ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS
C = Conforming
CA = Conditional
NC = Nonconforming
NA = Not Applicable

Decision Date: February 9, 2016
Findings Date: February 9, 2016

Project Analyst: Celia C. Inman
Assistant Chief: Martha J. Frisone

Project ID #: F-11106-15
Facility: Randolph Surgery Center
FID #: 100778
County: Mecklenburg
Applicant(s): The Charlotte-Mecklenburg Hospital Authority
Charlotte Surgery Center, LP
Project: Relocate 3 operating rooms (ORs) from CMC-University, 2 ORs from CMC-Main and 1 OR from Charlotte Surgery Center for a total of 6 ORs upon project completion

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

G.S. 131E-183(a) The Department shall review all applications utilizing the criteria outlined in this subsection and shall determine that an application is either consistent with or not in conflict with these criteria before a certificate of need for the proposed project shall be issued.

(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, operating rooms, or home health offices that may be approved.

C

The applicants, Charlotte Surgery Center, LP and The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Healthcare System propose to relocate a combined total of six existing operating rooms from Charlotte Surgery Center (CSC) and Carolinas Healthcare System (CHS) to a new, separately licensed ambulatory surgery center (ASC), to be owned and operated by Charlotte Surgery Center, LP.

Need Determination

The proposed project does not involve the addition of any new health service facility beds, services or equipment for which there is a need determination in the 2015 State Medical Facilities Plan (SMFP). Therefore, there are no need determinations applicable to this review.

Policies

There is one policy in the 2015 SMFP that is applicable to this review: Policy GEN-4: ENERGY EFFICIENCY AND SUSTAINABILITY FOR HEALTH SERVICE FACILITIES, on page 39 of the 2015 SMFP. Policy GEN-4 states:

> *"Any person proposing a capital expenditure greater than $2 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178 shall include in its certificate of need application a written statement describing the project's plan to assure improved energy efficiency and water conservation.*
>
> *In approving a certificate of need proposing an expenditure greater than $5 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178, the Certificate of Need Section shall impose a condition requiring the applicant to develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. The plan must be consistent with the applicant's representation in the written statement as described in paragraph one of Policy GEN-4.*
>
> *Any person awarded a certificate of need for a project or an exemption from review pursuant to G.S. 131E-184 are required to submit a plan of energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation. The plan must be consistent with the applicant's representation in the written statement as described in paragraph one of Policy GEN-4. The plan shall not adversely affect patient or resident health, safety or infection control."*

The proposed capital expenditure for this project is greater than $5 million. In Section III.4, page 93, the applicants address Policy GEN-4 and the center's plan for energy efficiency and water conservation. The applicants state:

> *"Charlotte Surgery Center, LP is committed to energy efficiency and sustainability that balances the need for healthcare services and environmental sustainability in the communities it serves."*

The applicants further state that the renovations will be completed using modern energy conservation practices and methods, utilizing energy conserving mechanical equipment and construction methods.

The applicants adequately demonstrate the proposal includes a written statement describing the project's plan to assure improved energy efficiency and water conservation. Therefore, the application is consistent with Policy GEN-4 and conforming to this criterion, subject to Condition (10) in Criterion (4).

Conclusion

In summary, the applicants adequately demonstrate that the proposal is consistent with Policy GEN-4. Therefore, the application is conforming to this criterion, subject to Condition (10) in Criterion (4).

(2) Repealed effective July 1, 1987.

(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.

C

The applicants, Charlotte Surgery Center, LP and The Charlotte-Mecklenburg Hospital Authority, propose to relocate a combined total of six existing operating rooms – one from Charlotte Surgery Center, two from Carolinas Medical Center, and three from Carolinas HealthCare System University (two from its main campus and one from its Huntersville campus) – to a new, separately licensed ASC, to be owned and operated by Charlotte Surgery Center, LP.

Charlotte Surgery Center, LP, which also owns and operates Charlotte Surgery Center on 2825 Randolph Road in Charlotte, is a partnership with the following intended partners as of the filing of this application:

- Charlotte-SC, LLC (no less than 20 percent),
- The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas HealthCare System, (no less than 45 percent),
- Gaul Surgical Properties, LLC (23 percent), and
- Additional physician ownership (up to 12 percent).

The new ASC will be known as Randolph Surgery Center. Charlotte Surgery Center, LP will develop Randolph Surgery Center as proposed in the application and intends to register Randolph Surgery Center as a d/b/a during the development of the proposed project. Surgical Care Affiliates (SCA), Parent Company to Charlotte-SC, LLC, and the largest independent surgical care company in the United States, will manage Randolph Surgery Center.

The proposed facility, Randolph Surgery Center, will be located at 3621 Randolph Road in Mecklenburg County, in existing space where Randolph Surgery Center, LLC was previously

approved in Project ID #F-10218-13 to develop a two-room ambulatory surgery center. That project has not yet been developed.

Randolph Surgery Center, LLC (approved in Project ID #F-10218-13) is comprised of the following entities:

- CEENTA Surgery II, LLC (45 percent), and
- The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas HealthCare System (55 percent).

In Section I.7, page 9 of the application, the applicants state:

> *"Upon issuance of the Certificate of Need for the project proposed in this application, Randolph Surgery Center, LLC intends to relinquish its Certificate of Need for the previously approved two-room ambulatory surgery center on this site."*

Exhibit 4 documents Randolph Surgery Center, LLC's intent to relinquish its certificate of need for Project ID #F-10218-13 upon the issuance of the certificate of need for this project.

The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas HealthCare System (CHS), also operating under the business names of Carolinas Medical Center (CMC), and Carolinas HealthCare System University (CHSU), will fund the project and currently operates five of the six existing operating rooms which will be relocated to the new ASC.

In Exhibit 10, page 392, the applicants list the following CHS owned or leased, and separately licensed hospitals:

- CHS Anson
- Carolinas Medical Center
    - CMC-Mercy
    - Levine's Children's Hospital / CHS SouthPark (ED)
- CHS Lincoln
- CHS Pineville / CHS Steele Creek (ED)
- CHS NorthEast / CHS Harrisburg (ED) / CHS Kannapolis (ED)
- CHS Union / CHS Waxhaw (ED)
- CHS University / CHS Huntersville (ED)
- Carolinas Rehabilitation-Mount Holly / Carolinas Rehabilitation-Northeast
- CHS Cleveland
- CHS Kings Mountain Hospital
- Stanly Regional Medical Center

The applicants also list the following CHS owned and separately licensed surgery centers:

- Carolina Center for Specialty Surgery (WaveCo, LLC)
- Carolinas Gastroenterology Ballantyne
- Carolinas Gastroenterology Medical Center Plaza
- Cleveland Ambulatory Services, LLC
- Endoscopy Center Monroe, LLC

- Endoscopy Center Northcross, LLC
- Endoscopy Center Pineville, LLC
- Endoscopy Center University, LLC
- Gateway Ambulatory Surgery Center, LLC
- Iredell Surgical Center
- Union West Surgery Center

On page 393 of Exhibit 10, the applicants list the facilities managed by CHS as follows:

- Alamance Regional Medical Center
- Annie Penn Hospital
- CHS Blue Ridge (Morganton and Valdese)
- Columbus Regional Healthcare System
- Moses H. Cone Memorial Hospital (Cone Health, Wesley Long, Women's Hospital campuses / MedCenter High Point ED)
- Murphy Medical Center
- Scotland Memorial Hospital
- St. Lukes Hospital
- Wilkes Regional Medical Center

Population to Be Served

On page 60, the 2015 SMFP defines the service area for operating rooms as the planning area in which the operating room is located. *"The operating room planning areas are the single and multicounty groupings shown in Figure 6.1."* Figure 6.1 on page 65 of the SMFP shows Mecklenburg County as a single county operating room service area. Thus, the service area for this project consists of Mecklenburg County. Facilities may also serve residents of counties not included in their service area.

In Section III.5, page 93, the applicants state that the projected primary market for the ASC, includes patients from Mecklenburg County, and the contiguous North Carolina counties of Union, Gaston and Cabarrus; and York County in South Carolina. Patients from these counties represent 77% of the surgical volume projected to be performed at Randolph Surgery Center. The applicants provide a map illustrating patient origin on page 94.

In Section III.6, pages 95-96, the applicants provide the projected patient origin for the first two years of the project, as illustrated in the following tables:

Projected Operating Room Patient Origin

	PY 1 7/1/17-6/30/18		PY 2 7/1/18-6/30/19	
County	**Projected Patients**	**% of Total Patients**	**Projected Patients**	**% of Total Patients**
Mecklenburg	3,819	53.5%	4,296	53.5%
York, SC	591	8.3%	665	8.3%
Union	505	7.1%	568	7.1%
Gaston	339	4.7%	381	4.7%
Cabarrus	254	3.6%	286	3.6%
Iredell	240	3.4%	271	3.4%
Lincoln	182	2.5%	205	2.5%
Cleveland	162	2.3%	182	2.3%
Lancaster, SC	141	2.0%	159	2.0%
Catawba	88	1.2%	99	1.2%
Stanly	88	1.2%	99	1.2%
Other*	729	10.2%	820	10.2%
Total	**7,138**	**100.0%**	**8,031**	**100.0%**

Totals may not sum due to rounding.
*Includes Alamance, Alexander, Alleghany, Anson, Ashe, Avery, Brunswick, Buncombe, Burke, Caldwell, Carteret, Caswell, Clay, Columbus, Cumberland, Davidson, Davie, Durham, Forsyth, Guilford, Harnett, Henderson, Hoke, Jackson, Lee, Lenoir, Macon, Mitchell, Montgomery, Moore, New Hanover, Orange, Polk, Randolph, Richmond, Robeson, Rowan, Rutherford, Scotland, Stokes, Surry, Transylvania, Wake, Watauga, Wilkes and Wilson counties in North Carolina, as well as other states.

Projected Procedure Room Patient Origin

	PY 1 7/1/17-6/30/18		PY 2 7/1/18-6/30/19	
County	**Projected Patients**	**% of Total Patients**	**Projected Patients**	**% of Total Patients**
Mecklenburg	1,094	59.4%	1,231	59.4%
York, SC	169	9.2%	190	9.2%
Union	141	7.6%	158	7.6%
Gaston	110	5.9%	123	5.9%
Lancaster, SC	50	2.7%	56	2.7%
Cabarrus	43	2.3%	49	2.3%
Cleveland	38	2.1%	43	2.1%
Iredell	38	2.1%	43	2.1%
Stanly	22	1.2%	24	1.2%
Other*	139	7.6%	157	7.6%
Total	**1,843**	**100.0%**	**2,073**	**100.0%**

Totals may not sum due to rounding.
*Includes Alleghany, Anson, Burke, Caldwell, Catawba, Columbus, Davidson, Lincoln, Mitchell, New Hanover, Randolph, Richmond, Robeson, Rowan, Rutherford, Surry, Wake, Watauga and Wilkes counties in North Carolina, as well as other states.

On page 96, the applicants state that Randolph Surgery Center's expected future patient origin will closely match the historical patient origin of the cases projected to be performed at the ASC. They further state:

> *"Consequently, future patient origin for the proposed ASC is based on the 2015 operating room and procedure room patient origin for the physicians who are projected to perform procedures at the proposed ASC."*

The applicants adequately identify the population proposed to be served.

Analysis of Need

In Section III.1(a), page 64, the applicants state the unmet need that drives the proposed project is the need to create additional freestanding ASC capacity, based on:

- the continued demand for ambulatory surgical services by patients, physicians and payors;
- the growing and aging population in Mecklenburg County and surrounding area;
- the need for physician collaboration and coordination; and
- the need to enhance the quality of, access to and value of surgical services for the residents of Mecklenburg County and surrounding areas.

Demand for Ambulatory Surgical Services

On pages 64-68, the applicants discuss the shift of healthcare from inpatient to outpatient settings, stating:

> *"Over the past several decades, technological advances coupled with changes in healthcare financing have resulted in a significant shift of healthcare from inpatient to outpatient settings. This trend continues to persist and is expected to continue into the future, to an even greater extent."*

The applicants further state that the shift began over 30 years ago and is primarily the result of clinical advances, including improved technology, increased knowledge of pain management and anesthesiology, and decreased recovery times. Procedures such as tonsillectomies, hernia repairs and gallbladder removals were once highly invasive procedures that required an extensive inpatient stay. The applicants state that advances in technology have enabled these procedures to be performed on an outpatient basis and less invasively, such that patients require minimal recovery time and are most often released within the same day.

The applicants state that the recent adoption of the Affordable Care Act has led to an increase in the number of individuals with healthcare insurance nationwide and within North Carolina and that patients with health insurance are more likely to seek and be able to access outpatient surgical care, which is often elective and financially burdensome for those without insurance. The applicants further state that healthcare insurance plans are increasingly structured to steer physicians and patients toward lower cost options for care; with Medicare and private insurers shifting to bundled payments for a growing number of conditions and a greater number of

individuals enrolled in consumer-directed health plans with high deductibles. As a result, the applicants state that providers are focused more on delivering care in the most efficacious and efficient setting, which for those individuals who do not require a more intensive setting, the freestanding ASC provides high quality care at a lower cost.

Based on data provided by the applicants on page 67 and sourced to the 2007 State Medical Facilities Plan (SMFP) through the Proposed 2016 SMFP, the following table illustrates that outpatient surgery already represents over two-thirds of the total surgery volume in North Carolina and that the compound annual growth rate (CAGR) from 2005 through 2014 has increased for outpatient surgeries and decreased for inpatient surgeries.

North Carolina Surgical Volume

	Inpatient Surgeries	Outpatient Surgeries	Total Surgeries	Percent Outpatient
FFY 2005	266,949	631,063	898,012	70.3%
FFY 2006	265,117	638900	904,017	70.7%
FFY 2007	267,754	634,399	902,153	70.3%
FFY 2008	267,187	357,748	624,935	57.2%
FFY 2009	263,195	653,627	916,822	71.3%
FFY 2010	259,270	653,492	912,762	71.6%
FFY 2011	257,115	653,365	910,480	71.8%
FFY 2012	253,367	641,637	895,004	71.7%
FFY 2013	252,309	646,204	898,513	71.9%
FFY 2014	247,966	638,724	886,690	72.0%
CAGR 2005-2014	-0.8%	0.1%	-0.1%	0.3%

The table above shows that the nine-year CAGR of total surgical services decreased at a rate of -0.1%, while the CAGR for outpatient surgical services increased at a rate of 0.1%. On page 68, the applicants state:

> *"Similar to North Carolina data, outpatient surgery represents over two-thirds of total surgery volume performed in Mecklenburg County. Given the changes in payment and technology discussed previously, the shift to outpatient surgery is expected to continue, including the demand in freestanding ASCs."*

<u>*Mecklenburg County Population Growth*</u>

In Section III.1, pages 69-71, the applicants discuss population growth and aging as playing an important role in the need to create additional freestanding ASC capacity. In particular, the applicants discuss Mecklenburg County as one of the fastest growing counties in North Carolina, with a growing segment of residents over the age of 65, which will continue to create demand for surgical capacity in the future, stating:

> *"According to data from the North Carolina Office of State Budget and Management (NC OSBM), Exhibit 22, Mecklenburg County is the fastest growing county in North Carolina based on numerical growth and the second fastest behind Brunswick County based on percentage growth."*

The applicants further state that the NC OSBM projects Mecklenburg County's high growth will continue throughout this decade, growing 24.2% between 2010 and 2020 and adding over 222,680 people, with 12% of the total Mecklenburg population being over the age of 65 by 2020. The applicants note the significance of this data on page 70, saying, *"…typically, older residents utilize healthcare services at a higher rate than those who are younger."*

Collaboration and Coordination

In Section III, page 71, the applicants discuss the proposed project as a collaborative effort of The Charlotte Mecklenburg Hospital Authority, Surgical Care Affiliates, and well-regarded surgeons, stating that each party brings distinct competencies to create a joint venture that will be unique within the Charlotte region and unlike what any individual organization could achieve alone. Each party's individual expertise is discussed on pages 71-75. On pages 75-76, the applicants state:

> *"The jointly controlled ASC model will enable physicians to work with CHS to coordinate seamless patient care along a continuum, supported by the administrative and management functions of SCA.*
>
> …
>
> *This coordination and collaboration between primary care, surgeon, hospital, and ambulatory care center will support the level of integration necessary to respond to changing payment models, such as bundled payment. … The joint venture ASC model will provide a platform to allow CHS, SCA, and physicians to work together to improve the quality and coordination of care from the initial diagnosis through surgery and recovery."*

Enhanced Quality, Access and Value

On page 78, the applicants state that ASCs provide services in facilities specifically designed to perform outpatient surgical services and that patients have reported a 92 percent satisfaction rate after having a procedure in an ASC. The applicants further state that physicians enjoy enhanced productivity and greater scheduling flexibility, more consistent nurse staffing and faster turnaround time between cases which allows them to perform more surgeries in less time with superior patient outcomes, reduced infection rates, and low rates of medical error at ASCs.

According to the applicants, the proposed project will expand access to freestanding ASCs in the service area, offering an accessible setting with convenient patient parking in close proximity to public transportation. The applicants state that the operation of Randolph

Surgery Center and Charlotte Surgery Center, less than two miles apart, by one legal entity will allow management of the surgical centers to flex staff and surgical cases between the two facilities as appropriate, resulting in improved efficiencies and improved access for patients.

On page 79, the applicants state that the proposed project will enhance the cost effectiveness of surgical procedures. Five of the six operating rooms to be relocated to the proposed Randolph Surgery Center are currently hospital-based. In a freestanding ASC, there are no other hospital-based services (emergency room, intensive care, inpatient services, and overhead related to hospital services) allocated to surgery services; with the only expenses being generated directly by services provided by the ASC. As a result, the applicants state that patients and payors will not incur the additional charges associated with hospital-based care. Moreover, on page 80, the applicants state that the proposed project involving renovation of existing operating room space provides greater healthcare value than attempting to build a new ASC to house the relocated operating rooms.

The applicants further state that the resulting joint venture that will encompass both the proposed Randolph Surgery Center and the existing Charlotte Surgery Center will enhance the quality, access, and cost effectiveness of outpatient surgical services in Mecklenburg County and surrounding areas.

Projected Utilization

In Section III.1(b), pages 81-89, the applicants discuss the existing and projected volume of surgical cases of the surgeons that are expected to practice at Randolph Surgery Center, which will predominantly be composed of members of the OrthoCarolina practice. OrthoCarolina is one of the nations' leading independent orthopedic practices with physicians currently practicing at numerous sites around the region, including Charlotte Surgery Center and CHS hospitals. The applicants state that unlike much of the rest of the state and Mecklenburg County, OrthoCarolina physicians have experienced significant growth in surgical cases over the past three years, as shown in the table on page 81 and below.

OrthoCarolina Surgical Cases – Total Practice at All Locations

	2013	2014	2015*	CAGR
Inpatient Cases	10,609	10,951	12,029	6.5%
Outpatient Cases	21,361	22,178	22,735	3.2%
Total Cases	**31,970**	**33,129**	**34,764**	**4.3%**

*Based on year-to-date September data, annualized

The applicants state that many of the cases shown above were performed at Charlotte Surgery Center, which based on 2015 year-to-date volume, annualized, as provided by the applicants, is operating above defined capacity. With the development of the proposed project and its larger operating rooms, OrthoCarolina surgeons, as well as other surgeons, will shift cases currently performed at Charlotte Surgery Center and CHS facilities to Randolph Surgery Center.

On page 84, the applicants provide the following table illustrating the number of cases by existing facility that physicians expect to shift to the proposed facility by project year three, July 1, 2019 through June 30, 2020.

Shift to Randolph Surgery Center

Facility	Cases
Charlotte Surgery Center *	5,577
CHS University	120
CHS Huntersville	50
CMC	1,349
CMC-Mercy	1,827
Total Cases	**8,923**

*5,577 is only a portion of CSC's total cases

On page 85, the applicants include a listing of the physicians and their commitments from Exhibit 36, totaling 8,923 surgical cases. These amounts are based on actual 2015 volumes performed by the physicians. On page 83, the applicants state that the projected growth in surgical volume of the affiliated physician members would likely not be sustainable at their current ambulatory surgery sites given current capacity.

Exhibit 36 contains physician support letters documenting intent to utilize Randolph Surgery Center. Thirty-nine physicians document their intent to perform more than 8,600 surgical cases at the proposed ASC and another five physicians document their intent to perform more than 2,300 minor procedures at the proposed ASC.

On page 84, the applicants state:

> *"As demonstrated in Exhibit 18, even with the shift of cases from CSC and other facilities, these facilities, particularly CSC, will continue to be well utilized."*

Representatives of Charlotte Eye, Ear, Nose & Throat Associates, PA (CEENTA) and Urology Specialists of the Carolinas, PLLC (USOC) provide letters documenting their intent to obtain practice privileges and shift at least 2,760 and 1,136 surgical cases, respectively, from CHS facilities to Charlotte Surgery Center. The Chair of the Department of Surgery at Carolinas HealthCare System provides a letter stating an expectation of shifting 2,046 current inpatient and specialized outpatient surgeries from CMC to CMC-Mercy.

On page 86, the applicants show the shift in surgical cases to Randolph Surgery Center by surgical specialty. Exhibit 23 contains a listing of the procedures and CPT codes that comprise the volumes by specialty as shown below.

Shift to Randolph Surgery Center by Specialty

Facility	Cases
Orthopedics	7,582
Plastic Surgery	57
General Surgery	173
Other (includes Podiatry and other specialties)	1,112
Total Cases	**8,923**

Totals may not sum due to rounding

The applicants state that they project the volume to remain static at the 2015 volume which will be achieved in the third project year, not the first, following a ramp-up period, using estimates of 80% for the first year and 90% for the second year, as shown in the table on page 87 and below.

Projected Randolph Surgery Center Surgical Cases

	PY 1 7/1/17-6/30/18	PY 2 7/1/18-6/30/19	PY 3 7/1/19-6/30/20
Outpatient Cases	7,138	8,031	8,923
Outpatient Hours*	10,708	12,046	13,385
ORs Needed^	5.7	6.4	7.1
ORs Projected	6	6	6

*Outpatient Hours = outpatient cases x 1.5 hours
^ORs Needed = outpatient hours / 1,872 hours per OR

In summary, the proposed ASC is projected to perform 8,923 outpatient cases in the third project year, which results in 13,385 surgical hours and adequately demonstrates the need for the six proposed operating rooms at Randolph Surgery Center.

The applicants are also proposing two procedure rooms to perform pain management and other minor procedures and state that the need is both quantitative and qualitative. In Section III, pages 87-88, the applicants state that the pain management procedures performed in two of the procedure rooms at Charlotte Surgery Center are expected to shift to Randolph Surgery Center. The YAG laser procedures performed by ophthalmologists in the third procedure room at Charlotte Surgery Center are expected to remain at Charlotte Surgery Center. The resulting procedure room utilization is shown on page 88 and below.

Projected Randolph Surgery Center Procedure Room Cases

	PY 1 7/1/17-6/30/18	PY 2 7/1/18-6/30/19	PY 3 7/1/19-6/30/20
Procedures	1,843	2,073	2,304
Procedure Rooms	2	2	2
Procedures per Room	922	1,037	1,152

The applicants state that the above projections are conservative because they include only pain management procedures and no other types of minor procedures. Any additional procedures,

either by the identified physicians expected to shift volume to Randolph Surgery Center or others, will only further increase the utilization of the facility.

The proposed project also includes 12 Preparation bays, 16 Recovery I bays, and 16 Recovery II bays. This is 1.5 (12 / 8 = 1.5) prep spaces and 4 (32 / 8 = 4) recovery spaces per operating and procedure room (6 + 2 = 8). The applicants state that the proposed number of prep spaces is appropriate to accommodate expected turn-over times and patient volume and the proposed number of recovery spaces is reasonable for the projected volume of surgical specialties (largely orthopedic surgeries) because it is not uncommon for the recovery period to exceed the procedure time itself. Having adequate recovery space avoids holding patients in operating rooms (more expensive space) waiting on recovery space to become available.

The applicants adequately demonstrate the need the population to be served has for the proposed project to develop a new ASC with the relocation of six existing operating rooms and the addition of two procedure rooms.

Access

In Section III, page 79, the applicants state the proposed project will increase access to timely, clinically appropriate and high quality surgical services in Mecklenburg County with a freestanding ASC that has accessible parking at the facility and is located close to public transportation. The applicants further state their anticipation of more effective scheduling of procedures based on the concentration of specialties, thus improving access for patients. The applicants also state that the joint ownership and operation of the proposed Randolph Surgery Center and the existing Charlotte Surgery Center, less than two miles apart, by Charlotte Surgery Center, LP, will allow both surgical centers to flex staff and surgical cases between the two facilities, as appropriate, resulting in improved efficiencies for the facilities and improved access for patients.

In Section VI, page 113, the applicants state, *"Randolph Surgery Center will provide services to all persons in need of medical care, regardless of race, color, religion, natural origin, sex, age, disability, or source of payment."* Exhibit 29 contains SCA's Non-Discrimination and Financial Policies for Charlotte Surgery Center, which will be used as a model for policies to be used at Randolph Surgery Center.

The applicants adequately demonstrate the extent to which all residents of the area, including underserved groups, are likely to have access to the services proposed.

Conclusion

In summary, the applicants adequately identify the population to be served; adequately demonstrate the need the population to be served has for the proposed services; and adequately demonstrate the extent to which all residents of the area, including underserved groups, are likely to have access to the services. Therefore, the application is conforming to this criterion.

(3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

C

The applicants propose to relocate six existing operating rooms from Charlotte Surgery Center and CHS facilities to develop Randolph Surgery Center. In Section III.9(d), page 101, the applicants state that the majority of the surgical volume at Randolph Surgery Center will shift from Charlotte Surgery Center and CHS facilities.

The proposed Randolph Surgery Center is located only two miles from Charlotte Surgery Center and will be owned and operated by the same legal entity. The proposed shift in surgical specialties will allow surgeons to choose to use the larger operating rooms at the new facility, as appropriate. Therefore the needs of the population presently served by Charlotte Surgery Center will be adequately met by the proposed relocation of the proposed surgical services.

In reference to the population currently served by the CHS facilities, on page 101, the applicants state:

> *"…., the proposed reduction and shift of patients from CHS facilities will greatly benefit patients due to the joint venture model and the opportunity to receive their services at a freestanding ASC with lower costs and charge, for those that do not require a hospital-based setting."*

In Section VI.6, page 116, the applicants state that Randolph Surgery Center's services will be accessible to Medicare and Medicaid recipients, the uninsured, and the underinsured. The applicants demonstrate that the needs of the population presently served will be adequately met and that the proposal will not adversely affect the ability of medically underserved groups to obtain needed health care. The discussions regarding analysis of need, including projected utilization, and access found in Criterion (3) are incorporated herein by reference. Therefore, the application is conforming to this 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.

CA

In Section III.8, pages 97-99, the applicants describe the alternatives considered prior to the submission of this application, which include:

1) Maintain the Status Quo – The applicants state they quickly rejected this alternative because maintaining the status quo does not achieve the applicants' primary goal: to create additional freestanding ASC capacity in a unique collaborative model.

2) Develop a New ASC with Fewer Operating Rooms - The applicants state they briefly considered relocating fewer operating rooms. However, the applicants determined that six operating rooms are needed to accommodate the volume of surgical cases projected to be shifted from Charlotte Surgery Center and CHS facilities to Randolph Surgery Center. Therefore, this alternative was rejected.

3) Relocate Operating Rooms from Another CHS Facility - The applicants state they briefly considered relocating operating rooms from CMC-Mercy instead of CMC-One Day Surgery and CHS University. However, the operating rooms at CMC-Mercy have been recently renovated and are home to specialized surgical programs, which have been designed to take full advantage of the capacity and configuration of CMC-Mercy's operating room capacity. Therefore, this alternative was rejected.

4) Construct a New ASC with Six Operating Rooms in Mecklenburg County – the applicants rejected this alternative as cost-prohibitive given that the proposed project can be developed in existing space.

5) Develop Project as Proposed - the applicants state that after much consideration, it was decided to develop a multispecialty ASC with six ORs in the existing space approved for a new ASC in Project ID #G-10218-13, by relocating one existing OR from Charlotte Surgery Center, two from CMC, and three from CHS University. The applicants state that this alternative can be developed in considerably less time and is a cost-effective use of the existing space. The applicants also discuss the added efficiency of the joint operation of Charlotte Surgery Center and Randolph Surgery Center and the benefits of the individual expertise of the joint venture participants.

For the reasons as stated above, the applicants propose to develop the project as described in Section II.1, and consider the project as proposed to be the most effective alternative to meet the need for the proposed project.

The applicants adequately demonstrate that the proposed alternative is the most effective or least costly alternative to meet the identified need.

Furthermore, the application is conforming to all other applicable statutory and regulatory review criteria and thus, is approvable. A project that cannot be approved cannot be an effective alternative.

In summary, the applicants adequately demonstrate that the project as proposed is the least costly or most effective alternative to meet the identified need. Therefore, the application is conforming to this criterion and approved subject to the following conditions:

1. **Charlotte Surgery Center, LP and The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas HealthCare System d/b/a Carolinas Medical Center d/b/a Carolinas Healthcare System University shall materially comply with all representations made in the certificate of need application.**

2. **Charlotte Surgery Center, LP and The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas HealthCare System d/b/a Carolinas Medical Center d/b/a Carolinas Healthcare System University shall relocate no more than six operating rooms to Randolph Surgery Center: one from Charlotte Surgery Center, two from Carolinas Medical Center, and three from Carolinas HealthCare System University (two from the main campus and one from the Huntersville campus).**

3. **Upon completion of the project, Charlotte Surgery Center, LP shall take steps necessary to de-license one dedicated outpatient operating room located at Charlotte Surgery Center. Charlotte Surgery Center shall be licensed for no more than six dedicated outpatient operating rooms at project completion.**

4. **Upon completion of the project, The Charlotte-Mecklenburg Hospital Authority shall take steps necessary to de-license two operating rooms at Carolinas Medical Center and three operating rooms at Carolinas HealthCare System University (two on the main campus and one on the Huntersville campus).**

5. **The following table illustrates the approved ORs, by type, following completion of this project for the impacted facilities.**

	CMC-Main License		CHS-University License	
Operating Rooms	**CMC-Main**	**CMC-Mercy**	**CHS-University**	**CHS-Huntersville**
Dedicated Inpatient	1	0	0	0
Dedicated Outpatient	9	0	0	1
Shared	26	15	7	0
Dedicated Open Heart	5	0	0	0
Dedicated C-Section	4	0	1	0
Totals	**45**	**15**	**8**	**1**

6. **Upon issuance of the certificate of need for this project, Randolph Surgery Center, LLC shall relinquish the certificate of need for Project ID #F-10218-13 to relocate two dedicated outpatient operating rooms from Carolinas Medical Center to a new separately licensed ambulatory surgery center.**

7. **Gastrointestinal endoscopy procedures shall not be performed in the procedure rooms.**

8. **Charlotte Surgery Center, LP and The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas HealthCare System d/b/a Carolinas Medical Center d/b/a Carolinas Healthcare System University shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditure in Section VIII of the application and which would otherwise require a certificate of need.**

9. **Accreditation of the ambulatory surgical facility from The Joint Commission, The Accreditation Association of Ambulatory Health Care or a comparable accreditation authority shall be obtained within two years following the completion of the facility.**

10. **An Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes shall be developed and implemented. The plan must be consistent with the applicants' representations in the written statement as described in paragraph one of Policy GEN-4.**

11. **Charlotte Surgery Center, LP and The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas HealthCare System d/b/a Carolinas Medical Center d/b/a Carolinas Healthcare System University shall acknowledge acceptance of and agree to comply with all conditions stated herein in writing to the Certificate of Need Section prior to the issuance of the certificate of need.**

(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.

C

The applicants, Charlotte Surgery Center, LP and The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Healthcare System propose to relocate a combined total of six existing operating rooms from Charlotte Surgery Center and Carolinas Healthcare System to a new, separately licensed ASC, to be owned and operated by Charlotte Surgery Center, LP.

Capital and Working Capital Costs

In Section VIII.1, page 132-134, the applicants project that the total capital cost of the project will be $13,979,728 as shown in the table below.

Project Capital Costs

Site Costs	$ 21,476
Construction Contract	$ 8,301,709
Equipment/Furniture	$ 3,842,314
Landscaping	$ 25,000
Consultant Fees	$ 1,040,839
Financing / Interest	$ 257,575
Contingency	$ 490,815
Total Capital Cost	**$ 13,979,728**

Exhibit 35 contains a letter from the architect which documents the total estimated construction costs are $8,301,709, which is consistent with the information in Section VIII. CHS will finance the total capital cost from accumulated reserves.

In Section IX.1-3, page 139, the applicants state start-up and initial operating expenses required for the project will total $4,191,811 and that the source of the working capital will be CHS accumulated cash reserves.

Availability of Funds

Exhibit 32 contains a letter dated October 15, 2015 from the Executive Vice-President and CFO of Carolinas Healthcare System, which states CHS's intent to provide capital in the amount of $13,979,728 and working capital of $4,191,811 from accumulated cash reserves for the development of the proposed project.

Exhibit 33 contains the financial statements for The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas HealthCare System for the years ending December 31, 2014 and 2013. As of December 31, 2014, CHS had $96,271,000 in cash and cash equivalents, $7,213,587,000 in total assets and $4,029,263,000 in total net assets (total assets less total liabilities).

The applicants adequately demonstrate availability of sufficient funds for the capital and working capital needs of the project.

Financial Feasibility

The applicants provide pro forma financial statements for the first three years of the project. The applicants project revenues will exceed operating expenses in each of the first three operating years of the project, as illustrated in the table below.

Randolph Surgery Center	**PY1 7/1/17-6/30/18**	**PY2 7/1/18-6/30/19**	**PY3 7/1/19-6/30/20**
Projected # Surgical Cases	7,138	8,031	8,923
Projected Average Charge Surgical Cases	$11,972	$12,331.41	$12,701
Gross Patient Revenue Surgical Cases	$85,458,927	$99,025,531	$113,329,219
Projected # of Procedure Room Procedures	1,843	2,073	2,304

Projected Average Charge PR Procedures	$4,798	$4,942.24	$5,090
Gross Patient Revenue Procedure Room	$8,843,447	$10,247,344	$11,727,516
Total Gross Patient Revenue	$94,302,374	$109,272,875	$125,056,735
Deductions from Gross Patient Revenue	$72,578,132	$84,099,910	$96,247,675
Net Patient Revenue	$21,724,242	$25,172,965	$28,809,060
Total Expenses	$14,793,807	$16,247,815	$17,778,008
Net Income	$6,930,434	$8,925,151	$11,031,052

The assumptions used by the applicants in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See the related assumption notes in the Pro Forma Section for the assumptions regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

Conclusion

In summary, the applicants adequately demonstrate that sufficient funds will be available for the capital and working capital needs of the project. Furthermore, the applicants adequately demonstrate that the financial feasibility of the proposal is based upon reasonable projections of costs and charges. Therefore, the application is conforming to this 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.

C

The applicants propose to relocate a combined total of six existing operating rooms from Charlotte Surgery Center and Carolinas Healthcare System to a new, separately licensed ASC, to be owned and operated by Charlotte Surgery Center, LP.

On page 60, the 2015 SMFP defines the service area for operating rooms as the planning area in which the operating room is located. *"The operating room planning areas are the single and multicounty groupings shown in Figure 6.1."* Figure 6.1 on page 65 of the SMFP shows Mecklenburg County as a single county operating room planning area. Thus, the service area for this facility's project consists of Mecklenburg County. Facilities may also serve residents of counties not included in their service area.

The following table illustrates the existing and approved operating rooms located in Mecklenburg County, per the 2016 SMFP.

Facility	Number of Operating Rooms by Type				
	Inpatient	Ambulatory	Shared	CON Adjustments	Total
Presbyterian Hospital Mint Hill				5	5
Randolph Surgery Center				2	2
Charlotte Surgery Center		7			7
Carolina Center for Specialty Surgery		2			2
SouthPark Surgery Center		6			6
Novant Health Ballantyne Outpatient Surgery		2			2
Novant Health Huntersville Outpatient Surgery		2			2
Matthews Surgery Center		2			2
Mallard Creek Surgery Center*		2			2
Novant Health Presbyterian Medical Center**	6	6	34	-6	40
CMC –Pineville (CHS Pineville)	3		9		12
CMC	10	11	41	-2	60
CMC-University (CHS University)	1	2	9		12
Novant Health Matthews Medical Center	2		6		8
Novant Health Huntersville Medical Center	1		4	1	6
Total	23	42	103	0	168

*Single specialty demonstration project
**Novant Health Charlotte Orthopedic Hospital (CON F-8765-11), was relicensed under Novant Health Presbyterian Medical Center, effective 3/22/14. Data from 3/22/14-9/30/14 was reported by Presbyterian Medical Center.

As shown in the table above, Randolph Surgery Center reflects a CON adjustment for Project ID # F-10218-13, which the applicants state will be relinquished upon approval of the proposed project (Exhibit 4). Charlotte Surgery Center currently has seven ambulatory operating rooms, which will be reduced to six upon completion of the proposed project. CMC's operating room inventory will be reduced by two; however, the relinquishment of the CON for Project ID #F-10218-13 adds back two operating rooms to CMC, which results in the total number of operating rooms at CMC remaining at 60. CHS University will have a total of 9 operating rooms after the relocation of two from its main campus and one from its Huntersville campus. The total number of operating rooms in Mecklenburg County remains at 168.

The applicants do not propose to increase the number of licensed operating rooms, add services, or acquire equipment for which there is a need determination methodology in the 2015 SMFP. The total number of operating rooms in the CHS system and in Mecklenburg County will not change as a result of the proposed project.

The applicants adequately demonstrate that the proposal would not result in an unnecessary duplication of existing and approved operating room services. Therefore, the application is conforming to this criterion.

(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.

C

The following table illustrates the projected staffing at the proposed facility, as reported by the applicants in Section VII.2, page 124, for project year two.

Employee Category	# of Full Time Equivalent (FTE) Positions
Administrator	1.0
RNs	32.3
Nurse Aides	3.1
Surgical Techs	11.3
Medical Record Admin	1.0
Sterile Processing	2.1
Radiological Tech	1.0
Non-health personnel	6.2
TOTAL	**58.0**

As shown in the table above, the applicants propose a total of 58.0 FTE positions in project year two. In Section VII, pages 125-127, the applicants describe their experience and process for recruiting and retaining staff. Exhibit 15 contains a letter signed by Roy Alan Majors, MD, which states his commitment to serve as Medical Director for the proposed facility. Exhibit 28 contains Dr. Majors' curricula vitae.

The applicants adequately demonstrate the availability of sufficient health manpower and management personnel to provide the proposed surgical services. Therefore, the application is conforming to this criterion.

(8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

C

In Section II.2, page 33, the applicants identify the ancillary and support services that are required for the proposed project. On page 34, the applicants state that all ancillary and support services necessary for the project will be provided by the patient's physician, or via physician referral to a CHS facility, or by staff listed in Section VII, or are the responsibility of SCA to provide per the obligations of the Management Services Agreement in Exhibit 8. The applicants discuss coordination with the existing health care system in Section V, pages 108-111. The applicants provide supporting documentation in Exhibits 15, 21, 26, 27, 28 and 36. The information provided in the application is reasonable and supports a finding of conformity with this criterion.

(9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA

(10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers: (i) would be available under a contract of at least 5 years duration; (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO; (iii) would cost no more than if the services were provided by the HMO; and (iv)would be available in a manner which is administratively feasible to the HMO.

NA

(11) Repealed effective July 1, 1987.

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

C

The applicants propose to sublease space in a former surgical facility and renovate that space to meet the needs of the proposed six-operating room ASC. The physical space that is the site for the proposed ASC is vacated space that was formerly licensed as CSC-Randolph, a freestanding ASC and previously approved in Project ID # F-10218-13 for a two-OR surgery center. In Section XI.5, the applicants state the proposed Randolph Surgery Center will occupy 31,780 square feet of renovated space. Exhibit 11 contains line drawings of the proposed six-operating room ASC. Exhibit 35 contains a letter from an architect that estimates site preparation costs at $21,476, construction costs at $8,301,838 and consultant fees at $1,040,838, which corresponds to the capital cost projections provided by the applicants in Section VIII.1, pages 133-134. In Section XI.8, pages 150-151, the applicants describe the methods that will be used by the facility to maintain efficient energy operations and contain the costs of utilities. The discussion regarding costs and charges found in Criterion (5) is incorporated herein by reference. The applicants adequately demonstrate that the cost, design and means of construction represent the most reasonable alternative, and that the construction cost will not unduly increase costs and charges for health services. Therefore, the application is conforming to this criterion.

(13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:

(a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C

The Randolph Surgery Center proposed in this application is a new ambulatory surgery facility and as such has no history of service. In Section VI.13, pages 120-121, the applicants provide the payor mix for the surgical programs at CMC, CMC-Mercy, CHS University, CHS Huntersville and Charlotte Surgery Center for CY2014, as illustrated in the table below.

Surgical Cases as a Percent of Total Cases
CY2014

Payor	CMC	CMC-M	CHSU	CHSH	CSC
Self Pay/Indigent/Charity	6.0%	1.9%	4.6%	0.4%	0.9%
Medicare/Medicare Managed Care	26.2%	40.0%	21.7%	41.2%	30.9%
Medicaid	19.8%	4.7%	17.0%	11.5%	4.2%
Commercial Insurance/Managed Care	44.7%	47.9%	55.0%	45.4%	55.2%
Other (Work Comp and Other Gov't)	3.3%	5.5%	1.7%	1.6%	8.9%
TOTAL	**100.0%**	**100.0%**	**100.0%**	**100.0%**	**100.0%**

Totals may not sum due to rounding

The Division of Medical Assistance (DMA) maintains a website which offers information regarding the number of persons eligible for Medicaid assistance and estimates of the percentage of uninsured for each county in North Carolina. More current data, particularly with regard to the estimated uninsured percentages, was not available. The following counties comprise the projected counties of residence for the majority of the patients to be served by the proposed services.

	2010 Total # of Medicaid Eligibles as % of Total Population	2010 Total # of Medicaid Eligibles Age 21 and older as % of Total Population	2008-2009 % Uninsured (Estimate by Cecil G. Sheps Center)
Mecklenburg	14.7%	5.1%	20.1%
Union	10.9%	3.4%	18.0%
Gaston	19.8%	8.6%	19.0%
Cabarrus	14.3%	4.9%	18.5%
Statewide	16.5%	6.7%	19.7%

The majority of Medicaid eligibles are children under the age of 21. This age group does not utilize the same health services at the same rate as older segments of the population, particularly the imaging services proposed in this application.

Moreover, the number of persons eligible for Medicaid assistance may be greater than the number of Medicaid eligibles who actually utilize health services. The DMA website includes information regarding dental services which illustrates this point. For dental services only, DMA provides a comparison of the number of persons eligible for dental services with the number actually receiving services. The statewide percentage of persons eligible to receive dental services who actually received dental services was 48.6% for those age 20 and younger and 31.6% for those age 21 and older. Similar information is not provided on the website for other types of services covered by Medicaid. However, it is reasonable to assume that the percentage of those actually receiving other types of health services covered by Medicaid is less than the percentage that is eligible for those services.

The Office of State Budget & Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina. In addition, data is available by age, race or gender. However, a direct comparison to the

applicants' current payor mix would be of little value. The population data by age, race or gender does not include information on the number of elderly, minorities, women, or handicapped persons utilizing health services.

The applicants demonstrate that medically underserved populations currently have adequate access to the services offered by the Carolinas Healthcare System and Charlotte Surgery Center. Therefore, the application is conforming to this criterion.

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

C

In Section VI.11, page 119, the applicants state that the proposed ASC will have no federal obligation to provide uncompensated care, but will comply with all access requirements for Americans with Disabilities Act. In Section VI.2, page 113, the applicants state:

"Randolph Surgery Center will provide services to all persons in need of medical care, regardless of race, color, religion, national origin, sex, age, disability, or source of payment. ... Patients are admitted and services are rendered in compliance with:

1. *Title VI of Civil Rights Act of 1963.*
2. *Section 504 of Rehabilitation Act of 1973.*
3. *The Age Discrimination Act of 1975."*

In Section VI.10, page 119, in reference to civil rights complaints, the applicants state,

"Not applicable. Randolph Surgery Center is not an existing facility. No civil rights equal access complaints have been filed against either CHS or SCA in the last five years."

The application is conforming to this criterion.

(c) That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services; and

C

In Section VI.14, page 122, the applicants provide the projected payor mix for Project Year 2, as shown in the following tables.

Randolph Surgery Center
Projected Surgical Cases as a Percent of Total
PY 2 (July 1, 2018- June 30, 2019)

Payor Category	% of Total Cases
Self Pay/ Indigent /Charity	1.8%
Medicare/ Medicare Managed Care	17.8%
Medicaid	6.5%
Commercial Insurance / Managed Care	61.2%
Other (Workers Comp and Other Gov't)	12.7%
Total	100.0%

Totals may not sum due to rounding

Randolph Surgery Center
Projected Procedures as a Percent of Total
PY 2 (July 1, 2018- June 30, 2019)

Payor Category	% of Total Procedures
Self Pay/ Indigent /Charity	0.3%
Medicare/ Medicare Managed Care	40.1%
Medicaid	7.4%
Commercial Insurance / Managed Care	33.6%
Other (Workers Comp and Other Gov't)	18.6%
Total	100.0%

Totals may not sum due to rounding

Exhibit 29 contains copies of Charlotte Surgery Center's Non-Discrimination and Financial policies, which the applicants state will be used as a model for Randolph Surgery Center. Page 117 provides Randolph Surgery Center's projected charity care of 4.3% of net revenue and bad debt of 2.0% of net revenue in the first two project years.

The applicants demonstrate that medically underserved populations will continue to have adequate access to the proposed services. Therefore, the application is conforming to this criterion.

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

C

In Section VI.9(a), page 118, The applicants state that patients will gain access to Randolph Surgery Center via physician referral. The applicants further state that they expect the majority of referrals to Randolph Surgery Center will originate from OrthoCarolina physicians as well as other surgeons practicing at the facility. The applicants adequately demonstrate that the facility will offer a range of means by which patients will have access to the proposed services. Therefore, the application is conforming to this criterion.

(14) The applicant shall demonstrate that the proposed health services accommodate the clinical needs of health professional training programs in the area, as applicable.

C

In Section V.1, pages 106-107, the applicants describe how the facility will accommodate the clinical needs of area health professional training programs. Charlotte Surgery Center, LP and SCA will own and manage Randolph Surgery Center along with Charlotte Surgery Center, which has training agreements with Cabarrus College of Health Sciences, Eastern Virginia Medical School, and Wingate University. See Exhibit 25 for copies of Charlotte Surgery Center's training agreements. In addition, CHS houses 14 Accreditation Council for Graduate Medical Education accredited residency programs, including a general surgical residency which use the facilities of CHS to meet their clinical training requirements and can be expected to use the proposed surgery center. The information provided is reasonable and adequately supports a determination that the application is conforming to this criterion.

(15) Repealed effective July 1, 1987.
(16) Repealed effective July 1, 1987.
(17) Repealed effective July 1, 1987.
(18) Repealed effective July 1, 1987.

(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.

C

The applicants, Charlotte Surgery Center, LP and The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Healthcare System propose to relocate a combined total of six existing operating rooms from Charlotte Surgery Center and Carolinas Healthcare System to a new, separately licensed ASC, to be owned and operated by Charlotte Surgery Center, LP.

On page 60, the 2015 SMFP defines the service area for operating rooms as the planning area in which the operating room is located. *"The operating room planning areas are the single and multicounty groupings shown in Figure 6.1."* Figure 6.1 on page 65 of the SMFP shows Mecklenburg County as a single county operating room planning area. Thus, the service area for this facility's project consists of Mecklenburg County. Facilities may also serve residents of counties not included in their service area.

Per the 2016 SMFP, Mecklenburg County has a total of 168 existing operating rooms, as shown in the table below.

	Number of Operating Rooms by Type				
Facility	Inpatient	Ambulatory	Shared	CON Adjustments	Total
Presbyterian Hospital Mint Hill				5	5
Randolph Surgery Center				2	2
Charlotte Surgery Center		7			7
Carolina Center for Specialty Surgery		2			2
SouthPark Surgery Center		6			6
Novant Health Ballantyne Outpatient Surgery		2			2
Novant Health Huntersville Outpatient Surgery		2			2
Matthews Surgery Center		2			2
Mallard Creek Surgery Center*		2			2
Novant Health Presbyterian Medical Center**	6	6	34	-6	41
CMC –Pineville (CHS Pineville)	3		9		12
CMC	10	11	41	-2	60
CMC-University (CHS University)	1	2	9		12
Novant Health Matthews Medical Center	2		6		8
Novant Health Huntersville Medical Center	1		4	1	6
Total	23	42	103	0	168

*Single specialty demonstration project
**Novant Health Charlotte Orthopedic Hospital (CON F-8765-11), was relicensed under Novant Health Presbyterian Medical Center, effective 3/22/14. Data from 3/22/14-9/30/14 was reported by Presbyterian Medical Center.

In Section III.1, pages 78-80, the applicants discuss how the project will enhance quality, access and value to outpatient surgical services for Mecklenburg and the surrounding area. The applicants state that physicians in ambulatory surgery settings experience enhanced productivity and greater scheduling flexibility, more consistent nurse staffing and faster turnaround time between cases. The applicants further state that as the proposed project will be developed as a joint venture with physician ownership and oversight of clinical services, the physicians will be positioned to standardize surgical devices and supplies, thus enhancing quality and value of services provided. The applicants state the project will also serve to increase access to timely, clinically appropriate and high quality surgical services in Mecklenburg County. In Section V.7, page 112, the applicants discuss how any enhanced competition in the service area will have a positive impact on cost-effectiveness, quality and access, stating, *"Competition will be enhanced because the proposed facility will improve access to high-quality, value-based services, specifically outpatient surgery, in Mecklenburg County and surrounding areas."* See also Sections II, III, V, VI and VII where the applicants discuss the impact of the project on cost-effectiveness, quality and access.

The information provided by the applicants in the application is reasonable and adequately demonstrates that any enhanced competition in the service area includes a positive impact on the cost-effectiveness, quality and access to the proposed services. This determination is based on the information in the application and the following analysis:

- The applicants adequately demonstrate the need to relocate operating rooms to establish a new ambulatory surgery center and that it is a cost-effective alternative. The discussions regarding analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.
- The applicants adequately demonstrate that they will continue to provide quality services. The discussion regarding quality found in Criterion (20) is incorporated herein by reference.
- The applicants demonstrate that they will continue to provide adequate access to medically underserved populations. The discussion regarding access found in Criterion (13) is incorporated herein by reference.

The application is conforming to this criterion.

(19) Repealed effective July 1, 1987.

(20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C

The applicants propose to relocate six existing operating rooms from Carolinas Healthcare System and Charlotte Surgery Center to a new, separately-licensed ambulatory surgery center to be known as Randolph Surgery Center. Randolph Surgery Center is not an existing facility, but will have the same ownership and management as Charlotte Surgery Center. Upon completion of the project, the applicants state Randolph Surgery Center will seek accreditation from the Joint Commission, the Accreditation Association for Ambulatory Health Care or another appropriate accrediting organization. Exhibit 2 contains documentation of the intended ownership interests in Charlotte Surgery Center, LP. Exhibit 10 contains a list of Carolinas Healthcare System owned, managed and leased health care facilities. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, no incidents occurred within the eighteen months immediately preceding submission of the application through the date of this decision, for which any sanctions or penalties related to quality of care were imposed by the State on any facility owned and operated by Carolinas HealthCare System or Surgical Care Affiliates in North Carolina. After reviewing and considering information provided by the applicants and by the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at Carolinas HealthCare System facilities and Charlotte Surgery Center / Surgical Care Affiliates owned and managed facilities, the applicants provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

(21) Repealed effective July 1, 1987.

(b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of

health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

CA

The Criteria and Standards for Surgical Services and Operating Rooms, promulgated in 10A NCAC 14C .2100, are applicable to this review. The specific criteria are discussed below.

SECTION .2100 – CRITERIA AND STANDARDS FOR SURGICAL SERVICES AND OPERATING ROOMS

.2102 INFORMATION REQUIRED OF APPLICANT

.2102(a) An applicant proposing to establish a new ambulatory surgical facility, to establish a new campus of an existing facility, to establish a new hospital, 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 identify each of the following specialty areas that will be provided in the facility:

(1) gynecology;
(2) otolaryngology;
(3) plastic surgery;
(4) general surgery;
(5) ophthalmology;
(6) orthopedic;
(7) oral surgery; and
(8) other specialty area identified by the applicant.

-C- In Section II.10, page 40, the applicants state,

> *"The proposed multispecialty ASC will not limit specialties but at this time expects to perform outpatient orthopedic, plastics, and general surgery procedures."*

.2102(b) An applicant proposing to increase the number of operating rooms in a service area, 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 provide the following information:

(1) the number and type of operating rooms in each licensed facility which the applicant or a related entity owns a controlling interest in and is located in the service area (separately identifying the number of dedicated open heart and dedicated C-Section rooms);

(2) the number and type of operating rooms to be located in each licensed facility which the applicant or a related entity owns a controlling interest in and is located in the service area after completion of the proposed project and all previously approved projects related to these facilities (separately identifying the number of dedicated open heart and dedicated C-Section rooms);

(3) The number of inpatient surgical cases, excluding trauma cases reported by Level I, II and III trauma centers, cases reported by designated burn intensive care units, and cases performed in dedicated open heart and dedicated C-Section rooms, and the number of outpatient surgical cases performed in the most recent 12 month period for which data is available, in the operating rooms in each licensed facility listed in response to Subparagraphs (b)(1) and(b)(2) of this Rule:

(4) The number of inpatient surgical cases, excluding trauma cases reported by Level I, II and III trauma centers, cases reported by designated burn intensive care units, and cases performed in dedicated open heart and dedicated C-Section rooms, and the number of outpatient surgical cases projected to be performed in each of the first three operating years of the proposed project, in each licensed facility listed in response to Subparagraphs (b)(1) and (b)(2) of this Rule;

(5) A detailed description of and documentation to support the assumptions and methodology used in the development of the projections required by this Rule;

(6) The hours of operation of the proposed operating rooms;

(7) If the applicant is an existing facility, the average reimbursement received per procedure for the 20 surgical procedures most commonly performed in the facility during the preceding 12 months and a list of all services and items included in the reimbursement;

(8) the projected average reimbursement to be received per procedure for the 20 surgical procedures which the applicant projects will be performed most often in the facility and a list of all services and items in the reimbursement; and

(9) identification of providers of pre-operative services and procedures which will not be included in the facility's charge.

-NA- In Section II.10, page 41, the applicants state: *"As noted previously, Charlotte Surgery Center, LP is proposing to relocate existing operating rooms from existing licensed facilities, CMC, Carolinas HealthCare System University, and*

Charlotte Surgery Center, to the proposed ASC, which is located within the same service area."

.2102(c) *An applicant proposing to relocate existing or approved operating rooms within the same service area shall provide the following information:*

(1) the number and type of existing and approved operating rooms in each facility in which the number of operating rooms will increase or decrease (separately identifying the number of dedicated open heart and dedicated C-Section rooms);

-C - Randolph Surgery Center does not have any existing or approved operating rooms. Randolph Surgery Center, LLC was approved in Project ID #F-10218-13 to relocate two existing ORs from CMC-Main. In Exhibit 4, the applicants provide documentation of Randolph Surgery Center, LLC's intent to relinquish that certificate of need upon approval of this proposed project to relocate six existing ORs to the new Randolph Surgery Center.

On page 42 of the application, the applicants provide operating room data for CMC, CMC-Mercy, CHS University, CHS Huntersville and Charlotte Surgery Center, prior to the proposed relocation of the six ORs.

	CMC*	**CMC-Mercy^**	**CHSU**	**CHSH^**	**Charlotte Surgery Center**
Dedicated Inpatient ORs	1	0	0	0	0
Dedicated Outpatient ORs	11	0	0	2	0
Shared ORs	26	15	9	0	7
Dedicated Open Heart ORs	5	0	0	0	0
Dedicated C-Section ORs	4	0	1	0	0
Total ORs by Facility	**47**	**15**	**10**	**2**	**7**
Total Number of ORs					**81**

*Includes the two ORs approved to be relocated from CMC to Randolph Surgery Center, LLC in Project ID #F-10218-13.
^CMC-Mercy is on CMC's license (62 ORs on the license, including the two to be relocated in Project ID #F-10218-13). CHS Huntersville is on CHS University's license (12 ORs on the license).

(2) the number and type of operating rooms to be located in each affected facility after completion of the proposed project and all previously approved projects related to these facilities (separately identifying the number of dedicated open heart and dedicated C-Section rooms);

-C- In Section II.10, page 43, the applicants provide the following information to illustrate the number of ORs at each site following completion of the proposed project and the transfer of operating rooms.

	CMC	CMC-Mercy^	CHSU	CHSH^	Charlotte Surgery Center	Randolph Surgery Center
Dedicated Inpatient ORs	1	0	0	0	0	0
Dedicated Outpatient ORs	9	0	0	1	0	6
Shared ORs	26	15	7	0	6	0
Dedicated Open Heart ORs	5	0	0	0	0	0
Dedicated C-Section ORs	4	0	1	0	0	0
Total ORs by Facility	**45**	**15**	**8**	**1**	**6**	**6**
Total Number of ORs						**81**

^CMC-Mercy is on CMC's license (60 ORs on the license). CHS Huntersville is on CHS University's license (nine ORs on the license).

(3) the number of inpatient surgical cases, excluding trauma cases reported by Level I, II, or III trauma centers, cases reported by designated burn intensive care units, and cases performed in dedicated open heart and dedicated C-section rooms, and the number of outpatient surgical cases performed in the most recent 12 month period for which data is available, in the operating rooms in each facility listed in response to Subparagraphs (c)(1) and (c)(2) of this Rule;

-C- In Section II, page 44-45, the applicants provide the number of inpatient surgical cases and outpatient surgical cases performed in the most recent 12 month period (September 2014 to August 2015) in the operating rooms in each facility listed in Subparagraphs (c)(1) and (c)(2) of this Rule:

	CMC	CMC-Mercy	CHSU	CHSH	Charlotte Surgery Center
Inpatient Cases	15,935	4,798	1,026	0	0
Outpatient Cases	17,231	6,902	4,706	2,190	8,774

*Excluding trauma cases, dedicated open heart and C-Section rooms.

(4) the number of inpatient surgical cases, excluding trauma cases reported by level I, II, or III trauma centers, cases reported by designated burn intensive care units and cases performed in dedicated open heart and dedicated C-section rooms, and the number of outpatient surgical cases projected to be performed in each of the first three operating years of the proposed project, in each facility listed in response to Subparagraphs (c)(1) and (c)(2) of this Rule;

-C- On pages 44-45, the applicants provide the number of surgical cases projected to be performed in each of the first three operating years of the proposed project at CHS, Charlotte Surgery Center and Randolph Surgery Center, as listed in (c)(1) and (c)(2) of this Rule:

Project Year 1 (July 1, 2017 to June 30, 2018) Surgical Cases

	CMC	CMC-Mercy	CHSU	CHSH	Charlotte Surgery Center	Randolph Surgery Center
Inpatient Cases	14,588	6,017	1,017	0	0	0
Outpatient Cases	14,398	4,813	4,154	1,623	7,596	7,138

*Excluding trauma, dedicated open heart and C-Section cases.

Project Year 2 (July 1, 2018 to June 30, 2019) Surgical Cases

	CMC	CMC-Mercy	CHSU	CHSH	Charlotte Surgery Center	Randolph Surgery Center
Inpatient Cases	14,579	6,015	1,017	0	0	0
Outpatient Cases	14,240	4,581	4,086	1,551	7,428	8,031

*Excluding trauma, dedicated open heart and C-Section cases.

Project Year 3 (July 1, 2019 to June 30, 2020) Surgical Cases

	CMC	CMC-Mercy	CHSU	CHSH	Charlotte Surgery Center	Randolph Surgery Center
Inpatient Cases	14,579	6,015	1,017	0	0	0
Outpatient Cases	14,097	4,352	4,018	1,478	7,260	8,923

*Excluding trauma, dedicated open heart and C-Section cases.

The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

(5) a detailed description of and documentation to support the assumptions and methodology used in the development of the projections required by this Rule;

-C- In Section II.10, page 48, the applicants refer to Section III.1(b), Section IV and the methodologies in Exhibit 18 for the assumptions and methodology used in the development of the projections required by this Rule. The assumptions used to project the number of outpatient surgical cases at the proposed Randolph Surgery Center are reasonable and supported. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference. Therefore, the application is conforming to this Rule.

(6) the hours of operation of the facility to be expanded;

-C- In Section II.10, page 49, the applicants state that the proposed ASC's hours of operation will be 7:00 am to 5:00 pm, Monday through Friday.

(7) the average reimbursement received per procedure for the 20 surgical procedures most commonly performed in each affected facility during the preceding 12 months and a list of all services and items included in the reimbursement;

-C- In Section II.10, page 49, the applicants refer to Exhibit 19 for tables with the average reimbursement for the 20 most commonly performed surgical procedures at the affected facilities. The applicants state that reimbursement at CHS hospital facilities includes the hospital's surgery fee as well as other fees related to the entire patient stay for inpatients but not professional fees, which are billed separately by physicians. Charlotte Surgery Center's reimbursement includes nursing, technical and other related services, use of ASC facilities, drugs and biologicals, administrative, recordkeeping, and housekeeping, blood and blood products, and materials for anesthesia.

(8) the projected average reimbursement to be received per procedure for the 20 surgical procedures which the applicant projects will be performed most often in the facility to be expanded and a list of all services and items included in the reimbursement; and

-C- In Section II.10, page 50, the applicants refer to Exhibit 20 for a table that includes the projected average reimbursement per procedure for the 20 surgical procedures projected to be performed most often in the proposed ASC. Reimbursement includes nursing, technical and other related services, use of ASC facilities, drugs and biologicals, administrative, recordkeeping, and housekeeping, blood and blood products, and materials for anesthesia.

9) identification of providers of pre-operative services and procedures which will not be included in the facility's charge.

-C- In Section II.10, page 50, the applicants state, *"The physician's fees – surgeon, assistant surgeon, and anesthesiologist – are not included in the projected facility fee. These fees are controlled and billed by the individual physician."*

.2102(d) An applicant proposing to establish a new single specialty separately licensed ambulatory surgical facility pursuant to the demonstration project in the 2010 State Medical Facilities Plan shall provide:

(1) the single surgical specialty area in which procedures will be performed in the proposed ambulatory surgical facility;

(2) a description of the ownership interests of physicians in the proposed ambulatory surgical facility;
(3) a commitment that the Medicare allowable amount for self pay and Medicaid surgical cases minus all revenue collected from self-pay and Medicaid surgical cases shall be at least seven percent of the total revenue collected for all surgical cases performed in the proposed facility;

(4) for each of the first three full fiscal years of operation, the projected number of self-pay surgical cases;

(5) for each of the first three full fiscal years of operation, the projected number of Medicaid surgical cases;

(6) for each of the first three full fiscal years of operation, the total projected Medicare allowable amount for the self pay surgical cases to be served in the proposed facility, i.e. provide the projected Medicare allowable amount per self-pay surgical case and multiply that amount by the projected number of self pay surgical cases;

(7) for each of the first three full fiscal years of operation, the total projected Medicare allowable amount for the Medicaid surgical cases to be served in the facility, i.e. provide the projected Medicare allowable amount per Medicaid surgical case and multiply that amount by the projected number of Medicaid surgical cases;

(8) for each of the first three full fiscal years of operation, the projected revenue to be collected from the projected number of self-pay surgical cases;

(9) for each of the first three full fiscal years of operation, the projected revenue to be collected from the projected number of Medicaid surgical cases;

(10) for each of the first three full fiscal years of operation, the projected total revenue to be collected for all surgical cases performed in the proposed facility;

(11) a commitment to report utilization and payment data for services provided in the proposed ambulatory surgical facility to the statewide data processor, as required by G.S. 131E-214.2;

(12) a description of the system the proposed ambulatory surgical facility will use to measure and report patient outcomes for the purpose of monitoring the quality of care provided in the facility;

(13) descriptions of currently available patient outcome measures for the surgical specialty to be provided in the proposed facility, if any exist;

(14) if patient outcome measures are not currently available for the surgical specialty area, the applicant shall develop its own patient outcome measures to be used for monitoring and reporting the quality of care provided in the proposed facility, and shall provide in its application a description of the measures it developed;

(15) a description of the system the proposed ambulatory surgical facility will use to enhance communication and ease data collection, e.g. electronic medical records;

(16) a description of the proposed ambulatory surgical facility's open access policy for physicians, if one is proposed;

(17) a commitment to provide to the Agency annual reports at the end of each of the first five full years of operation regarding:

(A) patient payment data submitted to the statewide data processor as required by G.S. 131E-214.2;

(B) patient outcome results for each of the applicant's patient outcome measures;

(C) the extent to which the physicians owning the proposed facility maintained their hospital staff privileges and provided Emergency Department coverage, e.g. number of nights each physician is on call at a hospital; and

(D) the extent to which the facility is operating in compliance with the representations the applicant made in its application relative to the single specialty ambulatory surgical facility demonstration project in the 2010 State Medical Facilities Plan.

-NA- The applicants do not propose to establish a new single specialty separately licensed ambulatory surgical facility pursuant to the demonstration project in the 2010 State Medical Facilities Plan.

.2103 PERFORMANCE STANDARDS

.2103(a) In projecting utilization, the operating rooms shall be considered to be available for use five days per week and 52 weeks per year.

-C- In Section II.10, page 53, the applicants state that the proposed facility will be available for use at least five days per week and 52 weeks per year.

.2103(b) 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:

(1) demonstrate the need for the number of proposed operating rooms in the facility, which is proposed to be developed or expanded, in the third operating year of the project is based on the following formula: {[(Number of facility projected inpatient cases, excluding trauma cases reported by Level I or II trauma centers, cases reported by designated burn intensive care units and cases performed in dedicated open heart and C-Section rooms, times 3.0 hours) plus (Number of facilities projected outpatient cases times 1.5 hours) plus (Number of facility's projected outpatient cases times 1.5 hours)] divided by 1,872 hours} minus the facility's total number of existing and approved operating rooms and operating rooms proposed in another pending application, excluding one operating room for level I or II trauma centers, one operating room for facilities with designated burn intensive care units, and all dedicated open heart and C-section operating rooms or demonstrate conformance of the proposed project to Policy AC-3 in the State Medical Facilities Plan titled "Exemption From Plan Provisions for Certain Academic Medical Center Teaching Hospital Projects;" and

(2) The number of rooms needed is determined as follows:

(A) in a service area which has more than 10 operating rooms, if the difference is a positive number greater than or equal to 0.5, then the need is the next highest whole number for fractions of 0.5 or greater and the next lowest whole number for fractions less than 0.5; and if the difference is a negative number less than 0.5, then the need is zero;

(B) in a service area which has 6 to 10 operating rooms, if the difference is a positive number greater than or equal to 0.3, then the need is the next highest whole number for fractions of 0.3 or greater and the next lowest whole number for fractions less than 0.3, and if the difference is a negative number or a positive number less than 0.3, the need is zero; and

(C) in a service area which has five or fewer operating rooms, if the difference is a positive number greater than or equal to 0.2, then the need is the next highest whole number for fractions of 0.2 or greater and the next lowest whole number for fractions of less than 0.2; and the difference is a negative number or a positive number less than 0.2, the need is zero; or

-C- The applicants adequately demonstrate the need to relocate six existing operating rooms from CHS facilities and Charlotte Surgery Center to Randolph Surgery Center, a new ambulatory service center. The discussions regarding analysis of need, including projected utilization, and access found in Criterion (3) are incorporated herein by reference. On page 54, the applicants document the need for the six ORs at Randolph Surgery Center as shown below.

Project Year 3 Total Cases	8,923
Project Year 3 Total Hours	13,385
ORs Needed = Hours/1,872	7.1
ORs Proposed	6.0

The applicants are not proposing to increase the number of operating rooms in the proposed service area. Rather, the applicants propose to relocate six existing ORs to a new ambulatory surgery center.

.2103(c) *A proposal to increase the number of operating rooms (excluding dedicated C-Sections operating rooms) in a service area shall:*

(1) demonstrate the need for the number of proposed operating rooms in addition to the rooms in all of the licensed facilities identified in response to 10A NCAC 14C .2102(b)(2) in the third operating year of the proposed project based on the following formula: {[(Number of projected inpatient cases for all the applicant's or related entities' facilities, excluding trauma cases report by Level I or II trauma centers, cases reported by designated burn intensive care units and cases performed in dedicated open heart and C-section rooms, times 3.0 hours) plus (Number of projected outpatient cases for all the applicant's or related entities' times 1.5 hours)] divided by 1,872 hours} minus the total number of existing and approved operating rooms and operating rooms proposed in another pending application, excluding one operating room for Level I or II trauma centers, one operating room for facilities with designated burn intensive care units, and all dedicated open heart and C-section operating rooms in all of the applicant's or related entities' licensed facilities in the service area; and

(2) The number of rooms needed is determined as follows:

(A) in a service area which has more than 10 operating rooms, if the difference is a positive number greater than or equal to 0.5, then the need is the next highest whole number for fractions of 0.5 or greater and the next lowest whole number for fractions less than 0.5; and if the difference is a negative number or a positive number less than 0.5, the need is zero;

(B) in a service area which has 6 to 10 operating rooms, if the difference is a positive number greater than or equal to 0.3, then the need is the next highest whole number for fractions of 0.3 or greater and the next lowest whole number for fractions less than 0.3, and if the difference is a negative number or a positive number less than 0.3, the need is zero; and

(C) in a service area which has five or fewer operating rooms, if the difference is a positive number greater than or equal to 0.2, then the

need is the next highest whole number for fractions of 0.2 or greater and the next lowest whole number for fractions of less than 0.2; and if the difference is a negative number or a positive number less than 0.2, the need is zero.

-NA- The applicants do not propose to increase the number of operating rooms in the service area.

.2103(d) *An applicant that has one or more existing or approved dedicated C-section operating rooms and is proposing to develop an additional dedicated C-section operating room in the same facility shall demonstrate that an average of at least 365 C-sections per room were performed in the facility's existing dedicated C-section operating rooms in the previous 12 months and are projected to be performed in the facility's existing, approved and proposed dedicated C-section rooms during the third year of operation following completion of the project.*

-NA- The applicants do not propose to develop an additional dedicated C-section room.

.2103(e) *An applicant proposing 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:*

(1) provide documentation to show that each existing ambulatory surgery program in the service area that performs ambulatory surgery in the same specialty area as proposed in the application is currently utilized an average of at least 1,872 hours per operating room per year, excluding dedicated open heart and C-Section operating rooms. The hours utilized per operating room shall be calculated as follows: [(Number of projected inpatient cases, excluding open heart and C-sections performed in dedicated rooms times 3.0 hours) plus (Number of projected outpatient cases times 1.5 hours)] divided by the number of operating rooms, excluding dedicated open heart and C-Section operating rooms; and

(2) demonstrate the need in the third operating year of the project based on the following formula: [Total number of projected outpatient cases for all ambulatory surgery programs in the service area times 1.5 hours) divided by 1,872 hours] minus the total number of existing, approved and proposed outpatient or ambulatory surgical operating rooms and shared operating rooms in the service area. The need for the conversion is demonstrated if the difference is a positive number greater than or equal to one, after the number is rounded to the next highest number for fractions of 0.50 or greater.

-NA- In Section II.10, page 57, the applicants state: *"Charlotte Surgery Center, LP is not proposing to convert a specialty ambulatory surgical program to a*

multispecialty ambulatory surgical program or to add a specialty to a specialty ambulatory surgical program."

.2103(f) *The applicant shall document the assumptions and provide data supporting the methodology used for each projection in this Rule.*

-C- In Section III.1(b), Section IV and Exhibit 18, the applicants provide a description of the assumptions and methodology used in the development of the projections required by this Rule. The discussion regarding analysis of need, including projected utilization, found in Criterion (3) is incorporated herein by reference.

.2104 SUPPORT SERVICES

.2104(a) *An applicant proposing to establish a new ambulatory surgical facility, a new campus of an existing facility, or a new hospital shall provide copies of the written policies and procedures that will be used by the proposed facility for patient referral, transfer, and follow-up.*

-C- The applicants refer to Exhibit 14 for the above policies to be used at Randolph Surgery Center. Exhibit 14 contains a copy of Charlotte Surgery Center's admissions and discharge policies and follow-up. Exhibits 26 and 27 contain a letter from CMC President documenting willingness to accept all transfers from the proposed ASC and a sample patient transfer agreement, respectively.

.2104(b) *An applicant proposing to establish a new ambulatory surgical facility, a new campus of an existing facility, or a new hospital shall provide documentation showing the proximity of the proposed facility to the following services:*

(1) emergency services;
(2) support services;
(3) ancillary services; and
(4) public transportation.

-C- In Section II.10, pages 57-58, the applicants state that emergency services are available at CMC, 3.47 miles from the proposed ASC and at CMC-Mercy and Presbyterian Hospital, approximately two miles from the proposed ASC. Support services will be provided on-site by staff or through contract with the facility manager, SCA. Ancillary services, including laboratory tests, diagnostic imaging, and other services will be provided through the patients' physicians, at CMC or CMC-Mercy and elsewhere in the community. Public transportation is available through public bus service, Charlotte Area Transit System (CATS) at the intersection of Randolph Road and Billingsley Road, located less than a mile from the proposed ASC. Staff will also be available to contact taxi service as needed by patients.

.2105 STAFFING AND STAFF TRAINING

.2105(a) *An applicant proposing 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 a facility, 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 identify, justify and document the availability of the number of current and proposed staff to be utilized in the following areas:*

(1) administration;
(2) pre-operative;
(3) post-operative;
(4) operating room; and
(5) other.

- C- The applicants provide the proposed staffing for the new facility in Section VII.2, page 124, and state that the proposed staffing is based on the experience of CHS and SCA, both of whom have a long history of providing surgical services.

.2105(b) *The applicant shall identify the number of physicians who currently utilize the facility and estimate the number of physicians expected to utilize the facility and the criteria to be used by the facility in extending surgical and anesthesia privileges to medical personnel.*

-C- In Section II.10, page 59, the applicants state that Randolph Surgery Center is not an existing facility and therefore has no physicians who currently use the facility. Exhibit 36 contains letters of support from numerous physicians who intend to utilize the facility. Additionally, Exhibit 21 contains copies of SCA's privileging and credentialing policies, which will be used for the proposed ASC.

.2105(c) *The applicant shall provide documentation that physicians with privileges to practice in the facility will be active members in good standing at a general acute care hospital within the service area in which the facility is, or will be, located or documentation of contacts the applicant made with hospitals in the service area in an effort to establish staff privileges.*

-C- Exhibit 15 contains a letter from Roy Alan Majors, M.D., which states his willingness to serve as Medical Director for the proposed facility. The letter also documents that physicians with privileges to practice at the ASC will be active members in good standing at a general acute care hospital within the service area.

.2105(d) *The applicant shall provide documentation that physicians owning the proposed single specialty demonstration facility will meet Emergency Department coverage responsibilities in at least one hospital within the service*

area, or documentation of contacts the applicant made with hospitals in the service area in an effort to commit its physicians to assume Emergency Department coverage responsibilities.

-NA- The applicants do not propose to establish a new single specialty separately licensed ambulatory surgical facility pursuant to the demonstration project in the 2010 State Medical Facilities Plan.

.2106 FACILITY

.2106(a) An applicant proposing to establish a licensed ambulatory surgical facility that will be physically located in a physician's or dentist's office or within a general acute care hospital shall demonstrate that reporting and accounting mechanisms exist and can be used to confirm that the licensed ambulatory surgery facility is a separately identifiable entity physically and administratively, and is financially independent and distinct from other operations of the facility in which it is located.

-NA- The applicants do not propose to establish a licensed ambulatory surgical facility that will be physically located in a physician's or dentist's office or within a general acute care hospital.

.2106(b) An applicant proposing a licensed ambulatory surgical facility or a new hospital shall receive accreditation from the Joint Commission for the Accreditation of Healthcare Organizations, the Accreditation Association for Ambulatory Health Care or a comparable accreditation authority within two years of completion of the facility.

-C- The applicants state that they will seek accreditation from an appropriate accreditation authority within two years of completion of the facility. The letter in Exhibit 15 from the ASC's proposed Medical Director documents Randolph Surgery Center's commitment to meet this requirement.

.2106(c) All applicants shall document that the physical environment of the facility to be developed or expanded conforms to the requirements of federal, state, and local regulatory bodies.

-C- In Section II.10, page 61, the applicants state, *"Please see Exhibit 16 for a letter documenting that the physical environment of the ASC conforms to the requirements of federal, state, and local regulatory bodies."* Exhibit 16 contains a letter from the project architect, verifying compliance with the standards as required above.

.2106(d) *An applicant proposing to establish a new ambulatory surgical facility, a new campus of an existing facility or a new hospital shall provide a provide a floor plan of the proposed facility identifying the following areas:*

(1) receiving/registering area;
(2) waiting area;
(3) pre-operative area;
(4) operating room by type;
(5) recovery area; and
(6) observation area.

-C- Exhibit 11 contains a copy of the floor plan for the proposed facility, which identifies the specific areas required by this Rule.

.2106(e) *An applicant proposing to expand by converting a specialty ambulatory surgical program to a multispecialty ambulatory surgical program or by adding a specialty to a specialty ambulatory surgical program that does not propose to add physical space to the existing ambulatory surgical facility shall demonstrate the capability of the existing ambulatory surgical program to provide the following for each additional specialty area:*

(1) physicians;
(2) ancillary services;
(3) support services;
(4) medical equipment;
(5) surgical equipment;
(6) receiving/registering area;
(7) clinical support areas;
(8) medical records;
(9) waiting area;
(10) pre-operative area;
(11) operating rooms by type;
(12) recovery area; and
(13) observation area.

-NA- The applicants propose to develop a new ambulatory surgical facility by relocating six existing operating rooms.