

**Competitive Comments on Wake County  
2019 Operating Room Need Determination  
Submitted by Triangle Orthopaedic Surgery Center**

Five applications were submitted in response to the need determination in the 2019 State Medical Facilities Plan for two additional operating rooms in the Wake County service area. These are summarized in the following table:

| Applicant    | Triangle Orthopaedics Surgery Center                         | Duke Health Green Level ASC            | WakeMed Cary Hospital   | Rex Hospital   | Wake Spine and Specialty Surgery            |
|--------------|--|--|---|--|---|
| Project ID   | J-11752-19   | J-11753-19                             | J-11759-19  | J-11761-19   | J-11747-19                                  |
| Description  | Add 2 ORs by converting procedure rooms for a total of 4 ORs | Add 2 ORs for a total of 3 ORs         | Develop 1 shared OR for a total of 11 ORs (9 shared +2 C-Section) | Develop 2 ORs for a total of 29 ORs (with previous projects pending) | Develop ASF with 1 OR and 3 procedure rooms |
| Capital Cost | \$5,642,178  | \$6,000,000                            | \$2,265,178   | \$789,000  | \$5,680,800                                 |
| Location     | 7921 ACC Blvd, Raleigh (North West)                          | 3208 Green Level West Rd., Cary (West) | 1900 Kildaire Farm Rd, Cary (West)                                | 4420 Lake Boone Trail, Raleigh (West Central)                        | 5241 Six Forks Rd. Raleigh (North Central)  |

The following comments are submitted in accordance with N.C. Gen. Stat. § 131E-185(a1) (1) and address the representations in the project applications, including a comparative analysis and discussion as to whether the applications comply with the Certificate of Need (“CON”) review criteria.

## Comparative Comments

### Conformity to CON Review Criteria

The Duke Health Green Level application is nonconforming with Criteria 1, 3, 4, 5, 6, 13c, 18a and the Performance Standard, 10A NCAC.2103. The WakeMed Cary application is nonconforming with Criteria 1, 3, 4, 5, 6, 18a and the Performance Standard, 10A NCAC.2103. The Rex Hospital application is nonconforming with Criteria 1, 3, 4, 5, 6, 18a and the Performance Standard, 10A NCAC.2103. The Wake Spine and Specialty Surgery (WSSS) application is nonconforming with Criteria 1, 3, 4, 5, 6, 18a and the Performance Standard, 10A NCAC.2103. The Triangle Orthopaedics Surgery Center (TOSC) application conforms to all Criteria and the Performance Standard and is comparatively superior to the other proposals.

### Geographic Accessibility

WakeMed Cary and Rex Hospital (in Raleigh) propose to add operating rooms to their existing hospitals and do not enhance geographic accessibility. TOSC proposes to add two operating rooms to its existing facility which is categorized as a single specialty demonstration project ASC that is not included in the SMFP OR inventory for planning purposes. Approval of this proposal would allow TOSC to become a multispecialty ASC that would be included in the future SMFPs for health planning purposes so that its utilization actually reflects its contributions to serving the unmet needs of the Wake County service area population. Duke Green Level proposes to add two operating rooms to a previously-approved ASC. WSSS proposes a new ASC with one operating room in a new ASC. Therefore, with regard to expanding geographic access to surgical services, WakeMed Cary and Rex Hospital are the least effective alternatives, and the applications submitted by the applicants ambulatory surgery centers are more effective alternatives to expand geographic access.

### Physician Support

The WSSS application includes physicians support letters that unreasonably predict that the neurosurgeons will perform higher numbers of surgery cases in the proposed OR as compared to their historical utilization at existing hospitals and ASCs. Each of the other applications document adequate physician support of their proposed projects. Therefore, with regard to the demonstration of physician support, the WSSS proposal is the least effective and the other proposals are equally effective.

### Documentation of Physician Recruitment

As seen in the applicants' responses to the questions in the CON application Section I.3(c), WakeMed Cary and WSSS do not provide documentation of a physician recruitment plan that is specific to their proposed projects. Each of the other applications document physician recruitment plans that support their proposed projects. Therefore, with regard to the demonstration of physician recruitment, the WakeMed Cary and the WSSS proposals are the least effective and the other proposals are equally effective.

### Patient Access to a New Alternative Provider

Generally, the application proposing to increase patient access to a new provider in the service area is the more effective alternative with regard to this comparative factor.

TOSC proposes to add two operating rooms to its existing facility which is designated as a single specialty demonstration project ASC that is not included in the SMFP OR inventory for planning purposes. TOSC proposes to become a multispecialty ASC that would no longer be omitted from future SMFPs. Thus for health planning purposes TOSC proposes to become a new alternative provider that has the same recognition, responsibilities and rights as any other new CON-approved ASCs. WSSS proposes to develop a new ASC with one OR.

Therefore, with regard to introducing a new provider of surgical services in Wake County that has its utilization included in the SMFP OR methodology, the applications submitted by TOSC and WSSS are more effective alternatives.

### Patient Access to Lower Cost Surgical Services

Many outpatient surgical procedures that are currently being performed in hospitals can be performed at much lower cost (to both patients and payors) in ambulatory surgical facilities. The WakeMed Cary and Rex Hospital applications propose to add operating rooms that are hospital-licensed and would not increase patient access to low cost ambulatory surgical facilities.

The three projects that involve ambulatory surgical facilities – TOSC, Duke Green Level and WSSS -- would each provide increased access to low cost ambulatory surgery. Consequently, the WakeMed Cary and the Rex Hospital applications are the least effective proposals and the TOSC, Duke Green Level and WSSS applications are the more effective projects.

### Patient Access to Multiple Specialties

TOSC is an existing single-specialty center that proposes to add operating rooms to provide multiple surgical specialties that include orthopedic (including spine surgery), general surgery, pain management and plastic surgery specialties. Duke Green level is a previously approved multispecialty ASC that proposes to add operating rooms to be utilized to perform multiple surgical specialties. WakeMed Cary and Rex Hospital propose to add hospital-based operating rooms to perform multiple surgical specialties. In contrast, the WSSS application proposes to develop one operating room in a new ASF that would only be utilized to perform neurosurgery cases.

Therefore, with regard to patient access to multiple specialties, the WSSS application is the least effective and the other proposals are equally effective.

### Comparative Comments Summary

| Applicant                                       | Triangle Orthopaedics Surgery Center   | Duke Health Green Level ASC  | WakeMed Cary Hospital  | Rex Hospital   | Wake Spine and Specialty Surgery   |
|---|--|--|--|--|--|
| Project ID                                      | J-11752-19   | J-11753-19   | J-11759-19   | J-11761-19   | J-11747-19   |
| Description                                     | Add 2 ORs to ASC for a total of 4 ORs  | Add 2 ORs to ASC for a total of 3 ORs                                  | Develop 1 shared OR for a total of 11 ORs (9 shared + 2 C-Section)                   | Develop 2 ORs for a total of 29 ORs (with previous projects pending)   | Develop ASC with 1 OR and 3 procedure rooms  |
| Capital Cost                                    | \$5,642,178  | \$6,000,000  | \$2,265,178  | \$789,000  | \$5,680,800  |
| Location  | 7921 ACC Blvd, Raleigh (Northern)  | 3208 Green Level West Rd., Cary (West)                                 | 1900 Kildaire Farm Rd, Cary (West)   | 4420 Lake Boone Trail, Raleigh (West Central)                          | 5241 Six Forks Rd. Raleigh (North Central)   |
| Conformity to Review Criteria                   | Most Effective   | Least Effective - Nonconforming to multiple criteria                   | Least Effective - Nonconforming to multiple criteria                                 | Least Effective - Nonconforming to multiple criteria                   | Least Effective - Nonconforming to multiple criteria                                   |
| Geographic Accessibility                        | Effective - Existing ASC in NW Raleigh / Leesville                             | Effective - New ASC in West Cary                                       | Less Effective - Existing Hospital in Cary   | Less Effective - Existing Hospital in Raleigh                          | Effective - New ASC in North Raleigh   |
| Physician Support                               | Equally Effective - Physician Letters Included                                 | Equally Effective - Physician Letters Included                         | Equally Effective - Physician Letters Included                                       | Equally Effective - Physician Letters Included                         | Equally Effective - Physician Letters Included   |
| Documentation of Physician Recruitment          | Equally Effective - Documentation of physician recruitment is included         | Equally Effective - Documentation of physician recruitment is included | Less Effective - No documentation of physician recruitment plan specific to project. | Equally Effective - Documentation of physician recruitment is included | Less Effective - No documentation of a physician recruitment plan specific to project. |
| Patient Access to New Provider                  | Equally Effective - Demonstration ASC to add ORs & become a Multispecialty ASC | Equally Effective - New Multispecialty ASC in development to add 2 ORs | Least Effective - Existing hospital  | Least Effective - Existing hospital                                    | Equally Effective - New ASC  |
| Patient Access to Lower Cost Surgical Services  | Equally Effective  | Equally Effective  | Least Effective  | Least Effective  | Equally Effective  |
| Patient Access to Multiple Surgical Specialties | Equally Effective - Multiple Specialties                                       | Equally Effective - Multiple Specialties                               | Equally Effective - Multiple Specialties   | Equally Effective - Multiple Specialties                               | Least Effective - Only Neurosurgery in the Proposed OR                                 |

The following table demonstrates that four of the five applications were not approvable and therefore cannot be considered effective alternatives. The Duke Green Level, WakeMed Cary, Rex Hospital and WSSS applications are not effective alternatives with respect to conformity with the Review Criteria and therefore are not approvable.

Therefore, the TOSC application is the only approvable application that can be considered an effective alternative.

| Applicant                                       | Triangle Orthopaedics Surgery Center  | Duke Health Green Level ASC                          | WakeMed Cary Hospital  | Rex Hospital   | Wake Spine and Specialty Surgery                     |
|---|---------------------------------------|--|--|--|--|
| Project ID                                      | J-11752-19                            | J-11753-19   | J-11759-19   | J-11761-19   | J-11747-19   |
| Description                                     | Add 2 ORs to ASC for a total of 4 ORs | Add 2 ORs to ASC for a total of 3 ORs                | Develop 1 shared OR for a total of 11 ORs (9 shared + 2 C-Section) | Develop 2 ORs for a total of 29 ORs (with previous projects pending) | Develop ASC with 1 OR and 3 procedure rooms          |
| Capital Cost                                    | \$5,642,178                           | \$6,000,000  | \$2,265,178  | \$789,000  | \$5,680,800  |
| Location  | 7921 ACC Blvd, Raleigh (North West)   | 3208 Green Level West Rd., Cary (West)               | 1900 Kildaire Farm Rd, Cary (West)                                 | 4420 Lake Boone Trail, Raleigh (West Central)                        | 5241 Six Forks Rd. Raleigh (North Central)           |
| Conformity to Review Criteria                   | Most Effective                        | Least Effective - Nonconforming to multiple criteria | Least Effective - Nonconforming to multiple criteria               | Least Effective - Nonconforming to multiple criteria                 | Least Effective - Nonconforming to multiple criteria |
| Geographic Accessibility                        | More Effective                        | Not Approvable                                       | Not Approvable   | Not Approvable   | Not Approvable                                       |
| Physician Support                               | More Effective                        | Not Approvable                                       | Not Approvable   | Not Approvable   | Not Approvable                                       |
| Documentation of Physician Recruitment          | More Effective                        | Not Approvable                                       | Not Approvable   | Not Approvable   | Not Approvable                                       |
| Patient Access to New Provider                  | More Effective                        | Not Approvable                                       | Not Approvable   | Not Approvable   | Not Approvable                                       |
| Patient Access to Lower Cost Surgical Services  | More Effective                        | Not Approvable                                       | Not Approvable   | Not Approvable   | Not Approvable                                       |
| Patient Access to Multiple Surgical Specialties | More Effective                        | Not Approvable                                       | Not Approvable   | Not Approvable   | Not Approvable                                       |

## TOSC Comments Regarding Duke Health Green Level ASC CON Project ID # J-11753-19

Pursuant to CON Project ID # J-11557-18, Duke University Health System entered into a settlement agreement with the Agency to develop Duke Health Green Level ASC, a new ASC with one (1) OR and five (5) procedure rooms. Now in Project ID # J-11753-19, the applicant proposes to develop two (2) additional ORs for a total of three (3) ORs and five (5) procedure rooms.

In accordance with N.C. GEN. STAT. § 131E-185(a1)(1), Triangle Orthopaedics Surgery Center (TOSC) provides comments and documentation regarding why the Duke Health Green Level ASC (Duke Green Level) application does not conform to multiple CON criteria as follows:

- The Duke Green Level proposal fails to demonstrate that its proposal will maximize healthcare value.
- The applicant omits patient origin projections for its procedure rooms.
- Utilization projections are not based on reasonable assumptions because the historical data for Duke Raleigh Hospital (DRAH) is unreliable based on inaccurate reported surgical case volumes for DRAH for an unknown number of previous years.
- The applicant's assumptions about the number of outpatient surgical cases projected to "shift" from DRAH to the proposed Green Level are unreasonable and unsupported.
- Financial projections are not based on reasonable assumptions and adequately supported utilization projections causing the application to be nonconforming to Criterion 5.
- Payor mix percentages are unreliable and inconsistent with the previous CON application Project ID # J-11558-18.

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

**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 information provided by the Duke Green Level application fails to demonstrate that the applicant's proposal would maximize healthcare value because the utilization projections are not based on reasonable and adequately supported assumptions. The discussion regarding utilization found in Criterion (3) is incorporated herein by reference. The Duke Green Level application does not conform to Criterion 1 and Policy GEN-3.

**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.”*

Page 19 of the application provides incomplete patient origin data for the proposed project. Duke Green Level provides patient origin data for its proposed operating rooms but omits the projected patient origin data for the procedure rooms. This omission is critical because the applicant’s methodology assumes that utilization of the proposed ORs will be based on the historical utilization of existing ORs and hospital-based procedure rooms. Furthermore, the CON application form specifically requests patient origin data for the procedure rooms in addition to the operating rooms. The applicant fails to adequately identify the population to be served and is nonconforming to Criterion 3.

The applicant’s projected surgical case volumes and growth rates are unreliable because the applicant reported in its 2019 Hospital License Renewal Application that the historical surgical case volume data for Duke Raleigh Hospital has been overstated for an unknown number of years. The 2019 Hospital LRA was emailed on January 23, 2019 to Martha Frisone, Chief. The applicant’s email states, “While total surgical cases continue to increase, in previous years, Duke Raleigh inadvertently included all cases performed in the surgical suite, including procedures in both licensed ORs and in procedure rooms, in this category. ... We apologize for our previous reporting errors and greatly regret any difficulties that this causes in the planning process or the review of Wake County certificate of need applications.”

On page 122 of the application, Step 1 of the Duke Green level ASC methodology included in Section Q shows that the applicant wrongly asserts that its need for additional operating room capacity should be based on the historical utilization of both its existing operating rooms and its hospital-based procedure rooms. This assumption is entirely inconsistent with the operating room methodology in the 2019 State Medical Facilities Plan because the SMFP methodology is based solely on the surgery cases performed in the operating rooms.

The applicant’s methodology is incorrect to assume that the average case times for surgery cases performed in the operating rooms from the License Renewal Application should be multiplied times the numbers of cases performed in both the operating rooms and its hospital-based procedure rooms. Clearly, this is not what is represented in the operating room methodology in the 2019 SMFP. Thus the Duke Green Level application is nonconforming to Criterion 3.

The applicant fails to provide adequate assumptions and explanation of why it expects to shift outpatient surgery utilization from hospital-based procedure rooms to ASC operating rooms instead of shifting cases from hospital-based procedure rooms to ASC procedure rooms. None of the physician support letters explain the rationale to support the projected shift of utilization from procedure rooms to the proposed ASC ORs.

The utilization data for Duke Raleigh Hospital shows a decline in the FY2019 Outpatient Surgical Cases performed in its licensed ORs due to the loss of a community-based practice that shifted its surgical cases to another facility. The applicant does not provide any data to demonstrate that this decline has been reversed. Because there are multiple CON-approved ASC facilities in development in Wake County to compete with the hospitals, it is reasonable to assume that Duke Raleigh Hospital will continue to experience declines in its outpatient surgery utilization for its licensed operating rooms.

**For all of these reasons, the Duke Green level application is nonconforming to Criterion 3.**

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

**The Duke Green Level ASC application does not adequately demonstrate that the alternative proposed in this application is the most effective alternative to meet the identified need because the application is not conforming to all statutory and regulatory review criteria. See Criteria 1, 3, 6, 18), and 10A NCAC 14C .2103. An application that cannot be approved cannot be the most effective alternative. Therefore the Duke Green Level application is nonconforming to Criterion 4.**

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

**The assumptions in the pro forma financial statements are not reasonable because the utilization projections are not based on reasonable and adequately supported assumptions. The discussion regarding projected utilization found in Criterion 3 is incorporated herein by reference. Based on the unreasonable utilization, the projection revenues and expenses are unreliable.**

**Furthermore the applicant’s utilization projections for the procedure rooms in Form C are inconsistent with the procedure room utilization provided in the financial assumptions page as seen in the following table.**

|                                 |           |           |           |
|---------------------------------|-----------|-----------|-----------|
| Duke Green Level ASC            | 7/1/2022  | 7/1/2023  | 7/1/2024  |
|                                 | 6/30/2023 | 6/30/2024 | 6/30/2025 |
| Form C of Section Q             | 339       | 566       | 819       |
| Financial Assumptions Section Q | 687       | 1007      | 1517      |

**These errors cause the financial statements in Section Q to be incorrect causing the applicant to fail to demonstrate the long-term financial feasibility of the proposal. For these reasons the Duke Green Level application is nonconforming to Criterion 5.**

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

**Duke Green Level does not adequately demonstrate that additional operating rooms are needed at the proposed ambulatory surgery center in Cary. The discussion regarding need and projected utilization found in Criterion 3 is incorporated herein by reference. Therefore, the applicant does not adequately demonstrate that the proposal would not result in an unnecessary duplication of existing or approved services in the service area for the following reasons:**

- **The applicant does not adequately demonstrate that the assumptions used to project surgical cases are reasonable and adequately supported.**

- The applicant does not adequately demonstrate that the proposed operating rooms are needed at Duke Green Level ASC in addition to the existing and approved operating rooms in Wake County.

Based on this analysis, the Duke Green Level application is nonconforming to Criterion 6.

*Criterion 13 (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 project application fails to demonstrate that its payor mix projections are based on reasonable assumptions because Duke Raleigh Hospital's historical surgery utilization data is unreliable and the projected payor percentages for Project ID # J-11753-19 are inconsistent with the payor projections for CON Project ID # J-11558-18.

**Duke Health Green Level ASC CON Project ID # J-11753-19**

**Green Level ASC Projected Payor Mix, Project Year Three (FY2025)**

| Payor Source                      | Entire Facility or Campus | Operating Rooms | Procedure Rooms | GI Endo Rooms |
|-----------------------------------|---------------------------|-----------------|-----------------|---------------|
| Self-Pay/Charity Care             | 2.0%                      | 2.0%            | 1.9%            | %             |
| Medicare *                        | 40.4%                     | 43.7%           | 33.6%           | %             |
| Medicaid *                        | 5.2%                      | 4.7%            | 6.3%            | %             |
| Insurance *                       | 46.1%                     | 45.4%           | 47.7%           | %             |
| Other (workers comp, VA, TRICARE) | 6.3%                      | 4.3%            | 10.6%           | %             |
| Total                             | 100.0%                    | 100.0%          | 100.0%          | N.A.          |

\* Including any managed care plans

**Duke Health Green Level ASC CON Project ID # J-11558-18**

| Payor Category            | Operating Room Services as Percent of Total | Procedure Room Services as Percent of Total |
|---------------------------|---|---|
| Self-Pay/Charity          | 1.6%  | 1.8%  |
| Medicare *                | 43.4%                                       | 33.8%                                       |
| Medicaid *                | 4.8%  | 5.5%  |
| Insurance *               | 43.1%                                       | 48.6%                                       |
| Workers Comp, VA, TRICARE | 7.0%  | 10.3%                                       |
| Total                     | 100.0%                                      | 100.0%                                      |

Source: Table on page 103 of the application.

\* Including any managed care plans

Contrary to the statements on page 105 and 106 of the application, the payor percentages for the procedure rooms in CON application Project ID # J-11753-19 are dissimilar to the projections for Project ID # J-11558-18 due to the difference in the Medicaid percentages.

Furthermore the applicant’s utilization projections for the procedure rooms in Form C are inconsistent with the procedure room utilization provided in the financial assumptions page as seen in the following table.

|                                 |           |           |           |
|---------------------------------|-----------|-----------|-----------|
| Duke Green Level ASC            | 7/1/2022  | 7/1/2023  | 7/1/2024  |
|                                 | 6/30/2023 | 6/30/2024 | 6/30/2025 |
| Form C of Section Q             | 339       | 566       | 819       |
| Financial Assumptions Section Q | 687       | 1007      | 1517      |

It is not possible to determine which of the above procedure room utilization projections should be multiplied times the payor percentages to determine the numbers of medically underserved patients to be served by the proposed project.

For these reasons, the Duke Green Level application is nonconforming to Criterion 13c.

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

Duke Green Level does not adequately demonstrate how any enhanced competition in the service area would have a positive impact on the cost effectiveness of the proposal because it does not adequately demonstrate the need the population to be served has for the proposed services. The application is based on an incorrect methodology that wrongly assumes that the procedure room volume should be included in the analysis for the proposed operating rooms. This assumption is inconsistent with the operating room methodology in the 2019 SMFP (and the 2018 SMFP). In addition, the application makes inconsistent representations regarding the projected utilization for the proposed procedure rooms. Additional discussion regarding analysis of need and projected utilization found in Criterion 3 is incorporated herein by reference. The application is not conforming to Criterion 18a for all the reasons stated above.

**10A NCAC 14C .2103 PERFORMANCE STANDARDS**

*(a) A proposal to establish a new ambulatory surgical facility, to establish a new campus of an existing facility, to establish a new hospital, to increase the number of operating rooms in an existing facility (excluding dedicated C-section operating rooms), to convert a specialty ambulatory surgical program to a multispecialty ambulatory surgical program, or to add a specialty to a specialty ambulatory surgical program shall demonstrate the need for the number of proposed operating rooms in the facility that is proposed to be developed or expanded in the third operating year of the project based on the Operating Room Need Methodology set forth in the 2018 State Medical Facilities Plan. The applicant is not required to use the population growth factor.*

Duke Green Level’s proposal is not conforming to this administrative rule because the application is based on an incorrect methodology that wrongly assumes that the procedure room volume should be included in the analysis for the proposed operating rooms. This assumption is inconsistent with the operating room methodology in the 2018 SMFP. Additional discussion regarding analysis of need and

projected utilization found in Criterion 3 is incorporated herein by reference. Therefore, the Duke Green Level application does not conform to this rule.

**10A NCAC 14C .2103 PERFORMANCE STANDARDS**

*(e) The applicant shall document the assumptions and provide data supporting the methodology used for each projection in this Rule.*

The application is not conforming to this administrative rule because the applicant's projected utilization is not reasonable and adequately supported. The application is based on an incorrect methodology that wrongly assumes that the procedure room volume should be included in the analysis for the proposed operating rooms. This assumption is inconsistent with the 2019 SMFP operating room methodology. In addition, the application makes inconsistent representations regarding the projected utilization for the proposed procedure rooms. Additional discussion regarding analysis of need and projected utilization found in Criterion 3 is incorporated herein by reference. Therefore, the Duke Green Level application does not conform to this rule.

## **TOSC Comments Regarding WakeMed Cary Hospital CON Project ID # J-11759-19**

In Project ID # J-11759-19, WakeMed Cary proposes to develop one (1) additional shared OR for a total of thirteen (13) ORs (11 surgical operating rooms and 2 C-Section rooms).

In accordance with N.C. GEN. STAT. § 131E-185(a1)(1), Triangle Orthopaedics Surgery Center (TOSC) provides comments and documentation regarding why the WakeMed Cary application does not conform to multiple CON criteria as follows:

- The application fails to demonstrate the need for the proposed project because WakeMed Cary's historical OR utilization data is incorrect and overstated causing its projections to be unreasonable.
- WakeMed Cary's methodology results in unreasonable projections because the application is based on incorrect historical data and inaccurate compound annual growth rates.
- WakeMed Cary incorrectly projects annual surgical hours using different case times than what is required in the 2019 SMFP operating room methodology.
- The application fails to demonstrate that WakeMed Cary has an unmet need for additional operating rooms based on the OR methodology and case times provided in the 2019 SMFP.
- The financial projections are not based on reasonable assumptions and adequately supported utilization projections causing the application to be nonconforming to Criterion 5.
- WakeMed Cary's proposal would not enhance competition and have a positive impact on cost effectiveness because the application does not demonstrate the need for the proposed services.

For all of these reasons, WakeMed Cary application is not an approvable Certificate of Need (CON) application.

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

**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 information provided by the WakeMed Cary application fails to demonstrate that the applicant's proposal would maximize healthcare value because the utilization projections are not based on reasonable and adequately supported assumptions. The discussion regarding utilization found in Criterion 3 is incorporated herein by reference. The WakeMed Cary application does not conform to Criterion 1 and Policy GEN-3.

**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.”

WakeMed Cary’s utilization projections are unreliable because the methodology is based on inaccurate historical data and incorrect compound annual growth rates. Even though Duke Raleigh Hospital admitted that its historical utilization for its operating rooms for 2015 through 2017 was overstated and incorrect due to the inclusion of cases performed in procedure rooms, WakeMed incorporates this incorrect data into its own tables and calculations beginning on page 115 of its methodology. Furthermore, the OR utilization for WakeMed Cary is incorrect in the tables on page 115 in Tables Q.2A and Q.2B. The incorrect Duke Raleigh data is shown below with the red and the incorrect WakeMed Cary data is circled. Thus the totals in these tables for 2015 through 2017 are not correct.

**Table Q.2A**  
**HOSPITAL SURGICAL INPATIENTS**  
 Reported by All Wake County Hospitals, FYs 2015-2018  
 All Surgery Patients Regardless of Patient Origin  
 Volumes Exclude Cases Performed in Dedicated C-Section ORs

| Facility                            | 2015              | 2016              | 2017              | 2018   |
|-------------------------------------|-------------------|-------------------|-------------------|--------|
| Duke Raleigh Hospital               | <del>3,616</del>  | <del>4,389</del>  | <del>4,094</del>  | 3,328  |
| Rex Hospital                        | 7,984             | 8,557             | 8,453             | 8,366  |
| WakeMed Raleigh Campus <sup>1</sup> | 7,825             | 8,507             | 8,184             | 7,941  |
| WakeMed Cary Hospital               | 2,769             | 3,037             | 3,162             | 2,973  |
| Total Cases                         | <del>22,194</del> | <del>24,490</del> | <del>23,893</del> | 22,608 |

Source: 2016-2019 Hospital License Renewal Applications FYs 2015-2018 data) on file at DHSR

**Table Q.2B**  
**HOSPITAL SURGICAL OUTPATIENTS**  
 Reported by All Wake County Hospitals, FYs 2015-2018  
 All Surgery Patients Regardless of Patient Origin  
 Volumes Exclude Cases Performed in Dedicated C-Section ORs

| Facility                            | 2015              | 2016              | 2017              | 2018   |
|-------------------------------------|-------------------|-------------------|-------------------|--------|
| Duke Raleigh Hospital               | <del>9,875</del>  | <del>10,855</del> | <del>11,084</del> | 7,474  |
| Rex Hospital <sup>2</sup>           | 13,216            | 13,026            | 12,636            | 12,060 |
| WakeMed Raleigh Campus <sup>3</sup> | 9,128             | 9,918             | 9,893             | 11,189 |
| WakeMed Cary Hospital               | 4,815             | 4,820             | 5,242             | 4,956  |
| Total Cases                         | <del>37,054</del> | <del>38,619</del> | <del>38,855</del> | 35,679 |

Source: 2016-2019 Hospital License Renewal Applications FYs 2015-2018 data) on file at DHSR

The table on the next page shows WakeMed Cary’s actual OR utilization based on utilization data as published in the 2014 SMFP to the proposed 2020 SMFP.

### WakeMed Cary Hospital

|                          | FY2012 | FY2013 | FY2014 | FY2015 | FY2016 | FY2017 | FY2018 | CAGR   |
|--------------------------|--------|--------|--------|--------|--------|--------|--------|--------|
| Inpatient Surgery Cases* | 1909   | 2042   | 2172   | 2560   | 2914   | 3014   | 2973   | 7.66%  |
| Outpatient Surgery Cases | 5239   | 4463   | 4076   | 4228   | 4132   | 4663   | 4956   | -0.92% |
| Total Surgery cases      | 7148   | 6505   | 6248   | 6788   | 7046   | 7677   | 7929   | 1.74%  |

\* Excludes C-Section Cases

Therefore, WakeMed Cary’s methodology results in unreasonable projections because the application is based on incorrect historical data and inaccurate compound annual growth rates.

On pages 121 to 123 of Section Q, the applicant incorrectly projects annual surgical hours using different case times that what is required in the operating room methodology in the 2019 SMFP. The application provides no documentation that anyone with the Health Planning and Certificate of Need Section provided authorization to use the substituted average case times.

WakeMed Cary shows that it has no unmet need for operating rooms based on the OR methodology that is provided in the 2019 SMFP. Since this is the methodology that is required by the administrative rules, the application fails to demonstrate the need that the population has for the proposed additional operating room.

For all of these reasons, the WakeMed Cary application is nonconforming to Criterion 3.

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

The WakeMed Cary application does not adequately demonstrate that the alternative proposed in this application is the most effective alternative to meet the identified need because the application is not conforming to all statutory and regulatory review criteria. See Criteria 1, 3, 6, 18a, and 10A NCAC 14C .2103. An application that cannot be approved cannot be the most effective alternative. Therefore, the WakeMed Cary application is nonconforming to Criterion 4.

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

WakeMed Cary’s assumptions in the pro forma financial statements are not reasonable because utilization projections are not based on reasonable and adequately supported assumptions. The discussion regarding projected utilization found in Criterion 3 is incorporated herein by reference. Based on the unreasonable utilization, the projection revenues and expenses are unreliable. Consequently the WakeMed Cary application does not conform to Criterion 5.

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

WakeMed Cary does not adequately demonstrate that additional operating rooms are needed at the hospital. The discussion regarding need and projected utilization found in Criterion 3 is incorporated

herein by reference. Therefore, the applicant does not adequately demonstrate that the proposal would not result in an unnecessary duplication of existing or approved services in the service area for the following reasons:

- The applicant does not adequately demonstrate that the assumptions used to project surgical cases are reasonable and adequately supported.
- The applicant does not demonstrate an unmet need for the proposed additional operating room based on the Operating Room Need Methodology set forth in the 2018 State Medical Facilities Plan.
- The applicant does not adequately demonstrate that the proposed operating room is needed at WakeMed Cary in addition to the existing and approved operating rooms in Wake County

Based on this analysis, the WakeMed Cary application is nonconforming to Criterion 6.

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

WakeMed Cary does not show how the project would enhance competition in the service area and have a positive impact on cost effectiveness because the application does not demonstrate the need for the proposed services. The applicant incorrectly projects annual surgical hours using different case times than what is required in the 2019 SMFP operating room methodology. When the calculations are performed using the annual case times that are provided in the 2019 SMFP, WakeMed Cary has no unmet need for additional operating rooms.

In addition, the application makes inaccurate representations regarding the historical utilization for WakeMed Cary. Additional discussion regarding analysis of need and projected utilization found in Criterion 3 is incorporated herein by reference. The application is not conforming to Criterion 18a for all the reasons stated above.

#### **10A NCAC 14C .2103 PERFORMANCE STANDARDS**

*(a) A proposal to establish a new ambulatory surgical facility, to establish a new campus of an existing facility, to establish a new hospital, to increase the number of operating rooms in an existing facility (excluding dedicated C-section operating rooms), to convert a specialty ambulatory surgical program to a multispecialty ambulatory surgical program, or to add a specialty to a specialty ambulatory surgical program shall demonstrate the need for the number of proposed operating rooms in the facility that is proposed to be developed or expanded in the third operating year of the project based on the Operating Room Need Methodology set forth in the 2018 State Medical Facilities Plan. The applicant is not required to use the population growth factor.*

The WakeMed Cary proposal is not conforming to this administrative rule because the application is based on incorrect annual case times that are inconsistent with the operating room methodology as required in the 2018 SMFP. Additional discussion regarding analysis of need and projected utilization found in Criterion 3 is incorporated herein by reference.

**10A NCAC 14C .2103 PERFORMANCE STANDARDS**

*(e) The applicant shall document the assumptions and provide data supporting the methodology used for each projection in this Rule.*

**The application is not conforming to this administrative rule because the applicant's projected utilization is not reasonable and adequately supported. The application is based on an incorrect historical data and a flawed methodology that does not use the SMFP's annual average case times.**

**In addition, the application makes incorrect representations regarding WakeMed Cary's utilization for its existing operating rooms. Additional discussion regarding analysis of need and projected utilization found in Criterion 3 is incorporated herein by reference.**

## TOSC Comments Regarding Rex Hospital CON Project ID # J-11761-19

Pursuant to CON Project ID # J-11555-18, Rex Hospital entered into a settlement agreement with the Agency to develop two additional operating rooms. Also, the hospital was previously approved to relocate three operating rooms to UNC Rex Holly Springs Hospital which has not yet been completed. Now in Project ID # J-11761-19, the applicant proposes to develop two (2) additional ORs at Rex Hospital for a total of twenty-nine (29) ORs at completion.

In accordance with N.C. GEN. STAT. § 131E-185(a1)(1), Triangle Orthopaedics Surgery Center (TOSC) provides comments and documentation regarding why the Rex Hospital application does not conform to multiple CON criteria as follows:

- The Rex Hospital proposal fails to demonstrate that its proposal will maximize healthcare value.
- Utilization projections are not based on reasonable assumptions because the Rex Hospital historical data as reported in the State Medical Facilities Plans shows a decline in actual utilization for the most recent three years.
- Rex Hospital incorrectly chose to rely on unverified internal surgery utilization data that does not correspond to the operating room utilization data that is included in the 2019 SMFP.
- The applicant's assumptions about the number of outpatient surgical cases projected to "shift" from Rex Hospital to other CON-approved projects are not adequately supported.
- Financial projections are not based on reasonable assumptions and adequately supported by utilization projections, causing the application to be nonconforming to Criterion 5.
- Rex Hospital's proposal would not enhance competition and have a positive impact on cost effectiveness because the application does not demonstrate the need for the proposed services.

For all of these reasons, the Rex Hospital application is not an approvable Certificate of Need (CON) application.

**Criterion 1** *"The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which shall constitute a determinative limitation on the provision of any health services, health service facility, health service beds, dialysis stations. Operating rooms, or home health offices that may be approved."*

**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."*

Rex Hospital's application fails to demonstrate that the applicant's proposal would maximize healthcare value because the utilization projections are not based on reasonable and adequately supported

assumptions. The discussion regarding utilization found in Criterion 3 is incorporated herein by reference. The Rex Hospital application does not conform to Criterion 1 and Policy GEN-3.

**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.”*

Table 6B of the 2019 State Medical Facilities Plan shows that Rex Health System has an overall deficit of 1.78 operating rooms. However, this calculation was made prior to the CON settlement agreement for ID # J-11555-18 that authorizes Rex Hospital to add two (2) operating rooms. Consequently, this recent settlement agreement obviates the 2019 SMFP OR deficit such that no unmet need for operating rooms remains for Rex Health System. Furthermore, the projected surpluses / deficits in the proposed 2020 SMFP have not been updated to reflect the other recent CON approvals and settlement agreements related to the 2018 OR review for Wake County.

The Rex Hospital operating room utilization that is included in Section Q does not correspond to the operating room utilization that has been reported in its license renewal applications and is included in the State Medical Facilities Plans. As seen below, surgery utilization at Rex Hospital has declined on based the authorized SMFP data that has been verified data and authorized by the State Health Coordinating Council for use in the “OR Need Methodology”.

| FY 2015 - 2018   | Rex Hospital |        |        |        |
|------------------|--------------|--------|--------|--------|
|                  | 2016         | 2017   | 2018   | CAGR   |
| Inpatient Cases  | 8,557        | 8,453  | 8,366  | -1.12% |
| Outpatient Cases | 13,026       | 12,636 | 12,060 | -3.78% |
| Total Cases      | 21,583       | 21,089 | 20,426 | -2.74% |

Sources: 2018, 2019 and proposed 2020 State Medical Facilities Plans

Rex failed to reconcile the utilization projections that are included in its CON application with the data that is reported in the most recent SMFPs. Furthermore, Rex chose to develop its OR need methodology using unverified data that is inconsistent with the 2019 SMFP OR data and case times.

In addition to the decline in utilization at Rex Hospital, surgery utilization at Rex Surgery Center of Cary reflects decreases based on their actual surgery volumes. The 2019 License Renewal Application for Rex Surgery Center of Cary reported 4,585 annual OR cases for the 12 months ending September 30, 2018 as compared to 4,854 in the previous 2018 LRA. This 5.5 percent decrease demonstrates that Rex Surgery Center of Cary lost market share.

Utilization projections for the operating rooms at Rex Surgery Center of Wakefield are not based on reasonable assumptions. The historical OR utilization data for Rex Surgery Center of Wakefield shows that its total volume decreased by 23 percent over the past two years from 1,998 total cases for the 12 months ending June 30, 2017 down to 1,530 cases for the 12 months ending June 30, 2019. This 23 percent decrease during the two year period demonstrates a dramatic declined for Rex Surgery Center of Wakefield. Further, the application does not adequately explain why the utilization is expected to maintain at 1,530 annual cases for future years. The applicant provides insufficient information

regarding the medical staff, physician recruitment or changes in market share to support the utilization projections Rex Surgery Center of Wakefield.

Page 62 of the application describes Rex Hospital's recruitment plan to add eight surgical specialists. However, Rex provides no historical data or surgical projections to demonstrate that physician recruitment will result in a net increase in physicians and total surgery cases at the hospital or any of the other UNC Rex facilities. In fact, the physician letters of support for the Rex Hospital application do not include any surgery volume projections or estimates.

As seen in the 2019 SMFP, the UNC Health System has multiple CON-approved projects in development including Raleigh Orthopedic Surgery Center - West Cary, Rex Holly Springs Hospital and the recent settlement agreement that allows Rex Hospital to add two operating rooms to the hospital's OR inventory. Because Rex Hospital has multiple projects that will change its distribution of surgery capacity, its projections regarding the expected shift of cases from Rex Hospital to its other OR facilities are entirely speculative because:

- The application fails to provide data and assumptions to demonstrate the numbers of surgeons that will utilize the Rex Hospital ORs and the operating rooms at the other facilities that are pending development.
- New competing ASC facilities have been approved and are being developed to provide different alternatives to the operating rooms at the UNC Health System facilities.
- Surgeons are free to choose where they perform surgery.

For all of these reasons, the Rex Hospital application does not conform to Criterion 3.

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

The Rex application does not adequately demonstrate that the alternative proposed in this application is the most effective alternative to meet the identified need because the application is not conforming to all statutory and regulatory review criteria. See Criteria 1, 3, 6, 18a and 10A NCAC 14C .2103. An application that cannot be approved cannot be the most effective alternative. Therefore the Rex Hospital application does not conform to Criterion 4.

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

The assumptions in the pro forma financial statements are not reasonable because the utilization projections are not based on reasonable and adequately supported assumptions. Unreasonable utilization projections cause the projected revenues and expenses for the project to be unreliable. The discussion regarding projected utilization found in Criterion 3 is incorporated herein by reference. Based on the unreasonable utilization, the projection revenues and expenses are unreliable.

The financial statements in Section Q are incorrect, causing the application to fail to demonstrate the long-term financial feasibility of the proposal. For these reasons the Rex Hospital application is nonconforming to Criterion 5.

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

Rex Hospital does not adequately demonstrate that additional operating rooms are needed at the hospital because the utilization projections are not based on reasonable assumptions. The discussion regarding need and projected utilization found in Criterion 3 is incorporated herein by reference. Therefore, the applicant does not adequately demonstrate that the proposal would not result in an unnecessary duplication of existing or approved services in the service area for the following reasons:

- Rex Hospital does not adequately demonstrate that the assumptions used to project surgical cases are reasonable and adequately supported for Rex Hospital, for Rex Surgery Center of Wakefield, and Rex Surgery Center of Cary.
- The settlement agreement for Project ID # J-11555-18 permits Rex Hospital to add two (2) operating rooms so that the Rex Healthcare System has no projected deficit of operating rooms in Wake County.
- UNC Healthcare is a dominant health system with multiple CON-approved projects to relocate and add operating rooms in Wake County. The applicant does not adequately demonstrate that the proposed additional operating rooms are needed at Rex Hospital in addition to the existing and approved operating rooms in Wake County.

For these reasons, the Rex Hospital application does not conform to Criterion 6.

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

Rex Hospital does not adequately demonstrate how its project will enhanced competition in the service area and have a positive impact on the cost effectiveness of services because it does not adequately demonstrate the need that the population to be served has for the proposed services. The application is based on unreasonable utilization projections. Additional discussion regarding analysis of need and projected utilization found in Criterion 3 is incorporated herein by reference. The application is not conforming to Criterion 18a for these reasons stated above.

#### **10A NCAC 14C .2103 PERFORMANCE STANDARDS**

**(a)** *A proposal to establish a new ambulatory surgical facility, to establish a new campus of an existing facility, to establish a new hospital, to increase the number of operating rooms in an existing facility (excluding dedicated C-section operating rooms), to convert a specialty ambulatory surgical program to a multispecialty ambulatory surgical program, or to add a specialty to a specialty ambulatory surgical program shall demonstrate the need for the number of proposed operating rooms in the facility that is proposed to be developed or expanded in the third operating year of the project based on the Operating Room Need Methodology set forth in the 2018 State Medical Facilities Plan. The applicant is not required to use the population growth factor.*

Rex Hospital’s projections are not based on reasonable assumptions because the OR utilization data as reported in the SMFPs shows a decline in actual utilization for the most recent three years. Rex Hospital

wrongly chose to rely on unverified internal surgery utilization data that does not correspond to the operating room utilization data that is included in the 2019 SMFP. Therefore the Rex Hospital application fails to conform to this administrative rule.

**10A NCAC 14C .2103 PERFORMANCE STANDARDS**

*(e) The applicant shall document the assumptions and provide data supporting the methodology used for each projection in this Rule.*

Rex Hospital provides unverified internal surgical utilization data that is inconsistent with the OR utilization as reported in the 2019 SMFP. The application does not adequately demonstrate that the assumptions used to project surgical cases are reasonable and adequately supported for Rex Hospital, Rex Surgery Center of Wakefield and Rex Surgery Center of Cary. Therefore the Rex Hospital application does not conform to this administrative rule.

**TOSC Comments Regarding Wake Spine and Specialty Surgery CON Project ID # J-11747-19**

**Wake Spine and Specialty Surgery proposes to develop a new ambulatory surgical facility with one operating room and three procedure rooms in Wake County.**

**In accordance with N.C. GEN. STAT. § 131E-185(a1)(1), Triangle Orthopaedics Surgery Center (TOSC) provides comments and documentation regarding why the Wake Spine and Specialty Surgery (WSSS) application does not conform to multiple CON criteria as follows:**

- **The WSSS proposal fails to demonstrate that its proposal will maximize healthcare value.**
- **The proposed project does not meet the definition of a multispecialty ambulatory surgical program because the surgical specialties do not include at least three of the following specialty areas: gynecology, otolaryngology, plastic surgery, general surgery, ophthalmology, orthopedics or oral surgery. Also the one proposed operating room would only be utilized by the neurosurgeons.**
- **The applicant’s assumptions regarding the number of outpatient surgical cases projected to be performed at the proposed OR are not adequately supported. No methodology and assumptions are included in Section Q Form C to demonstrate that the projected cases are reasonable.**
- **Utilization projections are not based on reasonable assumptions because the application includes no physician recruitment plan and several of the neurosurgeons will likely retire prior to October 2023, the third year following completion of the project.**
- **The financial projections are not based on reasonable assumptions and adequately supported utilization projections causing the application to be nonconforming to Criterion 5.**
- **The WSSS proposal would not enhance competition and have a positive impact on cost effectiveness because the application does not demonstrate the need for the proposed services.**

**For all of these reasons, the WSSS application is not an approvable Certificate of Need (CON) application.**

**Criterion 1** *“The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which shall constitute a determinative limitation on the provision of any health services, health service facility, health service beds, dialysis stations. Operating rooms, or home health offices that may be approved.”*

**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 WSSS application fails to demonstrate that the applicant's proposal would maximize healthcare value because the utilization projections are not based on reasonable and adequately supported assumptions. The discussion regarding utilization found in Criterion 3 is incorporated herein by reference. Therefore the WSSS application does not conform to Criterion 1 and Policy GEN-3.

**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 WSSS application does not adequately identify the population to be served by the proposed project because:

- 1) WSSS fails to provide the methodology and assumptions to demonstrate that the projected total numbers of OR patients are reasonable.
- 2) The application provides no explanation for the differences in the projected patient origin for the operating room and procedure rooms. The OR patient origin includes some patients from Wayne, Halifax, Wilson and Durham Counties; no patients from these counties are included in the patient origin projections for the procedure rooms.
- 3) In addition to the discrepancy in the patient origin counties that are listed, the tables on pages 23 and 24 of the application fail to identify the patient origin counties for 9.8 percent of projected patients that will originate from "Other."
- 4) Historical patient origin data for the participating physicians is omitted and the Agency has no information to evaluate the reasonableness of the patient origin projections for the operating room and the procedure rooms.

Section Q of the WSSS application does not include the mandatory methodology and assumptions that demonstrate why the projected OR cases provided in Form C on page 87 are based on the information provided in the physician support letters. There is no explanation as to why it is reasonable for the Raleigh Neurosurgical Clinic physician support letters to project higher numbers of cases for the proposed OR at WSSS as compared to the physicians' historical numbers of cases. As discussed in the CON application, several of the surgeons with Raleigh Neurological Clinic perform surgery cases at existing hospitals and ambulatory surgical facilities. However, the WSSS physician support letters and Form Q provide no explanation or timeframe regarding the expected shift of cases from these existing facilities to the proposed project. In fact, it is entirely unreasonable to assume that 100 percent of their historical outpatient cases could be safely shifted from hospitals to the proposed ASC because:

- 1) Not all neurosurgery patients would meet the patient selection criteria for outpatient surgery in a freestanding surgery center.
- 2) Not all types of outpatient neurosurgery cases are reimbursed in the ASC setting.
- 3) Not all patients would choose to obtain neurosurgery in a freestanding ASC due to travel distances and the need for some patients to have extended post-operative observation.

Several of the physicians with Raleigh Neurological Clinic are approaching retirement age. According to the online database Healthgrades ([www.healthgrades.com](http://www.healthgrades.com)), Kenneth Rich, MD is currently age 67, Robert Lee Allen, MD is age 66, and Timothy Garner, MD is age 62. Support letters from these three physicians provide their historical OR cases and future projections of OR cases but their OR projections exceed their historical volumes without any rationale. Their support letters and the WSSS application fail to document that these three physicians are committed to perform surgery at the proposed facility

through September 30, 2024. Furthermore, the WSSS application does not contain a physician recruitment plan that supports the replacement of retiring physicians.

The applicant's utilization projections for the proposed procedure rooms are mostly comprised of pain and ophthalmology procedures. The physician support letters do not include any explanation regarding how the projected volumes were determined and if the projections take into consideration that some patients may choose to have their procedure at other existing facilities.

For all these reasons the WSSS application does not conform to Criterion 3.

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

The WSSS application does not adequately demonstrate that the alternative proposed in this application is the most effective alternative to meet the identified need because the application is not conforming to all statutory and regulatory review criteria. See Criteria 1, 3, 6, 18a, and 10A NCAC 14C .2103. An application that cannot be approved cannot be the most effective alternative. Thus the WSSS application does not conform to Criterion 4.

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

The assumptions in the proforma financial statements are not reasonable because the utilization projections are not based on reasonable and adequately supported assumptions. Consequently, unsupported utilization projections cause the projected revenues and expenses for the project to be unreliable. The discussion regarding projected utilization found in Criterion 3 is incorporated herein by reference. Based on the unreasonable utilization, the projection revenues and expenses are unreliable.

The financial statements in Section Q are incorrect causing the application to fail to demonstrate the long-term financial feasibility of the proposal. For these reasons the WSSS application is also nonconforming to Criterion 5.

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

WSSS does not adequately demonstrate that an additional operating room is needed at the proposed ASC because the utilization projections are not based on reasonable assumptions. The discussion regarding need and projected utilization found in Criterion 3 is incorporated herein by reference. Therefore, the applicant does not adequately demonstrate that the proposal would not result in an unnecessary duplication of existing or approved services in the service area. Consequently the WSSS application does not conform to Criterion 6.

**Criterion 18a** *"The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of*

*applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.”*

**The WSSS application does not adequately demonstrate how its project will enhanced competition in the service area and have a positive impact on the cost effectiveness of services because it does not adequately demonstrate the need the population to be served has for the proposed services. The application is based on unreasonable utilization projections. Additional discussion regarding analysis of need and projected utilization found in Criterion 3 is incorporated herein by reference. The application is not conforming to Criterion 18a for the reasons stated above.**

**10A NCAC 14C .2103 PERFORMANCE STANDARDS**

*(a) A proposal to establish a new ambulatory surgical facility, to establish a new campus of an existing facility, to establish a new hospital, to increase the number of operating rooms in an existing facility (excluding dedicated C-section operating rooms), to convert a specialty ambulatory surgical program to a multispecialty ambulatory surgical program, or to add a specialty to a specialty ambulatory surgical program shall demonstrate the need for the number of proposed operating rooms in the facility that is proposed to be developed or expanded in the third operating year of the project based on the Operating Room Need Methodology set forth in the 2018 State Medical Facilities Plan. The applicant is not required to use the population growth factor.*

**WSSS fails to provide adequate assumptions and methodology for its operating room projections. Section Q of the WSSS application does not include the mandatory methodology and assumptions that demonstrate why the projected OR cases provided in Form C on page 87 are based on the information provided in the physician support letters. The WSS application does not conform to this rule.**

**10A NCAC 14C .2103 PERFORMANCE STANDARDS**

*(e) The applicant shall document the assumptions and provide data supporting the methodology used for each projection in this Rule.*

**WSSS fails to provide adequate assumptions and methodology for its operating room projections. Section Q of the WSSS application does not include the mandatory methodology and assumptions that demonstrate why the projected OR cases provided in Form C on page 87 are based on the information provided in the physician support letters. There is no explanation as to why it is reasonable for the Raleigh Neurosurgical Clinic physician support letters to project higher numbers of cases for the proposed OR at WSSS as compared to the physicians’ historical numbers of cases. Therefore, the WSS application does not conform to this rule.**