



WakeMed 

WakeMed Health & Hospitals

3000 New Bern Avenue  
Raleigh, North Carolina 27610  
919-350-8000

December 31, 2013

**HAND-DELIVERED**

Ms. Tanya Rupp, Project Analyst  
Division of Health Service Regulation  
Certificate of Need Section  
2704 Mail Service Center  
Raleigh, NC 27699-2704

Dear Ms. Rupp:

WakeMed is providing the attached comments regarding the certificate of need application filed by Same Day Surgery Center Franklin LLC and Novant Health, Inc. (Project No. K-10229-13) for the December 1, 2013 review cycle.

Thank you for your consideration of these comments. If you have questions or require additional information, please do not hesitate to contact us.

Sincerely,



Donald R. Gintzig  
President & CEO

**Comments Regarding the Certificate of Need Application  
Filed by Same Day Surgery Center Franklin LLC and Novant Health, Inc.  
Project No. K-10229-13**



**Submitted by: WakeMed Health & Hospitals  
December 31, 2013**

**Overview**

A certificate of need application was filed for the December 1, 2013 review cycle to relocate one operating room from Novant Health Franklin Medical Center (FMC) to Same Day Surgery Center Franklin (SDSC Franklin), which already has State approval to develop an ambulatory surgery center with one operating room in Youngsville in Franklin County.

The following comments will demonstrate that this application should not be approved, as it does not conform to all applicable certificate of need Review Criteria, found in G.S. §131E-183, as outlined below.

**CON Review Criterion 3**

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

The SDSC Franklin application does not conform to Review Criterion 3. The applicants failed to demonstrate that the project is needed for the following reasons:

- Although the project will be developed in Franklin County, its volume projections are highly dependent upon residents of Wake County ZIP Codes utilizing the facility;
- Assumptions regarding market shares are not reasonable;
- Assumptions regarding patient "inmigration" are not reasonable;
- The application assumes demographic disparities between the service area regions that were not substantiated;
- The project location does not materially improve access to surgical services in Franklin County;
- Development of a new surgery center in Franklin County does not equate to improved utilization of an existing facility.

Projections Dependent Upon Wake County ZIP Codes in Service Area

The SDSC Franklin service area is defined in the application as 10 ZIP Codes in Franklin, Wake, Vance and Nash Counties. The service area includes all ZIP Codes based in Franklin County, as well as ZIP Codes that are based in surrounding counties which have some overlap into Franklin County, including Wake County-based Wake Forest (27687), Rolesville (27571) and Zebulon (27597). Approximately 55 percent of the current total SDSC Franklin service area population is based in these three Wake County ZIPs, a proportion which is slated to increase by 2018. Also, roughly 25 percent of SDSC Franklin’s proposed service area cases will originate in Wake County.

SDSC Franklin characterizes the service area population as rapidly growing, and this is certainly true for the Wake County ZIPs, as well as Youngsville. Using population data contained in Application Exhibit 3, Table 3, it is evident that the majority of the population growth that is projected to occur in the service area will be in the Wake County ZIPs. Please see the following table.

<b>Table 1</b> <b>Population Growth in SDSC Franklin Service Area, 2013-2018</b> <b>Showing Percent Changes and Proportions of Total Service Area Population</b>								
ZIP Code	Town	County	2013 Population	2018 Population	Percent Change 2013-18	CAGR 2013-18	Percent of 2013 Svc. Area Pop.	Percent of 2018 Svc. Area Pop.
27508	Bunn	Franklin	1,993	1,972	-1.1%	-0.2%	1.3%	1.2%
27525	Franklinton	Franklin	13,844	14,364	3.8%	0.7%	9.0%	8.7%
27549	Louisburg	Franklin	23,988	24,537	2.3%	0.5%	15.6%	14.9%
27596	Youngsville	Franklin	16,171	17,356	7.3%	1.4%	10.5%	10.5%
27816	Castalia	Franklin	2,685	2,691	0.2%	0.0%	1.7%	1.6%
27882	Spring Hope	Nash	7,062	7,239	2.5%	0.5%	4.6%	4.4%
27544	Kittrell	Vance	3,966	4,070	2.6%	0.5%	2.6%	2.5%
27571	Rolesville	Wake	3,973	4,464	12.4%	2.4%	2.6%	2.7%
27587	Wake Forest	Wake	57,645	64,588	12.0%	2.3%	37.5%	39.2%
27597	Zebulon	Wake	22,585	23,657	4.7%	0.9%	14.7%	14.3%
TOTAL			153,912	164,938	7.2%	1.39%	100.0%	100.0%
<i>Source: SDSC Franklin application, page 214</i>								
Percent of 2013 service area population based in Wake County ZIPs							54.7%	
Percent of 2018 service area population based in Wake County ZIPs							56.2%	
Percent of 2013 service area population based in Franklin County ZIPs							38.1%	
Percent of 2018 service area population based in Franklin County ZIPs							36.9%	
Wake County ZIPs CAGR, 2013-2018							1.94%	
Franklin County ZIPs CAGR, 2013-2018							0.75%	
2013-2018 CAGR Excluding Wake County ZIPs							0.71%	

The information above clearly demonstrates that the service area population growth rate of 1.4 percent per year will be chiefly driven by the Wake County portion of the service area. The population of the three Wake County ZIPs is projected to grow by 1.94 percent per year, compared with 0.71 percent per year for the non-Wake County ZIPs. The choice of service area is an important component of SDSC Franklin’s projected surgical volumes. It should be clear to the Agency that SDSC Franklin’s service area was selected to take advantage of population growth in adjacent northeastern Wake County, which is growing more rapidly than Franklin County. This becomes important throughout the SDSC Franklin need methodology.

Projected Market Shares Too Aggressive

In addition to population growth within its service area, SDSC Franklin’s projections are predicated on dramatic increases in surgical market shares through Project Year 3. The SDSC Franklin volume projections are dependent upon quickly increasing market shares within the service area ZIP Codes, even in those ZIPs outside Franklin County. On Application page 63, SDSC Franklin provides its market share assumptions for Project Years 1-3. When combined with the historic and interim market shares found on Application page 212, it is apparent that Novant’s projections will require a substantial shift in outpatient surgical services utilization to its facilities in Franklin County. Please see Table 2.

<b>Table 2</b> <b>SDSC Franklin and Novant Franklin Medical Center</b> <b>Projected Changes in Outpatient Surgery Market Share in Service Area</b> <b>FY 2013-2019</b> <i>Source: SDSC Franklin application, page 212</i>					
ZIP Code	Town	County	FY 2013 OP Surgery Market Share	FY 2019 OP Surgery Market Share	Percent Change in Market Share, 2013-2019
27508	Bunn	Franklin	30.2%	50.0%	66%
27525	Franklinton	Franklin	8.0%	40.0%	400%
27549	Louisburg	Franklin	19.4%	50.0%	158%
27596	Youngsville	Franklin	3.0%	40.0%	1233%
27816	Castalia	Franklin	10.4%	25.0%	140%
27882	Spring Hope	Nash	2.3%	7.0%	204%
27544	Kittrell	Vance	8.8%	15.0%	70%
27571	Rolesville	Wake	1.4%	25.0%	1686%
27587	Wake Forest	Wake	0.2%	7.0%	3400%
27597	Zebulon	Wake	1.1%	7.0%	536%

In each of the ZIP Codes of its service area, Novant projects a significant increase in outpatient surgery market share from 2013-2019 – in most ZIPs, the increases in market share are greater than 100 percent, and they exceed 1000 percent for the three ZIP Codes with the highest projected population growth above noted in Table 1 (Youngsville, Rolesville and Wake Forest). The increase in market share in Wake Forest reaches 7.0 percent in Project Year 3, which seems

benign, until one realizes that the Wake Forest ZIP Code alone comprises nearly 40 percent of total service area population.

Despite no proposed increase in surgical operating room capacity in Franklin County, Novant projects that its two facilities that provide surgical services will garner substantial increases in market shares within the service area. Novant predicts that this increase in market share will begin at FMC before the planning opening of SDSC Franklin in FY 2017, despite Novant's admission on page 71 that FMC operates only two of its three operating rooms and indicated no intention of renovating or otherwise improving these ORs for the benefit of its surgeons. To accept these assumptions requires a suspension of disbelief. Novant's projected market shares for its Franklin County facilities are not reasonable. The application does not adequately explain how the shift in market share will occur, or how existing providers outside Franklin County will be impacted. Increases in market share at one facility connote a *decline* in market share for one or more other facilities. There is no reason to believe that these projections can be achieved, given the presence of existing facilities in close proximity to the SDSC Franklin service area. Even a slight decrease in SDSC Franklin's market shares threatens the projections' ability to justify two operating rooms.

Novant projects increases in outpatient surgery market share at Franklin Medical Center throughout the service area, both before and after the opening of SDSC Franklin. The following table provides detail on projected outpatient surgery market share increases at Novant facilities in Franklin County, using data provided in the SDSC Franklin application.

<b>ZIP Code - Town</b>	<b>OP Surgery Cases and Market Shares</b>	<b>2013</b>	<b>2014</b>	<b>2015</b>	<b>2016</b>	<b>Year 1 2017</b>	<b>Year 2 2018</b>	<b>Year 3 2019</b>
27508 - Bunn	Cases at FMC	36	38	40	41	43	46	48
	FMC Market Share	30.2%	31.8%	33.4%	35.1%	36.9%	39.1%	40.7%
	Cases at SDSC Franklin	0	0	0	0	0	4	11
	SDSCF Market Share	0.0%	0.0%	0.0%	0.0%	0.0%	3.4%	9.3%
	FMC+SDSCF Mkt Share	30.2%	31.8%	33.4%	35.1%	36.9%	42.5%	50.0%
27525 - Franklinton	Cases at FMC	66	69	72	76	80	84	88
	FMC Market Share	8.0%	8.3%	8.7%	9.0%	9.4%	9.8%	10.2%
	Cases at SDSC Franklin	0	0	0	0	158	208	257
	SDSCF Market Share	0.0%	0.0%	0.0%	0.0%	18.6%	24.2%	29.8%
	FMC+SDSCF Mkt Share	8.0%	8.3%	8.7%	9.0%	28.0%	34.0%	40.0%
27549 - Louisburg	Cases at FMC	277	290	304	319	335	373	441
	FMC Market Share	19.4%	20.2%	21.1%	22.0%	23.0%	25.5%	30.0%
	Cases at SDSC Franklin	0	0	0	0	175	248	294
	SDSCF Market Share	0.0%	0.0%	0.0%	0.0%	12.0%	17.0%	20.0%
	FMC+SDSCF Mkt Share	19.4%	20.2%	21.1%	22.0%	35.0%	42.5%	50.0%

<p align="center"><b>Table 3</b>  <b>Novant Franklin Medical Center (FMC) and Same Day Surgery Center Franklin (SDSCF)</b>  <b>Projected Outpatient Surgery Cases and Market Shares from Service Area ZIP Codes</b>  <b>During Interim Years and Project Years 1-3 (FYs 2017-19)</b>  <i>Source: SDSC Franklin application, page 212</i></p>								
ZIP Code - Town	OP Surgery Cases and Market Shares	2013	2014	2015	2016	Year 1 2017	Year 2 2018	Year 3 2019
27596 - Youngsville	Cases at FMC	29	31	32	34	35	37	39
	FMC Market Share	3.0%	3.1%	3.2%	3.4%	3.4%	3.6%	3.7%
	Cases at SDSC Franklin	0	0	0	0	250	315	381
	SDSCF Market Share	0.0%	0.0%	0.0%	0.0%	24.6%	30.4%	36.3%
	FMC+SDSCF Mkt Share	3.0%	3.1%	3.2%	3.4%	28.0%	34.0%	40.0%
27816 - Castalia	Cases at FMC	17	17	18	19	20	21	22
	FMC Market Share	10.4%	10.9%	11.4%	12.0%	12.5%	13.1%	13.8%
	Cases at SDSC Franklin	0	0	0	0	8	13	18
	SDSCF Market Share	0.0%	0.0%	0.0%	0.0%	5.0%	8.1%	11.3%
	FMC+SDSCF Mkt Share	10.4%	10.9%	11.4%	12.0%	17.5%	21.3%	25.0%
27882 - Spring Hope	Cases at FMC	11	11	12	12	13	14	14
	FMC Market Share	2.3%	2.4%	2.5%	2.6%	2.7%	2.9%	2.9%
	Cases at SDSC Franklin	0	0	0	0	11	15	20
	SDSCF Market Share	0.0%	0.0%	0.0%	0.0%	2.2%	3.1%	4.1%
	FMC+SDSCF Mkt Share	2.3%	2.4%	2.5%	2.6%	4.9%	6.0%	7.0%
27544 - Kittrell	Cases at FMC	21	23	23	25	26	27	28
	FMC Market Share	8.8%	9.2%	9.6%	10.0%	10.5%	10.8%	11.3%
	Cases at SDSC Franklin	0	0	0	0	0	5	9
	SDSCF Market Share	0.0%	0.0%	0.0%	0.0%	0.0%	2.0%	3.6%
	FMC+SDSCF Mkt Share	8.8%	9.2%	9.6%	10.0%	10.5%	12.8%	15.0%
27571 - Rolesville	Cases at FMC	3	3	4	5	4	4	4
	FMC Market Share	1.4%	1.5%	1.5%	1.5%	1.6%	1.5%	1.5%
	Cases at SDSC Franklin	0	0	0	0	41	52	63
	SDSCF Market Share	0.0%	0.0%	0.0%	0.0%	16.0%	19.8%	23.5%
	FMC+SDSCF Mkt Share	1.4%	1.5%	1.5%	1.5%	17.5%	21.3%	25.0%
27587 - Wake Forest	Cases at FMC	6	6	7	7	7	8	8
	FMC Market Share	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%
	Cases at SDSC Franklin	0	0	0	0	175	219	265
	SDSCF Market Share	0.0%	0.0%	0.0%	0.0%	4.7%	5.8%	6.8%
	FMC+SDSCF Mkt Share	0.2%	0.2%	0.2%	0.2%	4.9%	6.0%	7.0%
27597 - Zebulon	Cases at FMC	15	15	16	17	18	19	19
	FMC Market Share	1.1%	1.1%	1.2%	1.2%	1.3%	1.4%	1.4%
	Cases at SDSC Franklin	0	0	0	0	50	65	79
	SDSCF Market Share	0.0%	0.0%	0.0%	0.0%	3.6%	4.6%	5.6%
	FMC+SDSCF Mkt Share	1.1%	1.1%	1.2%	1.2%	4.9%	6.0%	7.0%
TOTAL SERVICE AREA	Cases at FMC	481	503	528	555	581	633	711
	FMC Market Share	5.5%	5.7%	5.6%	5.8%	6.0%	6.4%	7.1%
	Cases at SDSC Franklin	0	0	0	0	868	1144	1397
	SDSCF Market Share	0.0%	0.0%	0.0%	0.0%	8.9%	11.7%	14.0%
	FMC+SDSCF Mkt Share	5.5%	5.7%	5.6%	5.8%	14.9%	18.1%	21.2%

Novant projects that FMC will increase its outpatient surgery market share in every service area ZIP Code between FY 2013 and FY 2019, with no cases or share shifted to SDSC Franklin.

Several changes in market share are noteworthy:

- FMC's outpatient surgery market share in Louisburg (27549), estimated at 19.4 percent in 2013, is projected to grow to 30.0 percent in 2019, an increase of 59.2 percent. At the same time, SDSC Franklin is projected to attain a 20.0 percent market share in Louisburg by 2019, despite being located approximately 17 miles away;
- In Youngsville (27596), Novant estimates that FMC's outpatient surgery market share will increase by 34.5 percent from 2013-2019, despite the development of SDSC Franklin.
- Although SDSC Franklin's and FMC's combined market share in Wake Forest (27587) will increase to seemingly benign 7.0 percent by 2019, this represents a 3400 percent jump in market share (see Table 2). When market share growth is combined with the projected increase in total outpatient surgical cases in Wake Forest, the effect is compounded. Wake Forest's population – nearly as large as Franklin County's total population – is projected to increase by 2.3 percent per year, and will generate significantly more surgical cases than any other ZIP Code in the service area. By 2019, Wake Forest will comprise 13 percent of SDSC Franklin's and FMC's outpatient surgery patients, up from 1.2 percent in 2013.
- Population growth in Rolesville (27571), projected to be 2.4 percent per year, will have a similar impact as Wake Forest when combined with projected market share gains.

FMC, which had a calculated outpatient surgery market share of 5.5 percent in the service area in FY 2013, is projected to increase this share to 7.1 percent by FY 2019, while SDSC Franklin increases its overall market share to 14.0 percent. To suggest that SDSC Franklin will capture market share in the service area from other facilities, but not FMC, is unreasonable.

#### Projections of Inmigration Are Not Reasonable

SDSC Franklin applies an "inmigration factor" of 15 percent to its surgery projections for Project Years 1-3, for patients who will originate from outside the service area. This is problematic, because SDSC Franklin does not expound upon from which counties these patients will originate, although it is implied that some unnamed proportion will come from the regions of Wake County not included in the service area, based on the following passage on Application page 68:

*"...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 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.” [emphasis added]*

SDSC Franklin provided no basis for the inmigration percentage, aside from it being a lower, and arguably more conservative percentage, than that for FMC. However, the number of cases attributed to inmigration is not insignificant – the 15 percent inmigration pushes the SDSC Franklin projections over the performance threshold required in 10A NCAC 14C .2103(b)(1), if this standard were applied to the project. Moreover, northern Wake County is currently home to two providers of outpatient surgery: WakeMed North Healthplex and Rex Surgery Center of Wakefield, and is served by other surgery providers located throughout the county.

#### Service Area Disparities Not Explained

In Application Section III, SDSC Franklin divided Franklin County into “northern” and “southern” regions, and determined that the population of “southern” Franklin County (which includes Youngsville) is growing more rapidly than its northern counterpart. The application concludes that southern Franklin County is underserved for surgical services, and that relocating one operating room from Franklin Medical Center in Louisburg (northern Franklin County) to SDSC Franklin in Youngsville (southern Franklin County) will more equitably distribute ORs within the county. Missing from this analysis, however, are comparisons of population growth by age group, socioeconomic status (including underserved groups), and access to services for the northern and southern regions, which might better flesh out the differences that may exist between these two regions. This data is available at both the ZIP Code and census tract levels – the original SDSC Franklin application in 2009 used Federal census tracts, which do not cross county lines, for its demographic analysis. In reality, there are no natural or man-made barriers that divide Franklin County, so the delineation of regions is completely arbitrary.

In Step 2 of the need methodology, SDSC Franklin applies a county-specific outpatient surgical use rate per 1000 to each ZIP Code in its service area. For example, the Franklin County outpatient surgery use rate of 59.62 cases per 1000 population is applied to the Bunn, Franklinton, Louisburg, Youngsville and Castalia ZIP Code populations. Likewise, the Wake County outpatient surgery use rate of 59.06 cases per 1000 is applied to the Rolesville, Wake Forest and Zebulon ZIPs. An inherent flaw in this method is that it assumes that the population of each ZIP Code in a given county utilizes outpatient surgical services equally. In reality, there is no way to determine whether the residents of Castalia (27816) utilize surgical services at a different rate than persons living in Youngsville (27596), which is approximately 27 miles away. Equally problematic is the fact that many of the service area ZIP Codes cross county boundaries. Do residents of Wake Forest (27587) residing in Wake County have a different use rate per 1000 than the Wake Forest residents in Franklin County?



Thus, the SDSC Franklin application applies selective criteria to the service area. While the geography of the service area is acknowledged to have unequal rates of population growth, there is no proof provided that all areas of the service area counties utilize surgical services equally. This is an unreasonable assumption and a fundamental flaw in the SDSC Franklin application.

#### No Material Improvement in Access to Surgical Services

The SDSC Franklin application provides no tangible evidence that residents of the service area have suffered for lack of an ambulatory surgery center in Youngsville. There was no data or anecdotal information provided suggesting that residents of the service area in Franklin, Wake, Nash or Vance Counties have been detrimentally affected by travel to existing facilities offering surgical services. The proposed surgery center is located approximately 17 road miles from FMC, but only 7 miles from Rex Surgery Center of Wakefield and approximately 12 miles from WakeMed North Healthplex. Each of these facilities is in close proximity to the service area, is a current provider of outpatient surgery, and offers the same surgical specialties as those proposed for SDSC Franklin. Given the presence of these existing surgery providers, it is not clear how the proposed accessibility for residents of the service area, aside from simply from being located in Franklin County.

#### Proposed Project's Impact on Franklin Medical Center is Not Realistic

The proposed project would relocate one surgical operating room from FMC in Louisburg to SDSC Franklin, thereby reducing the number of licensed ORs at FMC from three to two. Despite this proposed reduction in licensed operating room capacity, Novant projects surgical utilization at FMC to increase from FY 2013 to FY 2019, for both inpatient and outpatient surgery. On Application page 73, Novant provides its surgical projections for FMC, using a compound annual growth rate (CAGR) of 8.8 percent for inpatient cases based on its historical utilization during 2011-2013. Novant assumes that inpatient surgery cases at FMC will increase by 8.8 percent per year through FY 2019. During the period 2013-2019, inpatient surgery volume at FMC is projected to increase 66.1 percent. By FY 2019, inpatient surgery is projected to constitute 14 percent of all surgeries at FMC, up from 12 percent in FY 2013. This trend contradicts the information provided in the SDSC Franklin application, which indicated that inpatient surgery is declining as a percent of total surgeries.

Outpatient surgery volume at FMC, also based on historical utilization, is projected to increase 4.9 percent per year until the opening of SDSC Franklin, based on its historical CAGR during 2011-2013. Beginning in FY 2018 (Project Year 2), outpatient surgery at FMC is projected to increase by 7.1 percent per year. Novant reasons that the opening of SDSC Franklin, rather than shifting outpatient cases away from FMC, will actually *accelerate* its outpatient surgery utilization, despite being located approximately 17 road miles away. Thus, the market share increases anticipated to be gained by SDSC Franklin will come at the expense of non-Novant facilities in the service area counties.

A closer look at FMC’s surgical utilization in the preceding five-year period paints a more complete picture, one that suggests a negative trend in surgery utilization. Please see the following table.

<p align="center"><b>Table 4</b>  <b>Surgery Utilization at Novant Franklin Medical Center</b>  <b>FYs 2009-2013</b></p> <p align="center"><i>Source: Annual License Renewal Applications and SDSC Franklin application, page 73</i></p>									
<b>Fiscal Year</b>	<b>Inpt. Surgery Cases</b>	<b>Inpt. Hours (IP Cases x 3.0)</b>	<b>Outpt. Surgery Cases</b>	<b>Outpt. Hours (OP Cases x 1.5)</b>	<b>Total Cases</b>	<b>Total Hours</b>	<b>ORs Needed at 1872 Hrs/Yr (Total hrs ÷ 1872)</b>	<b>No. Licensed ORs</b>	<b>OR Surplus (Deficit)</b>
2009	151	453	834	1,251	985	1,704	0.91	3	2.09
2010	103	309	752	1,128	855	1,437	0.77	3	2.23
2011	92	276	742	1,113	834	1,389	0.74	3	2.26
2012	153	459	838	1,257	991	1,716	0.92	3	2.08
2013	109	327	816	1,224	925	1,551	0.83	3	2.17
Pct. Change, 2009-11	-39.1%		-11.0%		-15.3%				
Pct. Change, 2011-13	18.5%		10.0%		10.9%				
Pct. Change, 2009-13	-27.8%		-2.2%		-6.1%				

While FMC’s surgery utilization increased somewhat between 2011-13, it actually experienced an overall *decline* in both inpatient and outpatient volumes between 2009 and 2013. Given these fluctuations, projections using more conservative growth rates would have been prudent. However, it is obvious that using lower growth rates would prevent FMC from reaching the threshold of 1.2 ORs required to justify 2 operating rooms in Project Year 3, using the performance standard found in 10A NCAC 14C .2013(b)(1)(C).

While Novant projects that 15 percent of outpatient surgery cases at SDSC Franklin will result from immigration outside the service area, it estimates that approximately 40 percent of outpatient surgery cases at FMC will come from outside the service area ZIPs. Because FMC is an existing provider of outpatient surgery, the application did not provide sufficient information regarding the projected patient origin of surgical cases at FMC. Will the development of SDSC Franklin change FMC’s patient origin? Will the proportion of cases from outside the SDSC Franklin service area change between FY 2013 and FY 2019? Questions such as these were not addressed in the application, which further case doubt on the projections.

**Review 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, or other underserved and the elderly to obtain needed health care.*

The proposed project will relocate one of the three operating rooms at FMC in Louisburg to the proposed ambulatory surgery center in Youngsville. The distance between these two facilities will be approximately 17 road miles. Novant’s assumptions regarding projected surgery utilization at FMC are completely unreasonable and unreliable, and without capital improvements made to its remaining operating rooms at FMC, surgeons may not choose to utilize them.

The surgical payer mixes at SDSC Franklin and FMC are provided in Section VI, and illustrate a great disparity between the market Novant currently serves and that which it wishes to serve. Please see the following table.

<b>Table 5</b> <b>Surgery Payer Mix at Franklin Medical Center and SDSC Franklin</b> <i>Sources: SDSC Franklin application, pages 116, and</i> <i>2013 Franklin Regional Medical Center LRA (corrected page 5)</i>		
<b>Payer</b>	<b>SDSC Franklin, Project Year 2 (FY 2018)</b>	<b>Franklin Medical Center – Outpatient Surgery Only, FY 2012</b>
Self Pay/Indigent	2.36%	2.29%
Commercial	3.05%	17.79%
Medicare	38.84%	58.22%
Medicaid	6.18%	16.44%
Managed Care	45.10%	0.27%
Other	4.47%	4.99%
Total	100.00%	100.00%

The most striking disparities between FMC’s actual outpatient surgery payer mix and the proposed SDSC Franklin payer mix occur in the Commercial/Managed Care, Medicare, and Medicaid categories. SDSC Franklin proposes to provide a significantly greater proportion of service than FMC to Commercial/Managed Care patients, and significantly less to Medicare and Medicaid enrollees. Based on this information, it would appear that SDSC Franklin will not provide the same level of service to medically underserved groups in Youngsville as is currently being provided by FMC in Louisburg.

Because of the reasons stated above, the project does not conform with Review Criterion 3a. Please also see the discussion for Review Criterion 3.

**Review Criterion 4**

*Where alternative methods of meeting the needs for the proposed project exist, the applicants shall demonstrate that the least costly or most effective alternative has been proposed.*

In response to Question III.8, SDSC Franklin provided four alternatives, one of which is the proposed project. However, the applicants did not discuss other potentially less expensive or more effective options, including development of the surgery center in closer proximity or adjacent to FMC, where the majority of surgeons who would utilize the project currently practice, and in such a manner that would benefit FMC. Novant touts the ability to recruit additional surgeons to Franklin County, but there is no evidence that these surgeons would utilize both SDSC Franklin and FMC, which will be located approximately 17 miles apart. By contrast, SDSC Franklin will be located only 7 miles from Rex Surgery Center of Wakefield and only 12 miles from WakeMed North. A surgery center located closer to FMC might provide greater incentive for surgeons to utilize both facilities.

While Novant expressed the need for the project to meet population growth in the service area, as well as to stem the tide of patients leaving Franklin County for outpatient surgery, the application did not fully explore the alternative of opening SDSC Franklin with 1 operating room, and using its growth in case volume to justify the need for a second operating room. The application discussed the merits of developing the ASC with two operating rooms as opposed to one, but in doing so there appears to be little sense of urgency to meet the needs of the service area. The original capital cost of SDSC Franklin is considerably lower than the updated project cost, even when the cost of site purchase is considered.

Because the other less costly and/or more effective were not considered, the application is nonconforming with Review Criterion 4.

#### **Review 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 and charges for providing health services by the person proposing the service.*

SDSC Franklin failed to demonstrate that the financial and operational projections are based on reasonable assumptions, as required by this Criterion. Therefore, the application does not conform with Review Criterion 5. Please see the discussion for Review Criterion 3 above.

#### **Review Criterion 6**

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

The original application for SDSC Franklin (Project No. J-8357-09) was in response to an allocation of one operating room to Franklin County in the 2009 State Medical Facilities Plan. For the proposed project, SDSC Franklin did not fully explore the impact of the project on established ambulatory surgery resources in Franklin, Wake, Nash and Vance Counties, including Franklin Medical Center. Given recent declines in surgical utilization at FMC, it would

appear that the SDSC Franklin project will further negatively impact FMC's surgery utilization, despite Novant's claims to the contrary. Please also see the discussion for Criterion 18a.

For these reasons, the SDSC Franklin proposal is not conforming with Review Criterion 6.

### **Review Criterion 8**

*The application 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.*

In Exhibit 5, the SDSC Franklin application included letters of support from seven surgeons who practice in or near Franklin County. Many of the surgeons offered a numeric range of cases that they expect to perform at SDSC Franklin. When summed, their case volumes range from 427-543 cases per year – one surgeon alone stated that he expects to perform 300-350 cases. Most of the other surgeons who provided volumes expect to perform fewer than 30 cases per year on the high side. These totals are well below the projected number of outpatient surgery cases shown throughout the application, ranging from 1,022 cases in Project Year 1 to 1,644 cases in Project Year 3, and call into question the reliability of the projections.

Therefore, the project is nonconforming with Criterion 8, in that the project is not coordinated with the existing health care system.

### **Review 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.*

Please see the response to Review Criterion 3. According to the SDSC Franklin application, approximately 85 percent of its ambulatory surgery patients will originate in ZIP Codes in Franklin, Wake, Nash and Vance Counties, which comprise the service area. SDSC Franklin notes on Application page 68 that the remaining 15 percent of patients will be the result of "inmigration", originating from areas outside the service area. However, the application does not identify the other areas from which SDSC Franklin will draw its patients, or the specific number of patients. Further, surgery projections for FMC do not describe where 40 percent of that facility's outpatient surgery patients will originate, although the project directly impacts FMC. Therefore, the project does not conform to Criterion 9.

### **Review 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 applicants shall demonstrate that its application is for a service on which competition will not have a favorable impact.*

SDSC Franklin has already received State approval to develop the first freestanding ambulatory surgery center in Franklin County. The only current provider of surgical services in the county, Franklin Medical Center (FMC), is currently licensed for 3 shared inpatient/outpatient ORs, and operates 2 of these 3 ORs. FMC has experienced a declining trend in surgery volume in recent years (see Table 4 above). The proposed project will not change the inventory of existing and approved operating rooms in Franklin County.

The SDSC Franklin application does not adequately explain how the development of SDSC Franklin, with 2 operating rooms, will enhance competition, nor does it explain the impact SDSC Franklin will have on FMC and other surgery centers located in close proximity to the proposed project, although the need methodology indicates that growth in utilization at SDSC Franklin will be at least partially at the expense of existing providers of surgical services in Wake, Nash and Vance Counties. The application's response to Question V.7 outlines a number of operational initiatives being undertaken by Novant Health, Inc. regarding cost effectiveness and quality, yet none of these were translated back to enhanced competition, as many hospitals and health systems are undertaking similar initiatives.

Based on the points above, the SDSC Franklin application is not conforming with Review Criterion 18a, in that the favorable effects of competition were not demonstrated.

### **Summary**

Based on the information provided in these comments, the SCSC Franklin application does not conform to numerous CON Review Criteria, and should not be approved.