Comments on Same Day Surgery Center Franklin, LLC

submitted by

Rex Healthcare

In accordance with N.C. GEN. STAT. § 131E-185(a1)(1), Rex Healthcare (Rex) submits the following comments related to an application to relocate an existing operating room and to develop an ambulatory surgical facility in a new location. Rex's comments include "*discussion and argument regarding whether, in light of the material contained in the application and other relevant factual material, the application complies with the relevant review criteria, plans and standards*." *See* N.C. GEN. STAT. § 131E-185(a1)(1)(c). In order to facilitate the Agency's review of these comments, Rex has organized its discussion by issue, noting some of the general CON statutory review criteria and specific regulatory criteria and standards creating the non-conformity relative to each issue, as they relate to the following application:

- **Same Day Surgery Center Franklin, LLC (SDSCF), Project ID # K-10229-13**

GENERAL COMMENTS

While Rex understands the need to redeploy assets from time to time in order to address the changing needs of the population, and has, in fact, done so in order to better meet the need of its patients, it does not believe that the proposed application should be approved, for the reasons discussed below. Among other factors, the application discusses the lack of an ambulatory surgical center (ASC) in the area and the inefficiency of a one-OR ASC as reasons the proposed project is needed. However, both of those factors exist because of the actions (or lack thereof) of SDSCF. The original application proposed only a one-room ASC, even though the second room, now proposed to be relocated, already existed at the hospital and could have been proposed to be relocated at the time. Moreover, that application was approved several years ago; the delay in the facility's development, for whatever the reasons, is the sole responsibility of the applicant. In addition, no other entity can develop an ASC with operating rooms in Franklin County. Thus, the lack of an ASC and the approved CON for only a one-OR ASC are both the result of choices made by the applicant.

In addition, although some of the special rules for operating rooms may not apply to this proposal, the applicant must still reasonably demonstrate the need the population has for the two-room ASC, as well as the need for two ORs at the

hospital. As shown in the comments below, Rex does not believe that SDSCF has done so, and the application should be denied.

Finally, as shown in the application, even with the aggressive assumptions employed to achieve the utilization projections, the volume for year three is barely sufficient to demonstrate the need for a second OR at the ASC, even if it were credible. SDSCF has already been approved for an ASC with one OR and one procedure room; a more prudent approach would be to develop the project as approved, then determine whether an increase in utilization actually occurs to the extent that a second OR is needed. Novant Health already operates a one-OR ASC in Union County, which has nearly four times the population of Franklin County and includes 98 physicians on its medical staff; however, that ASC performed only 787 cases in 2012, according to its 2013 License Renewal Application. Although there are certainly differences in the markets between the two counties, the point is that SDSCF already has a CON for a one-room ASC, which can be developed a lower cost than the proposed two-room ASC and, if a significant growth in utilization does occur, the applicant may then have a more reasonable basis for proposing a second OR.

APPLICATION-SPECIFIC COMMENTS

SDSCF's application should not be approved as proposed. In summary, SDSCF's application failed to adequately demonstrate the need for its proposed project as its utilization projections are unreasonable.

Rex identified the following specific issues, each of which contributes to SDSCF's non-conformity:

(1) Failure to include necessary applicant;
(2) Unreasonable utilization projections;
(3) Failure to adequately demonstrate that the proposed project represents the least costly and/or most effective and reasonable alternative; and,
(4) Unreasonable payor mix assumptions.

Each of the issues listed above are discussed in turn below. Please note that relative to each issue, Rex has identified the statutory review criteria and specific regulatory criteria and standards creating the non-conformity.

<u>Failure to Include Necessary Applicant</u>

SDSCF proposes to relocate an existing operating room from Novant Health Franklin Medical Center to the ASC in Youngsville. Since the original application

(Project ID # K-8357-09) involved the development of an operating room proposed in the *SMFP*, and not the relocation of an existing operating room to be transferred from another entity, the only necessary applicant was the entity proposing to develop the newly allocated operating room. In this instance, however, SDSCF proposes to develop a second operating room, which will be relocated from the hospital in Louisburg, which is not owned or operated by Same Day Surgery Center Franklin, LLC. Specifically, according to its 2013 License Renewal Application, the hospital is owned by Louisburg Novant, LLC. Although both entities may have Novant Health as their ultimate "parent," the applicant entity in this application has no authority to transfer the operating room from the hospital in Louisburg. Moreover, if a certificate of need is ultimately issued for this project, any conditions of the CON would pertain only to the applicant, and not to the hospital entity from which the operating room would be transferred. Thus, the application fails to include the hospital entity as a necessary applicant and the application should not be approved on that basis, or, at a maximum, should be conditioned to be developed at the new location with only the one approved operating room.

Unreasonable Utilization Projections

SDSCF's market share projections are unreasonable. Starting on page 62, the application explains the rationale for the market share assumptions by ZIP code, which are also detailed in Exhibit 3. These reasons do not support the market share projections for the following reasons.

1. The market share projections include both the ASC and the hospital. The application fails to demonstrate how the market share for the hospital will increase. Novant Health has owned the hospital for several years, yet the volume of surgical cases has dropped precipitously. In FFY 2013, only 109 inpatient cases were performed at the hospital. Yet, in 2019, the application projects inpatient volume of 181 cases, which represents a compound annual growth rate (CAGR) of 8.8 percent and a total growth of 66 percent. For total cases, the application projects volume at the hospital to grow from 925 cases to 1,339 cases, a growth of 45 percent. The application fails to demonstrate that the development of an ASC in southernmost Franklin County, near the border of Wake County, will positively and significantly impact surgical utilization at the hospital, particularly to this incredible extent.

2. The market share assumptions are also not credible given the amount of market share growth projected from ZIP codes closer to the hospital. For instance, the application projects the market share in the Louisburg ZIP code to grow from 19 percent to 50 percent; however, the application fails

to demonstrate how the development of an ASC in Youngsville will drive such an increase in Louisburg, where the hospital has existed and been owned by Novant for many years.

3. The application also states as support for its assumptions the fact that 85 percent of Franklin County residents travel outside the county for surgery. However, that fact is also driven by the large numbers of Franklin County residents, including many that live in the Youngsville area, that commute into Wake County for work and to access other services. Moreover, even assuming that a portion of local residents would choose to access care in their home county at the proposed ASC, such a change in pattern contradicts SDSCF's assumption of market share growth from Wake County. In the case of the Wake County ZIPs, the application assumes that *more* people will leave their home county for care, traveling from Wake to Franklin County, which is clearly opposite the normal travel and work patterns. As shown on page 212 of the application, FMC provided outpatient surgery to 24 patients from the Wake County ZIP codes within the service area (27572, 27587, and 27597) in 2013. In PY3, FMC's volume is projected to increase to 32 cases in those ZIP codes and SDSCF is projected to serve 407 cases, which is more than 17 times FMC's 2013 volume. As SDSCF notes, there are two existing ambulatory surgery centers in northern Wake County where patients from these ZIP codes receive care. As such it is unreasonable for SDSCF to project such substantial growth from this area.

4. SDSCF also suggests that the population growth in the area supports its market share assumptions. That is a fallacy; population growth and market share are unrelated. For example, if a ZIP code has a population of 10,000 and the market share is 10 percent, then the patient count is 1,000. If the population doubles to 20,000 and the market share remains 10 percent, then the patient count doubles to 2,000. The volume may increase with population growth; however, projecting market share increases along with increases from population growth *compounds* the growth. If the market share is assumed to grow to 20 percent along with the population growth, then the volume would be 4,000. The application states that the population growth will support the market share growth; however, clearly the two are not related.

5. The application also points to the physician letters of support as rationale for its market share assumptions. However, the application fails to demonstrate how the support letters relate to the market share assumptions by ZIP code, nor does it explain why certain market share projections were chosen for certain ZIP codes based on the support

physicians located in or treating patients from those ZIP codes. In addition, as a community hospital and an ASC, neither facility will perform all types of surgical cases, either ambulatory or inpatient; thus, the rationale for assuming a particular market share is not linked to the types of surgery either to be performed at both sites or to be referred by the physicians who signed support letters. Moreover, the majority of patients from Wake County shown in Exhibit 3, Table 12 are from primary care physicians. While these physicians may support the project, they are not surgeons and therefore will not perform surgery at either location. There is no analysis to demonstrate that patients of these providers need surgery, particularly in the specialties to be provided at the ASC or the hospital. Thus, the letters do not demonstrate the reasonableness of the market share percentages.

6. The application also states in support of its market share assumptions that the proposed ASC will be convenient and close to the entire Franklin County population. However, the Agency has already determined, in two sets of findings on the applications to relocate the hospital to Youngsville (Project ID # K-7806-07 and Project ID # K-8024-07) that a Youngsville location was not convenient or close to all of Franklin County. Thus, assuming that market share will increase for all the ZIP codes in the service area, particularly those farther from the ASC than they are from the hospital, reflects a premise that the Agency has already found to be implausible.

7. On page 65, the application rationalizes its market share projections by stating that the current total outpatient surgical market share from the SDSCF service area is 5.2 percent, and with the projected changes, will increase to 21.1 percent, which it cites as an increase of "only" 15.9 percent. While this increase is 15.9 percentage *points*, ***the actual increase is over 300 percent, or three times the current market share***. Thus, the actual increase in market share is much more significant that the application would suggest, and the reasonableness of such an increase is not supported by the application.

8. On the same page, the application states that the total market share of Franklin County for both the hospital and the ASC is projected to be 43.7 percent. The application cites the analysis in Exhibit 3, Table 24 as support. However, as shown in that Exhibit, the projected market share for this application exceeds both the mean and the median market shares for the other counties, as well as the average for the counties with a hospital and an ASC—and projects to do so just three years after developing the ASC. Moreover, while the counties are similar to Franklin

based on population size, they are not all as similar in terms of location and proximity to other providers. For instance, Watauga, Surry and Haywood counties are rather mountainous, which presents a natural geographic barrier to traveling out of the county for care. Other counties, such as Columbus, are large and rather isolated. In contrast, the more populous areas of Franklin County, such as Youngsville and Bunn, border Wake County and serve as bedroom communities for one of the state's largest metropolitan areas. Even in counties such as Lincoln and Granville, which border metro areas but in which the hospitals are some distance from the border of the county, the percentage of patients receiving care in the county are much lower than SDSCF is projecting to achieve. Given the relative short distance of the proposed ASC to the Wake County border, the higher market share projections are not reasonable.

9. On page 66, SDSCF assumes that outpatient surgical cases at FMC will grow 4.9 percent annually and notes that "*while an outpatient CAGR of 4.9% may appear high, it is high only because annual outpatient surgical volume at NHFRMC is low.*" The use of FMC's historical growth rate to project forward is unreasonable. Growth of 4.9 percent from a small base number of cases is easier to achieve than with a higher base number. However, as FMC's volume is projected forward, its base number grows, and is compounded, and thus 4.9 percent growth becomes increasingly large. Moreover, SDSCF appears to have selected a time period (2011 to 2013) that is unrepresentative of the larger historical trend at FMC. The table below shows volume for FMC since 2008, which shows a strong downward trend overall and annual declines in every year except from 2011 to 2012.

Year	*OP Cases*	*Annual Growth*
2008	1,422	
2009	834	-41.4%
2010	752	-9.8%
2011	742	-1.3%
2012	838	12.9%
2013	816	-2.6%
CAGR	**-10.5%**	**NA**

Source: Hospital License Renewal Applications.

The projected 4.9 percent growth rate is expected to continue through project year three and no cases are expected to shift to SDSCF. It is simply

unreasonable to expect that FMC's historical volume will not be affected at all by a new surgery center. In fact, the application's assumes that the creation of SDSCF will increase volume at FMC over and above its historical growth. As shown in the summary table below, FMC's outpatient cases are projected to grow a 6.0 percent annually or 1.1 percent more than its historical rate due to its unreasonable market share assumptions for Louisburg as discussed above.

Each of these factors shows clearly that the rationale for SDSCF's market share assumptions is unreasonable and does not support the utilization projections in the application. In addition, it is important to review the impact of these assumptions on the utilization projections as a whole. The table below shows the historical surgical utilization at NHFMC and the projected utilization for both the hospital and the ASC.

	2013	*2017*	*2018*	*2019*	*CAGR*	*Total Growth*
FMC IP	109	153	167	181	8.8%	66.1%
FMC OP	816	987	1,057	1,158	6.0%	41.9%
ASC OP	0	1,022	1,346	1,644	NA	NA
Total	**925**	**2,009**	**2,403**	**2,802**	**21.5%**	**222.5%**

As shown, the application projects an incredible amount of total growth from 2013 to 2019 that is simply not supported in the application.

The application also fails to account for the challenges with reimbursement for bariatric surgery, which negatively impacts its volume and financial projections. SDSCF includes bariatric surgery as one of the specialties it intends to perform; however, reimbursement for bariatric surgery is limited by both CMS and other payors. In particular, some payors require a provider to be an accredited bariatric center of excellence in order to be reimbursed, and others do not provide reimbursement in an ASC setting, but only pay for bariatric surgery in a hospital setting. The application fails to show that SDSCF considered or accounted for these factors, and as such, its volume projections, particularly relating to bariatric surgery, are not reasonable.

Given these factors, SDSCF should be found non-conforming with Criteria 3 and 5.

Failure to Consider Most Effective Alternative

The application lists several alternatives considered by the applicant, including the status quo. What is clearly missing from the consideration is that the

applicant could have proposed a relocated second OR in its original application, even though the need determination was only for one operating room. Since that application was proposed, however, surgical utilization in Franklin County has decreased precipitously, obviating the need for the four existing and approved ORs, including the two proposed for the ASC. Since the need for a second OR at the ASC has not been demonstrated, it is clear that the most effective alternative would be to proceed with the original project as proposed, then apply for a second OR in the future if volume actually warrants it.

The application also suggests that the OR to be relocated from the hospital would require a significant amount of capital in order to make it able to be utilized effectively at the hospital. Such an argument does not support the need to relocate the OR, however, since the relocation of the OR is increasing the cost of the original project by over $6 million. The applicant fails to provide the cost of the renovation required at the hospital, but it is difficult to imagine that the cost of renovating one operating room would exceed $6 million. Thus, this rationale does not demonstrate that the chosen alternative is the least costly.

Based on these issues, the application should be found non-conforming with Criterion 4.

Unreasonable Payor Mix Assumptions

In Section VI and in the financials, the application presents its projected payor mix, which it states is based on that of other ASCs. However, payor mix relates to the population being served, in terms of both geography and the specialties being performed. For instance, poorer, more rural areas typically have higher percentages of Medicaid and Medicare than more upscale, urban communities. Similarly, payor mix for various specialties reflects the patients served by that specialty. For example, ENT cases are often performed on children, and thus often reflect higher Medicaid but lower Medicare payor mix, while ophthalmology cases are often performed on seniors, and thus often show a higher Medicare but lower Medicaid payor mix. The application fails to demonstrate that its projected payor mix is based on either the population to be served or the types of cases proposed and therefore does not show that it is reasonable.

This fact is also demonstrated by the significant decrease in Medicaid access proposed in the application. On page 115, the applicant shows the payor mix for its existing surgical services, which includes 20.29 percent Medicaid and 55.03 percent Medicare. The proposed payor mix on page 116 shows only 6.18 percent

Medicaid and 38.84 percent Medicare, a significant decrease from the historical percentages. The application repeatedly discusses the advantages of a freestanding ASC compared to a hospital-based setting, yet it is clear that these advantages will not be provided to the same extent to the Medicaid and Medicare populations, which are medically underserved. This lack of access is also an important factor, given that the applicant proposes to relocate an operating room from the hospital to the ASC; as such, the Agency must determine that the relocation of this asset will not have a detrimental impact on the population to be served. According to the applicant's own projections, fewer medically underserved will receive access with the proposed project.

As a result of these factors, the application should be found non-conforming with Criteria 3, 3a, 5, and 13(c).