

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: April 29, 2014

FINDINGS DATE: May 6, 2014

PROJECT ANALYST: Tanya S. Rupp

INTERIM CHIEF: Martha J. Frisone

PROJECT I.D. NUMBER: K-10229-13 / Same Day Surgery Center, Franklin, LLC / Relocate one operating room from Novant Health Franklin Regional Medical Center which is a change in scope and cost overrun for Project ID#K-8357-09 (develop a new, separately licensed ambulatory surgical facility with one operating room) / Franklin County

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

G.S. 131E-183(a) The Department 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

Same Day Surgery Center Franklin, LLC (SDSC Franklin) was issued a certificate of need (CON) effective December 29, 2009 for Project I.D. #K-8357-09 to develop a new, separately-licensed ambulatory surgical facility (ASC) with one operating room, one procedure room, two pre-operative rooms, and four post-operative rooms in Youngsville, Franklin County. The approved capital cost for that project was \$4,310,512. SDSC Franklin is owned by Novant Health, Inc., which also owns Novant Health Franklin Regional Medical Center in Louisburg, also in Franklin County. Novant Health, Inc. acquired the hospital in 2009, shortly before Project ID#K-8357-09 was filed. The previous owner was HMA. According to the 2013 License Renewal Application, Novant Health Franklin Medical Center is licensed for three (3) shared operating rooms (ORs).

The applicant submits this current application, K-10229-13, to request approval for a change in scope and cost overrun. The applicant proposes to relocate one shared OR from the hospital in Louisburg to the ASC in Youngsville, for a total of two ORs at the previously

approved ASC. Thus, the applicant proposes to construct space for a total of two ORs in the ASC; develop space for equipment storage, add space for sterile processing, add space for an additional pre- and post-operative room, and add space as needed for observation, support, and waiting/administration. Furthermore, the applicant now projects the capital cost to be \$10,440,572, which is an increase of \$6,130,060, or approximately 145% of the originally approved capital cost.

The total complement of licensed ORs in Franklin County will not change as a result of this proposal. The applicant does not propose add any new health services or acquire any equipment for which there is a need determination in the 2013 State Medical Facilities Plan (SMFP).

However, Policy GEN-4, on page 42 of the 2013 SMFP is applicable to this review. Policy GEN-4: ENERGY EFFICIENCY AND SUSTAINABILITY FOR HEALTH SERVICE FACILITIES states:

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

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

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

In Section III.4, page 76, the applicant refers to Exhibit 12 for a description of its plan to provide improved energy and water conservation in accordance with Policy GEN-4. In Exhibit 12, the applicant provides a copy of its Sustainable Energy Management Plan, which states in part:

“Novant Health Same Day Surgery Center Franklin’s SEMP [Sustainable Energy Maintenance Plan] will be guided by these principles:

***Taking a Strategic Approach:** Novant Health Same Day Surgery Center Franklin will actively manage energy costs by continuously looking for opportunities to reduce consumption by more efficiently utilizing our energy resources. Novant Health Same Day Surgery Center Franklin can significantly improve its energy-related performance by acting strategically through the adoption of a SEMP, internalizing energy management into our organization’s every-day decision-making, policies, and operating procedures will help assure substantial and long-lasting reductions in energy use throughout the facility.*

***Supporting Mission-Critical Goals:** Strategic energy management will directly support Novant Health Same Day Surgery Center Franklin’s mission-critical goal of improving the health of our communities in which we conduct business by improving the environment through active efforts to reduce energy consumption and prevent pollution. The impacts of Novant Health Same Day Surgery Center Franklin’s energy management efforts will provide a more consistent comfort level for our patients, provide a cleaner patient care environment, and ensure better reliability of utility infrastructure and back-up power systems.*

***Pursuing Long-Term Change to Core Business Practices:** The core of a strategic approach is the consistent incorporation of energy management into our organization’s core practices and decision-making, such as the strategic planning and budgetary processes. Change in energy-related business practice will cover all applications of energy management - new construction and major renovations, existing facility operations and upgrades, and the economic analysis and procurement practices underlying these practices.*

...

***Using Available Resources and Assistance:** Use national, regional and local sources of strategic, technical and financial assistance to help achieve our energy management goals.” [emphasis in original].*

Also in Exhibit 12 the applicant lists the steps it will take in order to facilitate its plans for developing an energy efficiency and sustainability plan for the project. The applicant states it will establish a *Sustainability Team* that will have membership composed of “*Senior Leaders, Physician partners, Nursing, Sourcing, Support Services, Public Affairs and others as appropriate.*” [emphasis in original].

The application includes a written statement describing the project’s plan to assure improved energy efficiency and water conservation. The application is conforming to Policy GEN-4; therefore, the application is conforming to this criterion.

- (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

Same Day Surgery Center Franklin, LLC (SDSC Franklin) was issued a certificate of need effective December 29, 2009 for Project I.D. #K-8357-09 to develop a new, separately-licensed ambulatory surgical facility (ASC) with one operating room, one procedure room, two pre-operative rooms, and four post-operative rooms in Youngsville, Franklin County. The approved capital cost for that project was \$4,310,512. SDSC Franklin is owned by Novant Health, Inc., which also owns Novant Health Franklin Regional Medical Center in Louisburg, also in Franklin County. Novant Health, Inc. acquired the hospital in 2009, shortly before Project ID#K-8357-09 was filed. The previous owner was HMA. According to the 2013 License Renewal Application, Novant Health Franklin Medical Center is licensed for three (3) shared operating rooms (ORs).

This application, K-10229-13, is for a change in scope and cost overrun for the previously approved application. The applicant proposes to relocate one shared OR from the hospital in Louisburg to the ASC in Youngsville, for a total of two ORs at the previously approved ASC. In Section II.6, page 13, the applicant states:

“The applicant proposes to relocate one underutilized OR from NHFRMC in Louisburg to the SDSC Franklin in Youngsville. If approved, the result would be that 2 dedicated outpatient ORs are operational in Youngsville and 2 shared inpatient/outpatient ORs are operational at the hospital in Louisburg. Thus, four ORs will remain in Franklin County and will be fully utilized. ... Thus the re-distribution of the four ORs will result in 2 ORs in southern Franklin County and 2 ORs in central Franklin County.”

In Section XI.2, on page 144, the applicant states the site proposed in this application is at the same intersection in Youngsville as the previously approved ASC; however, it is approximately 750 feet away from the originally approved site. Furthermore, the applicant now projects the capital cost to be \$10,440,572, which is an increase of \$6,130,060, or approximately 145% of the originally approved capital cost. As proposed, this facility would be twice the size of the previously approved ASC.

In Section I.1, page 1, SDSC Franklin is the only entity identified as an applicant. However, Novant Health Inc., the owner of both SDSC Franklin and the hospital, executed a Certification page, which states in part:

“The undersigned hereby assures and certifies that:

...

(d) the applicant will materially comply with the representations made in its application in the development of the project and the offering of the services pursuant to N.C.G.S. 131E-181(b); and,

(e) that the information included in this application and all attachments is correct to the best of my knowledge and belief and that it is my intent to carry out the proposed project as described.”

Furthermore, Exhibit 4 contains a letter signed by the President of the hospital, which states in part:

“I have the authority to authorize the relocation of one operating room within Franklin County from the hospital in Louisburg to the proposed 2-OR surgery center in Youngsville”

Novant Health, Inc. is not required to be identified in Section I.1 as a co-applicant. However, if Section I.1 did require Novant Health, Inc. to be identified as a co-applicant, that would merely mean it would have to sign a certification page, which it already did.

Population to Be Served

Since SDSC Franklin has not yet been developed there is no historical patient origin for that ASC on which to base projected patient origin. In Section III.5, page 77, the applicant states that the proposed service area for the ASC is based on the hospital’s outpatient surgical services; particularly during FFY 2013. The applicant states:

“SDSC Franklin reviewed historical zip code level patient origin for NHFRMC in Franklin County and Novant Health Medical Group (NHMG) physician practices in Franklin County and in Wake Forest, in northern Wake County ... to determine the service area to be served by SDSC Franklin in Youngsville, NC. In addition, SDSC Franklin considered the higher population growth in southern Franklin County, and the lack of any health care facilities in southern part of the County in determining the service area. Finally, SDSC Franklin considered the lack of any freestanding separately licensed ambulatory surgical facility in northern Wake County in determining the defined service area”

On page 77, the applicant provides a table, reproduced below, to illustrate the proposed service area:

SDSC Franklin Service Area by ZIP Code

ZIP CODE	TOWN	COUNTY
27508	Bunn	Franklin
27525	Franklinton	Franklin
27549	Louisburg	Franklin
27596	Youngsville	Franklin
27816	Castalia	Franklin
27882	Spring Hope	Nash/Franklin
27544	Kittrell	Vance/Franklin
27587	Wake Forest	Wake/Vance
27597	Zebulon	Wake/Franklin
27508	Rolesville	Wake

The applicant states:

“These ten zip codes include all zip codes in Franklin County and zip codes adjacent to southern Franklin County and represent 58.9% of total patient origin for NHFRMC outpatient surgical services in FFY 2013. Additional zip codes located adjacent to northern Franklin County and other areas north and west of NHFRMC make up the remaining 41.1% of the zip codes served by NHFRMC outpatient surgical services in FFY 2013.”

On page 79, the applicant illustrates the projected patient origin for the first three project years following project completion, as shown in the following table:

COUNTY	PROJECT YEAR 1		PROJECT YEAR 2		PROJECT YEAR 3	
	# CASES	PERCENT	# CASES	PERCENT	# CASES	PERCENT
Franklin*	591	57.8%	788	58.6%	961	58.5%
Nash [♦]	11	1.0%	15	1.1%	20	1.2%
Vance [●]	0	0.0%	5	0.3%	9	0.6%
Wake [▲]	267	26.1%	336	24.9%	407	24.8%
All Other	153	15.0%	202	15.0%	247	15.0%
Total	1,022	100.0%	1,346	100.0%	1,644	100.0%

*The applicant states this includes all of the Franklin County ZIP codes.

♦The applicant states this includes only those Nash County ZIP codes that are in the SDSC Franklin Service area.

●The applicant states this includes only those Vance County ZIP codes that are in the SDSC Franklin Service area.

▲The applicant states this includes only those Wake County ZIP codes that are in the SDSC Franklin Service area.

In Section III.5, page 79, the applicant states “All Other” refers to all other North Carolina counties and those other states from which patients are served, as reported on the hospital’s license renewal application.

In the previously approved application, SDSC Franklin projected patient origin to consist of only Franklin County residents; in particular, three census tracts that comprise the southern

and southeastern area of the county. The applicant stated in 2009 that a secondary service area included five additional census tracts in Franklin County.

In this application, the applicant extends the projected service area to include specific ZIP codes in northern Wake County, and specific ZIP codes in Nash and Vance counties, both of which border Franklin County. The applicant demonstrates, through letters in Exhibits 5 and 16, that its expanded service area as proposed in this application is reasonable, credible and adequately supported. Furthermore, a review of the hospital's license renewal applications for CYs 2010 through 2013 show a fairly consistent number of patients from outside of Franklin County received outpatient surgical services at the hospital in Louisburg, including residents of Nash, Vance and Wake counties.

The applicant adequately identifies the population to be served.

Demonstration of Need

In Section III.1, pages 40 - 57, the applicant discusses the need for the change in scope of the previously approved project. Specifically, the need the population to be served has for a second OR at the ASC.

There are currently four existing or approved ORs in Franklin County, all of which are owned by Novant Health: three at the hospital in Louisburg, and one that was previously approved to be located at SDSC Franklin in Youngsville. This application proposes to relocate one of the three shared ORs from the hospital to the surgery center, for a total of two ORs at each location following development of this project and Project ID# K-8357-09. The total complement of ORs in Franklin County will not change as a result of this proposal.

In Section II.6, on page 13, the applicant states:

“The proposed development of a new Youngsville ambulatory surgery facility with two operating rooms will allow much improved access for residents of Franklin County and northern Wake County to the first freestanding, multi-specialty surgery center to be located in Franklin County. Currently, the two most proximate providers to the proposed SDSC Franklin (in Youngsville, NC, near the northern Wake County border) are Rex Healthcare of Wakefield and WakeMed North Healthplex. Rex operates a 3-OR hospital-based ambulatory surgery center in Wakefield. WakeMed North offers outpatient surgery at its 4 hospital-based outpatient ORs at the WakeMed North Healthplex. Thus, Novant Health's Same Day Surgery Center Franklin in Youngsville, presents the only outpatient surgery center option in the northern Wake County / Youngsville market that is a freestanding separately licensed, multi-specialty surgery center. Thus, Novant Health's SDSC Franklin believes it can offer lower co-pays and charges than are typically associated with care delivered in freestanding, licensed surgery centers.”

In Section III.1(a), page 40, citing information obtained from the 2013 Hospital License Renewal Applications (LRAs), the applicant states:

“In FFY 2012 nearly 70% of all surgery performed in North Carolina was done on an outpatient basis. Outpatient surgery cases performed in separately licensed freestanding ambulatory surgery centers represented 16% of total surgery and outpatient surgery cases performed in hospital based outpatient surgery centers represented 54% of total surgery in FFY 2012.”

In Section III.1, pages 43 – 57, the applicant states the following factors support the need for a second OR at SDSC Franklin:

- Population and Economic Growth in the SDSC Franklin Service Area
- Improved Access to Outpatient Surgical Services
- Franklin County and North Carolina Outpatient Surgical Use Rate Comparison
- Freestanding vs. Hospital Based Ambulatory Surgery Centers
- Need Assessment and Recruitment for Additional Surgeons in Franklin County and Physician Support for SDSC Franklin
- Efficiencies in Ambulatory Surgical Facilities with Two Operating Rooms

Each factor is discussed below.

Population and Economic Growth in the SDSC Franklin Service Area

Louisburg, the location of the hospital, is located approximately 18 miles from Youngsville, the proposed location of SDSC Franklin, which is located near the borders with Wake and Granville counties. In Section III.1, page 43, the applicant states that Youngsville is the fastest growing ZIP code in Franklin County, with a projected compound annual growth rate (CAGR) of 1.4% from 2013 to 2018. See the following table, from page 43:

SDSC Service Area Population Projections

ZIP CODE	TOWN	COUNTY	2013	2018	ACTUAL GROWTH	CAGR
27596	Youngsville	Franklin	16,171	17,356	1,185	1.4%
27597	Zebulon	Wake/Franklin	22,585	23,657	1,072	0.9%
27549	Louisburg	Franklin	23,988	24,537	549	0.5%
27525	Franklinton	Franklin	13,844	1,4364	520	0.7%
27882	Spring Hope	Nash/Franklin	7,062	7,239	177	0.5%
27544	Kittrell	Vance/Franklin	3,966	4,070	104	0.5%
27816	Castalia	Franklin	2,685	2,691	6	0.0%
27508	Bunn	Franklin	1,993	1,972	-21	-0.2%
27571	Rolesville	Wake	3,973	4,464	491	2.4%
27587	Wake Forest	Wake/Granville	57,645	64,588	6,943	2.3%
Total			92,294	95,886	3,592	0.8%

As shown in the table above, Youngsville is projected to grow by 1,185 people, or a CAGR of 1.4% through the third project year. The projected growth rate is the highest among the

Franklin County ZIP codes that are in the proposed service area, and is also the proposed location of SDSC Franklin.

In addition, the analyst researched population projections as reported by the North Carolina Office of State Budget and Management. That website projects Franklin County will experience “medium” population growth of between 7.5% and 15.0% during the ten year period from 2010 to 2020¹. Franklin County is one of 19 counties in the state projected to grow at a “medium” rate. The same website also projects that Wake County will experience “high” population growth, defined as over 15% for the same time period². Wake County is one of 13 counties projected to grow at a “high” rate. Granville, Vance and Nash counties are projected to grow by less than 7.5%³.

In Section III.1, pages 48 – 50, the applicant discusses economic growth projections in Franklin County. The applicant states business and residential developments are increasing in that region.

Improved Access to Outpatient Surgical Services and Freestanding vs. Hospital-Based Ambulatory Surgery Centers

In Section III.1, page 50, the applicant provides data obtained from the 2013 SMFP to compare Franklin County outpatient surgical use rates to North Carolina surgical use rates, as shown in the following table:

Franklin County	2009	2010	2011	2012	4 Year Avg.
Outpatient Cases	3,611	3,675	3,637	3,594	
Population	59,502	60,813	61,603	61,633	
Use Rate	60.69	60.43	59.04	58.13	59.62
North Carolina					
Outpatient Cases	661,556	663,772	659,512	651,016	
Population	9,435,396	9,574,477	9,666,068	9,765,229	
Use Rate	70.11	69.33	68.23	66.67	68.58

On page 51, the applicant states the reason for the gap between use rates per 1,000 population for North Carolina as a whole versus Franklin County is “*probably due to lack of surgeons and a lack of surgical choices in Franklin County.*” On page 52, the applicant states:

“The health reform objectives articulated by the Congress and the Administration in the Affordable Care Act -promoting efficient use of services in the health care system and improving the value of Medicare’s spending-- are inextricably linked to promoting the use of ASCs for beneficiaries’ outpatient surgical needs. The results of this research demonstrate that ASCs have already been a beneficial partner to the Medicare program and its beneficiaries in constraining Medicare

¹ See http://osbm.nc.gov/ncosbm/facts_and_figures/socioeconomic_data/population_estimates

² *Id.*

³ *Id.*

spending growth by providing a lower-priced option for outpatient surgical needs. The reforms discussed in Congress should provide further incentives to move additional clinically appropriate surgeries into ASCs at a savings to the beneficiary, Medicare program, and U.S. taxpayers.”

On page 50, the applicant illustrates the market share for outpatient surgical services provided to residents of Franklin County from FFY 2010 to FFY 2012, as shown in the following table:

**Market Share – Outpatient Surgical Services
 Franklin County Residents**

SURGICAL FACILITY	FFY 2010	FFY 2011	FFY 2012
Novant Health Franklin Medical Center	9.6%	9.0%	13.6%
Rex Hospital	24.3%	25.7%	22.6%
WakeMed	19.1%	18.5%	20.6%
Duke Health Raleigh Hospital	17.3%	16.2%	14.5%
Blue Ridge Surgery Center (Freestanding)	7.3%	7.8%	7.0%
Duke University Hospital	5.8%	4.9%	6.4%
University of North Carolina Hospitals	2.9%	3.0%	3.5%
All Other Freestanding	3.4%	3.8%	4.0%
All Other Hospital	10.3%	10.9%	7.7%

The applicant states:

“The data illustrates the growth in NHFRMC’s market share of outpatient surgical volume but also illustrates that over 85% of Franklin County residents left the county for outpatient surgery in 2012.

...

NHFRMC’s share of outpatient surgical cases for Franklin County residents has increased from 9.6% in FFY 2010 to 13.6% in FFY 2012. Of note in the previous table, is the fact that only 14.7% of all outpatient surgery performed on Franklin County residents was performed in a freestanding ambulatory surgery center. This is less than the state average of 22.9%. In FFY 2012 nearly 70% of all surgery performed in North Carolina was done on an outpatient basis and cases performed in separately licensed freestanding ambulatory surgery centers represented 22.9% of outpatient surgery.”

The data provided by the applicant shows that over two thirds of the Franklin County residents who received outpatient surgery left the county for those services in FFY 2012. The data also shows that the hospital’s market share increased from FFY 2010 to FFY 2012.

Freestanding vs. Hospital Based Ambulatory Surgery Centers

In Section III.1, pages 52 – 53, the applicant states the following factors support the development of an ASC:

- Cost and convenience – the cost of a surgical procedure performed in an ASC is less than in a hospital, and the patient is able to leave sooner after the surgery.
- More efficiency for surgeons – the time involved in preparing the room and the patient is less because of the nature of outpatient surgery. Thus, the surgeons are able to more efficiently perform surgical procedures with greater throughput.
- Greater autonomy for the surgeons – in an ASC, surgeons can set their own standards for staffing, safety and other issues.

There is currently no freestanding ASC in either northern Wake County or anywhere in Franklin County. On page 53, the applicant calculated potential drive times from the existing ASCs in Wake and Durham counties to the town of Wake Forest, which is on the border of Wake and Franklin counties. Drive times range from 20 to 39 minutes without factoring in traffic conditions. The only major highways into or out of Franklin County are US Highway 1 and US Highway 401, both of which run north and south. The roads that run east and west through Franklin County are secondary county and state roads. According to MapQuest,[®] Youngsville, the proposed location of SDSC Franklin, is located approximately 4 miles from Wake Forest. The drive times from Wake Forest to the existing ASCs and the proposed SDSC Franklin are reported by the applicant on page 53, as follows:

- *“SDSC Franklin, Youngsville, NC = 8 minutes*
- *James E. Davis Surgery Center, Durham, NC = 30+ minutes*
- *Triangle Orthopaedic Specialty Surgery Center, Brier Creek/Raleigh = 20 minutes*
- *Raleigh Orthopaedic Surgery Center, Raleigh/Near Rex Healthcare = 20 minutes*
- *Blue Ridge Ambulatory Surgery Center, Raleigh, NC (near Rex), = 21 minutes*
- *Rex Ambulatory Surgery Center, Cary, NC = 30+ minutes*
- *Capital City Surgery Center, Raleigh, NC (near WakeMed) = 18 minutes*
- *Holly Springs Surgery Center, Holly Springs, NC (southern Wake County) = 39 minutes.”*

In addition, the applicant states that SDSC Franklin will be located on US Highway 1, thus providing easy accessibility and a lower cost alternative for patients. In Exhibit 16, the applicant provides 52 letters signed by patients and members of the business community in Youngsville. Each of the patient letters describes the difficulty of traveling to and from surgical facilities in Wake County. Each patient letter also states that a second OR located in southern Franklin County would help alleviate that burden.

Physician Needs Assessment / Physician Recruitment in Franklin County, and Physician Support

Utilizing population projections reported by the North Carolina Office of State Budget and Management (NCOSBM), the applicant prepared a *“physician needs assessment”* which

illustrates a shortage of surgeons in the SDSC Franklin service area. In Section III.1, page 55, the applicant states:

“Novant Health assumed ownership and management of NHFMC in fall 2009 and has been working with the physician community and residents of Franklin County to identify necessary facility improvements and strategic needs since that time. The Board of NHFRMC consists of Franklin County residents and physicians. Novant Health has invested in stabilizing the existing physician practices in Franklin County in Louisburg and Franklinton, as well as expanding to add practices in northern Wake County.... The NHMG Triangle Region (northern Wake County & Franklin County) has 14 physicians and surgeons, in addition to 3 mid-level physician providers, in seven primary care and specialty practice locations in Wake Forest, Franklinton, Franklin, and Louisburg, NC. When the NHMG-Triangle physicians practicing in Durham County are considered, the NHMG-Triangle footprint is 29 physicians and 5 mid-level providers in 9 physician office locations. In addition, NHMG is considering the development of a primary care practice in Youngsville and has had preliminary discussions with existing providers about the development of a satellite location there.

...

The Franklin County Surgeon Need Assessment is included in Exhibit 3, Tables 19-20. The Assessment, which is based upon Franklin County population data projections from the NC Office of State Budget & Management (NCOSBM) reflects a shortage of surgeons in Franklin County in the following specialties: general surgery, neurosurgery, ophthalmology, orthopedic surgery, otolaryngological surgery, ENT, and urological surgery. The study suggests there is a need for more surgeons in each of these categories. At the present time, NHFRMC has two general surgeons on its active medical staff and an identified deficit in 2013 of 3.1 general surgeons. Currently, NHFRMC is in negotiation to bring 2.5 FTE additional general surgeons to practice in Franklin County.”

The following tables, reproduced from Exhibit 3, illustrate the projected need in Franklin County for additional surgeons:

Franklin County Surgical Needs Assessment - 2013

SPECIALTY	POPULATION	MDS NEEDED PER 100,000	TOTAL MDS NEEDED	CURRENT NUMBER OF MDS	SURPLUS (DEFICIT)
General Surgery	62,311	8.12	5.06	2.00	(3.1)
Neurology		1.29	0.81	0.00	(0.8)
Ophthalmology		4.89	3.05	1.00	(2.0)
Orthopedic Surgery		8.62	5.37	1.00	(4.4)
Otolaryngology		3.12	1.94	1.00	(0.9)
Urology Surgery		3.44	2.15	0.00	(2.1)

Franklin County Surgical Needs Assessment - 2018

SPECIALTY	POPULATION	MDS NEEDED PER 100,000	TOTAL MDS NEEDED	CURRENT NUMBER OF MDS	SURPLUS (DEFICIT)
General Surgery	64,967	8.12	5.27	2.00	(3.3)
Neurology		1.29	0.84	0.00	(0.8)
Ophthalmology		4.89	3.18	1.00	(2.2)
Orthopedic Surgery		8.62	5.60	1.00	(4.6)
Otolaryngology		3.12	2.02	1.00	(1.0)
Urology Surgery		3.44	2.24	0.00	(2.2)

In Exhibit 5, the applicant provides eight letters signed by individual surgeons in both Wake and Franklin counties. Each of the surgeons indicates that he or she currently performs outpatient surgery on Franklin County residents; furthermore, those residents who must travel out of county for outpatient surgery would benefit from an outpatient surgical facility in Franklin County. In addition, each surgeon indicated that he or she would seek privileges at SDSC Franklin.

Also in Exhibit 5 are nine letters from physicians in and around Franklin County and northern Wake County which indicate that each physician would refer patients to SDSC Franklin because so many of their patients are from Franklin County and currently leave the county for outpatient surgical services. The applicant also provides letters from anesthesiologists, pathologists, and radiologists, each of which states that the physician who signed the letter would seek privileges at SDSC Franklin for both outpatient surgery and pain management.

Improved Efficiencies in ASCs with Two Operating Rooms

In Section III.1, pages 56 – 57, the applicant explains how adding a second OR to the previously approved SDSC Franklin would improve efficiencies and thus reduce cost to the patients. The applicant states:

“Adding a second operating room at SDSC Franklin will improve the efficiency of the approved facility. The fixed costs associated with operating a one-OR ambulatory surgical facility, such as administrative space, waiting areas and HVAC expenses, will be shared between two operating rooms with twice as much surgical capacity. In addition, staffing expense is shared resulting in lower staffing expense per OR The additional staffing required for the second operating room does not result in double the staff.”

The applicant also states that, overall, an ASC is more cost-effective because less time is involved in preparing the room between patients, thus improving throughput.

In addition, on page 57, the applicant states the ASC will have a non-sterile minor procedure room, as previously approved in Project ID#K-8357-09, for pain management and other minor procedures that would not require surgery.

Projected Utilization

The following table, from page 68, illustrates projected utilization during the first three operating years following project completion:

	PY 1 (FFY 2017)	PY 2 (FFY 2018)	PY 3 (FFY 2019)
Projected Cases from Service Area	869	1,144	1,397
In-migration (15%)	153	202	246
Total Cases	1,022	1,346	1,644

In Section III.1(b), pages 58 – 69, the applicant describes the assumptions and methodology used to project utilization, which are described below.

Step 1: Determine County Specific Outpatient Surgery Use Rates

On pages 58 – 60, using data reported in the hospital LRAs and population data obtained from the NCOSBM, the applicant calculates an average outpatient surgical use rate in the four counties [ten ZIP codes] included in SDSC Franklin’s service area, as shown in the following table:

COUNTY	OUTPATIENT SURGICAL USE RATE (2009 – 2012)
Franklin	59.62
Vance	61.12
Wake	59.06
Nash	66.62
Four County Combined	59.82
North Carolina	68.58

As shown in the table above, both Franklin and Wake County use rates are lower than the statewide use rate. On page 59, the applicant states that the Affordable Care Act (ACA), combined with the aging baby boomer population support a projected increase in outpatient surgical services. Citing various other sources, the applicant states that outpatient surgery volume is projected to increase by 8% to 12% between 2012 and 2025.

On page 60, the applicant states:

“The four year average outpatient surgical use rates for Franklin and Wake Counties are less than the four-county average and the North Carolina average. The four year average outpatient surgical use rates for Vance and Nash Counties are less than the statewide ambulatory surgical use rate. SDSC Franklin utilized county specific four year outpatient surgery use rates to project future utilization and held the rate constant through FFY 2019, Project Year 3. These rates are lower than the State average so are conservative in that respect. Holding the use rate constant assumes that utilization will increase at the same rate as population growth. SDSC Franklin chose not increase use rates even though the impact of

the ACA and the aging population would support growth in outpatient surgery use rates.”

Step 2: Calculate Total Outpatient Surgery Volume in the SDSC Franklin Service Area

On pages 60 – 61, utilizing the outpatient surgical use rates calculated in Step 1, the applicant projects outpatient surgery volume for the entire service area for all ten ZIP codes in SDSC Franklin’s service area, as shown in the following table:

SDSC Franklin Service Area Total Outpatient Surgical Volume (All Facilities)

ZIP CODE	TOWN	COUNTY	PY 1 (FFY 2017)	PY 2 (FFY 2018)	PY 3 (FFY 2019)
27508	Bunn	Franklin	118	118	117
27525	Franklin	Franklin	850	856	863
27549	Louisburg	Franklin	1,456	1,463	1,469
27596	Youngsville	Franklin	1,020	1,035	1,049
27816	Castalia	Franklin	160	160	161
27882	Spring Hope	Nash	480	482	485
27554	Kittrell	Vance	247	249	250
27571	Rolesville	Wake	258	264	270
27587	Wake Forest	Wake	3,729	3,815	3,903
27597	Zebulon	Wake	1,384	1,397	1,410
Total Service Area Outpatient Surgical Volume			9,702	9,839	9,977

Step 3: Market Share Assumptions

On pages 62 – 63, the applicant provides assumptions it used to project its market share of outpatient surgical volume in the first three project years, for both the hospital and SDSC Franklin, as follows:

“The impact of new surgeons in Franklin County and the new SDSC Franklin will decrease surgery out-migration from Franklin County and increase the market share for Novant Health in Franklin County and in the SDSC Franklin Service Area. To determine future Novant Health market share by zip code in the SDSC Franklin Service Area, the applicant considered many variables which will impact the utilization of SDSC Franklin, including

- *NHFRMC in Louisburg is the only existing provider of surgical services in Franklin County. Currently, there is no ambulatory surgery center in Louisburg, Youngsville, or other areas of Franklin County.*
- *There is no freestanding, separately licensed ambulatory surgery center in northern Wake County.*
- *Over 85% of the residents of Franklin County who need outpatient surgical care out-migrate to Wake, Durham, and other counties for ambulatory surgery services.*
- *The proposed location for SDSC Franklin in Youngsville is in the most populous and fastest growing zip code in Franklin County.*

- *The SDSC Franklin Service Area population is projected to grow 7.2% from 2013 through 2018, at a compound annual growth rate (CAGR) of 1.4% during that five-year period.*
- *Included in Exhibit 5 are letters of support from surgeons and primary care referring physicians. In addition, NHFRMC is in negotiation to bring 2.5 FTE additional general surgeons to practice in Franklin County. Novant Health does not foresee difficulty recruiting additional surgeons to utilize the proposed ambulatory surgical facility.*
- *SDSC Franklin will be a multispecialty freestanding ambulatory surgery center, wholly owned by Novant Health, and will be locally-accessible, high quality, and cost-effective, in a comfortable and convenient location close to the homes of all residents of Franklin County.*
- *NHMG-Triangle includes physicians practicing in Franklin County and the northern Wake County communities of Wake Forest and is considering development of a satellite office in Youngsville. This NHMG presence in the Triangle reflects the ability of NHMG to recruit and retain physicians in the Triangle market. When the NHMG-Triangle physicians practicing in Durham County are considered, the NHMG-Triangle footprint is 29 physicians and 5 mid-level providers in 9 physician office locations. ... ”*

See the following table, reproduced from page 63, which illustrates the total outpatient surgery market share for the hospital and the ASC combined:

ZIP CODE	TOWN	COUNTY	PY 1 (FFY 2017)	PY 2 (FFY 2018)	PY 3 (FFY 2019)
27508	Bunn	Franklin	36.9%	42.5%	50.0%
27525	Franklin	Franklin	28.0%	34.0%	40.0%
27549	Louisburg	Franklin	35.0%	42.5%	50.0%
27596	Youngsville	Franklin	28.0%	34.0%	40.0%
27816	Castalia	Franklin	17.5%	21.3%	25.0%
27882	Spring Hope	Nash	4.9%	6.0%	7.0%
27554	Kittrell	Vance	10.5%	12.8%	15.0%
27571	Rolesville	Wake	17.5%	21.3%	25.0%
27587	Wake Forest	Wake	4.9%	6.0%	7.0%
27597	Zebulon	Wake	4.9%	6.0%	7.0%

On page 63, the applicant states:

“...market share assumptions also took into consideration projected growth of outpatient surgery at NHFRMC, proximity to SDSC Franklin and other hospital based surgical programs in northern Wake County, NHMG primary care practice patient origin data from northern Wake County, and the expertise of NHFRMC and NHMG Administration. Market share is projected to grow in the first three years of operation to achieve the target identified for Project Year 3. Ramp up of market share is estimated to be 70% in PY 1 and 85% PY 2.”

Step 4: Project Combined Outpatient Surgery Volume ad SDSC Franklin and NHFRMC

On page 64, the applicant projects total outpatient surgery volume for the hospital and the ASC combined, using the projections from Steps 2 and 3, as shown in the following table:

SDSC Franklin and NHFRMC Outpatient Surgical Volume					
ZIP CODE	TOWN	COUNTY	PY 1 (FFY 2017)	PY 2 (FFY 2018)	PY 3 (FFY 2019)
27508	Bunn	Franklin	43	50	59
27525	Franklin	Franklin	238	291	345
27549	Louisburg	Franklin	510	622	735
27596	Youngsville	Franklin	286	352	420
27816	Castalia	Franklin	28	34	40
27882	Spring Hope	Nash	24	29	34
27544	Kittrell	Vance	26	32	38
27571	Rolesville	Wake	45	56	67
27587	Wake Forest	Wake	183	227	273
27597	Zebulon	Wake	68	83	99
Total Combined Outpatient Surgical Volume			1,451	1,776	2,110

On page 65, the applicant states:

“To test the overall impact of zip level market share assumptions used in the previous table, SDSC Franklin compared county-level market share data from other counties with a comparable population base to projected Franklin County market share calculated in the previous table. Projected combined NHFRMC and SDSC Franklin market share of Franklin County outpatient surgical volume in Project Year 3 is calculated to be 43.7% of total Franklin County outpatient surgical volume in FFY 2019. This includes just the five zip codes labeled as Franklin County in the previous table. If the three zip codes which overlap into Nash, Vance and Wake County are included, the overall market share decreases to 30.5% in Project Year 3. The combined NHFRMC and SDSC Franklin market share of the total SDSC Franklin Service Area, all ten zip codes, is 21.1% of total outpatient surgical volume. NHFRMC provided 5.2% of total outpatient surgical volume from the SDSC Franklin Service Area in FFY 2012; therefore, SDSC Franklin projects an increase in market share of only 15.9%. In FFY 2012, 86.4% of Franklin County residents in need of outpatient surgery left Franklin County for outpatient surgical services. Franklin County has a population of approximately 61,500 in 2012, which is projected to increase to approximately 65,000 by FFY 2019. Outpatient surgical market share for FFY 2012 for all North Carolina counties with a population of 50,000 to 70,000 was analyzed to test the reasonableness of the SDSC Franklin market share assumptions. SDSC Franklin determined that in FFY 2012: the average outpatient surgical market share for all surgical facilities in counties with a comparable population base was 39.0%; the median outpatient surgical market share for all surgical facilities in counties with a comparable population base was 41.1%; the range of

outpatient surgical market share for all surgical facilities in counties with a comparable population base was 5.2% to 66.4%; and the average outpatient surgical market share for counties with a comparable population base with two licensed surgical providers was 44.2%.”

See also Exhibit 3. Note: the applicant states its market share is projected to increase 15.9%. In actuality, it is projected to increase 15.9 percentage points [21.1% - 5.2% = 15.9%], not 15.9%.

Step 5: Calculate SDSC Franklin Projected Outpatient Surgical Volume

In Section III.1, pages 65 – 68, the applicant calculates projected outpatient surgical volume at the ASC by subtracting the outpatient surgical procedures projected to be performed at the hospital from the total projected in Step 4. On page 66, the applicant provides data showing that outpatient surgical utilization at the hospital increased by a CAGR of 4.9% between FFY 2011 and FFY 2013, as shown in the table below:

SURGERY	FFY 2011	FFY 2012	FFY 2013	CAGR FFY 2011 - 13
Outpatient	742	836	816	4.9%

On page 66, the applicant states:

“Projected growth in outpatient surgical volume at NHFRMC for patients from the Louisburg zip code utilizes the CAGR in the interim years. For PY 2 and in PY 3, it is assumed that 60% of the combined SDSC Franklin and NHFRMC outpatient surgery volume for the Louisburg zip code, which increases due to population growth and market share as previously discussed, remains at NHFRMC....

Franklin assumes that the development of the freestanding ambulatory surgery facility in Youngsville with two operating rooms will provide additional incentive to recruit needed surgeons to Franklin County. The impact of additional surgeons in Franklin County will increase projected outpatient surgical growth at NHFRMC in Louisburg.”

Step 6: Calculate Total Surgical Volume at SDSC Franklin

On page 68, the applicant states:

“In addition to the surgical volume calculated in Step 5 from the SDSC Franklin Zip Code Service Area, SDSC Franklin will have patients from outside the Service Area choose to receive care at SDSC Franklin. This may result from a patient living outside the SDSC Franklin Service Area choosing to have a specific surgeon perform their surgery, or may be due to a family or friend having a positive experience at SDSC Franklin, or result from a patient from another Wake

County zip code or surrounding county choosing to have their outpatient surgery performed in a freestanding ambulatory surgery center in Youngsville to save money. This volume is considered to be in-migration to the facility and reflects patient choice.

SDSC Franklin used a 15% in-migration factor which was determined based upon review of historical in-migration to Franklin County for outpatient surgical services at NHFRMC. Historical in-migration at NHFRMC from all other zip codes was 41.1%.... The 15% in-migration factor utilized in the SDSC Franklin methodology was determined to be reasonable as it is less than half of the outpatient surgical in-migration to Franklin County in FFY 2013. In addition, over 20% of patients receiving care from NHMG practices in the defined SDSC Franklin Service Area come from zip codes and counties outside of the defined SDSC Service Area ... and will most often be referred, as clinically appropriate, to surgeons performing surgery at SDSC Franklin as reflected in the referring physician letters of support....”

Below is a table reproduced from page 68 that illustrates the calculations described above:

	PY 1 FFY 2017	PY 2 FFY 2018	PY 3 FFY 2019
Projected outpatient surgical volume from Step 5	869	1,144	1,397
All other in-migration (15%)	153	202	247
Total outpatient surgical volume at SDSC Franklin	1,022	1,346	1,644

Step 7: Project Operating Room Need at SDSC Franklin

On page 69, the applicant provides the following table:

	PY 1 FFY 2017	PY 2 FFY 2018	PY 3 FFY 2019
Projected ambulatory surgical cases	1,022	1,346	1,644
Projected weighted ambulatory surgical hours	1,533	2,019	2,466
Total ambulatory surgical ORs needed	0.8	1.1	1.3
Total ambulatory surgical ORs rounded*	1	1	2

*In accordance with the 2013 SMFP methodology.

Projected utilization of the ASC is based on reasonable, credible and adequately supported assumptions.

The applicant adequately demonstrates the need for its proposal based on the following:

- There is no existing ASC in Franklin County.
- Over 85% of Franklin County residents are leaving the county for outpatient surgical services.
- The hospital in Franklin County is actively recruiting more surgeons.

- The ASC is already approved to be developed in Youngsville with one OR. All this proposal would do is increase the number of ORs at the ASC to two, which will allow the ASC to operate more efficiently. The OR to be relocated from the hospital is not in use.
- The applicant provides adequate documentation of support from surgeons and referring physicians.

Access

In Section III.8, page 82, the applicant states:

“Currently, the two most proximate providers to the proposed SDSC Franklin (in Youngsville, NC, near the northern Wake County border) are Rex Healthcare of Wakefield and WakeMed North Healthplex. Rex operates a 3-OR hospital-based ambulatory surgery center in Wakefield. WakeMed North offers outpatient surgery at its 4 hospital-based outpatient ORs at the WakeMed North Healthplex. Thus, [SDSC Franklin] presents the only outpatient surgery center option in the northern Wake County/Youngsville market that is a freestanding separately licensed, multi-specialty surgery center.”

In addition, in Section VI.4, page 107, the applicant states: *“SDSC Franklin will provide outpatient surgery services to all [underserved groups]. Any service deemed medically necessary (by a physician) will be available to a patient, regardless of ability to pay.”* In Section VI.14, page 116, the applicant projects that 2.36% of SDSC Franklin’s patients will be self-pay or indigent, and 6.18% will be Medicaid recipients.

In summary, the applicant adequately identifies the population to be served, adequately demonstrates the need the population to be served has for the proposed project and adequately demonstrates the extent to which all residents, and in particular, the medically underserved are likely to have access to the ASC. Therefore, the application is conforming to this criterion.

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

C

The applicant proposes to relocate one existing shared OR from the hospital to the previously approved ASC in Youngsville. The hospital is currently licensed for three shared ORs, only two of which are currently utilized.

In Section III.1(c), page 73, the applicant provides current and projected utilization of the ORs at the hospital, as shown in the following table:

	FFY 2013	FFY 2014	FFY 2015	FFY 2016	FFY 2017 (PY 1)	FFY 2018 (PY 2)	FFY 2019 (PY 3)
Projected Cases from SDSC Franklin ZIP code service area	481	504	528	554	581	631	712
Projected Cases from other ZIP codes	335	352	369	387	406	425	446
Total Projected Cases at the Hospital	816	856	897	941	987	1,057	1,158
Growth Rate	--	4.9%	4.9%	4.9%	4.9%	7.1%	9.6%
Weighted Hours (cases x 1.5)	1,224	1,284	1,346	1,412	1,480	1,585	1,737
Total IP Cases	109	119	129	141	153	167	181
Growth Rate	--	8.8%	8.8%	8.8%	8.8%	8.8%	8.8%
Weighted hours (cases x 3.0)	327	356	387	422	459	500	544
Total Weighted Hours	1,551	1,640	1,733	1,833	1,939	2,085	2,281
Number of ORs needed (total hours / 1,872)	0.8	0.9	0.9	1.0	1.0	1.1	1.22

On page 73, the applicant states:

“Total inpatient surgical growth from FFY 2013 to FFY 2019 is 72 inpatient surgical cases. Total outpatient surgical growth from FFY 2013 to FFY 2019 is 342 outpatient surgical cases. ... this volume is less than the impact of recruiting one general surgeon working full time at NHFRMC. Ongoing recruitment at NHFRMC will meet or exceed this goal.

Projected surgical volume results in a need for 1.22 operating rooms as reflected in the previous table When rounded using as a guideline, Step 5 of the 2013 SMFP Operating Room Need Methodology, NHFRIVIC has an identified need for two operating rooms in 2018.”

As shown in the table above, in FFY 2013, based on the need methodology in the 2013 SMFP, the hospital only needed one of its three existing shared ORs. In FFY 2019 (PY 3), the hospital only needs 1.22 ORs, based on an assumption that total weighted hours would increase from 1,551 to 2,281, an increase of 47.1% [$2,281 - 1,551 = 730$; $730 / 1,551 = 0.471$].

The applicant demonstrates that the needs of the population presently served at the hospital will continue to be adequately met with the two ORs currently in use which will remain at the hospital. Therefore, the application is conforming to this criterion.

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

CA

In Section III.8, pages 80 - 82, the applicant describe the alternatives it considered prior to submitting this change of scope application, which include:

- 1) Maintain the Status Quo – The ASC in Youngsville was previously approved in Project ID #K-8357-09 with one OR and one procedure room. The applicant states it is more cost-effective to develop the approved ASC with two ORs rather than one.
- 2) Joint Venture with another provider - The applicant states it considered a joint venture but was unable to identify any potential joint venture partners.
- 3) Develop SDSC Franklin as a hospital-based outpatient center - The applicant states this alternative is less effective because a hospital-based outpatient center would not be as cost-effective for patients as a separately licensed ASC.

For the reasons stated in Section III of the application, the applicant determined that the project, as modified by this change of scope application, is the most effective alternative to meet the need for outpatient surgery services in Franklin County.

Furthermore, the application is conforming to all other applicable statutory and regulatory review criteria and thus, is approvable. A project that cannot be approved cannot be an effective alternative.

In summary, the applicant adequately demonstrates that the project is the least costly or most effective alternative to meet the identified need. Therefore, the application is conforming to this criterion and approved subject to the following conditions:

1. **Same Day Surgery Center Franklin shall materially comply with all representations made in this certificate of need application and in Project ID #K-8357-09. In those instances in which representations conflict, Same Day Surgery Center Franklin shall materially comply with the last-made representation.**
2. **Same Day Surgery Center Franklin shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditure in Section VIII of the application and that would otherwise require a certificate of need.**
3. **Same Day Surgery Center Franklin shall construct an ambulatory surgical facility that shall be licensed for no more than two ambulatory surgical operating rooms and one procedure room.**
4. **Same Day Surgery Center Franklin shall meet all criteria to receive accreditation of the ambulatory surgical facility from JCAHO, AAAHC**

or a comparable accreditation authority within two years following completion of the facility.

5. **Upon relocation of the existing operating room to the new location, Novant Health Franklin Regional Medical Center shall reduce the number of licensed operating rooms in the hospital by 1, such that the hospital shall not be licensed for more than two shared operating rooms.**
 6. **Same Day Surgery Center Franklin shall acknowledge acceptance of and agree to comply with all conditions stated herein in writing to the Certificate of Need Section prior to the issuance of the certificate of need.**
- (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

In Project ID #K-8357-09, the applicant was previously approved for a capital cost of \$4,310,512. In this application, the applicant projects a capital cost of \$10,440,572, which represents approximately a 140% increase. In Section VII.2, page 128, the applicant provides a table to illustrate the difference in capital cost between the two applications. See the following table:

CATEGORY	PREVIOUSLY APPROVED CAPITAL COST (K-8357-09)	INCREASE IN CAPITAL COST (K-10229-13)	TOTAL CAPITAL COST
Site Costs			
Purchase Price of Land	\$0	\$1,482,354	\$1,482,354
Closing Costs	\$0	\$40,000	\$40,000
Site Preparation Costs	\$297,524	\$378,745	\$676,269
Off-Site Improvements	\$347,000	\$0	\$347,000
Subtotal Site Costs	\$644,524	\$1,901,099	\$2,545,623
Construction Contract			
Materials	\$921,280	\$925,719	\$1,846,999
Labor	\$614,186	\$1,232,813	\$1,846,999
Construction Contingency	\$79,042	\$202,162	\$281,204
Subtotal Construction Contract	\$1,614,508	\$2,360,694	\$3,975,202
Miscellaneous Project Costs			
Fixed and Moveable Equipment	\$1,037,741	\$1,437,081	\$2,474,822
Information Technology	\$495,064	\$4,936	\$500,000
Furniture/Fixtures	\$35,486	\$26,668	\$62,154
Artwork	\$0	\$3,530	\$3,530
Signage	\$0	\$10,338	\$10,338
Consultant Fees	\$232,768	\$202,471	\$435,239
Interest During Construction	\$101,365	\$143,229	\$244,664
Project Contingency	\$149,056	\$39,944	\$189,000
Subtotal Miscellaneous Costs	\$2,051,480	\$1,868,267	\$3,919,747
Total Project Capital Cost	\$4,310,512	\$6,130,060	\$10,440,572

In the previously approved application (Project ID# K-8357-09), the applicant proposed to lease the site on which to construct the ASC; thus there were no costs for purchase of land associated with that application. In the present application, the applicant proposes to purchase the land. In a footnote to the table on page 128, the applicant explains that the site to be purchased is actually a 4.25 acre parcel costing \$1,750,000. However, only 3.6 acres will be utilized; consequently, the purchase price has been adjusted to reflect the difference.

In the previously approved application, the total square feet associated with the project was 6,440, which is a construction cost per square foot of \$582.85. This application, which proposes a second OR, additional waiting room space, administration space, equipment space, and other areas as needed to effectively operate an ASC with two ORs. This application proposes 12,782 total square feet, which is a construction cost per square foot of \$311.00.

In Section IX, page 138, the applicant projects an additional \$13,174 for the working capital needs of the project over and above \$313,000, the amount projected in the previously approved 2009 application.

In Section VIII.3, page 129, and Section IX, page 138, the applicant states the capital and working capital costs of the project will be funded with the accumulated reserves of Novant Health, Inc.

Exhibit 8 contains a letter dated November 8, 2013 from the Senior Vice-President Operational Finance of Novant Health Inc., which confirms Novant Health's intent to provide \$10,453,746 from its accumulated cash reserves for the development of the proposed project.

Exhibit 8 also contains a letter dated November 8, 2013 from the Vice President and Chief Operating Officer, Triangle Market Novant Health, Inc. committing those funds for the development of the proposed project.

Exhibit 8 also contains the audited financial statements for Novant Health, Inc. As of December 31, 2012, Novant Health, Inc. had \$276,637,000 in Cash and Cash Equivalents, \$1,157,218,000 in Total Assets, and \$2,163,123,000 in Net Assets [Total Assets less Total Liabilities]. The applicant adequately demonstrates the availability of sufficient funds for the capital and working capital needs of the project.

The applicant projects revenues will exceed operating expenses in the second and third operating years of the project, as illustrated in the table below.

SDSC FRANKLIN	PY 1 (FFY 2017)	PY 2 (FFY 2018)	PY 3 (FFY 2019)
Total Net Revenue	\$2,176,498	\$2,941,807	\$3,717,794
Total Expenses	\$2,438,540	\$2,598,653	\$2,757,902
Net Income	(\$262,042)	\$343,154	\$959,892

The assumptions used by the applicant in preparation of the pro forma financial statements, including projected utilization, are adequately supported. See the Financials section of the

application following Tab 12 for the assumptions. See Criterion (3) for discussion regarding projected utilization which is incorporated hereby as if set forth fully herein. The applicant adequately demonstrates that the financial feasibility of the proposal is based upon reasonable projections of costs and charges. Therefore, the application is conforming to this criterion.

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

C

The original application (Project ID #K-8357-09) was conforming to this criterion. In this application, the applicant proposes to relocate one existing shared OR from the hospital to SDSC Franklin. The OR to be relocated is not currently in use at the hospital. This proposal will not alter the number of existing or approved facilities or ORs in Franklin County. It will shift one OR such that the hospital will have two, not three (one of which is not in use) and the ASC will have two, not one. The ASC will be able to operate more efficiently according to the applicant.

The applicant adequately demonstrates that this project will not result in an unnecessary duplication of existing or approved health service capabilities or facilities in Franklin County. Therefore, the application is conforming to this criterion.

- (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

The following table illustrates the projected staffing at the proposed facility, as reported by the applicants in Section VII.2, page 119.

EMPLOYEE CATEGORY	# OF FULL TIME EQUIVALENT (FTE) POSITIONS
Nurse Manager	1.0
OP Registered Nurse	4.0
OP Surgical Technologist	4.0
Patient Access Specialist	2.0
Sterile Processing Technician	1.0
TOTAL	12.0

As shown in the table above, the applicant proposes a total of 12.0 FTE positions in Project Year Two. On page 120, the applicant states that, as an existing health care provider in Franklin County, it does not anticipate difficulty in recruiting staff.

Exhibit 4 contains a letter signed by Barbara Burggraaff, MD, which indicates her commitment to serve as Medical Director for the ASC. Exhibit 4 also contains Dr. Burggraaff's curriculum vitae.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed surgical services. Therefore, the application is conforming to this criterion.

- (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

In Section II.2(b), page 10, the applicant states:

“SDSC Franklin will provide directly or through contract the following services including, but are [sic] not limited to, materials management, pathology/laboratory, laundry, patient access, IT (for business office), finance, accounts payable, biomedical engineering, plant engineering, mail courier, human resources, corporate education, anesthesia, pharmacy, supply distribution, infection control, translation services, patient education, and medical records. ... In this application, SDSC Franklin proposes to provide sterile processing services on site in the surgery center. SDSC Franklin patients will also be able to access pre-op and post-op lab services at NHFRMC, as well as at other providers of lab and imaging services in Franklin County and northern Wake County.”

Exhibit 4 contains a letter dated November 13, 2013 from the President of Novant Health Franklin Medical Center which confirms that the hospital will provide laboratory, ED, pathology, imaging, and “*other ancillary and support services*” to the ASC. Exhibit 5 includes letters from area surgeons and physicians indicating their support for the proposed project. These letters also estimate the number of surgical procedures they expect to refer or perform at SDSC Franklin.

The applicant adequately demonstrates that all necessary ancillary and support services will be available and that the services will be coordinated with the existing health care system. Therefore, 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

- (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

- (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

In Section XI.5, page 147, the applicant compares the square footage (SF) as proposed in 2009 in Project ID #K-8357-09 and in this application, as shown in the following table:

AREA	SF PROPOSED IN K-8357-09	SF PROPOSED IN PRESENT APPLICATION	TOTAL ESTIMATED SF FOR SDSC FRANKLIN WITH TWO ORS
Administration	940	545	1,485
Pre-Operative Area	730	1,441	2,171
Operating Rooms	715	3,027	3,742
Post-Operative Recover Area	1,090	623	1,713
Anesthesia	195	4	199
Support Space	2,770	-137	2,633
Sterile Processing	0	839	839
Total Facility	6,440	6,342	12,782

See Exhibit 8 for line drawings for the ASC.

In Section XI.6, page 148, the applicant estimates the following construction costs per square foot:

ESTIMATED CONSTRUCTION COST PER SQUARE FOOT			
	ESTIMATED SQUARE FEET	CONSTRUCTION COST/ SQUARE FOOT	TOTAL COST / SQUARE FOOT
Total	12,782	\$311.00	\$3,975,202

In Section III.4, pages 75 - 76, and Section XI.8, pages 149 - 150, the applicant discusses the project's plan to assure improved energy and water conservation. In Exhibit 12, the applicant provides a copy of SDSC Franklin's Sustainable Energy Management Plan. See Criterion (1) for discussion which is incorporated hereby as if set forth fully herein.

In Exhibit 12, the applicant provides a letter dated November 14, 2013, from an architect which confirms the increase in square footage, the cost per square foot and the site preparation costs for the ASC as proposed in this application. The costs identified by the architect in Exhibit 12 are consistent with the construction costs presented in Section VIII of the application.

The applicant adequately demonstrates that the cost, design and means of construction represent the most reasonable alternative for the project as proposed and that the proposed project will not unduly increase the costs and charges of providing health services. See Criterion (5) for discussion of costs and charges which is incorporated hereby as if set forth fully herein. The applicant adequately demonstrates that applicable energy saving features have been incorporated into the construction plans. Therefore, the application is conforming to this criterion.

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

C

SDSC Franklin was previously approved but does not yet exist. In Section VI.13, page 115, the applicant provides the CY 2012 payor mix for the hospital's surgical program, as illustrated in the table below.

PAYOR	CASES AS % OF TOTAL CASES
Self Pay/ Indigent	11.5%
Commercial Insurance	2.63%
Medicare / Medicare Managed Care	41.58%
Medicaid	24.93%
Managed Care	17.91%
Other (Work Comp and Other government)	1.90%
Total	100.0%

The Division of Medical Assistance (DMA) maintains a website which offers information regarding the number of persons eligible for Medicaid assistance and estimates of the percentage of uninsured for each county in North Carolina. The following table illustrates those percentages for the proposed service area and statewide.

	2010 Total # of Medicaid Eligibles as % of Total Population *	2010 Total # of Medicaid Eligibles Age 21 and older as % of Total Population *	2008-2009 % Uninsured (Estimate by Cecil G. Sheps Center) *
Franklin	17.5%	7.4%	19.7%
Wake	9.82%	3.4%	18.4%
Nash	19.8%	8.6%	19.7%
Vance	30.4%	13.4%	22.8%
Statewide	16.5%	6.7%	19.7%

* More current data, particularly with regard to the estimated uninsured percentages, was not available.

The majority of Medicaid eligibles are children under the age of 21. They do not utilize the same health services at the same rates as older segments of the population, particularly the surgical services to be offered by SDSC Franklin.

Moreover, the number of persons eligible for Medicaid assistance may be greater than the number of Medicaid eligibles who actually utilize health services. The DMA website includes information regarding dental services which illustrates this point. For dental services only, DMA provides a comparison of the number of persons eligible for dental services with the number actually receiving services. The statewide percentage of persons eligible to receive dental services who actually received dental services was 48.6% for those age 20 and younger and 31.6% for those age 21 and older. Similar information is not provided on the website for other types of services covered by Medicaid. However, it is reasonable to assume that the percentage of those actually receiving other types of health services covered by Medicaid is less than the percentage that is eligible for those services.

The Office of State Budget & Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina. In addition, data is available by age, race or gender. However, a direct comparison to

the hospital's current payor mix would be of little value. The population data by age, race or gender does not include information on the number of elderly, minorities or women utilizing health services. Furthermore, OSBM's website does not include information on the number of handicapped persons.

The applicant demonstrates that medically underserved populations currently have adequate access to outpatient surgery services available at the hospital. 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;

C

Recipients of Hill-Burton funds were required to provide uncompensated care, community service and access by minorities and handicapped persons. In Section VI.11, page 114, the applicant states that the proposed ASC will have no federal obligation to provide uncompensated care, but will comply with all access requirements for Americans with Disabilities Act, as documented in the Charity Care policies included in Exhibit 7. In Section VI.2, page 102, the applicant states:

"It is the policy of all the Novant Health facilities and programs, including Same Day Surgery Center Franklin, to provide necessary services to all individuals without regard to race, creed, color, or handicap. Novant Health facilities and programs do not discriminate against the above-listed persons, regardless of their ability to pay."

In Section VI.10(a), page 113, in reference to patient civil rights complaints, the applicant states:

"A complaint was filed on July 11, 2007 alleging that Novant Health Charlotte Orthopaedic Hospital engaged in unlawful discrimination based on disability (hearing impaired) in violation of Section 504 of the Rehabilitation Act of 1973. Specifically, the complainant alleged he was denied access to a qualified sign language interpreter during two hospital stays in 2006."

In Section VI.10(b), page 114, the applicant states:

"The Office of Civil Rights completed its investigation in April 2010 and determined that Novant Health Charlotte Orthopaedic Hospital did not violate Section 504 of the Rehabilitation Act."

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

In Section VI.14, page 116, the applicant provides the projected payor mix for SDSC Franklin in Project Year Two (FFY 2018).

PAYOR	PROJECTED CASES AS % OF TOTAL CASES
Self Pay/ Indigent	2.36%
Commercial Insurance	3.05%
Medicare / Medicare Managed Care	38.84%
Medicaid	6.18%
Managed Care	45.10%
Other	4.47%
Total	100.0%

Exhibit 7 contains a copy of Novant Health Inc.'s Charity Care policies which the applicant states will be followed by SDSC Franklin.

The applicant demonstrates that medically underserved populations will have adequate access to the proposed services at SDSC Franklin. Therefore, 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

In Section VI.9(a), page 112, the applicant states, *“Typically, patients will have access to the services at SDSC Franklin by physician referral to a surgeon with privileges at SDSC Franklin. Outpatient surgery services will be available to any person upon referral and a written order from a licensed physician.”* The information provided is reasonable and credible and supports a finding of conformity with 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

In Section V.1(a), page 86, the applicant states that SDSC Franklin will provide clinical educational experiences to students of the following schools:

- Campbell University (Pharmaceutical Training)
- East Carolina University (Allied Health)
- Edgecombe Community College (Health Information Technology)
- Husson University (Physical Therapy)
- Nash Community College (EMS)
- Providence Training Institute (Phlebotomy)
- Richmond School of Health Technology (Health & Applied Sciences)
- St. Augustine University (Occupational Physician Therapy)
- Thomas Healthcare Institute (Phlebotomy & Lab Services)
- Vance Granville Community College (Nursing, Nursing Assistant, Pharmacy Technology, Phlebotomy, and Radiologic Technology)

The information provided is reasonable and credible and supports a finding of conformity with 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

The applicant proposes to relocate one existing OR from the hospital in Louisburg to the previously approved SDSC Franklin in Youngsville. The proposed project does not result in an increase in the total number of facilities or ORs located in Franklin County.

According to the 2014 SMFP, Franklin County has a total of 4 existing and approved ORs, as shown in the table below.

NUMBER OF OPERATING ROOMS BY TYPE					
FACILITY	IP	OP	SHARED	CON ADJUSTMENTS	TOTAL
Novant Health Franklin Regional Medical Center	0	0	3	0	3
SDSC Franklin	0	0	0	1	1
Total	0	0	3	1	4

In Section V.7, pages 93 - 101, the applicant discusses how any enhanced competition in the service area will have a positive impact on the cost-effectiveness, quality and access to outpatient surgical services for residents of the service area. See also Sections II, III, V, VI and VII in which the applicant discusses the impact of the project on cost-effectiveness, quality and access.

The information provided by the applicant in those sections is reasonable and credible and adequately demonstrates that any enhanced competition in the service area includes a positive impact on the cost-effectiveness, quality and access to the proposed services. This determination is based on the information in the application and the following analysis:

- The applicant adequately demonstrates the need to relocate one shared OR from the hospital to the previously approved SDSC Franklin, and that it is a cost-effective alternative;
- The applicant adequately demonstrates that it will continue to provide quality services; and
- The applicant demonstrates that it will continue to provide adequate access to medically underserved populations.

The application is conforming to this criterion.

- (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

The applicant proposes to relocate one existing shared OR from the hospital to the previously approved SDSC. The hospital is accredited by the Joint Commission and certified for Medicare and Medicaid participation. According to the records in the Acute and Home Care Licensure and Certification Section of the Division of Health Service Regulation, no incidents have occurred at Novant Health Franklin Regional Medical Center within the eighteen months immediately preceding the date of this decision for which any sanctions or penalties related to

quality of care were imposed by the State. 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

The Criteria and Standards for Surgical Services and Operating Rooms, promulgated in 10A NCAC 14C .2100, are applicable to this review. The specific criteria are discussed below.

SECTION .2100 – CRITERIA AND STANDARDS FOR SURGICAL SERVICES AND OPERATING ROOMS

.2102 INFORMATION REQUIRED OF APPLICANT

.2102(a) An applicant proposing to establish a new ambulatory surgical facility, to establish a new campus of an existing facility, to establish a new hospital, 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 identify each of the following specialty areas that will be provided in the facility:

- (1) gynecology;*
- (2) otolaryngology;*
- (3) plastic surgery;*
- (4) general surgery;*
- (5) ophthalmology;*
- (6) orthopedic;*
- (7) oral surgery; and*
- (8) other specialty area identified by the applicant.*

-NA- The applicant proposes to relocate one OR to the previously approved SDSC Franklin, a multispecialty ASC.

.2102(b) An applicant proposing to increase the number of operating rooms in a service area, 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 provide the following information:

(1) the number and type of operating rooms in each licensed facility which the applicant or a related entity owns a controlling interest in and is located in the service area (separately identifying the number of dedicated open heart and dedicated C-Section rooms);

(2) the number and type of operating rooms to be located in each licensed facility which the applicant or a related entity owns a controlling interest in and is located in the service area after completion of the proposed project and all previously approved projects related to these facilities (separately identifying the number of dedicated open heart and dedicated C-Section rooms);

(3) The number of inpatient surgical cases, excluding trauma cases reported by Level I, II and III trauma centers, cases reported by designated burn intensive care units, and cases performed in dedicated open heart and dedicated C-Section rooms, and the number of outpatient surgical cases performed in the most recent 12 month period for which data is available, in the operating rooms in each licensed facility listed in response to Subparagraphs (b)(1) and(b)(2) of this Rule:

(4) The number of inpatient surgical cases, excluding trauma cases reported by Level I, II and III trauma centers, cases reported by designated burn intensive care units, and cases performed in dedicated open heart and dedicated C-Section rooms, and the number of outpatient surgical cases projected to be performed in each of the first three operating years of the proposed project, in each licensed facility listed in response to Subparagraphs (b)(1) and (b)(2) of this Rule;

(5) A detailed description of and documentation to support the assumptions and methodology used in the development of the projections required by this Rule;

(6) The hours of operation of the proposed operating rooms;

(7) If the applicant is an existing facility, the average reimbursement received per procedure for the 20 surgical procedures most commonly performed in the facility during the preceding 12 months and a list of all services and items included in the reimbursement;

(8) *the projected average reimbursement to be received per procedure for the 20 surgical procedures which the applicant projects will be performed most often in the facility and a list of all services and items in the reimbursement; and*

(9) *identification of providers of pre-operative services and procedures which will not be included in the facility's charge.*

-NA- The applicant's proposal does not increase the number of existing and approved ORs in Franklin County.

.2102(c) *An applicant proposing to relocate existing or approved operating rooms within the same service area shall provide the following information:*

(1) *the number and type of existing and approved operating rooms in each facility in which the number of operating rooms will increase or decrease (separately identifying the number of dedicated open heart and dedicated C-Section rooms);*

-C - On page 20, the applicant provides the number and type of ORs at the hospital and SDSC Franklin, as shown below:

OPERATING ROOMS	EXISTING AND APPROVED OR CAPACITY	PROPOSED CHANGE	PROPOSED OR CAPACITY
SDSC FRANKLIN			
Ambulatory ORs	1	+1	2
NOVANT HEALTH FRANKLIN MEDICAL CENTER			
Shared ORs	3	-1	2
NOVANT HEALTH TOTAL OPERATING ROOMS IN FRANKLIN COUNTY			
Ambulatory Ors	1	+1	2
Shared ORs	3	-1	2
Total Operating Rooms	4	0	4

(2) *the number and type of operating rooms to be located in each affected facility after completion of the proposed project and all previously approved projects related to these facilities (separately identifying the number of dedicated open heart and dedicated C-Section rooms);*

-C- In Section II.10, page 21, the applicant provides a copy of the same table reproduced above. In addition, the applicant states:

“SDSC Franklin is a CON-approved multi-specialty freestanding ambulatory surgical center in Franklin County with one approved operating room.... NHFRMC is a licensed acute care hospital with three shared inpatient/outpatient operating rooms. Both SDSC Franklin in

Youngsville and Franklin Medical Center ('NHFRMC') in Louisburg are owned by Novant Health."

(3) the number of inpatient surgical cases, excluding trauma cases reported by Level I, II, or III trauma centers, cases reported by designated burn intensive care units, and cases performed in dedicated open heart and dedicated C-section rooms, and the number of outpatient surgical cases performed in the most recent 12 month period for which data is available, in the operating rooms in each facility listed in response to Subparagraphs (c)(1) and (c)(2) of this Rule;

- C- In Section II, page 22, the applicant provides the number of inpatient surgical cases and outpatient surgical cases performed in the most recent 12 month period (October 1, 2012 to September 30, 2013) at the hospital, as shown below:

SURGICAL CASES (UNWEIGHTED)	
Inpatient	109
Outpatient / Ambulatory	816
Total Surgical Cases	925

(4) the number of inpatient surgical cases, excluding trauma cases reported by level I, II, or III trauma centers, cases reported by designated burn intensive care units and cases performed in dedicated open heart and dedicated C-section rooms, and the number of outpatient surgical cases projected to be performed in each of the first three operating years of the proposed project, in each facility listed in response to Subparagraphs (c)(1) and (c)(2) of this Rule;

- C- In Section II, page 22, the applicant provides the number of surgical cases projected to be performed in each of the first three operating years of the proposed project at SDSC Franklin and the hospital, as shown below:

Same Day Surgery Center Franklin

	PY 1	PY 2	PY 3
Unweighted OP Cases	1,022	1,346	1,644

Novant Health Franklin Regional Medical Center

	PY 1	PY 2	PY 3
Unweighted IP Cases*	153	167	181
Unweighted OP Cases*	987	1,057	1,158
Total	1,140	1,161	1,339

***In the application, it is clear that the labels in the first two rows of the left column are "reversed."**

(5) a detailed description of and documentation to support the assumptions and methodology used in the development of the projections required by this Rule;

- C- See Section III, pages 43 – 69, and the tables provided in Exhibit 3 for the assumptions and methodology used in the development of the projections required by this Rule. See also Criterion (3) for discussion regarding utilization which is incorporated hereby as if set forth fully herein.

(6) the hours of operation of the facility to be expanded;

- C- In Section II.10, page 24, the applicant states that the hours of operation in Project Year One will be 6:00 AM to 3:00 PM, Monday through Friday. In Project Year Two, the hours of operation will be from 6:00 AM to 4:00 PM Monday through Friday. In Project Year Three, the hours of operation will be 6:00 AM to 5:00 PM, Monday through Friday.

(7) the average reimbursement received per procedure for the 20 surgical procedures most commonly performed in each affected facility during the preceding 12 months and a list of all services and items included in the reimbursement;

- C- See Section II.10, pages 24 – 25, for the 20 inpatient surgical procedures most commonly performed at the hospital. The applicant states that reimbursement includes the facility fee and the charges for the inpatient stay. Furthermore, the applicant states the reimbursement rates typically include OR time charges, recovery room time charges, pharmaceuticals, room charges, ER and implants, if applicable. On pages 25 – 26, the applicant provides the same information for the 20 outpatient surgical procedures most commonly performed at the hospital.

(8) the projected average reimbursement to be received per procedure for the 20 surgical procedures which the applicant projects will be performed most often in the facility to be expanded and a list of all services and items included in the reimbursement; and

- C- In Section II.10, page 26, the applicant provides the projected average reimbursement to be received per procedure for the 20 surgical procedures projected to be performed most often at SDSC Franklin.

9) identification of providers of pre-operative services and procedures which will not be included in the facility's charge.

- C- In Section II.10, page 27, the applicant states the pre-operative fees and procedures which will not be covered in the facility charge include per-

operative and post-operative anesthesia services, laboratory services, and radiology and pathology services. The separately covered fees will be billed to the patient by the provider of the service.

.2102(d) *An applicant proposing to establish a new single specialty separately licensed ambulatory surgical facility pursuant to the demonstration project in the 2010 State Medical Facilities Plan shall provide:*

(1) the single surgical specialty area in which procedures will be performed in the proposed ambulatory surgical facility;

(2) a description of the ownership interests of physicians in the proposed ambulatory surgical facility;

(3) a commitment that the Medicare allowable amount for self pay and Medicaid surgical cases minus all revenue collected from self-pay and Medicaid surgical cases shall be at least seven percent of the total revenue collected for all surgical cases performed in the proposed facility;

(4) for each of the first three full fiscal years of operation, the projected number of self-pay surgical cases;

(5) for each of the first three full fiscal years of operation, the projected number of Medicaid surgical cases;

(6) for each of the first three full fiscal years of operation, the total projected Medicare allowable amount for the self pay surgical cases to be served in the proposed facility, i.e. provide the projected Medicare allowable amount per self-pay surgical case and multiply that amount by the projected number of self pay surgical cases;

(7) for each of the first three full fiscal years of operation, the total projected Medicare allowable amount for the Medicaid surgical cases to be served in the facility, i.e. provide the projected Medicare allowable amount per Medicaid surgical case and multiply that amount by the projected number of Medicaid surgical cases;

(8) for each of the first three full fiscal years of operation, the projected revenue to be collected from the projected number of self-pay surgical cases;

(9) for each of the first three full fiscal years of operation, the projected revenue to be collected from the projected number of Medicaid surgical cases;

(10) for each of the first three full fiscal years of operation, the projected total revenue to be collected for all surgical cases performed in the proposed facility;

(11) a commitment to report utilization and payment data for services provided in the proposed ambulatory surgical facility to the statewide data processor, as required by G.S. 131E-214.2;

(12) a description of the system the proposed ambulatory surgical facility will use to measure and report patient outcomes for the purpose of monitoring the quality of care provided in the facility;

(13) descriptions of currently available patient outcome measures for the surgical specialty to be provided in the proposed facility, if any exist;

(14) if patient outcome measures are not currently available for the surgical specialty area, the applicant shall develop its own patient outcome measures to be used for monitoring and reporting the quality of care provided in the proposed facility, and shall provide in its application a description of the measures it developed;

(15) a description of the system the proposed ambulatory surgical facility will use to enhance communication and ease data collection, e.g. electronic medical records;

(16) a description of the proposed ambulatory surgical facility's open access policy for physicians, if one is proposed;

(17) a commitment to provide to the Agency annual reports at the end of each of the first five full years of operation regarding:

(A) patient payment data submitted to the statewide data processor as required by G.S. 131E-214.2;

(B) patient outcome results for each of the applicant's patient outcome measures;

(C) the extent to which the physicians owning the proposed facility maintained their hospital staff privileges and provided Emergency Department coverage, e.g. number of nights each physician is on call at a hospital; and

(D) the extent to which the facility is operating in compliance with the representations the applicant made in its application relative to the single specialty ambulatory surgical facility demonstration project in the 2010 State Medical Facilities Plan.

- NA- The applicant does not propose to establish a new single specialty separately licensed ambulatory surgical facility pursuant to the demonstration project in the 2010 State Medical Facilities Plan.

.2103 PERFORMANCE STANDARDS

- .2103(a) *In projecting utilization, the operating rooms shall be considered to be available for use five days per week and 52 weeks per year.*

- C- In Section II.10, page 29, the applicant states that SDSC Franklin will be available for use at least five days per week and 52 weeks per year.

- .2103(b) *A proposal to establish a new ambulatory surgical facility, to establish a new campus of an existing facility, to establish a new hospital, to increase the number of operating rooms in an existing facility (excluding dedicated C-section operating rooms), to convert a specialty ambulatory surgical program to a multispecialty ambulatory surgical program or to add a specialty to a specialty ambulatory surgical program shall:*

(1) demonstrate the need for the number of proposed operating rooms in the facility, which is proposed to be developed or expanded, in the third operating year of the project is based on the following formula: $\{[(\text{Number of facility projected inpatient cases, excluding trauma cases reported by Level I or II trauma centers, cases reported by designated burn intensive care units and cases performed in dedicated open heart and C-Section rooms, times 3.0 hours}) \text{ plus } (\text{Number of facilities projected outpatient cases times 1.5 hours}) \text{ plus } (\text{Number of facility's projected outpatient cases times 1.5 hours})] \text{ divided by } 1,872 \text{ hours}\}$ minus the facility's total number of existing and approved operating rooms and operating rooms proposed in another pending application, excluding one operating room for level I or II trauma centers, one operating room for facilities with designated burn intensive care units, and all dedicated open heart and C-section operating rooms or demonstrate conformance of the proposed project to Policy AC-3 in the State Medical Facilities Plan titled "Exemption From Plan Provisions for Certain Academic Medical Center Teaching Hospital Projects;" and

(2) The number of rooms needed is determined as follows:

(A) in a service area which has more than 10 operating rooms, if the difference is a positive number greater than or equal to 0.5, then the need is the next highest whole number for fractions of 0.5 or greater and the next lowest whole number for fractions less than 0.5; and if the difference is a negative number less than 0.5, then the need is zero;

(B) in a service area which has 6 to 10 operating rooms, if the difference is a positive number greater than or equal to 0.3, then the need is the next highest whole number for fractions of 0.3 or greater and the next lowest whole number for fractions less than 0.3, and if the difference is a negative number or a positive number less than 0.3, the need is zero; and

(C) in a service area which has five or fewer operating rooms, if the difference is a positive number greater than or equal to 0.2, then the need is the next highest whole number for fractions of 0.2 or greater and the next lowest whole number for fractions of less than 0.2; and the difference is a negative number or a positive number less than 0.2, the need is zero; or

-NA- The applicant proposes to relocate an existing shared OR from the hospital in Louisburg to the previously approved SDSC Franklin in Youngsville. The applicant does not propose to increase the number of ORs in an existing facility, since SDSC Franklin does not yet exist.

.2103(c) *A proposal to increase the number of operating rooms (excluding dedicated C-Sections operating rooms) in a service area shall:*

(1) demonstrate the need for the number of proposed operating rooms in addition to the rooms in all of the licensed facilities identified in response to 10A NCAC 14C .2102(b)(2) in the third operating year of the proposed project based on the following formula: {[(Number of projected inpatient cases for all the applicant's or related entities' facilities, excluding trauma cases report by Level I or II trauma centers, cases reported by designated burn intensive care units and cases performed in dedicated open heart and C-section rooms, times 3.0 hours) plus (Number of projected outpatient cases for all the applicant's or related entities' times 1.5 hours)] divided by 1,872 hours} minus the total number of existing and approved operating rooms and operating rooms proposed in another pending application, excluding one operating room for Level I or II trauma centers, one operating room for facilities with designated burn intensive care units, and all dedicated open heart and C-section operating rooms in all of the applicant's or related entities' licensed facilities in the service area; and

(2) The number of rooms needed is determined as follows:

(A) in a service area which has more than 10 operating rooms, if the difference is a positive number greater than or equal to 0.5, then the need is the next highest whole number for fractions of 0.5 or greater and the next lowest whole number for fractions less than 0.5; and if the

difference is a negative number or a positive number less than 0.5, the need is zero;

(B) in a service area which has 6 to 10 operating rooms, if the difference is a positive number greater than or equal to 0.3, then the need is the next highest whole number for fractions of 0.3 or greater and the next lowest whole number for fractions less than 0.3, and if the difference is a negative number or a positive number less than 0.3, the need is zero; and

(C) in a service area which has five or fewer operating rooms, if the difference is a positive number greater than or equal to 0.2, then the need is the next highest whole number for fractions of 0.2 or greater and the next lowest whole number for fractions of less than 0.2; and if the difference is a negative number or a positive number less than 0.2, the need is zero.

- NA- The applicant does not propose to increase the number of ORs in Franklin County.
- .2103(d) *An applicant that has one or more existing or approved dedicated C-section operating rooms and is proposing to develop an additional dedicated C-section operating room in the same facility shall demonstrate that an average of at least 365 C-sections per room were performed in the facility's existing dedicated C-section operating rooms in the previous 12 months and are projected to be performed in the facility's existing, approved and proposed dedicated C-section rooms during the third year of operation following completion of the project.*
- NA- The applicant does not have a dedicated C-section OR and does not propose to develop a dedicated C-section OR.
- .2103(e) *An applicant proposing to convert a specialty ambulatory surgical program to a multispecialty ambulatory surgical program or to add a specialty to a specialty ambulatory surgical program shall:*
- (1) provide documentation to show that each existing ambulatory surgery program in the service area that performs ambulatory surgery in the same specialty area as proposed in the application is currently utilized an average of at least 1,872 hours per operating room per year, excluding dedicated open heart and C-Section operating rooms. The hours utilized per operating room shall be calculated as follows: [(Number of projected inpatient cases, excluding open heart and C-sections performed in dedicated rooms times 3.0 hours) plus (Number of projected outpatient cases times 1.5 hours)] divided*

by the number of operating rooms, excluding dedicated open heart and C-Section operating rooms; and

(2) demonstrate the need in the third operating year of the project based on the following formula: [Total number of projected outpatient cases for all ambulatory surgery programs in the service area times 1.5 hours) divided by 1,872 hours] minus the total number of existing, approved and proposed outpatient or ambulatory surgical operating rooms and shared operating rooms in the service area. The need for the conversion is demonstrated if the difference is a positive number greater than or equal to one, after the number is rounded to the next highest number for fractions of 0.50 or greater.

-NA- The applicant does not propose to convert a specialty ambulatory surgical program to a multispecialty ambulatory surgical program.

.2103(f) *The applicant shall document the assumptions and provide data supporting the methodology used for each projection in this Rule.*

-NA- There are no projections required in this Rule that are applicable to SDSC Franklin. Nevertheless, in Section III, the applicant provides a description of the assumptions and methodology used in the development of the projections provided in this application. See Criterion (3) for discussion of projected utilization which is incorporated hereby as if set forth fully herein.

.2104 SUPPORT SERVICES

.2104(a) *An applicant proposing to establish a new ambulatory surgical facility, a new campus of an existing facility, or a new hospital shall provide copies of the written policies and procedures that will be used by the proposed facility for patient referral, transfer, and follow-up.*

-NA- The applicant does not propose to establish a new ASC, a new campus of an existing facility or a new hospital.

.2104(b) *An applicant proposing to establish a new ambulatory surgical facility, a new campus of an existing facility, or a new hospital shall provide documentation showing the proximity of the proposed facility to the following services:*

- (1) emergency services;*
- (2) support services;*
- (3) ancillary services; and*
- (4) public transportation.*

-NA- The applicant does not propose to establish a new ASC, a new campus of an existing facility or a new hospital.

.2105 STAFFING AND STAFF TRAINING

.2105(a) *An applicant proposing 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 a facility, 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 identify, justify and document the availability of the number of current and proposed staff to be utilized in the following areas:*

- (1) *administration;*
- (2) *pre-operative;*
- (3) *post-operative;*
- (4) *operating room; and*
- (5) *other.*

-C- The applicant provides the proposed staffing for the previously approved SDSC Franklin in Section VII.2, page 119, in each area listed above.

.2105(b) *The applicant shall identify the number of physicians who currently utilize the facility and estimate the number of physicians expected to utilize the facility and the criteria to be used by the facility in extending surgical and anesthesia privileges to medical personnel.*

-C- SDSC Franklin, although previously approved, is not an existing facility and therefore has no physicians who currently use the facility. However, on page 36, the applicant provides the number of physicians expected to utilize the ASC: 9 surgeons, 1 – 2 anesthesiologists, 1 – 5 radiologists, and 1 pathologist. On page 37, the applicant describes the criteria to be used to extend privileges. See Exhibit 4 for the medical staff bylaws.

.2105(c) *The applicant shall provide documentation that physicians with privileges to practice in the facility will be active members in good standing at a general acute care hospital within the service area in which the facility is, or will be, located or documentation of contacts the applicant made with hospitals in the service area in an effort to establish staff privileges.*

-C- In Section II.10, page 36, the applicant states several surgeons who have expressed support for the facility are currently credentialed at the hospital. Other physicians and surgeons are members in good standing at other hospitals located in Wake County, such as Rex, WakeMed and Duke Health Raleigh Hospital.

.2105(d) *The applicant shall provide documentation that physicians owning the proposed single specialty demonstration facility will meet Emergency Department coverage responsibilities in at least one hospital within the*

service area, or documentation of contacts the applicant made with hospitals in the service area in an effort to commit its physicians to assume Emergency Department coverage responsibilities.

-NA- The applicant does not propose to establish a new single specialty separately licensed ambulatory surgical facility.

.2106 FACILITY

.2106(a) *An applicant proposing to establish a licensed ambulatory surgical facility that will be physically located in a physician's or dentist's office or within a general acute care hospital shall demonstrate that reporting and accounting mechanisms exist and can be used to confirm that the licensed ambulatory surgery facility is a separately identifiable entity physically and administratively, and is financially independent and distinct from other operations of the facility in which it is located.*

-NA- The applicant does not propose to establish a licensed ambulatory surgical facility that will be physically located in a physician's or dentist's office or within a general acute care hospital.

.2106(b) *An applicant proposing a licensed ambulatory surgical facility or a new hospital 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 of completion of the facility.*

-C- The applicant states that it will seek accreditation from an appropriate accreditation authority within two years of completion of the facility. See the letter in Exhibit 4 which documents a commitment to meet this requirement.

.2106(c) *All applicants shall document that the physical environment of the facility to be developed or expanded conforms to the requirements of federal, state, and local regulatory bodies.*

-C- In Section II.10, page 38, the applicant states, "*See the letter from Laura McFadden, which documents that the physical environment of SDSC Franklin will be developed to conform to the requirements of federal, state, and local regulatory bodies.*" Exhibit 4 contains a letter from Laura McFadden which verifies compliance with the standards as required above.

.2106(d) *An applicant proposing to establish a new ambulatory surgical facility, a new campus of an existing facility or a new hospital shall provide a provide a floor plan of the proposed facility identifying the following areas:*
(1) *receiving/registering area;*

- (2) *waiting area;*
- (3) *pre-operative area;*
- (4) *operating room by type;*
- (5) *recovery area; and*
- (6) *observation area.*

-NA- The applicant does not propose to establish a new ASC, a new campus of an existing facility or a new hospital.

.2106(e) *An applicant proposing to expand by converting a specialty ambulatory surgical program to a multispecialty ambulatory surgical program or by adding a specialty to a specialty ambulatory surgical program that does not propose to add physical space to the existing ambulatory surgical facility shall demonstrate the capability of the existing ambulatory surgical program to provide the following for each additional specialty area:*

- (1) *physicians;*
- (2) *ancillary services;*
- (3) *support services;*
- (4) *medical equipment;*
- (5) *surgical equipment;*
- (6) *receiving/registering area;*
- (7) *clinical support areas;*
- (8) *medical records;*
- (9) *waiting area;*
- (10) *pre-operative area;*
- (11) *operating rooms by type;*
- (12) *recovery area; and*
- (13) *observation area.*

-NA- The applicant does not propose to expand by converting a specialty ambulatory surgical program to a multispecialty ambulatory surgical program or by adding a specialty to a specialty ambulatory surgical program.