employed physicians. Similarly, the Cone's medical staff will be comprised of a majority of Cone Health surgeons. The Triad Center for Surgery application is the only application that clearly demonstrates a medical staff composition that is accessible to a wide range of individual surgeons and physician groups and not solely to health system-employed physicians.

	N C Baptist Hospital	Novant Clemmons	Novant FMC Main	Cone	Triad Center
	G-11519-18	G-11518-18	G-11517-18	G-11516-18	G-11513-18
Project Descriptions	Add 4 shared ORs for a total of 51 at NCBH Includes OR projections for CON Project G-8460-10	Add 2 Ambulatory ORs to previously approved project for total of 4 ORs (Change of Scope for G-11200-17)	Add 2 shared ORs to previously approved project for total of 22 ORs at FMC Main	New ASF with 2 ORs, 1 GI Endoscopy and 1 Procedure Room	New ASF with 2 ORs, 3 Procedure Rooms
Address and Locations	Medical Center Blvd. Winston-Salem	7210 Village Medical Center, Clemmons	3334 Silas Creek Pky. Winston-Salem	1635 NC-66 South Kernersville	180 Kimel Park Dr. Winston-Salem
Geographic Location	Winston-Salem Central Forsyth	Clemmons Southwest Forsyth	Winston-Salem Central Forsyth	Kernersville East Forsyth	Winston-Salem Central Forsyth
Total Capital Cost	\$9,982,500	\$3,106,882	\$4,181,671	\$12,713,263	\$7,158,685
Percent of Patients from Forsyth County	Inpatient and Outpatient Combined 25.9% Forsyth	Ambulatory OR 57.2% Forsyth	Inpatient 46.9% Forsyth Outpatient 49.9% Forsyth	Ambulatory OR 46.6% Forsyth GI Endo 38.3% Forsyth Proc. Rm 46.6% Forsyth	Ambulatory OR 56.2% Forsyth
Operational Dates	7/1/2024	1/1/2021	4/1/2021	9/30/2020	1/1/2021

N C Baptist Hospital	Novant Clemmons	Novant FMC Main	Cone	Triad Center
G-11519-18	G-11518-18	G-11517-18	G-11516-18	G-11513-18
<p>Does not conform to Criteria 1, 3, 4, 5, 6, 13c, 18a, 20 and Performance Standard 10A NCAC.2103. Please see the individual application comments.</p>	<p>Does not conform to Criteria 1, 3, 4, 5, 6, 13c, 18a, and Performance Standard 10A NCAC.2103. Please see the individual application comments.</p>	<p>Does not conform to Criteria 1, 3, 4, 5, 6, 13c, 18a, and Performance Standard 10A NCAC.2103. Please see the individual application comments.</p>	<p>Does not conform to Criteria 1, 3, 4, 5, 6, 13c, 18a, 20, and Performance Standard 10A NCAC.2103 and j)A NCAC.3903. Please see the individual application comments.</p>	<p>Conforms to all Criteria and the Performance Standard 10A NCAC 2103.</p>
<p>Conformity to CON Criteria</p>				

	N C Baptist Hospital G-11519-18	Novant Clemmons G-11518-18	Novant FMC Main G-11517-18	Cone G-11516-18	Triad Center G-11513-18
Patient Access to Alternative Provider	Existing Provider	Existing Provider	Existing Provider	Existing Provider in Guilford County	New Provider / Most Effective
Physician Support	Numerous letters	20 letters from surgeons	29 letters from surgeons; <u>No support letters from</u> Obstetrics-Gynecology, Ophthalmology, Oral Surgery/Dental, Otolaryngology, Plastic Surgery.	Numerous letters	24 letters from surgical specialists and pain management physicians
Surgical Specialties	Cardiothoracic, General Surgery, Neurosurgery, Obstetrics-Gynecology, Ophthalmology, Orthopedic, Otolaryngology, Plastic Surgery, Vascular Surgery	General Surgery, Obstetrics-Gynecology, Orthopedic, Neurosurgery, Urology, Podiatry	Cardiothoracic, General Surgery, Neurosurgery, Obstetrics-Gynecology, Ophthalmology, Orthopedic, Oral Surgery/Dental, Otolaryngology, Plastic Surgery, Vascular Surgery	Orthopedic, Gynecology, Otolaryngology, General Surgery, Neurosurgery, Urology, Plastic Surgery, Podiatry	Orthopedic, Neurosurgery, Ophthalmology, Plastic Surgery, Oral Surgery, Pain Management
Access by Underserved Groups (OR Cases) Form F.4	Inpatient Ambulatory ORs Combined Medicare 33.84% Medicaid 19.83%	Ambulatory OR Medicare 44.2% Medicaid 5.3%	Inpatient OR Medicare 58.4% Medicaid 8.6% Ambulatory OR Medicare 34.9% Medicaid 10.4%	Ambulatory OR Medicare 31.1% Medicaid 1.0%	Ambulatory OR Medicare 46.59% Medicaid 3.82%
	Data not reported in accordance with CON forms	Data not reported in accordance with CON forms	Data not reported in accordance with CON forms		Highest Combined

	N C Baptist Hospital G-11519-18	Novant Clemmons G-11518-18	Novant FMC Main G-11517-18	Cone G-11516-18	Triad Center G-11513-18
Projected Average Gross Revenue Per OR Case	Inpatient & Ambulatory ORs Combined		Inpatient OR		
	YR 1 \$ 94,077		YR 1 \$70,018		
	YR 2 \$ 98,781		YR 2 \$71,419		
	YR 3 \$103,719		YR 3 \$72,847		
	Ambulatory OR	Ambulatory OR	Ambulatory OR	Ambulatory OR	Ambulatory OR
	YR 1 \$11,038	YR 1 \$23,472	YR 1 \$7,122	YR 1 \$4,307	YR 1 \$4,307
	YR 2 \$11,259	YR 2 \$23,942	YR 2 \$7,336	YR 2 \$4,307	YR 2 \$4,307
	YR 3 \$11,484	YR 3 \$24,421	YR 3 \$7,556	YR 3 \$4,307	YR 3 \$4,307
Projected Average Gross Revenue Per Procedure Room Case	Procedure Room	Procedure Room	Procedure Room	Procedure Room	Procedure Rooms
	N/A	YR 1 \$2,123		YR 1 \$1,972	YR 1 \$2,313
		YR 2 \$2,165	N/A	YR 2 \$2,031	YR 2 \$2,313
		YR 3 \$2,029		YR 3 \$2,092	YR 3 \$2,313
Projected Average Net Revenue Per OR Case	Inpatient & Ambulatory ORs		Inpatient OR		
	YR 1 \$23,998		YR 1 \$21,549		
	YR 2 \$24,541		YR 2 \$21,975		
	YR 3 \$25,308		YR 3 \$22,419		
	Ambulatory OR	Ambulatory OR	Ambulatory OR	Ambulatory OR	Ambulatory OR
	YR 1 \$4,107	YR 1 \$4,189	YR 1 \$9,939	YR 1 \$3,636	YR 1 \$2,152
	YR 2 \$4,189	YR 2 \$4,273	YR 2 \$10,138	YR 2 \$3,746	YR 2 \$2,152
	YR 3 \$4,273	YR 3 \$10,341	YR 3 \$3,820	YR 3 \$3,820	YR 3 \$2,153
Projected Average Gross Revenue Per Procedure Room Case	Procedure Room	Procedure Room	Procedure Room	Procedure Room	Procedure Room
	N/A	YR 1 \$790		YR 1 \$1,007	YR 1 \$1,157
		YR 2 \$806	N/A	YR 2 \$1,037	YR 2 \$1,157
		YR 3 \$822		YR 3 \$1,062	YR 3 \$1,157

	N C Baptist Hospital G-11519-18	Novant Clemmons G-11518-18	Novant FMC Main G-11517-18	Cone G-11516-18	Triad Center G-11513-18
Projected Average Cost per OR and Procedure Room Combined	Inpatient Ambulatory ORs Combined	Ambulatory OR	Inpatient & Ambulatory OR	Ambulatory OR, GI and Procedure Rooms	Ambulatory OR and Procedure Rooms
	YR 1 \$16,105	YR 1 \$2,901	YR 1 \$6,811	YR 1 \$1,336	YR 1 \$1,788
	YR 2 \$16,466	YR 2 \$2,855	YR 2 \$6,981	YR 2 \$1,395	YR 2 \$1,594
	YR 3 \$16,800	YR 3 \$2,916	YR 3 \$7,157	YR 3 \$1,455	YR 3 \$1,481
Record of Applicant and Health System for Developing Projects	Substantial delays in development for CON G-8460-10	Previous OR projects in Union (closed), New Hanover and Franklin Counties (not timely)	Previous OR projects in Union (closed), New Hanover and Franklin Counties (not timely)	Cone Health converted existing Wesley Long and Cone ASCs to HOPD in 2008	University Surgery Center developed timely following CON appeal.
Quality of Care Incidents	February 2018 Immediate Jeopardy CMS Survey April 2018 Notice of termination rescinded June 2018 Review of corrective action to occur Closed – Staff Limited to Full Time or Part Time Faculty of Wake Forest School of Medicine	No Recent Reports of Immediate Jeopardy	No Recent Reports of Immediate Jeopardy	Application omits quality data for existing Come Health hospitals.	No Recent Reports of Immediate Jeopardy
Medical Staff Composition		Limited to Novant Health Surgeons	Limited to Novant Health Surgeons	Numerous physicians with many employed by Cone	Multiple physician groups not employed by hospitals

Summary of Comparative Factors Analysis

	N C Baptist Hospital	Novant Clemmons	Novant FMC Main	Cone	Triad Center
	G-11519-18	G-11518-18	G-11517-18	G-11516-18	G-11513-18
Geographic Location	Effective	Not Effective	Not Effective	Not Effective	Effective
Percent of Patients from Forsyth County	Lowest & Least Effective	Highest & Effective	Moderately Effective	Not based on reasonable assumptions	Second Highest & Effective
Operational Dates	2024 & Least Effective	All within six month period between 9/30/2020 and 4/1/2021 & Equality Effective			
Conformity to CON Criteria	Nonconforming to Multiple Criteria	Nonconforming to Multiple Criteria	Nonconforming to Multiple Criteria	Nonconforming to Multiple Criteria	Conforming to All Criteria
Patient Access to Alternative Provider	Not Effective	Not Effective	Not Effective	Effective	Most Effective
Physician Support	Effective	Not Effective	Not Effective	Not Effective	Effective
Surgical Specialties	Most Specialties	Moderately Effective	Most Specialties	Moderately Effective	Moderately Effective
Medicare % Access	Percentages combined for Inpatient and Outpatient	Highest for Ambulatory	Highest for Inpatient	Lowest & Least Effective	Second Highest for Ambulatory
Combined Medicare % and Medicaid % for Ambulatory	NA	Second Highest	Third Highest for Ambulatory	Lowest & Least Effective	Highest and Most Effective
Combined Medicare and Medicaid # of Patients per OR	Third lowest	Second Highest	Lowest	Second Lowest	Highest and Most Effective
Projected Average Gross Revenue Per OR Case	Highest and Least Effective	Highest for Ambulatory and Least Effective	Second Highest and Not Effective	Second Lowest for Ambulatory and Moderately Effective	Lowest for Ambulatory and Most Effective
Projected Average Net Revenue Per OR Case	Highest and Least Effective	Highest for Ambulatory and Least Effective	Second Highest and Not Effective	Second Lowest for Ambulatory and Moderately Effective	Lowest for Ambulatory and Most Effective
Projected Average Cost per OR and Procedure Room Combined	Highest and Least Effective	Highest for Ambulatory and Least Effective	Second Highest and Not Effective	Lowest for Ambulatory and Most Effective	Second Lowest for Ambulatory and Moderately Effective
History of Project Development	Not effective	Not effective	Not effective	Not effective	Effective
Quality of Care	Not effective	Effective	Effective	Not effective	Effective

**Comments Specific to North Carolina Baptist Hospital (Project ID No. G-11519-18)
Add four operating rooms at the main hospital for a total of 51 total operating rooms in Winston-Salem.**

The North Carolina Baptist Hospital (NC Baptist) project application is nonconforming with the CON Review Criteria due to multiple deficiencies.

- Surgery utilization projections and assumptions for the proposed project are incorrectly based on the analysis of the combined historical surgery utilization of NC Baptist and Davie Medical Center.
- By itself, NC Baptist shows no growth in total surgery volume from 2012 to 2017 with a 5 Year Compound Annual Growth Rate of -0.01%.
- The applicant does not adequately explain the surgical specialty mix for inpatient and ambulatory cases that are projected to remain at NC Baptist.
- The NC Baptist projected operating room volumes are based on highly speculative, overly complex and dubious assumptions for how surgery cases will be redirected to various newly-developed and approved surgery locations.
- The application projects 1.0% annual growth for each of the seven interim years and the first three years of the project which far exceeds NC Baptist's 5-year (2012-2017) -0.01% CAGR percentage.
- Payor mix categories in Forms F.4 and F.5 are inconsistent with the CON application form.
- NC Baptist's surgery charges are astronomically high, causing it to be less likely to increase utilization in future years.
- The CMS survey of NC Baptist in February 2018 resulted in an immediate jeopardy notice; compliance with CMS conditions of participation was not adequately documented.

These deficiencies cause the application to be nonconforming with the following criteria:

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

POLICY GEN-3: BASIC PRINCIPLES states:

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

The NC Baptist application fails to conform with Criterion 1 and Policy GEN-3 because the projected surgery patient volumes are overstated. Volume projections for the project are unreliable because:

- The future surgery growth projections at NC Baptist far exceed the historical growth.
- The NC Baptist application does not provide adequate description of the factors that support one percent annual growth for both inpatient and outpatient surgery.
- It is impossible for NC Baptist to make reasonable predictions regarding the expected shift of cases to other surgery venues due to the extended timeline for development and the multiple surgery projects that are pending or incomplete.

Criterion 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 NC Baptist surgery projections and assumptions for the proposed project are unreasonable, causing the proposal to be nonconforming with Criterion 3. The following table provides the historical surgery utilization at NC Baptist from 2012 through 2017 based on its license renewal applications.

	2012	2013	2014	2015	2016	2017	5-YR CAGR
Inpatient	14,146	13,988	13,944	14,214	14,534	14,392	0.35%
Ambulatory	20,266	20,355	19,749	19,549	19,925	20,000	-0.26%
Combined	34,412	34,343	33,693	33,763	34,459	34,392	-0.01%
Numerical Change from Previous Year	NA	-69	-650	70	696	-67	
Percentage Change from Previous Year	NA	-0.20%	-1.89%	0.21%	2.06%	-0.19%	

No growth has occurred, which is one of the reasons NC Baptist delayed the development of CON Project # G-8460-10 for the relocation of one operating room and the addition of seven operating rooms. Such a long delay for this previously approved project clearly demonstrates stagnation. Despite this prolonged stasis, the application now unreasonably predicts sudden rejuvenation with 1 percent annual growth for both inpatient and outpatient surgery.

It appears that NC Baptist feels compelled to submit this CON application for four additional operating rooms not because it has a pressing need for additional capacity but, instead, to limit competition. Over the next seven to ten years, patient and physician preferences are likely to change regarding what facilities will be utilized for inpatient and ambulatory surgery. Patients have greater access to online tools to compare surgery charges including the website at NC Department of Health and Human Services Transparency in Health Care Costs (www2.ncdhhs.gov/dhsr/ahc/hb834/search.asp).

With access to comparative cost information, patients with high deductible insurance plans and co-payments for surgery will be unlikely to select NC Baptist.

NC Baptist's methodology should win the "Rube Goldberg Award"² because it is built with deviously complex and impractical projections and multiple shifty assumptions for the myriad of operating rooms that are pending relocation and development. It is really just guess work because there are so many moving parts to the methodology that if just one assumption is varied slightly, all the projections fall down like dominos. Given NC Baptist's poor track record of developing previously-approved operating room projects, there is no certainty that its pending projects will be completed in a timely manner in order for these precarious projections to occur. It is not until next decade that NC Baptist predicts it will have a true need for additional operating rooms. For all of these reasons, NC Baptist's proposal should be denied.

Criterion 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."*

The NC Baptist application fails to comply to Criterion 4 because the application proposes to develop additional hospital-based OR capacity that is not an effective alternative. NC Baptist has achieved no growth in surgery utilization even though it has no constraints and has additional ORs pending development. Utilization projections are overstated and unreasonable. The timeline for this proposed project is not an effective alternative to improve access because NC Baptist chose to put off the implementation of the proposed project until 2024 and continues to drag its feet on CON Project # G-8460-10

In Section E of the application, NC Baptist assumes that Criterion 4 means the least costly or most effective for the hospital but does not consider the cost of services to the patients. The application fails to demonstrate how additional shared (inpatient and ambulatory)

² Rube Goldberg was a cartoonist known for depicting machines designed to perform simple tasks in complicated, indirect, overly complex ways.

operating rooms are the least costly or most effective for patients and payors. As seen in NC Baptist Forms F.4 and F.5, the projected average charges and reimbursements are extraordinarily high.

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

The NC Baptist application fails to comply with Criterion 5 because the operational and financial projections are not based on reasonable assumptions. As explained in the Criterion 3 comments, the proposal is not reasonable due to the overall complexity of the numerous assumptions in the methodology and the prolonged timeline to develop the project. The revenues and expenses in the project application predict continual increases in future years with no opportunities for cost savings to patients or payors.

Forms F.4 and F.5 in the NC Baptist application do not list the payor categories in accordance with the CON forms that define the following payor categories:

- Self Pay
- Charity Care
- Medicare (including any managed care plans)
- Medicaid (including any managed care plans)
- Insurance (including any managed care plans)
- Workers Compensation
- TRICARE
- Other (Specify)

Due to the applicant's modification of the CON form, NC Baptist fails to provide the financial data required by the Agency.

Criterion 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 NC Baptist proposal fails to comply with Criterion 6 because the operational projections are not based on reasonable assumptions. As explained in the Criterion 3 comments, the methodology and assumptions are flawed resulting in overstated volumes. NC Baptist previously obtained CON approval for additional operating rooms (CON Project # G-8460-10) in accordance with Policy AC-3, which allows academic medical centers to submit CON applications for additional regulated capacity even when there is no need determination in the SMFP. Since these AC-3 ORs have not yet been developed, they have no utilization to demonstrate that they are truly necessary in 2018. Furthermore, the G-11519-18 application, which proposes four additional ORs to be developed by 2024, indicates that these additional operating rooms are unnecessary through 2023.

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

(c) That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services.”

NC Baptist fails to comply with Criterion 13c because the proposed project will not provide adequate access to low income persons, including Medicare patients:

- The projected utilization and payor percentages are not based on reasonable assumptions.
- The applicant deceptively chose to provide payor percentages for the combined volumes of inpatient and ambulatory cases rather than the payor percentages for inpatient and ambulatory separately, as it is reported in the hospital license renewal application.
- The proposed timeline for the project does not demonstrate improved access to services until the operating rooms become operational in 2024.
- Hospital-based shared operating rooms have much higher costs and charges as compared to freestanding ambulatory surgical facilities.
- By modifying the CON application form, the applicant omitted specified payor categories.

Criterion 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.”*

NC Baptist fails to comply with Criterion 18a regarding the expected effects on competition related to cost, quality and access. Operational and financial projections in the NC Baptist application are unreasonable as discussed in the Criteria 3 and 5 comments. Accordingly, the application fails to demonstrate that the project will provide any enhanced competition in the service area. Moreover, even assuming the operational and financial projections were reasonable, competition and patient access will not be enhanced because the proposed operating rooms will not be available until 2024. Furthermore, NC Baptist has still not developed its previously-approved project # G-8460-10. Because NC Baptist is a dominant healthcare provider in Forsyth County, with more than 50 percent of the existing and approved operating rooms, its proposal has the least

potential to improve competition. The NC Baptist proposal fails to enhance cost-effectiveness because hospital-based operating rooms have the highest costs and charges. Serious quality issues at NC Baptist are documented in the 2018 surveys by the Centers for Medicare and Medicaid Services.

Criterion 20 *“An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.”*

The NC Baptist application is nonconforming with Criterion 20 due to the Centers for Medicare and Medicaid Services (CMS) survey findings of noncompliance with multiple Medicare conditions of participation. In February 2018, CMS surveyors documented “Immediate Jeopardy” noncompliance that has caused or is likely to cause serious injury, harm, impairment or death to a patient. The CMS survey listed four problem areas including (1) the medical center’s governing body, (2) patient rights, (3) quality assessment and performance improvement, and (4) laboratory services. Initially, NC Baptist was given a notice of termination notice by CMS that it would lose Medicare reimbursement. In April 2018, CMS rescinded its notice of termination. NC Baptist has submitted a corrective action plan and a follow-up survey is scheduled for June 2018.

On May 15, 2018, the date the application was submitted, NC Baptist was not in compliance with the conditions of participation in the Medicare Program because it had not yet completed a full Medicare and Medicaid Survey with no conditions of participation out of compliance. Consequently, NC Baptist did not meet its burden, under Criterion 20, of demonstrating it had provided quality care in the past.

10A NCAC 14C.2103 Performance Standards.

(f) The applicant shall document the assumptions and provide data supporting the methodology used for each projection in this Rule.

The NC Baptist application documents the assumptions and provides data supporting the methodology used for its operating room projections. However, the applicant’s projected

utilization is not reasonable and adequately supported. NC Baptist has failed to develop previously approved projects in a timely manner. The discussion regarding analysis of need, including projected utilization, found in Criterion 3 is incorporated herein by reference. Consequently, the application is not conforming with this rule.

Comments Specific to Novant Clemmons (Project ID No. G-11518-18), Add 2 operating rooms to a previously-approved ambulatory surgical facility project (Project G-11200-17) for a total of 4 operating rooms.

The Novant Clemmons project application is nonconforming with CON Review Criteria based on the multiple deficiencies in the project application.

- The Novant Clemmons application wrongly claims that it has a need for ORs based on location-specific assumptions that are inconsistent with the OR methodology in the 2018 SMFP.
- Novant chooses to operate its existing operating rooms that are licensed under Novant FMC (HO209) at less than the standard 1950 annual hours per operating room as assigned on the 2018 SMFP.
- Novant chooses to operate its existing operating rooms that are licensed under Novant Medical Park (HO229) at less than the standard 1755 annual hours per operating room as assigned on the 2018 SMFP.
- The application uses an unreasonable and overstated 3.4 percent annual growth rate for all inpatient and outpatient surgery locations that exceeds the historical 5-year compound annual growth rate for the Novant Health Forsyth facilities.
- Assumptions regarding the expected ambulatory shift of cases from various Novant facilities are not adequately supported. Thus, the need to add ORs at the Clemmons facility is not adequately demonstrated.
- The proposed ASC location in Clemmons does not need additional operating rooms because the previously-approval ASC project is not operational.
- Financial statements for the proposed project lack credibility due to overstated utilization and inconsistent payor percentages.

These deficiencies cause the application to be nonconforming with the following criteria:

Criterion 1 *“The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which shall*

constitute a determinative limitation on the provision of any health services, health service facility, health service beds, dialysis stations. Operating rooms, or home health offices that may be approved.”

POLICY GEN-3: BASIC PRINCIPLES states:

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

The proposed Novant Clemmons application fails to conform with Criterion 1 and Policy GEN-3 because the patient origin projections are unreasonable, and the projected patient volumes for surgery are overstated. Page 13 of the application explains that the projected patient origin data is based on the FFY 2018 YTD outpatient surgery data; however, this partial year data is omitted from the project application. Volume projections for the project are unreliable because the Novant Clemmons application lacks letters of support from ophthalmologists, oral surgeons, otolaryngologists and plastic surgeons. It is unreasonable to project a shift in outpatient surgery volumes from the Novant facilities to a proposed new ambulatory surgical facility that lacks adequate physician support. Clemmons already has excess operating room capacity with the Wake Forest Baptist Outpatient Surgery Center, plus Novant Health Clemmons Medical Center and Novant Health Clemmons Outpatient Surgery.

Criterion 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 Novant application does not provide reasonable patient origin projections:

- The application fails to explain why the projected patient origin percentages in Project ID No. G-11518-18 differ from the data that was contained in the previous application Project ID No. G-11300-17.
- The FFY 2018 YTD outpatient surgery data referenced in the current application is partial year data that is omitted from the project application.
- The projections include 18.3 percent of the ambulatory surgery patients will originate from “All Other” but fails to identify what Counties are now included in this category.
- The discrepancies in the patient origin data included in Project ID No. G-11518-18 and the previous Project ID No. G-11300-17 cannot be explained without amending the application.

Novant thinks it has an unmet need for ORs but in reality, it is not utilizing its existing ORs up to the average annual hours that are assigned to its facilities in the 2018 SMFP. The operating room methodology in the 2018 SMFP categorizes each licensed facility with ORs into Groups (1 through 6) and assigns the average annual hours of operation and average case times. Novant dislikes this methodology and irrationally argues that each of its locations should use their actual 2018 annual hours of operation even though these hours vary significantly by location and the Novant Kernersville ASC and the Novant Clemmons ASC are not yet operational.

The Novant application predicts that the Novant Health System in Forsyth County will repeatedly need additional surgical capacity to continue its game of musical chairs by shifting its operating room locations. Novant Health assumes that for the next six years, all surgical services will achieve 3.4 percent annual growth for both inpatient and outpatient cases at all locations. This blanket assumption is most unreasonable because

the historical 5-year CAGR varies greatly by licensed facility. Additionally, the overall Novant inpatient CAGR is -0.04 percent and the overall outpatient CAGR is 2.88 percent.

NHFMC	2012	2013	2014	2015	2016	2017	5 YR CAGR
Inpatient	10,905	11,892	12,409	9,519	9,262	10,483	-0.79%
Ambulatory	14,387	13,750	14,610	17,445	17,706	18,792	5.42%
NH Medical Park							
Inpatient	542	523	575	897	871	943	11.71%
Ambulatory	9,540	9,295	9,195	8,613	8,665	8,782	-1.84%
NHFMC + NH Medical Park	2012	2013	2014	2015	2016	2017	5 YR CAGR
Inpatient	11,447	12,415	12,984	10,416	10,133	11,426	-0.04%
Ambulatory	23,927	23,045	23,805	26,058	26,371	27,574	2.88%

It would be more reasonable to use the above 5-year CAGR to predict utilization for inpatient and ambulatory cases at the existing facilities plus the expected shift in cases for the approved Novant projects.

The 3.4 percent annual growth assumption for both inpatient and outpatient cases at all Novant locations is inconsistent with the representations in Project ID # G-11300-17. Previously, Novant stated that outpatient surgery continues to increase in the United States for two major reasons: continued advances in medical technology and increasing emphasis on cost containment initiatives. Furthermore, Novant stated that concern over rising health care costs and changes resulting from the Affordable Care Act have changed reimbursement for outpatient surgery and resulted in payors and patients demanding a shift of less complex surgery to outpatient settings. The applicant also states that Medicare and Medicaid are approving more procedures for reimbursement in a freestanding outpatient setting, such that many types of surgeries previously performed in hospitals and requiring overnight stays increasingly are performed during outpatient visits.

Utilization projections are flawed because the application erroneously projects that the proposed addition of two operating rooms at the Clemmons facility will not disrupt scheduling of cases and productivity at the Clemmons facility. The application does not explain how the renovations and addition of two proposed operating rooms could be

accomplished because these ORs are in the same sterile corridor as the previously approved rooms.

Volume projections for the proposed project are unreliable because the Novant Clemmons application lacks letters of support from ophthalmologist, oral surgeons, otolaryngologists and plastic surgeons. It is unclear in the project application if these ambulatory surgery cases are included in the expected shift of cases from other Novant facilities to support the need for additional OR capacity in Clemmons. In previous CON findings, the Agency has not accepted surgery volumes that lacked adequate physician support.

Criterion 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.”*

The Novant Clemmons application fails to comply to Criterion 4 because the application proposes to develop additional ambulatory surgery OR capacity that is not an effective alternative:

- Utilization projections are overstated and unreasonable.
- Novant fails to consider increasing the hours of operation for its existing operating rooms to meet or exceed the standards set for in the 2018 SMFP.
- Locating additional ORs in Clemmons would make these rooms distant from most low-income Forsyth County residents.

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

The Novant Clemmons application fails to comply to Criterion 5 because the operational and financial projections are not based on reasonable assumptions. As explained in the

Criterion 3 comments, the methodology and assumptions are flawed, resulting in overstated volumes. Financial projections are flawed because the application erroneously projects that the proposed addition of two operating rooms the facility will not incur operational costs prior to the licensure of the two additional ORs.

Forms F.4 and F.5 in the Novant Clemmons application do not list the payor categories in accordance with the CON forms that define the following payor categories:

- Self Pay
- Charity Care
- Medicare (including any managed care plans)
- Medicaid (including any managed care plans)
- Insurance (including any managed care plans)
- Workers Compensation
- TRICARE
- Other (Specify)

Due to the modification of the CON form, the application fails to provide the financial data requested by the Agency. The payor percentages for the Novant Clemmons No. G-11518-18 application are inconsistent with the projections in the previous application.

Payor Source	Entire Facility: Novant Health Clemmons Outpatient Surgery, LLC	Operating Rooms at Novant Health Clemmons Outpatient Surgery, LLC	Procedure Rooms	GI Endo Rooms
Self-Pay/Charity	1.5%	1.5%	1.5%	N/A%
Medicare *	44.2%	44.2%	44.2%	N/A%
Medicaid *	5.3%	5.3%	5.3%	N/A%
Insurance *	44.4%	44.4%	44.4%	N/A%
Workers Compensation and Other Government	4.6%	4.6%	4.6%	N/A%
Total	100.0%	100.0%	100.0%	100.0%

* Including any managed care plans.

Source: Section Q, Form F4

This project does not involve Procedure Rooms or GI Endo Rooms.

In contrast, the payor percentages for the previous Project ID No. G-11300-17 are as follows:

Payor Category	Outpatient Surgical Cases as Percent of Total
Self Pay/Indigent	2.1%
Medicare/Medicare Managed Care	31.1%
Medicaid	5.8%
Commercial Insurance/ Managed Care	53.3%
Other (not specified)	7.7%
Total	100.00%

The major discrepancies in the payor percentages included in Project ID No. G-11518-18 and the previously-approved Project ID No. G-11300-17 cannot be explained without amending the application.

Criterion 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 Novant Clemmons proposal fails to comply with Criterion 6 because the operational and financial projections are not based on reasonable assumptions. As explained in the Criterion 3 comments, the methodology and assumptions are flawed, resulting in overstated volumes. The application documents that the previously-approved Novant Clemmons ambulatory surgery center (with the initial two ORs) is not yet operational. Its projected utilization is now entirely speculative because the 2018 SMFP provides need determinations for additional operating rooms that have potential to shift utilization to a new provider.

By its own admission, Novant Health is not fully utilizing its existing operating rooms at its Forsyth facilities up to the average annual hours that are assigned in the 2018 SMFP. The Novant FMC operating rooms averaged less than 10 hours per day and 260 days per year. Also, the Novant Medical Park operating rooms averaged less than 9 hours per day and 260 days per year. Limiting the hours of operation restricts access and contributes to unnecessary duplication of existing health services.

As demonstrated in the CON capital cost worksheet and the financial pro formas, operating rooms are very costly to construct and operate. Novant Health fails to demonstrate that the proposed project is cost-effective because it consistently underutilizes its surgical resources at less than the average annual hours per year that are assigned in the 2018 SMFP. Novant's inability or unwillingness to staff and operate its existing and approved operating rooms up to the minimum standards makes its services less efficient and costlier.

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

(c) That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services."

Novant Clemmons fails to comply to Criterion 13c because the proposed project in Clemmons will not provide adequate access to low income persons, including Medicare and Medicaid patients. This project application includes payor percentages that are Inconsistent, as seen below for Novant Clemmons No. G-11518-18 with the projections in the previous application:

Payor Source	Entire Facility: Novant Health Clemmons Outpatient Surgery, LLC	Operating Rooms at Novant Health Clemmons Outpatient Surgery, LLC	Procedure Rooms	GI Endo Rooms
Self-Pay/Charity	1.5%	1.5%	1.5%	N/A%
Medicare *	44.2%	44.2%	44.2%	N/A%
Medicaid *	5.3%	5.3%	5.3%	N/A%
Insurance *	44.4%	44.4%	44.4%	N/A%
Workers Compensation and Other Government	4.6%	4.6%	4.6%	N/A%
Total	100.0%	100.0%	100.0%	100.0%

* Including any managed care plans.

Source: Section Q, Form F4

This project does not involve Procedure Rooms or GI Endo Rooms.

The payor percentages for the previous Project ID No. G-11300-17 is as follows:

Payor Category	Outpatient Surgical Cases as Percent of Total
Self Pay/Indigent	2.1%
Medicare/Medicare Managed Care	31.1%
Medicaid	5.8%
Commercial Insurance/Managed Care	53.3%
Other (not specified)	7.7%
Total	100.00%

There are major discrepancies in the payor percentages that are projected for Medicare and Commercial Insurance based on the comparison of the Novant Clemmons Project ID No. G-11518-18 and Project ID No. G-11300-17. Page 72 of the G-11518-18 application states that the payor mix is based on historical data for Novant Health Clemmons Medical Center and the budgeted Novant Health Kernersville Outpatient Surgery. However, these historical data and budget are omitted from the application.

Criterion 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.”

Operational and financial projections in the Novant Clemmons application are unreasonable as discussed in the Criterion 3 and 5 comments. Therefore, the application fails to demonstrate that the project will provide any enhanced competition in the service area. Access to services is uncertain due to the discrepancies in the payor percentages that are projected for Medicare and Commercial Insurance based on the comparison of the Novant Clemmons No. G-11518-18 and Project ID No. G-11300-17.

Consequently, the application is nonconforming with Criterion 18a.

10A NCAC 14C.2103 Performance Standards.

(f) The applicant shall document the assumptions and provide data supporting the methodology used for each projection in this Rule.

Novant Clemmons documents the assumptions and provides data supporting the methodology used for its operating room projections. However, the applicant's projected utilization is not reasonable and adequately supported. Novant Health has a surplus of operating rooms and fails to utilize its operating rooms up to the average annual hours that are assigned in the 2018 SMFP. The discussion regarding analysis of need, including projected utilization, found in Criterion (3) is incorporated herein by reference. Thus, the Novant Clemmons application is not conforming with this rule.

Comments Specific to Novant FMC Project ID No. G-11517-18). Add two operating rooms for a total of 35 operating rooms on the hospital's license

The Novant FMC project application is nonconforming with CON Review Criteria based on the multiple deficiencies in the project application.

- The Novant FMC application wrongly claims that it has a need for ORs based on location-specific assumptions that are inconsistent with the OR methodology in the 2018 SMFP.
- Novant chooses to operate its existing operating rooms that are licensed under Novant FMC (HO209) at less than the standard 1950 annual hours per operating room as assigned in the 2018 S MFP
- Novant chooses to operate its existing operating rooms that are licensed under Novant Medical Park (HO229) at less than the standard 1755 annual hours per operating room as assigned in the 2018 SMFP.
- For the most recent five-year period, the inpatient surgery utilization at Novant FMC shows no growth; inpatient cases for the most recent three consecutive years (2015, 2016 and 2017) are all less than the annual cases for 2012, 2013, 2014.
- The Novant FMC application fails to explain why the continued recruitment of physicians in 2015 through 2017 have not increased inpatient surgery utilization to the higher annual volumes achieved in previous years 2012 to 2014.
- The Novant FMC application uses an unreasonable and overstated 3.4 percent annual growth rate for all inpatient and outpatient surgery locations that exceeds the historical 5-year compound annual growth rate for the Novant Health Forsyth facilities.
- Financial statements for the proposed project lack credibility due to overstated utilization and inconsistent payor percentages

These deficiencies cause the application to be nonconforming with the following criteria:

Criterion 1 *“The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which shall constitute a determinative limitation on the provision of any health services, health service facility, health service beds, dialysis stations. Operating rooms, or home health offices that may be approved.”*

POLICY GEN-3: BASIC PRINCIPLES states:

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

The proposed Novant FMC application fails to conform with Criterion 1 and Policy GEN-3 because the projected surgery patient volumes are overstated. Volume projections for the project are unreliable because the Novant FMC application uses overstate growth projections. Novant fails to explain why the continued recruitment of physicians at Novant FMC from 2015 through 2017 have not increased inpatient surgery utilization to the higher annual volumes achieved in previous years.

Criterion 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 patient origin percentages on page 16 of the application are incorrect because the application fails to take into consideration the shift of inpatients to Novant Health Clemmons Medical Center. This shift is not reflected in the historical data because it only began to occur in August 2017. If this shift of surgery cases is expected to continue to ramp up, then the percentages of patients from Davis and Yadkin Counties to be served at the proposed ORs at Novant FMC would not remain the same as the historical 2017 data.

Novant alleges that it has an unmet need for ORs. However, Novant is not utilizing its existing ORs up to the average annual hours that are assigned to its facilities in the 2018 SMFP. If Novant had a genuine need for additional ORs, it would be staffing and utilizing its existing ORs for more annual hours than the standards assigned in the 2018 SMFP.

The operating room methodology in the 2018 State Medical Facilities Plan categorizes each licensed facility with ORs into Groups (1 through 6) and assigns the average annual hours of operation and average case times. Novant dislikes this methodology and irrationally argues that each of its locations should use their actual 2018 annual hours of operation even though these hours vary significantly by location and the Novant Kernersville ASC and the Novant Clemmons ASC are not yet operational.

Novant Health unreasonably assumes that for the next six years all its surgical services, inpatient and outpatient, will achieve 3.4 percent annual growth at all of its locations. This blanket assumption is most unreasonable because the historical 5-year CAGR varies greatly by licensed facility. Additionally, the overall Novant inpatient CAGR is -0.04 percent and the overall outpatient CAGR is 2.88 percent.

NHFMC	2012	2013	2014	2015	2016	2017	5 YR CAGR
Inpatient	10,905	11,892	12,409	9,519	9,262	10,483	-0.79%
Ambulatory	14,387	13,750	14,610	17,445	17,706	18,792	5.42%
NH Medical Park							
Inpatient	542	523	575	897	871	943	11.71%
Ambulatory	9,540	9,295	9,195	8,613	8,665	8,782	-1.84%
NHFMC + NH Medical Park	2012	2013	2014	2015	2016	2017	5 YR CAGR
Inpatient	11,447	12,415	12,984	10,416	10,133	11,426	-0.04%
Ambulatory	23,927	23,045	23,805	26,058	26,371	27,574	2.88%

It would be more reasonable to use the above 5-year CAGR to predict utilization for inpatient and ambulatory cases at the existing facilities, plus the expected shift in cases to the approved Novant projects.

The 3.4 percent annual growth assumption for both inpatient and outpatient cases at all Novant locations is inconsistent with the representations in Project ID # G-11300-17. Previously, Novant stated that outpatient surgery continues to increase in the United States for two major reasons: continued advances in medical technology and increasing emphasis on cost containment initiatives. Furthermore, Novant stated that concern over rising health care costs and changes resulting from the Affordable Care Act have changed reimbursement for outpatient surgery and resulted in payors and patients demanding a shift of less complex surgery to outpatient settings. The applicant also states that Medicare and Medicaid are approving more procedures for reimbursement in a freestanding outpatient setting, so that many types of surgeries previously performed in hospitals and requiring overnight stays are increasingly performed on an outpatient basis.

Novant FMC's proposed operating rooms do not improve patient access for low income persons because the existing hospital-based operating rooms are very costly and have day-to-day operational issues. Even if Novant FMC were to obtain additional OR capacity, there is no commitment in the application to increase the hours of operation to meet the standard of 1950 annual hours per OR.

Criterion 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.”*

The Novant FMC application fails to comply to Criterion 4 because the application proposes to develop additional hospital-based OR capacity that is not an effective alternative:

- Utilization projections are overstated and unreasonable.
- Novant fails to consider increasing the hours of operation for its existing operating rooms to meet or exceed the standards set in the 2018 SMFP.
- Locating additional shared ORs at Novant FMC Main (Winston-Salem) does not extend the hours of operation or improve access at the multiple other locations that are under the Novant FMC license.

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

The Novant FMC application fails to comply to Criterion 5 because the operational and financial projections are not based on reasonable assumptions. As explained in the Criterion 3 comments, the methodology and assumptions are flawed resulting in overstated volumes. The revenues and expenses in the project application predict continual increases in future years with no opportunities for cost savings to patients or payors.

Forms F.4 and F.5 in the Novant FMC application do not list the payor categories in accordance with the CON forms that define the following payor categories:

- Self Pay
- Charity Care
- Medicare (including any managed care plans)
- Medicaid (including any managed care plans)
- Insurance (including any managed care plans)
- Workers Compensation
- TRICARE
- Other (Specify)

Due to the modification of the CON form, the application fails to provide the financial data required by the Agency.

Criterion 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 Novant FMC proposal fails to comply with Criterion 6 because the operational and financial projections are not based on reasonable assumptions. As explained in the Criterion 3 comments, the methodology and assumptions are flawed, resulting in overstated volumes. Novant Health admits that it not fully utilizing its existing operating rooms at its Forsyth facilities up to the average annual hours that are assigned in the 2018 SMFP. The Novant FMC operating rooms averaged less than 10 hours per day and 260 days per year. The application provides no commitment to utilize its existing and proposed operating rooms at 1950 annual hours per operating room. Continuing to limit the hours of operation restricts access and contributes to unnecessary duplication of existing health services.

Criterion 13c *“The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed*

services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:

(c) That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services."

Novant FMC fails to comply to Criterion 13c because the proposed project will not provide adequate access to low income persons, including Medicare and Medicaid patients:

- The projected utilization and payor percentages are not based on reasonable assumptions.
- Hospital-based shared operating rooms have much higher costs and charges as compared to freestanding ambulatory surgical facilities.
- The applicant chose to modify the CON application form to omit specified payor categories.

Criterion 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."*

Operational and financial projections in the Novant FMC application are unreasonable as discussed in the Criteria 3 and 5 comments. Accordingly, the application fails to demonstrate that the project will provide any enhanced competition in the service area. Access to services is uncertain due to the lack of commitment by the applicant to utilize its existing and proposed operating rooms at 1950 annual hours per operating room. For these reasons, the application is nonconforming with Criterion 18a.

10A NCAC 14C.2103 Performance Standards.

(f) The applicant shall document the assumptions and provide data supporting the methodology used for each projection in this Rule.

Novant FMC documents the assumptions and provides data supporting the methodology used for its operating room projections. However, the applicant's projected utilization is not reasonable and adequately supported. Novant Health has a surplus of operating rooms and fails to utilize its operating rooms up to the average annual hours that are assigned in the 2018 SMFP. The discussion regarding analysis of need, including projected utilization, found in Criterion 3 is incorporated herein by reference. Consequently, the Novant FMC application is not conforming with this rule.

Comments Specific to Triad Surgery Center / Cone Health Project ID No. G-11516-18. New ambulatory surgical facility with two operating rooms, one GI endoscopy procedure room and one procedure room in Kernersville

The Triad Surgery Center/Cone Health (Cone) project application does not conform with the CON Review Criteria for multiple reasons:

- The projected patient origin is unreasonable because it is based on the expected referrals from four primary care practices, two of which are in Guilford County, rather than the historical patient origin of the participating surgeons who expressed support for the project.
- The Form C assumptions and methodology includes a map with the locations of the primary care physicians who are expected to refer patients to the surgeons who want to obtain privileges at Cone. Omitted from the map are the practice locations of the participating surgeons because most have offices in Greensboro, 20 miles distant from the proposed facility location.
- Letters of support included in the Cone proposal are inadequate with less volume projected for operating rooms as compared to OR projections for Years 2 and 3..
- The need methodology wrongly assumes that patients referred by Cone primary care physicians will always choose the Cone-affiliated surgeons and not seek a second opinion or choose non-Cone surgeons.
- The historical data for Cone Health inpatient and ambulatory surgery data shows that the referral relationship with primary care physicians and surgeons has consistently failed to increase utilization of the existing Cone Health operating rooms in Guilford County.
- Financial statements for the proposed project lack credibility due to overstated utilization, omitted expenses, and the misleading representation of combined lease, housekeeping, maintenance and utilities expenses.
- Quality of care data is omitted for the Cone Health hospital-based operating rooms.

These deficiencies cause the application to be nonconforming with the following criteria:

Criterion 1 *“The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which shall constitute a determinative limitation on the provision of any health services, health service facility, health service beds, dialysis stations. Operating rooms, or home health offices that may be approved.”*

POLICY GEN-3: BASIC PRINCIPLES states:

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

The Cone application is nonconforming with Criterion 1 and Policy GEN-3 because the patient origin projections are unreasonable and the projected patient volumes for surgery and GI endoscopy are overstated. Affluent Kernersville is not an optimal location to provide equitable access for patients with limited financial resources.

Cone Health has historically seen a decline in ambulatory surgery market share, decreasing from 40 percent in 2008 to 37.4 percent in 2017. Further, Cone Health has surplus operating room capacity in Greensboro. It makes no sense to suggest that Greensboro-based surgeons will drive to Kernersville to perform cases in two ambulatory ORs, because the surgeons have far greater access to existing operating room capacity in established Greensboro facilities.

Criterion 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.”*

Failing to accurately identify the population to be served by the project is where this application initially goes awry. While the application asserts that the four primary care practices referred a combined 7,009 patients to surgical specialists in 2017, the methodology only guesses at the number of patients that obtained surgery. Further, the methodology provides no information regarding where these patients originated or where the surgeries were performed. With the surplus of operating rooms at Cone Health in Guilford County, it is unreasonable to expect that the Cone Health primary care practices will be referring more Guilford County patients to Kernersville. If this were to occur, then the surplus of ORs at Guilford Cone Health facilities would increase.

The Cone methodology is based on guesswork instead of historical data because the Cone Health surgery utilization trend is negative as seen in the next table:

Moses Cone Health System

Year	Inpatient Surgery	Ambulatory Surgery	Total Cases
FY 2008	13,723	20,083	33,806
FY 2009	13,325	19,361	32,686
FY 2010	13,430	17,878	31,308
FY 2011	13,111	17,199	30,310
FY 2012	13,081	17,140	30,221
FY 2013	13,869	15,870	29,739
FY 2014	12,798	16,251	29,049
FY 2015	13,014	16,229	29,243
FY 2016	13,363	16,139	29,502
FY 2017	13,232	15,788	29,020
Change FY 2008 to FY 2017	-491	-4295	-4786
% Change FY 2008 to FY 2017	-3.58%	-21.39%	-14.16%
CAGR 2008 to 2017	-0.40%	-2.64%	-1.86%

In 2007, Cone Health made the business decision to convert Wesley Long Surgery Center and Moses Cone Surgery Center from freestanding ambulatory surgical facilities to licensed hospital operating rooms under Cone Health (HO159). Since that time, patients and payors have been billed at the higher hospital rates for outpatient surgery at these locations. Thus, Cone Health chose to maximize revenues, even though competing ambulatory surgical facilities in Guilford County would gain market share because these facilities offer outpatient surgery at substantially lower costs.

Letters of support included in the Cone proposal are inadequate and total hundreds less cases than the volume projected for operating rooms in Year 2. The applicant wrongly projects 3.5 percent annual growth in referral volume for intervening years prior to the opening of the facility. It is impossible to grow referral volume in a facility that does not exist.

One of the steps in the Cone methodology (Form C Assumptions and Methodology, page 4) assumes 70 percent of the referrals will be outpatient and ASC-appropriate for each of

the surgical specialties; this is not consistent with reality. Cone Health’s 2018 LRA data shows that the percentages for orthopedics, general surgery and neurosurgery are less than 70 percent ambulatory. Using the overstated 70 percent assumption causes the projected numbers of cases for orthopedics, general surgery and neurosurgery to be unreasonable.

Cone Health 2018 LRA Data

OR Surgery Cases	Inpatient	Ambulatory	Total	Inpatient %	Ambulatory %
Orthopedics	5,096	3,966	9,062	56.23%	43.77%
General Surgery	1,894	3,765	5,659	33.47%	66.53%
Neurosurgery	1,408	606	2,014	69.91%	30.09%

The 70 percent assumption fails to consider that lower percentages should be assigned to many of the high-volume cases that include orthopedics, general surgery and neurosurgery as documented in the HCUP AHRQ Statistical Brief 223 (www.hcup-us.ahrq.gov/reports/statbriefs/sb223-Ambulatory-Inpatient-Surgeries-2014.pdf)

In addition to the erroneous 70 percent assumption, the Cone methodology includes a 3.5 percent annual growth factor when the actual 2008-2017 CAGR for Cone Health total ambulatory surgery utilization has been -2.64 percent. It is unreasonable to assume that the 3.5 percent growth factor should be applicable to the Cone project because approximately 40 percent of the patients are projected to be from Guilford County and the 2014 to 2017 CAGR for Guilford ambulatory surgery is only 0.08 percent.

The application attempts to justify the proposed ambulatory surgical facility project in conjunction with the Triad HealthCare Network (THN) as an opportunity to extend high quality care and cost savings. However, the absence of any existing Cone Health freestanding ambulatory surgery centers in Guilford, Randolph and Alamance Counties demonstrates that the success of the THN relates to the performance of the physicians and not due to the coordination of care between THN and Cone-managed ambulatory surgical facilities.

The application's discussion of the proposed project's ambulatory surgery market share surgery is based on comparisons to other markets and is not credible because the operating room inventory in Forsyth County is skewed by the dominance of NC Baptist and Novant Health. Cone Health has been unable to increase ambulatory surgery volumes and market share in its home county. Therefore, the applicant's market share assumptions and analysis for Forsyth County are not convincing.

The application states that Cone Health identified 3,406 referrals to gastroenterologists from primary care practices but failed to provide the patient origin and where these patients chose to obtain their GI endoscopy procedures. It is also unclear if these 3,406 referrals include or exclude patients who self-refer to gastroenterologists. The 2018 SMFP shows that Cone Health has surplus GI endoscopy room capacity in Guilford County. The GI endoscopy utilization at Cone Health decreased from 5,477 cases in 2012 to 4,476 cases in 2017, for an 18.3 percent reduction. Cone Health has been unable to increase GI endoscopy volumes and market share in its home county. It is clear that primary care referrals to the existing Cone Health endoscopy procedure rooms are decreasing.

Furthermore, it is unreasonable to expect that Cone Health primary care practices will refer more GI endoscopy patients from Guilford County to Kernersville (which is in Forsyth County). If this were to occur, then the surplus of GI endoscopy rooms at Cone Health facilities in Guilford would increase in future years.

Criterion 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."*

Cone fails to comply with Criterion 4 because the application proposes to develop a new ambulatory surgical facility that is not an effective alternative:

- Utilization projections are overstated and unreasonable.

- Locating the facility in Kernersville would make it distant from most low-income Forsyth County residents.
- It is unlikely that increased numbers of patients from Guilford County will choose to go to Kernersville.
- It is unlikely that Greensboro-based surgeons will choose to go the Kernersville when they have abundant access to operating rooms in close proximity to their offices.
- The proposed project is not an effective alternative in terms of providing access to Medicare and Medicaid patients.

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

Cone fails to comply with Criterion 5 because the operational and financial projections are not based on reasonable assumptions. As explained in the Criterion 3 comments, the methodology and assumptions are flawed resulting in overstated volumes.

The lease expense for the proposed project is unreasonable because it includes the lease of the building and land plus operating expenses for housekeeping, laundry, and utilities. No information is provided in the application to demonstrate that the budgeted amount for these combined line items is adequate and based on reasonable assumptions for the proposed 15,500 square foot building. Combining these expenses misrepresents estimated costs, which should be a warning sign to potential physician investors.

According to Form F.1a, the project includes \$3,579,620 in medical equipment, \$1,198,323 of nonmedical equipment and \$54,750 for furniture. Based on this capital cost, the Form F.3 and F.4 financial statements omit \$693,513 in annual depreciation costs.

Section F, page 62 of the application states that the working capital amount is projected to be \$1,041,467. Amortizing this cost over 5 years demonstrates that the omitted amount for annual amortization expense is \$208,293.

The financial statements Form F.3 and F.4 are incorrect based on the omitted expenses for depreciation and amortization. The following table shows the calculations for these omitted expenses:

	Amount	Depreciation Life	Annual Depreciation Expense
Medical Equipment	\$3,579,620	7	\$511,374
Non Medical Equipment	\$1,198,323	7	\$171,189
Furniture	\$54,750	5	\$10,950
Total			\$693,513
		5 Year Amortization	
Working Capital	\$1,041,467		\$208,293
Depreciation and Amortization			\$901,807

Cone’s financial assumptions include the statement, *“Additionally, Cone Health relied upon the experience of other comparable freestanding ASCs including Union West Surgery Center (UWSC) as documented in its approved CON (Project ID #11348-17) to add a third OR pursuant to a need determination in the 2017 SMFP for a total of three ORs. Cone Health believes that UWSC serves as a reasonable basis for comparison based on a comparable number of ORs, scope of services and operate in a similar market.”* This assumption regarding the reasonableness of using UWSC financial metrics for the Cone pro forma is incorrect as follows:

- Cone unreasonably predicts higher numerical growth than UWSC. Cone projects to provide more than 2,000 surgery cases in its first full year of operation; UWSC did not exceed 2,000 annual OR cases until 2015, its third full year of operation.
- Unlike the proposed Cone project that includes no ophthalmology, approximately 65 percent of the surgery cases performed at UWSC are ophthalmology procedures.

- Cone states that its proposed ORs are Group 6 with 68.6 minutes assigned per ambulatory surgery case; the ORs at UWSC are categorized as Group 5 with 45 minutes assigned per ambulatory surgery case.
- Cone proposes one GI endoscopy procedure room while UWSC has no GI endoscopy rooms.
- Cone proposes to develop one procedure room for non-surgical procedures while UWSC does not report performing any non-surgical procedures.
- Cone proposes to serve 31.1 percent Medicare and 1.0 percent Medicaid as compared to UWSC, which serves 47.3 percent Medicare and 11.0 percent Medicaid.
- Forsyth County has two existing hospitals, neither of which is operated by Cone Health (or Carolinas Healthcare System), while the one hospital in Union County is Carolinas Healthcare System-Union.
- Cone's financial statements omit depreciation and amortization expenses which is inconsistent with the Union West Surgery Center application that includes depreciation and amortization.

Forms F.5 and F.6 in the Cone application do not list the payor categories in accordance with the CON forms that define the following payor categories:

Self Pay
 Charity Care
 Medicare (including any managed care plans)
 Medicaid (including any managed care plans)
 Insurance (including any managed care plans)
 Workers Compensation
 TRICARE
 Other (Specify)

Due to the modification of the CON form, the application fails to provide the financial data requested by the Agency.

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

Cone fails to comply with Criterion 6 because the operational and financial projections are not based on reasonable assumptions. As explained in the Criterion 3 comments, the methodology and assumptions are flawed resulting in overstated volumes. The application documents that the Cone Health primary care physicians have referred patients to the surgeons and gastroenterologists who have interest in participating in the proposed Kernersville project. It is unclear if these patients are currently being referred to existing operating rooms in Forsyth or Guilford Counties. Cone Health has existing health service capabilities in Guilford County with abundant capacity to serve ambulatory surgery and GI endoscopy patients. It is unreasonable to assume that patients from Guilford County have a need to be referred to Kernersville because there are existing ambulatory surgical facilities and hospitals in Guilford County.

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

(c) That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services.”

Cone fails to comply with Criterion 13c because the proposed project in Kernersville will not provide adequate access to low income persons, including Medicare and Medicaid patients. Developing a new ASF in Kernersville does not improve access for low income

persons that reside in Winston-Salem. This project proposes to serve the lowest combined percentages of Medicare and Medicaid of any licensed facility in Forsyth County as seen in the following table:

	NC Baptist		Novant FMC		Novant Medical Park		Piedmont Outpatient Surgery Center	
Self Pay/Charity/Indigent	1097	5.49%	383	2.04%	267	3.04%	25	1.07%
Medicare	5754	28.77%	9192	48.91%	3419	38.93%	232	9.97%
Medicaid	3926	19.63%	1651	8.79%	507	5.77%	801	34.42%
Commercial	123	0.62%	74	0.39%	34	0.39%	1261	54.19%
Managed Care	7998	39.99%	6893	36.68%	4357	49.61%	0	0.00%
Other	1102	5.51%	600	3.19%	198	2.25%	8	0.34%
Total	20000	100.00%	18793	100.00%	8782	100.00%	2327	100.00%
Combined Medicare and Medicaid		48.40%		57.70%		44.70%		44.39%

	TSC/CH
Self Pay/Charity/Indigent	0.30%
Medicare	31.10%
Medicaid	1.00%
Commercial	64.10%
Managed Care	
Other	3.50%
Total	100.00%
Combined Medicare and Medicaid	32.10%

Criterion 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 operational and financial projections in the Cone application are unreasonable as discussed in the Criteria 3 and 5 comments. Therefore, the application fails to demonstrate that the project will provide any enhanced competition in the service area. Cone fails to demonstrate that the project is cost effective because the financial projections are unreliable. The proposal will limit access and will serve unacceptably low percentages of patients who are low income, Medicare and Medicaid. Consequently, the application is nonconforming with Criterion 18a.

Criterion 20 *“An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.”*

The Cone application is nonconforming with Criterion 20 because the applicant omitted the quality information for the operating rooms at the Cone Health Hospitals in its responses to Section O, question 3a through c. The Criterion states that the applicant “shall provide evidence” that quality of care has been provided in the past. Now that the CON deadline has passed, Cone Health is not permitted to supplement its application to provide the missing information. Since the information provided by Cone is deficient and incomplete, it is not the responsibility of the CON analyst to attempt to evaluate data that is not present.

10A NCAC 14C.2103 Performance Standards.

(f) The applicant shall document the assumptions and provide data supporting the methodology used for each projection in this Rule.

Cone documents the assumptions and provides data supporting the methodology used for its operating room projections. However, Cone’s projected utilization is not reasonable and adequately supported. Cone Health has a surplus of operating rooms and a clear trend of decreasing ambulatory surgery utilization. The discussion regarding analysis of need, including projected utilization, found in Criterion (3) is incorporated herein by reference. Thus, the Cone application is not conforming with this rule.

10A NCAC 14C.3903 Performance Standards.

(e) An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop an additional GI endoscopy room in an existing licensed health service facility shall describe all assumptions and the methodology used for each projection in the Rule.

Cone documents the assumptions and provides data supporting the methodology used for its GI endoscopy projections. However, Cone's projected utilization is not reasonable and adequately supported. The GI endoscopy utilization at Cone Health decreased from 5,477 cases in 2012 to 4,476 cases in 2017, for an 18.3 percent reduction. Cone Health has been unable to increase GI endoscopy volumes and market share in its home county. Additional discussion regarding analysis of need, including projected utilization, found in Criterion 3 is incorporated herein by reference. Thus, the Cone application is not conforming with this rule.