ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

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

Decision Date:	October 26, 2018
Findings Date:	November 2, 2018
Droiget Analyst	Colio C. Inmon

Project Analyst:	Celia C. Inman
Assistant Chief:	Lisa Pittman
Chief:	Martha Frisone

COMPETITIVE REVIEW

Project ID #:	G-11513-18
Facility:	Triad Center for Surgery
FID #:	180267
County:	Forsyth
Applicant:	Triad Center for Surgery, LLC
Project:	Develop a new ASF with 2 ORs, pursuant to the 2018 SMFP need
	determination, and 3 procedure rooms
Project ID #:	G-11516-18
Facility:	Triad Surgery Center
FID #:	180260
County:	Forsyth
Applicants:	The Moses H. Cone Memorial Hospital
	MC Kernersville, LLC
Project:	Develop a new ASF in Kernersville with 2 ORs, pursuant to the 2018 SMFP
	need determination, 1 GI endoscopy room and 1 procedure room
Project ID #:	G-11517-18
Facility:	Novant Health Forsyth Medical Center
FID #:	923174
County:	Forsyth
Applicants:	Novant Health, Inc.
	Forsyth Memorial Hospital, Inc.
Project:	Add 2 ORs, pursuant to the 2018 SMFP need determination, for a total of 35
	ORs on the hospital license upon completion of this project

Project ID #: Facility: FID #: County: Applicants: Project:	G-11518-18 Novant Health Clemmons Outpatient Surgery 170068 Forsyth Novant Health, Inc. Novant Health Clemmons Outpatient Surgery, LLC Add 2 ORs, pursuant to the 2018 SMFP need determination, to the previously
	approved ASF for a total of 4 ORs upon completion of this project and Project ID #G-11300-17 (relocate 2 ORs from Novant Health Winston-Salem)
Project ID #:	G-11519-18
Facility:	North Carolina Baptist Hospital
FID #:	943495
County:	Forsyth
Applicant:	North Carolina Baptist Hospital
Project:	Add 4 ORs, pursuant to the 2018 SMFP need determination, for a total of 51 ORs upon completion of this project and Project ID #G-8460-10 (add 7 dedicated outpatient ORs pursuant to Policy AC-3)

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C TCS Cone Health NCBH

NC NH Forsyth NH Clemmons

Need Determination

Chapter 6 of the 2018 State Medical Facilities Plan (SMFP) includes a methodology for determining the need for additional operating rooms (ORs) by service area. Application of the standard need methodology in the 2018 SMFP identifies a need for four additional ORs in the Forsyth County operating room service area. Five applications were submitted to the Healthcare Planning and Certificate of Need Section (Agency): one proposing to develop four new ORs, and the other four applications each proposing to develop two ORs in the Forsyth County operating room service area. The five applicants have applied for a combined total of 12 new Forsyth County ORs. Pursuant to the need determination in Table 6C, page 80 of the 2018 SMFP, only four new ORs may be approved in this review for the Forsyth County operating room service area.

Policies

There are two policies in the 2018 SMFP which are applicable to each of the applications in this review: Policy GEN-3: Basic Principles and Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities.

Policy GEN-3, on page 33 of the 2018 SMFP, states:

"A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area." Policy GEN-4, on page 33 of the 2018 SMFP, states:

"Any person proposing a capital expenditure greater than \$2 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178 shall include in its certificate of need application a written statement describing the project's plan to assure improved energy efficiency and water conservation.

In approving a certificate of need proposing an expenditure greater than \$5 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178, Certificate of Need shall impose a condition requiring the applicant to develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. The plan must be consistent with the applicant's representation in the written statement as described in paragraph one of Policy GEN-4.

Any person awarded a certificate of need for a project or an exemption from review pursuant to G.S. 131E-184 are required to submit a plan of energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation. The plan must be consistent with the applicant's representation in the written statement as described in paragraph one of Policy GEN-4. The plan shall not adversely affect patient or resident health, safety or infection control."

Triad Center for Surgery, LLC (TCS), "the applicant", proposes to establish a new ambulatory surgery facility (ASF) in Winston-Salem, Forsyth County by developing two new ORs and three procedure rooms.

Need Determination. The applicant does not propose to develop more new ORs than are determined to be needed in the 2018 SMFP for the Forsyth County service area.

Policy GEN-3. The application under review is in response to the 2018 SMFP need determination for additional ORs in Forsyth County; therefore, Policy GEN-3 is applicable. The applicant addresses Policy GEN-3 as follows:

<u>Promote Safety and Quality</u> – The applicant describes how it believes the proposed project would promote safety and quality in Section B.3, pages 14-16, Section N, pages 92-94, Section O, pages 95-97, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would promote safety and quality.

<u>Promote Equitable Access</u> – The applicant describes how it believes the proposed project would promote equitable access in Section B.3, pages 15-16, Section C.8, pages 45-46, Section L, pages 85-90, Section N, pages 92-94, and referenced exhibits. The information

provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would promote equitable access.

<u>Maximize Healthcare Value</u> – The applicant describes how it believes the proposed project would maximize healthcare value in Section B.3, pages 15-16, Section E.2, pages 57-59, and the pro forma financial statements in Section Q. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would maximize healthcare value.

Policy GEN-4. The proposed capital expenditure for this project is greater than \$5 million; therefore, Policy GEN-4 is applicable. The applicant addresses Policy GEN-4 in Section B.3, page 18, where the applicant describes its plan to implement energy efficiency and water conservation standards at the proposed facility, including, LED lighting, low volume water flow restrictors, HVAC system with energy saving controls, energy efficient windows, high value insulation, natural light, and water conserving landscaping design.

Conclusion. The Agency reviewed the:

- application,
- exhibits to the application, and
- information publicly available during the review and used by the Agency.

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

- The applicant does not propose to develop more ORs than are determined to be needed in the service area; therefore, the application is consistent with the need determination in the 2018 SMFP.
- The applicant adequately demonstrates how the projected volumes incorporate the concepts of quality, equitable access and maximum value for resources expended in meeting the identified need. Therefore, the application is consistent with Policy GEN-3.
- The applicant adequately demonstrates that the application includes a written statement describing the project's plan to assure improved energy efficiency and water conservation. Therefore, the application is consistent with Policy GEN-4.

The Moses H. Cone Memorial Hospital (MHCMH) and MC Kernersville, LLC (MCK), collectively referred to as "Cone Health", or "the applicant", proposes to establish a new ASF in Kernersville, Forsyth County by developing two ORs, one gastrointestinal endoscopy (GI endo) room, and one procedure room.

Need Determination. The applicant does not propose to develop more new ORs than are determined to be needed in the 2018 SMFP for the Forsyth County service area.

Policy GEN-3. The application under review is in response to the 2018 SMFP need determination for additional ORs in Forsyth County; therefore, Policy GEN-3 is applicable. The applicant addresses Policy GEN-3 as follows:

<u>Promote Safety and Quality</u> – The applicant describes how it believes the proposed project would promote safety and quality in Section B.3, pages 15-18, Section N, pages 94-95, Section O, pages 97-99, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would promote safety and quality.

<u>Promote Equitable Access</u> – The applicant describes how it believes the proposed project would promote equitable access in Section B.3, pages 17-18, Section C.8, page 44, Section L, pages 87-90, Section N, page 95, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would promote equitable access.

<u>Maximize Healthcare Value</u> – The applicant describes how it believes the proposed project would maximize healthcare value in Section B.3, pages 17-18, Section E.2, page 58, Section N, page 93, and the pro forma financial statements in Section Q. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would maximize healthcare value.

Policy GEN-4. The proposed capital expenditure for this project is greater than \$5 million; therefore, Policy GEN-4 is applicable. In Exhibit B.4., the applicant's describes the plan to assure improved energy efficiency and water conservation, including energy efficient mechanical systems, low-flow plumbing fixtures, water-saving landscaping and reclaimed water for irrigation, and selection of construction materials to reduce negative impact on the environment.

Conclusion. The Agency reviewed the:

- application,
- exhibits to the application, and
- information publicly available during the review and used by the Agency.

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

- The applicant does not propose to develop more ORs than are determined to be needed in the service area; therefore, the application is consistent with the need determination in the 2018 SMFP.
- The applicant adequately demonstrates how the projected volumes incorporate the concepts of quality, equitable access and maximum value for resources expended in meeting the identified need. Therefore, the application is consistent with Policy GEN-3.

• The applicant adequately demonstrates that the application includes a written statement describing the project's plan to assure improved energy efficiency and water conservation. Therefore, the application is consistent with Policy GEN-4.

Novant Health, Inc. (NH) and Forsyth Memorial Hospital, Inc. (FMH), collectively referred to as "**NH Forsyth**" or "the applicant", proposes to add two ORs at the Novant Health Forsyth Medical Center main campus (FMC Main) in Winston-Salem, Forsyth County for a total of 22 ORs at FMC Main, including 2 dedicated C-Section and 3 Open Heart ORs. The NHFMC hospital license will have a total of 35 ORs upon completion of this project.

As defined by the 2018 SMFP operating room methodology, a "health system" includes all licensed health service facilities with operating rooms located in the same service area that are owned by the same parent company. According to the 2018 SMFP, the Novant Health System (NH Health System) has four existing and/or approved licensed surgical facilities in the Forsyth County operating room service area:

- 1. Novant Health Forsyth Medical Center (NHFMC), License H0209
 - Novant Health Forsyth Medical Center Main Campus (FMC Main)
 - Novant Health Kernersville Medical Center (NHKMC)
 - Novant Health Clemmons Medical Center (NHCMC)
 - Novant Health Hawthorne Outpatient Surgery (NHHOS)
 - Novant Health Orthopedic Outpatient Surgery (NHOOS)
- 2. Novant Health Medical Park Hospital (NHMPH), License H0229
- 3. Novant Health Kernersville Outpatient Surgery (NHKOS), Project ID #G-11150-16, scheduled to open June 2018
- 4. Novant Health Clemmons Outpatient Surgery (NHCOS), Project ID #G-11300-17, scheduled to open July 2019

The NH Health System submitted two separate applications on May 15, 2018: 1) Project ID #G-11517-18 / Add two ORs at FMC Main, and 2) Project ID #G-11518-18 / Add two ORs to NHCOS, a freestanding ASF under development in Clemmons, NC. Together, the two applications apply for four ORs, pursuant to the 2018 SMFP need determination for four ORs in Forsyth County.

The addition of two ORs at FMC Main, as proposed in this application, would bring the total number of ORs (including 2 dedicated C-Section and 3 Open Heart) at FMC Main and on the NHFMC hospital license to 22 and 35, respectively, upon completion of this project, Project ID #G-11300-17 and Project ID #G-11150-16.

Need Determination. The applicant does not propose to develop more new ORs than are determined to be needed in the 2018 SMFP for the Forsyth County service area.

Policy GEN-3. The application under review is in response to the 2018 SMFP need determination for additional ORs in Forsyth County; therefore, Policy GEN-3 is applicable. The applicant addresses Policy GEN-3 as follows:

<u>Promote Safety and Quality</u> – The applicant describes how it believes the proposed project would promote safety and quality in Section B.3, page 8, Section N, page 83, Section O, pages 84-86, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would promote safety and quality.

<u>Promote Equitable Access</u> – The applicant describes how it believes the proposed project would promote equitable access in Section B.3, page 9, Section C.8, pages 35-36, Section L, pages 75-78, Section N, page 83, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would promote equitable access.

<u>Maximize Healthcare Value</u> – The applicant describes how it believes the proposed project would maximize healthcare value in Section B.3, pages 9-10, Section E.2, pages 46-47, Section N, pages 82-83, and the pro forma financial statements in Section Q. However, the information provided by the applicant is not reasonable and does not adequately support the determination that the applicant's proposal would maximize healthcare value because the applicant does not adequately demonstrate that its projected utilization is based on reasonable and adequately supported assumptions. The discussion regarding utilization found in Criterion (3) is incorporated herein by reference.

Policy GEN-4. The proposed capital expenditure for this project is greater than \$2 million but less than \$5 million; therefore Policy GEN-4 is applicable. In Section B.4, page 11, and Exhibit B-4, the applicant discusses its plan to assure improved energy efficiency and water conservation and provides the Novant Health Sustainable Energy Management Plan (SEMP), which outlines Novant Health's initiatives for energy efficiency.

Conclusion. The Agency reviewed the:

- application,
- exhibits to the application, and
- information publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is not conforming to this criterion because the applicant does not adequately demonstrate how the projected volumes incorporate the concepts of quality, equitable access and maximum value for resources expended in meeting the identified need. Therefore, the application is not consistent with Policy GEN-3.

Novant Health, Inc. (NH) and Novant Health Clemmons Outpatient Surgery, LLC (NHCOS), collectively referred to as "NH Clemmons" or "the applicant", proposes to add

two ORs at the previously approved Novant Health Clemmons Outpatient Surgery (NHCOS) facility in Clemmons, Forsyth County for a total of 4 ORs upon completion of this project and Project ID #G-11300-17 (relocate 2 ORs from NHFMC). NHCOS was approved as a separately licensed ASF to be developed with 2 ORs on the campus of Novant Health Clemmons Medical Center in Clemmons and is scheduled to open July 2019. Therefore, the proposed project results in a change of scope for Project ID #G-11300-17, requiring that applicable "Change of Scope" questions be addressed in the application form.

As defined by the 2018 SMFP operating room methodology, a "health system" includes all licensed health service facilities with operating rooms located in the same service area that are owned by the same parent company. According to the 2018 SMFP, the NH Health System has four existing and/or approved licensed surgical facilities in the Forsyth County operating room service area:

- 1. Novant Health Forsyth Medical Center (NHFMC), License H0209
 - Novant Health Forsyth Medical Center Main Campus (FMC Main)
 - Novant Health Kernersville Medical Center (NHKMC)
 - Novant Health Clemmons Medical Center (NHCMC)
 - Novant Health Hawthorne Outpatient Surgery (NHHOS)
 - Novant Health Orthopedic Outpatient Surgery (NHOOS)
- 2. Novant Health Medical Park Hospital (NHMPH), License H0229
- 3. Novant Health Kernersville Outpatient Surgery (NHKOS), Project ID #G-11150-16, scheduled to open June 2018
- 4. Novant Health Clemmons Outpatient Surgery (NHCOS), Project ID #G-11300-17, scheduled to open July 2019

The addition of two ORs at NHCOS, as proposed in this application, would bring the total number of ORs at the separately licensed ASF to four upon completion of this project and Project ID #G-11300-17.

Need Determination. The applicant does not propose to develop more new ORs than are determined to be needed in the 2018 SMFP for the Forsyth County service area.

Policy GEN-3. The application under review is in response to the 2018 SMFP need determination for additional ORs in Forsyth County; therefore, Policy GEN-3 is applicable. The applicant addresses Policy GEN-3 as follows:

<u>Promote Safety and Quality</u> – The applicant describes how it believes the proposed project would promote safety and quality in Section B.3, page 8, Section N, page 78, Section O, pages 79-82, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would promote safety and quality.

<u>Promote Equitable Access</u> – The applicant describes how it believes the proposed project would promote equitable access in Section B.3, page 9, Section C.8, pages 32-33, Section L, pages 72-74, Section N, page 78, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would promote equitable access.

<u>Maximize Healthcare Value</u> – The applicant describes how it believes the proposed project would maximize healthcare value in Section B.3, pages 9-10, Section E.2, pages 43-44, Section N, pages 77-78, the pro forma financial statements in Section Q, and referenced exhibits. However, the information provided by the applicant is not reasonable and does not adequately support the determination that the applicant's proposal would maximize healthcare value because the applicant does not adequately demonstrate that its projected utilization is based on reasonable and adequately supported assumptions. The discussion regarding utilization found in Criterion (3) is incorporated herein by reference.

Policy GEN-4. The proposed capital expenditure for this project is greater than \$2 million but less than \$5 million; therefore Policy GEN-4 is applicable. In Section B.4, pages 10-11, and Exhibit B-4, the applicant discusses its plan to assure improved energy efficiency and water conservation and provides the Novant Health Sustainable Energy Management Plan (SEMP), which outlines Novant Health's initiatives for energy efficiency.

Conclusion. The Agency reviewed the:

- application,
- exhibits to the application, and
- information publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is not conforming to this criterion because the applicant does not adequately demonstrate how the projected volumes incorporate the concepts of quality, equitable access and maximum value for resources expended in meeting the identified need. Therefore, the application is not consistent with Policy GEN-3.

North Carolina Baptist Hospital (NCBH), "the applicant", proposes to add four new ORs at NCBH in Winston-Salem, Forsyth County for a total of 51 ORs upon completion of this project and Project ID #G-8460-10 (add seven dedicated outpatient ORs pursuant to Policy AC-3).

In Section A, page 5, the applicant provides a description of the organizational structure of NCBH, summarized as follows. NCBH is an academic medical center teaching hospital and part of an umbrella for facilities within the Wake Forest Baptist Medical Center (WFBMC) system. WFBMC is divided into an academic enterprise (Wake Forest School of Medicine or WFSM), a clinical enterprise (WFBH), and a commercial enterprise (Wake Forest Innovations or WFI). The applicant further states:

"WFBH, the clinical arm of WFBMC, includes North Carolina Baptist Hospital (NCBH), Davie Medical Center (DMC), Wilkes Medical Center [WMC], and Lexington Medical Center. [sic] (LMC), among others."

As defined by the 2018 SMFP operating room methodology, a "health system" includes all licensed health service facilities with operating rooms located in the same service area that are owned by the same parent company. The 2018 SMFP lists three WFBMC Health System surgical facilities in the Forsyth County operating room service area:

- 1. Clemmons Medical Park Ambulatory Surgical Center (CMPASC), now referred to as Wake Forest Baptist Health-Outpatient Surgery Clemmons (WFBH-OSC) by the applicant
- 2. Plastic Surgery Center of North Carolina (PSCNC)
- 3. North Carolina Baptist Hospital (NCBH)

WFBH-OSC was licensed February 22, 2018 for three ORs, which were relocated from PSCNC. PSCNC no longer operates any operating rooms in Forsyth County. However, the address and the facility identification number (FID) on the license issued on February 22, 2018 are different from the address and FID on the certificate of need. The location remains the same as approved in the CON; the address was changed by the US Postal System, and the change was submitted to the CON Section through a Material Compliance request. Per Azzie Conley, Chief, Acute and Home Care Licensure and Certification Section, the Licensure Section is in the process of addressing the FID error.

The addition of four ORs at NCBH, as proposed in this application, would bring the total number of ORs on the NCBH hospital license to 51 (36 shared ORs + four inpatient ORs, including 2 excluded trauma/burn ORs + seven ORs approved in Project ID #G-8460-10 but undeveloped thus far + the proposed four ORs in this application) upon completion of this project and previously approved Project ID #G-8460-10. It would bring the number of ORs in the WFBMC Health System to a total of 54 (51 ORs at NCBH + 3 ORs at WFBH-OSC) in Forsyth County.

Need Determination. The applicant does not propose to develop more new ORs than are determined to be needed in the 2018 SMFP for the Forsyth County service area.

Policy GEN-3. The application under review is in response to the 2018 SMFP need determination for additional ORs in Forsyth County; therefore, Policy GEN-3 is applicable. The applicant addresses Policy GEN-3 as follows:

<u>Promote Safety and Quality</u> – The applicant describes how it believes the proposed project would promote safety and quality in Section B.3, pages 10-13, Section C.8, pages 38-40, Section N, pages 110-113, Section O, page 116-118, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would promote equitable access.

<u>Promote Equitable Access</u> – The applicant describes how it believes the proposed project would promote equitable access in Section B.3, pages 13-15, Section L, pages 104-107, Section N, pages 113-115, and the pro forma financial statements in Section Q. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would maximize healthcare value.

<u>Maximize Healthcare Value</u> – The applicant describes how it believes the proposed project would maximize healthcare value in Section B.3, pages 16-17, Section E.2, pages 76-78, Section N, pages 109-110, and the pro forma financial statements in Section Q. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would maximize healthcare value.

Policy GEN-4. The proposed capital expenditure for this project is greater than \$5 million; therefore, Policy GEN-4 is applicable. In Section B.4, page 18, the applicant discusses its plan to assure improved energy efficiency and water conservation and its intent to submit a plan for energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation.

Conclusion. The Agency reviewed the:

- application,
- exhibits to the application, and
- information publicly available during the review and used by the Agency.

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

- The applicant does not propose to develop more ORs than are determined to be needed in the service area; therefore, the application is consistent with the need determination in the 2018 SMFP.
- The applicant adequately demonstrates how the projected volumes incorporate the concepts of quality, equitable access and maximum value for resources expended in meeting the identified need. Therefore, the application is consistent with Policy GEN-3.
- The applicant adequately demonstrates that the application includes a written statement describing the project's plan to assure improved energy efficiency and water conservation. Therefore, the application is consistent with Policy GEN-4.

Decision

The applications submitted by each of the five applicants are conforming to the need determination. Three of the five applications are conforming to the applicable policies in the 2018 SMFP. The limit on the number of ORs that can be approved is four. Collectively, the applicants propose a total of 12 ORs. Therefore, all of the applications

cannot be approved even if all were fully conforming to this criterion. See the Conclusion following the Comparative Analysis for the decision.

- (2) Repealed effective July 1, 1987.
- (3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C TCS Cone Health NCBH

NC NH Forsyth NH Clemmons

TCS. The applicant proposes to establish a new ASF in Winston-Salem, Forsyth County by developing two new ORs and three procedure rooms. In Section C.1, pages 19-20, the applicant describes the proposed project as follows:

"Triad Center for Surgery proposes to develop a multispecialty ambulatory surgical facility with two operating rooms and three procedure rooms. No GI endoscopy rooms are proposed.

•••

Triad Center for Surgery offers patients and physicians a new choice of surgical provider that is not owned by an existing health system. The proposed project offers a new freestanding [sic] in central Forsyth County in close proximity to the majority of low income population of the county."

The applicant states (page 19) that the surgical specialties to be provided in the ORs include:

- orthopedic,
- neurosurgery,
- ophthalmology,
- oral surgery and maxillofacial surgery,
- plastic surgery, and
- pain management procedures when special needs require it.

The applicant proposes to provide at least three of the specialty areas listed in §131E-176(15a) to qualify its program as a "multispecialty ambulatory surgical program". N.C. Gen. Stat. §131E-176(15a) states:

"Multispecialty ambulatory surgical program" means a formal program for providing on a same-day basis surgical procedures for at least three of the following specialty areas: gynecology, otolaryngology, plastic surgery, general surgery, ophthalmology, orthopedic, or oral surgery."

The applicant further states (page 20) that the surgical specialties to be provided in the procedure rooms include:

- orthopedic arthroscopy and other minimally invasive procedures,
- ophthalmology, including YAG laser and other procedures,
- oral surgery extractions and other minor oral surgery procedures, and
- pain management, including injections and pain control implants.

In Section A.10, pages 10-13, the applicant states that TCS does not currently own, manage or operate any hospitals or ASFs in North Carolina. The applicant states that OrthoCarolina and Compass Surgical Partners are involved in the proposed project through the participation of OrthoCarolina physicians and ownership structure.

OrthoCarolina physicians own and operate University Surgery Center d/b/a Mallard Creek Surgery Center, a licensed and accredited ASF in Mecklenburg County. Compass Surgical Partners provides management services to two facilities in Wake County: Capital City Surgery Center and Holly Springs Surgery Center.

Patient Origin

On page 57, the 2018 SMFP states, "An operating room's service area is the operating room planning area in which the operating room is located. The operating room planning areas are the single and multicounty groupings shown in Figure 6.1." In Figure 6.1, page 62 of the 2018 SMFP, Forsyth County is shown as a single-county operating room service area. Thus, in this application, the service area is Forsyth County. Providers may serve residents of counties not included in their service area.

A summary of the 2016 data compiled on patient origin for Forsyth County providers of ambulatory surgical cases is shown in the table below.

County	# of Patients	% of Patients
Forsyth	22,119	45.2%
Guilford	3,481	7.1%
Davidson	3,125	6.4%
Stokes	2,981	6.1%
Surry	2,812	5.7%
Davie	2,406	4.9%
Other*	12,004	24.5%
Total	48,928	100.0%

2016 Patient Origin for Ambulatory Surgical
Services in Forsyth County Operating Rooms

Source: 2017 LRAs

Totals may not sum due to rounding

*Other includes 85 NC counties and other states, with each contributing 4% or less of the total patient origin for the Forsyth facilities.

As the table above shows, on average, 45.2% of the Forsyth ambulatory surgical patients were Forsyth County residents, with surrounding counties of Davie, Surry, Stokes, Davidson and Guilford each being the county of origin for between 5% and 7% of the total surgical patients, and all others 4% or less.

In Section C.3, page 24, the applicant provides the projected patient origin for ORs and procedure rooms, by number of patients and percentage, for the proposed facility for the first three operating years (CY2021-CY2023), as summarized in the tables below.

Operating Rooms						
	PY1 CY2021 PY2 CY2022		PY3 CY2023			
County	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Forsyth	1,314	56.20%	1,647	56.20%	1,980	56.20%
Stokes	212	9.09%	266	9.09%	320	9.09%
Davidson	150	6.40%	188	6.40%	225	6.40%
Surry	145	6.19%	181	6.19%	218	6.19%
Davie	124	5.30%	155	5.30%	187	5.30%
Yadkin	109	4.67%	137	4.67%	165	4.67%
Guilford	82	3.50%	103	3.50%	123	3.50%
Wilkes	44	1.89%	55	1.89%	67	1.89%
Rowan	19	0.82%	24	0.82%	29	0.82%
Rockingham	19	0.79%	23	0.79%	28	0.79%
Iredell	17	0.72%	21	0.72%	26	0.72%
Other Counties	57	2.45%	72	2.45%	86	2.45%
Virginia	37	1.57%	46	1.57%	55	1.57%
Other States	9	0.40%	12	0.40%	14	0.40%
TOTAL	2,338	100.00%	2,930	100.00%	3,522	100.00%

Triad Center for Surgery Projected Patient Origin

Other includes 26 NC counties and seven other states, as stated on page 24

Totals may not sum due to rounding

Triad Center for Surgery Projected Patient Origin Procedure Rooms

	PY1 CY2021		PY2 CY2022		PY3 CY2023	
County	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Forsyth	404	56.20%	493	56.20%	582	56.20%
Stokes	65	9.09%	80	9.09%	94	9.09%
Davidson	46	6.40%	56	6.39%	66	6.38%
Surry	45	6.26%	54	6.26%	64	6.26%
Davie	38	5.30%	47	5.30%	55	5.30%
Yadkin	34	4.67%	41	4.67%	48	4.67%
Guilford	25	3.50%	31	3.50%	36	3.50%
Wilkes	14	1.89%	17	1.89%	20	1.89%
Rowan	6	0.82%	7	0.82%	8	0.82%
Rockingham	6	0.79%	7	0.79%	8	0.79%
Iredell	5	0.72%	6	0.72%	7	0.72%
Other Counties	18	2.45%	21	2.45%	25	2.45%
Virginia	11	1.57%	14	1.57%	16	1.57%
Other States	3	0.40%	3	0.40%	4	0.40%
TOTAL	719	100.00%	877	100.00%	1,035	100.00%

Other includes 26 NC counties and seven other states, as stated on page 24

Totals may not sum due to rounding

As shown in the tables above, the applicant projects 56.2% of its patients will originate from Forsyth County, with 4% to 9% of its total patients originating from each of the

following surrounding counties of Stokes, Davidson, Surry, Davie, Yadkin, and Guilford. The projected patient origin is consistent with the historical patient origin of Forsyth County ambulatory surgery services.

In Section C, page 25, the applicant states that the above projections are based on the historical patient origin of the participating OrthoCarolina physicians as provided in Exhibit C.3 and shown in the table on page 25 of the application. The applicant's assumptions are reasonable and adequately supported.

Analysis of Need

In Section C, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. On page 26, the applicant states that the need for the proposed project is based on the following factors:

- the projected growth and aging of the population in Forsyth and neighboring counties (pages 27-28),
- advances in surgical technology and anesthesia techniques (page 29),
- changes in reimbursement, cost savings and patient choice for freestanding ambulatory surgery centers (pages 30-32),
- the historical and projected growth of ambulatory surgery services in Forsyth County (pages 33-34),
- physician support letters and a "conservative" methodology (pages 35-39), and
- the need for positive competition and increased choice of a new provider (page 40).

The information provided in the sections as noted above is reasonable and adequately supported for the following reasons:

- The applicant adequately documents that the growing and aging Forsyth County population, particularly those over age 65, will continue to utilize healthcare services, supporting future increase in demand for ambulatory surgery services.
- The applicant adequately documents that the proposed Winston-Salem location is central to Forsyth County and close in proximity to Forsyth county's low income patients. The applicant also demonstrates that patients from other counties travel to Winston-Salem in Forsyth County to obtain care from physician specialists, because of the concentration of specialists in academic medical centers and rural counties with smaller populations typically have few physician specialists.
- The applicant adequately documents that changes in surgical and anesthesia techniques, including use of fiber optics, miniature video cameras and special surgical instruments handled via tubes and surgical microscopes, support the continued shift of surgical procedures to the ambulatory setting.
- The applicant adequately documents that changes in reimbursement, cost savings and patient choice for freestanding ambulatory surgery centers have influenced the increase in demand for ambulatory surgical services.

- The applicant adequately documents the need for additional ambulatory ORs by documenting the historical and expected growth in ambulatory surgical cases in Forsyth County, based on the compound annual growth of ambulatory surgical cases from FY2011 through FY2016. The applicant provides a calculation of an inpatient five-year compound annual decline of -0.37% and an ambulatory five-year compound average growth rate (CAGR) of 1.18%, which when projected forward supports the need for four additional ORs in Forsyth County. In its discussion and summary of methodology and assumptions for the proposed project (pages 36-39), the applicant confuses the dates of its project years, and shows the first and second project years as CY2020 and CY2021, respectively, and the third project year as CY2023, which is correct. The first and second project years should have been labeled as CY2021 and CY2022, respectively.
- The applicant adequately demonstrates physician support for its proposed 2 OR project, providing documentation of physician support letters with annual estimates for surgical volume to be performed at the proposed facility. It is noted that several of the OrthoCarolina surgeons participating in this proposed project previously supported Novant Health's Project ID #G-11300-17 to develop a two OR ASF in Clemmons, Forsyth County. The project under review was not an alternative at that time. Furthermore, there is nothing to prevent the surgeons from changing their minds from supporting Project ID #G-11300-17 to participating in the development of the proposed ASF.
- The applicant adequately demonstrates that the proposed project, which offers patients and physicians a new choice of surgical provider that is not owned by an existing health system, could create positive competition and have a positive impact on Forsyth County surgical services.

Projected Utilization

Operating Rooms

In Section Q, Form C, page 100, the applicant provides projected utilization for the proposed ORs, as illustrated in the following table.

	Last FFY (Proposed New ASF)	1 st Full FY CY2021	2 nd Full FY CY2022	3 rd Full FY CY2023
Adjusted Planning Inventory (1)	NA	2	2	2
Standard Hours per OR per Year (2)	NA	1,312.5	1,312.5	1,312.5
Inpatient Surgical Cases	NA	NA	NA	NA
Final Inpatient Case Time (3)	NA	NA	NA	NA
Inpatient Surgical Hours (4)	NA	NA	NA	NA
Ambulatory Surgical Cases	NA	2,338	2,930	3,522
Final Ambulatory Case Time (3)	NA	68.6	68.6	68.6
Ambulatory Surgical Hours (4)	NA	2,673	3,350	4,027
Total Surgical Hours (5)	NA	2,673	3,350	4,027
# of ORs Needed (6)	NA	2.0	2.6	3.1

TCS
Operating Room Projected Utilization

(1) Last Full FY is from Table 6B in the 2018 SMFP. The first three full FYs includes the proposed OR(s).

(2) From Page 59 in the 2018 SMFP, Group 6.

(3) From Page 59 in the 2018 SMFP in minutes.

(4) Surgical Hours equals Surgical Cases multiplied by the Final Case Time.

(5) Total Surgical Hours equals Inpatient Surgical Hours plus Ambulatory Surgical Hours.

(6) # of ORs Needed equals Total Surgical Hours divided by the Standard Hours per OR per Year.

In Section Q, Form C Methodology and Assumptions, pages 101-105, the applicant provides the assumptions and methodology used to project operating room utilization, which is summarized below:

• Step 1, page 101

Determine projected utilization per physician by specialty, based on physician letters with estimated procedures to be performed at the proposed facility. The bulk of the physician letters provide a projected range of surgical cases to be performed per year. To project the orthopedic and neurosurgery cases, the applicant uses the low estimate for PY1, the high estimate for PY3, and averages the two for PY2. The applicant projects ophthalmology and oral/facial cases at 50% of the low estimate in physician letters for PY1, 60% for PY2, and 70% for PY3. For plastic surgery, the applicant assumes 1 case per month. All pain management cases are projected to be procedure room cases.

• Step 2, page 102

Calculate combined volume based on physician projections, with conservative downward adjustments for ophthalmology, oral/facial surgery, and pain management

• Step 3, page 103

Distribute total volume between ORs and procedure rooms based on complexity of procedures as determined through discussions with physicians and other ASFs

- Step 4, page 104 Calculate annual OR hours
- Step 5, page 105

Calculate number of ORs needed based on number of annual surgical hours projected; the bottom table on page 105 uses 1,832 hours per OR and calculates the need for 1.4, 1.8 and 2.2 ORs in project years 1 through 3, respectively. However, the applicant uses the correct 1,312.5 hours per OR and calculates the need for 2.0, 2.6 and 3.1 ORs in project years 1 through 3, respectively in the top table on page 105 and in Form C on page 100.

Procedure Rooms

In Section Q, page 100, the applicant provides projected utilization for the proposed procedure room, as illustrated in the following table.

	PY1 CY2021	PY2 CY2022	PY3 CY2023
# of Procedure Rooms	3	3	3
# of Procedures	719	877	1,035

Procedure Room Projected Utilization

In Section Q, Form C Methodology and Assumptions, pages 101-105, the applicant provides the assumptions and methodology used to project procedure room utilization, which is summarized below:

- Step 1, page 101 Determine projected utilization per physician by specialty
- Step 2, page 102 Calculate combined volume based on physician projections
- Step 3, page 103

Distribute total volume between ORs and procedure rooms based on complexity, with 90% of the orthopedic, neurosurgery and plastic surgery; and 60% of the ophthalmology and oral/facial surgery being appropriate to be performed in an OR; with the remainder of the identified cases being appropriate to be performed in a procedure room.

In its discussion and summary of methodology and assumptions for the proposed project (pages 36-39), the applicant confuses the dates of its project years, and shows the first and second project years as CY2020 and CY2021, respectively, and the third project year as CY2023, which is correct. The first and second project years should have been labeled as CY2021 and CY2022, respectively. The tables

are also incorrectly labeled in Section C.7(c), page 44. In addition, the projected procedure table on page 44 shows 856 and 1,010 procedures in the second and third project years, respectively, which is different from the correct utilization provided on pages 36-39 and page 100 (877 and 1,035 procedures in the second and third project years, respectively).

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

- the applicant bases future utilization on a percentage of the number of projected cases proposed by the physician support letters, which provide annual volume estimates, distributed to operating rooms and procedures rooms by complexity.
- the applicant uses reasonable estimates to project utilization, including:
 - the low estimate for physician volumes for the first project year and the high estimate for the third project year, with the second year being an average of the two for orthopedics and neurosurgery;
 - a percentage, increasing by year from 50% to 70% for ophthalmology, oral and facial surgery and pain management, based on physician direction; and
 - \circ one case per month for plastic surgery.

Access

In Section C.8, pages 45-46, the applicant states:

"Triad Center for Surgery will expand access to healthcare services for the medically underserved by providing surgical procedures to patients who are indigent, lack health insurance or are otherwise medically underserved. . . . As a multi-specialty ambulatory surgical facility, Triad Center for Surgery is committed to provide access for all payer categories of patients."

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

F 1 2 C 1 2022					
Payor Source	Entire Facility	Operating Rooms	Procedure Room		
Self-Pay	1.02%	1.00%	1.10%		
Charity Care	0.77%	0.78%	0.76%		
Medicare *	50.27%	46.59%	62.56%		
Medicaid *	3.60%	3.82%	2.88%		
Insurance *	39.68%	42.59%	29.95%		
Workers	3.41%	3.94%	1.61%		
Compensation					
TRICARE	1.25%	1.28%	1.14%		
Other	0.00%	0.00%	0.00%		
Total	100.00%	100.00%	100.00%		

Proposed Payor Mix PV2 CV2022

* Including any managed care plans

Totals may not sum due to rounding

The proposed project does not involve GI endoscopy rooms. The applicant states on page 85 that the projected payor mix is based on specialty-specific data from the historical payor mix of the physicians planning to use the facility. The projected payor mix is reasonable and adequately supported.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application,
- written comments,
- remarks made at the public hearing,
- responses to comments, and
- information publicly available during the review and used by the Agency.

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

- The applicant adequately identifies the population to be served for all the reasons discussed above.
- The applicant adequately explains why the population to be served needs the services proposed in this application for all the reasons discussed above.
- Projected utilization is reasonable and adequately supported for all the reasons discussed above.

• The applicant projects the extent to which all residents, including underserved groups, will have access to the proposed services (payor mix) and adequately supports its assumptions for all the reasons discussed above.

Cone Health. The applicant proposes to establish a new multispecialty ASF in Kernersville, Forsyth County by developing two ORs, one GI endoscopy room, and one procedure room. The proposed facility will be developed at Cone Health's MedCenter Kernersville campus. In Section C.1, page 21, the applicant describes the proposed project as follows:

"As noted above, MC Kernersville, LLC and Cone Health propose to develop a freestanding ASC in Kernersville – Triad Surgery Center – with two operating rooms, one GI endoscopy room, and one procedure room. Triad Surgery Center will provide outpatient surgical services including, but not limited to, orthopedic surgery, gynecology surgery, otolaryngology (ENT) surgery, general surgery, and plastic surgery.

•••

While MC Kernersville, LLC is currently wholly owned by Cone Health, the establishment of the ASC as a separate legal entity allows for future physician investment. Triad Surgery Center will be managed and staffed by Cone Health through a management services agreement."

In Section A.10, pages 13-14, the applicant states that MC Kernersville, LLC is a new entity that does not currently own, manage or operate any healthcare facilities in North Carolina. The applicant states that the sole member of MC Kernersville at application filing was The Moses H. Cone Memorial Hospital. The Moses H. Cone Memorial Hospital and its subsidiaries, collectively known as Cone Health, own and operate North Carolina facilities offering surgical and procedural services, including Moses Cone Hospital, Wesley Long Hospital, Alamance Regional Medical Center, Women's Hospital, Annie Penn Hospital, Moses Cone Surgery Center, Wesley Long Surgery Center, Mebane Surgery Center and LeBauer Endoscopy Center.

In Section C.1, page 21, the applicant states that the proposed ASF will provide outpatient surgical services including, but not limited to:

- orthopedic surgery,
- gynecology surgery,
- otolaryngology (ENT),
- general surgery, and
- plastic surgery.

The applicant proposes to provide at least three of the specialty areas listed in §131E-176(15a) to qualify its program as a "multispecialty ambulatory surgical program". N.C. Gen. Stat. §131E-176(15a) states:

"Multispecialty ambulatory surgical program" means a formal program for providing on a same-day basis surgical procedures for at least three of the following specialty areas: gynecology, otolaryngology, plastic surgery, general surgery, ophthalmology, orthopedic, or oral surgery."

In Section C.6, page 42, the applicant provides a table with the following proposed specialties and percent of cases at the proposed ASF, as summarized below:

	% of Total
Orthopedics	33.1%
Dermatology	3.8%
ENT	19.3%
Urology	9.0%
General Surgery	11.6%
Gynecology	5.8%
Podiatry	7.3%
Neurosurgery	8.5%
OB/Gyn	0.5%
Plastic Surgery	1.2%
Total	100.0%

Totals may not sum due to rounding

Patient Origin

On page 57, the 2018 SMFP states, "An operating room's service area is the operating room planning area in which the operating room is located. The operating room planning areas are the single and multicounty groupings shown in Figure 6.1." In Figure 6.1, page 62 of the 2018 SMFP, Forsyth County is shown as a single-county operating room service area. Thus, in this application, the service area is Forsyth County. Providers may serve residents of counties not included in their service area.

A summary of the 2016 data compiled on patient origin for Forsyth County providers of ambulatory surgical cases is shown in the table below.

County	#of Patients	% of Patients
Forsyth	22,119	45.2%
Guilford	3,481	7.1%
Davidson	3,125	6.4%
Stokes	2,981	6.1%
Surry	2,812	5.7%
Davie	2,406	4.9%
Other*	12,004	24.5%
Total	48,928	100.0%

2016 Patient Origin for Ambulatory Surgical
Services in Forsyth County Operating Rooms

Source: 2017 LRAs

Totals may not sum due to rounding

*Other includes 85 NC counties and other states, with each contributing 4% or less of the total patient origin for the Forsyth facilities.

As the table above shows, on average, 45.2% of the Forsyth ambulatory surgical patients were Forsyth County residents, with surrounding counties of Davie, Surry, Stokes, Davidson and Guilford each being the county of origin for between 5% and 7% of the total surgical patients, and all others 4% or less.

In Section C.3, pages 24-25, the applicant provides the projected patient origin, by number of patients and percentage, for the proposed facility for the first three operating years (FFY2021-FFY2023), as summarized in the tables below.

Operating Rooms							
	PY1 FFY2021 10/1/20-9/30/21		PY2 FF 10/1/21-	-	PY3 FFY2023 10/1/22-9/30/23		
County / Area	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total	
Kernersville*	825	39.3%	854	39.3%	884	39.3%	
Other Forsyth	153	7.3%	159	7.3%	164	7.3%	
Other Guilford	853	40.7%	884	40.7%	915	40.7%	
Other^	265	12.7%	275	12.7%	285	12.7%	
TOTAL	2,097	100.0%	2,171	100.0%	2,247	100.0%	

Cone Health Triad Surgery Center Projected Patient Origin Operating Rooms

*ZIP Codes 27009, 27051, 27235, 27265, 27284, 27285, and 27310. This grouping of ZIP codes includes Forsyth and Guilford counties.

^Other includes 31 NC counties and other states, as stated on page 24

GI Endo Rooms							
	PY1 FF	Y2021	PY2 FF	'Y2022	PY3 FFY2023		
	10/1/20-	9/30/21	1 10/1/21-9/30/22			10/1/22-9/30/23	
County / Area	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total	
Kernersville*	633	33.6%	638	33.6%	642	33.6%	
Other Forsyth	89	4.7%	89	4.7%	90	4.7%	
Other Guilford	935	49.7%	942	49.7%	948	49.7%	
Other^	225	12.0%	227	12.0%	228	12.0%	
TOTAL	1,883	100.0%	1,896	100.0%	1,909	100.0%	

Cone Health Triad Surgery Center Projected Patient Origin

*ZIP Codes 27009, 27051, 27235, 27265, 27284, 27285, and 27310. This grouping of ZIP codes includes Forsyth and Guilford counties.

^Other includes 23 NC counties and other states, as stated on page 24

Cone Health Triad Surgery Center Projected Patient Origin Procedure Rooms

	PY1 FFY2021 10/1/20-9/30/21		PY2 FF 10/1/21-	-	PY3 FFY2023 10/1/22-9/30/23	
County / Area	# of Patients			of Patients % of Total		% of Total
Kernersville*	273	39.3%	273	39.3%	273	39.3%
Other Forsyth	51	7.3%	51	7.3%	51	7.3%
Other Guilford	283	40.7%	283	40.7%	283	40.7%
Other^	88	12.7%	88	12.7%	88	12.7%
TOTAL	695	100.0%	695	100.0%	695	100.0%

*ZIP Codes 27009, 27051, 27235, 27265, 27284, 27285, and 27310. This grouping of ZIP codes includes Forsyth and Guilford counties.

^Other includes 31 NC counties and other states, as stated on page 24

As shown in the tables above, the applicant projects 39.3% of its Forsyth County surgical facility patients will originate from its proposed "Kernersville" region, which includes Guilford County ZIP codes; 27235, 27265, and 27310. The applicant does not identify the total Forsyth County and Guilford County population from within the "Kernersville" region; therefore, the Kernersville region in the applicant's service area includes an undetermined number of Guilford County residents. These Guilford County residents are in addition to the 40.7% of "Other Guilford County" residents, as listed above. The patient origin regions and percentages for GI and the procedure rooms follow the same methodology as the proposed OR patient origin. Although, the total projected number of patients from Forsyth County and Guilford County is undetermined, the total patient origin is adequately supported and identified.

In Section C, page 25, the applicant states that the above projections are consistent with the utilization methodology detailed in Form C Assumptions and Methodology in Section Q. The applicant states that its projected patient origin is based on the historical patient origin of referrals generated by four Cone Health primary care practices located near the proposed facility: Cone Health Primary Care & Sports Medicine at MedCenter

Kernersville, Piedmont Triad Family Medicine, LeBauer Primary Care at MedCenter High Point, and LeBauer HealthCare at Oak Ridge. The applicant does not disclose the patient origin of these practices or where these practices currently refer patients for surgical procedures and why that would change. The applicant states that the ZIP codes of the referrals were then analyzed based on the assumptions in Form C to reflect those that result in ASF-appropriate surgical procedures, GI endoscopy procedures, or procedure room procedures for patients who may choose to have them performed at the proposed facility.

Analysis of Need

In Section C, the applicant discusses why it believes the population projected to utilize the proposed services needs the proposed OR services. On page 26, the applicant states that the need for the proposed project is based on the following factors:

- demand for ambulatory surgery services, including growth and aging of the population (pages 26-32),
- need for additional freestanding ASF capacity in Forsyth County, particularly in Kernersville (pages 32-36), and
- need for a Cone Health ASF (pages 36-40).

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

- The applicant adequately documents that clinical advances, including improved technology, increased knowledge of pain management, anesthesiology, rehabilitation, and decreased recovery times have enabled many procedures that were once highly invasive and required extensive inpatient care to now be done in an outpatient setting.
- The applicant adequately documents that rising healthcare costs and healthcare reimbursement pressures are moving physicians and patients toward outpatient settings that provide enhanced productivity, scheduling flexibility and faster turnaround.
- The applicant adequately documents that the growing and aging Forsyth County population, particularly those over age 65 and in the Kernersville ZIP code area will continue to utilize healthcare services and the improvement in access to outpatient surgical services will support the expected higher utilization.
- The applicant adequately documents that the proposed project will allow Cone Health and its accountable care organization (ACO), Triad HealthCare Network (THN), to refer patients to a site of care under their control where they can receive the highest quality care at the lowest cost.

The information provided above adequately supports the need for Cone Health to develop a Forsyth County ASF in Kernersville to serve a large number of Guilford County patients in addition to Forsyth County patients. Although, the applicant does not discuss where the Cone Health physicians and members of THN (referral physicians) currently refer their surgical patients, the applicant adequately demonstrates the need for the proposed services.

Projected Utilization

Operating Rooms

In Section Q, the applicant provides projected utilization for the proposed operating rooms as illustrated in the following table.

Operating Room Projected Utilization							
	Last FFY (Proposed New ASF)	1 st Full FY FY2021	2 nd Full FY FY2022	3 rd Full FY FY2023			
Adjusted Planning Inventory (1)	NA	2	2	2			
Standard Hours per OR per Year (2)	NA	1,312.5	1,312.5	1,312.5			
Inpatient Surgical Cases	NA	NA	NA	NA			
Final Inpatient Case Time (3)	NA	NA	NA	NA			
Inpatient Surgical Hours (4)	NA	NA	NA	NA			
Ambulatory Surgical Cases	NA	2,097	2,171	2,247			
Final Ambulatory Case Time (3)	NA	68.6	68.6	68.6			
Ambulatory Surgical Hours (4)	NA	2,397	2,482	2,570			
Total Surgical Hours (5)	NA	2,397	2,482	2,570			
# of ORs Needed (6)	NA	1.8	1.9	2.0			

Cone Health
Operating Room Projected Utilization

(1) Last Full FY is from Table 6B in the 2018 SMFP. The first three full FYs includes the proposed OR(s).

(2) From Page 59 in the 2018 SMFP, Group 6.

(3) From Page 59 in the 2018 SMFP in minutes.

(4) Surgical Hours equals Surgical Cases multiplied by the Final Case Time.

(5) Total Surgical Hours equals Inpatient Surgical Hours plus Ambulatory Surgical Hours.

(6) # of ORs Needed equals Total Surgical Hours divided by the Standard Hours per OR per Year.

In Section Q, Form C Assumptions, pages 1-9, the applicant provides the assumptions and methodology used to project operating room utilization, which is summarized below:

- Services begin April 1, 2020 first full fiscal year is FY2021, October 1, 2020 through September 30, 2021.
- The types of surgical cases proposed at the facility identifies the facility as a Group 6 facility with an average ambulatory case time of 68.6 minutes per case and 1312.5 standard hours per operating room.
- Analysis of Cone Health primary care referrals appropriate for outpatient surgery at the proposed facility results in a base of 1,825 outpatient surgical cases in FY2017 (Table 4, page 5). The base number of surgical cases is dependent upon a set percentage of referrals from the primary care clinics resulting in surgeries (Table 2, page 3), of which a set percentage (70% for all specialties, page 3) would be

appropriate to be performed in an ASF, of which a set percentage (100% for Cone Health Primary Care at MC Kernersville and Piedmont Triad Family Medicine and 60% for LeBauer High Point and LeBauer Oak Ridge, page 4) would be done at the proposed ASF. The applicant states that the percentages were all chosen based on Cone Health experience and discussion with its physicians. The following table summarizes the result of the above assumptions as provided by the applicant in Table 4, page 5 of the Section Q, Form C Assumptions and Methodology.

	CH Primary Care at MCK	Piedmont Triad Family Medicine	LeBauer High Point	LeBauer Oak Ridge	Total
Percent of Projected Outpatient		meanente			Totul
Appropriate Surgeries to be					
Performed at Proposed ASF	100%	100%	60%	60%	
Orthopedics	306	97	187	14	604
Dermatology	21	9	38	2	69
Urology	54	19	83	7	164
General Surgery	71	29	103	9	211
Gynecology	20	19	65	2	105
Podiatry	40	25	66	4	134
Neurosurgery	58	5	88	4	155
OB/Gyn	5	1	2	0	9
Plastic Surgery	13	1	7	0	22
ENT	137	36	160	20	353
Total	725	241	799	62	1,825

Number of Baseline Surgical Cases Projected for the Proposed ASC

Totals may not sum due to rounding

• Growth is projected at 3.5% annually based on Forsyth County's two years of growth in outpatient surgery from FY2014 to FY2016. The following table summarizes Table 6 on page 6 of the Assumptions in Section Q.

	FY17	FY18	FY19	FY20	FY21	FY22	FY23	CAGR
Cases from Existing Cone Health								
Primary Care Referral Practices	1,825	1,889	1,956	2,025	2,097	2,171	2,247	3.5%
Percent of Year in Operation				50%	100%	100%	100%	
Total				1,013	2,097	2,171	2,247	

Totals may not sum due to rounding

The applicant grows projected utilization for its ORs based upon a 3.5% CAGR, a higher growth rate than the historical Forsyth County growth rates (5-yr 2011-16 CAGR of 1.8%, 3-yr 2013-16 CAGR of 2.5%, 3-yr 2014-2017 CAGR of 3.1%, and 5-yr 2012-17 CAGR of 2.5%) for outpatient surgical procedures. Although the three and five-year trends show lower growth rates, using the applicant's methodology and projecting its FY2017 base year of 1,825 outpatient surgical

cases forward at the most conservative growth rate of 1.8% still results in a need for 1.8 ORs, rounded to 2 ORs in the second and third project years. Indeed, 1,825 outpatient surgical cases at 68.6 minutes per case and 1,312.5 hours per OR per year results in a need for 1.8 ORs, which rounds to 2.

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

- the applicant bases its initial volume of referral surgeries on percentages from its referral practices that result in surgery, percentages of the referral surgeries that result in outpatient surgeries appropriate for ASFs, which in turn will produce a percent of surgeries performed at the proposed facility,
- the applicant bases future utilization upon the proposed service area's Cone Health referral physicians' 2017 historical surgical referrals and assumes those referrals will grow between 2017 and the opening of the proposed ASF at 3.5% annually. Although the three and five-year trends show lower growth rates, using the applicant's methodology and projecting its FY2017 base year of 1,825 outpatient surgical cases forward at the most conservative growth rate of 1.8% still results in a need for 1.8 ORs, rounded to 2 ORs.

GI Endoscopy Rooms

Kernersville currently has two existing GI endoscopy rooms developed by Digestive Health Specialists. Gastroenterology Associates of the Piedmont (GAP) was approved to relocate two GI endoscopy rooms from Winston-Salem to Kernersville Endoscopy Center (KEC) in Kernersville (Project ID G-11442-17). Thus, there are four existing and approved GI endoscopy ASF ORs in Kernersville. In addition, ZIP code 27265 (Guilford County) contains seven GI endoscopy rooms: Bethany Medical Center has two, High Point Endoscopy Center has three, and High Point Regional Hospital has two GI endoscopy rooms.

In Section Q, the applicant provides projected utilization for the proposed GI endoscopy room, as illustrated in the following table.

GI Endoscopy Room Projected O tilization								
	PY1 FFY2021 PY2 FFY2022		PY3 FFY2023					
	10/1/20-9/30/21	10/1/21-9/30/22	10/1/22-9/30/23					
# of GI Endo Rooms	1	1	1					
# of GI Endo Procedures	1,883	1,896	1,909					
# of GI Endo Procedure								
Rooms Needed	1.3	1.3	1.3					

GI Endoscopy Room Projected Utilization

In Section Q, Form C Assumptions, pages 9-12, the applicant provides the assumptions and methodology used to project GI endoscopy utilization, which is summarized below:

- Services begin April 1, 2020 first full fiscal year is FY2021, October 1, 2020 through September 30, 2021.
- The applicant identifies 3,406 referrals to gastroenterologists from Cone Health Primary Care at MC Kernersville, Piedmont Triad Family Medicine, LeBauer High Point and LeBauer Oak Ridge during FY2017.
- Analysis of Cone Health primary care GI endoscopy referrals appropriate for outpatient surgery at the proposed facility results in a base of 1,831 GI endoscopy procedures in FY2017.
- Growth is projected at 0.7% annually based on Forsyth County's historical threeyear CAGR for GI endoscopy procedures.
- The minimum number of GI endoscopy procedures per room is 1,500 procedures. See N.C. Gen. Stat. §131E-182(a).

Projected utilization is reasonable and adequately supported for the reasons stated above.

Procedure Rooms

In Section Q, the applicant provides projected utilization for the proposed procedure room as illustrated in the following table.

	PY1 FFY2021	PY2 FFY2022	PY3 FFY2023				
	10/1/20-9/30/21	10/1/21-9/30/22	10/1/22-9/30/23				
# of Procedure Rooms	1	1	1				
# of Procedures	695	695	695				

Procedure Room Projected Utilization

In Section Q, Form C Assumptions, page 12, the applicant provides the assumptions and methodology used to project procedure room utilization, which is summarized below:

- Services begin April 1, 2020 first full fiscal year is FY2021, October 1, 2020 through September 30, 2021.
- There are no promulgated standards against which to measure the need for procedure rooms.
- The projections are based on discussions with the Cone Health area physicians who expected to practice at the proposed facility.
- For conservatism, the applicant assumes procedure room utilization will remain constant.

Projected utilization is reasonable and adequately supported for the reasons stated above.

Access

In Section C.8, page 44, the applicant states:

"Cone Health is a private, not-for-profit organization established to serve the community by providing high quality, affordable, and comprehensive care to all patients, regardless of their economic status. . . . As a facility managed by Cone Health, MC Kernersville, LLC will follow similar guidelines and as such, Triad Surgery Center also will not discriminate against low-income persons, racial and ethnic minorities, women, handicapped persons, the elderly, or any other underserved groups."

In Section L, page 87, the applicant projects the following payor mix during the second full fiscal year of operation following completion of the project, as illustrated in the table below.

FFY2022							
Payor Source	Entire Facility	Operating Rooms	GI Endo Rooms	Procedure Room			
Self-Pay	0.2%	0.3%	0.1%	0.3%			
Charity Care [^]							
Medicare *	28.2%	31.1%	24.8%	31.1%			
Medicaid *	0.9%	1.0%	0.8%	1.0%			
Insurance *	67.5%	64.1%	71.3%	64.1%			
Workers							
Compensation**							
TRICARE**							
Other (Other Gov't,	3.2%	3.5%	2.9%	3.5%			
Worker's Comp)							
Total	100.0%	100.0%	100.0%	100.0%			

Proposed Payor Mix FFY2022

* Including any managed care plans

**Included in Other

[^]Cone Health's internal data does not include Charity Care as a payor source for patients. Patients in any payor category can and do receive charity care. Please see Forms F.3 and 4 for charity care projections.

Totals may not sum due to rounding

The applicant states on page 88 that the projected payor mix is reflective of the historical payor mix of the patients it proposes to serve. The projected payor mix is reasonable and adequately supported.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application,
- written comments,
- remarks made at the public hearing,

- responses to comments, and
- information publicly available during the review and used by the Agency.

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

- The applicant adequately identifies the population to be served for all the reasons discussed above.
- The applicant adequately demonstrates why the population to be served needs the OR services as proposed in this application for all the reasons discussed above.
- The applicant adequately demonstrates why the population to be served needs the GI endoscopy services as proposed in this application for all the reasons discussed above.
- Projected utilization of OR surgical cases is based on reasonable and adequately supported assumptions for all the reasons discussed above.
- Projected utilization of GI endoscopy procedures is based on reasonable and adequately supported assumptions for all the reasons discussed above.
- The applicant projects the extent to which all residents, including underserved groups, will have access to the proposed services (payor mix) and adequately supports its assumptions for all the reasons discussed above.

NH Forsyth. The NH Health System submitted two separate applications on May 15, 2018, pursuant to the 2018 SMFP need determination for four ORs in Forsyth County: 1) Project ID #G-11517-18 / Add two ORs at FMC Main, and 2) Project ID #G-11518-18 / Add two ORs to Novant Health Clemmons Outpatient Surgery (NHCOS), a freestanding ASF under development in Clemmons, NC. Together, the two applications apply for four ORs in Forsyth County.

In this application, Project ID #G-11517-18, the applicant proposes to add two ORs at FMC Main in Winston-Salem, Forsyth County. The applicant describes the scope of this project in Section C.1, page 12, where the applicant states:

"NHFMC is seeking to add two new inpatient/outpatient shared ORs to the firstfloor surgical suite at FMC Main. Existing space in the main NHFMC surgical suite will be renovated to increase the surgical capacity at NHFMC. The first operating room opened will be one of the two ORs that closes in June 2018 when NHKOS opens. This OR will be renovated to meet current OR standards. For the second OR, an existing support/storage space in the first-floor surgical suite at NHFMC will be converted to add the second OR to the main surgical suite. Both ORs are projected to open in April 2021."

In Section A.6, page 3, the applicant states:

"Upon project completion, FMC Main will have 20 shared ORs and two dedicated C-section ORs."

This is not an accurate statement. If the two ORs are approved for addition to FMC Main, FMC Main will have 17 shared ORs and five inpatient ORs (including two dedicated C-Section and three Open Heart ORs) for a total of 22 ORs at FMC Main and a total of 35 ORs on the NHFMC License H0209.

The applicant also appears to provide conflicting information on OR counts in its discussion of the two previously approved applications: Project ID #'s G-11150-16 and G-11300-17. On pages 26-27, the applicant states that upon the completion of the previously approved relocations of ORs, Project ID #'s G-11150-16 and G-11300-17, FMC Main will have 18 ORs: 13 shared ORs, three open heart ORs and two dedicated C-Section ORs. However, that does not agree with the applicant's statement on page 24, where it states that NH Orthopedic Outpatient Surgery (NHOOS) will close upon the relocation of ORs to NH Clemmons Outpatient Surgery (Project ID #G-11300-17), which reduces the OR inventory on the NHFMC License H0209, but not the OR inventory at FMC Main. If the two ORs approved in Project ID #G-11300-17 are relocated from NHOOS to NHCOS, the number of ORs at FMC Main remains at 20, including the two dedicated C-Section rooms, and the number of ORs at NH Orthopedic Outpatient Surgery is zero.

The table below represents the projected operating room inventory in the NH Health System following the scheduled completion of previously approved CON Project ID #G-11150-16, scheduled for completion in June 2018 and Project ID #G-11300-17, scheduled for completion in July 2019, assuming the ORs are relocated from NHOOS to NHCOS, as shown by the applicant's table on page 24.

Facility	2018 LRA	Project ID #G- 11150-16*	CY2018	Project ID #G-11300-17**	CY2019
V		11150-10		#G-11500-17**	
NHFMC Main [^]	22	-2	20		20
NH Kernersville Medical Center	4		4		4
NH Clemmons Medical Center	5		5		5
NH Hawthorne Outpatient Surgery	4		4		4
NH Orthopedic Outpatient Surgery	2		2	-2	0
NHFMC License H0209 Total	37		35		33
NH Medical Park Hospital	10		10		10
NH Kernersville Outpatient					
Surgery	0	+2	2		2
NH Clemmons Outpatient Surgery	0		0	+2	2
NH Health System Total	47	+0	47	+0	47

^ The 22 NHFMC Main ORs listed on the 2018 LRA includes 2 dedicated C-Section and 3 inpatient open heart ORs.

*Project ID #G-11150-16, (relocate 2 ORs from Winston-Salem campus to NHKOS), scheduled to open June 2018.

**Project ID #G-11300-17, (relocate 2 ORs from Winston-Salem campus to NHCOS), scheduled to open July 2019, at which time NHOOS will close.

As the table above shows, upon completion of Project ID #G-11150-16 and Project ID #G-11300-17, by the end of CY2019, FMC Main will have 20 licensed ORs, including 15 shared ORs, three dedicated open heart ORs and two excluded dedicated C-section ORs; the NHFMC license H0209 will have 33 ORs and the NH Health System will have 47 ORs.

The applicant proposes in this project to add two ORs at FMC Main for a total of 22 ORs at FMC Main. The following table shows the NH Health System total ORs upon project completion, assuming approval of this project.

Facility	CY2019	CY2020	Project ID #G-11517-18*	CY2021
NHFMC Main^	20	20	+ 2	22
NH Kernersville Medical Center	4	4		4
NH Clemmons Medical Center	5	5		5
NH Hawthorne Outpatient Surgery	4	4		4
NH Orthopedic Outpatient Surgery	0	0		0
NHFMC License H0209 Total	33	33		35
NH Medical Park Hospital	10	10		10
NH Kernersville Outpatient Surgery	2	2		2
NH Clemmons Outpatient Surgery	2	2		2
NH Health System Total	47	47	+ 2	49

^ The 22 NHFMC Main ORs listed above includes 2 dedicated C-Section and 3 inpatient open heart ORs.

*Project ID #G-11517-18, scheduled to be completed April 2021

As the table above shows, upon completion of this project by the end of CY2021, FMC Main will have 22 ORs (17 shared ORs, three inpatient open heart ORs, and two dedicated C-Section ORs), the NHFMC hospital license H0209 will have 35 ORs, and the NH Health System in Forsyth County will have 49 total ORs, including two dedicated C-Section ORs and three open heart ORs.

In the event that companion Project ID #G-11518-18 (add two ORs at NHCOS) is also approved, the total number of ORs in the NH Health System in Forsyth County would increase to 51, as shown in the table below.

Facility	CY2019	Project ID #G-11518-18*	CY2020	Project ID #G-11517-18**	CY2021
NHFMC Main [^]	20		20	+ 2	22
NH Kernersville Medical Center	4		4		4
NH Clemmons Medical Center	5		5		5
NH Hawthorne Outpatient Surgery	4		4		4
NH Orthopedic Outpatient Surgery	0		0		0
NHFMC License H0209 Total	33		33		35
NH Medical Park Hospital	10		10		10
NH Kernersville Outpatient					
Surgery	2		2		2
NH Clemmons Outpatient Surgery	2	+2	4		4
NH Health System Total	47	+2	49	+ 2	51

^ The NHFMC Main ORs listed above includes 2 dedicated C-Section and 3 inpatient open heart ORs. *Project ID #G-11518-18, scheduled to be completed April 2020

**Project ID #G-11517-18, scheduled to be completed April 2020

As the table above shows, in the event that both NH Health System applications are approved and completed as projected, the NH Health System would have 51 total ORs at the end of CY2021, including two dedicated C-Section and three Open Heart ORs.

In Section C.1, page 12, the applicant states that the FFY2017 data on page 12B of the 2018 Hospital Licensure Renewal Application (LRA) shows NHFMC has the following surgical specialties:

- cardiothoracic surgery,
- open heart surgery,
- general surgery,
- neurosurgery,
- obstetrics & gynecology,
- oral surgery/dental
- orthopedics,
- otolaryngology,
- plastic surgery,
- podiatry,
- urology, and
- vascular surgery.

The applicant further states that NHFMC specialty surgeon recruitment plans for 2017-2021 expect additional surgeons in these additional sub-specialties will use the expanded NHFMC facility:

- gynecology-pelvic pain,
- gynecology,
- uregynecology,
- spine surgery, and
- colorectal surgery.

Patient Origin

On page 57, the 2018 SMFP states, "An operating room's service area is the operating room planning area in which the operating room is located. The operating room planning areas are the single and multicounty groupings shown in Figure 6.1." In Figure 6.1, page 62 of the 2018 SMFP, Forsyth County is shown as a single-county operating room service area. Thus, in this application, the service area is Forsyth County. Providers may serve residents of counties not included in their service area.

In Section C.2, pages 13-14, the applicant provides the historical patient origin by county, by number of patients and percentage, for the total number of ORs on the NHFMC License #H0209, and at FMC Main, for the last full fiscal year, FY2017, as summarized in the tables below.

FF 12017										
	Inpa	atient	Outpa	tient						
County	# of Patients	% of Total	# of Patients	% of Total						
Forsyth	6,195	50.3%	10,719	57.0%						
Stokes	882	7.2%	1,444	7.7%						
Surry	858	7.0%	1,067	5.7%						
Davidson	857	7.0%	1,056	5.6%						
Davie	638	5.2%	1,032	5.5%						
Yadkin	584	4.7%	915	4.9%						
Guilford	601	4.9%	923	4.9%						
All Other*	1,704	13.8%	1,636	8.7%						
TOTAL	12,319	100.0%	18,792	100.0%						

NHFMC License #H0209 Historical Patient Origin FFY2017

Source: 2018 NHFMC LRA, per page 13 of application

*The applicant does not identify "All Other"; the 2018 NHFMC LRA lists inpatients and outpatients from 49 and 52 other NC counties, respectively, and other states.

FMC Main Historical Patient Origin FFY2017

	Inpa	atient	Outpa	tient					
County	# of Patients	% of Total	# of Patients	% of Total					
Forsyth	3,987	46.9%	2,664	49.9%					
Stokes	666	7.8%	368	6.9%					
Surry	667	7.9%	378	7.1%					
Davidson	587	6.9%	379	7.1%					
Davie	514	6.1%	304	5.7%					
Yadkin	469	5.5%	299	5.6%					
Guilford	258	3.0%	206	3.9%					
All Other*	1,346	15.8%	744	13.9%					
TOTAL	8,494	100.0%	5,343	100.0%					

Source: NH Trendstar, per Page 14 of application

*The applicant does not identify "All Other" or provide access to the Trendstar data

The applicant's patient origin tables vary the order of the counties in the different tables. The Project Analyst maintains the same order of the counties as was originally provided throughout this analysis for consistency.

In Sections C.3, page 15, the applicant provides the projected patient origin by county, by number of patients and percentage, for the total number of ORs on the NHFMC License #H0209 and for FMC Main for the first three full operating years (CY2022-CY2024), as shown in the tables below.

Page 15							
County	PY1 C	Y2022	PY2 CY	72023	РҮЗ СҮ	(2024	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total	
Forsyth	6,285	50.3%	6,607	50.3%	6,852	50.3%	
Stokes	900	7.2%	941	7.2%	976	7.2%	
Surry	875	7.0%	915	7.0%	949	7.0%	
Davidson	875	7.0%	914	7.0%	948	7.0%	
Davie	650	5.2%	680	5.2%	706	5.2%	
Yadkin	587	4.7%	623	4.7%	646	4.7%	
Guilford	612	4.9%	641	4.9%	665	4.9%	
All Other*	1,724	13.8%	1,817	13.8%	1,885	13.8%	
TOTAL	12,496	100.0%	12,921	100.0%	13,360	100.0%	

NHFMC Total All Locations (License #H0209) Inpatient Surgical Patient Origin

Source: *"Response to Section C.2 Historical Patient Origin, Section Q, Form C"*, per Page 15 of application *The applicant does not identify "All Other"; the 2018 NHFMC LRA lists surgical inpatients from 49 other NC counties and other states

Page 15								
County	PY1 CY	Y 2022	PY2 CY	72023	PY3 CY2024			
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total		
Forsyth	11,980	57.0%	17,995	57.0%	18,657	57.0%		
Stokes	1,614	7.7%	2,424	7.7%	2,513	7.7%		
Surry	1,193	5.7%	1,791	5.7%	1,857	5.7%		
Davidson	1,180	5.6%	1,773	5.6%	1,838	5.6%		
Davie	1,153	5.5%	1,732	5.5%	1,796	5.5%		
Yadkin	1,023	4.9%	1,536	4.9%	1,593	4.9%		
Guilford	1,032	4.9%	1,549	4.9%	1,607	4.9%		
All Other*	1,828	8.7%	2,746	8.7%	2,848	8.7%		
TOTAL	18,395	100.0%	19,020	100.0%	19,667	100.0%		

NHFMC Total All Locations (License #H0209) Outpatient Surgical Patient Origin Page 15

Source: *"Response to Section C.2 Historical Patient Origin, Section Q, Form C"*, per Page 15 of application The table is italicized regardless of the fact that the Project Analyst changed the order of the counties of Stokes, Surry, and Davidson to maintain consistency among the applicant's patient origin tables.

*The applicant does not identify "All Other"; the 2018 NHFMC LRA lists surgical outpatients from 52 other NC counties and other states

However, the figures as provided in the application and shown in the two tables above are not accurately totaled and do not provide accurate percentages. The following tables provide the correct totals and percentages, as calculated by the Project Analyst using the numbers of patients by county, as provided by the applicant on page 15.

Calculated by I Toject Analyst from Number of Fatients, Fage 15							
County	PY1 CY	PY1 CY2022		PY2 CY2023		PY3 CY2024	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total	
Forsyth	6,285	50.2%	6,607	50.3%	6,852	50.3%	
Stokes	900	7.2%	941	7.2%	976	7.2%	
Surry	875	7.0%	915	7.0%	949	7.0%	
Davidson	875	7.0%	914	7.0%	948	7.0%	
Davie	650	5.2%	680	5.2%	706	5.2%	
Yadkin	587	4.7%	623	4.7%	646	4.7%	
Guilford	612	4.9%	641	4.9%	665	4.9%	
All Other*	1,724	13.8%	1,817	13.8%	1,885	13.8%	
TOTAL	12,508	100.0%	13,138	100.0%	13,627	100.0%	

NHFMC Total All Locations (License #H0209) Inpatient Surgical Patient Origin Calculated by Project Analyst from Number of Patients, Page 15

Culculated by Hojeet Hullyst Holl Hulliber of Hatelits, Huge 10							
County	PY1 CY2022		PY2 CY	PY2 CY2023		PY3 CY2024	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total	
Forsyth	11,980	57.0%	17,995	57.0%	18,657	57.0%	
Stokes	1,614	7.7%	2,424	7.7%	2,513	7.7%	
Surry	1,193	5.7%	1,791	5.7%	1,857	5.7%	
Davidson	1,180	5.6%	1,773	5.6%	1,838	5.6%	
Davie	1,153	5.5%	1,732	5.5%	1,796	5.5%	
Yadkin	1,023	4.9%	1,536	4.9%	1,593	4.9%	
Guilford	1,032	4.9%	1,549	4.9%	1,607	4.9%	
All Other*	1,828	8.7%	2,746	8.7%	2,848	8.7%	
TOTAL	21,003	100.0%	31,546	100.0%	32,709	100.0%	

NHFMC Total All Locations (License #H0209) Outpatient Surgical Patient Origin Calculated by Project Analyst from Number of Patients, Page 15

The following table compares the total number of inpatients and outpatients as calculated by the applicant and the Project Analyst using the data provided on page 15. There is a significant difference in the total numbers of patients.

Comparison of Totals Calculated by Applicant and Project Analyst								
County	PY 1 CY2022 # of Patients	PY2 CY2023 # of Patients	PY3 CY2024 # of Patients					
Applicant								
Total Inpatients	12,496	12,921	13,360					
Total Outpatient	18,395	19,020	19,667					
Total Surgical Patients	30,891	31,941	33,027					
Project Analyst								
Total Inpatients	12,508	13,138	13,627					
Total Outpatients	21,003	31,546	32,709					
Total Surgical Patients	33,511	44,684	46,336					
DIFFERENCE	-2,620	-12,743	-13,309					

NHFMC Total All Locations (License #H0209) Inpatient and Outpatient Surgical Patient Origin Comparison of Totals Calculated by Applicant and Project Analys

Source: data on page 15, as calculated by applicant and Project Analyst

As the table above shows, the difference is 13,309 patients in PY3. Therefore, the numbers of patients, calculation totals, and/or percentages are incorrectly calculated and/or totaled. The information in the application as submitted is not sufficient to allow the Project Analyst to determine where the errors lie. Is the total number to be served correct and the individual county numbers wrong? Are the individual county numbers correct and the total incorrect? Are the percentages accurate and just not distributed and totaled correctly? There simply is not enough information provided in the application as submitted to make a determination.

In Section C.3, page 16, the applicant provides the projected patient origin by county, by number of patients and percentage, for the total number of ORs at FMC Main for the first three full operating years (CY2022-CY2024), as shown in the following tables.

Projected Inpatient Surgical Patient Origin Page 16									
County	PY1 C	Y2022	PY2 CY	Y2023	РҮЗ СҮ	(2024			
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total			
Forsyth	4,491	46.9%	4,657	46.9%	4,830	46.9%			
Stokes	750	7.8%	778	7.8%	807	7.8%			
Surry	752	7.9%	779	7.9%	808	7.9%			
Davidson	661	6.9%	685	6.9%	711	6.9%			
Davie	579	6.0%	600	6.0%	622	6.0%			
Yadkin	529	5.5%	548	5.5%	568	5.5%			
Guilford	290	3.0%	301	3.0%	312	3.0%			
All Other*	1,516	15.8%	1,572	15.8%	1,630	15.8%			
TOTAL	9,839	100.0%	10,173	100.0%	10,519	100.0%			

FMC Main

Source: "Response to Section C.2 Historical Patient Origin, Section Q, Form C", per Page 16 of application *The applicant does not identify "All Other"; the 2018 NHFMC LRA lists inpatients from 49 other NC counties and other states

FMC Main **Projected Outpatient Surgical Patient Origin** Page 16

l age 10							
County	PY1 C	Y2022	PY2 CY	PY2 CY2023		2024	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total	
Forsyth	3,051	49.9%	3,134	49.9%	3,229	3,051	
Stokes	433	7.1%	445	7.1%	458	433	
Surry	434	7.1%	446	7.1%	460	434	
Davidson	422	6.9%	433	6.9%	446	422	
Davie	348	5.7%	357	5.7%	368	348	
Yadkin	342	5.6%	351	5.6%	362	342	
Guilford	236	3.9%	243	3.9%	250	236	
All Other*	853	13.9%	876	13.9%	902	853	
TOTAL	6,341	100.0%	6,557	100.0%	6,780	6,341	

Source: "Response to Section C.2 Historical Patient Origin, Section Q, Form C", per Page 16 of application The table is italicized regardless of the fact that the Project Analyst changed the order of the counties of Stokes, Surry, and Davidson to maintain consistency among the applicant's patient origin tables.

*The applicant does not identify "All Other"; the 2018 NHFMC LRA lists outpatients from 52 other NC counties and other states

However, the figures as provided on page 16 in the application and shown in the two tables above are not accurately totaled and do not provide accurate percentages. The following tables provide the correct totals and percentages, as calculated by the Project Analyst using the numbers of patients by county, as provided by the applicant on page 16.

Calculated by Project Analyst from Number of Patients, Page 16						
County	PY1 CY	72022	PY2 CY	72023	РҮЗ СҮ	Z 2024
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Forsyth	4,491	46.9%	4,657	46.9%	4,830	46.9%
Stokes	750	7.8%	778	7.8%	807	7.8%
Surry	752	7.9%	779	7.9%	808	7.9%
Davidson	661	6.9%	685	6.9%	711	6.9%
Davie	579	6.1%	600	6.0%	622	6.0%
Yadkin	529	5.5%	548	5.5%	568	5.5%
Guilford	290	3.0%	301	3.0%	312	3.0%
All Other*	1,516	15.8%	1,572	15.8%	1,630	15.8%
TOTAL	9,568	100.0%	9,920	100.0%	10,288	100.0%

FMC Main Inpatient Surgical Patient Origin Calculated by Project Analyst from Number of Patients, Page 16

FMC Main Outpatient Surgical Patient Origin Calculated by Project Analyst from Number of Patients, Page 16

County	PY1 CY2022		ty PY1 CY2022 PY2 CY2023		PY3 CY2024	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Forsyth	3,051	49.9%	3,134	49.9%	3,229	49.9%
Stokes	433	7.1%	445	7.1%	458	7.1%
Surry	434	7.1%	446	7.1%	460	7.1%
Davidson	422	6.9%	433	6.9%	446	6.9%
Davie	348	5.7%	357	5.7%	368	5.7%
Yadkin	342	5.6%	351	5.6%	362	5.6%
Guilford	236	3.9%	243	3.9%	250	3.9%
All Other*	853	13.9%	876	13.9%	902	13.9%
TOTAL	6,119	100.0%	6,285	100.0%	6,475	100.0%

The following table compares the total number of inpatients and outpatients as calculated by the applicant and the Project Analyst using the data provided on page 16. There is a significant difference in the total numbers of patients.

FMC Main

Comparison of Totals Calculated by Applicant and Troject Analys								
		PY2	PY3					
County	PY1 CY2022	CY2023	CY2024					
	# of Patients	# of Patients	# of Patients					
Applicant								
Total Inpatients	9,839	10,173	10,519					
Total Outpatient	6,341	6,557	6,780					
Total Surgical Patients	16,180	16,730	17,299					
Project Analyst								
Total Inpatients	9,568	9,920	10,288					
Total Outpatients	6,119	6,285	6,475					
Total Surgical Patients	15,687	16,205	16,763					
DIFFERENCE	493	525	536					

Inpatient and Outpatient Surgical Patient Origin Comparison of Totals Calculated by Applicant and Project Analyst

Source: data on page 16, as calculated by applicant and Project Analyst

As the table above shows, the difference is 536 patients in PY3. Therefore, the numbers of patients, calculation totals, and/or percentages are incorrectly calculated and/or totaled. The information in the application as submitted is not sufficient to allow the Project Analyst to determine where the errors lie. Is the total number to be served correct and the individual county numbers wrong? Are the individual county numbers correct and the total incorrect? Are the percentages accurate and just not distributed and totaled correctly? There simply is not enough information provided in the application as submitted to make a determination. Therefore, the applicant has not adequately identified the population to be served.

Analysis of Need

In Section C.4, pages 16-22, the applicant discusses the NH Health System operating room need in Forsyth County per the SMFP operating room methodology. The applicant first explains why it believes Novant Health needs the four new ORs identified as needed in Forsyth County in the 2018 SMFP and then discusses why it believes FMC Main needs two of the four ORs. On pages 19-22, the applicant states that Novant Health's need for the four ORs in Forsyth County (two of which are the subject of this project) is based on the following factors:

- Novant Health's historical surgical utilization, based on its 2015-2017 CAGR for surgical services
 - Inpatient surgery 4.7%
 - Outpatient surgery 2.9%
 - All surgical services 3.4%

On page 20, the applicant provides the calculations for the 2015-2017 CAGR, as summarized below.

Surgical Facility	FFY2015	FFY2016	FFY2017		
# of Inpatient Surgical Cases*					
NH Forsyth Medical Center	9,519	9,262	10,483		
NH Medical Park Hospital	897	871	943		
NH Forsyth County Total	10,416	10,133	11,426		
NH Forsyth County CAGR 2015-2017	4.7%				
# of Outpatient Surgical Cases					
NH Forsyth Medical Center	17,445	17,706	18,792		
NH Medical Park Hospital	8,613	8,665	8,782		
NH Forsyth County Total	26,058	26,371	27,574		
NH Forsyth County CAGR 2015-2017		2.9%			
# of Total Surgical Cases					
NH Forsyth County Total	36,474	36,504	39,000		
NH Forsyth County CAGR 2015-2017		3.4%			

Source: *"Section Q, Form C Assumptions and Methodology, Figure 1"* *Excludes C-Sections done in a dedicated C-Section OR

• Surgical specialist growth of 35% from 2013 through 2017, with NH planning to continue its physician recruitment plan

On page 22, the applicant provides the following table, which it believes shows the Novant Health System's need for additional ORs based on projected OR deficits and surpluses for Novant Health System.

Novant Health Forsyth Hojected OK Denent / Surphas(-)					
Surgical Facility	CY2021	CY2022	CY2023	CY2024	
NHCOS Application Project Year	PY1	PY2	PY3		
NHFMC Application Project Year		PY1	PY2	PY3	
NH Forsyth Medical Center	-0.4	0.6	1.7	2.8	
NH Medical Park Hospital	0.0	0.4	0.7	1.1	
NH Kernersville Outpatient Surgery	-0.6	-0.6	-0.6	-0.5	
NH Clemmons Outpatient Surgery	1.9	2.0	2.1	2.3	
NH Health System Forsyth Total	0.8	2.4	4.0	5.7	

SMFP Operating Room Methodology
Novant Health Forsyth Projected OR* Deficit / Surplus(-)

Source: Section Q, Form C Assumptions and Methodology, Figure 12 *Excludes C-Sections done in a dedicated C-Section OR

Totals may not sum due to rounding

In Section C, pages 26-28, the applicant explains why it believes the proposed population projected to utilize the proposed service needs the two additional ORs at FMC Main. The applicant states that upon the completion of the previously approved relocations of ORs from FMC Main, including Project ID #'s G-11150-16 and G-11300-17, FMC Main will

have 18 ORs: 13 shared ORs, three open heart ORs and two dedicated C-Section ORs. However, that does not agree with the applicant's statement on page 24, where it states that NH Orthopedic Outpatient Surgery will close upon the relocation of ORs to NH Clemmons Outpatient Surgery (Project ID #G-11300-17), which reduces the OR inventory on the NHFMC License H0209, but not the OR inventory at FMC Main. If the two ORs approved in Project ID #G-11300-17 to be relocated to NH Clemmons Outpatient Surgery come from NH Orthopedic Outpatient Surgery, the number of ORs at FMC Main remains 20, including the two dedicated C-Section rooms, as shown below.

Facility	2018 LRA	Project ID #G- 11150-16*	CY2018	Project ID #G-11300-17**	CY2019
NHFMC Main [^]	22	-2	20	#G 11000 17	20
NH Kernersville Medical Center	4		4		4
NH Clemmons Medical Center	5		5		5
NH Hawthorne Outpatient Surgery	4		4		4
NH Orthopedic Outpatient Surgery	2		2	-2	0
NHFMC License H0209 Total	37		35		33
NH Medical Park Hospital	10		10		10
NH Kernersville Outpatient					
Surgery	0	+2	2		2
NH Clemmons Outpatient Surgery	0		0	+2	2
NH Health System Total	47	+0	47	+0	47

[^] The 22 NHFMC Main ORs listed on the 2018 LRA includes 2 dedicated C-Section and 3 inpatient open heart ORs.

*Project ID #G-11150-16, (relocate 2 ORs from Winston-Salem campus to NHKOS), scheduled to open June 2018.

**Project ID #G-11300-17, (relocate 2 ORs from Winston-Salem campus to NHCOS), scheduled to open July 2019, at which time NHOOS will close.

As the table above shows, upon completion of Project ID #G-11150-16 and Project ID #G-11300-17, by the end of CY2019, FMC Main will have 20 licensed ORs, including 15 shared ORs, three dedicated open heart ORs and two excluded dedicated C-section ORs; the NHFMC license H0209 will have 33 ORs and the NH Health System will have 47 ORs.

Therefore, the applicant does not accurately identify the number of ORs at FMC Main in this section. However, Section Q assumptions state that all calculations exclude the two C-Section ORs and uses the correct number of ORs for FMC Main, excluding C-Section ORs.

The applicant states that the opening of the outpatient surgery facilities approved in the two projects mentioned (Project ID #sG-11150-16 and G-11300-17) will shift some hours related to lower acuity outpatient surgery away from FMC Main. However, the applicant states that the hours related to inpatient surgery and higher acuity outpatient surgery will continue to increase with population growth and the recruitment of additional surgeons to

meet community needs. On pages 27-28, the applicant states that FMC Main needs more ORs to:

- serve the growing population,
- reduce bumping of scheduled surgeries by unscheduled surgeries, reducing the patient's length of stay and reducing patient stress,
- reduce the need to extend operating hours to complete the surgical schedule for the day, reducing physician and staff fatigue and staff overtime,
- allow better block scheduling for physician productivity, and
- help more surgical patients who require financial assistance.

However, the applicant does not adequately demonstrate that the reasons it cites for additional growth are reasonable and adequately supported. The reasons cited by the applicant for continued growth in surgical cases are factors which are nothing new. And, the population has been aging and growing for some time. Specifically, the applicant relies on the increase between 2015 and 2017 to project positive growth, but does not address the decline in surgical cases when different time periods are assessed. Total surgery cases performed at FMC Main declined between 2012 and 2017 and between 2014 and 2017 (5-yr CAGR of -0.4% from 2012 through 2017 and a 3-yr CAGR of -1.5% from 2014 through 2017).

Projected Utilization Operating Rooms

As discussed earlier in the findings, the NH Health System submitted two separate applications on May 15, 2018, pursuant to the 2018 SMFP need determination for four ORs in Forsyth County: 1) Project ID #G-11517-18 / Add two ORs at FMC Main, and 2) Project ID #G-11518-18 / Add two ORs to Novant Health Clemmons Outpatient Surgery (NHCOS), a freestanding ASF under development in Clemmons, NC. Together, the two applications apply for four ORs in Forsyth County. The first three full fiscal years for this application are CY2022, CY2023, and CY2024. The first three full fiscal years for Project ID #G-11518-18 are CY2021, CY2022, and CY2023. The table below shows the applicant's historical and projected utilization for the system, followed by projected utilization for the individual facilities within the system. The tables were developed from the information provided in Section Q, Form Cs.

		CY2021	CY2022	CY2023	CY2024
Project Years NHCOS	Last Full	1 st Full FY	2 nd Full FY	3 rd Full FY	
Project Years NHFMC	FY		1 st Full FY	2 nd Full FY	3 rd Full FY
Adjusted Planning Inventory (1)	45	47	49	49	49
Inpatient Surgical Hours (4)	29,052	37,730	39,013	40,339	41,711
Ambulatory Surgical Hours (4)	40,549	46,385	47,963	49,594	51,279
Total Surgical Hours (5)	69,600	84,116	86,976	89,932	92,990
# of ORs Needed (6)	36.7	45.8	47.4	49.0	50.7

Novant Health "Health System" Operating Room Utilization

(1) Last Full FY is from Table 6B in the 2018 SMFP. Excludes two C-Section ORs at FMC Main. System includes NHFMC-20, NHKMC-4, NHCMC-5, NHHOS-4, NHKOS-2, NHCOS-2, and NHMPH - 10. The first three full FYs includes the proposed OR(s).

(4) Surgical Hours equals Surgical Cases multiplied by the Final Case Time for each separate facility and added together for the System.

(5) Total Surgical Hours equals Inpatient Surgical Hours plus Ambulatory Surgical Hours.

(6) # of ORs Needed equals Total Surgical Hours divided by the Standard Hours per OR per Year.

The table above shows the applicant's historical and projected OR utilization for the NH Health System, which includes NH License H0209 (NH Forsyth Main, NH Kernersville Medical Center, NH Clemmons Medical Center, and NH Hawthorne Outpatient Surgery), NH Medical Park Hospital, NH Kernersville Outpatient Surgery and NH Clemmons Outpatient Surgery. Following are tables with projected utilization for the individual licensed facilities within the health system.

		CY2021	CY2022	CY2023	CY2024
Project Years NHCOS	Last Full	1 st Full FY	2 nd Full FY	3 rd Full FY	
Project Years NHFMC	FY		1 st Full FY	2 nd Full FY	3 rd Full FY
Adjusted Planning Inventory (1)	31	33	33	33	33
Standard Hours per OR per Year (2)	1,950	1,950	1,950	1,950	1,950
Inpatient Surgical Cases	9,262	12,085	12,496	12,921	13,360
Final Inpatient Case Time (3)	168	168	168	168	168
Inpatient Surgical Hours (4)	25,934	33,838	34,989	36,179	37,408
Ambulatory Surgical Cases	17,706	17,790	18,395	19,020	19,667
Final Ambulatory Case Time (3)	87	87	87	87	87
Ambulatory Surgical Hours (4)	25,674	25,796	26,673	27,579	28,517
Total Surgical Hours (5)	51,607	59,633	61,660	63,757	65,925
# of ORs Needed (6)	26.5	30.6	31.6	32.7	33.8

NH Forsyth Medical Center License # H0209 Operating Room Utilization

(1) Last Full FY is from Table 6B in the 2018 SMFP. Excludes two C-Section ORs. License includes NHKMC-4, NHCMC-5, NHHOS-4. NH Orthopedic Outpatient Surgery ORs will have moved to NH Clemmons and NHOOS will have closed. The first three full FYs includes the proposed OR(s).

⁽²⁾ From Page 59 in the 2018 SMFP, Group 2.

⁽³⁾ From Table 6B in the 2018 SMFP in minutes.

- (4) Surgical Hours equals Surgical Cases multiplied by the Final Case Time.
- (5) Total Surgical Hours equals Inpatient Surgical Hours plus Ambulatory Surgical Hours.
- (6) # of ORs Needed equals Total Surgical Hours divided by the Standard Hours per OR per Year.

		CY2021	CY2022	CY2023	CY2024
Project Years NHCOS	Last Full	1 st Full FY	2 nd Full FY	3 rd Full FY	
Project Years NHFMC	FY		1 st Full FY	2 nd Full FY	3 rd Full FY
Adjusted Planning Inventory (1)	12	10	10	10	10
Standard Hours per OR per Year (2)	1,755	1,755	1,755	1,755	1,755
Inpatient Surgical Cases	871	1,087	1,124	1,162	1,202
Final Inpatient Case Time (3)	214.8	214.8	214.8	214.8	214.8
Inpatient Surgical Hours (4)	3,118	3,892	4,024	4,160	4,303
Ambulatory Surgical Cases	8,665	7,998	8,270	8,551	8,842
Final Ambulatory Case Time (3)	103	103	103	103	103
Ambulatory Surgical Hours (4)	14,875	13,730	14,197	14,679	15,179
Total Surgical Hours (5)	17,994	17,622	18,221	18,840	19,481
# of ORs Needed (6)	10	10.0	10.4	10.7	11.1

NH Medical Park Hospital Operation Room Utilization

(1) Last Full FY is from Table 6B in the 2018 SMFP. The first three full FYs includes the proposed OR(s).

(2) From Page 59 in the 2018 SMFP, Group 3.

(3) From Table 6B in the 2018 SMFP in minutes.

(4) Surgical Hours equals Surgical Cases multiplied by the Final Case Time.

(5) Total Surgical Hours equals Inpatient Surgical Hours plus Ambulatory Surgical Hours.

(6) # of ORs Needed equals Total Surgical Hours divided by the Standard Hours per OR per Year.

	Last FFY	CY2021	CY2022	CY2023	CY2024
Project Years NHCOS	(Proposed	1 st Full FY	2 nd Full FY	3 rd Full FY	
Project Years NHFMC	ASF)		1 st Full FY	2 nd Full FY	3 rd Full FY
Adjusted Planning Inventory (1)	NA	4	4	4	4
Standard Hours per OR per Year (2)	NA	1,312.5	1,312.5	1,312.5	1,312.5
Inpatient Surgical Cases	NA	NA	NA	NA	NA
Final Inpatient Case Time (3)	NA	NA	NA	NA	NA
Inpatient Surgical Hours (4)	NA	NA	NA	NA	NA
Ambulatory Surgical Cases	NA	4,447	4,598	4,754	4,916
Final Ambulatory Case Time (3)	NA	68.6	68.6	68.6	68.6
Ambulatory Surgical Hours (4)	NA	5,084	5,257	5,436	5,620
Total Surgical Hours (5)	NA	5,084	5,257	5,436	5,620
# of ORs Needed (6)	NA	3.9	4.0	4.1	4.3

NH Clemmons Outpatient Surgery Operation Room Utilization

(1) Last Full FY is from Table 6B in the 2018 SMFP. The first three full FYs includes the proposed OR(s).

(2) From Page 59 in the 2018 SMFP, Group 6.

(3) From Table 6B in the 2018 SMFP in minutes.

(4) Surgical Hours equals Surgical Cases multiplied by the Final Case Time.

(5) Total Surgical Hours equals Inpatient Surgical Hours plus Ambulatory Surgical Hours.

(6) # of ORs Needed equals Total Surgical Hours divided by the Standard Hours per OR per Year.

	Last FFY	CY2021	CY2022	CY2023	CY2024
Project Years NHCOS	(Proposed	1 st Full FY	2 nd Full FY	3 rd Full FY	
Project Years NHFMC	ASF)		1 st Full FY	2 nd Full FY	3 rd Full FY
Adjusted Planning Inventory (1)	NA	2	2	2	2
Standard Hours per OR per Year (2)	NA	1,312.5	1,312.5	1,312.5	1,312.5
Inpatient Surgical Cases	NA	NA	NA	NA	NA
Final Inpatient Case Time (3)	NA	NA	NA	NA	NA
Inpatient Surgical Hours (4)	NA	NA	NA	NA	NA
Ambulatory Surgical Cases	NA	1,553	1,606	1,661	1,717
Final Ambulatory Case Time (3)	NA				
	NA	68.6	68.6	68.6	68.6
Ambulatory Surgical Hours (4)	NA	1,776	1,836	1,899	1,963
Total Surgical Hours (5)	NA	1,776	1,836	1,899	1,963
# of ORs Needed (6)	NA	1.4	1.4	1.4	1.5

NH Kernersville Outpatient Surgery Operating Room Utilization

(1) Last Full FY is from Table 6B in the 2018 SMFP. The first three full FYs includes the proposed OR(s).

(2) From Page 59 in the 2018 SMFP, Group 6.

(3) From Table 6B in the 2018 SMFP in minutes.

(4) Surgical Hours equals Surgical Cases multiplied by the Final Case Time.

(5) Total Surgical Hours equals Inpatient Surgical Hours plus Ambulatory Surgical Hours.

(6) # of ORs Needed equals Total Surgical Hours divided by the Standard Hours per OR per Year.

In this application, Project ID #G-11517-18, the applicant proposes to add two ORs at FMC Main in Winston-Salem, Forsyth County. In Section Q, Form C, the applicant provides projected utilization for the proposed operating rooms at FMC Main, as illustrated in the following table.

		CY2021	CY2022	CY2023	CY2024
Project Years NHCOS	Last Full	1 st Full FY	2 nd Full FY	3 rd Full FY	
Project Years NHFMC Main	FY		1 st Full FY	2 nd Full FY	3 rd Full FY
Adjusted Planning Inventory (1)	18	20	20	20	20
Standard Hours per OR per Year (2)	1,950	1,950	1,950	1,950	1,950
Inpatient Surgical Cases	8,209	9,515	9,839	10,173	10,519
Final Inpatient Case Time (3)	168	168	168	168	168
Inpatient Surgical Hours (4)	22,985	26,642	27,549	28,484	29,453
Ambulatory Surgical Cases	5342	6,133	6,341	6,557	6,780
Final Ambulatory Case Time (3)	87	87	87	87	87
Ambulatory Surgical Hours (4)	7,746	8,893	9,194	9,508	9,831
Total Surgical Hours (5)	30,731	35,535	36,744	37,993	39,285
# of ORs Needed (6)	15.8	18.2	18.8	19.5	20.1

NH Forsyth Main Campus Operating Room Utilization

(1) Last Full FY is from Form C. Excludes two C-Section ORs. The first three full FYs includes the proposed OR(s).

(2) From Page 59 in the 2018 SMFP, Group 2.

(3) From Table 6B in the 2018 SMFP in minutes.

(4) Surgical Hours equals Surgical Cases multiplied by the Final Case Time.

(5) Total Surgical Hours equals Inpatient Surgical Hours plus Ambulatory Surgical Hours.

(6) # of ORs Needed equals Total Surgical Hours divided by the Standard Hours per OR per Year.

In Section Q, Form C Assumptions, Figures 1-12, the applicant provides the assumptions and methodology used to project operating room utilization, which are summarized below:

- The project begins April 1, 2021 first full fiscal year is CY2022.
- All calculations exclude the two C-Section ORs and their utilization.
- The NHFMC facility is identified as a Group 2 facility with an average inpatient time of 168 minutes or 2.8 hours per case, an average ambulatory case time of 87 minutes per case and 1,950 standard hours per operating room. The applicant designates surgical cases it believes would be appropriate to shift from FMC Main to other NH Health System facilities, as discussed in Section Q. The following table summarizes the applicant's outcome from Figures 1-12 in Section Q and shows the applicant's table from page 22 of its application, which the applicant believes shows the Novant Health System's need for additional ORs.

Surgical Facility	CY2021	CY2022	CY2023	CY2024
NHCOS Application Project Year	PY1	PY2	PY3	
NHFMC Application Project Year		PY1	PY2	PY3
NH Forsyth Medical Center (FMC				
Main)	0.2	0.8	1.5	2.1
NH FMC License H0209	-0.4	0.6	1.7	2.8
NH Medical Park Hospital	0.0	0.4	0.7	1.1
NH Kernersville Outpatient Surgery	-0.6	-0.6	-0.6	-0.5
NH Clemmons Outpatient Surgery	1.9	2.0	2.1	2.3
NH Health System Forsyth Total	0.8	2.4	4.0	5.7

SMFP Operating Room Methodology Novant Health Forsyth Projected OR* Deficit / Surplus(-) Section O Figure 12

Source: Section Q, Form C Assumptions and Methodology, Figures1-12, using a 3.4% CAGR to project future utilization

*Excludes C-Sections done in a dedicated C-Section OR

• Growth is projected at 3.4% from CY2017 through CY2024, based on Novant Health's average growth rate of total inpatient and outpatient surgeries from FY2015 to FY2017 (page 20 and Figure 1, Section Q), which actually shows a decrease of 2.7% for 2016 inpatient cases and only a small increase of 1.2% in outpatient cases for a total growth from FY2015 to FY2016 of 0.08%, with the growth coming from FY2016 to FY2017, as shown below.

Surgical Facility	FFY2015	FFY2016	FFY2017
# of Inpatient Surgical Cases*			
NH Forsyth Medical Center	9,519	9,262	10,483
NH Medical Park Hospital	897	871	943
NH Forsyth County Total	10,416	10,133	11,426
NH Forsyth County Growth		-2.7%	12.8%
# of Outpatient Surgical Cases			
NH Forsyth Medical Center	17,445	17,706	18,792
NH Medical Park Hospital	8,613	8,665	8,782
NH Forsyth County Total	26,058	26,371	27,574
NH Forsyth County Growth		1.2%	4.6%
# of Total Surgical Cases			
NH Forsyth County Total	36,474	36,504	39,000
NH Forsyth County Growth		0.08%	6.8%

Source: "Section Q, Form C Assumptions and Methodology, Figure 1" per application page 20.

*Excludes C-Sections done in a dedicated C-Section OR

Thus the 2-yr CAGR reflects one year of little to no growth and one year of growth. The following table shows the three and five-year growth rates for the NH Health System and all surgical cases in Forsyth County, using the applicant's data on page 20 and in Figure 1, Section Q.

Total Inpatient and Outpatient Surgical Cases	NH Health System	Forsyth County
5-yr CAGR 2012-2017	2.0%	1.6%
3-yr CAGR 2014-2017	2.0%	1.5%

Source: Applicable hospital and surgery center LRAs

As the table above illustrates, the NH Forsyth Health System's 5 and 3-year CAGRs are the same and are only 2%. Applying all the applicant's adjustments for volume shifts within the NH Health System and using a 2.0% growth rate for the NH Forsyth Health System results in a need for only 1.3 and 2.2 ORs in CY2023 and CY2024, respectively, not 4.0 and 5.7 ORs. Using a 2% growth rate results in a need for only 0.2 of an additional OR at FMC Main in CY2024, as shown in the table below. Pursuant to the Operating Room Need Methodology in the 2018 SMFP, the need at FMC Main in CY2024 is zero additional ORs.

Surgical Facility	CY2021	CY2022	CY2023	CY2024		
NHCOS Application Project Year	PY1	PY2	PY3			
NHFMC Application Project Year		PY1	PY2	PY3		
NH Forsyth Medical Center (FMC						
Main)	-0.8	-0.5	-0.1	0.2		
NH FMC License H0209	-1.1	-0.5	0.1	0.7		
NH Medical Park Hospital	-0.6	-0.5	-0.3	-0.1		
NH Kernersville Outpatient Surgery	-0.6	-0.6	-0.6	-0.6		
NH Clemmons Outpatient Surgery	1.9	2.0	2.1	2.1		
NH Health System Forsyth Total	-0.5	0.4	1.3	2.2		

SMFP Operating Room Methodology Novant Health Forsyth Projected OR* Deficit / Surplus(-)

Source: Section Q, Form C Assumptions and Methodology, Figures1-12, using a reasonable 2.0% CAGR to project future utilization

*Excludes C-Sections done in a dedicated C-Section OR

Projected utilization is not reasonable and not adequately supported because the applicant relies on an unsupported growth rate to show a need for two additional ORs at FMC Main for all the reasons described above.

Access

In Section C.8, pages 35-36, the applicant states:

"Novant Health does not exclude, deny benefits to, or otherwise discriminate against patients, students, or visitors on the basis of race; color; religion; national origin; culture; language; physical or mental disabilities; genetic information; age; sex, including pregnancy, childbirth or related medical conditions; marital status; sexual orientation; gender identity or expression; socioeconomic status; or source of payment in admission to, participation in, or receipt of the services and benefits of any of its programs and other activities, whether carried out by Novant Health directly or through a contractor or other entity with whom Novant Health arranges to carry out its programs or activities. "

In Section L, page 76, the applicant projects the following payor mix during the second full fiscal year of operation following completion of the project, as illustrated in the table below.

C 1 2023	
Entire Facility FMC Main	Operating Rooms
10.0%	4.1%
41.0%	49.2%
16.0%	9.3%
31.0%	34.9%
2.0%	2.5%
100.0%	100.0%
	10.0% 41.0% 16.0% 31.0% 2.0%

Proposed Payor Mix CY2023

* Including any managed care plans

Totals may not sum due to rounding

The applicant states on page 76 that this project does not involve procedure rooms or GI endoscopy rooms and that the projected payor mix is based on actual FMC Main operating room cases and is not expected to change over the project years. The projected payor mix is reasonable and adequately supported.

The applicant projects the extent to which all residents, including underserved groups, will have access to the proposed services (payor mix) and adequately supports its assumptions.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application,
- written comments,
- remarks made at the public hearing,
- responses to comments, and
- information publicly available during the review and used by the Agency.

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

- The applicant does not adequately identify the population to be served for all the reasons described above.
- Projected utilization is not based upon reasonable and adequately supported assumptions for all the reasons described above.
- The applicant does not adequately demonstrate the need for the two additional ORs at the FMC Main campus where the ORs under review would be located, for the reasons described above.

NH Clemmons. The NH Health System submitted two separate applications on May 15, 2018, pursuant to the 2018 SMFP need determination for four ORs in Forsyth County: 1) Project ID #G-11517-18 / Add two ORs at FMC Main, and 2) Project ID #G-11518-18 / Add two ORs to NHCOS, a freestanding ASF under development in Clemmons, NC. Together, the two applications apply for four ORs in Forsyth County.

In this application, Project ID #G-11518-18, the applicant proposes to add two ORs at the previously approved NHCOS facility in Clemmons, Forsyth County for a total of four ORs upon completion of this project and Project ID #G-11300-17 (relocate 2 ORs from NHFMC). In Section A.6, page 3, the applicant describes the proposed project as follows:

"Add two new ORs for a total of four ORs at the CON approved Novant Health Clemmons Outpatient Surgery (NHCOS). NHCOS was approved to develop a freestanding ambulatory surgery center ("ASC") with two operating rooms in June 2017, CON Project I.D. #G-11300-17, and is on schedule to open July 2019. The proposed project will increase total operating rooms at NHCOS to four. As a result, this project is both in response to a need determination in the 2018 SMFP and a scope change for CON Project I.D. #G-11300-17."

The proposal in this application results in a change of scope for Project ID #G-11300-17. The table below represents the projected operating room inventory in the NH Health System following the scheduled completion of previously approved CON Project ID #G-11150-16, scheduled for completion in June 2018 and Project ID #G-11300-17, scheduled for completion in July 2019, assuming the ORs are relocated from NH Orthopedic Outpatient Surgery to NH Clemmons Outpatient Surgery, as first stated by the applicant on page 18 of this application.

Facility	2018 LRA	Project ID #G- 11150-16*	CY2018	Project ID #G-11300-17**	CY2019
NHFMC Main [^]	22	-2	20		20
NH Kernersville Medical Center	4		4		4
NH Clemmons Medical Center	5		5		5
NH Hawthorne Outpatient Surgery	4		4		4
NH Orthopedic Outpatient Surgery	2		2	-2	0
NHFMC License H0209 Total	37		35		33
NH Medical Park Hospital	10		10		10
NH Kernersville Outpatient					
Surgery	0	+2	2		2
NH Clemmons Outpatient Surgery	0		0	+2	2
NH Health System Total	47	+0	47	+0	47

^ The 22 NHFMC Main ORs listed on the 2018 LRA includes 2 dedicated C-Section and 3 inpatient open heart ORs.

*Project ID #G-11150-16, (relocate 2 ORs from Winston-Salem campus to NHKOS), scheduled to open June 2018.

**Project ID #G-11300-17, (relocate 2 ORs from Winston-Salem campus to NHCOS), scheduled to open July 2019, at which time NHOOS will close.

As the table above shows, upon completion of Project ID #G-11150-16 and Project ID #G-11300-17, by the end of CY2019, FMC Main will have 20 licensed ORs, including 15 shared ORs, three dedicated open heart ORs and two excluded dedicated C-section ORs; NHKOS will be licensed for two ORs; NHOOS will be licensed for 0 ORs and closed; NHCOS will be licensed for two ORs; the NHFMC license H0209 will have 33 ORs and the NH Health System will have 47 ORs, including the two dedicated C-section ORs at FMC Main.

The applicant proposes in this project to add two ORs at NHCOS for a total of four ORs following completion of this project and previously approved Project ID #G-11300-17. The following table shows the NH Health System total ORs upon project completion, assuming approval of this project, Project ID #G-11518-18.

Facility	CY2018	Project ID #G-11300-17*	CY2019	Project ID #G-11518-18**	CY2020
NHFMC Main	20		20		20
NH Kernersville Medical Center	4		4		4
NH Clemmons Medical Center	5		5		5
NH Hawthorne Outpatient Surgery	4		4		4
NH Orthopedic Outpatient Surgery	2	-2	0		0
NHFMC License H0209 Total	35		33		33
NH Medical Park Hospital	10		10		10
NH Kernersville Outpatient					
Surgery	2		2		2
NH Clemmons Outpatient Surgery	0	+2	2	+2	4
NH Health System Total	47	+0	47	+2	49

*Project ID #G-11300-17, scheduled to be completed July 2019

**Project ID #G-11518-18, scheduled to be completed April 2020

As the table above shows, upon completion of this project (and Project ID #G-11300-17) by the end of CY2020, NHCOS will have four ORs, the NHFMC hospital license H0209 will have 33 ORs, and the NH Health System in Forsyth County will have 49 ORs.

In the event that companion application, Project ID #G-11517-18 (add two ORs at FMC Main), is also approved, the total number of ORs in the NH Health System in Forsyth County would increase to 51, as shown in the table below.

		Project ID		Project ID	
Facility	CY2019	#G-11518-18*	CY2020	#G-11517-18**	CY2021
NHFMC Main^	20		20	+ 2	22
NH Kernersville Medical Center	4		4		4
NH Clemmons Medical Center	5		5		5
NH Hawthorne Outpatient Surgery	4		4		4
NH Orthopedic Outpatient Surgery	0		0		0
NHFMC License H0209 Total	33		33		35
NH Medical Park Hospital	10		10		10
NH Kernersville Outpatient					
Surgery	2		2		2
NH Clemmons Outpatient Surgery	2	+2	4		4
NH Health System Total	47	+2	49	+ 2	51

^ The NHFMC Main ORs listed above includes 2 dedicated C-Section and 3 inpatient open heart ORs.

*Project ID #G-11518-18, scheduled to be completed April 2020

**Project ID #G-11517-18, scheduled to be completed April 2021

As the table above shows, in the event that both NH Health System applications are approved and completed as projected, the total number of ORs at NH Clemmons Outpatient Surgery will be four, the total at NH FMC Main will be 22; the total on the NHFMC License #H0209 will be 35; and the total number of ORs in the NH Health System will be 51 at the end of CY2021.

In Section C.1, page 12, the applicant states that the CON Project ID #G-11300-17 application included support letters indicating an interest in practicing at the proposed surgery center in surgical specialties including:

- orthopedics,
- urology,
- podiatry,
- general surgery, and
- obstetrics/gynecology.

The discussion provided in Project ID #G-11300-17 addressed the shift of outpatient surgeries to the proposed NHCOS and specifically mentioned orthopedic surgeries. There is no mention in that application of moving the ORs from NHOOS and closing that facility or of other specific surgical specialties that were to shift to NHCOS. In fact, Condition (3) on the certificate issued for Project ID #G-11300-17 states that NHFMC shall de-license two shared ORs, not ambulatory ORs.

In the project under review, the applicant provides extensive discussion in Section Q Assumptions and Methodology related to NH Health System shifts in surgical cases, both inpatient and outpatient; however, the applicant does not discuss what surgical specialties (other than orthopedic from NHOOS) are shifting and now being proposed at NHCOS.

Therefore, other than relying on letters from physicians stating their intent to apply for privileges at NHCOS, there is no information in the application to support the offering of specific surgical specialties at NHCOS. Project ID #G-11300-17 and the letters in Exhibit H-Letters stating intent to apply for privileges in the application under review infer that NHCOS will offer the surgical specialties of:

- obstetrics/gynecology
- urology,
- general surgery,
- neurological surgery,
- podiatry, and
- orthopedics.

Based upon references in this application to Project ID #G-11300-17 and representations in this application's Exhibit H-Letters, the applicant proposes to provide at least three of the specialty areas listed in §131E-176(15a) to qualify its program as a "multispecialty ambulatory surgical program". §131E-176(15a) states:

"Multispecialty ambulatory surgical program" means a formal program for providing on a same-day basis surgical procedures for at least three of the

following specialty areas: gynecology, otolaryngology, plastic surgery, general surgery, ophthalmology, orthopedic, or oral surgery."

Patient Origin

On page 57, the 2018 SMFP states, "An operating room's service area is the operating room planning area in which the operating room is located. The operating room planning areas are the single and multicounty groupings shown in Figure 6.1." In Figure 6.1, page 62 of the 2018 SMFP, Forsyth County is shown as a single-county operating room service area. Thus, in this application, the service area is Forsyth County. Providers may serve residents of counties not included in their service area.

A summary of the 2016 data compiled on patient origin for Forsyth County providers of ambulatory surgical cases is shown in the table below.

County	# of Patients	% of Patients
Forsyth	22,119	45.2%
Guilford	3,481	7.1%
Davidson	3,125	6.4%
Stokes	2,981	6.1%
Surry	2,812	5.7%
Davie	2,406	4.9%
Other*	12,004	24.5%
Total	48,928	100.0%

2016 Patient Origin for Ambulatory Surgical Services in Forsyth County Operating Rooms

Source: 2017 LRAs

Totals may not sum due to rounding

*Other includes 85 NC counties and other states, with each contributing 4% or less of the total patient origin for the Forsyth facilities.

As the table above shows, on average, 45.2% of the Forsyth ambulatory surgical patients were Forsyth County residents, with surrounding counties of Davie, Surry, Stokes, Davidson and Guilford each being the county of origin for between 5% and 7% of the total surgical patients, and all others 4% or less.

In Section C.2, page 12, the applicant states that NHCOS is not yet operational and therefore has no historical patient origin information. In Sections C.3, page 13, the applicant provides the projected patient origin, by number of patients and percentage, for the proposed facility for the first three operating years (CY2021-CY2023), as summarized in the table below.

	PY1 C	Y2021	PY2 CY2022		PY3 CY2023		
County	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total	
Forsyth	2,543	57.2%	2,630	57.2%	2,719	57.2%	
Stokes	431	9.7%	446	9.7%	461	9.7%	
Davie	396	8.9%	409	8.9%	423	8.9%	
Yadkin	262	5.9%	271	5.9%	280	5.9%	
All Other*	814	18.3%	841	18.3%	870	18.3%	
TOTAL	4,447	100.0%	4,598	100.0%	4,754	100.0%	

NHCOS Proposed Patient Origin Operating Rooms

Source: the applicant sources Trendstar Internal Data, Section Q, Form C; however, Trendstar data is not provided in Section Q

*The applicant does not specify All Other

In Section C, page 13, the applicant states that the projected patient origin for NHCOS, Project ID #G-11300-17, was based upon 2016 outpatient surgical patient origin at NHCMC. The following table is summarized from Section III.6, page 49 of Project ID #G-11300-17.

Projected Patient Origin							
PY 1 PY 2 PY 3							
County	Percent	7/1/19- 6/30/20	7/1/20-6/30/21	7/1/21-6/30/22			
Davie	12.6%	237	268	300			
Forsyth	54.2%	1,022	1,155	1,291			
Yadkin	9.4%	177	200	223			
Other*	23.9%	450	509	569			
TOTAL	100.0%	1,885	2,133	2,382			

Novant Health Clemmons Outpatient Surgery Projected Patient Origin

Sums may not total due to rounding

Source: Table on page 49 of the application.

*The applicant states the counties included in the "Other" category are Stokes, Surry and "all other counties and locations identified on the NHCMC outpatient surgery patient origin in the 2017 NHFMC LRA." The 2017 License Renewal Application (LRA) for Novant Health Forsyth Medical Center includes a listing of the North Carolina counties and other states from which NHCMC ambulatory surgical patients originated in FY2016, including Alleghany, Ashe, Caldwell, Carteret, Caswell, Catawba, Chatham, Davidson, Davie, Forsyth, Guilford, Henderson, Iredell, Orange, Pamlico, Randolph, Rockingham, Rowan, Stokes, Surry, Watauga, Wilkes, Yadkin, and other states.

On page 13, the applicant states that patient origin for the expanded NHCOS proposed in this application is now "assumed to be consistent with the current YTD FFY2018 outpatient surgery patient origin at NHCMC." However, the applicant does not identify the 18.3% "All Other", nor does it adequately address the difference in the projected patient origin from the previously approved Project ID #G-11300-17 in the Change of Scope section of this application.

Furthermore, the applicant does not explain how the patient origin of NHCMC in Clemmons would be representative of the patients being served at NHOOS in Winston-Salem, which the applicant states (in this application) will close when those ORs are relocated to NHCOS. The relocation of ORs and surgical cases from NHOOS contribute 52% of the projected CY2023 (PY3) utilization at NHCOS. But the applicant fails to address the patient origin of the patients that would be served at NHCOS rather than NHOOS.

Analysis of Need

In Section C.4, the applicant discusses the Novant Health System operating room need in Forsyth County per the SMFP operating room methodology. The applicant first discusses why it believes Novant Health needs the four new ORs identified as needed in Forsyth County in the 2018 SMFP and then discusses why it believes that two ORs are needed at FMC Main and two ORs are needed at NHCOS. On pages 18-23, the applicant states that Novant Health's need for the four ORs in Forsyth County (two of which are the subject of this application) is based on the following factors:

- Novant Health's historical surgical utilization, based on its 2015-2017 CAGR for surgical services
 - Inpatient surgery 4.7%
 - Outpatient surgery 2.9%
 - All surgical services 3.4%
- Surgical specialist growth of 35% from 2013 through 2017, with NH planning to continue its physician recruitment plan

On page 19, the applicant provides the following table, which it believes shows the Novant Health System's need for additional ORs.

Surgical Facility	CY2021	CY2022	CY2023	CY2024	
NHCOS Application Project Year	PY1	PY2	PY3		
NHFMC Application Project Year		PY1	PY2	PY3	
NH Forsyth Medical Center	-0.4	0.6	1.7	2.8	
NH Medical Park Hospital	0.0	0.4	0.7	1.1	
NH Kernersville Outpatient Surgery	-0.6	-0.6	-0.6	-0.4	
NH Clemmons Outpatient Surgery	1.9	2.0	2.1	2.3	
NH Health System Forsyth Total	0.8	2.4	4.0	5.7	

SMFP Operating Room Methodology Novant Health Forsyth Projected OR* Deficit / Surplus(-)

Source: Section Q, Form C Assumptions and Methodology, Figure 12 *Excludes C-Sections done in a dedicated C-Section OR

In Section C, pages 25-27, the applicant discusses why the proposed population projected to utilize the proposed service needs the two additional ORs at NHCOS. The applicant

states that NHOOS is expected to shift all volume to NHCOS and close its doors, "with the support of the orthopedic group accounting for most of the volume at that facility" (page 23). The applicant does not discuss why the patients currently served at NHOOS in Winston-Salem would prefer to travel to Clemmons or whether they will have adequate access to services at other locations in Winston-Salem. The applicant also discusses a shift in lower acuity volume from NHMPH in Winston-Salem to NHCOS in Clemmons, stating the shift will reduce cost to the patient and the health care system, reduce the potential for outpatient surgery delays caused by higher acuity surgeries. The information, as provided, was not discussed in Project ID #G-11300-17, for which this application becomes a "Change of Scope" application, and is not explained or adequately discussed in this application.

In addition, NHOOS is co-located in Winston-Salem with an OrthoCarolina practice, many of whose surgeons supported Project ID #G-11300-17, but now have committed to support TCS's proposed project, Project ID #G-11513-18, submitted in the same review cycle as this application. The applicant does not provide sufficient documentation in the application as submitted to show that all of the patients now utilizing NCOOS would use NHCOS instead.

Projected Utilization

Operating Rooms

In response to providing the projected utilization required in Section C.7, the applicant states:

"The applicant's response is found in Section Q, Form C Utilization and the Assumptions and Methodology immediately following."

Form C Utilization for NH Clemmons Outpatient Surgery provides the following projected utilization.

	CY2021 PY1	CY2022 PY2	CY2023 PY3			
# of Outpatient Surgical Cases	4,447	4,598	4,754			
Surgical Hours*	5,084	5,257	5,436			
# of ORs Needed*	3.9	4.0	4.1			

NHCOS Projected Utilization

*Group 6 – New facility – 68.6 minutes average case time and 1,312.5 standard hours per OR

As discussed earlier in this section, the NH Health System submitted two separate applications on May 15, 2018, pursuant to the 2018 SMFP need determination for four ORs in Forsyth County: 1) Project ID #G-11517-18 / Add two ORs at FMC Main, and 2)

Project ID #G-11518-18 / Add two ORs to Novant Health Clemmons Outpatient Surgery (NHCOS), a freestanding ASF under development in Clemmons, NC. Together, the two applications apply for four ORs in Forsyth County. The first three full fiscal years for Project ID #G-11517-17 (FMC Main) are CY2022, CY2023, and CY2024. The first three full fiscal years for Project ID #G-11518-18 (NHCOS) are CY2021, CY2022, and CY2023. The table below shows the applicant's historical and projected utilization for the system, followed by projected utilization for the individual facilities within the system. The tables were developed from the information provided in Section Q, Form Cs, Figures 1-12.

Last Full CY2021 CY2022 CY2023					
Project Years NHCOS	FY	1 st Full FY	2 nd Full FY	3 rd Full FY	
Project Years NHFMC	FY2016		1 st Full FY	2 nd Full FY	3 rd Full FY
Adjusted Planning Inventory (1)	45	47	49	49	49
Inpatient Surgical Hours (4)	29,052	37,730	39,013	40,339	41,711
Ambulatory Surgical Hours (4)	40,549	46,385	47,963	49,594	51,279
Total Surgical Hours (5)	69,600	84,116	86,976	89,932	92,990
# of ORs Needed (6)	36.7	45.8	47.4	49.0	50.7

Novant Health Forsyth County Health System Operating Room Utilization

(1) Last Full FY is from Table 6B in the 2018 SMFP. Excludes two C-Section ORs at FMC Main. System includes NHFMC-20, NHKMC-4, NHCMC-5, NHHOS-4, NHKOS-2, NHCOS-2, and NHMPH - 10. The first three full FYs includes the proposed OR(s).

(4) Surgical Hours equals Surgical Cases multiplied by the Final Case Time for each separate facility and added together for the System.

(5) Total Surgical Hours equals Inpatient Surgical Hours plus Ambulatory Surgical Hours.

(6) # of ORs Needed equals Total Surgical Hours divided by the Standard Hours per OR per Year.

Totals may not sum due to rounding

The table above shows the applicant's historical and projected OR utilization for the NH Health System, which includes NH License H0209 (NH Forsyth Main, NH Kernersville Medical Center, NH Clemmons Medical Center, and NH Hawthorne Outpatient Surgery), NH Medical Park Hospital, NH Kernersville Outpatient Surgery and NH Clemmons Outpatient Surgery. Following are tables with projected utilization for the individual licensed facilities within the health system.

	Last Full	CY2021	CY2022	CY2023	CY2024
Project Years NHCOS	FY	1 st Full FY	2 nd Full FY	3 rd Full FY	
Project Years NHFMC	FY2016		1 st Full FY	2 nd Full FY	3 rd Full FY
Adjusted Planning Inventory (1)	31	33	33	33	33
Standard Hours per OR per Year (2)	1,950	1,950	1,950	1,950	1,950
Inpatient Surgical Cases	9,262	12,085	12,496	12,921	13,360
Final Inpatient Case Time (3)	168	168	168	168	168
Inpatient Surgical Hours (4)	25,934	33,838	34,989	36,179	37,408
Ambulatory Surgical Cases	17,706	17,790	18,395	19,020	19,667
Final Ambulatory Case Time (3)	87	87	87	87	87
Ambulatory Surgical Hours (4)	25,674	25,796	26,673	27,579	28,517
Total Surgical Hours (5)	51,607	59,633	61,660	63,757	65,925
# of ORs Needed (6)	26.5	30.6	31.6	32.7	33.8

NH Forsyth Medical Center License # H0209 Operating Room Utilization

(1) Last Full FY is from Table 6B in the 2018 SMFP. Excludes two C-Section ORs. License includes NHKMC-4, NHCMC-5, NHHOS-4. The first three full FYs includes the proposed OR(s).

(2) From Page 59 in the 2018 SMFP, Group 2.

(3) From Table 6B in the 2018 SMFP in minutes.

(4) Surgical Hours equals Surgical Cases multiplied by the Final Case Time.

(5) Total Surgical Hours equals Inpatient Surgical Hours plus Ambulatory Surgical Hours.

(6) # of ORs Needed equals Total Surgical Hours divided by the Standard Hours per OR per Year.

	Last Full	CY2021	CY2022	CY2023	CY2024
Project Years NHCOS	FY	1 st Full FY	2 nd Full FY	3 rd Full FY	
Project Years NHFMC	FY2016		1 st Full FY	2 nd Full FY	3 rd Full FY
Adjusted Planning Inventory (1)	12	10	10	10	10
Standard Hours per OR per Year (2)	1,755	1,755	1,755	1,755	1,755
Inpatient Surgical Cases	871	1,087	1,124	1,162	1,202
Final Inpatient Case Time (3)	214.8	214.8	214.8	214.8	214.8
Inpatient Surgical Hours (4)	3,118	3,892	4,024	4,160	4,303
Ambulatory Surgical Cases	8,665	7,998	8,270	8,551	8,842
Final Ambulatory Case Time (3)	103	103	103	103	103
Ambulatory Surgical Hours (4)	14,875	13,730	14,197	14,679	15,179
Total Surgical Hours (5)	17,994	17,622	18,221	18,840	19,481
# of ORs Needed (6)	10	10.0	10.4	10.7	11.1

NH Medical Park Hospital Operation Room Utilization

(1) Last Full FY is from Table 6B in the 2018 SMFP. The first three full FYs includes the proposed OR(s).

(2) From Page 59 in the 2018 SMFP, Group 3.

(3) From Table 6B in the 2018 SMFP in minutes.

(4) Surgical Hours equals Surgical Cases multiplied by the Final Case Time.

(5) Total Surgical Hours equals Inpatient Surgical Hours plus Ambulatory Surgical Hours.

(6) # of ORs Needed equals Total Surgical Hours divided by the Standard Hours per OR per Year.

	Last FFY	CY2021	CY2022	CY2023	CY2024
Project Years NHCOS	(Proposed	1 st Full FY	2 nd Full FY	3 rd Full FY	
Project Years NHFMC	ASF)		1 st Full FY	2 nd Full FY	3 rd Full FY
Adjusted Planning Inventory (1)	NA	4	4	4	4
Standard Hours per OR per Year (2)	NA	1,312.5	1,312.5	1,312.5	1,312.5
Inpatient Surgical Cases	NA	NA	NA	NA	NA
Final Inpatient Case Time (3)	NA	NA	NA	NA	NA
Inpatient Surgical Hours (4)	NA	NA	NA	NA	NA
Ambulatory Surgical Cases	NA	4,447	4,598	4,754	4,916
Final Ambulatory Case Time (3)	NA	68.6	68.6	68.6	68.6
Ambulatory Surgical Hours (4)	NA	5,084	5,257	5,436	5,620
Total Surgical Hours (5)	NA	5,084	5,257	5,436	5,620
# of ORs Needed (6)	NA	3.9	4.0	4.1	4.3

NH Clemmons Outpatient Surgery Operation Room Utilization

(1) Last Full FY is from Table 6B in the 2018 SMFP. The first three full FYs includes the proposed OR(s).

(2) From Page 59 in the 2018 SMFP, Group 6.

(3) From Table 6B in the 2018 SMFP in minutes.

(4) Surgical Hours equals Surgical Cases multiplied by the Final Case Time.

(5) Total Surgical Hours equals Inpatient Surgical Hours plus Ambulatory Surgical Hours.

(6) # of ORs Needed equals Total Surgical Hours divided by the Standard Hours per OR per Year.

		CY2021	CY2022	CY2023	CY2024
Project Years NHCOS	Proposed	1 st Full FY	2 nd Full FY	3 rd Full FY	
Project Years NHFMC	ASF		1 st Full FY	2 nd Full FY	3 rd Full FY
Adjusted Planning Inventory (1)	NA	2	2	2	2
Standard Hours per OR per Year (2)	NA	1,312.5	1,312.5	1,312.5	1,312.5
Inpatient Surgical Cases	NA	NA	NA	NA	NA
Final Inpatient Case Time (3)	NA	NA	NA	NA	NA
Inpatient Surgical Hours (4)	NA	NA	NA	NA	NA
Ambulatory Surgical Cases	NA	1,553	1,606	1,661	1,717
Final Ambulatory Case Time (3)	NA				
	INA	68.6	68.6	68.6	68.6
Ambulatory Surgical Hours (4)	NA	1,776	1,836	1,899	1,963
Total Surgical Hours (5)	NA	1,776	1,836	1,899	1,963
# of ORs Needed (6)	NA	1.4	1.4	1.4	1.5

NH Kernersville Outpatient Surgery Operating Room Utilization

(1) Last Full FY is from Table 6B in the 2018 SMFP. The first three full FYs includes the proposed OR(s).

(2) From Page 59 in the 2018 SMFP, Group 6.

(3) From Table 6B in the 2018 SMFP in minutes.

(4) Surgical Hours equals Surgical Cases multiplied by the Final Case Time.

(5) Total Surgical Hours equals Inpatient Surgical Hours plus Ambulatory Surgical Hours.

(6) # of ORs Needed equals Total Surgical Hours divided by the Standard Hours per OR per Year.

In this application, Project ID #G-11518-18, the applicant proposes to add two ORs at NHCOS. In Section Q, Form C, the applicant provides projected utilization for the proposed operating rooms at NHCOS as summarized above and shown in the following table.

Design Vicos	CY2021	CY2022	CY2023	CY2024	
Project Years NHCOS	1 st Full FY	2 nd Full FY	3 rd Full FY		
Adjusted Planning Inventory (1)	4	4	4	4	
Standard Hours per OR per Year (2)	1,312.5	1,312.5	1,312.5	1,312.5	
Inpatient Surgical Cases	NA	NA	NA	NA	
Final Inpatient Case Time (3)	NA	NA	NA	NA	
Inpatient Surgical Hours (4)	NA	NA	NA	NA	
Ambulatory Surgical Cases	4,447	4,598	4,754	4,916	
Final Ambulatory Case Time (3)	68.6	68.6	68.6	68.6	
Ambulatory Surgical Hours (4)	5,084	5,257	5,436	5,620	
Total Surgical Hours (5)	5,084	5,257	5,436	5,620	
# of ORs Needed (6)	3.9	4.0	4.1	4.3	

NH Clemmons Outpatient Surgery Operation Room Utilization

(1) Last Full FY is from Table 6B in the 2018 SMFP. The first three full FYs includes the proposed OR(s).

(2) From Page 59 in the 2018 SMFP, Group 6.

(3) From Table 6B in the 2018 SMFP in minutes.

(4) Surgical Hours equals Surgical Cases multiplied by the Final Case Time.

(5) Total Surgical Hours equals Inpatient Surgical Hours plus Ambulatory Surgical Hours.

(6) # of ORs Needed equals Total Surgical Hours divided by the Standard Hours per OR per Year.

In Section Q, Form C Utilization Assumptions and Methodology, on unnumbered pages, the applicant provides the assumptions and methodology used to project operating room utilization, which is summarized below:

- PY1 is CY2021 (January 1, 2021 December 31, 2021). PY3 is CY2023, not CY2024, which is PY3 for its sister application Project ID #G-11517-18 and is the final year shown in all the applicant's methodology and tables for this application.
- NHCOS is a new ambulatory surgical facility and therefore a Group 6 facility with an average ambulatory case time of 68.6 minutes and 1,312.5 standard hours per operating room.
- Growth is projected at 3.4% through CY2024, based on Novant Health's average growth rate of total inpatient and outpatient surgeries from FY2015 to FY2017 (page 17 and Figure 1, Section Q), which actually shows a decrease of 2.7% for inpatient cases and only a small increase of 1.2% in outpatient cases for a total growth from FY2015 to FY2016 of 0.08%, with the growth coming from FY2016 to FY2017, as shown below.

Surgical Facility	FFY2015	FFY2016	FFY2017
# of Inpatient Surgical Cases*			
NH Forsyth Medical Center	9,519	9,262	10,483
NH Medical Park Hospital	897	871	943
NH Forsyth County Total	10,416	10,133	11,426
NH Forsyth County Growth		-2.7%	12.8%
# of Outpatient Surgical Cases			
NH Forsyth Medical Center	17,445	17,706	18,792
NH Medical Park Hospital	8,613	8,665	8,782
NH Forsyth County Total	26,058	26,371	27,574
NH Forsyth County Growth		1.2%	4.6%
# of Total Surgical Cases			
NH Forsyth County Total	36,474	36,504	39,000
NH Forsyth County Growth		0.08%	6.8%

Source: "Section Q, Form C Assumptions and Methodology, Figure 1" per application page 20.

*Excludes C-Sections done in a dedicated C-Section OR

Thus the 2-yr CAGR reflects one year of little to no growth and one year of growth. The following table shows the three and five-year growth rates for the NH Health System and all surgical cases in Forsyth County, using the applicant's data on page 20 and in figure 1, Section Q.

Total Inpatient and Outpatient Surgical Cases	NH Health System	Forsyth County
5-yr CAGR 2012-2017	2.0%	1.6%
3-yr CAGR 2014-2017	2.0%	1.5%

Source: Applicable hospital and surgery center LRAs

As the table above illustrates, the NH Forsyth Health System 5 and 3-year CAGRs are the same and are only 2%. Applying all the applicant's adjustments for volume shifts within the NH Health System and using a 2% growth rate for the NH Forsyth Health System results in a NH Health System need for only 0.4 and 1.3 ORs in CY2022 and CY2023, not 2.4 and 4.0 ORs.

Using a 2% growth rate results in a need for 2.1 additional ORs at NHCOS in CY2023, which is this application's third operating year, as shown in the table below.

Surgical Facility	CY2021	CY2022	CY2023	CY2024
NHCOS Application Project Year	PY1	PY2	PY3	
NHFMC Application Project Year		PY1	PY2	PY3
NH Forsyth Medical Center (FMC				
Main)	-0.8	-0.5	-0.1	0.2
NH FMC License H0209	-1.1	-0.5	0.1	0.7
NH Medical Park Hospital	-0.6	-0.5	-0.3	-0.1
NH Kernersville Outpatient Surgery	-0.6	-0.6	-0.6	-0.6
NH Clemmons Outpatient Surgery	1.9	2.0	2.1	2.1
NH Health System Forsyth Total	-0.5	0.4	1.3	2.2

SMFP Operating Room Methodology Novant Health Forsyth Projected OR* Deficit / Surplus(-)

Source: Section Q, Form C Assumptions and Methodology, Figures1-12, using a reasonable 2.0% CAGR to project future utilization

*Excludes C-Sections done in a dedicated C-Section OR

• Outpatient surgical cases are shifted from NHOOS and NHMPH to NHCOS, as discussed in Section Q. The need for the additional 2.1 ORs is based on the applicant's proposed shift in surgical cases from NHOOS and NHMPH. The number of cases proposed to be shifted from NHMPH would drop the need for ORs at NHMPH below its 10 existing ORs (assuming a 2% growth rate). Some OrthoCarolina physicians performing surgeries at NHOOS have pledged support for the TCS application, which was filed in the same review cycle, pursuant to the same need determination as this application.

On page 25, the applicant states:

"As reflected in the projections for NHCOS in Project I.D. #G-11300-17, outpatient surgical volume from Novant Health Orthopedic Outpatient Surgery ("NHOOS") is expected to shift to NHCOS when NHOOS closes and NHCOS opens in July 2019. The table below shows the projected volume for the first two ORs at NHCOS."

	PY1	РҮ2	РҮЗ
	Jul2019-Jun2020	Jul2020-Jun2021	Jul2021-Jun2022
Projected Outpatient Cases	4,447	4,598	4,754
Surgical Time per Outpatient Case	68.6	68.6	68.6
Projected Surgical Hours	5,084	5,257	5,436
Standard Hours Group 6	1,312.50	1,312.50	1,312.50
Operating Rooms Needed	3.9	4.0	4.1

Projected NHCOS OR Need

The above quote and table imply that the projected outpatient cases, as provided above, is the number of cases projected/approved in Project ID #G-11300-17. It also implies that Project ID #G-11300-17 actually identified NHOOS as the location of the two ORs that would be relocated to Clemmons and that NHOOS would then close. In Project ID G-11300-17, the applicant simply identified the NHFMC license as the source of the two ORs to be relocated to NHCOS. The application contained no mention of NHOOS closing. Furthermore, the Condition (3) of the certificate for Project ID G-11300-17, which the applicant accepted, states:

"Novant Health Forsyth Medical Center shall de-license two <u>shared</u> operating rooms. Following completion of this project and Project I.D. #G-8165-08, and Project I.D. #G-11150-16, Novant Health Forsyth Medical Center shall be licensed for no more than 18 operating rooms, including 13 shared operating rooms, three dedicated open heart surgery operating rooms, and two dedicated Csection operating rooms." (Emphasis added.)

Project ID#G-11300-17 projected the following utilization on page 54 of that application:

	<u></u>					
	PY 1 7/1/19– 6/30/20	PY 2 7/1/20- 6/30/21	PY 3 7/1/21-6/30/22			
Outpatient Surgical Operating Rooms	2	2	2			
Outpatient Surgical Cases	1,885	2,133	2,382			

Novant Health Clemmons Outpatient Surgery Projected Utilization, July 1, 2019 – June 30, 2022

The applicant's table as provided on page 25 and shown in the previous paragraphs, represents the proposed utilization at NHCOS after the addition of the proposed two ORs in this application and the shift of 2,273 cases from NHMPH in PY3.

The applicant states in the fourth unnumbered page of Form C Assumptions and Methodology in Section Q that the projected utilization in the application under review is higher than that of Project ID#G-11300-17 "*due to changes in the projected volume of cases at NHOOS*." The applicant further states that it is using the most recent three years of historical data to project growth in surgical services which are higher than those used in the first application because of recruitment of new surgeons. The applicant also states that it now intends to shift a significant number (21%, per Figure 5 in Section Q) of lower acuity outpatient surgeries on patients from the Clemmons market from NHMPH to NHCOS. The applicant does not provide any support for the amount of the percentage shift.

In the fourth unnumbered page of Form C Assumptions and Methodology in Section Q of the project under review, the applicant states:

"When NHCOS opens in July 2019 with ORs 1 & 2, NHOOS will close and all surgeries will shift to NHCOS as explained in CON Project I.D. #G-11300-17 and found reasonable by DHHS."

The above statement is contrary to the information provided in Project ID #G-11300-17. The application for Project ID#G-11300-17 did not identify NHOOS as the location from which the ORs would be relocated, nor did it state that NHOOS would close upon the opening of NHCOS in July 2019. In fact, the application did not specify which ORs on the NHFMC License #H0209 would be delicensed upon the development of NHCOS. However, Condition (3) on the certificate issued for Project ID #G-11300-17 requires NHFMC to delicense two <u>shared</u> ORs. The certificate states that two shared ORs will be de-licensed upon the relocation of ORs from the NHFMC to NHCOS. Pursuant to 10A NCAC 14C .2101(13), a *"Shared operating room means an operating room that is used for the performance of both ambulatory and inpatient surgical procedures."* The two ORs at NHOOS are not located in the hospital and not used for inpatient surgical cases. Therefore, they are not shared ORs.

The only specialty specifically discussed in Project ID #G-11300-17 as being shifted to NHCOS was orthopedic surgeries. The applicant now proposes to shift a large number of low acuity cases from NHMPH, but does not specify any specialties. The applicant does not adequately discuss the differences in the shifts in surgeries now proposed, as compared to those in Project ID #G-11300-17, for which this application has become a Change in Scope application. The applicant should have addressed the closing of NHOOS and the difference in the projected utilization in detail in Section C.10, as a part of the Change of Scope and in the assumptions in Section Q, and did not.

Projected utilization is not reasonable or adequately supported for the following reasons:

- The applicant proposes changes in this application to the previously approved Project ID #G-11300-17 without adequately explaining those differences and why they are needed for all the reasons discussed above.
- The applicant does not adequately demonstrate that the projected shifts of surgical cases from NHOOS and NHMPH are based on reasonable and adequately supported assumptions for all the reasons discussed above.

Access

In Section C.8, pages 32-33, the applicant states:

"Novant health does not exclude, deny benefits to, or otherwise discriminate against patients, students, or visitors on the basis of race; color; religion; national origin; culture; language; physical or mental disabilities; genetic information; age; sex, including pregnancy, childbirth or related medical conditions; marital status; sexual orientation; gender identity or expression; socioeconomic status; or source of payment in admission to, participation in, or receipt of the services and

benefits of any of its programs and other activities, whether carried out by Novant Health directly or through a contractor or other entity with whom Novant Health arranges to carry out its programs or activities. "

In Section L, page 72, the applicant projects the following payor mix during the second full fiscal year of operation following completion of the project, as illustrated in the table below.

CY2022						
Payor Source	Entire Facility NHCOS	Operating Rooms	Procedure Room			
Self-Pay/ Charity	1.5%	1.5%	1.5%			
Medicare *	44.2%	44.2%	44.2%			
Medicaid *	5.3%	5.3%	5.3%			
Insurance *	44.4%	44.4%	44.4%			
Workers Comp and						
Other Government	4.6%	4.6%	4.6%			
Total	100.0%	100.0%	100.0%			

Proposed Payor Mix CY2022

* Including any managed care plans

Totals may not sum due to rounding

The proposed project does not involve GI endoscopy rooms. The applicant states on page 72 that the projected payor mix is based on the historical NHCMC outpatient surgery data and NHKOS payor mix. However, the projected payor mix is different from the payor mix projected in the approved and undeveloped Project ID #G-11300-17, for which this application becomes a "Change of Scope" application. In Section VI.14, page 77 of Project ID #G-11300-17, the applicant projected the following payor mix for NHCOS surgical cases during the second project year (July 2020-June 2021).

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 two projected payor mixes differ significantly in the percentage of service to Medicare recipients. Therefore, the difference in the proposed payor mix should have been addressed in detail in Section L.6 Change of Scope and was not. In fact, the applicant states, "*There is no difference in the information provided above and the original application.*" Without an adequate explanation for the proposed differences, the applicant does not adequately demonstrate that the new projected payor mix is reasonable and adequately supported.
Conclusion

The Agency reviewed the:

- application,
- exhibits to the application,
- written comments,
- remarks made at the public hearing,
- responses to comments, and
- information publicly available during the review and used by the Agency.

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

- The applicant does not adequately identify the population to be served for all the reasons discussed above.
- Projected utilization is not based on reasonable and adequately supported assumptions for all the reasons discussed above.
- The applicant does not adequately demonstrate the need the population to be served has for the proposed services for all the reasons discussed above.
- The applicant did not adequately demonstrate the extent to which all residents, including underserved groups will have access to the proposed services for all the reasons discussed above.

NCBH. The applicant proposes to add four new ORs at NCBH in Winston-Salem, Forsyth County for a total of 51 ORs, including two trauma/burn ORs, upon completion of this project and Project ID #G-8460-10 (add seven dedicated outpatient ORs pursuant to Policy AC-3).

In Section A, page 5, the applicant provides a description of the organizational structure of NCBH, summarized as follows. NCBH is an academic medical center teaching hospital and part of an umbrella for facilities within the Wake Forest Baptist Medical Center (WFBMC) system. WFBMC is divided into an academic enterprise (Wake Forest School of Medicine or WFSM), a clinical enterprise (WFBH), and a commercial enterprise (Wake Forest Innovations or WFI). The applicant further states:

"WFBH, the clinical arm of WFBMC, includes North Carolina Baptist Hospital (NCBH), Davie Medical Center (DMC), Wilkes Medical Center [WMC], and Lexington Medical Center. [sic] (LMC), among others."

The 2018 SMFP provides the total number of WFBMC Health System ORs in Forsyth County, as shown below adjusted for relocation of three ORs from PSCNC to CMPASC.

Facility	Inpatient ORs*	Ambulatory ORs**	Shared ORs	CON Adjustments^	Total*
PSCNC/CMPASC (WFBH-OSC)	0	3	0	0	3
NCBH	4	0	36	+7	47
WFBMC Health System Total	4	3	36	+7	50

*Includes two trauma/burn ORs

** WFBH-OSC, formerly referred to as CMPASC, was licensed February 22, 2018 for three ORs, which were relocated from PSCNC. NCBH now refers to CMPASC as Wake Forest Baptist Hospital - Outpatient Surgery Clemmons (WFBH-OSC)

^ Project ID #G-8460-10 / Add seven ORs pursuant to Policy AC-3

As shown above, the table includes four inpatient ORs and a CON adjustment for the seven ORs approved pursuant to Policy AC-3 in Project ID #G-8460-10. The 2018 SMFP includes the seven ORs in its need determination calculation which still results in the deficit of four ORs for the WFBMC Health System. The following Agency information related to Project ID #G-8460-10 is provided for further clarification on the undeveloped Policy AC-3 ORs. The applicant states that the project was delayed first by an extensive appeal and settlement process which resulted in an effective date on the certificate of April 2, 2013, and then by financial losses that resulted from business disruption associated with the installation of a system-wide electronic medical record. Following these delays, NCBH conducted an evaluation process to confirm facility need, including a Master Plan for hospital renovations which includes a new patient services tower. The new tower will allow the relocation of 38 NCBH ORs, which vacates space in Ardmore Tower which can be cost effectively renovated for the seven approved Policy AC-3 ORs. The Agency approved a May 1, 2018 NCBH Material Compliance request to develop the seven ORs in the renovated Ardmore Tower vacated space, along with an eighth existing OR, rather than developing the seven ORs in new construction on campus. Because the Ardmore Tower renovation cannot begin until the completion of the new tower and relocation of the 38 ORs, the approved timeline for NCBH's development of seven Policy AC-3 ORs in Project ID #G-8460-10 begins with the construction/renovation contract being executed in June 2022 and services being offered in July 2024.

In Section C.1, page 19, the applicant describes the proposed project as follows:

"NCBH is proposing to obtain and operate the four identified operating rooms as shared inpatient/outpatient ORs to be developed on the NCBH main campus. The four new ORs are planned for development on the first floor of Ardmore Tower within the current location of the NCBH surgical services suites."

The applicant further states that prior to the development of the proposed project, 38 of the 40 licensed ORs at NCBH will be relocated (exempt from CON review) to the new patient services tower that will be constructed in the current location of Parking Deck B on the NCBH campus. Exhibit C.1. includes a NCBH campus map for reference. A portion of the vacated space formerly occupied by the relocated ORs will be renovated for the

development of the proposed ORs. Exhibit C.1.2 includes a copy of the Agency's exempt from review letter. Exhibit C.1.3 includes pre and post renovation floor plans.

On pages 19-21, the applicant states that the surgical specialties provided in the NCBH ORs include:

- cardiothoracic surgery,
- general surgery,
- neurosurgery,
- ophthalmology,
- orthopaedic surgery,
- otolaryngology,
- plastic surgery,
- urology, and
- vascular surgery.

Patient Origin

On page 57, the 2018 SMFP states, "An operating room's service area is the operating room planning area in which the operating room is located. The operating room planning areas are the single and multicounty groupings shown in Figure 6.1." In Figure 6.1, page 62 of the 2018 SMFP, Forsyth County is shown as a single-county operating room service area. Thus, in this application, the service area is Forsyth County. Providers may serve residents of counties not included in their service area.

In Section C.2, pages 21-22, the applicant provides the historical patient origin, by number of patients and percentage of total, for NCBH's last full fiscal year, July 1, 2016 – June 30, 2017, as summarized below.

	Last FY 7/1/16-6/30/17				
County	# of Patients	% of Total			
Forsyth	9,172	26.3%			
Guilford	3,589	10.3%			
Davidson	3,001	8.6%			
Surry	1,548	4.4%			
Randolph	1,265	3.6%			
Wilkes	1,251	3.6%			
Iredell	1,249	3.6%			
Davie	1,132	3.2%			
Catawba	1,131	3.2%			
Stokes	905	2.6%			
Rockingham	822	2.4%			
Rowan	752	2.2%			
Yadkin	693	2.0%			
Other*	8,343	23.9%			
TOTAL	34,853	100.00%			

*Other represents Caldwell, Burke, Mecklenburg, Alexander, Watauga, Ashe, Alleghany, and Buncombe counties in NC and other states with patients of less than 2% of total patients.

In Section C.3, pages 22-23, the applicant provides the projected patient origin, by number of patients and percentage, for the first three operating years (FY2025-FY2027), as summarized in the following table.

Operating Rooms						
		PY1 FY2025 PY2 FY2026 PY3 FY2 7/1/2024-6/30/2022 7/1/2025-6/30/2026 7/1/2026-6/3				
County	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Forsyth	8,844	25.9%	8,933	25.9%	9,022	25.9%
Guilford	3,483	10.2%	3,518	10.2%	3,553	10.2%
Davidson	2,971	8.7%	3,001	8.7%	3,031	8.7%
Surry	1,502	4.4%	1,518	4.4%	1,533	4.4%
Randolph	1,263	3.7%	1,276	3.7%	1,289	3.7%
Wilkes	1,263	3.7%	1,276	3.7%	1,289	3.7%
Iredell	1,263	3.7%	1,276	3.7%	1,289	3.7%
Davie	1,093	3.2%	1,104	3.2%	1,115	3.2%
Catawba	1,127	3.3%	1,138	3.3%	1,150	3.3%
Stokes	854	2.5%	862	2.5%	871	2.5%
Rockingham	820	2.4%	828	2.4%	836	2.4%
Rowan	751	2.2%	759	2.2%	766	2.2%
Yadkin	683	2.0%	690	2.0%	697	2.0%
Other*	8,230	24.1%	8,310	24.1%	8,393	24.1%
TOTAL	34,147	100.0%	34,489	100.0%	34,834	100.0%

NCBH Projected Patient Origin

*Other represents Caldwell, Burke, Mecklenburg, Alexander, Watauga, Ashe, Alleghany, and Buncombe counties in NC and other states with patients of less than 2% of total patients.

In Section C, pages 23-25, the applicant states that the above patient origin is projected using the historic FY2017 NCBH patient origin and applying an adjustment to account for surgical cases shifting to WFBH-OSC (formerly referred to as CMPASC). The applicant also provides detailed steps for the projection in that section. The applicant's assumptions are reasonable and adequately supported.

Analysis of Need

In Section C.4, pages 26-34, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. On page 26, the applicant states:

"As illustrated in the 2018 SMFP and in Table C.4.1 below, the need for ORs in the Forsyth County OR Service Area was produced by the patients choosing WFBMC facilities, particularly patients choosing NCBH for surgical care."

As shown in the 2018 SMFP and in the applicant's Table C.4.1 on page 26, NCBH shows a need for 6.65 ORs and the WFBMC Health System shows a need for 3.65 ORs, based solely on the WFBMC 2016 utilization projected forward with the Forsyth County population growth factor of 4.02% to FY2020.

Beginning on page 26 of the application, the applicant states that the need for the proposed project is based on the following factors:

- patients choosing to have surgery at NCBH (pages 26-27),
- historic growth in surgical cases at NCBH demonstrates a need for additional ORs since 2012 (pages 27-29),
- the planned opening of three new ASFs from February 2018 to July 2019 provides adequate incremental capacity for patients seeking outpatient surgical care in an ASF
- rising complexity and the aging of the population limits the opportunity for care to safely shift to outpatient settings (pages 31-33), and
- the new OR need methodology will likely result in an ongoing OR need determination in the Forsyth County OR Service Area until NCBH has adequate OR capacity (pages 33-34).

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

- The applicant adequately demonstrates the need for additional ORs at NCBH based on the 2018 SMFP OR need methodology.
- The applicant adequately documents that volume at NCBH grew steadily from 2005 through 2012, plateauing around the 34,000 range, which the applicant states is the maximum capacity that can be accommodated with the ORs at NCBH.
- The applicant adequately demonstrates that the capacity constraints of the ORs at NCBH are the driver of the flat surgical growth and not a lack of demand.
- The applicant adequately demonstrates that in addition to the WFBMC's recent opening of WFBH-OSC, Novant Health has CON approval for the development of two new multispecialty ASFs in Forsyth County, creating additional ASF capacity in Forsyth County by relocating existing ORs.
- The applicant adequately demonstrates that NCBH has experienced greater growth in inpatient surgery as compared to outpatient surgery, with inpatient surgical volume growing from 2014-2017 at 7.3% at NCBH while outpatient surgical volume was relatively flat at -0.1%.
- The applicant adequately demonstrates that the new OR need methodology does not include an elimination of a need due to an offsetting surplus of ORs in another health system in the same OR Service Area; therefore, it is likely that the SMFP will continue to include a need determination for ORs in the Forsyth County OR Service Area until NCBH is equipped with adequate OR inventory for the volume and type of surgical cases performed at NCBH.

Projected Utilization

Operating Rooms

In Section Q, Form C NCBH, the applicant provides projected utilization for the proposed operating rooms at NCBH. The following table summarizes the applicant's information, exclusive of the two trauma/burn ORs which the 2018 SMFP excludes from the OR methodology.

Opera	ting Room U			
	Last Full FY	1 st Full FY FY2025 7/24-6/25	2 nd Full FY FY2026 7/25-6/26	3 rd Full FY FY2027 7/26-6/27
Adjusted Planning Inventory (1)	45	49	49	49
Standard Hours per OR per Year (2)	1,950	1,950	1,950	1,950
Inpatient Surgical Cases	14,534	15,569	15,725	15,882
Final Inpatient Case Time (3)	238.9	238.9	238.9	238.9
Inpatient Surgical Hours (4)	57,870	61,991	62,612	63,237
Ambulatory Surgical Cases	19,925	18,578	18,765	18,952
Final Ambulatory Case Time (3)	117.3	117.3	117.3	117.3
Ambulatory Surgical Hours (4)	38,953	36,320	36,686	37,051
Total Surgical Hours (5)	96,823	98,311	99,297	100,288
# of ORs Needed (6)	49.7	50.4	50.9	51.4

NCBH Operating Room Utilization

Totals may not sum due to rounding.

(1) Last Full FY is from Table 6B in the 2018 SMFP. The first three full FYs includes the proposed OR(s). Excludes two Trauma/Burn ORs, per Table 6A.

(2) From Table 6A in the 2018 SMFP, Group 1.

- (3) From Table 6B in the 2018 SMFP.
- (4) Surgical Hours equals Surgical Cases multiplied by the Final Case Time.
- (5) Total Surgical Hours equals Inpatient Surgical Hours plus Ambulatory Surgical Hours.

(6) # of ORs Needed equals Total Surgical Hours divided by the Standard Hours per OR per Year.

The applicant provides the projected utilization at WFBH-OSC in Section Q, Form C WFBH-OSC, as summarized in the following table.

(Formerly CMPASC with ORs Relocated from PSCNC)							
Operating Room Utilization							
1st Full FY 2nd Full FY 3rd Full F Last Full FY2025 FY2026 FY2027 FY 7/24-6/25 7/25-6/26 7/26-6/27							
Adjusted Planning Inventory (1)	3	3	3	3			
Standard Hours per OR per Year (2)	1,312.5	1,312.5	1,312.5	1,312.5			
Inpatient Surgical Cases	NA	NA	NA	NA			
Final Inpatient Case Time (3)	NA	NA	NA	NA			
Inpatient Surgical Hours (4)	NA	NA	NA	NA			
Ambulatory Surgical Cases	169	3,102	3,133	3,164			

WFBH-OSC

Totals may not sum due to rounding.

Final Ambulatory Case Time (3)

Ambulatory Surgical Hours (4)

Total Surgical Hours (5)

of ORs Needed (6)

(1) Last Full FY is from Table 6B in the 2018 SMFP.

(2) From Table 6A in the 2018 SMFP, Group 6.

(3) From Table 6B in the 2018 SMFP.

(4) Surgical Hours equals Surgical Cases multiplied by the Final Case Time.

(5) Total Surgical Hours equals Inpatient Surgical Hours plus Ambulatory Surgical Hours.

(6) # of ORs Needed equals Total Surgical Hours divided by the Standard Hours per OR per Year.

68.6

193

507

0.39

The applicant also provides the projected utilization combined for NCBH and WFBH-OSC (the total operating rooms owned and operated by the WFBMC Health System in Forsyth County), as summarized in the following table.

68.6

3,547

3,547

2.7

68.6

3,582

3,582

2.7

68.6

3,618

3,618 2.8

	Last Full FY	1 st Full FY FY2025 7/24-6/25	2 nd Full FY FY2026 7/25-6/26	3 rd Full FY FY2027 7/26-6/27
Adjusted Planning Inventory (1)	48	52	52	52
Inpatient Surgical Cases	14,534	15,569	15,725	15,882
Inpatient Surgical Hours (4)	38,953	61,991	62,612	63,237
Ambulatory Surgical Cases	20,094	21,680	21,898	22,116
Ambulatory Surgical Hours (4)	39,147	39,867	40,268	40,669
Total Surgical Hours (5)	97,330	101,857	102,879	103,905
# of ORs Needed (6)	50	53.1	53.6	54.2

WFBMC Health System Forsyth County (NCBH & WFBH-OSC) Operating Room Utilization

Totals may not sum due to rounding

(1) Last Full FY is from Table 6B in the 2018 SMFP. The first three full FYs includes the proposed OR(s). Excludes two Trauma/Burn ORs.

(4) Surgical Hours equals Surgical Cases multiplied by the Final Case Time for each separate facility and added together for the System.

(5) Total Surgical Hours equals Inpatient Surgical Hours plus Ambulatory Surgical Hours.

(6) # of ORs Needed equals Total Surgical Hours divided by the Standard Hours per OR per Year.

The applicant also includes the projected utilization of Davie Medical Center in Davie County, in its discussion in Section Q, as a part of the total WFBMC system; however, Davie County is not in the Forsyth County OR service area; therefore, the Project Analyst does not include the applicant's discussion regarding DMC.

In Section Q, Form C Assumptions, pages 121-140, the applicant provides the assumptions and methodology used to project operating room utilization, which is summarized below:

- The project begins July 1, 2024. PY1 is the first full fiscal year July 1, 2024 through June 30, 2025, FY2025.
- Project WFBH-OSC volumes, surgical hours and OR need (pages 121-126)
 - determine NCBH surgical volume appropriate to shift to WFBH-OSC
 - determine growth rate to project future surgical volume at WFBH-OSC 1.0% annually, based on 2018 SMFP Forsyth County four-year (2016-2020) population growth factor of 4.02%.
 - project WFBH-OSC surgical volume through interim and project years
 - determine case length and standard hours per OR Group 6: 68.6 minutes per case and 1312.5 standard hours per OR
 - o determine surgical hours and WFBH-OSC OR need

		I age 127			
Year	Case Volume	Surgical Minutes	Surgical Hours	OR Need	
Interim Years					
FY2018	723	49,597.8	826.6	0.6	1
FY2019	2,922	200,449.2	3,340.8	2.5	3
FY2020	2,951	202,438.6	3,374.0	2.6	3
FY2021	2,981	204,496.6	3,408.3	2.6	3
FY2022	3,011	206,554.6	3,442.6	2.6	3
FY2023	3,041	208,612.6	3,476.9	2.6	3
FY2024	3,071	210,670.6	3,511.2	2.7	3
Project Years					
FY2025	3,102	212,797.2	3,546.6	2.7	3
FY2026	3,133	214,923.8	3,582.1	2.7	3
FY2027	3,164	217,050.4	3,617.5	2.8	3

Table C.7.7 WFBH-OSC OR Need Page 127

Totals may not sum due to rounding

- Project NCBH volumes, surgical hours, and OR need (pages 130-136)
 - o determine NCBH historic inpatient and outpatient surgical volume
 - determine growth rate to project future surgical volume at WFBH-OSC 1.0% annually, based on 2018 SMFP Forsyth County four-year (2016-2020) population growth factor of 4.02%.
 - o project NCBH surgical volume through interim and project years
 - adjust NCBH projected surgical volume to account for volume shifts to WFBH-OSC and DMC in Davie County
 - \circ determine case length and standard hours per OR Group 1: Inpatient minutes per case = 238.9, Outpatient minutes per case = 117.3 and 1,950 standard hours per OR
 - o determine surgical hours and NCBH OR need

	1 age	100		
Year	Case Volume	Surgical Hours	OR N	Veed
Interim Years				
FY2018	34,026	95,950.1	49.2	49
FY2019	32,167	92,609.6	47.5	48
FY2020	32,489	93,537.0	48.0	48
FY2021	32,814	94,472.3	48.4	48
FY2022	33,143	95,419.5	48.9	49
FY2023	33,474	96,372.7	49.4	49
FY2024	33,809	97,337.7	49.9	50
Project Years				
FY2025	34,147	98,310.6	50.4	50
FY2026	34,489	99,295.3	50.9	51
FY2027	34,834	100,288.0	51.4	51

Table C.7.23 NCBH OR Need Page 136

Totals may not sum due to rounding

- Project the health system (NCBH and WFBH-OSC) volumes, surgical hours and OR need in Forsyth County, as summarized above in the table headed "NCBH Health System Forsyth County". (pages 137-138)
- Project NCBH-West Campus Surgery Center (WCSC) volumes, surgical hours and OR need.

In Section C.7, pages 36-37, the applicant discusses the NCBH volume shift and utilization of the WCSC ORs awarded to NCBH in CON Project ID #G-8460-10. The WCSC ORs were approved to be developed on the NCBH license in 2013. Though the total NCBH utilization provided above includes the projected utilization at WCSC, the applicant provides the projected utilization for WCSC separately in Section Q, Form C Utilization NCBH-WCSC and discusses the development of the ORs in Section Q, Form C Assumptions, pages 138-140, resulting in the following volume, hours and OR need for WCSC.

Rebit Webe operating Room Projected Otilization					
	PY1 FY2025	PY2 FY2026	PY3 FY2027		
	7/1/24-6/30/25	7/1/25-6/30/26	7/1/26-6/30/27		
# of Operating Rooms	8	8	8		
Outpatient Surgical Cases	7,751	7,647	7,721		
Outpatient Surgical Hours	14,801	14,950	15,100		
# of ORs Needed	7.6	7.7	7.7		

NCBH WCSC Operating Room Projected Utilization

Totals may not sum due to rounding

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

- the applicant bases future utilization on historical utilization,
- the applicant uses a growth rate based on the Forsyth County projected population growth rate, and
- the applicant uses the accurate OR Group, minutes per case, and standard hours per OR for utilization projections.

Access

In Section C.8, page 38, the applicant states:

"NCBH is committed to providing services to all persons regardless of race, ethnicity, gender, age, religion, creed, disability, national origin, or ability to pay. Services are available to all persons including low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved persons including the medically indigent, the uninsured and the underinsured."

In Section L, page 104, the applicant projects the payor mix during the second full fiscal year of operation following completion of the project, as illustrated in the table below.

FY 2026				
Payor Source	Entire Facility	Operating Rooms		
Self-Pay	11.8%	5.4%		
Charity Care**	NA	NA		
Medicare *	26.7%	33.8%		
Medicaid *	19.7%	19.8%		
Insurance *	38.6%	34.8%		
Other***	3.2%	6.1%		
Total	100.0%	100.0%		

Proposed Payor Mix FY2026

* Including any managed care plans

**Charity care is not considered a payor source. Payor mix above is calculated by the percent of encounters.

*** Other includes liability, other government programs, Worker's comp, and TRICARE. Totals may not sum due to rounding

The proposed project does not involve GI endoscopy rooms or procedure rooms. The applicant states on page 105 that the projected payor mix for the entire facility will not change from historical. The applicant further states that the projected payor mix for the ORs was adjusted to account for the shift of surgical cases to WFBH-OSC, as outlined in the steps on pages 105-106. The projected payor mix is reasonable and adequately supported.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application,
- written comments,
- remarks made at the public hearing,
- responses to comments, and
- information publicly available during the review and used by the Agency.

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

- The applicant adequately identifies the population to be served for all the reasons discussed above.
- Projected utilization is based on reasonable and adequately supported assumptions for all the reasons discussed above.
- The applicant adequately demonstrates the need the population to be served has for the proposed project for all the reasons discussed above.
- The applicant projects the extent to which all residents, including underserved groups, will have access to the proposed services (payor mix) and adequately supports its assumptions for all the reasons discussed above.
- (3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.
 - NA TCS Cone Health NH Forsyth NCBH

NC NH Clemmons

TCS, Cone Health, NH Forsyth, and **NCBH.** The listed applicants do not propose to reduce a service, eliminate a service or relocate a facility or service. Therefore, Criterion (3a) is not applicable to the review of their applications.

NH Clemmons. The applicant proposes to develop two new ORs at NHCOS in Clemmons and to close NHOOS in Winston-Salem after relocating its ORs and transferring its volume to NHCOS, as a Change of Scope to Project ID #G-11300-17. Contrary to the applicant's representation in this application, the closing of NHOOS was not addressed in Project ID #G-11300-17. Because it was not addressed in Project ID #G-

11300-17, the closing of NHOOS and how the Winston-Salem patients currently served at that location will have access to surgical services in the future should have been addressed in Section D of this application.

However, the applicant does not explain how the needs of the population presently utilizing the ORs located at NHOOS will be adequately met following completion of the proposed project. In addition, the applicant does not adequately demonstrate that access by underserved groups to the services being relocated as part of this project will not be negatively impacted for the following reasons:

- NHOOS is located in Winston-Salem and NHCOS is located in Clemmons.
- The socio-economic patient population and payor mix between NHOOS and NHCOS would likely differ: 24.3% of the Winston-Salem population is living below the poverty level, while only 9.7% of the Clemmons population is living below the poverty level.¹

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application,
- written comments,
- remarks made at the public hearing,
- responses to comments, and
- information publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is not conforming to this criterion for the applicant does not adequately demonstrate that:

- The needs of the population currently using the ORs located at NHOOS would be adequately met following project completion, as the closing of NHOOS was not addressed in the application under review or in Project ID #G-11300-17.
- The project would not adversely impact the ability of underserved groups to access these services following project completion, as the closing of NHOOS was not addressed in the application under review or in Project ID #G-11300-17.
- (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.

¹ www.census.gov/quickfacts

C TCS Cone Health NCBH

NC NH Forsyth NH Clemmons

TCS. The applicant proposes to establish a new ASF in Winston-Salem, Forsyth County by developing two new ORs and three procedure rooms.

In Section E, pages 57-59, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- maintain the status quo,
- develop a single-specialty orthopedic ASF,
- develop a smaller multi-specialty ASF,
- develop a larger ASF, and
- develop the project as proposed.

On pages 58-59, the applicant states that its proposal is the most effective alternative for the following reasons:

- 1. The TCS projected utilization supports the two operating rooms and three procedure rooms because of the growth of the population, strong support from the prospective medical staff, and the cost-savings and quality factors that would encourage physicians and patients to choose the facility.
- 2. The project will expand patient access to cost-effective OR capacity through a broad range of surgical specialists.
- 3. Two ORs and three procedure rooms will support high productivity and favorable staffing ratios and long-term financial sustainability.
- 4. TCS is committed to staff and operate the ORs and procedure rooms for nine hours per day, five days per week to enhance patient access and achieve high productivity.
- 5. The project will be developed in existing leased space which will hold down capital costs and expedite the development of the project.
- 6. The facility plans include design components to promote patient access as well as energy-saving and water-conserving design features.

The applicant provides supporting documentation in Section C and Exhibit C.4.

The applicant adequately demonstrates that the alternative proposed in this application is the most effective alternative to meet the need for the following reasons:

- Maintaining the status quo is not an effective option due to the high demand for ambulatory surgery services and the limited options available in Forsyth County.
- A single-specialty orthopedic ASF would not provide improved access to a broad range of surgical specialties and would limit the flexibility of the facility.
- A facility with only one OR would not accommodate the sizable number of surgeons who have expressed support for the project and a single OR would likely have scheduling constraints.
- Developing a larger ASF with more ORs and procedure rooms would not be cost effective due to higher initial fixed costs.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application,
- written comments,
- remarks made at the public hearing,
- responses to comments, and
- information publicly available during the review and used by the Agency.

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

Cone Health. The applicant proposes to establish a new ASF at MedCenter Kernersville, Forsyth County by developing two ORs, one GI endoscopy room, and one procedure room.

In Section E, pages 56-58, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- maintain the status quo,
- develop the proposed ASF at a different location,
- develop an ASF with four operating rooms, and
- develop the project as proposed.

On page 58, the applicant states that its proposal is the most effective alternative because,

"Development of an ASC with two operating rooms, one GI endoscopy room, and one procedure room on Cone Health's existing MedCenter Kernersville campus will result in a right-sized facility that is conveniently co-located with numerous

other healthcare services in the area of Forsyth County with the greatest demonstrated need for additional operating room capacity."

The applicant provides supporting documentation in Section C.4 and Exhibit C.4.

The applicant adequately demonstrates that the alternative proposed in this application is the most effective alternative to meet the need for the following reasons:

- Maintaining the status quo would not be responsive to the need identified in the 2018 SMFP for additional operating rooms in Forsyth County, nor would it be responsive to the need for additional operating room capacity in Kernersville.
- Cone Health has identified a greater need for additional operating room capcity in Kernersville than in any other area in Forsyth County. Developing the ASF in a different location would not address the need in Kernersville of take advantage of the cost-effectiveness and convenience of providing the services at the Cone Health MedCenter Kernersville campus.
- Development all four ORs was not pursued because it was not as cost-effective as developing two ORs and developing two ORs alongside a GI endoscopy room and procedure room met the expected demand at the proposed ASF.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application,
- written comments,
- remarks made at the public hearing,
- responses to comments, and
- information publicly available during the review and used by the Agency.

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

NH Forsyth. The applicant proposes to add two ORs at FMC in Winston-Salem Forsyth County for a total of 35 ORs on the hospital license upon completion of this project.

In Section E, pages 46-47, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- maintain the status quo,
- add ORs at another existing Novant Health hospital, and
- develop the project as proposed.

On page 46, the applicant states that its proposal is the most effective alternative because:

"An efficient, high quality surgery program requires not just ORs, but a care team covering surgery and post-surgical care. Concentrating tertiary procedures at NHFMC provides the volume need [sic] for efficiency and quality of care. Surgeons who perform tertiary procedures also perform non-tertiary procedures. The will use their time more efficiently if they can perform all procedures at one facility."

However, in companion application, Project ID #G-11518-18, submitted by in the same review cycle, in Section E, page 43, Novant Health states:

"It is architecturally possible to add ORs to FMC Main, NHMPH or NHCMC to balance projected demand and surgical capacity. However, this is not the most cost-effective way to add capacity for outpatient surgeries. Performing outpatient surgeries in a dedicated ASC has several advantages over performing outpatient surgeries in shared ORs in even the best run hospital."

The applicant does not adequately demonstrate that the alternative proposed in this application is the most effective alternative to meet the need because the application is not conforming to all statutory and regulatory review criteria. See Criteria (1), (3), (5), (6), (18a), and 10A NCAC 14C .2103. An application that cannot be approved cannot be the most effective alternative.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application,
- written comments,
- remarks made at the public hearing,
- responses to comments, and
- information publicly available during the review and used by the Agency.

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

NH Clemmons. The applicant proposes to add two ORs at the previously approved NHCOS facility in Clemmons, Forsyth County for a total of 4 ORs upon completion of this project and Project ID #G-11300-17 (relocate 2 ORs from NHFMC).

In Section E, pages 43-44, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- maintain the status quo,
- add ORs to existing Novant Health hospitals,
- renovate NHOOS, and
- build a new outpatient surgery facility in a different location.

On pages 43-44, the applicant states that its proposal to expand NHCOS is the most effective alternative because:

- maintaining the status quo does not meet the needs of the Forsyth County residents for additional surgical capacity;
- adding surgical capacity at FMC Main, NHMPH or NHCMC is not as costeffective, nor does it provide the same advantages as developing ORs in an outpatient setting;
- renovating NHOOS is not cost effective because there are numerous deficiencies at the facility that would have to be brought up to licensure standards, the lease expires on the space in January 2020, and the location of NHOOS is less accessible to residents of the Clemmons service area; and
- developing the two ORs in a separate facility than NHCOS would have higher operating costs for the same number of surgeries than adding the ORs to NHCOS. The applicant further states:

"Adding two operating rooms at NHCOS will allow Novant Health to relocate outpatient surgeries for Clemmons area residents from Winston-Salem in addition to the surgeries relocated from NHOOS and FMC Main. Moving lower acuity outpatient surgeries to a separately licensed outpatient surgery center will reduce costs to health plans and patients, will improve quality, and will improve access for Clemmons area residents."

The applicant provides supporting documentation in Exhibit E.2.

However, the applicant does not adequately demonstrate that the alternative proposed in this application is the most effective alternative to meet the identified need because the application is not conforming to all statutory and regulatory review criteria. See Criteria (1), (3), (3a), (5), (6), (13c), (18a), and 10A NCAC 14C .2103. An application that cannot be approved cannot be the most effective alternative.

Conclusion

The Agency reviewed the:

• application,

- exhibits to the application,
- written comments,
- remarks made at the public hearing,
- responses to comments, and
- information publicly available during the review and used by the Agency.

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

NCBH. The applicant proposes to add four new ORs at NCBH in Winston-Salem, Forsyth County for a total of 51 ORs, including two trauma/burn ORs, upon completion of this project and Project ID #G-8460-10 (add seven dedicated outpatient ORs pursuant to Policy AC-3). The total number of ORs in the WFBMC Health System in Forsyth County would be 54 (51 ORs at NCBH + 3 ORs at WFBH-OSC).

In Section E, pages 76-78, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- develop all four ORs as a separately licensed ASF,
- develop a portion of the ORs as a separately licensed ASF and a portion at NCBH as shared inpatient/outpatient ORs,
- develop a portion of the ORs as an addition to the WFBH-OSC ASF and a portion at NCBH, and
- develop all four ORs at NCBH as shared inpatient/outpatient ORs.

On page 78, the applicant states that its proposal is the most effective alternative because,

"Ultimately, NCBH decided that development of all four operating rooms at NCBH was the only alternative that would truly meet the need for ORs in the Forsyth County OR Service Area. The operating rooms at NCBH provide a unique service to the county and region, and in some cases to the nation.

•••

The needs of NCBH and the patients served cannot be met by any other healthcare provider, neither hospital nor ASC, as these providers are not equipped to meet the needs of the patients that created the demand for more ORs."

The applicant provides supporting documentation in Section C.4(a) and Exhibits C.4.1 – C.4.9.

The applicant adequately demonstrates that the alternative proposed in this application is the most effective alternative to meet the need for the following reasons:

- The 2018 SMFP identified need for surgical services in Forsyth County is driven by utilization of the ORs at NCBH.
- The development of an ambulatory surgical facility at NCBH would require duplication of capital and operating resources.
- The development of the project as proposed will allow NCBH to provide complex operations and care of complex comorbidities due to the NCBH surgeons and other physician specialists and the unique surgical services offered at NCBH.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application,
- written comments,
- remarks made at the public hearing,
- responses to comments, and
- information publicly available during the review and used by the Agency.

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

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

C TCS Cone Health NCBH

NC NH Forsyth NH Clemmons

TCS. The applicant proposes to establish a new ASF in Winston-Salem, Forsyth County by developing two new ORs and three procedure rooms.

Capital and Working Capital Costs

In Section Q, Form F.1a Capital Cost, page 107, the applicant states the total capital cost is projected to be as follows:

100110jeee ee	P -ma 0 050	
Renovation Costs	\$	4,100,000
Medical Equipment	\$	2,142,885
Miscellaneous	\$	915,800
TOTAL CAPITAL COST	\$	7,158,685

TCS	Projec	t Car	nital	Cost
IUD	IIUJCU	i Cap	лаі	CUSL

In Section Q, page 107, the applicant provides the assumptions used to project the capital cost. In its response to comments, the applicant states:

"The Manager's Development Fee of \$225,000 is not omitted from the project cost because the Total Capital Cost in Form F.1a includes \$232,880 in the contingency line item that covers the Development Fee amount. Furthermore, the Medical Equipment and Furniture line items include a contingency component amount within the \$2,148,885 to cover taxes and installation costs, which could be allocated to absorb any shortfall."

Exhibit F.1(a) contains the renovation cost estimate prepared by a North Carolina licensed architect, as shown in the table above. In Section F.3, page 62, the applicant projects that start-up costs will be \$150,000 and initial operating expenses will be \$550,000, for total working capital required of \$700,000. On page 62, the applicant also provides the assumptions used to project the working capital costs.

Availability of Funds

In Section F, page 60, the applicant states that the capital cost will be funded as shown in the table below.

Bources of Capital Cost Financing			
Туре	Triad Center for Surgery, LLC		
Loans	\$ 7,158,685		
Accumulated reserves or OE *			
Bonds			
Other (Specify)			
Total Financing	\$ 7,158,685		

Sources of Capital Cost Financing

* OE = Owner's Equity

In Section F, page 63, the applicant states that the working capital needs of the project will be funded as shown in the table below.

	Sources of Financing for Working Capital	Amount
(a)	Loans	\$ 700,000
(b)	Cash or Cash Equivalents, Accumulated Reserves Owner's Equity	
(c)	Lines of credit	
(d)	Bonds	
(e)	Total	\$ 700,000

Exhibit F-2 contains letters from First Citizens Bank documenting intent to provide financing for the capital and working capital needs for the proposed project.

The amortization worksheet provided in Section Q, page 118, shows that the applicant based the amortization on \$100,000 of working capital, not the \$700,000 as shown above, which could conceivably understate annual interest expense, which, if not covered elsewhere in Form F-3, could affect the project's financial feasibility.

Financial Feasibility

The applicant provides pro forma financial statements for the first three full fiscal years of operation following completion of the project. In Form F.3 Revenues and Operating Expenses, the applicant projects that revenues will exceed operating expenses in the first three operating years of the project, as shown in the Project Analyst's table below.

I riad Center for Surgery ASF				
	PY1 CY2021	PY2 CY2022	PY3 CY2023	
Total Surgical Cases	2,338	2,930	3,522	
Total Gross Revenues (Charges)	\$10,068,464	\$12,617,878	\$15,167,293	
Total Net Revenue	\$5,031,673	\$6,305,732	\$7,579,791	
Average Net Revenue per Surgical Case	\$2,152	\$2,152	\$2,152	
Total Procedure Room (PR)Cases	719	877	1035	
Total Gross PR Revenues (Charges)	\$1,663,012	\$2,028,458	\$2,393,905	
Total Net PR Revenue	\$831,606	\$1,014,351	\$1,197,096	
Average Net Revenue per Procedure	\$1,157	\$1,157	\$1,157	
Total Cases/Procedures	3,057	3,807	4,557	
Total Gross Revenue	\$11,731,476	\$14,646,337	\$17,561,197	
Total Contractual Adjustments*	\$5,868,197	\$7,326,253	\$8,784,310	
Total Net Revenue	\$5,863,279	\$7,320,084	\$8,776,887	
Average Net Revenue per Case	\$1,918	\$1,923	\$1,926	
Total Operating Expenses (Costs)	\$5,464,490	\$6,071,678	\$6,756,586	
Average Operating Expense per Case	\$1,788	\$1,595	\$1,483	
Net Income	\$398,789	\$1,248,406	\$2,020,302	

Triad Center for Surgery ASF

Totals may not sum due to rounding

Includes Charity Care and Bad Debt as follows:						
	PY	1 CY2021	PY2	2 CY2022	PY3	3 CY2023
Charity Care	\$	90,741	\$	113,296	\$	135,851
Bad Debt	\$	351,944	\$	439,390	\$	526,836

As shown in the table above, the project has a net income of more than \$1 million and \$2 million in project years two and three, respectively. The excess of revenue over expenses more than covers the omission of partial interest expense on working capital amortization.

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

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application,
- written comments,
- remarks made at the public hearing, and
- responses to comments.

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

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

Cone Health. The applicant proposes to establish a new ASF in Kernersville, Forsyth County by developing two ORs, one GI endoscopy room, and one procedure room.

Capital and Working Capital Costs

In Section Q, Form F.1a Capital Cost, the applicant states the total capital cost is projected to be as follows:

Site Costs	\$163,367		
Construction Contract	\$6,571,810		
Miscellaneous	\$5,978,086		
TOTAL CAPITAL COST	\$12,713,263		

Cone Health Project Capital Cost

In Section Q, the applicant provides the assumptions used to project the capital cost. Exhibit F.1 contains the construction cost estimate prepared by a North Carolina licensed architect, as shown in the table above.

In Section F.3, pages 61-62, the applicant projects that start-up costs will be \$425,544 and initial operating expenses will be \$615,923, for total working capital required of \$1,041,467. On pages 61-62, the applicant also provides the assumptions used to project the working capital costs.

Availability of Funds

In Section F, page 60, the applicant states that the capital cost will be funded as shown in the table below.

Туре	MC Kernersville, LLC	The Moses H. Cone Memorial Hospital	Total
Loans			
Accumulated reserves or OE *	\$0	\$12,713,263	\$12,713,263
Bonds			
Other (Specify)			
Total Financing	\$0	\$12,713,263	\$12,713,263

Sources of Capital Cost Financing

* OE = Owner's Equity

In Section F, page 62, the applicant states that the working capital needs of the project will be funded as shown in the table below.

Туре	MC Kernersville, LLC	The Moses H. Cone Memorial Hospital	Total
Loans			
Cash or Cash Equivalents, Accumulated reserves or OE *	\$0	\$1,041,467	\$1,041,467
Lines of Credit			
Bonds			
Total Financing	\$0	\$1,041,467	\$1,041,467

Sources of Financing for Working Capital

Exhibit F.2 contains a letter from Cone Health's Chief Financial Officer indicating The Moses H. Cone Memorial Hospital's willingness to fund the proposed project's capital and working capital costs from existing accumulated reserves. Cone Health's September 30, 2017 audited financial statement (Exhibit F.2-2) shows cash and cash equivalents of \$57,808,000, total current assets of \$404,295,000 and total net assets of \$1,654,539,000.

Financial Feasibility

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

Cone Health MedCenter ASF				
	PY1 FFY2021	PY2 FFY2022	PY3 FFY2023	
Total Surgical Cases	2,097	2,171	2,247	
Total Gross Revenues (Charges)	\$ 14,933,239	\$15,924,529	\$16,981,623	
Total Net Revenue	\$ 7,624,668	\$ 8,130,805	\$ 8,584,313	
Average Net Revenue per Surgical Case	\$ 3,636	\$ 3,745	\$ 3,820	
Total GI Endoscopy Procedures	1,883	1,896	1,909	
Total Gross GI Revenues (Charges)	\$ 2,752,897	\$ 2,855,241	\$ 2,961,390	
Total Net GI Revenue	\$ 1,793,603	\$ 1,860,284	\$ 1,929,443	
Average Net Revenue per GI Procedure	\$ 953	\$ 981	\$ 1,011	
Total Procedure Room (PR)Cases	695	695	695	
Total Gross PR Revenues (Charges)	\$ 1,370,230	\$ 1,411,337	\$ 1,453,677	
Total Net PR Revenue	\$ 699,617	\$ 720,606	\$ 742,224	
Average Net Revenue per Procedure	\$ 1,007	\$ 1,037	\$ 1,068	
Total Cases/Procedures	4,675	4,762	4,851	
Total Gross Revenue	\$ 19,056,366	\$20,191,107	\$21,396,690	
Total Contractual Adjustments	\$ 8,891,460	\$ 9,429,468	\$10,087,634	
Charity Care	\$ 47,017	\$ 49,945	\$ 53,076	
Bad Debt	\$ 381,127	\$ 403,822	\$ 427,934	
Total Net Revenue	\$ 9,736,761	\$10,307,872	\$10,828,046	
Average Net Revenue per Case	\$ 2,083	\$ 2,165	\$ 2,232	
Total Operating Expenses (Costs)	\$ 6,244,553	\$ 6,644,791	\$ 7,062,615	
Average Operating Expense per Case	\$ 1,336	\$ 1,395	\$ 1,456	
Net Income	\$ 3,492,208	\$ 3,663,081	\$ 3,765,431	

Cone Health MedCenter ASF

Totals may not sum due to rounding

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

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application,
- written comments,
- remarks made at the public hearing, and
- responses to comments.

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

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

NH Forsyth. The applicant proposes to add two ORs at FMC Main in Winston-Salem, Forsyth County for a total of 22 ORs at FMC Main, including two dedicated C-Section and three Open Heart ORs, and a total of 35 ORs on the NHFMC license upon completion of this project.

Capital and Working Capital Costs

In Section Q, Form F.1a Capital Cost, the applicant states the total capital cost is projected to be as follows:

	Forsyth Memorial Hospital, Inc.	Novant	Health, Inc.
	(Applicant)	(P	arent)
Construction/Renovation Contract		\$	1,801,851
Medical Equipment		\$	1,801,818
Miscellaneous		\$	578,002
TOTAL CAPITAL COST		\$	4,181,671

NH Forsyth Project Capital Cost

In Section Q, the applicant provides the assumptions used to project the capital cost. Exhibit K.4 contains the construction cost estimate prepared by a North Carolina licensed architect, as shown in the table above.

In Section F.3, page 50, the applicant states that there is no need for start-up expenses, initial operating expenses or working capital because the project involves an existing and ongoing hospital surgical program.

Availability of Funds

In Section F.2, page 48, the applicant states that the capital cost will be funded, as shown in the table below.

	Sources of Capital	Cost Financing	
Туре	Forsyth Memorial	Novant Health, Inc.	Total
	Hospital, Inc. (Applicant)	(Parent)	
Loans			
Accumulated reserves	\$0	\$4,181,761	\$4,181,761
or OE *			
Bonds			
Other (Specify)			
Total Financing	\$0	\$4,181,761	\$4,181,761

Sources of Capital Cost Financing

* OE = Owner's Equity

Exhibit F.2 contains a letter from Novant Health's Senior Vice President of Finance documenting Novant Health's willingness to commit accumulated reserves for the capital costs of the proposed project. Novant Health's December 31, 2017 audited financial statement (Exhibit F.2) shows cash and cash equivalents of \$408,698,000, total current assets, net of receivables, of \$905,817,000 and total net assets of \$3,929,878,000.

Financial Feasibility

The applicant provides pro forma financial statements for the first three full fiscal years of operation following completion of the project. In Form F.3 Revenues and Expenses, the applicant projects that revenues will exceed operating expenses in the first three operating years of the project, as shown in the table below.

	1 0		
	PY1 CY2022	PY2 CY2023	PY3 CY2024
Total Surgical Cases	16,180	16,730	17,299
Total Gross Revenues (Charges)	\$837,748,343	\$883,528,577	\$931,850,030
Total Contractual Adjustments*	\$604,482,628	\$637,513,950	\$672,380,541
Total Net Revenue	\$233,265,715	\$246,014,626	\$259,469,489
Average Net Revenue per Case	\$14,417	\$14,705	\$14,999
Total Operating Expenses (Costs)	\$110,209,914	\$116,801,814	\$123,812,155
Average Operating Expense per Case	\$6,811	\$6,982	\$7,157
Net Income	\$123,055,801	\$129,212,812	\$135,657,334

FMC Main Operating Rooms

Totals may not sum due to rounding

*Includes Charity Care and Bad Debt as follows:

-	PY1 CY2022	PY2 CY2023	PY3 CY2024
Charity Care	\$33,398,963	\$35,224,110	\$37,150,567
Bad Debt	\$8,377,483	\$8,835,286	\$9,318,500

However, the assumptions used by the applicant in preparation of the pro forma financial statements are not reasonable and adequately supported because projected utilization is not based on reasonable and adequately supported assumptions. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference. Therefore,

since projected revenues and expenses are based at least in part on projected utilization, projected revenues and expenses are also questionable.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application,
- written comments,
- remarks made at the public hearing, and
- responses to comments.

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

NH Clemmons. The applicant proposes to add two ORs at the previously approved NHCOS facility in Clemmons, Forsyth County for a total of 4 ORs upon completion of this project and Project ID #G-11300-17 (relocate 2 ORs from NHFMC).

Capital and Working Capital Costs

In Section Q, Form F.1b Capital Cost, the applicant states the total capital cost is projected to be as follows:

	Previously Approved Project ID #G-11300-17	Total New Capital Cost	Capital Cost Project ID #G-11518-18
Site Costs	\$796,654	\$796,654	
Construction Contract	\$6,514,461	\$6,917,961	\$403,500
Medical Equipment	\$3,353,825	\$5,636,479	\$2,282,654
Miscellaneous	\$2,505,952	\$2,926,680	\$420,728
TOTAL CAPITAL COST	\$13,170,892	\$16,277,774	\$3,106,882

NH Clemmons Project Capital Cost

In Section Q, the applicant provides the assumptions used to project the capital cost. Exhibit K.4 contains the construction cost estimate prepared by a North Carolina licensed architect, as shown in the table above as the difference between the total new capital cost and the previously approved capital cost in Project ID #G-11300-17.

In Section F.3, page 48, the applicant projects that there will be no additional start-up expenses, initial operating expenses, or working capital required beyond what was contained in Project ID #G-11300-17.

Availability of Funds

In Section F, page 46, the applicant states that the capital cost will be funded, as shown in the table below.

Туре	Novant Health Clemmons Outpatient Surgery, LLC (Applicant 1)	Novant Health, Inc. (Applicant 2)	Total
Loans			
Accumulated reserves or OE *	\$0	\$3,106,882	\$3,106,882
Bonds			
Other (Specify)			
Total Financing	\$0	\$3,106,882	\$3,106,882

Sources of Capital Cost Financing

* OE = Owner's Equity

Exhibit F.2 contains a letter from Novant Health's Senior Vice President of Finance documenting Novant Health's willingness to commit accumulated reserves for the capital costs of the proposed project. Novant Health's December 31, 2017 audited financial statement (Exhibit F.2) shows cash and cash equivalents of \$408,698,000, total current assets, net of receivables, of \$905,817,000 and total net assets of \$3,929,878,000.

Financial Feasibility

The applicant provides pro forma financial statements for the first three full fiscal years of operation following completion of the project. In Form F.3 Revenues and Expenses, the applicant projects that revenues will exceed operating expenses in the first three operating years of the project, as shown in the table below.

NH Clemmons Outpatient Surgery							
	PY1 CY2021	PY2 CY2022	PY3 CY2023				
Total Surgical Cases	4,447	4,598	4,754				
Total Gross Revenues (Charges)	\$49,088,017	\$51,769,921	\$54,596,887				
Total Net Revenue	\$18,262,264	\$19,260,015	\$20,311,735				
Average Net Revenue per Surgical Case	\$4,107	\$4,189	\$4,273				
Total Procedure Room (PR) Cases	1,284	1,327	1,372				
Total Gross PR Revenues (Charges)	\$2,725,650	\$2,873,268	\$3,030,118				
Total Net PR Revenue	\$1,014,026	\$1,068,945	\$1,127,298				
Average Net Revenue per Procedure	\$790	\$806	\$822				
Total Cases/Procedures	\$5,731	\$5,925	\$6,126				
Total Gross Revenue	\$51,813,667	\$54,643,189	\$57,627,005				
Total Contractual Adjustments*	\$33,817,174	\$35,663,915	\$37,611,360				
Total Net Revenue	\$17,996,493	\$18,979,273	\$20,015,645				
Average Net Revenue per Case	\$3,140	\$3,203	\$3,267				
Total Operating Expenses (Costs)	\$16,023,717	\$16,914,264	\$17,861,106				
Average Operating Expense per Case	\$2,796	\$2,855	\$2,916				
Net Income	\$1,972,776	\$2,065,009	\$2,154,539				

NH Clemmons Outpatient Surgery

Totals may not sum due to rounding

*Includes Charity Care and Bad Debt (reduces the calculation of total Net Revenue from the amounts presented on the separate Form F.5's by the same amount) as follows:

	PY1 CY2021	PY2 CY2022	PY3 CY2023
Charity Care	\$761,661	\$803,255	\$847,117
Bad Debt	\$518,137	\$546,432	\$576,270

However, the assumptions used by the applicant in preparation of the pro forma financial statements are not reasonable and adequately supported because projected utilization is not based on reasonable and adequately supported assumptions. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference. Therefore, since projected revenues and expenses are based at least in part on projected utilization, projected revenues and expenses are also questionable.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application,
- written comments,
- remarks made at the public hearing, and
- responses to comments.

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

NCBH. The applicant proposes to add four new ORs at NCBH in Winston-Salem, Forsyth County for a total of 51 ORs upon completion of this project and Project ID #G-8460-10 (add seven dedicated outpatient ORs pursuant to Policy AC-3).

Capital and Working Capital Costs

In Section Q, Form F.1a Capital Cost, the applicant states the total capital cost is projected to be as follows:

Construction/Renovation Contract	\$	4,407,500			
Medical Equipment	\$	4,700,000			
Miscellaneous	\$	875,000			
TOTAL CAPITAL COST	\$	9,982,500			

In Section Q, the applicant provides the assumptions used to project the capital cost. F.1.1 contains the cost certification letter, verifying the projected cost as shown in the table above.

In Section F.3, page 81, the applicant states that as an expansion of an existing service, there are no start-up costs or initial operating expenses associated with the project. Exhibit

Availability of Funds

In Section F, page 79, the applicant states that the capital cost will be funded as shown in the table below.

Sources of Capital Cost Financing						
Туре	NCBH	Total				
Loans						
Accumulated reserves or OE *	\$9,982,500	\$9,982,500				
Bonds						
Other (Specify)						
Total Financing	\$9,982,500	\$9,982,500				
* OF - O						

Sources of Capital Cost Finan	cing
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* OE = Owner's Equity

Exhibit F.2.1 contains a letter from WFBMC's Chief Financial Officer committing accumulated reserves for the capital costs of the proposed project. WFBMC's June 30, 2017 audited financial statement (Exhibit F.2) shows cash and cash equivalents of \$226,286,000, total current assets of \$664,998,000 and total net assets of \$1,897,854,000.

Financial Feasibility

The applicant provides pro forma financial statements for the first three full fiscal years of operation following completion of the project. In Form F.3 Revenues and Operating Expenses, the applicant projects that revenues will exceed operating expenses in the first three operating years of the project, as shown in the table below.

	PY1 FY2025	PY2 FY2026	PY3 FY2027			
Total Surgical Cases	34,147	34,489	34,834			
Total Gross Revenues (Charges)	\$3,212,431,050	\$3,406,843,703	\$3,612,931,253			
Total Contractual Adjustments*	\$2,399,758,372	\$2,560,438,339	\$2,731,345,280			
Total Net Patient Revenue	\$812,672,679	\$846,405,364	\$881,585,974			
Average Net Revenue per Case	\$23,799	\$24,541	\$25,308			
Other Revenue	\$9,296,421	\$9,389,385	\$9,483,279			
Total Revenue	\$821,969,099	\$855,794,749	\$891,069,252			
Total Operating Expenses (Costs)	\$549,930,681	\$567,201,798	\$585,209,070			
Average Operating Expense per Case	\$16,105	\$16,446	\$16,800			
Net Income	\$272,038,418	\$288,592,952	\$305,860,182			

NCBH Operating Rooms

Totals may not sum due to rounding

*Includes Charity Care and Bad Debt as follows:						
PY1 FY2025 PY2 FY2026 PY3 FY2027						
Charity Care	\$110,828,871	\$117,536,108	\$124,646,128			
Bad Debt	\$76,134,616	\$80,742,196	\$85,626,471			

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

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application,
- written comments,
- remarks made at the public hearing, and
- responses to comments.

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

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions.
- The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal.
- The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.
- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

C TCS Cone Health NCBH

NC NH Forsyth NH Clemmons

On page 57, the 2018 SMFP states, "An operating room's service area is the operating room planning area in which the operating room is located. The operating room planning areas are the single and multicounty groupings shown in Figure 6.1." In Figure 6.1, page 62 of the 2018 SMFP, Forsyth County is shown as a single-county operating room service area. Thus, in this application, the service area is Forsyth County. Providers may serve residents of counties not included in their service area.

The following table identifies the existing and approved inpatient (IP), outpatient (OP), and shared operating rooms located in Forsyth County, and the inpatient and outpatient case volumes for each provider, from pages 65 and 73-74 of the 2018 SMFP, respectively.

	IP ORs	OP ORs	Shared ORs	Excluded C- Section/ Trauma/Burn ORs	CON Adjust- ments	IP Surger y Cases	OP Surger y Cases	Group
NH Clemmons Outpatient Surgery Center	0	0	0	0	2			
NH Kernersville Outpatient Surgery	0	0	0	0	2			
NH Forsyth Medical Center	5	6	24	-2	-2	9,262	17,706	2
NH Medical Park Hospital	0	0	12	0	-2	871	8,665	3
Novant Health Total	5	6	36	-2	0			
Clemmons Medical Park Ambulatory Surgical Center [^]	0	0	0	0	0			
Plastic Surgery Center of North Carolina^	0	3	0	0	0		169	6
North Carolina Baptist Hospital*	4	0	36	-2	7	14,534	19,925	1
Wake Forest Baptist Health Total	4	3	36	-2	7			
Piedmont Outpatient Surgery Center**	0	2	0	0	0		2,514	
Total Forsyth County ORs	9	11	72	-4	7			

Forsyth County 2016 Operating Room Inventory and Cases As Reported in the 2018 SMFP and on the 2017 License Renewal Applications

Source: 2018 SMFP

^Plastic Surgery Center of NC is underutilized. All 3 ORs were relocated to Clemmons Medical Park and licensed 2/22/18. The table above reflects the inventory prior to the relocation.

*NCBH has an undeveloped CON (G-8460-10) for 7 ORs pursuant to Policy AC-3. The ORs are listed as CON adjustments and included when determining OR need.

**Ambulatory surgery demonstration project included in the inventory, but not included in the need determination calculations.

As the table above indicates, there are three hospitals and four existing or approved ASFs in Forsyth County with a total of nine inpatient, 11 ambulatory and 72 shared operating rooms. All the Forsyth County facilities with ORs, except for the demonstration project with two ambulatory ORs, are Novant Health or Wake Forest Baptist Health owned and operated.

The 2018 SMFP shows a need for four additional ORs based on the utilization of Wake Forest Baptist Health. However, anyone can apply to meet the need.

TCS. The applicant proposes to establish a new ASF in Winston-Salem, Forsyth County by developing two new ORs and three procedure rooms.

In Section G, pages 69-70, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved OR services in Forsyth County. The applicant states:

"Triad Center for Surgery proposes to develop two operating rooms in a multispecialty ambulatory surgical facility which will not result in unnecessary duplication of existing or approved facilities because 1) the proposed project does not exceed the operating room need determination in the 2018 SMFP; 2) the vast majority of operating rooms are hospital based or hospital owned; 3) hospitals in Forsyth County have not developed previously-approved operating room / ASC
projects in a timely manner; and 4) the project offers a new alternative provider to enhance patient access."

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

- There is a need determination in the 2018 SMFP for four ORs and TCS proposes two ORs.
- The applicant adequately demonstrates that the proposed ORs are needed in addition to the existing or approved ORs in Forsyth County.

The Agency reviewed the:

- application,
- exhibits to the application,
- written comments,
- remarks made at the public hearing,
- responses to comments, and
- information publicly available during the review and used by the Agency.

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

Cone Health. The applicant proposes to establish a new ASF in Kernersville, Forsyth County by developing two ORs, one GI endoscopy room, and one procedure room.

In Section G, pages 67-68, the applicant discusses why it believes its proposal would not result in the unnecessary duplication of existing or approved OR services in Forsyth County. The applicant provides tables showing the total annual utilization during FFY2017 of the existing and approved facilities that provide outpatient surgical services and GI endoscopy services in Forsyth County. The applicant states:

"The 2018 SMFP includes a need determination for four additional operating rooms in Forsyth County. As described in Section C.4, the identified need can best be met by the development of a Cone Health freestanding ASC. Given the growing demand for outpatient surgery and the benefits of freestanding ASCs. Further, the Kernersville region of Forsyth County, where the proposed project will be located, needs and can support additional operating room capacity based on its population and projected growth. The patients Triad Surgery Center proposes to serve currently originate from a THN [Triad HealthCare Network, a physician-led clinically integrated accountable care organization, sponsored by Cone Health and located in the Piedmont Triad area] primary care physician, are referred to a THN surgeon, and then return to their primary care physician for ongoing care. Cone Health will leverage THN's information exchanges and its own reporting systems to provide a seamless continuum of care for the patient. The proposed project will allow patients to remain within a system for care – no other existing provider currently meets or could meet this need."

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

- There is a need determination in the 2018 SMFP for four ORs and Cone Health proposes two ORs.
- The applicant adequately demonstrates that the proposed ORs are needed in addition to the existing or approved ORs in Forsyth County.

The Agency reviewed the:

- application,
- exhibits to the application,
- written comments,
- remarks made at the public hearing,
- responses to comments, and
- information publicly available during the review and used by the Agency.

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

NH Forsyth. The applicant proposes to add two ORs at FMC Main in Winston-Salem, Forsyth County for a total of 22 ORs at FMC Main, including two C-Section and three Open Heart ORs and 35 ORs on the hospital license upon completion of this project.

In Section G, pages 55-56, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved OR services in Forsyth County. The applicant lists the existing and approved facilities that provide surgical services in Forsyth County, as shown in the 2018 SMFP on page 65 and in the introduction to Criterion (6) above.

On page 56, the applicant states:

"The 2018 SMFP shows a need for four new ORs in Forsyth County. Therefore, this application will not create unnecessary duplication of facilities at the county level.

FMC Main is one of the facilities covered by Novant Health Forsyth Medical Center license. Form C in Section Q shows that by CY2024 this licensed facility has a need for 7.2 additional ORs. Therefore, adding two ORs to this licensed facility does not result in unnecessary duplication." However, the applicant does not adequately demonstrate in the application as submitted that additional ORs are needed at FMC Main. The discussion regarding need and projected utilization found in Criterion (3) is incorporated herein by reference. Therefore, the applicant does not adequately demonstrate that the proposal would not result in an unnecessary duplication of existing or approved services in the service area for the following reasons:

- The applicant does not adequately demonstrate the growth rate used to project surgical cases is reasonable and adequately supported.
- Thus the applicant does not adequately demonstrate that the proposed ORs are needed at FMC Main in addition to the existing or approved ORs at FMC Main.

The Agency reviewed the:

- application,
- exhibits to the application,
- written comments,
- remarks made at the public hearing,
- responses to comments, and
- information publicly available during the review and used by the Agency.

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

NH Clemmons. The applicant proposes to add two ORs at the previously approved NHCOS facility in Clemmons, Forsyth County for a total of 4 ORs upon completion of this project and Project ID #G-11300-17 (relocate 2 ORs from NHFMC).

In Section G, pages 52-53, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved OR services in Forsyth County. The applicant lists the existing and approved facilities that provide surgical services in Forsyth County, as shown in the 2018 SMFP on page 65 and in the introduction to Criterion (6) above. On page 53, the applicant states:

"The operating need projections in Section Q, Form C show that all the existing and CON approved Novant Health operating rooms in Forsyth County will meet the utilization standard by the third project year. The Novant Health CON for NHCOS showed it would meet the utilization standard based on shifting existing Novant Health patients from FMC Main and NHOOS.

•••

Approval of this application will not result in unnecessary duplication of existing or approved facilities."

However, the applicant does not adequately demonstrate that additional ORs are needed at NHCOS. The discussion regarding need and projected utilization found in Criterion (3) is incorporated herein by reference. Therefore, the applicant does not adequately demonstrate that the proposal would not result in an unnecessary duplication of existing or approved services in the service area for the following reasons:

- The applicant does not adequately demonstrate that the growth rate used to project surgical cases is reasonable and adequately supported.
- The applicant does not adequately demonstrate that projected utilization was based on reasonable and adequately supported assumptions regarding the proposed shift of cases from NHOOS and NHMPH to NHCOS.
- The applicant does not adequately demonstrate that the proposed ORs are needed at NHCOS in addition to the approved ORs in Forsyth County.

The Agency reviewed the:

- application,
- exhibits to the application,
- written comments,
- remarks made at the public hearing,
- responses to comments, and
- information publicly available during the review and used by the Agency.

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

NCBH. The applicant proposes to add four new ORs at NCBH in Winston-Salem, Forsyth County for a total of 51 ORs, including two trauma/burn ORs, upon completion of this project and Project ID #G-8460-10 (add seven dedicated outpatient ORs pursuant to Policy AC-3).

In Section G, pages 87-88, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved OR services in Forsyth County. The applicant provides a table showing the total annual utilization during FFY2017 of the existing and approved facilities that provide surgical services in Forsyth County. The applicant states:

"The proposed project will not result in an unnecessary duplication of existing or approved surgical facilities as demonstrated by the following factors: 1) the project involves development of ORs pursuant to a need determination in the 2018 SMFP; 2) the need for ORs was generated by NCBH and the ORs are planned for development at NCBH; and 3) NCBH is unique in the services provided and cannot be duplicated in the Forsyth County OR Service Area.." The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area for the following reasons:

- There is a need determination in the 2018 SMFP for four ORs and NCBH proposes four ORs.
- The applicant adequately demonstrates that the proposed ORs are needed in addition to the existing or approved ORs at NCBH.

The Agency reviewed the:

- application,
- exhibits to the application,
- written comments,
- remarks made at the public hearing,
- responses to comments, and
- information publicly available during the review and used by the Agency.

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

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

C – All Applications

TCS. The applicant proposes to establish a new ASF in Winston-Salem, Forsyth County by developing two new ORs and three procedure rooms.

In Section Q, Form H, pages 116-117, the applicant provides the projected staffing by number of full time equivalent (FTE) positions for the proposed services, as illustrated in the following table.

	Projected		
Position	PY1 CY2021	PY2 CY2022	PY3 CY2023
Clerical / Registration	2.0	2.0	2.0
RN	11.0	11.5	13.0
Surgical Tech	4.0	5.0	6.0
RN Supervisor	1.0	1.0	1.0
CNAs	2.0	2.5	2.5
Central Sterile Tech	2.0	2.0	2.0
Administrator	1.0	1.0	1.0
CFO	1.0	1.0	1.0
Materials Management Tech	1.0	1.0	1.0
RN Quality Coordinator	0.5	0.5	0.5
Radiological Tech	0.5	0.5	0.5
TOTAL	26.0	28.0	30.5

Source: Section Q Form H, pages 116-117 of the application.

The applicant states in Section H.1, page 71, that the projected staffing is based on staffing information obtained from Compass Surgical Partners and OrthoCarolina and includes staff coverage from 7 am to 4 pm Monday through Friday and for scheduled occurrences of extended stay patients. The assumptions and methodology used to project staffing are provided in Section Q, Form H. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.3, which is found in Section Q. In Section H, pages 71-72, the applicant describes the methods to be used to recruit or fill new positions and its proposed training and continuing education programs. In Section H.4(b), page 73, the applicant identifies the proposed Medical Director as William Craig, MD. In Exhibit H.4, the applicant provides a letter from Dr. Craig indicating an interest in serving as medical director for the proposed services. In Section H.4(c), page 73, the applicant recruitment plans. In Exhibit C.4(b), the applicant provides supporting documentation.

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

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application,
- written comments,
- remarks made at the public hearing, and
- responses to comments.

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

Cone Health. The applicant proposes to establish a new ASF in Kernersville, Forsyth County by developing two ORs, one GI endoscopy room, and one procedure room.

In Section Q, Form H, the applicant provides the projected staffing by number of FTE positions for the proposed services, as illustrated in the following table.

Cone Health MedCenter ASF			
	Projected FTE Positions		
	1 st Full Fiscal	3 rd Full Fiscal	
Position	Year	Year	Year
Administrator	1.00	1.00	1.00
Director of Nursing	1.00	1.00	1.00
RN	11.00	12.00	13.00
Surgical Technologist	4.00	5.00	6.00
Operative Clinical	2.00	2.00	2.00
Technicians	2.00	2.00	2.00
CRNAs	3.50	3.50	3.50
Nurse Techs	3.25	3.25	3.25
Sterile Processing Technicians	3.00	3.00	3.00
Nurse Secretary	1.00	1.00	1.00
Inventory Analyst	1.00	1.00	1.00
Reception/Registration	2.00	2.00	2.00
TOTAL	32.75	32.75[34.75]	36.75

Source: Form H in Section Q of the application.

The assumptions and methodology used to project staffing are provided in Section Q. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Forms B & C - Revenues and Expenses, which is found in Section Q. In Section H, pages 70-72, the applicant describes the methods to be used to recruit or fill new positions and its proposed training and continuing education programs. In Section H.4, page 72, the applicant identifies the proposed medical director as James Daniel Singer, MD. In Exhibit H.4, the applicant provides a letter from Dr. Singer indicating an interest in serving as medical director for the proposed services. In Section H.4(c), page 72, the applicant describes its physician recruitment plans. In Exhibit C.4, the applicant provides supporting documentation.

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

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application,
- written comments,
- remarks made at the public hearing, and
- responses to comments.

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

NH Forsyth. The applicant proposes to add two ORs at FMC Main in Winston-Salem, Forsyth County for a total of 22 ORs, including two C-Section ORs and three open heart ORs, and 35 ORs on the hospital license upon completion of this project.

In Section Q, Form H - Staffing for NHFMC Main Operating Rooms, the applicant provides current and projected staffing by number of FTE positions for the proposed services, as illustrated in the following table.

	Current	Projected FTE Positions			
	Time Period^	PY2	PY3	3 PY 3	
Position	Time Period.	CY2022	CY2023	CY2024	
CRNA	5.57	5.57	5.57	5.57	
Anesthesia Tech Lead*	1.00	1.00	1.00	1.00	
Anesthesia Tech Lead*	1.71	1.71	1.71	1.71	
Clinical Reporting Analyst	3.00	3.00	3.00	3.00	
Business Reporting Analyst	1.00	1.00	1.00	1.00	
Sterile Processing Coordinator	2.00	2.00	2.00	2.00	
Sterile Reprocessing Technician*	6.70	7.53	7.79	8.05	
Sterile Reprocessing Tech*	22.69	25.51	26.38	27.27	
Director Surgical Services	2.00	2.00	2.00	2.00	
LPN	0.58	0.58	0.58	0.58	
Anesthesia Manager	0.52	0.52	0.52	0.52	
Nurse Manager	4.00	4.00	4.00	4.00	
Bariatric Program Manager	1.00	1.00	1.00	1.00	
Sterile Processing Manager	1.00	1.00	1.00	1.00	
CNA 1	4.16	4.16	4.16	4.16	
Surgical Services Charge Poster	5.00	5.00	5.00	5.00	
Patient Representative Assistant	1.00	1.00	1.00	1.00	
Instrument & Supply Tech	2.00	2.00	2.00	2.00	
Supply Distribution Technician	1.20	1.20	1.20	1.20	
Clinical Coordinator (RN)	6.00	6.00	6.00	6.00	
RM CVOR	10.41	10.41	10.41	10.41	
RN	89.17	100.25	103.66	107.18	
Robotic Coordinator RN	1.00	1.00	1.00	1.00	
Anesthesia Office Liaison	0.58	0.58	0.58	0.58	
Administrative Specialist	2.45	2.45	2.45	2.45	
Executive Assistant	0.99	0.99	0.99	0.99	
Charge Capture Coordinator	1.00	1.00	1.00	1.00	
OR Assistant	14.29	14.29	14.29	14.29	
OR Access Specialist*	8.26	8.26	8.26	8.26	
Surgical Flow Coordinator	1.00	1.00	1.00	1.00	
OR Access Specialist*	1.00	1.00	1.00	1.00	
Lead Surgical Technician	3.08	3.08	3.08	3.08	
Surgical Tech CVOR	2.08	2.08	2.08	2.08	
Surgical Technician	30.19	33.94	35.09	36.29	
Supervisor SS Charge Capture	1.00	1.00	1.00	1.00	
Assistant Nurse Manager	4.00	4.00	4.00	4.00	
Sterile Processing Supervisor*	1.00	1.00	1.00	1.00	
Supervisor Sterile Processing*	2.00	2.00	2.00	2.00	
OR Flow Supervisor	1.00	1.00	1.00	1.00	
Total	246.63	265.11	270.79	276.68	

Source: Form H in Section Q of the application. ^Time Period not identified *Position is listed two times

The assumptions and methodology used to project staffing are provided in Section Q. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.3, which is found in Section Q. In Section H, pages 58-60, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. In Section H, page 61, the applicant identifies the current medical director as John Mann, MD. In Exhibit H-Letters, the applicant provides a letter from Dr. Mann indicating his support for the project and providing his curriculum vitae. In Section H, pages 61-62, the applicant describes its physician recruitment plans. In Exhibit H-Letters, the applicant provides physician support letters.

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

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application,
- written comments,
- remarks made at the public hearing, and
- responses to comments.

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

NH Clemmons. The applicant proposes to add two ORs at the previously approved NHCOS facility in Clemmons, Forsyth County for a total of 4 ORs upon completion of this project and Project ID #G-11300-17 (relocate 2 ORs from NHFMC).

In Section Q, Form H, the applicant provides the projected staffing for the proposed new services, as illustrated in the following table.

	Projected FTE Positions		
Position	PY1 CY2021	PY2 CY2022	PY3 CY2023
Administrator	1.00	1.00	1.00
CNA	3.00	3.00	3.00
Patient Access Specialist	1.50	1.50	1.50
Registered Nurse	16.00	16.00	16.00
Clinical Coordinator (RN)	2.00	2.00	2.00
Surgical Tech	6.00	6.00	6.00
Sterile Process Tech	3.00	3.00	3.00
TOTAL	32.50	32.50	32.50

NHCOS	Pro	iected	Staffing
111000	I I U	<i>i</i> ccicu	Statility

Source: Form H in Section Q of the application.

The assumptions and methodology used to project staffing are provided in Section Q. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.3, which is found in Section Q. In Section H, page 55-57, the applicant describes the methods to be used to recruit or fill new positions and its proposed training and continuing education programs. In Section H, page 57, the applicant identifies John Mann, MD as the proposed medical director. In Exhibit H-1, the applicant provides a letter from Dr. Mann indicating an interest in serving as medical director for the proposed services. In Section H, page 58, the applicant describes its physician recruitment plans. In Exhibit H, the applicant provides physician support letters.

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

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application,
- written comments,
- remarks made at the public hearing, and
- responses to comments.

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

NCBH. The applicant proposes to add four new ORs at NCBH in Winston-Salem, Forsyth County for a total of 51 ORs upon completion of this project and Project ID #G-8460-10 (add seven dedicated outpatient ORs pursuant to Policy AC-3).

In Section Q, Form H Staffing, the applicant provides current and projected staffing for the existing and proposed services, as illustrated in the following table.

NCBH Projected Staffing				
Position	Current Projected FTE Positions			ons
	As of 4/11/18	PY1 FY2025	PY2 FY2026	PY3 FY2027
Surgery Manager	7.00	7.00	7.00	7.00
Surgery RN	254.21	272.61	272.61	272.61
Surgery LPN	0.38	0.38	0.38	0.38
Surgery Technician	70.73	77.63	77.63	77.63
Central Sterile Manager	4.13	4.13	4.13	4.13
Central Sterile Technician	85.07	86.07	86.07	86.07
Environmental Service Tech	19.50	21.50	21.50	21.50
Administrator	1.50	1.50	1.50	1.50
Assistant Administrator	1.00	1.00	1.00	1.00
Materials Management Manager	1.00	1.00	1.00	1.00
Materials Management Technician	12.63	12.63	12.63	12.63
Clerical*	22.97	22.97	22.97	22.97
Other**	96.18	100.78	100.78	100.78
TOTAL	576.30	609.20	609.20	609.20

Source: Form H in Section Q of the application.

*Clerical includes staffing in Surgery, Administration, Finance and Materials Management

**Other includes staffing as listed on page 2 of Form H Staffing in Section Q

The assumptions and methodology used to project staffing are provided in Section Q. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.3, which is found in Section Q. In Section H, pages 89-91, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. In Section H, page 92, the applicant identifies the current medical director as Wayne Meredith, MD. In Exhibit H.4.2, the applicant provides a letter from Dr. Meredith indicating support for the proposed services. In Section H, page 92, the applicant describes its physician recruitment plans. In Exhibit H.4.2, the applicant provides physician support letters.

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

Conclusion

- application,
- exhibits to the application,
- written comments,
- remarks made at the public hearing, and
- responses to comments.

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

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

C – All Applications

TCS. The applicant proposes to establish a new ASF in Winston-Salem, Forsyth County by developing two new ORs and three procedure rooms.

In Section I, page 75, the applicant states that the following ancillary and support services are necessary for the proposed services:

- patient registration,
- billing,
- medical records,
- housekeeping,
- administration,
- management services,
- anesthesia,
- pathology, and
- pharmacy consulting.

On page 75, the applicant adequately explains how each ancillary and support service will be made available and provides supporting documentation in Exhibits A.9 and I.1.

In Section I, pages 75-76, the applicant describes its efforts to develop relationships with other local health care and social service providers and provides supporting documentation in Exhibits C.4(b) and I.2.

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

Conclusion

- application,
- exhibits to the application,
- written comments,
- remarks made at the public hearing, and

• responses to comments.

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

Cone Health. The applicant proposes to establish a new ASF in Kernersville, Forsyth County by developing two ORs, one GI endoscopy room, and one procedure room.

In Section I, page 74, the applicant states that the following ancillary services are necessary for the proposed services:

- laboratory tests,
- diagnostic imaging,
- pathology, and
- anesthesia.

In Section I, page 74, the applicant states that the following support services are necessary for the proposed services:

- reception,
- medical records,
- billing and insurance
- housekeeping, and
- maintenance.

On pages 74-75, the applicant adequately explains how each ancillary and support service will be made available and provides supporting documentation in Exhibit I.1.

In Section I, page 75, the applicant describes Cone Health's existing relationships with other local health care and social service providers and provides examples of such relationships. Supporting documentation is provided in Exhibit C.4.

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

Conclusion

- application,
- exhibits to the application,
- written comments,
- remarks made at the public hearing, and
- responses to comments.

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

NH Forsyth. The applicant proposes to add two ORs at FMC Main in Winston-Salem, Forsyth County for a total of 22 ORs, including two C-Section ORs, and 35 ORs on the hospital license upon completion of this project.

In Section I, page 64, the applicant states that the following ancillary and support services are necessary for the proposed services:

- Pre-operative services
- OR facility component (RNs, OP Surgical Technicians)
- OR professional component (Surgeons, Anesthesiologiests)
- Post-operative services
- Anesthesia
- Chief of surgical services
- Sterile processing services
- Lab
- Pathology
- Radiology

On page 64, the applicant adequately explains how each ancillary and support service is or will be made available.

In Section I, page 65, the applicant describes its existing and proposed relationships with other local health care and social service providers.

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

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application,
- written comments,
- remarks made at the public hearing, and
- responses to comments.

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

NH Clemmons. The applicant proposes to add two ORs at the previously approved NHCOS facility in Clemmons, Forsyth County for a total of 4 ORs upon completion of this project and Project ID #G-11300-17 (relocate 2 ORs from NHFMC).

In Section I, page 59, the applicant states that the following ancillary and support services are necessary for the proposed services:

- Pre-operative services
- OR facility component
- OR professional component
- Post-operative services
- Anesthesia
- Chief of surgical services
- Sterile processing services
- Lab
- Pathology
- Radiology

On page 57, the applicant adequately explains how each ancillary and support service is or will be made available.

In Section I, page 60, the applicant states that the surgery center's partnerships will include those already in place with Novant Health and lists relationships with other local health care and social service providers.

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

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application,
- written comments,
- remarks made at the public hearing, and
- responses to comments.

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

NCBH. The applicant proposes to add four new ORs at NCBH in Winston-Salem, Forsyth County for a total of 51 ORs, including two trauma/burn ORs, upon completion of this

project and Project ID #G-8460-10 (add seven dedicated outpatient ORs pursuant to Policy AC-3).

In Section I, page 93, the applicant states that the following ancillary and support services are necessary for the proposed services:

- Operating room services (pre-op, post-op, and intra-op)
- Anesthesiology Services
- Pathology Services
- Pharmacy Services
- Physical Therapy and Occupational Therapy
- Inpatient Care Services (nursing, dietary, housekeeping, etc)
- Respiratory Therapy Services
- Emergency Services
- Radiology Services
- Other Diagnostic Services

On page 93, the applicant adequately explains how each ancillary and support service is or will be made available.

In Section I, page 94, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit I.2.1, pages 14-20.

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

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application,
- written comments,
- remarks made at the public hearing, and
- responses to comments.

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

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

NA- All Applications

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

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:
 - (i) would be available under a contract of at least 5 years duration;
 - (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
 - (iii) would cost no more than if the services were provided by the HMO; and
 - (iv) would be available in a manner which is administratively feasible to the HMO.

NA- All Applications

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

- (11) Repealed effective July 1, 1987.
- (12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

C – All Applications

TCS. The applicant proposes to establish a new ASF in Winston-Salem, Forsyth County by developing two new ORs and three procedure rooms.

In Section K, page 79, the applicant states that the project involves the renovation of 14,700 square feet of existing leased space. Line drawings are provided in Exhibit K.2.

The applicant did not respond to Section K.4, which addresses a) that the project is the most reasonable alternative, b) that the project will not unduly increase the costs to the applicant or costs and charges to the public for the proposed services, and c) any applicable energy saving features incorporated into the renovation. However, the applicant adequately addresses these questions in other areas of the application. The applicant explains how the cost, design and means of construction represent the most reasonable alternative for the proposed renovations in Section E, page 58.

In Sections B.3(c), pages15-16 and N, pages 92-94, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services and provides supporting documentation in Exhibit B.3(b).

On page 18, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

On pages 80-81, the applicant identifies the proposed site and provides information about the current owner, zoning and special use permits for the site, and the availability of water, sewer and waste disposal and power at the site.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application,
- written comments,
- remarks made at the public hearing, and
- responses to comments.

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

Cone Health. The applicant proposes to establish a new ASF in Kernersville, Forsyth County by developing two ORs, one GI endoscopy room, and one procedure room.

In Section K, page 78, the applicant states that the project involves constructing 15,500 square feet of new space. The applicant further states that The Moses H. Cone Memorial Hospital holds fee simple title to the proposed site and will construct the building and lease it to MC Kernersville, LLC to operate Triad Surgery Center. Line drawings are provided in Exhibit C.1.

On page 79, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposed construction.

On page 79, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services.

The applicant identifies the applicable energy saving features that will be incorporated into the construction plans and provides supporting documentation in Exhibit B.4.

On pages 80-82, the applicant identifies the proposed site and provides information about the current owner, The Moses H. Cone Memorial Hospital, zoning and special use permits for the site, and the availability of water, sewer and waste disposal and power at the site.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application,
- written comments,
- remarks made at the public hearing, and
- responses to comments.

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

NH Forsyth. The applicant proposes to add two ORs at FMC Main in Winston-Salem, Forsyth County for a total of 22 ORs, including two C-Section ORs, and 35 ORs on the hospital license upon completion of this project.

In Section K, page 68, the applicant states that the project involves renovating 1,239 square feet of existing space. Line drawings are provided in Exhibit K.4

On pages 68-69, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposed renovations and provides supporting documentation in Exhibit K.4

On page 69, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services.

On page 69, the applicant identifies any applicable energy saving features that will be incorporated into the renovation plans and provides supporting documentation in Exhibit K.4.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application,
- written comments,
- remarks made at the public hearing, and
- responses to comments.

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

NH Clemmons. The applicant proposes to add two ORs at the previously approved NHCOS facility in Clemmons, Forsyth County for a total of 4 ORs upon completion of this project and Project ID #G-11300-17 (relocate 2 ORs from NHFMC).

In Section K, page 63, the applicant states that the project involves renovating 1,056 square feet of the space in the previously approved facility in Project ID #G-11300-17. Line drawings are provided in Exhibit K-4.

On pages 63-64, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposed renovations and provides supporting documentation in Exhibit K-4.

On page 64, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services and provides supporting documentation in Exhibit K-4.

On page 64, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans and provides supporting documentation in Exhibit B-4.

On pages 65-66, the applicant identifies the proposed site and provides information about ownership, zoning and special use permits for the site, and the availability of water, sewer and waste disposal and power at the site. The applicant provides supporting documentation in Exhibit K-5.

Conclusion

- application,
- exhibits to the application,
- written comments,

- remarks made at the public hearing, and
- responses to comments.

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

NCBH. The applicant proposes to add four new ORs at NCBH in Winston-Salem, Forsyth County for a total of 51 ORs, including two trauma/burn ORs, upon completion of this project and Project ID #G-8460-10 (add seven dedicated outpatient ORs pursuant to Policy AC-3).

In Section K, page 97, the applicant states that the project involves renovation of 7,000 square feet of existing vacated OR space. Line drawings are provided in Exhibit C.1.3.

On page 98, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposed renovations and provides supporting documentation in Exhibits C.1.3 and F.1.1.

On page 98, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services.

On pages 98-99, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application,
- written comments,
- remarks made at the public hearing, and
- responses to comments.

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

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

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

NA TCS

C All Other Applications

TCS. Neither the applicant nor any related entities owns, operates or manages an existing facility located in the service area. Therefore, Criterion (13a) is not applicable.

Cone Health. The applicant proposes to establish a new ASF in Kernersville, Forsyth County by developing two ORs, one GI endoscopy room, and one procedure room.

In Section L, page 86, the applicant provides the historical payor mix during FFY2017 for Cone Health outpatient surgery services, as shown in the table below.

Payor Category	Outpatient Surgical Services as Percent of Total
Self-Pay	2.9%
Medicare	27.6%
Medicaid	17.4%
Insurance	49.0%
Other (Other Gov't, Worker's Comp)	3.1%
Total	100.0%

Source: Cone Health's internal data

In Section L, pages 84-85, the applicant provides the following comparison.

	Percentage of Total Patients Served by Cone Health Surgical Services FFY2017	Percentage of the Population of Forsyth County
Female	60.4%	52.7%
Male	39.6%	47.3%
Unknown	0.0%	0.0%
64 and Younger	59.0%	82.0%
65 and Older	41.0%	18.0%
American Indian	0.3%	0.0%
Asian	1.4%	2.6%
Black or African-American	33.0%	28.0%
Native Hawaiian or Pacific Islander	0.1%	1.1%
White or Caucasian	59.2%	65.8%
Other Race	4.7%	2.4%
Declined / Unavailable	1.3%	0.0%

Conclusion

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The Agency reviewed the:

- application,
- exhibits to the application,
- written comments,
- remarks made at the public hearing,
 - responses to comments, and information publicly available during the review and used by the Agency.

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

NH Forsyth. The applicant proposes to add two ORs at FMC Main in Winston-Salem, Forsyth County for a total of 22 ORs, including two C-Section ORs, and 35 ORs on the hospital license upon completion of this project.

In Section L, page 74, the applicant provides the historical payor mix during CY2017, the last full year, as shown in the table below.

012017			
	Entire Facility FMC	Operating	
Payor Source	Main	Rooms	
Self-Pay/ Charity	10%	4%	
Medicare *	41%	49%	
Medicaid *	16%	9%	
Insurance *	31%	35%	
Workers Comp and			
Other Government	2%	3%	
Total	100%	100%	

Historical Payor Mix CY2017

Source: Page 74 of application

* Including any managed care plans

Totals may not sum due to rounding

In Section L, page 74, the applicant provides the following comparison.

	Percentage of Total Patients Served by NHFMC CY2017	Percentage of the Population of the Service Area
Female	61.5%	52.7%
Male	38.5%	47.3%
Unknown	0.0%	0.0%
64 and Younger	66.7%	84.7%
65 and Older	33.3%	15.3%
American Indian	0.2%	1.1%
Asian	0.5%	2.6%
Black or African-American	20.3%	28.0%
Native Hawaiian or Pacific Islander	0.1%	0.0%
White or Caucasian	72.3%	65.8%
Other Race	4.3%	2.4%
Declined / Unavailable	2.4%	0.0%

Source: County data - NC Office State Budget & Management; NHFMC - Trendstar

Conclusion

- application,
- exhibits to the application,
- written comments,
- remarks made at the public hearing,
- responses to comments, and information publicly available during the review and used by the Agency.

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

NH Clemmons. The applicant proposes to add two ORs at the previously approved NHCOS facility in Clemmons, Forsyth County for a total of 4 ORs upon completion of this project and Project ID #G-11300-17 (relocate 2 ORs from NHFMC).

In Section L, page 69, the applicant provides the following comparison of NHCMC and the population of its service area.

	Percentage of Total Patients Served by NHCMC FY2017	Percentage of the Population of the Service Area 2017
Female	59.3%	52.7%
Male	40.7%	47.3%
Unknown	0.0%	0.0%
64 and Younger	72.5%	84.7%
65 and Older	27.5%	15.3%
American Indian	0.1%	1.1%
Asian	0.4%	2.6%
Black or African-American	14.3%	28.0%
Native Hawaiian or Pacific Islander	0.0%	0.0%
White or Caucasian	81.4%	65.8%
Other Race	3.0%	4.3%
Declined / Unavailable	0.8%	0.0%

Source: County data - NC Office State Budget & Management; NHCMC - Trendstar

NHCOS will be a new facility owned by the ultimate parent, NH. The applicant does not currently provide ASF services in Clemmons. However, the application often refers to NH's ownership, experience and policies as being relevant to NHCOS, as in Section B, pages 7-11 and throughout Section L. In Section L.3, page 72, the applicant states that its projected payor mix for NHCOS is based upon the historical outpatient surgical payor mix for NHCMC and budgeted NHKOS payor mix, however, the applicant does not provide the historical surgical payor mix for NHCMC or any payor mix for NHKOS.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application,
- written comments,
- remarks made at the public hearing,
- responses to comments, and information publicly available during the review and used by the Agency.

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

NCBH. The applicant proposes to add four new ORs at NCBH in Winston-Salem, Forsyth County for a total of 51 ORs, including two trauma/burn ORs, upon completion of this project and Project ID #G-8460-10 (add seven dedicated outpatient ORs pursuant to Policy AC-3).

In Section L, page 103, the applicant provides the historical payor mix during FY2017 for the proposed OR services, as shown in the table below.

Payor Category	OR Services as Percent of Total
Self-Pay	5.5%
Charity Care**	NA
Medicare*	34.2%
Medicaid*	18.8%
Insurance*	35.4%
Other (specify)***	6.1%
Total	100.0%

Source: Table L.1.2 on page 103

*Including any managed care plans

**Charity Care is not considered a payor source. See policy in Exhibit B.3.6

***Other includes liability, other government programs, Workers comp, and TRICARE

In Section L, page 103, the applicant provides the following comparison.

	Percentage of Total Patients Served by the Facility or Campus during the Last Full FY2017	Percentage of the Population of the Service Area: Forsyth County
Female	56.9%	52.3%
Male	43.0%	47.7%
Unknown	0.1%	0.0%
64 and Younger	71.8%	84.5%
65 and Older	28.2%	15.5%
American Indian	0.4%	0.5%
Asian	1.3%	2.3%
Black or African-American	20.5%	24.6%
Native Hawaiian or Pacific Islander	0.1%	0.1%
White or Caucasian	67.3%	62.5%
Other Race	9.9%	10.0%
Declined / Unavailable	0.5%	0.0%

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application,
- written comments,
- remarks made at the public hearing,
- responses to comments, and information publicly available during the review and used by the Agency.

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

(b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

NA TCS

C All Other Applications

TCS. The applicant does not own, operate or manage an existing facility located in North Carolina.

Cone Health. The applicant proposes to establish a new ASF in Kernersville, Forsyth County by developing two ORs, one GI endoscopy room, and one procedure room.

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 86, the applicant states that though Cone Health has no such obligations under applicable federal regulations, it is dedicated to providing care for all in its community regardless of ability to pay, as demonstrated in its policies in Exhibit C.10.

In Section L, page 87, the applicant states that during the last five years it has had one patient civil rights access complaint filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina. The applicant further states that the Office of Civil Rights closed the case without any request for additional information or remediation.

The Agency reviewed the:

- application,
- exhibits to the application,
- written comments,
- remarks made at the public hearing, and
- responses to comments.

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

NH Forsyth. The applicant proposes to add two ORs at FMC Main in Winston-Salem, Forsyth County for a total of 22 ORs, including two C-Section ORs, and 35 ORs on the hospital license upon completion of this project.

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 75, the applicant states:

"Novant Health's hospitals (NHFMC and NHPMC) fulfilled their Hill-Burton obligations long ago.

•••

Since completing its Hill-Burton obligations, Novant Health's acute care hospitals have continued their commitment to provide care to all persons, regardless of their ability to pay."

In Section L, page 75, the applicant states that during the last five years no patient civil rights access complaints have been filed against the facility or any affiliated licensed hospitals located in North Carolina.

The Agency reviewed the:

- application,
- exhibits to the application,
- written comments,
- remarks made at the public hearing, and
- responses to comments.

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

NH Clemmons. The applicant proposes to add two ORs at the previously approved NHCOS facility in Clemmons, Forsyth County for a total of 4 ORs upon completion of this project and Project ID #G-11300-17 (relocate 2 ORs from NHFMC).

NHCOS will be a new facility owned by the ultimate parent, NH. The applicant does not currently provide ASF services in Clemmons. However, the application often refers to NH's ownership, experience and policies as being relevant to NHCOS, as in Section B, pages 7-11 and throughout Section L.

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, pages 70-71, the applicant states:

"Novant Health's hospitals (NHFMC and NHPMC) fulfilled their Hill-Burton obligations long ago.

. . .

Since completing its Hill-Burton obligations, Novant Health's acute care hospitals have continued their commitment to provide care to all persons, regardless of their ability to pay."

In Section L, page 71, the applicant states that during the last five years no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina.

The Agency reviewed the:

- application,
- exhibits to the application,
- written comments,
- remarks made at the public hearing, and
- responses to comments.

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

NCBH. The applicant proposes to add four new ORs at NCBH in Winston-Salem, Forsyth County for a total of 51 ORs, including two trauma/burn ORs, upon completion of this project and Project ID #G-8460-10 (add seven dedicated outpatient ORs pursuant to Policy AC-3).

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, pages 103-104, the applicant states:

"Internal Revenue Code (IEC) Section 501(r), Enacted by the Patient Protection and Affordable Care Act, requires tax exempt hospitals exempt under IRC Section 501(c)(3) to have a written financial assistance policy and emergency medical care policy that provides discounts to emergent and other medically necessary care provided to eligible financial assistance patients ... Furthermore, the EMTALA policy ensures that emergency medical care is provided without discrimination and regardless of ability to pay."

In Section L, page 104, the applicant states that during the last five years no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina.

The Agency reviewed the:

- application,
- exhibits to the application,
- written comments,
- remarks made at the public hearing, and
- responses to comments.

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

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

C TCS Cone Health NH Forsyth NCBH

NC NH Clemmons

TCS. The applicant proposes to establish a new ASF in Winston-Salem, Forsyth County by developing two new ORs and three procedure rooms.

In Section L, page 85, the applicant projects the payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as shown in the table below.

CY2022			
Payor Source	Entire Facility	Operating Rooms	Procedure Rooms
Self-Pay	1.02%	1.00%	1.10%
Charity Care	0.77%	0.78%	0.76%
Medicare *	50.27%	46.59%	62.56%
Medicaid *	3.60%	3.82%	2.88%
Insurance *	39.68%	42.59%	29.95%
Workers Compensation	3.41%	3.94%	1.61%
TRICARE	1.25%	1.28%	1.14%
Other	0.00%	0.00%	0.00%
Total	100.00%	100.00%	100.00%

TCS Proposed Payor Mix As a Percent of Surgical Cases CY2022

* Including any managed care plans

Totals may not sum due to rounding

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 1.00% of surgical services will be provided to self-pay patients, 0.78% to charity care patients, 46.59% to Medicare patients and 3.82% to Medicaid patients.

On pages 85-89, the applicant provides the assumptions and methodology used to project payor mix during the second full fiscal year of operation following

completion of the project. The projected payor mix is reasonable and adequately supported for the following reasons:

- projected payor mix is based on historical payor percentages for OrthoCarolina physicians for orthopedics, neurosurgery and pain management,
- projected payor mix is based on a combined average of historical payor mix of five North Carolina ophthalmology ASFs for ophthalmology,
- projected payor mix is based on the experience of healthcare consultants for oral, facial and plastic surgery, and
- the applicant expresses a commitment to expand access to healthcare services for the medically underserved in Section C.8, pages 45-46.

The Agency reviewed the:

- application,
- exhibits to the application,
- written comments,
- remarks made at the public hearing, and
- responses to comments.

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

Cone Health. The applicant proposes to establish a new ASF in Kernersville, Forsyth County by developing two ORs, one GI endoscopy room, and one procedure room.

In Section L, page 87, the applicant projects the payor mix during the second full fiscal year of operation following completion of the project, as illustrated in the table below.

Payor Source	Entire Facility	Operating Rooms	GI Endo Rooms	Procedure Room
Self-Pay	0.2%	0.3%	0.1%	0.3%
Charity Care				
Medicare *	28.2%	31.1%	24.8%	31.1%
Medicaid *	0.9%	1.0%	0.8%	1.0%
Insurance *	67.5%	64.1%	71.3%	64.1%
Workers Compensation				
TRICARE				
Other (Other Gov't, Worker's Comp)	3.2%	3.5%	2.9%	3.5%
Total	100.0%	100.0%	100.0%	100.0%

Proposed Payor Mix As a Percent of Surgical Cases FFY2022

* Including any managed care plans

Totals may not sum due to rounding

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 0.3% of surgical services will be provided to self-pay patients, 31.1% to Medicare patients and 1.0% to Medicaid patients. Cone Health does not consider charity care as a payor source, but rather as a deduction from gross revenue.

On pages 87-89, the applicant provides the assumptions and methodology used to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported for the following reasons:

- projected payor mix is based on the historical payor mix of referrals generated by the four identified primary care facilities located near MedCenter Kernersville, and
- the applicant will continue Cone Health's commitment to underserved populations and be accessible to those who seek care there.

The Agency reviewed the:

- application,
- exhibits to the application,
- written comments,
- remarks made at the public hearing, and
- responses to comments.

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

NH Forsyth. The applicant proposes to add two ORs at FMC Main in Winston-Salem, Forsyth County for a total of 22 ORs, including two C-Section ORs, and 35 ORs on the hospital license upon completion of this project.

In Section L, page 76, the applicant projects the payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as shown in the table below.

CY2023			
Payor Source	Entire Facility FMC Main	Operating Rooms	
Self-Pay/ Charity	10.0%	4.1%	
Medicare *	41.0%	49.2%	
Medicaid *	16.0%	9.3%	
Insurance *	31.0%	34.9%	
Workers Comp and			
Other Government	2.0%	2.5%	
Total	100.0%	100.0%	

Proposed Payor Mix As a Percent of Surgical Cases

Source: Actual FMC Main OR payor mix

* Including any managed care plans

Totals may not sum due to rounding

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 4.1% of total surgical services will be provided to self-pay and charity care patients, 49.2% to Medicare patients and 9.3% to Medicaid patients.

On page 76, the applicant provides the assumptions and methodology used to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported for the following reasons:

- projected payor mix is based on the historical payor mix of like NH services in the service area, and
- the applicant will continue Novant Health's commitment to underserved populations and be accessible to those who seek care there.

- application,
- exhibits to the application,
- written comments,
- remarks made at the public hearing, and

• responses to comments.

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

NH Clemmons. The applicant proposes to add two ORs at the previously approved NHCOS facility in Clemmons, Forsyth County for a total of 4 ORs upon completion of this project and Project ID #G-11300-17 (relocate 2 ORs from NHFMC).

In Section L, page 72, the applicant projects the payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as shown in the table below.

CY2022			
Payor Source	Entire Facility NHCOS	Operating Rooms	Procedure Room
Self-Pay/ Charity	1.5%	1.5%	1.5%
Medicare *	44.2%	44.2%	44.2%
Medicaid *	5.3%	5.3%	5.3%
Insurance *	44.4%	44.4%	44.4%
Workers Comp and			
Other Government	4.6%	4.6%	4.6%
Total	100.0%	100.0%	100.0%

Proposed Payor Mix As a Percent of Surgical Cases

Source: Section Q, Form F4

* Including any managed care plans

Totals may not sum due to rounding

The applicant states on page 72 that the projected payor mix is based on the historical NHCMC outpatient surgery data and NHKOS payor mix. However, the projected payor mix is different from the payor mix projected in the approved and undeveloped Project ID #G-11300-17, for which this application becomes a "Change of Scope" application. The following table compares the proposed payor mix in this application with the previously approved Project ID #G-11300-17 payor mix for NHCOS surgical cases during the second project year (July 2020-June 2021).
Payor Category	Proposed Surgical Cases as Percent of Total	Previously Approved Surgical Cases as Percent of Total**	Difference Between Proposed and Previously Approved
Self Pay/Indigent /Charity	1.5%	2.1%	-0.6%
Medicare*	44.2%	31.1%	13.1%
Medicaid*	5.3%	5.8%	-0.5%
Commercial Insurance*	44.4%	53.3%	-8.9%
Other (not specified)	4.6%	7.7%	-3.1%
Total	100.00%	100.00%	0.0%

*Including any managed care plan

**Section VI.14, page 77

The two projected payor mixes differ significantly. Therefore, the difference in the proposed payor mix should have been addressed in detail in Section L.6, Change of Scope, and was not. In fact, the applicant states, *"There is no difference in the information provided above and the original application."* That is not an accurate statement as shown in the table above.

Furthermore, the applicant does not adequately demonstrate that access will be provided to the underserved groups using the relocated ORs from NHOOS in Winston-Salem (whose total utilization is projected to transfer to NHCOS). Winston-Salem has a much higher percentage of individuals living below poverty level than Clemmons. The difference in the two facilities' payor mix is not addressed. Without an explanation for the proposed differences, the projected payor mix is not reasonable and is not adequately supported.

The applicant does not demonstrate that the projected payor mix is reasonable and adequately supported because the applicant does not discuss the difference in the payor mix projected in Project ID #G-11300-17 or how the underserved individuals receiving care at NHOOS are factored into the payor mix when those ORs and the total volume of cases are relocated to NHCOS.

The Agency reviewed the:

- application,
- exhibits to the application,
- written comments,
- remarks made at the public hearing, and
- responses to comments.

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

NCBH. The applicant proposes to add four new ORs at NCBH in Winston-Salem, Forsyth County for a total of 51 ORs, including two trauma/burn ORs, upon

completion of this project and Project ID #G-8460-10 (add seven dedicated outpatient ORs pursuant to Policy AC-3).

In Section L, page 104 the applicant projects the payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as shown in the table below.

	FY2026	
Payor Source	Entire Facility NCBH	Operating Rooms
Self-Pay	11.8%	5.4%
Charity**	NA	NA
Medicare *	26.7%	33.8%
Medicaid *	19.7%	19.8%
Insurance *	38.6%	34.8%
Other***	3.2%	6.1%
Total	100.0%	100.0%

Proposed Payor Mix As a Percent of Surgical Cases EV2026

Source: Actual NCBH payor mix and actual NCBH OR payor mix, adjusted for shifts

* Including any managed care plans

**Charity Care is not considered a payor source

***Other includes liability, other government programs, Worker's Comp and TRICARE Totals may not sum due to rounding

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 5.4% of total surgical services will be provided to self-pay patients, 33.8% to Medicare patients and 19.8% to Medicaid patients.

On page 105, the applicant provides the assumptions and methodology used to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported for the following reasons:

- The applicant based the projected payor mix on actual FY2017 NCBH surgical payor mix.
- The applicant adjusted the payor mix to account for the shift of surgical cases to WFBH-OSC.
- The applicant states it will continue NCBH's commitment to underserved populations and be accessible to those who seek care there.

The Agency reviewed the:

- application,
- exhibits to the application,
- written comments,
- remarks made at the public hearing, and

• responses to comments.

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

(d) That the applicant offers a range of means by which a person will have access to its services. Examples of a range of means are outpatient services, admission by house staff, and admission by personal physicians.

C – All Applications

TCS. The applicant proposes to establish a new ASF in Winston-Salem, Forsyth County by developing two new ORs and three procedure rooms.

In Section L.5, page 90, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- application, and
- exhibits to the application.

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

Cone Health. The applicant proposes to establish a new ASF in Kernersville, Forsyth County by developing two ORs, one GI endoscopy room, and one procedure room.

In Section L, page 90, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- application, and
- exhibits to the application.

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

NH Forsyth. The applicant proposes to add two ORs at FMC Main in Winston-Salem, Forsyth County for a total of 22 ORs, including two C-Section ORs, and 35 ORs on the hospital license upon completion of this project.

In Section L, page 78, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- application, and
- exhibits to the application.

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

NH Clemmons. The applicant proposes to add two ORs at the previously approved NHCOS facility in Clemmons, Forsyth County for a total of 4 ORs upon completion of this project and Project ID #G-11300-17 (relocate 2 ORs from NHFMC).

In Section L, page74, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- application, and
- exhibits to the application.

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

NCBH. The applicant proposes to add four new ORs at NCBH in Winston-Salem, Forsyth County for a total of 51 ORs, including two trauma/burn ORs, upon completion of this project and Project ID #G-8460-10 (add seven dedicated outpatient ORs pursuant to Policy AC-3).

In Section L, page 107, the applicant adequately describes the range of means by which patients will have access to the proposed services. The Agency reviewed the:

- application, and
- exhibits to the application.

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

(14) The applicant shall demonstrate that the proposed health services accommodate the clinical needs of health professional training programs in the area, as applicable.

C – All Applications

TCS. The applicant proposes to establish a new ASF in Winston-Salem, Forsyth County by developing two new ORs and three procedure rooms.

In Section M, page 91, the applicant describes the extent to which health professional training programs in the area will have access to the facility for training purposes and provides supporting documentation in Exhibit M.2.

The Agency reviewed the:

- application, and
- exhibits to the application.

Based on that review, the Agency concludes that the applicant adequately demonstrates that the proposed services will accommodate the clinical needs of area health professional training programs, and therefore, the application is conforming to this criterion.

Cone Health. The applicant proposes to establish a new ASF in Kernersville, Forsyth County by developing two ORs, one GI endoscopy room, and one procedure room.

In Section M, pages 91-92, the applicant describes the extent to which health professional training programs in the area will have access to the facility for training purposes and provides a listing of the health professional training programs that currently utilize opportunities at Cone Health. The applicant states that these programs will also have access to clinical training opportunities at the proposed ASF.

The Agency reviewed the:

- application, and
- exhibits to the application.

Based on that review, the Agency concludes that the applicant adequately demonstrates that the proposed services will accommodate the clinical needs of area health professional training programs, and therefore, the application is conforming to this criterion.

NH Forsyth. The applicant proposes to add two ORs at FMC Main in Winston-Salem, Forsyth County for a total of 22 ORs, including two C-Section ORs, and 35 ORs on the hospital license upon completion of this project.

In Section M, page 80, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M-1.

The Agency reviewed the:

- application, and
- exhibits to the application.

Based on that review, the Agency concludes that the applicant adequately demonstrates that the proposed services will accommodate the clinical needs of area health professional training programs, and therefore, the application is conforming to this criterion.

NH Clemmons. The applicant proposes to add two ORs at the previously approved NHCOS facility in Clemmons, Forsyth County for a total of 4 ORs upon completion of this project and Project ID #G-11300-17 (relocate 2 ORs from NHFMC).

In Section M, page 75, the applicant describes the extent to which health professional training programs in the area will have access to the facility for training purposes based on extending Novant Health's relationships to NHCOS and provides supporting documentation in Exhibit M.1.

The Agency reviewed the:

- application, and
- exhibits to the application.

Based on that review, the Agency concludes that the applicant adequately demonstrates that the proposed services will accommodate the clinical needs of area health professional training programs, and therefore, the application is conforming to this criterion.

NCBH. The applicant proposes to add four new ORs at NCBH in Winston-Salem, Forsyth County for a total of 51 ORs, including two trauma/burn ORs, upon completion of this project and Project ID #G-8460-10 (add seven dedicated outpatient ORs pursuant to Policy AC-3).

In Section M, page 108, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M.1.1.

The Agency reviewed the:

- application, and
- exhibits to the application.

Based on that review, the Agency concludes that the applicant adequately demonstrates that the proposed services will accommodate the clinical needs of area health professional training programs, and therefore, the application is conforming to this criterion.

(15) Repealed effective July 1, 1987.

- (16) Repealed effective July 1, 1987.
- (17) Repealed effective July 1, 1987.
- (18) Repealed effective July 1, 1987.
- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

C TCS Cone Health NCBH

NC NH Forsyth NH Clemmons

On page 57, the 2018 SMFP states, "An operating room's service area is the operating room planning area in which the operating room is located. The operating room planning areas are the single and multicounty groupings shown in Figure 6.1." In Figure 6.1, page 62 of the 2018 SMFP, Forsyth County is shown as a single-county operating room service area. Thus, in this application, the service area is Forsyth County. Providers may serve residents of counties not included in their service area.

The following table identifies the existing and approved outpatient (OP), inpatient (IP) and shared operating rooms located in Forsyth County, and the outpatient and inpatient case volumes for each provider, from pages 65 and 73-74 of the 2018 SMFP, respectively.

	IP ORs	OP ORs	Shared ORs	Excluded C-Section/ Trauma/ Burn ORs	CON Adjust- ments	IP Surgery Cases	OP Surger y Cases	Group
NH Clemmons Outpatient Surgery Center	0	0	0	0	2			
NH Kernersville Outpatient Surgery	0	0	0	0	2			
NH Forsyth Medical Center	5	6	24	-2	-2	9,262	17,706	2
NH Medical Park Hospital	0	0	12	0	-2	871	8,665	3
Novant Health Total	5	6	36	-2	0			
Clemmons Medical Park Ambulatory								
Surgical Center^	0	0	0	0	0			
Plastic Surgery Center of North Carolina^	0	3	0	0	0		169	6
North Carolina Baptist Hospital*	4	0	36	-2	7	14,534	19,925	1
Wake Forest Baptist Health Total	4	3	36	-2	7			
Piedmont Outpatient Surgery Center**	0	2	0	0	0		2,514	
Total Forsyth County ORs	9	11	72	-4	7			

Forsyth County 2016 Operating Room Inventory and Cases As Reported in the 2018 SMFP and on the 2017 License Renewal Applications

Source: 2018 SMFP

...

^Plastic Surgery Center of NC is underutilized. All 3 ORs were relocated to Clemmons Medical Park and licensed 2/22/18. The table above reflects the inventory prior to the relocation.

*NCBH has an undeveloped CON (G-8460-10) for 7 ORs pursuant to Policy AC-3. The ORs are listed as CON adjustments and included when determining OR need.

**Ambulatory surgery demonstration project included in the inventory, but not included in the need determination calculations.

As the table above indicates, there are three hospitals and four existing or approved ASFs in Forsyth County with a total of nine inpatient, 11 ambulatory and 72 shared operating rooms. All of the Forsyth County facilities with ORs, except for the demonstration project with two ambulatory ORs, are Novant Health or Wake Forest Baptist Health owned and operated.

The 2018 SMFP shows a need for four additional ORs based on the utilization of Wake Forest Baptist Health. However, anyone can apply to meet the need.

TCS. The applicant proposes to establish a new ASF in Winston-Salem, Forsyth County by developing two new ORs and three procedure rooms.

In Section N, pages 92-94, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services. On page 92, the applicant states:

"TCS is expected to have a positive effect on competition because the project offers both patients and physicians a new facility alternative that is multispecialty and centrally located in Forsyth County. In contrast to previous applications by the two health systems that chose to relocate ORs to the high income census tracts in Kernersville and Clemmons, TCS proposes the development of a freestanding ambulatory surgical facility in proximity to the low income population census tracts in Winston-Salem.

•••

Triad Center for Surgery is committed to provide excellent quality of surgical service and will be entirely focused on the quality of care related to facility development in compliance with all requirements, medical staff credentialing, licensure, and accreditation."

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates:

- The cost-effectiveness of the proposal (see Sections F and Q of the application and any exhibits).
- Quality services will be provided (see Section O of the application and any exhibits).
- Access will be provided to underserved groups (see Section L of the application and any exhibits).

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application,
- written comments,
- remarks made at the public hearing,
- responses to comments, and
- information publicly available during the review and used by the Agency.

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

Cone Health. The applicant proposes to establish a new ASF in Kernersville, Forsyth County by developing two ORs, one GI endoscopy room, and one procedure room.

In Section N, pages 93-95, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services. On page 93, the applicant states:

"The proposed project is expected to enhance competition in the service area by promoting cost effectiveness, quality, and access to ambulatory surgery services."

The applicant further states that the proposed ambulatory setting will foster lower costs and charges for surgical cases than a hospital setting. On pages 94-95, the applicant states that Cone Health, as manager of the proposed facility, is committed to providing excellent high quality healthcare and will use Cone Health policies related to access which ensures that the facility will provide services to all persons in need of medical care.

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates:

- The cost-effectiveness of the proposal (see Sections F and Q of the application and any exhibits).
- Quality services will be provided (see Section O of the application and any exhibits).
- Access will be provided to underserved groups (see Section L of the application and any exhibits).

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application,
- written comments,
- remarks made at the public hearing,
- responses to comments, and
- information publicly available during the review and used by the Agency.

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

NH Forsyth. The applicant proposes to add two ORs at FMC Main in Winston-Salem, Forsyth County for a total of 22 ORs, including two C-Section ORs, and 35 ORs on the hospital license upon completion of this project.

In Section N, pages 82-83, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services. The applicant states:

"The proposed expansion of surgical services at NHFMC will enhance beneficial competition and choice for the populations served by NHFMC surgical series. The expanded surgical suite and recruitment of additional surgical specialists and subspecialists will allow surgeons and their patients expanded options to identify the best venue for their surgical care.

•••

The additional ORs will allow NHFMC to manage the flow of surgical patients better to avoid delays that extend inpatient stays and to avoid overtime costs for surgical staff. ... Better management of the flow of surgical patients will also make costs more predictable. This will facilitate our ability to negotiate flat rate and bundled prices with health plans.

...

Reducing extended hours will reduce the probability of medical errors caused by fatigue.

...

The same Novant Health financial assistance and non-discrimination policies and program currently in place at NHFMC will apply to services delivered in the two additional ORs."

However, the applicant does not adequately demonstrate how any enhanced competition in the service area would have a positive impact on the cost effectiveness of the proposal because it does not adequately demonstrate the need the population to be served has for the proposed services. The discussion regarding analysis of need and projected utilization found in Criterion (3).

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application,
- written comments,
- remarks made at the public hearing,
- responses to comments, and
- information publicly available during the review and used by the Agency.

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

NH Clemmons. The applicant proposes to add two ORs at the previously approved NHCOS facility in Clemmons, Forsyth County for a total of 4 ORs upon completion of this project and Project ID #G-11300-17 (relocate 2 ORs from NHFMC).

In Section N, pages 77-78, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services. The applicant states:

"The proposed project will foster competition with surgical facilities in Forsyth and surrounding counties by continuing to promote cost effectiveness, quality, and access to services in the proposed service area.

...

The expansion responds to the need for additional ORs in Forsyth County and is more cost effective and will provide more operational efficiencies than building a new facility.

•••

The project will also be held to the same quality standards as existing Novant Health surgical services.

•••

Novant Health has existing strategies with specific activities designed to assure services will be accessible by indigent patients without regard to ability to pay. As discussed in CON Project I.D. #G-11300-17, NHCOS will not discriminate in the provision of services on the basis of age, race, religion, disability, or the patient's ability to pay."

However, the applicant does not adequately demonstrate how any enhanced competition in the service area would have a positive impact on the cost effectiveness of and access to the proposed services for the following reasons:

- The applicant does not adequately demonstrate the need the population to be served has for the proposed services. The discussion regarding analysis of need and projected utilization found in Criterion (3) is incorporated herein by reference.
- The applicant does not adequately demonstrate that access by underserved groups is based on reasonable and adequately supported assumptions. The discussion regarding access found in Criteria (3), (3a) and (13c) is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application,
- written comments,

- remarks made at the public hearing,
- responses to comments, and
- information publicly available during the review and used by the Agency.

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

NCBH. The applicant proposes to add four new ORs at NCBH in Winston-Salem, Forsyth County for a total of 51 ORs, including two trauma/burn ORs, upon completion of this project and Project ID #G-8460-10 (add seven dedicated outpatient ORs pursuant to Policy AC-3).

In Section N, pages 109-115, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services. The applicant states:

"The project will promote cost effective services through the development of four new shared inpatient/outpatient ORs requiring minimal capital and operating investment.

•••

WFBMC Surgical Services continually assesses performance on quality measures that have been proven to improve patient outcomes.

...

This project will promote access to much needed surgical services at NCBH for the medically underserved as well as all other groups requiring surgical care."

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates:

- The cost-effectiveness of the proposal (see Sections F, N, and Q of the application and any exhibits).
- Quality services will be provided (see Sections N and O of the application and any exhibits).
- Access will be provided to underserved groups (see Sections L and N of the application and any exhibits).

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application,
- written comments,
- remarks made at the public hearing,
- responses to comments, and
- information publicly available during the review and used by the Agency.

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

- (19) Repealed effective July 1, 1987.
- (20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C – All Applications

TCS. The applicant proposes to establish a new ASF in Winston-Salem, Forsyth County by developing two new ORs and three procedure rooms.

In Section O.3, page 96, the applicant identifies the surgical facilities located in North Carolina and owned, operated or managed by the applicant or a related entity. The applicant identifies a total of three facilities of this type of facility located in North Carolina:

- Capital City Surgery Center in Wake County,
- Holly Springs Surgery Center in Wake County, and
- Mallard Creek Surgery center in Mecklenburg County.

In Section O.3(c), page 97, the applicant states that, during the 18 months immediately preceding the submittal of the application, no incidents related to quality of care occurred in any of these facilities. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, during the 18 months immediately preceding submission of the application through the date of this decision, incidents related to quality of care occurred in one of these facilities, which caused it to be out of compliance as of May 15, 2018, but was determined to be back in compliance on July 13, 2018. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure and Certification Section, and considering the quality of care provided at all three facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

Cone Health. The applicant proposes to establish a new ASF in Kernersville, Forsyth County by developing two ORs, one GI endoscopy room, and one procedure room.

In Section O.3, page 98, the applicant identifies the ambulatory surgical facilities located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of four facilities of this type of facility located in North Carolina:

- Moses Cone Surgery Center,
- Wesley Long Surgery Center,
- Mebane Surgery Center, and
- LaBauer Endoscopy Center.

The applicant also states that Cone Health has a minority ownership interest in Greensboro Specialty Surgical Center. In Section O.3(c), page 99, the applicant states that, during the 18 months immediately preceding the submittal of the application, no incidents related to quality of care occurred in any of these facilities. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, during the 18 months immediately preceding submission of the application through the date of this decision, incidents related to quality of care have not occurred in any of these facilities. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at all five facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

NH Forsyth. The applicant proposes to add two ORs at FMC Main in Winston-Salem, Forsyth County for a total of 22 ORs, including two C-Section ORs, and 35 ORs on the hospital license upon completion of this project.

In Section O.3, page 86, the applicant identifies the acute care hospitals located in North Carolina owned, operated or managed by the applicant or a related entity. There are a total of 13 hospitals with surgical services and four ASFs providing outpatient surgical services, in addition to the approved NHCOS facility, located in North Carolina.

In Section O, page 86, the applicant states that during the 18 months immediately preceding the submittal of the application, there were no incidents related to quality of care at any of the facilities. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, during the 18 months immediately preceding submission of the application through the date of this decision, there were no incidents related to quality of care occurred in any of the Novant Health related facilities. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at all 13 hospitals and four outpatient surgical facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

NH Clemmons. The applicant proposes to add two ORs at the previously approved NHCOS facility in Clemmons, Forsyth County for a total of 4 ORs upon completion of this project and Project ID #G-11300-17 (relocate 2 ORs from NHFMC).

In Section O.3, page 81, the applicant identifies the Novant Health facilities located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of 13 hospitals with surgical services and four ASFs providing outpatient surgical services, in addition to NHCOS, located in North Carolina.

In Section O, page 82, the applicant states that during the 18 months immediately preceding the submittal of the application, there were no incidents related to quality of care at any of the facilities. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, during the 18 months immediately preceding submission of the application through the date of this decision, there were no incidents related to quality of care occurred in any of the Novant Health related facilities. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at all 13 hospitals and four outpatient surgical facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

NCBH. The applicant proposes to add four new ORs at NCBH in Winston-Salem, Forsyth County for a total of 51 ORs, including two trauma/burn ORs, upon completion of this project and Project ID #G-8460-10 (add seven dedicated outpatient ORs pursuant to Policy AC-3).

In Section A, page 5, the applicant identifies the hospitals located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of four hospitals located in North Carolina, including NCBH, Davie Medical Center, Wilkes Medical Center, and Lexington Medical Center.

In Section O, pages 116-117, the applicant states that during the 18 months immediately preceding submission of the application, NCBH received a February 2018 CMS noncompliance finding, followed by an extensive on-site review of the NCBH remediative plan, after which CMS rescinded its notice of termination. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, during the 18 months immediately preceding submission of the application through the date of this decision, incidents related to quality of care occurred in the laboratory at NCBH, which caused a determination that NCBH was out of compliance as of February 8, 2018 and back in compliance, as of June 11, 2018. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at all four facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

(21) Repealed effective July 1, 1987.

(b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C TCS Cone Health NCBH

NC NH Forsyth NH Clemmons

The Criteria and Standards for Surgical Services and Operating Rooms, promulgated in 10A NCAC 14C.2100, are applicable to all five applications in this review.

SECTION .2100 – CRITERIA AND STANDARDS FOR SURGICAL SERVICES AND OPERATING ROOMS

.2103 PERFORMANCE STANDARDS

- .2103(a) A proposal to establish a new ambulatory surgical facility, to establish a new campus of an existing facility, to establish a new hospital, to increase the number of operating rooms in an existing facility (excluding dedicated C-section operating rooms), to convert a specialty ambulatory surgical program to a multispecialty ambulatory surgical program, or to add a specialty to a specialty ambulatory surgical program shall demonstrate the need for the number of proposed operating rooms in the facility that is proposed to be developed or expanded in the third operating year of the project based on the Operating Room Need Methodology set forth in the 2018 State Medical Facilities Plan. The applicant is not required to use the population growth factor.
 - -C- **TCS.** This proposal would develop a new two-OR ASF. The applicant projects sufficient surgical cases and hours to demonstrate the need for two ORs in the third operating year of the project based on the Operating Room Need Methodology in the 2018 SMFP. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

- -C- Cone Health. This proposal would develop a new two-OR ASF. The applicant projects sufficient surgical cases and hours to demonstrate the need for two ORs in the third operating year of the project based on the Operating Room Need Methodology in the 2018 SMFP. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.
- -NC- **NH Forsyth.** This proposal would add two new ORs at NHF Main for a total of 35 ORs on the hospital license. The applicant projects sufficient surgical cases and hours for two additional ORs in the third operating year of the project based on the Operating Room Need Methodology in the 2018 SMFP. However, the applicant does not adequately demonstrate that the projected utilization is based upon reasonable and adequately supported assumptions. The discussion regarding analysis of need, including projected utilization, found in Criterion (3) is incorporated herein by reference. Therefore, the application is not conforming to this Rule.
- -NC- **NH Clemmons.** This proposal would add two new ORs to the previously approved and undeveloped ASF, NHCOS, for a total of four ORs upon completion of this project and Project ID #G-11300-17 (relocate two ORs from Novant Health Winston-Salem. The applicant projects sufficient surgical cases and hours for two additional ORs in the third operating year of the project based on the Operating Room Need Methodology in the 2018 SMFP. However, the applicant does not adequately demonstrate that the projected utilization is based upon reasonable and adequately supported assumptions. The discussion regarding analysis of need, including projected utilization, found in Criterion (3) is incorporated herein by reference. Therefore, the application is not conforming to this Rule.
- -C- NCBH. This proposal would add four new ORs at NCBH for a total of 51 ORs upon completion of this project and Project ID #G-8460-20 (add seven dedicated outpatient ORs pursuant to Policy AC-3). The applicant projects sufficient surgical cases and hours to demonstrate the need for four ORs in the third operating year of the project based on the Operating Room Need Methodology in the 2018 SMFP. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.
- .2103(b) A proposal to increase the number of operating rooms (excluding dedicated C-section operating rooms) in a service area shall demonstrate the need for the number of proposed operating rooms in addition to the existing and approved operating rooms in the applicant's health system in the third operating year of the proposed project based on the Operating Room Need Methodology set forth in the 2018 State Medical Facilities Plan. The applicant is not required to use the population growth factor.

- -C- **TCS.** This proposal would develop a new two-OR ASF (health system). The applicant projects sufficient surgical cases and hours to demonstrate the need for two ORs in the applicant's health system in the third operating year of the project based on the Operating Room Need Methodology in the 2018 SMFP. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.
- -C- Cone Health. This proposal would develop a new two-OR ASF (health system). The applicant projects sufficient surgical cases and hours to demonstrate the need for two ORs in the applicant's health system in the third operating year of the project based on the Operating Room Need Methodology in the 2018 SMFP. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.
- -NC- **NH Forsyth.** This proposal would add two new ORs at NHF Main for a total of 35 ORs on the hospital license. The applicant projects sufficient surgical cases and hours for two additional ORs in the applicant's health system in the third operating year of the project based on the Operating Room Need Methodology in the 2018 SMFP. However, the applicant does not adequately demonstrate that the projected utilization is based upon reasonable and adequately supported assumptions. The discussion regarding analysis of need, including projected utilization, found in Criterion (3) is incorporated herein by reference. Therefore, the application is not conforming to this Rule.
- -NC- **NH Clemmons.** This proposal would add two new ORs to the previously approved and undeveloped ASF, NHCOS, for a total of four ORs upon completion of this project and Project ID #G-11300-17 (relocate two ORs from Novant Health Winston-Salem. The applicant projects sufficient surgical cases and hours for two additional ORs in the applicant's health system in the third operating year of the project based on the Operating Room Need Methodology in the 2018 SMFP. However, the applicant does not adequately demonstrate that the projected utilization is based upon reasonable and adequately supported assumptions. The discussion regarding analysis of need, including projected utilization, found in Criterion (3) is incorporated herein by reference. Therefore, the application is not conforming to this Rule.
- -C- NCBH. This proposal would add four new ORs at NCBH for a total of 51 ORs upon completion of this project and Project ID #G-8460-20 (add seven dedicated outpatient ORs pursuant to Policy AC-3). The applicant projects sufficient surgical cases and hours to demonstrate the need for four additional ORs in the applicant's health system in the third operating year

of the project based on the Operating Room Need Methodology in the 2018 SMFP. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

- .2103(c) An applicant that has one or more existing or approved dedicated C-section operating rooms and is proposing to develop an additional dedicated C-section operating room in the same facility shall demonstrate that an average of at least 365 C-sections per room were performed in the facility's existing dedicated C-section operating rooms in the previous 12 months and are projected to be performed in the facility's existing, approved, and proposed dedicated C-section rooms during the third year of operation following completion of the project.
 - -NA- All Applicants. None of the applicants propose to develop an additional dedicated C-section room.
- .2103(d) An applicant proposing to convert a specialty ambulatory surgical program to a multispecialty ambulatory surgical program or to add a specialty area to a specialty ambulatory surgical program shall:
 - (1) provide documentation to show that each existing ambulatory surgery program in the service area that performs ambulatory surgery in the same specialty area as proposed in the application is currently utilized an average of at least 1,312.5 hours per operating room per year; and
 - (2) demonstrate the need in the third operating year of the project based on the Operating Room Need Methodology set forth in the 2018 State Medical Facilities Plan. The applicant is not required to use the population growth factor.
 - -NA- All Applicants. None of the applicants propose to convert a specialty ambulatory surgical program to a multispecialty ambulatory surgical program or to add a specialty area to a specialty ambulatory surgical program.
- .2103(e) The applicant shall document the assumptions and provide data supporting the methodology used for each projection in this Rule.
 - -C- **TCS.** In Section Q, Methodology Assumptions and Data Form C, pages 101-105, the applicant provides the assumptions and methodology used in the development of the projections required by this Rule. The discussion regarding analysis of need, including projected utilization, found in Criterion (3) is incorporated herein by reference.
 - -C- Cone Health. In Section Q, Form C Utilization Assumptions and Methodology, pages 1-12, the applicant provides the assumptions and

methodology used in the development of the projections required by this Rule. The discussion regarding analysis of need, including projected utilization, found in Criterion (3) is incorporated herein by reference.

- -NC- **NH Forsyth.** In Section Q, Form C and Tables 1-12, the applicant provides the assumptions and methodology used in the development of the projections required by this Rule. However, the applicant does not adequately document its assumptions or provide sufficient data to support its methodology. The discussion regarding analysis of need, including projected utilization, found in Criterion (3) is incorporated herein by reference.
- -NC- **NH Clemmons.** In Section Q and Tables 1-12, the applicant provides the assumptions and methodology used in the development of the projections required by this Rule. However, the applicant does not adequately document its assumptions or provide sufficient data to support its methodology. The discussion regarding analysis of need, including projected utilization, found in Criterion (3) is incorporated herein by reference.
- -C- **NCBH.** In Section Q, Form C, pages 121-140, the applicant provides the assumptions and methodology used in the development of the projections required by this Rule. The discussion regarding analysis of need, including projected utilization, found in Criterion (3) is incorporated herein by reference.

The Criteria and Standards for Gastrointestinal Endoscopy Procedure Rooms in Licensed Health Service Facilities promulgated in 10A NCAC 14C .3900 is applicable to the application submitted by **Cone Health**.

SECTION .3900 – CRITERIA AND STANDARDS FOR GASTROINTESTINAL ENDOSCOPY PROCEDURE ROOMS IN LICENSED HEALTH SERVICE FACILITIES

.3903 PERFORMANCE STANDARDS

- (a) In providing projections for operating rooms, as required in this Rule, the operating rooms shall be considered to be available for use 250 days per year, which is five days per week, 52 weeks per year, excluding 10 days for holidays.
- -C- The applicant assumes that the GI endoscopy room will be available at least five days per week and 52 weeks per year excluding ten days for holidays.
- (b) An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an

existing licensed health service facility shall reasonably project to perform an average of at least 1,500 GI endoscopy procedures only per GI endoscopy room in each licensed facility the applicant or a related entity owns in the proposed service area, during the second year of operation following completion of the project.

- -C- This proposal would develop one GI endoscopy procedure room in a new licensed ASF. The applicant projects sufficient GI endoscopy procedures to demonstrate the need for one GI endoscopy rooms in the second operating year of operation following completion of the project. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.
- (c) An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall demonstrate that at least the following types of GI endoscopy procedures will be provided in the proposed facility or GI endoscopy room: upper endoscopy procedures, esophagoscopy procedures, and colonoscopy procedures.
- -C- In Section C, page 49, the applicant states:

"Triad Surgery Center will perform upper endoscopy procedures, esophagoscopy procedures, and colonoscopy procedures in the proposed facility consistent with the historical provision of those procedures by the gastroenterologists who support the proposed facility."

- (d)If an applicant, which proposes to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility, or a related entity to the applicant owns operating rooms located in the proposed service area, the applicant shall meet one of the following criteria: (1) if the applicant or a related entity performs GI endoscopy procedures in any of its surgical operating rooms in the proposed service area, reasonably project that during the second operating year of the project the average number of surgical and GI endoscopy cases per operating room, for each category of operating room in which these cases will be performed, shall be at least: 4.8 cases per day for each facility for the outpatient or ambulatory surgical operating rooms and 3.2 cases per day for each facility for the shared operating rooms; or (2) demonstrate that GI endoscopy procedures were not performed in the applicant's or related entity's inpatient operating rooms, outpatient operating rooms, or shared operating rooms in the last 12 months and will not be performed in those rooms in the future.
- -NA- The applicant does not own or operate any ORs in the service area (Forsyth County).

- (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 this Rule.
- -C- The applicant provides the assumptions and methodology used to project utilization in Section Q, pages 9-12. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

COMPARATIVE ANALYSIS

Pursuant to N.C. Gen. Stat. § 131E-183(a)(1) and the 2018 State Medical Facilities Plan, no more than four additional operating rooms may be approved for Forsyth County in this review. Because the five applications in this review collectively propose to develop 12 additional operating rooms to be located in Forsyth County, not all of the applications can be approved. Therefore, after considering all of the information in each application and reviewing each application individually against all applicable review criteria, the Project Analyst conducted a comparative analysis of the proposals to decide which proposal should be approved.

The following provides a brief description of each of the proposed projects being addressed in the comparative analysis:

TCS. Triad Center for Surgery, LLC, Project ID #G-11513-18, proposes to develop a new ASF with two ORs and three procedure rooms in Winston-Salem, Forsyth County. The applicant proposes to perform 3,522 total surgical cases in its two ORs in PY3.

Cone Health. The Moses H. Cone Memorial Hospital and MC Kernersville, LLC, **Project ID #G-11516-18**, propose to develop a new ASF with two ORs, one GI Endo room, and one procedure room in Kernersville, Forsyth County. The applicant proposes to perform 2,247 total surgical cases in its two ORs in PY3.

NH Forsyth. Novant Health, Inc. and Forsyth Memorial Hospital, Inc., Project ID #G-11517-18, propose to add two ORs on the Novant Health Forsyth Medical Center Main Campus in Winston-Salem, Forsyth County. The applicant proposes to perform 17,299 total surgical cases in its 20 ORs (excluding two C-Section ORs) in PY3.

NH Clemmons. Novant Health, Inc. and Novant Health Clemmons Outpatient Surgery, LLC, Project ID #G-11518-18, propose to add two ORs at the previously approved outpatient surgery center, NHCOS, in Clemmons in Forsyth County. The applicant proposes to perform 4,754 total surgical cases in its 4 ORs in PY3.

NCBH. North Carolina Baptist Hospital, Project ID #G-11519-18, proposes to add four ORs at the NCBH Main Campus in Winston–Salem, Forsyth County. The applicant proposes to perform 34,834 total surgical cases in its 49 ORs (excluding two trauma/burn ORs) in PY3.

As the above description of each proposed project indicates, two facilities are proposed new ASFs with two ORs each, and one is an approved, undeveloped ASF seeking to add two ORs for a total of four. The ASFs each project to perform between approximately 2,000 and 5,000 surgeries in PY3. The other two projects propose to add ORs to full-service acute care hospitals: one a tertiary medical center, which would have 20 ORs (excluding two C-section ORs) and projects to perform 17,299 surgeries in PY3; the other is a quaternary, teaching medical center, which would have 49 ORs (excluding two trauma/burn ORs), and projects performing 34,834 surgeries in PY3, respectively;

upon project completion. The hospitals project many times the number of surgeries projected by the proposed ASFs. Because of the significant differences in types of facilities, numbers of total ORs, numbers of projected surgeries, types of proposed surgical services offered, total revenues and expenses, and the differences in presentation of pro forma financial statements, the comparatives may be of less value and result in less than definitive outcomes than if all applications were for like facilities of like size proposing like services and reporting in like formats.

Conformity with Review Criteria

Table 6C, page 80, of the 2018 SMFP identifies a need for four new ORs in Forsyth County. As shown in Table 6B, page 74, the only two facilities that show a projected OR deficit (need) in 2020 are Novant Health Medical Park Hospital with a deficit of 0.66 ORs and NCBH with a deficit of 6.65 ORs. The Novant Health "Health System" shows a surplus of 6.81 ORs and the Wake Forest Baptist Health "Health System" shows a total deficit of 3.65 ORs, which results in the Forsyth County need determination for four ORs. However, the application process is not limited to the provider (or providers) that show a deficit and create the need for additional ORs. Any provider can apply to develop the four ORs in Forsyth County. Furthermore, it is not necessary that an existing provider have a deficit of ORs to apply for more ORs. However, it is necessary that an applicant adequately demonstrate the need to develop its project, as proposed.

The TCS, Cone Health, and NCBH applications, each adequately demonstrate the need for their respective proposals and are conforming with all applicable statutory and regulatory review criteria. The NH Forsyth and NH Clemmons applications do not adequately demonstrate the need for their respective proposals and were nonconforming to numerous applicable statutory and regulatory review criteria. Therefore, the applications submitted by Triad Center for Surgery, LLC; The Moses H. Cone Memorial Hospital and MC Kernersville, LLC; and North Carolina Baptist Hospital are equally effective alternatives with respect to this comparative and the applications submitted by Novant Health, Inc. and Forsyth Memorial Hospital, Inc. and Novant Health, Inc. and Novant Health Clemmons Outpatient Surgery, LLC are not effective alternatives with respect to this comparative.

Geographic Accessibility

The existing and approved Forsyth County ORs are located in Winston-Salem, Kernersville and Clemmons, the three population centers in the county. Winston-Salem, located near the center of Forsyth County, is identified as a city and has an estimated 2017 population of 244,605; whereas, Kernersville, located on the eastern Forsyth/Guilford county line, is identified as a town and has an estimated 2017 population of 24,386; and Clemmons, located in southwestern Forsyth County, is considered a village with an estimated 2017 population of 20,420.²

TCS, NH Forsyth, and **NCBH** propose to develop new ORs in Winston-Salem. **Cone Health** proposes to develop new ORs in Kernersville. **NH Clemmons** proposes to develop new ORs in Clemmons.

² <u>https://en.wikipedia.org/wiki/Forsyth County, North Carolina</u> and <u>www.census.gov/quickfacts</u>

The following table identifies the existing and approved Forsyth County ORs by location, facility name, and type of OR. As the table below shows, all Forsyth County ORs are located in one of the three population centers within the county; Winston-Salem, Kernersville, and Clemmons.

					C-Sec /	CON	
		IP	OP	Shared	Trauma	Adjust	Total
		ORs	ORs	ORs	/ Burn	-ments	ORs
Winston-Salem	NH FMC Main*	5	0	15	-2		18
	NH Hawthorne Outpatient Surgery		4				4
	NH Medical Park Hospital			10			10
	NCBH**	4		36	-2	7	45
	Piedmont Outpatient Surgery Center***		2				2
	Total Winston-Salem ORs	9	6	61	-4	7	79
Kernersville	NH Kernersville Medical Center			4			4
	NH Kernersville Outpatient Surgery		2				2
	Total Kernersville ORs	0	2	4	0	0	6
Clemmons	NH Clemmons Medical Center			5			5
	NH Clemmons Outpatient Surgery						
	Center		2				2
	Clemmons Medical Park Ambulatory						
	Surgery Center (WFBH-OSC relocated						
	ORs from PSCNS)		3				3
	Total Clemmons ORs	0	5	5	0	0	10
Total Forsyth C	ounty ORs	9	13	70	-4	7	95

*Total ORs exclude dedication C-Section ORs and include development of Project ID #G-11150-16, (relocate 2 ORs from Winston-Salem campus to NHKOS), scheduled to open June 2018 and Project ID #G-11300-17, (relocate 2 ORs from Winston-Salem campus to NHCOS), scheduled to open July 2019, at which time NHOOS will close.

** Total ORs exclude dedicated trauma/burn ORs and include the undeveloped 7 ORs approved in Project ID #G-8460-10

***ORs are included in the calculation for total ORs in Forsyth County, though these two demonstration project ORs are excluded from the planning inventory in the 2018 SMFP

The three population centers in Forsyth County, Winston-Salem, Kernersville, and Clemmons, include 77% of the county's population. The following table compares the number of ORs in the three areas with the 2017 estimate of the total population in that location and results in an OR deficit or surplus by area.

	2017 Population Estimate*	Percent of Total County Population Centers	OR Need Based on % Population	# of Existing/ Approved ORs	OR Deficit /Surplus(-)
Winston-Salem	244,605	85%	84	79	5
Kernersville	24,386	8%	8	6	2
Clemmons	20,420	7%	7	10	-3
Total Population Centers**	289,411	100%	99	95	4

OR Deficit /Surplus by Location

* Source: Population: ww.census.gov/quickfacts

**Total Population Center population represents 77% of the total Forsyth County population

As the table above reflects, Winston-Salem has a deficit of five ORs, Kernersville has a deficit of two ORs and Clemmons has a surplus of three ORs, resulting in the need for four new ORs in Forsyth County.

Another geographic comparison to consider is the socio-economic level in each of the three population centers. The following table provides the percent of individuals living below the poverty level in each area.

Percent of Individuals Below Poverty Level*					
	Percent of Population				
Winston-Salem	24.3%				
Kernersville	15.5%				
Clemmons	9.7%				

*https://factfinder.census.gov/faces/nav/jsf/pag es/community_facts.xhtml

As the table above shows, Winston-Salem has the highest percent of the population living below the poverty level, followed by Kernersville and then Clemmons.

Therefore, based on the demographics of the three population centers in Forsyth County and the existing OR inventory, Winston-Salem is the most effective location for new ORs, followed by Kernersville, with Clemmons being the least effective location.

TCS, NH Forsyth, and NCBH propose to develop new ORs in Winston-Salem. Cone Health proposes to develop new ORs in Kernersville. NH Clemmons proposes to develop new ORs in Clemmons. Therefore based on the proposed location for each applicant's project, the applications submitted by Triad Center for Surgery, LLC; Novant Health, Inc. and Forsyth Memorial Hospital, Inc.; and North Carolina Baptist Hospital are the more effective proposals; followed by The Moses H. Cone Memorial Hospital and MC Kernersville; LLC; with the application submitted by Novant Health, Inc. and NH Clemmons Outpatient Surgery Center, LLC being the least effective alternative based on its proposed location.

Physician Support

Each application documents adequate physician support of their proposed projects. Therefore, with regard to the demonstration of physician support, the proposals are equally effective.

Patient Access to New Provider

Generally, the application proposing to increase patient access to a new provider in the service area is the more effective alternative with regard to this comparative factor.

TCS. Triad Center for Surgery, LLC, proposes to develop Triad Center for Surgery in Forsyth County. In Section A, page 10 of its application, the applicant states that Triad Center for Surgery, LLC does not own or operate any existing surgical facilities anywhere in North Carolina. However, the applicant states that both OrthoCarolina and Compass Surgical Partners are involved in the proposed project and ownership structure. In Section O, page 96, the applicant states that neither Triad Center for Surgery, OrthoCarolina, nor Compass Surgical Partners own or operate existing surgical facilities in the Forsyth County service area; therefore, this provider would be a new provider of surgical services in Forsyth County.

Cone Health. The Moses H. Cone Memorial Hospital and MC Kernersville, LLC, propose to develop Triad Surgery Center, referred to throughout the Findings as Cone Health, in Forsyth County. Per Section A, page 13 of its application, the applicant states that MC Kernersville, LLC does not currently own or operate any existing surgical facilities in North Carolina. The Moses H. Cone Memorial Hospital is the sole member of MC Kernersville, LLC, and owns and operates both hospitals and ASFs in North Carolina. However, The Moses H. Cone Memorial Hospital does not currently offer surgical services in the Forsyth County service area; therefore, this provider would be a new provider of surgical services in Forsyth County.

NH Forsyth. Novant Health, Inc. serves Forsyth County residents by providing surgical services at the following existing and approved facilities in Forsyth County:

- Novant Health Forsyth Medical Center
- Novant Health Medical Park Hospital
- Novant Health Clemmons Outpatient Surgery Center
- Novant Health Kernersville Outpatient Surgery

NH Clemmons. Novant Health, Inc. serves Forsyth County residents by providing surgical services at the following existing and approved facilities in Forsyth County:

- Novant Health Forsyth Medical Center
- Novant Health Medical Park Hospital
- Novant Health Clemmons Outpatient Surgery Center
- Novant Health Kernersville Outpatient Surgery

NCBH. NCBH serves Forsyth County residents by providing surgical services at the following existing and approved facilities in Forsyth County:

- WFBH-OSC, approved as Clemmons Medical Park Ambulatory Surgical Center, licensed in February 2018 upon the relocation of three ORs from PSCNC, and
- North Carolina Baptist Hospital

Therefore, with regard to introducing a new provider of surgical services in Forsyth County, the applications submitted by **Triad Center for Surgery**, **LLC** and **The Moses H. Cone Memorial Hospital and MC Kernersville**, **LLC** are more effective alternatives. The applications submitted by **Novant Health**, **Inc. and Forsyth Memorial Hospital**, **Inc.; Novant Health**, **Inc. and Novant Health** Clemmons Outpatient Surgery, LLC; and North Carolina Baptist Hospital are less effective alternatives.

Patient Access to Lower Cost Surgical Services

There are currently 95 ORs (excluding two dedicated C-Section and Two Trauma Burn ORs) in the Forsyth County operating room service area (88 existing and 7 approved). Operating rooms can be licensed either under a hospital license or an ASF that does not operate under a hospital license. Based on the applications, written comments and response to comments and statements made at the public hearing, many, but not all outpatient surgical services can be either be performed in a hospital licensed operating room (either a shared OR or a dedicated outpatient OR) or in a non-hospital licensed operating room or ASF; however, the cost for that same service will often be much higher in a hospital licensed operating room of ASF. Nonetheless, along with inpatient surgical services, there are some outpatient surgical services that must be performed in a hospital setting.

% Shared Total IP % IP of OP % OP of Shared of Total ORs** ORs* ORs **Total ORs** ORs Total ORs ORs Total Winston-Salem ORs 79 5 6% 14 18% 60 76% Total Kernersville ORs 0 0% 2 33% 67% 6 4 **Total Clemmons ORs** 5 10 0 0% 5 50% 50% Total Forsyth County ORs 95 5 5% 21 22% 69 73%

The following table identifies the existing and approved Forsyth County ORs by location and type of OR.

*Total ORs includes existing and approved ORs and excludes dedicated C-Section and Burn ORs **The 14 Winston-Salem outpatient ORs listed above includes seven AC-3 dedicated ambulatory ORs and one dedicated ambulatory OR approved to be relocated from NCBH's shared OR count (Project ID# G-8460-10), four hospital-based ambulatory surgery center ORs, and the two single-specialty demonstration project ORs at POSC excluded from the 2018 need determination.

The table below shows what percent of the total Forsyth County surgical cases are performed as ambulatory surgeries as opposed to inpatient surgeries.

		Junty Surgica		I otal Forsyth County Surgical Cases								
Forsyth Surgical			Ambulatory		Percent							
Facility	Type of OR	Inpatient	(outpatient)	Total	Ambulatory							
	Hospital											
NHF Main	Inpatient/Shared	11,007	5,320	16,327	32.6%							
NHKMC	Hospital Shared	1,114	2,778	3,892	71.4%							
NHCMC	Hospital Shared	198	1,352	1,550	87.2%							
NHMPH	Hospital Shared	943	8,782	9,725	90.3%							
	Hospital											
NCBH	Inpatient/Shared	14,392	20,000	34,392	58.2%							
POSC	ASF		2,327	2,327	100.0%							
PSCNC (WFBH-OSC)	ASF		175	175	100.0%							
	Hospital											
NHOOS	Ambulatory		2,013	2,013	100.0%							
	Hospital											
NHHOS	Ambulatory		7,329	7,329	100.0%							
Total, including C-												
Sections		27,654	50,076	77,730	64.4%							

Ambulatory Surgical Cases as Percent of Total Forsyth County Surgical Cases

Source: Forsyth County surgical providers' 2018 LRAs

As the table above shows, 64.4% of the total Forsyth County surgical cases in 2017 were performed as ambulatory (outpatient) surgeries. Forsyth County currently has only two existing ASFs. PSCNC (WFBH-OSC) has three ORs, which were relocated from PSCNC in Winston-Salem to WFBH-OSC in Clemmons in early 2018. POSC has two ORs in Winston-Salem, developed through a CON demonstration project for a single-specialty ASF for ear, nose and throat procedures pursuant to the 2010 SMFP. Because POSC was a demonstration project, those two ORs are included in the inventory for Forsyth County, but were not included in the 2018 SMFP's need determination calculation.

A comparison of 2017 Forsyth County ASF surgical cases to total 2017 NC ASF surgical cases by specialty reported in 2018 LRAs, reveals a significant difference in types of surgeries performed in the two Forsyth County ASFs, including the demonstration project at POSC, and ASFs across North Carolina.

Surgical Specialty	Percent of Total 2017 ASF Surgeries	Percent of 2017 Forsyth County ASF Surgeries
Ophthalmology	38.0%	0.0%
Orthopedics	29.1%	0.0%
Otolaryngology	16.4%	93.0%
General Surgery	5.3%	0.0%
Urology	2.4%	0.0%
Podiatry	2.2%	0.0%
Obstetrics and Gynecology	2.0%	0.0%
Neurosurgery	1.7%	0.0%
Plastic Surgery	1.5%	7.0%
Oral Surgery	0.8%	0.0%
Vascular	0.2%	0.0%
Other	0.1%	0.0%
Total Cases	100.0%	100.0%

Surgical Cases by Specialty in NC ASFs vs Forsyth County ASFs

Totals may not sum due to rounding

Source: 2018 NC LRAs for total 2017 ASF surgeries (Truven) and 2018 LRAs for 2017 Forsyth County ASF surgeries

As shown in the comparison above, Forsyth County ASFs perform a higher percentage of otolaryngology and plastic surgery and far lower percentage of ophthalmology and orthopedics (two of the state's largest percentages of specialties performed in an ASF) than ASFs in North Carolina on average.

These statistics, as shown above, support the development of a multi-specialty ASF in Forsyth County to provide patients in Forsyth County access to non-hospital based surgical services, at typically lower costs.

The following table shows what type of OR is located where in Forsyth County.

	Total ORs*	IP ORs	Shared ORs	Hos-OP ORs	ASF ORs*
Total Winston-Salem ORs	79	5	60	14	0
Total Kernersville ORs	6	0	4		2
Total Clemmons ORs	10	0	5		5
Total Forsyth County ORs	95	5	69	14	7

Type of Forsyth County OR and Location

*Count excludes the two single-specialty demonstration project ORs at POSC, as they were excluded from the 2018 SMFP need determination

The total number of ASF ORs in Forsyth County, existing and approved, is seven: two ASF ORs approved for development in Kernersville (Project ID #G-11150-16), three existing ASF ORs at WFBH-OSC in Clemmons, and two ASF ORs approved for development in Clemmons (Project ID #G-11300-17).

Based upon the fact that 64.4% of Forsyth County's 2017 surgical cases were ambulatory cases and the lack of access to ASF ORs in Forsyth County and specifically in Winston-Salem, projects proposing the development of ASF ORs would be more effective. Therefore, the applications submitted by **Triad Center for Surgery, LLC**; **The Moses H. Cone Memorial Hospital and MC Kernersville, LLC**; and **Novant Health, Inc. and Novant Health Clemmons Outpatient Surgery, LLC** are the more effective proposal with respect to this comparative factor. **Novant Health, Inc. and Forsyth Memorial Hospital, Inc.** and **North Carolina Baptist Hospital** applications are less effective with respect to this comparative factor.

Patient Access to Multiple Services

The following table illustrates the surgical specialties (as defined on the North Carolina Hospital License Renewal Application) that the individual CON applicants in this review propose to provide:

Specialty and Related	TCS	Cone Health	NH Forsyth	NH Clemmons	NCBH
Sub-specialties	(OP only)	(OP only)	(IP and OP)	(OP only)	(IP and OP)
Cardiothoracic,			Х		Х
excluding Open Heart			Λ		Λ
Open Heart			Х		
General Surgery		Х	Х	Х	Х
Neurosurgery, including Spine Surgery	Х	Х	Х	Х	Х
Obstetrics and Gynecology, excluding C-Section		Х	Х	Х	Х
Ophthalmology	Х				Х
Oral Surgery /Dental	Х		Х		
Orthopedic, including Spine Surgery	Х	Х	Х	Х	Х
Otolaryngology (ENT)		Х	Х		Х
Plastic Surgery	Х	Х	Х		Х
Podiatry		Х	Х	Х	
Urology		Х	Х	Х	Х
Vascular			Х		Х
Other :					
Pain Management	Х				
Dermatology		Х			
Colorectal Surgery			Х		

Proposed Services to be Offered

As the above table illustrates, the two existing hospitals in Winston-Salem, **NH Forsyth** and **NCBH**, being acute care tertiary hospitals and offering a full continuum of emergency, medical

and surgical services, propose access to a broader range of specialties. **TCS**, **Cone Health**, and **NHCOS** each propose to provide surgical services at a separately licensed ASF: **TCS** in Winston-Salem, **Cone Health** in Kernersville and **NHCOS** in Clemmons.

The following table provides the number of cases by surgical specialty, as reported by the existing Forsyth County surgical providers on their 2018 LRAs:

	Inpatient	Outpatient (Outpt) in Shared OR	Outpt in H/B Am. OR*	Outpt in ASF	Total	Percent of Total
Orthopedic	6,880	8,463	2,013		17,356	22.90%
General Surgery	4,918	7,776	43		12,737	16.80%
Ophthalmology	81	2,846	5,985		8,912	11.80%
Otolaryngology (ENT)	854	3,676	194	2,327	7,051	9.30%
Urology	1,228	5,777			7,005	9.20%
Neurosurgery	3,079	1,836			4,915	6.50%
Obstetrics and GYN, excluding C-Section	947	2,973			3,920	5.20%
Plastic Surgery	711	2,342		175	3,228	4.30%
Other	2,130	955	52		3,137	4.10%
Vascular	1,924	908	95		2,927	3.90%
Open Heart	1,340				1,340	1.80%
Cardiothoracic, excluding Open Heart	1,098	90			1,188	1.60%
Oral Surgery /Dental	46	334	729		1,109	1.50%
Podiatry	505	256	231		992	1.30%
Totals, excluding C-Sections	25,741	38,232	9,342	2,502	75,817	100.0%

FY2017 Surgical Cases by Specialty Performed in Forsyth County Excluding C-Sections

Totals may not sum due to rounding

Source: Forsyth County surgical providers' 2018 LRAs

*Outpatient cases in a hospital-based ambulatory operating room

As the table above shows, of the eight most performed specialties, orthopedic surgery makes up 22.9% of the FY2017 surgery specialties performed in Forsyth County, followed by 16.8% general surgery, 11.8% ophthalmology, 9.3% otolaryngology, 9.2% urology, 6.5% neurosurgery, 5.2% obstetrics and gynecology, and 4.3% plastic surgery.

Orthopedic surgery is also projected to be the most often performed specialty by each of the applicants in this review. **TCS** proposes its surgeries to be 57.4% orthopedic, 31.0% ophthalmology, 10.7% neurosurgery, along with a small percentage of oral and plastic surgery. **Cone Health** proposes 33.1% orthopedic, 19.3% otolaryngology (ENT), 11.6% general surgery, and 9.0% urology. **NH Forsyth** proposes 29.5% orthopedic, 23% ophthalmology, 13.6% general surgery, and 8.1% obstetrics and gynecology. **NHCOS** proposes 52.2% orthopedic, 14.7% obstetrics and gynecology, 11.0% podiatry, and 7.4% each neurosurgery, general surgery, and urology. **NCBH**

proposes 21.5% orthopedic, 14.2% general surgery, 12.2% urology and 11.2% otolary ngology (ENT).³

As the analysis above confirms, each applicant is proposing to offer at least four of the top eight surgical specialties performed in Forsyth County; therefore, each applicant proposes to offer adequate access to multiple specialties; however, **NH Forsyth** and **NCBH** offer access to a broader range of specialties and are therefore more effective alternatives.

Access by Underserved Groups

Projected Charity Care

The following table shows each applicant's projected charity care to be provided in the project's third full operating year. Generally, the application proposing to provide the most charity care is the more effective alternative with regard to this comparative factor.

		113		
Applicant	Projected Total Charity Care	Charity Care per OR	Charity Care per Surgical Case	Percent of Total Net Surgical Revenue
TCS	\$135,851	\$67,926	\$39	1.80%
Cone Health	\$53,076	\$26,538	\$24	0.61%
NH Forsyth	\$35,224,110	\$1,857,528	\$2,148	12.14%
NH Clemmons	\$803,255	\$211,779	\$178	4.17%
NCBH	\$117,536,108	\$2,543,799	\$3,578	13.89%

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Source: Forms F.3, F.4 and F.5 for each applicant.

As shown in the table above, **NCBH** projects the most charity care in dollars and the highest charity care per OR, per surgical case and as a percent of net revenue to be provided to patients, followed by **NH Forsyth**. **NH Clemmons** and **TCS** project lower charity care amounts in each category and **Cone Health** projects providing the least charity care. Therefore, the application submitted by **North Carolina Baptist Hospital**, generally speaking, is the most effective alternative with regard to access to charity care. However, due to differences in the types of facilities and the number and types of surgical services proposed by each of the facilities, it is not possible to make conclusive comparisons with regard to Charity Care. Thus, this comparative factors may be of little value.

³ TCS provides the proposed PY3 cases by specialty on page 37 of its application. Cone Health provides the percentages of proposed cases by specialty in Table 7, Section Q Form C Assumptions and Methodology, page 7, which were applied to the projected PY3 cases. NH Forsyth, NHCOS and NCBH did not provide the projected utilization by specialty in their applications; therefore, the Project Analyst projected specialty cases based on available information, either in the application or in hospital LRAs. For NH Forsyth and NCBH, the percentages of specialty surgeries as reported in their 2018 LRAs was applied to their projected PY3 cases. For NHCOS, Section Q, Figure 4 provided the number of orthopedic cases (2,481) to be shifted from NHOOS to NHCOS in PY3. The remaining 2,273 PY3 cases were distributed per the number of surgeon letters provided in Exhibit H-Letters stating intent to seek privileges at NHCOS.

Projected Medicare

The following table shows each applicant's total number of projected surgical cases and the number of cases projected to be provided to Medicare patients in the applicant's third full year of operation following completion of their projects, based on the information provided in the applicant's pro forma financial statements in Section Q. Generally, the application proposing to serve the higher percent of total surgical cases to Medicare patients is the more effective alternative with regard to those comparative factors.

PY3					
			% of Total Cases		
	Projected	Projected	Provided to Medicare		
	Total Cases	Medicare Cases	Recipients		
TCS	3,522	1,641	46.59%		
Cone Health	2,247	698	31.06%		
NH Forsyth	17,299	8,508	49.18%		
NH	4,754	2,101	44.19%		
Clemmons	4,734	2,101	44.1970		
NCBH	34,834	11,788	33.84%		

Surgical Medicare Cases

Source: Forms F.3, F.4 and F.5 for each applicant.

As shown in the table above, **NH Forsyth** projects 49% and **TCS** projects 47% of their surgical cases will be performed on Medicare recipients. **NH Clemmons** projects 44%, **NCBH** projects 34% and **Cone Health** projects 31% of its cases will be Medicare cases.

The application submitted by **Novant Health, Inc. and Forsyth Memorial Hospital, Inc.** is the most effective application with regard to serving Medicare recipients. However, due to differences in the types of facilities and the number and types of surgical services proposed by each of the facilities, it is not possible to make conclusive comparisons with regard to Medicare and Medicaid. Thus, these comparative factors may be of little value.

Projected Medicaid

The following table shows each applicant's total number of projected surgical cases and the number of cases projected to be provided to Medicaid patients in the applicant's third full year of operation following completion of their projects, based on the information provided in the applicant's pro forma financial statements in Section Q. Generally, the application proposing to serve the higher percent of total surgical cases to Medicaid patients is the more effective alternative with regard to those comparative factors.

110						
	Projected Total Cases					
TCS	3,522	134	3.80%			
Cone Health	2,247	22	0.98%			
NH Forsyth	17,299	1,604	9.27%			
NH Clemmons	4,754	252	5.30%			
NCBH	34,834	6,909	19.83%			

Surgical Medicaid Cases PY3

Source: Forms F.3, F.4 and F.5 for each applicant.

As shown in the table above, **NCBH** projects 20% of its surgical cases will be performed on Medicaid recipients, **NH Forsyth** projects 9%, **NH Clemmons** projects 5%, **TCS** projects 4% and **Cone Health** projects 1% of its total surgical cases will be Medicaid cases.

The application submitted by **North Carolina Baptist Hospital** is the most effective application with regard to serving Medicaid recipients. However, due to differences in the types of facilities and the number and types of surgical services proposed by each of the facilities, it is not possible to make conclusive comparisons with regard to Medicare and Medicaid. Thus, these comparative factors may be of little value.

Projected Average Net Revenue per Case

The following table shows the projected average net surgical revenue per OR and per surgical case in the third year of operation for each of the applicants, based on the information provided in the applicants' pro forma financial statements. Generally, the application proposing the lowest average net revenue is the more effective alternative with regard to this comparative factor.

115						
	Net Revenue	# of ORs*	# of Cases	Net Revenue/OR	Net Revenue/Case	
TCS	\$7,579,791	2	3,522	\$3,789,896	\$2,152	
Cone Health	\$ 8,584,313	2	2,247	\$4,292,157	\$3,820	
NH Forsyth	\$305,938,556	20	17,299	\$15,296,928	\$17,685	
NH Clemmons	\$20,311,735	4	4,754	\$5,077,934	\$4,273	
NCBH	\$881,585,974	49	34,834	\$17,991,550	\$25,308	

Revenue per OR and per Surgical Case

Source: Forms F.3, F.4 and F.5 for OR revenue in each application *Excludes dedicated C-section and trauma/burn ORs

As shown in the table above, **TCS** projects the lowest net revenue per surgical case and per OR in the third operating year, with **Cone Health** projecting the second lowest, followed by **NH Clemmons, NH Forsyth** and **NCBH.** Therefore, the application submitted by **Triad Center for Surgery, LLC** is the most effective application with respect to net revenue per surgical case. However, due to differences in the types of facilities and the number and types of surgical services

proposed by each of the facilities, it is not possible to make conclusive comparisons with regard to net revenue per case. Thus, this comparative factor may be of little value.

Projected Average Operating Expense per Case

The following table compares the projected average operating expense in the third year of operation for each of the applicants, based on the information provided in the applicants' pro forma financial statements (Form B). Generally, the application proposing the lowest average operating expense is the more effective alternative with regard to this comparative factor.

PY3						
	Operating Expense	# of ORs*	# of Cases	Operating Expense/OR	Operating Expense/Case	
TCS	\$6,756,586	2	3,522	\$3,378,293	\$1,918	
Cone Health	\$7,062,615	2	2,247	\$3,531,308	\$3,143	
NH Forsyth	\$123,812,155	20	17,299	\$6,190,608	\$7,157	
NH Clemmons	\$17,861,106	4	4,754	\$4,465,277	\$3,757	
NCBH	\$585,209,070	49	34,834	\$11,943,042	\$16,800	

Operating Expense per OR and per Surgical Case

Source: Forms F.3 in each application – surgical, GI, or procedure room operating expenses were not shown separately for the ASFs proposed by TCS, Cone Health and NH Clemmons. NH Forsyth and NCBH provided operating expenses on their Forms F.3 for only the surgical services in the operating rooms. *Excludes dedicated C-section and trauma/burn ORs

As shown in the table above, **TCS** projects the lowest average operating expense per surgical case and per OR in the third operating year, **Cone Health** projects the second lowest, followed by **NH Clemmons** and **NH Forsyth. NCBH** projects the highest operating expense. Therefore, the application submitted by **Triad Center for Surgery, LLC** is the most effective application with respect to operating expense. However, as noted under the table above, the acute care hospitals provide operating expenses for the operating rooms only while the ASFs provide operating expenses for the entire facility, including surgical, GI and procedure rooms, if applicable, making a direct comparison of surgical operating expenses impossible. Therefore, it is not possible to make conclusive comparisons with regard to operating expense per case. Thus, this comparative factor may be of little value.

SUMMARY

The following is a summary of the comparative analysis performed on the proposed projects submitted during this review, ranking the proposals as most effective, more effective, less effective and least effective.

However, due to significant differences in the types of surgical facilities (acute care quaternary teaching medical center vs acute care tertiary medical center vs ASF), types of surgical services to be offered (higher acuity vs lower acuity), number of total operating rooms (two vs as many as 49, excluding trauma/burn ORs), total revenues and expenses, and the differences in presentation of pro forma financial statements, the comparatives may be of less value and result in less than definitive

outcomes than if all applications were for like facilities of like size, proposing like services and reporting in like formats.

Comparative Factor	TCS	Cone Health	NCBH	NH Clemmons	NH Forsyth
Comparative Factor Conformity with Review	105	nealth	псып	Cleminons	INE FORSYLL
Criteria	Yes	Yes	Yes	No	No
Geographic Accessibility	More Effective	Less Effective	More Effective	Not Approvable	Not Approvable
Physician Support	Equally Effective	Equally Effective	Equally Effective	Not Approvable	Not Approvable
Patient Access to New Provider	More Effective	More Effective	Less Effective	Not Approvable	Not Approvable
Patient Access to Lower Cost Surgical Services	More Effective	More Effective	Less Effective	Not Approvable	Not Approvable
Patient Access to Multiple Services	Less Effective	Less Effective	Most Effective	Not Approvable	Not Approvable
Access by Underserved Groups: Charity Care	Inconclusive	Inconclusive	Inconclusive	Inconclusive	Inconclusive
Access by Underserved Groups: Medicare	Inconclusive	Inconclusive	Inconclusive	Inconclusive	Inconclusive
Access by Underserved Groups: Medicaid	Inconclusive	Inconclusive	Inconclusive	Inconclusive	Inconclusive
Projected Average Net Revenue per Case	Inconclusive	Inconclusive	Inconclusive	Inconclusive	Inconclusive
Projected Average Operating Expense per Case	Inconclusive	Inconclusive	Inconclusive	Inconclusive	Inconclusive

The NH Forsyth and NH Clemmons applications are not effective alternatives with respect to conformity with Review Criteria and therefore are not approvable and will not be further discussed in the comparative evaluation below:

- With respect to conformity with Review Criteria, of the approvable applications, TCS, Cone Health and NCBH offer equally effective alternatives. See Comparative Analysis for discussion.
- With respect to geographic accessibility, of the approvable applications, TCS and NCBH propose equally effective alternatives and are therefore more effective alternatives with respect to this comparative factor than Cone Health. See Comparative Analysis for discussion.
- With respect to physician support, of the approvable applications, TCS, Cone Health and NCBH offer equally effective alternatives. See Comparative Analysis for discussion.
- Of the approvable applications, TCS and Cone Health project access to a new provider and enhanced competition and are therefore more effective alternatives with respect to this

comparative factor. See Comparative Analysis for discussion.

- Of the approvable applications, TCS and Cone Health offer equally effective alternatives with regard to offering low-cost freestanding ambulatory surgery services, and are therefore more effective alternatives. See Comparative Analysis for discussion.
- With respect to access to surgical services, of the approvable applications, NCBH offers the greatest access to multiple services and is therefore the most effective alternative. See Comparative Analysis for discussion.

The following is a summary of the reasons the proposals submitted by **Triad Center for Surgery**, **LLC** and **North Carolina Baptist Hospital** are determined to be the more effective alternatives in this review:

- TCS proposes effective geographical access.
- TCS proposes access to a new provider.
- TCS offers effective lower cost freestanding ambulatory surgery services.
- NCBH offers the most effective access to multiple services
- NCBH proposes effective geographical access.

CONCLUSION

Two of the five applications were not approvable and therefore cannot be considered effective alternatives. Therefore, only the three approvable applications can be considered effective Based upon the comparative factors as discussed and evaluated above, the alternatives. applications submitted by Triad Center for Surgery, LLC, Project I.D. G-11513-18 and North Carolina Baptist Hospital, Project I.D. G-11519-18, are the more effective alternatives proposed in this review for new operating rooms to be located in Forsyth County and are therefore conditionally approved. The approval of the applications submitted by The Moses H. Cone Memorial Hospital and MC Kernersville, LLC, Project I.D. G-11516-18, Novant Health, Inc. and Forsyth Memorial Hospital, Inc., Project I.D. G-11517-18 and Novant Health, Inc. and Novant Health Clemmons Outpatient Surgery, LLC, Project I.D. G-11518-18 would result in operating rooms in excess of the need determination for Forsyth County. Consequently, the applications submitted by The Moses H. Cone Memorial Hospital and MC Kernersville, LLC, Project I.D. G-11516-18; Novant Health, Inc. and Forsyth Memorial Hospital, Inc., Project I.D. G-11517-18; and Novant Health, Inc. and Novant Health Clemmons Outpatient Surgery, LLC, Project I.D. G-11518-18 are denied.

The application submitted by Triad Center for Surgery, LLC is approved subject to the following conditions.

- **1.** Triad Center for Surgery, LLC shall materially comply with all representations made in the certificate of need application.
- 2. Triad Center for Surgery, LLC shall develop a new multispecialty ambulatory surgical facility by developing no more than two operating rooms and three procedure rooms.

- **3.** Upon completion of the project, Triad Center for Surgery shall be licensed for no more than two operating rooms and three procedure rooms.
- 4. Triad Center for Surgery, LLC shall not acquire as part of this project any equipment that is not included in the project's proposed capital expenditures in Section VIII of the application and that would otherwise require a certificate of need.
- 5. Triad Center for Surgery, LLC shall receive accreditation from the Joint Commission for the Accreditation of Healthcare Organizations, the Accreditation Association for Ambulatory Health Care or a comparable accreditation authority within two years following licensure of the facility.
- 6. For the first three years of operation following completion of the project, Triad Center for Surgery, LLC shall not increase charges more than 5% of the charges projected in Section X and Section XIII of the application without first obtaining a determination from the Healthcare Planning and Certificate of Need Section that the proposed increase is in material compliance with the representations in the certificate of need application.
- 7. The procedure rooms shall not be used for procedures that should be performed only in an operating room based on current standards of practice.
- 8. Procedures performed in the procedure rooms shall not be reported for billing purposes as having been performed in an operating room and shall not be reported on the facility's license renewal application as procedures performed in an operating room.
- 9. Triad Center for Surgery, LLC shall develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes.
- 10. No later than three months after the last day of each of the first three full years of operation following initiation of the services authorized by this certificate of need, Triad Center for Surgery, LLC shall submit, on the form provided by the Healthcare Planning and Certificate of Need Section, an annual report containing the:
 - a. Payor mix for the services authorized in this certificate of need.
 - b. Utilization of the services authorized in this certificate of need.
 - c. Revenues and operating costs for the services authorized in this certificate of need.
 - d. Average gross revenue per unit of service.
 - e. Average net revenue per unit of service.
 - f. Average operating cost per unit of service.

11. Triad Center for Surgery, LLC shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.

The application submitted by North Carolina Baptist Hospital is conditionally approved subject to the following conditions.

- **1.** North Carolina Baptist Hospital shall materially comply with all representations made in the certificate of need application.
- 2. North Carolina Baptist Hospital shall develop no more than two additional operating rooms for a total of 49 operating rooms upon completion of this project and Project ID #G-8460-10 (add seven dedicated outpatient ORs pursuant to Policy AC-3).
- 3. Upon completion of the project, North Carolina Baptist Hospital shall be licensed for no more than 49 operating rooms: 34 shared ORs, four inpatient ORs and seven dedicated outpatient ORs pursuant to Policy AC-3, approved in Project ID #G-8460-10.
- 4. North Carolina Baptist Hospital shall not acquire as part of this project any equipment that is not included in the project's proposed capital expenditures in Section VIII of the application and that would otherwise require a certificate of need.
- 5. For the first three years of operation following completion of the project, North Carolina Baptist Hospital shall not increase charges more than 5% of the charges projected in Section X and Section XIII of the application without first obtaining a determination from the Healthcare Planning and Certificate of Need Section that the proposed increase is in material compliance with the representations in the certificate of need application.
- 6. North Carolina Baptist Hospital shall develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes.
- 7. No later than three months after the last day of each of the first three full years of operation following initiation of the services authorized by this certificate of need, North Carolina Baptist Hospital shall submit, on the form provided by the Healthcare Planning and Certificate of Need Section, an annual report containing the:
 - a. Payor mix for the services authorized in this certificate of need.
 - **b.** Utilization of the services authorized in this certificate of need.

- c. Revenues and operating costs for the services authorized in this certificate of need.
- d. Average gross revenue per unit of service.
- e. Average net revenue per unit of service.
- f. Average operating cost per unit of service.
- 8. North Carolina Baptist Hospital shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.