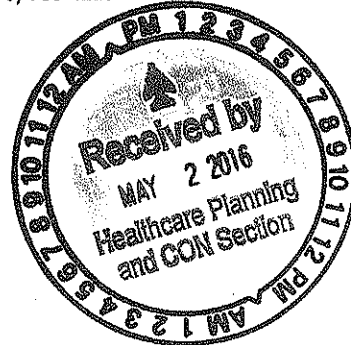


Sullivan Consulting Group, Inc.

2090 Bethany Way · Alpharetta, Georgia 30004 · (770) 753-4222 · Fax: (770) 753-4223

May 2, 2016

Martha Frisone
Certificate of Need Section
Division of Health Service Regulation
809 Ruggles Drive
Raleigh, NC 27603



**RE: Novant Health Kernersville Outpatient Surgery, LLC
Project G-011150-16**

Dear Ms. Frisone:

On behalf of Surgical Center of Greensboro and Greensboro Specialty Surgical Center, existing providers of ambulatory surgical services in Guilford County, North Carolina, I am submitting comments regarding the above-captioned Certificate of Need Application submitted by Novant Health Kernersville Outpatient Surgery, LLC ("NHKOS") to develop an ambulatory surgery center with two operating rooms in Kernersville, Forsyth County, North Carolina.

Pursuant to N.C. Gen. Stat. § 131E-185(a1)(2), Surgical Center of Greensboro and Greensboro Specialty Surgical Center hereby request a public hearing to be conducted on NHKOS' application.

I appreciate your consideration of this information.

Sincerely,

A handwritten signature in cursive script that reads 'Daniel J. Sullivan'.

Daniel J. Sullivan
President

Attachment

Novant Health Kernersville Outpatient Surgery, LLC
Project G-011150-16
Opposition Comments
on Behalf of
Surgical Center of Greensboro and Greensboro Specialty Surgical Center

Novant Health Kernersville Outpatient Surgery, LLC (“the Applicant” or “NHKOS”) is seeking Certificate of Need (“CON”) approval to relocate 2 existing operating rooms (“ORs”) from Novant Health Forsyth Medical Center (“NHFMC”) in Winston-Salem, NC (Forsyth County) to the proposed, separately licensed multi-specialty ambulatory surgical facility called Novant Health Kernersville Outpatient Surgery (“NHKOS”) located in Kernersville, NC on the campus of Novant Health Kernersville Medical Center (“NHKMC”).

NHKOS claims that the proposed facility will be the only freestanding, separately licensed surgery center in Forsyth County at the time it is developed (CON application, p. 2), but this claim is misleading. Novant Health operates two hospital-based surgery centers in Forsyth County that are in freestanding buildings that it chose to place under the license of Novant Health Forsyth Medical Center, rather than separately license them as freestanding facilities. These two facilities are Novant Health Hawthorne Outpatient Surgery and Novant Health Orthopedic Surgery. In addition, there are two other single-specialty ambulatory surgery centers (“ASCs”) in Forsyth County, Plastic Surgery Center of North Carolina and Piedmont Outpatient Surgery Center¹.

NHKOS includes Guilford County in its service area. Guilford County has a number of freestanding, separately licensed ASCs and hospital-based surgery centers, which are underutilized, including Surgical Center of Greensboro (“SCG”) and Greensboro Specialty Surgical Center (“GSSC”). As a result, NHKOS does not bring a new service or increase access to the residents of Forsyth or Guilford County for outpatient surgery services. Rather, it incurs significant capital expense in order to relocate underutilized, existing ORs in an effort to serve a population that already has ample access to outpatient surgery services.

The application should be denied based on the following:

- The claim that NHKMC requires additional OR capacity is not supported by the information presented in the NHKOS application. The projections of utilization for NHKMC, which are the basis for the NHKOS utilization projections are based on unreasonable assumptions.
- Access to freestanding ASCs will not be materially improved by this project. The population that NHKOS seeks to serve, which primarily is in Guilford County, already enjoys excellent access to outpatient surgical services at hospital-based and freestanding providers.

¹Piedmont Outpatient Surgery Center provides only otolaryngology, a surgery that is approved as a demonstration project and not counted in the inventory of operating rooms in the State Medical Facilities Plan. The center nonetheless serves residents of Forsyth County in a freestanding ASC environment.

- The Applicant fails to consider the availability of other providers in its analysis of need for the project, instead focusing exclusively on the institution-specific desires of Novant Health.
- The project represents an unnecessary duplication of existing health care resources.
- NHKOS will undoubtedly adversely impact existing providers, including SCG and GSSC.
- The application fails to conform with multiple review criteria based on the reasons above and others outlined in the following analysis.

Pursuant to N.C. Gen. Stat. § 131E-185(a1)(2), SCG and GSSC hereby request a public hearing to be conducted on NHKOS' application.

II. Review Criteria for New Institutional Health Services

The 2016 SMFP contains general policies applicable to review of all applications. The NHKOS projects fails to satisfy Policy GEN-3.

Policy GEN-3: Basic Principles

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

NHKOS is proposing to develop a new institutional health service for which there is a determination of need in the SMFP, although this application does not implicate the specific OR need calculation because it proposes to relocate ORs. The project will not promote equitable access because there is simply no access problem with respect to ambulatory surgical services in the area NHKOS proposes to serve. There are a number of different ambulatory surgical providers with abundant available capacity to address current and future needs.

As a starting point, NHKOS has not defined a reasonable service area for its project. A central theme of its application is that NHKOS will serve to offload some of the ambulatory surgery volume at NHKMC, which will permit NHKMC to accommodate projected growth in surgical demand. Rather than base the NHKMC service area definition on the ZIP Codes from which NHKMC historically has drawn the majority of its patients, the application states "NHKOS Target Market Area [was] defined by Novant Health's Greater Winston-Salem Market Business

& Strategic Planning staff and is based upon patient origin, market share, and input from leadership at Novant Health.” See CON application, p. 24.

Exhibit 1 presents a map of NHKOS’s proposed “target market area,” which includes ZIP Codes in both Forsyth and Guilford Counties. The locations of existing hospitals and other ambulatory surgery providers are also shown, and as is evident, there a number of existing providers located in proximity to NHKMC’s campus where NJKOS will be located.

Exhibit 1
Novant Health Kernersville Outpatient Surgery
Target Market Area

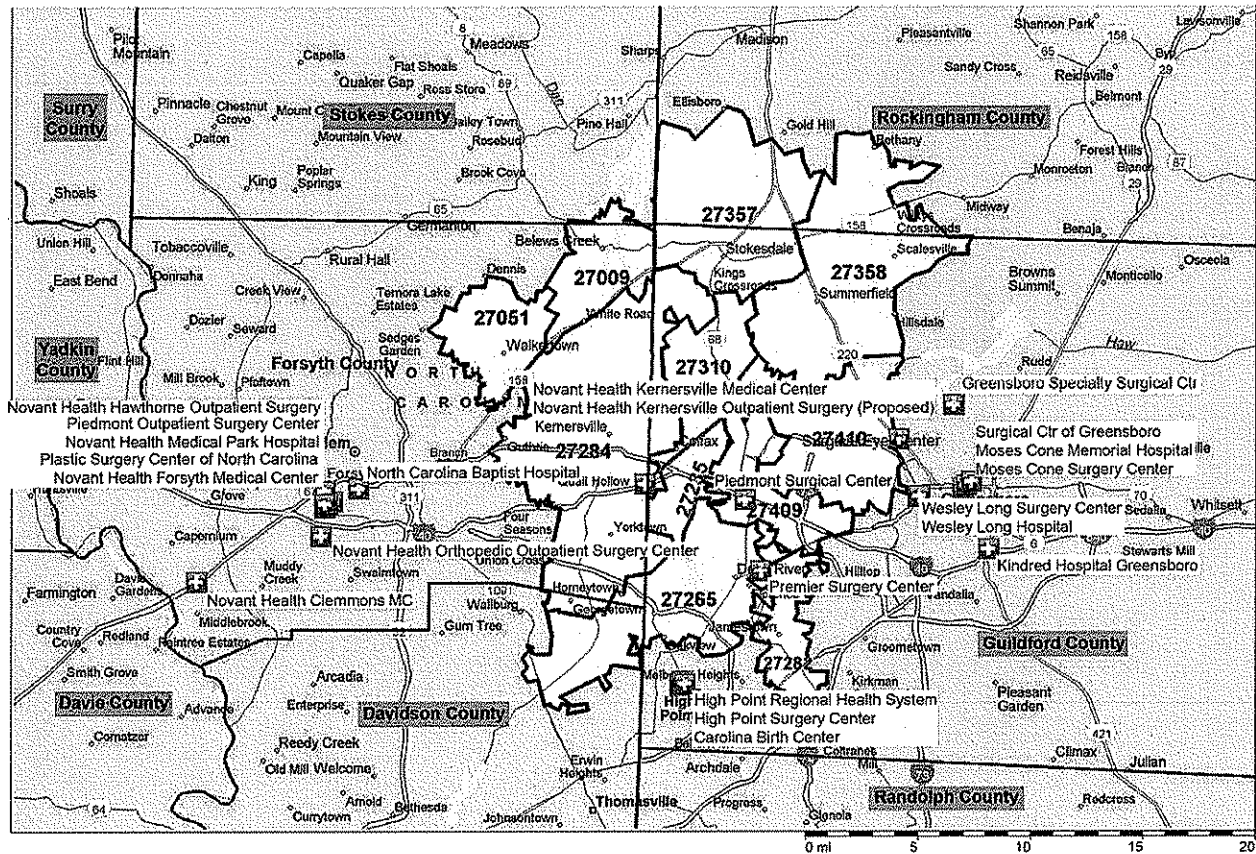


Exhibit 2 presents NHKMC’s FFY2015 outpatient surgery patient origin by ZIP Code for NHKMC. The ZIP Codes included in NHKOS’ target market area are highlighted. What is apparent is that NHKOS has excluded a number of ZIP Codes from which NHKMC has historically drawn material percentages of outpatient surgeries in favor of ZIP Codes that more neatly fit a service area that NHKMC would like to claim so as to avoid showing a number of existing surgical providers within its true service area. In fact, four of the top ten ZIP Codes on which NHKMC had the highest reliance for outpatient surgeries were excluded from the target market area, all of which are in Forsyth County near existing outpatient surgery providers. What is particularly illogical about the approach taken in defining the project’s service area is that

NHKOS will be located on the campus of NHKMC and ostensibly staffed by the same surgeons who perform surgery at NHKMC. There is no reason to expect NHKOS' service area to differ significantly from that of NHKMC.

Exhibit 2
Novant Health Kernersville Medical Center (NHKMC)
Historical ZIP Code Level Outpatient Surgery Patient Origin
FFY2015

ZIP Code	Town	County	Cases	Patient Origin %	Cumulative %
27284	Kernersville	Forsyth County	1,247	38.5%	38.5%
27107	Winston Salem	Forsyth County	226	7.0%	45.5%
27265	- High Point	Guilford County	124	3.8%	49.3%
27051	Walkertown	Forsyth County	117	3.6%	52.9%
27105	Winston Salem	Forsyth County	70	2.2%	55.1%
27101	Winston Salem	Forsyth County	62	1.9%	57.0%
27127	Winston Salem	Forsyth County	60	1.9%	58.9%
27357	Stokesdale	Guilford County	59	1.8%	60.7%
27009	Belews Creek	Forsyth County	58	1.8%	62.5%
27235	Colfax	Guilford County	54	1.7%	64.2%
27106	Winston Salem	Forsyth County	49	1.5%	65.7%
27262	High Point	Guilford County	42	1.3%	67.0%
27310	Oak Ridge	Guilford County	40	1.2%	68.2%
27012	Clemmons	Forsyth County	37	1.1%	69.3%
27104	Winston Salem	Forsyth County	33	1.0%	70.3%
27045	Rural Hall	Forsyth County	32	1.0%	71.3%
27103	Winston Salem	Forsyth County	32	1.0%	72.3%
27410	Greensboro	Guilford County	27	0.8%	73.1%
27407	Greensboro	Guilford County	26	0.8%	73.9%
27285	Kernersville	Forsyth County	25	0.8%	74.7%
27260	High Point	Guilford County	25	0.8%	75.5%
27023	Lewisville	Forsyth County	23	0.7%	76.2%
27358	Summerfield	Guilford County	21	0.6%	76.8%
27405	Greensboro	Guilford County	19	0.6%	77.4%
27406	Greensboro	Guilford County	19	0.6%	78.0%
27409	Greensboro	Guilford County	17	0.5%	78.5%
27282	Jamestown	Guilford County	16	0.5%	79.0%
27040	Pfafftown	Forsyth County	15	0.5%	79.5%
27050	Tobaccoville	Forsyth County	15	0.5%	80.0%
27455	Greensboro	Guilford County	9	0.3%	80.3%

ZIP Code	Town	County	Cases	Patient Origin %	Cumulative %
27214	Browns Summit	Guilford County	8	0.2%	80.5%
27313	Pleasant Garden	Guilford County	6	0.2%	80.7%
27403	Greensboro	Guilford County	6	0.2%	80.9%
27401	Greensboro	Guilford County	4	0.1%	81.0%
27408	Greensboro	Guilford County	4	0.1%	81.1%
27114	Winston Salem	Forsyth County	3	0.1%	81.2%
27301	McLeansville	Guilford County	3	0.1%	81.3%
27264	High Point	Guilford County	2	0.1%	81.4%
27120	Winston Salem	Forsyth County	1	0.0%	81.4%
27249	Gibsonville	Guilford County	1	0.0%	81.4%
27417	Greensboro	Guilford County	1	0.0%	81.4%
All Other			603	18.6%	100.0%
Grand Total			3,241	25.9%	

Source: NHKOS Application, Exhibit 3, Table 10

The ZIP Codes that were included in the target market area represented only 55.5% of NHKMC's FFY2015 outpatient surgeries. **Exhibit 3** presents a more logical definition of NHKOS's service area based on a rank order of the ZIP Codes in terms of the percentage of outpatient surgeries each provided to NHKMC. The service area ZIP Codes are highlighted, and reflect 75.5% of NHKMC's historical outpatient surgery cases, which is more typical of a service area definition.

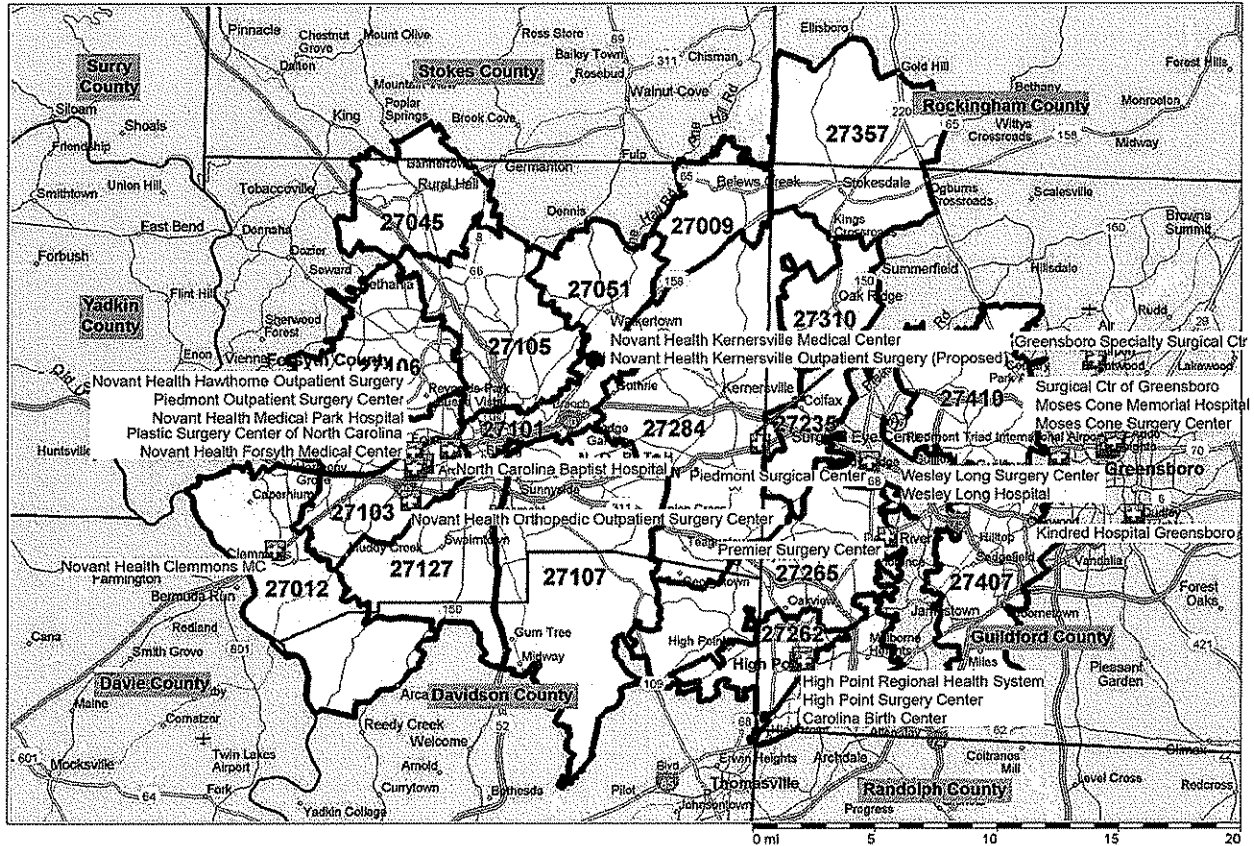
Exhibit 3
Novant Health Kernersville Medical Center Revised Service Area Definition
FFY2015

ZIP Code	Town	County	Cases	Patient Origin %	Cumulative %
27284	Kernersville	Forsyth County	1,247	38.5%	38.5%
27107	Winston Salem	Forsyth County	226	7.0%	45.5%
27265	- High Point	Guilford County	124	3.8%	49.3%
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ZIP Code	Town	County	Cases	Patient Origin %	Cumulative %
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All Other			603	18.6%	100.0%
Grand Total			3,241	25.9%	

Exhibit 4 maps the revised service area definition, which presents a much different picture than the fabricated one presented in the CON application.

**Exhibit 4
Actual Novant Health Kernersville Outpatient Surgery**



NHKOS' failure to adopt of reasonable service area definition means that any analyses presented in the application regarding access to or utilization of ambulatory surgical services are fundamentally flawed. NHKOS accordingly fails to satisfy Policy GEN-3.

(1) Consistency with the State Medical Facilities Plan

The NHKOS project does not directly conflict with a need determination outlined by the 2016 SMFP because it does not propose to add ORs. This project does, however, represents an unnecessary duplication of existing services and is a wasteful use of resources in constructing a new ASC in an area with excellent access to existing ambulatory surgical providers, several of which are underutilized.

(3) Populations to be Served and Need for the Project

The specific language of this criterion is:

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

As noted above, NHKOS has not reasonably defined the service area for its project. As a consequence, all of the analysis presented in its application regarding the population to be served and the need for the project is similarly flawed.

The application does not address the need for its proposal in terms of locations of existing ambulatory surgical providers, their available capacity, or their ability to serve as alternatives to the proposed project. The NHKOS application is written solely from the institution-specific perspective, considering only Novant Health's desires with respect redistributing its services to redirect patients away from other providers. This institution-specific approach conflicts directly with this criterion that requires applicants to consider need from a community, population-based perspective, particularly when proposing the development of a new health care facility such as NHKOS

Historical Utilization of Existing ORs

An important consideration in assessing the need for a new ASC is the utilization of existing providers. **Exhibit 5** (next page) presents the most recent inventory and utilization data for operating rooms in Forsyth and Guilford Counties for 2015. Utilization rates are based on the standards in the SMFP of 3.0 hours per inpatient surgical case and 1.5 hours per outpatient surgical case. The average operating room is anticipated to be staffed nine hours a day, for 260 days per year per the SMFP.

Exhibit 5

2015 Operating Room Utilization Forsyth and Guilford Counties

County	Facility	Inpatient Cases (Dedicated C- Section Cases Excluded)	Ambulatory Cases	Inpatient ORs	Ambulatory ORs	Shared ORs	Surgical Hours	Available Hours	Utilization Rate
Forsyth	Clemmons Medical Medical Center	-	1,019	-	3	-	1,529	5,616	0.0%
Forsyth	Plastic Surgery Center of North Carolina	-	171	-	3	-	257	7,020	3.7%
Forsyth	Piedmont Outpatient Surgery Center, LLC (Special Demonstration)	-	2,224	-	2	-	3,336	4,680	71.3%
Forsyth	North Carolina Baptist Hospital*	14,214	19,549	4	-	36	71,966	93,600	76.9%
Forsyth	Novant Health Forsyth Medical Center	8,665	5,552	3	-	18	34,323	49,140	69.8%
Forsyth	Novant Health Kernersville Medical Center	854	2,347	-	-	4	6,083	9,360	65.0%
Forsyth	Novant Health Hawthorne Outpatient Surgery	-	6,037	-	4	-	9,056	9,360	96.7%
Forsyth	Novant Health Orthopedic Outpatient Surgery	-	2,491	-	2	-	3,737	4,680	79.8%
Forsyth	Novant Health Medical Park Hospital	897	8,613	0	0	12	15,611	28,080	55.6%
Forsyth Total		24,630	48,003	7	14	70	145,895	211,536	69.0%
Guilford	Premier Surgery Center	-	-	-	-	-	-	-	-
Guilford	Greensboro Specialty Surgical Center	0	2,583	0	3	0	3,875	7,020	55.2%
Guilford	Carolina Birth Center	0	5	0	1	0	8	2,340	0.3%
Guilford	Surgical Center of Greensboro	0	12,994	0	13	0	19,491	30,420	64.1%
Guilford	Surgical Eye Center*	0	2,528	0	4	0	3,792	9,360	40.5%
Guilford	High Point Surgery Center*	0	4,858	0	6	0	7,287	14,040	51.9%
Guilford	Piedmont Surgical Center	0	380	0	2	0	570	4,680	12.2%
Guilford	High Point Regional Health System	2,667	2,558	3	1	9	11,838	30,420	38.9%
Guilford	Kindred Hospital - Greensboro	227	3	0	0	1	686	2,340	29.3%
Guilford	Cone Health**	13,014	16,229	4	13	37	63,386	126,360	50.2%
Guilford Total		15,908	42,138	7	43	47	110,931	226,980	48.9%

*Reflects data from 2015 Licensure Renewal Applications

**Cone Health was approved to delicense 4 ORs as part of its project to consolidate the services of the Women's Hospital on the Cone Campus (G-11104-15); as part of this project, Cone will delicense 4 Ors.

Sources: 2016 Licensure Renewal Applications and 2016 SMFP

This utilization data underscores several key aspects of OR utilization in Forsyth and Guilford Counties:

- There is considerable unused capacity of ORs in Forsyth and Guilford, with Forsyth's 2015 overall utilization rate at 69.0% and Guilford at only 48.9%.
- Despite the claims in the CON application of the need for additional ORs at NHKMC, NHKMC's utilization rate of its 4 existing ORs was only 65%.

- Novant Health Forsyth Medical Center, the facility from which the 2 ORS will be transferred to create NHKOS, had a higher OR utilization rate in 2015 (69.8%) than NHKMC.
- Novant Health’s two hospital-based outpatient surgery centers in Forsyth County, Novant Health Hawthorne Outpatient Surgery and Novant Health Orthopedic Outpatient Surgery were utilized near or above the 80% target in the SMFP. Inexplicably, Novant Health did not propose to relocate OR capacity to these well-utilized facilities, but instead to the underutilized NHKMC.
- Guilford County surgical providers had materially lower utilization rates than Forsyth County providers. All of the freestanding ASCs in Guilford County have substantial unused capacity.
- Cone Health recently received CON approval to consolidate the services of its Women’s Hospital on the Moses Cone Memorial Hospital campus. Because of the low utilization of its combined operating rooms, it agreed to delicense and eliminate 4 ORs from its total.

Despite this utilization profile indicating substantial unused capacity, which NHKOS apparently never considered, NHKOS has targeted a population that that resides primarily in Guilford County despite the greater underutilization of its existing OR capacity. As presented in **Exhibit 6**, NHKOS’ market area in 2016 includes 177,011 residents of Guilford county and only 65,106 Forsyth residents. This disparity will increase by 2021 with the Guilford population growing to 188,795 while the Forsyth increases to only 68,491. **Exhibit 7** displays the distribution of population in the NHKOS market area. By 2021 the Guilford potion of the market will represent 73% of the total, with Forsyth comprising only 27%.

Exhibit 6
Projected Population
Novant Health Kernersville Outpatient Surgery
Market Area

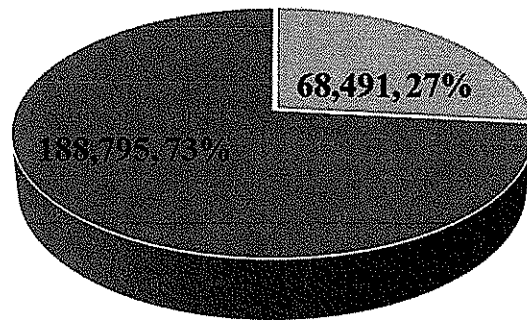
ZIP Code	Town	2016 Population	2021 Population	5 Year Growth	Average Annual Growth
Forsyth					
27009	Belews Creek	2,967	3,074	3.6%	0.7%
27051	Walkertown	7,552	7,795	3.2%	0.6%
27284	Kernersville	54,587	57,622	5.6%	1.1%
Forsyth Total		65,106	68,491	5.2%	1.0%

ZIP Code	Town	2016 Population	2021 Population	5 Year Growth	Average Annual Growth
Guilford					
27235	Colfax	4,767	5,176	8.6%	1.7%
27265	High Point	50,975	54,917	7.7%	1.5%
27282	Jamestown	16,076	16,807	4.5%	0.9%
27310	Oak Ridge	7,543	8,252	9.4%	1.9%
27357	Stokesdale	8,338	8,593	3.1%	0.6%
27358	Summerfield	14,974	16,079	7.4%	1.5%
27409	Greensboro	17,690	18,954	7.1%	1.4%
27410	Greensboro	56,648	60,017	5.9%	1.2%
Guilford Total		177,011	188,795	6.7%	1.3%
Total Market Area		242,117	257,286	6.3%	1.2%

Source: NC OSBM 2.6.16; Claritas (CON Application, p. 34)

Exhibit 7

**NHKOS Market Area
2021 ZIP Code Population by County**



■ Forsyth ■ Guilford

Source: Exhibit 6

Projected Utilization

NHKOS' attempt to document the need for its project is heavily focused on the historical growth in surgical volume at NHKMC and the projections of future surgical volumes. The Applicant's primary contention is that future growth will surpass the capacity of NHKMC's 4 existing ORs, and that the relocation of 2 ORs to its campus will provide another outlet for serving these

patients. Unfortunately, the projections presented in its application are based on unrealistic assumptions about future growth of outpatient and inpatient surgeries at NHKMC.

The starting point of its analysis is the consideration of the historical trends in inpatient surgical utilization growth at NHKMC, which is reproduced in **Exhibit 8**.

Exhibit 8
Historical Inpatient Surgical Growth
Novant Health Kernersville Medical Center

Year	Total CY Trendstar	Growth Rate	Total FFY Trendstar	Growth Rate	Total FFY LRA	Growth
2011					126	
2012	330		310		346	174.6%
2013	591	79.1%	531	71.3%	601	73.7%
2014	720	21.8%	673	26.7%	766	27.5%
2015	901	25.1%	837	24.4%	854	11.5%
		42.0%		40.8%		37.5%

Source: Exhibit 3, Table 3 (CON Application, p. 39)

The data in Exhibit 8 is presented from two different sources and two different timeframes. The following explanation was presented in the application for the consideration of two different data sources:

From the time NHKMC opened in March 2011 through July 2014, surgical data for the Annual LRA was reported using the surgical reporting system, Compass. This data reflected inpatient and outpatient case volume based upon whether the patient was "scheduled" as an inpatient or an outpatient and was measured based on the date of surgery. If patient status changed after surgery, such as, an inpatient did better than expected and was discharged in less than 24 hours, or an outpatient was admitted, the reported data did not reflect the change. In July 2014, the EPIC electronic health record system was implemented at NHKMC, allowing a more accurate reporting of inpatient and outpatient cases and this method tracked cases based on the date of discharge. The change in data system explains the FFY variances between LRA and Trendstar data for inpatient and outpatient volumes in 2012 to 2014. However, total surgical cases during this timeframe varied less than 3% annually. Data for 2015 is comparable and therefore, more current 2015 Trendstar calendar year data was determined to be reasonable for use in this Application.

See CON application, p. 25.

NHKOS has chosen the data source that reflects a lower number of inpatient surgical cases and, as will be discussed below, a higher number of outpatient surgical cases, which obviously is beneficial in projecting volume for an ASC that relies on redirection of cases from NHKMC.

These historical trends were used to project future utilization growth. **Exhibit 9** summarizes NHKMC’s projected growth in inpatient surgeries.

Exhibit 9

Novant Health Kernersville Medical Center								
Projected Incremental Growth in Inpatient Surgical Volume								
	Historical		Projected					Cumulative Increase
CY	2015	2016	2017	2018	2019	2020	2021	
Projected Inpatient Cases	901	1,005	1,120	1,249	1,392	1,552	1,730	
Incremental Changed from Prior Year	-	104	115	129	143	160	178	829
<i>Source: CON Application, p. 40</i>								

There a number of problems with this projection. The 11.5% annual growth rate used in projecting future inpatient utilization is not based on a specific market analysis of population growth, surgical use rates, and market share, but instead on picking one number out of **Exhibit 8** above, which happens to be the growth rate between 2014 and 2015 using LRA data.

There a number of problems with assuming this historical growth rate will be perpetuated in the future. NHKMC is a new hospital that only opened in March 2011. During the initial operations of new hospital or an ASC the rates of increase in the early years are often high because the facility is starting with relatively low volume and small additions of volumes in subsequent years reflect high percentage increases on this small base. As the number of surgical patients expands, it becomes increasingly difficult to maintain the same percentage growth that occurred historically because each year in the future requires an increasingly large incremental increase in volume. NHKMC’s own numbers in **Exhibit 8** from the LRA’s indicate that the annual growth rates declined in each year between 2012 and 2015.

Exhibit 9 illustrates the incremental growth in the absolute number of inpatient surgical cases using the assumptions in the NHKOS application. The 11.5% annual rate of growth projected for the increase in inpatient surgeries far surpasses the rate of growth in population, which as shown in **Exhibit 6** is 1.2% annually. As a result, the only way that NHKMC would achieve this level of growth would be by shifting market share from existing providers, which is not discussed in the application.

A similar approach was taken in projecting outpatient surgery growth. **Exhibit 10** presents the historical rates of growth of NHKMC’s outpatient surgeries included in the application.

Exhibit 10
Historical Outpatient Surgical Growth
Novant Health Kernersville Medical Center

Year	Total CY Trendstar	Growth Rate	Total FFY Trendstar	Growth Rate	Total FFY LRA	Growth Rate
2011					742	
2012	1,833		1,756		1,657	123.3%
2013	2,142	16.9%	2,055	17.0%	1,970	18.9%
2014	2,143	0.0%	2,186	6.4%	2,180	10.7%
2015	2,517	17.5%	2,404	10.0%	2,347	7.7%
		11.5%		11.1%		12.4%

Source: Exhibit 3, Table 3 (CON Application, p. 42)

NHKMC's projected outpatient surgery utilization is presented in **Exhibit 11**. This projection suffers from the same problems as the inpatient projections. Future utilization is assumed to increase at a constant annual rate of 7.7%, which is nearly seven times higher than the rate of population growth in the market area. The rationale for using this growth rate is that it is from the same time period as the rate used to project inpatient utilization and that it was the lowest rate since 2013. What was not presented, however, is any evidence that such a rate is reasonable and sustainable in the future.

Exhibit 11

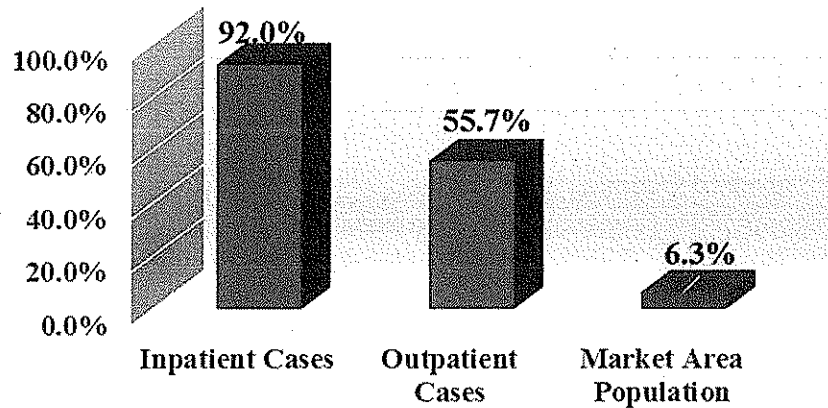
Novant Health Kernersville Medical Center								
Projected Incremental Growth in Outpatient Surgical Volume								
	Historical	Projected						Cumulative Increase
CY	2015	2016	2017	2018	2019	2020	2021	
Projected Outpatient Cases	2,517	2,710	2,917	3,141	3,382	3,641	3,919	
Incremental Changed from Prior Year	-	193	207	224	241	259	278	1,402

Source: CON Application, p. 43

As with inpatient utilization, the incremental addition of outpatient surgeries increases each year well beyond the increases that would result from population growth. The only way that these outpatient projections can be realized is if NHKMC's takes market share away from other existing providers serving the market, thereby reducing volumes at already underutilized facilities.

The aggressive and unrealistic nature of these utilization projections can be seen when comparing the total projected increases in surgical volumes at NHKMC to the market area's population growth. **Exhibit 12** graphically depicts the disparity in the assumed increases in NHKMC's surgical volumes in the future in comparison to the expected population increases.

Exhibit 12
NHKOS Projected Increase in Surgical Cases vs.
Population Growth:
2016-2021



According to the application, the final step was to determine the percentage of outpatient growth that could be shifted from NHKMC to NHKOS. The following explains the approach that was employed:

NHKOS estimated that 50% to 60% of the future projected NHKMC outpatient surgical volume will shift to the new ambulatory surgery center, NHKOS. This assumption is based on the level of support from surgeons who currently perform outpatient surgeries in the NHKMC ORs as reflected in the letters in Exhibit 4 and on expert input from the Novant Health Forsyth Medical Center Vice President of Surgical Services and the NHKMC Director of Operations.

See CON application, p. 44.

There was no discussion of how the rooms will be equipped or how ORs will be allocated to surgeons. With only two ORs, there will be limited ability for multiple surgeons to operate at NHKOS simultaneously. Moreover, there is no support for the assumption is that all of the cases projected for NHKOS would otherwise have been performed at NHKMC. Most freestanding ASCs developed by hospital operators are organized to provide investment opportunities for surgeons. The surgeon-investors are expected to shift substantial portions of their outpatient surgeries from other facilities where they operate to the ASC. There is no indication in the application about Novant Health intentions with respect to seeking surgeon-investors or that such investors would be limited to surgeons currently performing all of their surgery at NHKMC.

Exhibit 13 presents NHKOS’ projected utilization and need for ORs under these assumptions. Even with the unreasonably high rates of growth assumed in the projections, there is only a marginal need for the 2 proposed ORs that will be relocated to NHKOS. More reasonable, lower projections of future utilization at NHKMC would not support the approval of this project.

Exhibit 13
Novant Health Kernersville Medical Center
Projected Operating Room Need

CY	2015	Surgical Growth Rate	2016	2017	2018	2019	2020	2021
Inpatient	901	11.5%	1,005	1,120	1,249	1,392	1,552	1,730
Outpatient	2,517	7.7%	2,710	2,917	3,141	3,382	3,641	3,919
Converted to Project Years					PY 1 Apr18- Mar19	PY 2 Apr19- Mar20	PY3 Apr20- Mar21	
Inpatient Cases - NHKMC					1,284	1,432	1,596	
Outpatient Cases - NHKMC					3,201	3,446	3,710	
Percent Clinically Appropriate to shift to NHKOS					50.0%	55.0%	60.0%	
Adjusted Outpatient Cases - NHKMC					1,601	1,551	1,484	
Total Weighted Surgical Hours					6,254	6,622	7,016	
ORs Needed					3.3	3.54	3.7	
ORs Needed (Rounded per SMFP)					3.0	4.0	4.0	

Source: Exhibit 3, Table 1 (CON Application, p. 46)

The application also attempts to demonstrate that the proposed relocation of 2 ORs from Novant Health Forsyth Medical Center to NHKMC would still leave sufficient OR capacity at Novant Health Forsyth Medical Center. This projection is reproduced in **Exhibit 14**. Unlike the approach taken in the projections for NHKMC, historical rates of growth in inpatient and outpatient cases were not the bases for the projections. Instead, weighted annual population growth was used to project future volumes. Had a similar approach been employed in projecting NHKMC’s volume, the projected growth in surgical utilization would have been dramatically lower.

Exhibit 14
Projected Surgical Utilization Novant Health Forsyth Medical Center

CY	2015	Weighted Population Growth Rate	2016	2017	2018	2019	2020	2021
Projected Inpatient Cases	6,976	0.65%	7,022	7,068	7,114	7,160	7,207	7,254
Less Inpatient Volume shifted to NHCMC				625	1,500	1,500	1,500	1,500
Adjusted Inpatient Volume	6,976		7,022	6,443	5,614	5,660	5,707	5,754
Weighted Inpt Hrs	20,928		21,065	19,328	16,842	16,981	17,122	17,263
Inpatient ORs Needed	11.2		11.3	10.3	9.0	9.1	9.1	9.2
Projected Outpatient Cases	5,425	0.67%	5,461	5,498	5,535	5,572	5,609	5,647
Less Outpatient Volume shifted to NHCMC				100	240	240	240	240
Adjusted Outpatient Volume	5,425		5,461	5,398	5,295	5,332	5,369	5,407
Weighted Outpt Hrs	8,138		8,192	8,097	7,942	7,998	8,054	8,110
Outpatient OR Need	4.3		4.4	4.3	4.2	4.3	4.3	4.3
Total OR Need	15.5		15.6	14.6	13.2	13.3	13.4	13.6
NHFMC OR Inventory*	18.0		18.0	18.0	18.0	18.0	18.0	18.0
OR Surplus	2.5		2.4	3.4	4.8	4.7	4.6	4.4

Source: Exhibit 3, Table 8 (CON application, p. 51)

* Note: FMC OR inventory and volumes excludes OH and C-section operating rooms at NHFMC.

The applicant made an attempt to justify its utilization projections for NHKMC and NHKOS by discussing its expected addition of 4 additional surgeons using data purportedly from the Medical Group Management Association. The source of this data was not included in the application. **Exhibit 15** presents the alleged impact of these surgeons on NHKMC's surgical volume. The application focuses on the median projected impact of these additional surgeons, which would result in 2,306 additional surgeries at NHKMC by the fourth year these surgeons are in place.

Exhibit 15
Impact of New Surgeons at Novant Health Kernersville Medical Center

Surgeon Type	Number* of Surgeons	10% of Surgeons in this Specialty	Median Volume for Surgeons in this Specialty	75% of Surgeons in this Specialty	Estimated Percent at NHKMC or NHKOS Years 1- 3	Minimum Impact (10%)	Median Impact	High Impact (75%)
General Orthopedics	2	233	670	1,073		466	1,340	2,146
Potential Year 1					25%	117	335	537
Potential Year 2					50%	233	670	1,073
Potential Year 3					75%	350	1,005	1,610
Potential Year 4					100%	466	1,340	2,146
ENT	0.75	286	434	944		215	326	708
Potential Year 1					25%	54	81	177
Potential Year 2					50%	107	163	354
Potential Year 3					75%	161	244	531
Potential Year 4					100%	215	326	708
General Surgery	1	342	640	816		342	640	816
Potential Year 1					25%	86	160	204
Potential Year 2					50%	171	320	408
Potential Year 3					75%	257	480	612
Potential Year 4					100%	342	640	816
Combined Impact of New Surgeons	3.75	861	1,744	2,833				
Potential Year 1					25%	256	576	918
Potential Year 2					50%	511	1,153	1,835
Potential Year 3					75%	767	1,729	2,753
Potential Year 4					75%	1,023	2,306	3,670

Source: MGMA; Exhibit 3, Table 4 (CON Application, p.30)

*Note: The General Surgeon and the two Orthopedic Surgeons will be located in the NHKMC MOBs and will be operating solely at NHKMC and NHKOS. The ENT will be doing 75% of his surgical volume at NHKMC and NHKOS.

This projected impact of adding 4 surgeons is highly suspect. NHKMC currently has 98 surgeons on staff who in 2015 generated 3,418 total surgeries. Based on the projections in the application, four additional surgeons would produce a 67.5% increase in total surgical volume. This projection simply lacks credibility.

There is no basis to conclude that NHKMC will require 2 additional ORs or that these ORs could be supported at NHKOS when considering all of the different flaws in the projections presented in the application.

- The market area defined for NHKOS is illogical and unreasonable.

- The Applicant gave no consideration to the proximity and utilization levels of existing providers.
- There was also no specific analysis of population growth, historical outpatient surgical use rates, or historical and projected market shares by ZIP Code in developing the projections.
- The projections assume unsustainable rates of growth in projecting future volumes at NHKMC.
- The only way that these projections could be achieved would be to take patients away from other providers, which NHKOS never evaluated.

The project fails to demonstrate that the population it proposes to serve has a need for the proposed ASC, and as a result, the project is not conforming with Criterion 3.

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

The NHKOS application presents a project that addresses no need. There is a superior alternative to the proposed project, which is to maintain the status quo with respect to the distribution of ORs in Forsyth and Guilford Counties. The proposed location on the NHKMC campus brings these ORs closer to the existing, underutilized ambulatory surgical providers in Guilford County. NHKMC's ORs are not highly utilized today so there is no reason to expand capacity on its campus.

As discussed above, NHKOS has failed to document that it will achieve a reasonable utilization of the proposed operating rooms consistent with the performance standards in the CON review criteria. The project fails to satisfy Criterion 4.

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

NHKOS' project is nonconforming with Criterion 5 because its financial projections are based on flawed utilization projections that substantially overstate future volumes for NHKMC that could be shifted to NHKOS. As a result, the financial projections are overstated with respect to the projected revenues and expected net income of the project.

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

Because the NHKOS proposal is not needed and is not the best alternative, it will result in unnecessary duplication of existing and approved health facilities. There is not a need for another freestanding ASC to serve Forsyth and Guilford Counties. There is ample capacity at ambulatory surgical providers in each county to serve any growth in future demand for ambulatory surgery.

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;

The NHKOS application presents projections of services to be provided to underserved populations, but these projections are based on flawed utilization projections. There is no basis to find that the NHKOS project will conform with Criterion 13a.

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

For the same reasons discussed in the preceding response, NHKOS has not presented reliable information regarding its proposed level of service to the elderly and medically underserved groups. The project does not satisfy Criterion 13c.

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

The NHKOS proposal is inconsistent with this criterion in that it will offer no enhancements in competition that will have positive impact on the cost effectiveness, quality, and access to the

services. As a starting point, Novant Health is the dominant provider of surgery services in Forsyth County today. The approval of NHKOS would simply enhance its dominant market position in Forsyth County. The project also appears to be targeting an increased ambulatory surgery market presence for Novant in Guilford County, which is equally unnecessary. Guilford County has a number of different hospital and freestanding ASC providers, and the approval of an unneeded ASC in Kernersville will not have a positive effect on competition.

Instead, the NHKOS project will adversely impact existing providers in Forsyth and Guilford Counties. SCG and GSSC draw material portions of their outpatient surgical volumes from the ZIP Codes that NHKOS has targeted.

Exhibit 16 presents 2015 patient origin data for SCG by ZIP Code. SCG served patients from all ZIP Codes included in the NHKOS market area although it draws substantially more patients from the Guilford County area. The surgical patients from the NHKOS market represented 22% of SCG's 2015 total volume.

Exhibit 16
Surgical Center of Greensboro
2015 Patient Origin

ZIP Code	Cases	% of Total	Cumulative %
27410	1,423	9.9%	9.9%
27406	1,243	8.6%	18.5%
27407	792	5.5%	24.1%
27405	781	5.4%	29.5%
27455	733	5.1%	34.6%
27408	565	3.9%	38.5%
27320	547	3.8%	42.3%
27265	458	3.2%	45.5%
27358	375	2.6%	48.1%
27317	317	2.2%	50.3%
27205	300	2.1%	52.4%
27403	300	2.1%	54.5%
27288	284	2.0%	56.5%
27401	281	2.0%	58.4%
27214	254	1.8%	60.2%

27409	252	1.8%	62.0%
27284	251	1.7%	63.7%
27301	244	1.7%	65.4%
27215	237	1.6%	67.0%
27282	229	1.6%	68.6%
27313	208	1.4%	70.1%
27025	196	1.4%	71.4%
27217	187	1.3%	72.7%
27249	172	1.2%	73.9%
27377	155	1.1%	75.0%
27357	153	1.1%	76.1%
27360	150	1.0%	77.1%
27253	147	1.0%	78.2%
27263	147	1.0%	79.2%
27310	147	1.0%	80.2%
27298	143	1.0%	81.2%
27048	133	0.9%	82.1%
27260	114	0.8%	82.9%
27203	109	0.8%	83.7%
27244	100	0.7%	84.4%
27233	98	0.7%	85.0%
27262	86	0.6%	85.6%
27283	83	0.6%	86.2%
27027	79	0.5%	86.8%
27350	74	0.5%	87.3%
27370	71	0.5%	87.8%
27107	68	0.5%	88.3%

27235	65	0.5%	88.7%
All Other	1,623	11.3%	100.0%
Total	14,374	100.0%	

Source: SCG internal records

GSSC also has a significant reliance on the ZIP Codes included in the NHKOS market area, as demonstrated by its 2015 patient origin data presented in **Exhibit 17**. GSSC served patients from all ZIP Codes in the NHKOS market area, again relying more significantly on the Guildford area. Similar to SCG, GSSC received 22% of its surgical patients from the market area.

Exhibit 17
Greensboro Specialty Surgical Center
2015 Patient Origin

ZIP Code	Cases	% of Total	Cumulative %
27410	586	11.0%	11.0%
27406	345	6.5%	17.5%
27455	300	5.6%	23.2%
27408	248	4.7%	27.8%
27407	226	4.3%	32.1%
27405	207	3.9%	36.0%
27320	187	3.5%	39.5%
27265	180	3.4%	42.9%
27205	169	3.2%	46.0%
27358	137	2.6%	48.6%
27282	122	2.3%	50.9%
27284	116	2.2%	53.1%
27215	102	1.9%	55.0%
27317	97	1.8%	56.8%
27409	88	1.7%	58.5%
27214	87	1.6%	60.1%
27249	79	1.5%	61.6%
27288	77	1.4%	63.1%
27401	75	1.4%	64.5%
27403	72	1.4%	65.8%
27313	70	1.3%	67.2%
27262	69	1.3%	68.5%
27263	66	1.2%	69.7%
27301	66	1.2%	70.9%
27025	65	1.2%	72.2%
27217	62	1.2%	73.3%
27260	60	1.1%	74.5%
27203	57	1.1%	75.5%

27298	56	1.1%	76.6%
27357	52	1.0%	77.6%
27253	50	0.9%	78.5%
27310	50	0.9%	79.4%
27107	49	0.9%	80.4%
27283	49	0.9%	81.3%
27244	48	0.9%	82.2%
27370	48	0.9%	83.1%
27360	45	0.8%	83.9%
27048	40	0.8%	84.7%
27377	40	0.8%	85.4%
27235	31	0.6%	86.0%
27302	30	0.6%	86.6%
All Other	713	13.4%	100.0%
Total	5,316	100.0%	

Source: GSSC internal records

As discussed in detail above, NHKMC and NHKOS can only reach the utilization levels projected in the application by adversely impacting existing providers serving the market. Given that SCG and GSSC are freestanding ASCs with a presence in the NHKOS market, the impact on these facilities is expected to be significant. The precise level of impact is difficult to determine because NHKOS failed to provide sufficient detail in its projections, including projected cases by ZIP Code, in an effort to mask the negative impact of its project.

Because NHKOS also failed to provide reasonable utilization and financial projections, the cost effectiveness of its proposal from the standpoint of operating costs cannot be effectively assessed. The application does discuss the lower costs to patients associated with services in a freestanding ASC rather than a hospital-based program; however, the NHKOS project offers nothing in the way of cost efficiency that is not already available at other freestanding ASCs in the two counties. For all of these reasons, the NHKOS project fails to conform with Criterion 18a.

CRITERIA AND STANDARDS FOR SURGICAL SERVICES AND OPERATING ROOMS

The NHKOS project also fails to satisfy 10A NCAC 14C.2100, which contains the criteria and standards for surgical services and operating rooms. Specifically, the project is inconsistent with NCAC 14C .2101(b), which states:

(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 based on the following formula: {[(Number of facility's 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) plus (Number of facility's projected outpatient cases times 1.5 hours)] divided by 1872 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

For all of the reasons addressed in the discussion of Criterion 3, NHKOS has failed to demonstrate that it can achieve utilization sufficient to support two ORs in its third year of operation. The project fails to satisfy this criterion.

Conclusion

NHKOS' application should be denied. The claim that NHKMC requires additional OR capacity is not supported by the information presented in the NHKOS application. The projections of utilization for NHKMC, which are the basis for the NHKOS utilization projections, are based on unreasonable assumptions. Access to freestanding ASCs will not be materially improved by this project. The population that NHKOS seeks to serve, which primarily is in Guilford County, already enjoys excellent access to outpatient surgical services at hospital-based and freestanding providers. The Applicant fails to consider the availability of other providers in its analysis of need for the project, instead focusing exclusively on the institution-specific desires of Novant Health. The project represents an unnecessary duplication of existing health care resources. NHKOS will undoubtedly adversely impact existing providers, including SCG and GSSC. For these reasons, the application fails to conform with multiple review criteria.

Pursuant to N.C. Gen. Stat. § 131E-185(a1)(2), SCG and GSSC hereby request a public hearing to be conducted on NHKOS' application.