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CON Section

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January 3, 2011

Mr. Craig Smith, Chief
Certificate of Need Section
Division of Health Service Regulation
2704 Mail Service Center
Raleigh, NC 27699-2704

RE: Comments regarding Certificate of Need Application:
CON Project ID # J-8621-10, North State Surgery Center LLC (Orange County)
Single Specialty Ambulatory Surgical Facility in the Service Area that includes Wake, Durham and Orange Counties

Dear Mr. Smith:

I am submitting comments regarding the above referenced application on behalf of University of North Carolina Hospitals. These comments are submitted in accordance with NCGS 131E-185(a1)(1) and reference specific statutory criteria and special demonstration project criteria and rules relevant to this review.

Thank you for your consideration of the enclosed information. Should you have any questions, please do not hesitate to contact me.

Sincerely,

David J. French
Consultant to University of North Carolina Hospitals

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In CON Project Application J-8621-10, North State Surgery Center LLC proposes to develop a single specialty general surgery outpatient center with 2 ORs and one procedure room in Orange County. Owners of the proposed facility include Foundation Health System Corp., a wholly owned subsidiary of Novant and four general surgeons with Regional Surgical Associates ("RSA"), who are employees of Novant Medical Group.

The application fails to conform to the CON criteria as follows:

1. **Unreasonable assumptions, flawed methodology and unreliable utilization projections causing the application to be nonconforming to multiple CON review criteria and regulatory standards for the two proposed operating rooms**
2. **Omission of patient origin for the nonsurgical patients to be served in the procedure room**
3. **Failure to demonstrate the need for the "non-surgical" procedure room where GI endoscopy procedures are to be performed**
4. **Omission of the responses for criteria and standards for GI endoscopy procedure rooms**
5. **Failure to provide utilization projections and the specific procedure codes to demonstrate the need to develop a procedure room and obtain $350,000 of endoscopy equipment**
6. **Failure to identify the facility staffing for the procedure room separately from the surgical operating room and other clinical areas**
7. **Unreasonable financial projections for the allocation of revenues and expenses to the procedure room**
8. **Failure to demonstrate financial feasibility of the project based on reasonable assumptions**
9. **The application erroneously omits the landlord Europa Center LLC as a CON co-applicant even though the lease agreement requires Europa to spend $200,000 for facility improvements for the development of the proposed project.**
10. **Failure to demonstrate the sources and commitment of funds for Europa Center LLC to expend $200,000 for the facility improvements for the project**

These deficiencies are explained as they relate to the specific criteria:

CON Review Criteria:

(1) The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service, health service facility, health service facility beds, dialysis stations, surgical operating rooms, or home health offices that may be approved.

The need determination for two operating rooms in the Area (Wake/Durham/Orange Counties) is pursuant to the Single Specialty Ambulatory Surgery Facility Demonstration Project. The 2010 State Medical Facilities Plan includes written criteria. The SMFP plan states "The demonstration project must meet the criteria described in Table 6D." The North State Surgery Center application fails to conform to Criterion 1 because the proposed project includes two single specialty general surgery surgical operating rooms plus one procedure room where GI endoscopy procedures will be performed. The application fails to address the CON regulatory

criteria for GI endoscopy procedures. Therefore the proposed project differs from the need determination in terms of the scope of services.

North States Surgery Center attempts to deceive the CON Section by stating "The applicant is not seeking approval for a new GI endoscopy procedure room at NSSC." However the application does include endoscopy equipment in the list of equipment provided in Exhibit 13. While the applicant fails to identify the CPT codes of the "non-surgical" procedures, the average charges and reimbursement are consistent with charges and reimbursement for GI endoscopy procedures.

(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 North State Surgery Center (NSSC) application is nonconforming to Criterion 3 based on unreasonable assumptions, flawed methodology and unreliable utilization projections.

The applicant fails to adequately identify the population to be served by the proposed project because the specific patient origin data for the non-surgical (endoscopy) procedure patients has been omitted from the application. The application fails to document the unmet need the population has for "non surgical" procedures to be performed by the general surgeons. Furthermore the application fails to provide the projected number of non-surgical (endoscopy) procedures per patient. Consequently the projected volumes of "non-surgical" procedures and cases are unsubstantiated.

NSSC fails to adequately justify the assumption that four surgeons can increase their combined productivity from their 2009 volume of 1,060 cases to the projected volumes in Years 1, 2 and 3. The following table demonstrates the overstated and unreasonable percentage increases for the first three years following project completion.

	RSA Volumes	Percentage Increase over 2009 Volume
2009 Volume	1,060	NA
PY 1	1,777	67.6%
PY 2	2,011	89.7%
PY 3	2,239	111.2%

NSSC projects 67.6 percent increase in surgery cases Year 1 as compared to the historical volume. It is totally unreasonable for this growth to be achieved based on market share increases because the four RSA general surgeons only represent 4.65

percent of the 86 licensed and active general surgeons in Durham and Orange Counties. [1]

It is unreasonable for the applicant to use the total RSA volume of 1,060 as the basis for projecting future utilization because not all of RSA's general surgery outpatients meet the criteria to have outpatient surgical procedure in a freestanding ambulatory surgery center. By the applicants own admission in Exhibits 19 (Patient Screening Policy and High Risk Referrals), some high risk patients procedures must be performed in a hospital setting. RSA surgeons fail to provide documentation that they will be able to shift 100% or some other specific percentage of their outpatient cases from the existing facilities where they practice.

NSSC provides no historical data showing that RSA surgeons have established a trend of performing an increasing number of outpatient surgical cases. Furthermore the application omits the physicians' historical utilization of non-surgical procedures including endoscopy procedures.

The application fails to provide a physician recruitment plan to increase the number of surgeons that will perform procedures at the facility. One RSA surgeon, Walter Woodrow Burns Jr., M.D. is approaching retirement based on his 1969 UNC Chapel Hill Medical School graduation date. However, the NSSC application contains no mention of the ability of RSA to maintain 4 surgeons or grow the practice.

NSSC's projections are unreasonable as compared to the existing Novant owned ambulatory surgical centers. The following table shows the historical data for Novant's freestanding ambulatory surgical Centers that provide General Surgery.

		# General Surgeons	# General Surgery Cases
Presbyterian Same Day Surgery Ballantyne	Charlotte	13	145
South Park Surgery Center	Charlotte	0	0
Presbyterian Same Day Surgery, Monroe	Monroe	3	5

Novant has no freestanding ambulatory surgical facilities with four general surgeons performing 1,777 or more annual cases. The NSSC utilization projections are not credible.

[1] North Carolina Medical Board Licensee Search, December 8, 2010
And excludes inactive physicians and Physician Assistants
wwwapps.ncmedboard.org/Clients/NCBOM/Public/LicenseeInformationSearch.aspx

The projected growth in Years 2 and 3 are overstated and unachievable by 4 general surgeons. The incremental increase from Year 1 to Year 2 and Year 3 are not substantiated by the surgeons or the community physicians. RSA surgeons have not provided historical data to demonstrate a trend of growth in surgical cases that supports the 13.2% and 11.3% annual growth as seen in the following table.

	YR 1	YR 2	YR 3
Projected Surgical Cases	1,777	2,011	2,239
Percentage Increase from Previous year		13.2%	11.3%

Furthermore, page 75 of the NSSC states that growth of outpatient general surgery cases for Orange and Durham Counties has increase by 7.3 percent annually over the past three years. Consequently the percentages of growth that are shown for Years 2 and 3 are unreasonable because these far exceed the historical growth for the specific counties. The applicant fails to project growth based on additional general surgeons obtaining privileges at the facility in Years 2 and 3.

As stated in the application, RSA physicians have privileges at James E. Davis Surgery Center which has 8 surgical operating rooms and provided a total of 4,477 cases as reported in the 2010 License Renewal application (October 1, 2008 to September 30, 2009) for an average of only 559 cases per room per year. This freestanding facility has available capacity. Therefore, the surgical volume performed by RSA surgeons has not been constrained by lack of access to a ambulatory surgical facility with adequate capacity.

NSSC fails to demonstrate that the procedure room is needed in addition to the two operating rooms. General surgeons typically provide surgical procedures as well as GI endoscopy procedures. Exhibit 13, page 914 of the NSSC application shows the most expensive single line item of capital equipment expense is for endoscopy. The capital equipment list also includes endoscopy sterilizing equipment. Based on these facts, it is apparent that the applicant intends to provide GI endoscopy procedures. However, the application fails to respond to the criteria and standards for GI endoscopy 10A NCAC 14C.3900 that are applicable to *"an applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures.."*

NSSC on fails to provide the list of CPT codes to describe the types of non-surgical (endoscopy) procedures that are needed by the service area population. In Years 2 and 3 the applicant projects to provide only 1300 annual procedures. This is less than 1500 annual procedure performance standard that is required for GI endoscopy procedure room 10a NCAC 14C .3903(b).

(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 NCCS application fails to conform to CON Review Criterion 4 because the utilization projections are unreliable and the financial projections are inaccurate. The comments regarding Criterion 3 explain why the utilization projections are unreliable in terms of unreasonable unreliable assumptions and overstated projections. The projected volumes of "non-surgical" procedures are

unsubstantiated and nonconforming to the CON criteria and standards for GI endoscopy.

The financial projections are based on unreasonable and overstated utilization projections. Please see the comments above regarding Criteria 5. Revenues are overstated based on unreasonable and overstated utilization projections.

(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 application erroneously omits the landlord Europa Center LLC as a CON co-applicant even though the lease agreement requires Europa to spend $200,000 for facility improvements for the development of the proposed project.

The reason that Europa Center LLC should be listed as a co-applicant is because the following statements are included in the lease agreement in Exhibit 15, page 0954D:

"Notwithstanding the foregoing, Lessor and Lessee agree that certain improvements shall be made to the Lease Premises (the "Tenant Improvements") at the Landlords expense not to exceed $200,000.00. Lessee shall have no duty to reimburse Lessor for any portion of the Tenant Improvements."

The Landlord expense of $200,000 should be defined as a capital expenditure. [2] This is because it is a construction related cost for the development of the project and NSSC has no obligation to reimburse the Lessor for the expense. NSSC fails to show this $200,000 cost in the capital cost calculation on Section VIII, page 141. The application fails to demonstrate the sources and commitment of funds for the landlord, Europa Center LLC to spend up to $200,000 for the facility improvements for the project.

The financial projections are based on unreasonable and overstated utilization projections. Please see the comments above regarding Criterion 3. Revenues are overstated based on unreasonable and inflated utilization projections

Additional flaws in the financial pro forma statement include:

- The application fails to provide RSA historical data to show that it is reasonable to assume that the payor mix percentages for the surgery

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[2] ***131E-176. Definitions*** *(2d) "Capital expenditure" means an expenditure for a project, including but not limited to the cost of construction, engineering, and equipment which under generally accepted accounting principles is not properly chargeable as an expense of operation and maintenance. Capital expenditure includes, in addition, the fair market value of an acquisition made by donation, lease, or comparable arrangement by which a person obtains equipment, the expenditure for which would have been considered a capital expenditure under this Article if the person had acquired it by purchase.*

component should be the same as the payor mix for the nonsurgical procedures. Therefore Forms D and E for the Procedure Room are based on unreasonable assumptions.

- NSSC fails to provide assumptions for the net revenue amounts in Form E for the procedure room. The omission of the CPT codes and charges compounds the lack of adequate assumptions.

- The applicant fails to staffing assumptions in Section VII page 134 for the procedure room separately from the operating rooms. In fact no staffing is shown for the procedure room in Section VII. Therefore the salary expenses for the procedure room have no credibility or underlying assumptions.

- NSSC's assumption on the top of page 0179 regarding the expenses for the separate income statements for Surgery and non-surgical procedures is a mathematical obfuscation that is unsupported and unreliable. The application fails to define the hours of operation and specific types of procedures will be performed in the proposed procedure room. The application fails to explain what items are included and excluded in the proposed charges for the procedure room. Without these essential facts it is impossible to demonstrate that the projected gross revenues, net revenues and allocations of expenses including staffing / salary costs, medical supply costs are based on reasonable assumptions.

- The application fails to demonstrate the project is financially feasible without developing both ORs combined with the procedure room. This is because the application fails to accurately identify the procedure room staffing and facility costs that are specific to the procedure room. Consequently the CON application cannot be conditionally approved to be developed without the procedure room.

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

The application does not meet this criterion because it is nonconforming to criterion 3 as discussed on the previous pages.

The proposed NSSC project is unnecessary and duplicative of the existing ambulatory surgery capacity including the James E. Davis Ambulatory Surgical Center in Durham which is located 13 miles from the proposed project location. RSA surgeons have privileges at this underutilized ambulatory surgical facility. According to the applicant, most or all of the outpatient surgery procedures performed by RSA surgeons will be shifted from this facility and the hospitals. The shift from Davis Surgery Center will be most debilitating because the loss of surgical procedures would reduce total utilization. The following table shows the decline on total surgical volume for James E. Davis ASC for the most recent two years:

	2009-09	2009-10
James E. Davis ASC # ORs	8	8
James E. Davis ASC Cases	5,299	4,477
Annual OR Hours based on 1.5 hrs / case	7,949	6,716
# ORs x 1872 annual hours	14,976	14,976
Percentage of Annual Capacity	53.1%	44.8%
Calculated Surplus of ORs	3.75	4.4
Sources: 2009 and 2010 LRA for James E. Davis ASC		

As seen in the table above, the utilization at James E. Davis ASC is already declining. The added loss of RSA general surgery cases (677 cases during the past year) will contribute to the overall surplus of ORs at the facility and the inventory of the service area.

(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 NCCS application fails to meet CON review criterion 7 because no staffing is demonstrated for the procedure room in Section VII, table VII.7. Page 134 shows 6.25 FTEs (Nurse Manager, RNs, CRNA and Surgical Technologist positions) allocated to the operating rooms but <u>no specific assignment of registered nurses, CRNAs or surgical technologist to the proposed procedure room</u>.

The salary expenses provided in Form C for the Procedure Room are not substantiated by the Staffing Tables in Section VII of the application. In the financial forms the salaries are distributed to the procedure room component based on the percentage of gross revenues instead of any criteria specific staffing requirements and patient quality standards that relate to the project components.

If one were to apply the financial expense assumptions from page 0179 to determine the FTE staffing allocations the following information could be calculated:

Expense Allocation Assumption from Financials		Allocation of Expenses shown on page -0179 Financial Section	
Applied to Staffing Table VII.2		Surgery	Procedure Room
	Total Facility	86.19%	13.81%
	FTEs	FTEs	FTEs
Adminstrator (RN)/Nurse Manger	1	0.86	0.14
Registered Nurses	5	4.31	0.69
CRNAs	2	1.72	0.28
Surgical Technologist	2	1.72	0.28
Sterile Processing	1	0.86	0.14
Patient Access Specislist	1	0.86	0.14
Scheduler	1	0.86	0.14
Secretary/Nursing Asst.	1	0.86	0.14
	14	12.07	1.93

The above calculations show less than one registered nurse assigned to the procedure room even if allocation of the nurse manager allocation (0.14 FTE) is added to the Registered Nurse (0.69 FTE). This allocation of RN staff is unacceptably low because the staffing requirement for GI endoscopy procedure rooms (10A NCAC .3905 (d) (4) states that at least one registered nurse shall be employed per procedure room.

NSSC fails to document that all 4 RSA surgeons are board certified or board eligible as required by 10A NCAC 14C .3905 (b).

(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 existing health system.

NSSC fails to provide responses for 10A NCAC 14C .3904 support services criteria and standards for GI endoscopy procedure rooms. These requirements include the laboratory / pathology agreement for endoscopy procedures, the conscious sedation / anesthesia policies for endoscopy procedures and the endoscopy procedure room and equipment cleaning policies. No staffing is demonstrated for the necessary ancillary and support services of the procedure room in Section VII, table VII.7.

(13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and members of the medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicaid recipients, racial and ethnic minorities 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 priority. For the purpose of determining the extent to which the proposed services will be accessible, the applicant shall show:

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;

The application fails to comply with this criterion because the utilization projections are overstated and unreliable. Further, NSSC fails to demonstrate that it is reasonable for the payor mix percentages for the nonsurgical procedures should be the same as the payor mix for the surgery component.

Does UNC have historical data to show that the payor mix for GI endoscopy is different that General Surgery??

(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 NSSC application does not comply with Criterion 18a because the application is nonconforming with CON Review Criteria 3, 4, and 5.

Specific deficiencies related to cost effectiveness include the excessively large facility square footage that includes a procedure room and excess ancillary and support space. The cost effectiveness of the surgery component cannot be accurately compared to other projects because the application has arbitrarily assigned 13.81% of the operating expenses to the procedure room. This assignment of expenses has no rationale in terms of staffing, actual supply expenses, facility square footage or resource allocation.

The application fails to adequately document quality of care because NSSC wrongly withholds critical information regarding the procedure room:

1. **What other types of procedures in addition to endoscopy will be performed in the procedure room?**

2. **Are all of the RSA surgeons proposing to perform GI endoscopy procedures?**

3. **What are the facility policies for credentialing physicians to perform procedures in the procedure room?**

4. **Exhibit pages 1311 to 1337 relate to blood bank and blood transfusions. Does the applicant intend to administer blood in the two ORs and one procedure room?**

The application is not conforming to the Criteria and Standards for Surgical Services and Operating Rooms as follows.

> **10A NCAC 14C .2102 (b) (5) - The application is non-conforming because the methodology and assumptions are unreasonable as described in the comments regarding CON Review Criterion 3.**
>
> **10A NCAC 14C .2103 (b) and (c) – The application is non-conforming due to overstated utilization projections.**

The application fails to provide responses to the 10A NCAC 14C .3900 Criteria and Standards for GI Endoscopy Procedure Rooms.

> **The proposed project involves a licensed ambulatory surgical facility as defined in G.S. 131E-176(1b). The NSSC application includes endoscopy equipment in the capital equipment list and shows average procedure charges that are consistent with GI endoscopy. In a previous CON decision for UNC Hospitals, Project ID # J-8330-09, the applicant was condition not to develop a procedure room where GI endoscopy procedures would be performed because the application did not address the GI endoscopy criteria and standards.**
>
> **Also, the NSSC cannot be conditionally approved with regard to the procedure room because the application fails to conform to the CON review criteria and Operating Room regulatory criteria.**