

December 31, 2020

COMMENTS IN OPPOSITION FROM NOVANT HEALTH, INC.

**Regarding South Charlotte Surgery Center's CON Application for One Operating Room,
Filed November 15, 2020**

South Charlotte Surgery Center, Project I.D. #F-012004-20: Develop a new ASC with one OR pursuant to the need determination in the 2020 SMFP.

Executive Summary

These comments respond to the South Charlotte Surgery Center ("SCSC") application for a new ambulatory surgery center ("ASC") with one operating room ("OR"). The application left several aspects of the SCSC project unclear, and several CON questions were unanswered or had incomplete or unsupported answers. These comments discuss those deficiencies. For clarity, the section of the application and question number are noted or referenced in parentheses.

These comments show the SCSC Application is non-conforming with CON Review Criteria (1), (3), (4), (5), (6), (7), (8), (12), (13), and (18a). The Agency cannot approve a non-conforming application. A non-conforming application cannot be comparatively superior to other applications in the same review cycle. Novant Health ("NH") respectfully urges the Agency to deny the SCSC Application.

Project Description and Scope

Throughout the application, SCSC calls the project an ambulatory surgical center ("ASC") with one OR.¹ However, it appears SCSC intends to operate two cardiac catheterization laboratories, rather than a surgical facility. The items noted below support that conclusion:

- The floor plan in Exhibit K.1b does not have a space labeled as an OR.
- The application failed to identify the CPT codes expected to be performed at the ASC. With no list, it is impossible for the Agency to determine what procedures SCSC intends to provide at the ASC.
- The floor plan in Exhibit K.1b has two rooms labeled "Cath Lab."
- The floor plan in Exhibit K.1b has a space labeled "Cath Equip Rom" and a Control Room between the two "Cath Lab" spaces.
- Section N, Page 50, of the application states, "The ASC would be the first Vascular ASC in the area. With Medicare recently including more cardiac catheterization procedures for reimbursement,

¹ See SCSC CON Application (Project ID # F-012004-20), pp. 6, 9, 15, and Section Q Form F.2.

Vascular surgery procedures will be driven into these facilities traditional [sic] performed in hospitals.” This indicates SCSC intends to perform cardiac catheterization procedures.

If the application is for two cardiac catheterization laboratories, it does not meet the SMFP or CON requirements.

- It is not permissible to operate a cardiac catheterization laboratory without CON approval in North Carolina.
- There is no SMFP need for cardiac catheterization equipment in Mecklenburg County.
- SCSC does not show it would meet the performance standards for cardiac catheterization laboratories at 10A NCAC 14C.1601.
- Given there is no need determination in the 2020 SMFP for additional cardiac catheterization equipment in Mecklenburg County, SCSC’s application is non-conforming with Criteria (1), (3), (4), (5), (6), (7), (8), (12), and (18a), as well the cardiac catheterization performance standards, 10A NCAC 14C.1600 et seq.
- The applicant cannot now supply a different floor plan because that would be an impermissible amendment to the application, 10A NCAC 14C.0204.

If the application is for an ASC with one OR, it does not meet the CON requirements for approval. These comments show the application is non-conforming with several review criteria for ORs.

Criterion (1) and Policy GEN-3

Criterion (1): NCGS §131E-183(a)(1): The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on any health service, health service facility, health service facility beds, dialysis stations, or home health offices that may be approved.

The Agency should find the application non-conforming to Criterion (1) because it lacks complete answers to the questions responsive to Policy GEN-3. Policy GEN-3: Basic Principles, states:

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

The application lacks complete answers to Section B, Question 3 (the numbering below corresponds to question subparts, for ease of reference). Without more detailed answers, the Agency cannot find SCSC conforming with Policy GEN-3 and review Criterion (1).

3.
 - a. SCSC did not adequately demonstrate how it would promote safety and quality.
 - b. SCSC did not adequately explain or provide supporting documentation on how it would provide equitable access. It only addressed improved patient access in terms of travel time, parking, and scheduling.
 - c. *See detailed discussion, below.*
 - d. SCSC did not explain or document how the project incorporates concepts of safety, quality, access or value for resources expended. SCSC did not explain how it will ensure the safety of its patients. SCSC did not attach or reference any safety policies, procedures, or protocols.

Healthcare Value, SCSC Proposed Services and Appropriate Place of Service

SCSC answered Question 3(c) on how the project “will maximize healthcare value for resources expended” by stating it is “a low-cost provider compared to hospitals where most of these surgeries are currently performed.”² There are several problems with this statement:

- SCSC’s utilization projections are unreasonable and inadequately documented. We discuss the utilization projections at Criterion (3) and incorporate that critique by reference.
- Based on the floor plan, it is unclear SCSC intends to perform “surgeries.” There is no OR on the floor plan. Instead, there are two cardiac catheterization procedure rooms. Therefore, differences in facility fees for a hospital and an ASC are irrelevant.
- Even if SCSC intends to build an OR and perform surgical procedures, it has not shown it will result in cost savings. SCSC did not document that the interested physicians currently perform the procedures in a hospital rather than an existing ASC or a physician’s office.
- Moving surgical procedures or other procedures that can be safely performed in a physician’s office to an ASC increases cost to patients and health plans by adding an unnecessary facility fee to the total cost.

NH could not replicate the historical volumes SCSC reported for its interested physicians using IBM Health Watson / Truven Analytics data. NH then queried the Center for Medicare and Medicaid Services (“CMS”) Physician and Other Provider Public Use File (“PUF”) for 2018.³ This data file reports services provided by

² SCSC Application, p. 13

³ Data is available at <https://www.cms.gov/research-statistics-data-systems/medicare-provider-utilization-and-payment-data/medicare-provider-utilization-and-payment-data-physician-and-other-supplier/physician-and->

individual physicians to a Medicare beneficiary. Physicians are identified by National Provider Identifier (“NPI”). For each CPT code, the data show whether the service was provided in a physician’s office or in a facility. A facility may be either an ASC or a hospital. The data for 2018 (the most recent year available) are presented below.

Count of CPT Codes (Excluding Evaluation and Management) by Place of Service in CY 2018

| Physician | Facility | Office |
|------------------|----------|--------|
| Weston, Steve | 2,440 | 590 |
| Antezana, James | | 1,850 |
| Arbid, Elias | 137 | 690 |
| Ford, Peter | | 667 |
| Sicilia, Carlos | 14 | |
| Singh, Inderjeet | 130 | |

Source: 2018 CMS Provider of Services File.

Dr. Antezana and Dr. Ford performed all procedures for Medicare beneficiaries in an office, and none in a facility. SCSC included no data showing they are performing a significant number of procedures for non-Medicare patients in hospitals or ASCs. Moving procedures from a physician’s office to an ASC will increase costs.⁴ The Agency should find SCSC non-conforming with Criterion (3) because it does not “maximize healthcare value.” Keeping procedures safely performed in a physician’s office in that place of service maximizes healthcare value.

For these reasons, plus any additional reasons the Agency may discern, the SCSC Application is non-conforming with Criterion (1) and Policy GEN-3 and should be denied.

Criterion (3)

Criterion (3): NCGS §131E-183(a)(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 service area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups likely to have access to the services proposed.

The SCSC Application is non-conforming with Criterion (3) because:

- It did not define the population it will serve.
- It did not document the need the population has for its services.

other-supplier-data-cy-2018. This file is available to the Agency. It can be downloaded at no cost and without a data use agreement.

⁴ As discussed in Criterion (3), SCSC does not show a need for an operating room without the assumption that some volume of procedures previously performed in a physician’s office will move to the ASC.

- It did not clearly define the scope of its services (Section C, Question 1).
 - SCSC provides no list of CPT codes or ICD-10 procedure codes to identify the procedures the physicians will perform.
 - It is not clear if the facility will have an OR or two cardiac catheterization laboratories, based on the floor plans provided in Exhibit K.1b and the response provided to Section C, Question 1.
- It did not give a reasonable basis or supporting documentation for its expected patient origin. There is no data or explanation for its historical or projected patient origin (Section C, Questions 2 and 3).
- It did not show any need for the project other than the “area population growth”⁵ of Mecklenburg, Gaston, York, and Lancaster counties. Population growth alone is not a reasonable demonstration of need for a project. The Agency should find SCSC non-conforming with Criterion (3) based solely on its lack of documentation of demonstration of need (Section C, Question 4).
- The utilization projections are unreasonable and unsupported (Section C, Question 7).

SCSC’s Utilization Projections Are Unreasonable and Do Not Demonstrate Need for the Project (Section C, Question 7)

The application did not adequately document physician support.

It has no documentation the “interested” physicians (Drs. Singh, Ford, and Sicilia) will move the stated volumes to the ASC if it is approved. No “interested” physician provided a signed letter of support for the project.

The utilization projections are not reasonable or adequately supported.

The application shows 2019 volumes for the three physicians in the practice group and 2019 volumes for three “interested physicians.” The application did not state where the procedures were performed or the source of the data. The table below summarizes the 2019 volume in Form C.

| Physician | 2019 Volume | Participation | ASC Volume |
|------------------|-------------|---------------|------------|
| Weston, Steve | 20 | | 20 |
| Antezana, James | 319 | | 319 |
| Arbid, Elias | 44 | | 44 |
| Ford, Peter | 557 | 10% | 56 |
| Sicilia, Carlos | 357 | 10% | 36 |
| Singh, Inderjeet | 473 | 8% | 38 |

Source: SCSC Application, Form C.

⁵ SCSC Application, p. 19.

The data from IBM Health Watson is not consistent with Form C. NH tabulated the data for outpatient procedures by these physicians with an OR charge. The table below shows the results.

| Physician | 2015 | 2016 | 2017 | 2018 | 2019 |
|------------------|-------|-------|-------|-------|-------|
| Weston, Steve | 556 | 481 | 284 | 697 | 1132 |
| Antezana, James | | 4 | | | |
| Arbid, Elias* | | | | | |
| Ford, Peter | | 1 | 1 | | |
| Sicilia, Carlos | 282 | 369 | 338 | 275 | 358 |
| Singh, Inderjeet | 640 | 620 | 636 | 566 | 623 |
| Total | 1,478 | 1,475 | 1,259 | 1,538 | 2,113 |

*Source: IBM Health Watson, Limited to outpatient procedures with an OR charge. *Dr. Arbid appears to have been practicing outside of North Carolina before early 2019.*

The volumes for Dr. Antezana and Dr. Ford are significantly less than SCSC reported. Without the procedures SCSC assumed Dr. Antezana and Dr. Ford will perform at the ASC, the project does not show a need for an OR.

The volume projections appear to assume procedures now done in a physician’s office will move to the ASC. This would explain why the projected procedures for these two physicians do not appear in the past Truven Analytics data. Moving procedures to a higher-cost setting with no showing of advantage to patients or health plans makes the application non-conforming with Policy GEN-3, Criterion (1), Criterion (4), Criterion (6), Criterion (12), and Criterion (18a). In addition, because there are no letters of support from the physicians, the Agency has no documentation which procedures they intend to move.

Without moving procedures by Dr. Antezana and Dr. Ford from a physician’s office, SCSC does not demonstrate need for an operating room. The table below replicates SCSC’s projections in Form C of its application without the procedures from Drs. Antezana and Ford. SCSC’s application is non-confirming with Criterion (3).

Operating Room Need, Assuming No Volume Shift from Physician Office to ASC

| Physician | 2019 | 2022 (Partial) | 2023 | 2024 | 2025 |
|--|------------|-------------------|------------|------------|------------|
| Weston, Steve | 20 | 21 | 22 | 22 | 23 |
| Antezana, James | 0 | 0 | 0 | 0 | 0 |
| Arbid, Elias | 0 | 0 | 0 | 0 | 0 |
| Ford, Peter (Independent @ 10%) | 0 | 0 | 0 | 0 | 0 |
| Sicilia, Carlos (Independent @ 10%) | 36 | 38 | 39 | 40 | 41 |
| Singh, Inderjeet (Independent @ 8%) | 50 | 53 | 54 | 55 | 56 |
| Total | 106 | 112 | 115 | 117 | 119 |
| Total Surgical Hours (volume x 1.19 hours per case) | | | 136 | 139 | 142 |
| Total Surgical Hours / Standard Hours per OR per Year (1,312) | | | 10.39% | 10.60% | 10.81% |

The Agency should find:

- The application repeatedly misrepresented and overstated the physicians’ past surgical volumes.
- The application did not adequately document the physicians are performing surgical procedures that require an OR in a licensed facility.
- The application provides little to no documentation to support its assumptions.

These deficiencies make SCSC’s utilization projections and demonstration of need unreasonable and unreliable. For these reasons, plus any additional reasons the Agency may discern, the SCSC Application is non-conforming with Criterion (3) and should be denied.

Criterion (4)

Criterion (4) NCGS §131E-183(a)(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 SCSC Application does not adequately demonstrate opening a one OR ASC is the most effective alternative to meet the need because:

- It did not identify by CPT code or other means what procedures would be performed.
- It did not show where the projected procedures are currently performed.

- It did not show the majority of projected procedures could not be performed safely in a physician's office at a lower cost to patients and health plans.
- It did appear to have included two cardiac catheterization laboratories without a need determination for cardiac catheterization equipment. There is nothing in the application to explain why cardiac catheterization procedures could not be performed in existing cardiac catheterization laboratories in Mecklenburg County.
- It does not show the physicians have patients who reside in the service area for the ASC. Without more detailed information on projected patient origin, the Agency cannot discern if SCSC would be a more effective alternative than the existing facilities or physicians' offices where the physicians now practice.

For these reasons, plus any additional reasons the Agency may discern, the SCSC Application is non-conforming with Criterion (4) and should be denied.

Criterion (5)

Criterion (5) NCGS §131E-183(a)(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.*

The assumptions on procedure volume in the pro forma financial statements are not reasonable and adequately supported because projected utilization is unreasonable and unsupported. The discussion regarding projected utilization found in Criterion (3) is incorporated by reference. Because projected revenues and expenses are based on projected utilization, projected revenues and expenses are also unreasonable and not adequately supported.

The application did not specify the projected procedures by CPT code. Payment for outpatient procedures is based on CPT codes and payment varies greatly from one code to another. Without showing the mix of procedures the application cannot show its projected gross or net revenue is reasonable or adequately supported.

The application did not include working capital for the operating expenses in its initial operating period. SCSC states its initial operating period is six months. In Exhibit F.4a, SCSC provides revenue and expense assumptions, including "fixed costs" for "half year interim 2022." Presumably, this is the first six months of SCSC's operations (July–December 2022). Exhibit F.4a includes total fixed costs of \$331,385 and total expenses of \$375,460. The application shows total operating expenses of \$375,460 but only shows \$227,593 in working capital, when it defined its initial operating period (the number of months from opening until cash in-flow exceeds cash out-flow) as six months. The Agency should find SCSC non-conforming with Criterion (5) because it has not documented the short-term financial feasibility of the project.

The application’s assumptions for revenues and expenses are not reasonable or adequately documented. The past revenues and costs were obtained “from the system billing records for the physicians of SCGVS,” and each independent physician “provided the same billing data for the project that includes the FY of 2019.”⁶ Although SCSC provides some additional information in Exhibit F.4a, these data are not a reasonable basis for the revenues and expenses because:

- The revenues a physician earns from performing procedures are not equivalent to the facility fees for those procedures. SCSC did not explain how it translated physician billing data to facility revenues.
- The payor mix used in the application is not reasonable or adequately supported. The only explanation for its projected payor mix was “No change in Payor Mix.” SCSC never defined the population it uses in its base year payor mix. If past volumes include patients from outside the SCSC service area, it is not reasonable to assume the payor mix would not change. Because its payor mix is unreliable, SCSC’s revenue projections are unreliable.
- The operating expenses for an ASC differ from those for a physician’s office. If SCSC relied on operating expenses from the physicians’ offices, its projected expenses are unreasonable. If it relied on other expense data, it did not document the sources or method for the expense projections.
- The expenses in Exhibit F.4a (\$375,460) do not equal those shown in Form F.2 (\$363,721).
- The application says construction will be financed with a loan. However, Form F.3 shows no interest. Based on the loan documentation in Exhibit F.2b, this would increase expenses by \$113,399 per year.

For these reasons, plus any additional reasons the Agency may discern, the SCSC Application is non-conforming with Criterion (5) and should be denied.

Criterion (6)

Criterion (6) NCGS §131E-183(a)(6): *The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.*

In Section G, page 35, the applicant states the proposed project will not result in unnecessary duplication of existing or approved services or facilities because “there are no other single specialty vascular surgery ASCs in the Charlotte Area that provides [sic] these types of procedures.” SCSC provides no list of CPT or ICD-10 codes, or information on where its physicians currently perform procedures. Without such information, the Agency cannot reasonably rely on SCSC’s statement. The lack of a single-specialty ASC that provides interventional surgery “for the veins, arteries, and heart” does not show that the project does not duplicate existing facilities.

⁶ SCSC Application, p. 33.

The application did not base projected volume on reasonable and adequately supported assumptions. The application did not document whether existing multi-specialty ASCs perform the same procedures it proposes. It did not document which hospitals perform the proposed procedures. It did not document how many of the proposed procedures are currently performed or could be performed safely in physicians' offices. It appears SCSC would move procedures from physicians' offices to an ASC. NH incorporates those critiques here by reference. Because SCSC is non-conforming with Policy GEN-3 and Criterion (3), it cannot demonstrate it does not constitute an unnecessary duplication of existing facilities. Therefore, the application is non-conforming with Criterion (6).

For these reasons, plus any additional reasons the Agency may discern, the SCSC Application is non-conforming with Criterion (6) and should be denied

Criterion (7)

Criterion (7) NCGS §131E-183(a)(7): *The applicant shall show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided.*

The application did not give complete responses to the questions under Criterion (7). It did not document there will be adequate staffing for the proposed project. Assuming the project is for one OR (and not for two cardiac catheterization laboratories), the staffing shown in the application is inadequate because:

- It did not include detailed staffing assumptions or a recruitment plan. It did not answer Section H, Question 1 and Question 2.
- It has only 2.1 RNs in the staffing plan. It is not clear if this is sufficient nursing staff. A one-OR ASC would require one nurse in the OR, one Post-Anesthesia Care Unit nurse, and a surgical tech. The application did not specify its hours of operation. Without this information, it is not clear if the number of FTEs in the application are sufficient.
- It did not include a Director of Nursing or similar position.
- It did not increase nurse staffing as the patient volume increases in the first three years. It is normal for ASCs to increase staffing as volume increases.
- It did not describe how SCSC will provide anesthesia. No anesthesiologists are indicated on Form H. No anesthesia group signed a letter agreeing to provide coverage. The ASC may have to employ a CRNA.
- It has only a 0.5 FTE Administrator. It is not clear if this is sufficient staffing for this position.

For these reasons, plus any additional reasons the Agency may discern, the SCSC Application is non-conforming with Criterion (7) and should be denied.

Criterion (8)

Criterion (8) NCGS §131E-183(a)(8): *The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.*

The application did not adequately demonstrate the necessary ancillary and support services will be available for patients of the proposed project. It did not document how it will provide anesthesia services. SCSC states it will provide the majority of its ancillary services through the staff of the physicians' offices, before surgery. It did not document if the physicians' offices have the necessary staff or equipment. It did not explain how it will perform any required same-day imaging or laboratory services. It simply states that "patients will be directed . . . to ancillary vendors."⁷ The application included expenses for dietary and housekeeping services in its Form F.3 expenses, but did not say what companies or individuals will provide these services.

The application did not adequately respond to Section I, Question 3, regarding physicians who would use the ORs. It says only that the three primary surgeons at SCGVS and three other surgeons "have expressed interest in utilizing the ASC for their patients."⁸ However, it did not adequately document any commitment by the physicians to perform any number of procedures at SCSC. NH's discussion of physician participation and volumes in Criterion (3) is incorporated by reference. The application did not answer Section I, Question 3(c) on physician recruitment. It did not include a recruitment plan as an exhibit.

For these reasons, plus any additional reasons the Agency may discern, the SCSC Application is non-conforming with Criterion (8) and should be denied.

Criterion (12)

Criterion (12) NCGS §131E-183(a)(12): *Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.*

The application did not demonstrate that the design, cost, and means of construction are the most reasonable alternative for the proposed project. The floor plan does not have a space marked as an OR. Instead, it has two rooms shown as cardiac catheterization laboratories and a room for cardiac catheterization equipment. If this is a project for two cardiac catheterization laboratories, SCSC is non-conforming with multiple CON criteria as explained above, and the Agency should deny the application.

If the application is for an OR, it is non-conforming with Criterion (12) because:

- There is no space identified as an OR.

⁷ SCSC Application, Page 39.

⁸ SCSC Application, Page 40.

- The larger of the two rooms labeled as a cardiac catheterization laboratory appears large enough to be an OR, but the semi-restricted areas do not have the required entrances to staff changing areas (FGI Guidelines for Design and Construction of Outpatient Facilities, 2018, Section AS.7-3.1.1.4b).
- The floor plan shows the entire second floor of the building, with no demarcation or indication of the 4,250 square feet SCSC says are dedicated to the proposed project.
- It did not answer Section K, Question 3.
 - It did not document how the cost, design, and construction is the most reasonable alternative.
 - It did not document why the project will not unduly increase costs to the public.
 - It did not document any applicable energy-saving features.

For these reasons, plus any additional reasons the Agency may discern, the SCSC Application is non-conforming with Criterion (12) and should be denied.

Criterion (13)

Criterion (13) NCGS §131E-183(a)(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;

(b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

(c) 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

(d) That the applicant offers a range of means by which a person will have access to its services. Examples of a range of means are outpatient services, admission by house staff, and admission by personal physicians

The payor mix in the application is not reasonable. It should be found non-conforming with Criterion (13) because the only explanation given for its projected payor mix is “No change in Payor Mix.” The application never defined the population in its base year payor mix. As discussed in relation to Policy GEN-3, Criterion (3) and Criterion (4), the places of service where the physicians currently perform procedures are never made clear. It is not reasonable to assume that the payor mix for the physicians would be the same,

regardless of where they perform procedures. If these past volumes include patients from outside the service area, it is not reasonable to assume the payor mix would not change.

Regarding charity care, the application says it will “adopt the same policies and procedures of its practice, SCGVS, that accepts all patients regardless of the patient’s ability to pay.”⁹ If SCSC will provide medically necessary healthcare to “all patients regardless of the patient’s ability to pay” it is not reasonable to expect these patients will be only 2 percent of the facility’s payor mix. While SCGVS physicians may have used this policy, it is unlikely that the facilities in which they have provided outpatient surgeries have similar policies in place. These facilities were likely collecting facility payments from some patients for whom the physicians waived or reduced professional fees. As a facility, the proposed ASC cannot reasonably assume only 2 percent of its patients will be charity care patients, if it provides care to all patients regardless of ability to pay.

The application has a charity care policy as an exhibit, but did not provide clarity on the issue. The criteria for financial assistance are subjective and unclear. The policy states that “only procedures listed on the ASC’s Approved Procedure List will be considered for this care,” and that services eligible for charity care include services “deemed medically necessary.”¹⁰ The list of approved procedures was not provided. It is not clear if the physicians consider all the “interventional vascular surgery for the veins, arteries, and heart” medically necessary care, or if some are elective procedures. The charity care policy and the payor mix are irreconcilable.

For these reasons, plus any additional reasons the Agency may discern, the SCSC Application is non-conforming with Criterion (13) and should be denied.

Criterion (18a)

Criterion (18a) NCGS §131E-183(a)(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 application did not identify services on which competition would have a favorable impact. It did not clearly define the scope of services proposed, and whether it proposes an OR or two cardiac catheterization laboratories. The application did not demonstrate the need for the OR. It did not show how the award of an ASC with one OR would improve the cost-effectiveness, quality, or access to services for acute care services.

⁹ SCSC Application, p. 46.

¹⁰ SCSC Application, Exhibit L.4b.

The application did not adequately demonstrate the need which the population proposed to be served has for the proposed project. NH’s discussion of Criterion (3) is incorporated by reference.

In addition, the Agency should find the application non-conforming with Criterion (18a) because:

- It did not provide complete responses to the questions under Criterion (18a).
 - It did not answer Question 1, which requires an explanation of the project’s effect on competition.
 - It did not answer Question 2a on how any enhanced competition would affect the cost-effectiveness of the proposed services.
 - It did not answer Question 2b on how any enhanced competition would affect the quality of the proposed services.
 - It did not answer Question 2c on how any enhanced competition would affect access by medically underserved groups.
- It did not adequately demonstrate that projected utilization is based on reasonable and adequately supported assumptions. NH’s discussion of Criterion (3) is incorporated by reference.
- It did not adequately demonstrate that the proposal would not result in an unnecessary duplication of existing or approved services in the service area. NH’s discussion of Criterion (6) is incorporated by reference.

For these reasons, plus any additional reasons the Agency may discern, the SCSC Application is non-conforming with Criterion (18a) and should be denied.

OR Performance Standards

The application does not demonstrate conformity with the performance standards found in the OR rules at 10A NCAC 14C .2103. On page 23 of its application, SCSC notes that the Criteria and Standards for Surgical Services and Operating Rooms standard is applicable to the proposed project. The question following the performance standard asks applicants to “document that the proposal is consistent with the applicable Rules” and to “provide any supporting documentation in an exhibit.” SCSC did not supply an answer to these questions. The application refers the reader to Exhibit 9c, which is a copy of the rule.¹¹ There is no discussion of how the application meets the standard. The Agency should deny the application, as it does not document it is consistent with the applicable OR performance standards.

Comparative Review

¹¹ See SCSC CON Application, p. 23.

A non-conforming application cannot be comparatively superior to other applications in the same review cycle. As detailed above, SCSC is non-conforming with CON Review Criteria (1), (3), (4), (5), (6), (7), (8), (12), (13), and (18a), and therefore cannot be found superior to NH Steele Creek's application for ORs.

Novant Health's comments on the comparative analysis of the AH CMC OR Application are incorporated into these comments by reference.

Conclusion

Under G.S. §131E-183(a)(1) and the 2020 SMFP, no more than 12 ORs may be approved for Mecklenburg County in this review. Because the applications in this review collectively propose to develop 15 additional ORs in Mecklenburg County, all applications cannot be approved for the total number of ORs proposed. The application submitted by NH Steele Creek is conforming to all applicable statutory and regulatory review criteria. The SCSC Application is not conforming to all applicable statutory and regulatory review criteria. An application that is not conforming to all applicable statutory and regulatory review criteria cannot be approved.

The SCSC Application lacks support to reasonably project sufficient surgical procedures to demonstrate the need for an OR. The scope of the project is unclear, and the facility does not appear to have the appropriate spaces for surgical procedures. Its assumptions are not well documented and its utilization projections are unreliable and unreasonable. There is no evidence showing Mecklenburg County or Steele Creek residents need the SCSC project. There is no evidence the proposed project is the most reasonable and cost-effective setting for the projected procedures. SCSC did not submit a complete and sufficiently supported application for an OR. Accordingly, the SCSC Application should be denied.