ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

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

DECISION DATE: January 3, 2014
FINDINGS DATE: January 3, 2014

PROJECT ANALYST: Celia C. Inman
TEAM LEADER: Lisa Pittman

PROJECT I.D. NUMBER: F-10218-13 / Randolph Surgery Center, LLC and The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center / Relocate two dedicated outpatient operating rooms from Carolinas Medical Center to Randolph Surgery Center, a new separately licensed ambulatory surgical facility with two operating rooms and one procedure room / Mecklenburg County

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, Randolph Surgery Center, LLC and The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center (CMC) propose to relocate two existing dedicated outpatient operating rooms (ORs) from CMC to a new, separately licensed ambulatory surgery center (ASC), to be known as Randolph Surgery Center.

In Section II, page 23, the applicants state that the proposed facility, Randolph Surgery Center, will be located at 3621 Randolph Road in Mecklenburg County, in existing space which was previously vacated by Carolina Surgery Center-Randolph (CSC-Randolph), "*…as part of CHS's operating room master plan to relocate underutilized operating rooms.*" The applicants do not propose to increase the number of ORs in Mecklenburg County. There are no need determinations in the 2013 State Medical facilities Plan (SMFP) that are applicable to this review.

However, Policy GEN-4 is applicable to this review. Policy GEN-4: ENERGY EFFICIENCY AND SUSTAINABILITY FOR HEALTH SERVICE FACILIITES 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 for 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."*

In Section III.4, pages 84-85, the applicants discuss the project's plan to assure improved energy and water conservation in accordance with Policy GEN-4, stating,

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

The applicants list the following as Randolph Surgery Center's "*Guiding Principles* [emphasis in original]

1. *Implement environmental sustainability to improve and reduce our environmental impact.*
2. *Integrate sustainable operational and facility best practices into existing and new facilities.*
3. *Encourage partners to engage in environmentally responsible practices.*
4. *Promote environmental sustainability in work, home and community.*
5. *Deliver improved performance to provide a long term return on investment that supports our mission and values."*

The applicants state that Carolinas HealthCare System (CHS) and Randolph Surgery Center will work with a design team, experienced with Energy Star, Leadership in Energy and

Environmental Design (LEED) and Hospitals for a Healthy Environment Green Guide for HealthCare (GGHC), to ensure energy efficient systems are an inherent part of the proposed project to the degree appropriate with the proposed renovations. The design team will design for maximum efficiency and life cycle benefits within each mechanical system: heating, cooling water, sewer, and irrigation.

The application is conforming to Policy GEN-4. Therefore the application is conforming to this criterion.

(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, Randolph Surgery Center, LLC and CMC propose to relocate two existing dedicated outpatient ORs from Carolinas Medical Center, located at 1000 Blythe Boulevard, Charlotte (CMC-Main) to a new, separately licensed ASC, to be known as Randolph Surgery Center. The operating rooms to be relocated are two of the 11 dedicated outpatient ORs on the main floor in CMC-Main's same day surgery department (CMC-One Day Surgery) in the Medical Center.

Randolph Surgery Center, LLC is a newly formed joint venture comprised of CEENTA Surgery II, LLC (45%) and The Charlotte-Mecklenburg Hospital Authority (55%). CEENTA Surgery II, LLC (CEENTA II) is owned exclusively by the physicians listed on pages 13-14: 34 of the 85 providers associated with Charlotte Eye, Ear, Nose & Throat Associates, PA (CEENTA). CEENTA owns several physician offices throughout Mecklenburg and surrounding counties and one ASC, SouthPark Surgery Center, at 6035 Fairview Road in Charlotte.

The Charlotte-Mecklenburg Hospital Authority also does business as Carolinas HealthCare System (CHS). In Exhibit 10, page 309, the applicants list the following CHS owned or leased, and separately licensed hospitals:

- Anson Community Hospital
- Carolinas Medical Center
    - Carolinas Medical Center-Mercy
    - Carolinas Medical Center-Randolph
    - Levine's Children's Hospital
- Carolinas Medical Center-Lincoln
- Carolinas Medical Center-Pineville / Carolinas Medical Center-Steele Creek (ED)
- Carolinas Medical Center-NorthEast / Carolinas Medical Center-Kannapolis (ED)

- Carolinas Medical Center-Union / First Step Recovery Center / Carolinas Medical Center-Waxhaw (ED)
- Carolinas Medical Center-University / Carolinas Medical Center-Huntersville (ED)
- Carolinas Rehabilitation
- Carolinas Rehabilitation-Mount Holly
- Cleveland Regional Medical Center
- Crawley Memorial Hospital
- Kings Mountain Hospital

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 Ambulatory Surgical Center
- Endoscopy Center Monroe, LLC
- Endoscopy Center Northcrosse, LLC
- Endoscopy Center Pineville, LLC
- Endoscopy Center University, LLC
- Gateway Ambulatory Surgery Center, LLC
- Iredell Surgical Center
- Union Health Services, LLC (Union West Surgery Center)

Population to Be Served

In Section III.5, page 86, the applicants state that the service area, based on historical and projected CEENTA physicians' patient origin includes Mecklenburg County, and the contiguous North Carolina counties of Union, Gaston and Cabarrus; and York County in South Carolina. Patients from these counties represent 92% of CEENTA physicians' surgical volume performed in FY2012.

In Section III.6, pages 88-89, the applicants provide the projected patient origin for the first two years of the project, as illustrated in the following tables:

Operating Room Projected Patient Origin

	PY 1 4/1/15-3/31/16		PY 2 4/1/16-3/31/17	
County	**Projected Patients**	**% of Total Patients**	**Projected Patients**	**% of Total Patients**
Mecklenburg	2,173	57.3%	2,445	57.3%
Union	558	14.7%	628	14.7%
Gaston	305	8.0%	343	8.0%
York, SC	271	7.1%	305	7.1%
Cabarrus	81	2.1%	92	2.1%
Other	404	10.7%	455	10.7%
Total	**3,794**	**100.0%**	**4,268**	**100.0%**

Totals may not sum due to rounding.

YAG Laser Procedure Room Projected Patient Origin

	PY 1 4/1/15-3/31/16		PY 2 4/1/16-3/31/17	
County	**Projected Patients**	**% of Total Patients**	**Projected Patients**	**% of Total Patients**
Mecklenburg	138	57.3%	155	57.3%
Union	35	14.7%	40	14.7%
Gaston	19	8.0%	22	8.0%
York, SC	17	7.1%	19	7.1%
Cabarrus	5	2.1%	6	2.1%
Other	26	10.7%	29	10.7%
Total	**240**	**100.0%**	**270**	**100.0%**

Totals may not sum due to rounding.

The applicants state that "Other" for both the ORs and the YAG Laser procedure room patient origin includes Alexander, Alleghany, Anson, Avery, Brunswick, Buncombe, Burke, Caldwell, Carteret, Catawba, Cherokee, Cleveland, Cumberland, Davidson, Davie, Durham, Forsyth, Guilford, Haywood, Henderson, Iredell, Jackson, Lee, Lincoln, Macon, McDowell, Montgomery, New Hanover, Perquimans, Polk, Richmond, Rowan, Rutherford, Scotland, Stanly, Wake, Watauga and Wilkes counties in North Carolina; Aiken, Charleston, Cherokee, Chester, Chesterfield, Colleton, Darlington, Fairfield, Georgetown, Greenville, Horry, Kershaw, Lancaster, Laurens, Lee, Richland, Spartanburg and Union counties in South Carolina; and other states.

On page 89, the applicants state that Randolph Surgery Center's future patient origin is based on fiscal year 2012 patient origin for eye and ENT cases as well as YAG laser procedures performed by CEENTA physicians, the same physicians who are projected to perform procedures at the proposed ASC. They further state: *"Randolph Surgery Center, LLC expects that patient origin through the project years will closely match the historical patient origin of the CEENTA physicians."*

The applicants adequately identified the population proposed to be served.

Demonstration of Need

In Section III.1(a), page 61, the applicants state the unmet need that necessitates the proposed project is comprised of several factors, including:

- the continued demand for ambulatory surgical services by patients and physicians,
- the need to improve utilization of CHS's operating rooms,
- the need for physician collaboration, and
- the growing population in Mecklenburg County and surrounding area.

Demand for Ambulatory Surgical Services

On pages 61-62, the applicants discuss the shift of healthcare from inpatient to outpatient settings, stating:

> *"The shift toward outpatient surgery, both in hospital outpatient departments and in freestanding facilities, is primarily the result of clinical advances, including improved technology, increased knowledge of pain management and anesthesiology, and decreased recovery times."*

The applicants further state that advances in technology have enabled procedures such as tonsillectomies, hernia repairs and gallbladder removals, once highly invasive procedures that required an extensive inpatient stay, to be done less invasively, such that patients require minimal recovery time and are most often released within the same day.

Based on data provided by the applicants on pages 62-63 and sourced to the 2007 State Medical Facilities Plan (SMFP) through the Proposed 2014 SMFP, the following is a comparison of the growth in Mecklenburg County's surgical volume to that of North Carolina as a whole:

	Inpatient Surgeries	**Outpatient Surgeries**	**Total Surgeries**
Mecklenburg County CAGR 2005-2012	1.9%	1.2%	1.4%
NC CAGR 2005-2012	-0.7%	0.2%	0.0%
Difference in CAGR	2.7%	1.0%	1.5%

Totals do not sum due to rounding.

The table above shows that the compound average growth rate (CAGR) of total surgical services increased at a rate that was 1.5% more for Mecklenburg County than for the State of North Carolina. Mecklenburg County's outpatient surgical services also grew at a faster rate than the State's outpatient surgical services, as a whole.

In Section III.1(b), page 73, the applicants discuss the growth the CEENTA physicians' surgical cases sustained through the economic downturn and the beginning of the Affordable

Care Act implementation, in particular, the growth in outpatient eye and ENT cases over the past three years, as shown in the table below.

CEENTA Eye and ENT Historical Growth

	CY2011	CY2012	YTD 2013*	CY2013 Annualized	CAGR
Eye Cases	4,920	5,185	3,583	5,375	4.5%
ENT Cases	5,634	5,477	4,041	6,062	3.7%
Total Cases	10,554	10,662	7,624	11,436	4.1%

*The applicants state the most recent data available at the time of filing was year to date August 2013.

As the table above shows, and the applicants state on page 73, historically, eye and ENT cases performed by the CEENTA physicians have experienced 4.5% and 3.7% CAGRs, respectively, from 2011 through 2013. Combined, total cases increased at a CAGR of 4.1%. The applicants state that the majority of the above cases were performed at SouthPark Surgery Center (SPSC), the CEENTA-owned Mecklenburg County ASC, which based on FFY 2012 volume, is operating well above capacity, as the following table shows.

SouthPark Surgery Center

Number of ORs at SPSC	6
Hours per OR per Year	1,872
Capacity of 6 ASC ORs	11,232
SPSC FY2012 Cases	9,005
SPSC Hours (1.5 Hrs per Case)	13,508
Utilization Percent above Capacity ((13,508 - 11,232) / 11,232)	20.3%

On page 74, the applicants state:

> *"Given historical growth, the CEENTA physicians that will practice at the proposed facility have sufficient case volume to support a new ASC in Mecklenburg County. Further, the development of Randolph Surgery Center is expected to alleviate capacity constraints at SPSC. As such, the CEENTA physicians believe they will be able to increase their number of cases with the development of Randolph Surgery Center. In addition to the qualitative need to collaborate and improve coordination of care between the CHS referring primary care physicians and CEENTA, the projected growth of CEENTA volume would likely not be sustainable at SPSC given its current capacity. Thus, the redeployment of hospital-based ORs to a dedicated ASC setting specifically for these procedures is warranted."*

On page 63, the applicants state that Randolph Surgery Center, LLC believes that Mecklenburg County's trends in inpatient and outpatient surgical volume exceed statewide trends as a result of local factors, specifically: rural areas not experiencing economic recovery that urban areas are, and specialty and subspecialty medical care in the Charlotte area attracting patients from rural areas. The applicants state,

"The members of Randolph Surgery Center, LLC believe that although fluctuations in volume may continue, surgical volume, in particular outpatient will continue to grow in the coming years."

Improved Utilization of CHS's Operating Rooms

CMC-Main operates 26 shared, one dedicated inpatient and 5 dedicated open heart operating rooms for a total of 32 ORs in the main surgery department (CMC-Main's core surgical operations) located on the fifth floor of the medical center. CMC-Main also operates four C-Section rooms on the eighth floor of the medical center and 11 dedicated outpatient operating rooms on the main floor in the same day surgery department (CMC-One Day Surgery) in the Medical Center Plaza for a grand total of 47 surgical operating rooms at CMC-Main, as listed on CMC's 2013 License Renewal Application (LRA).

The two operating rooms to be relocated to the proposed Randolph Surgery Center are part of the 11 dedicated outpatient ORs in the CMC-One Day Surgery department. On page 64, the applicants state that CMC-One Day Surgery is in a relatively old building, has smaller rooms, and does not operate 24 hours a day. The applicants further state,

"…CMC believes that the relocation of the two operating rooms from CMC-One Day Surgery to Randolph Surgery Center will allow for better utilization of the existing operating rooms, particularly for outpatient cases in a dedicated ASC environment, while also allowing for more efficient utilization of the remaining nine operating rooms and associated resources at the CMC-One Day Surgery facility. Please see 10A NCAC 14C .2102(c)(4) for additional discussion. The two proposed operating rooms will be relocated to a newer facility with larger rooms. Once the proposed renovations are complete, the two proposed operating rooms will [sic] *housed in a state-of-the-art ASC."*

Physician Collaboration

In Section III, pages 64-65, the applicants discuss the proposed project as a collaborative effort of The Charlotte Mecklenburg Hospital Authority and CEENTA, stating that the hospital system, the physicians and patients will all benefit from the joint venture. The applicants state that through partnering with a larger hospital system, joint ventures help physicians realize greater cost savings and greater control over operations. The venture affords the hospital the opportunity to build physician relationships which support hospital recruiting and retention initiatives. Through this relationship, the applicants say, cost savings and increased quality and access are passed on to the patient because:

"The proposed project will enable the System and CEENTA physicians to work together as one – sharing knowledge, experience, and research – which will result in better outcomes and improved patient satisfaction."

Mecklenburg County Population Growth

In Section III.1, pages 69-70, the applicants state:

> *"According to data from the North Carolina Office of State Budget and Management (NC OSBM), Exhibit 20, Mecklenburg County is the second fastest growing county in North Carolina based on numerical growth and the seventh fastest behind Onslow, Hoke, Harnett, Wake, Brunswick and Chatham counties based on percentage growth."*

The applicants further state that the NC OSBM projects Mecklenburg County's high growth will continue throughout this decade, growing 23.8% between 2010 and 2020 and adding over 218,700 people, with 12% of the total Mecklenburg population being over the age of 65 by 2020, an increase of 41.1%. The applicants note the significance of this data on page 71, saying, *"…typically, older residents utilize healthcare services at a higher rate than those who are younger."*

In addition to the need for ambulatory operating rooms as proposed, the applicants also propose to develop a procedure room for YAG laser and other minor procedures. The applicants state the primary need for the procedure room at the ASC is to be able to provide these outpatient services in one centralized location. On page 72, the applicants state:

> *"The co-location of the procedure room with the operating rooms will enable CEENTA physicians to efficiently perform these cases in the same location as the outpatient surgical procedures."*

The applicants further state that they have observed the effectiveness of this ASC model at Carolina Center for Specialty Surgery in Charlotte and expect the proposed project to provide an opportunity for physician collaboration and enhance the quality, access and cost effectiveness of outpatient surgical procedures in Mecklenburg County and surrounding areas.

In summary, the applicants adequately demonstrate the need the population to be served has for the proposed project.

Projected Utilization

The applicant provides support letters from 25 ENT surgeons and 13 eye surgeons in Exhibit 36 of the application. The support letters project referrals of 4,742 surgical cases to the proposed Randolph Surgery Center upon its opening in April of 2015. On page 75, the applicants state that the majority of the cases, 2,982 or 63%, are expected to be shifted from SouthPark Surgery Center, as shown below.

Facility	Cases	Percent
SouthPark Surgery Center	2,982	62.9%
CMC	483	10.2%

CMC-Pineville	213	4.5%
CMC-Huntersville	268	5.7%
CMC-University	284	6.0%
CMC-Union	512	10.8%
Total	4,742	100.0%

The proposed shift of cases from SPSC in PY3 (April 1, 2017 through March 31, 2018) amounts to 26.5% of SPSC's 2012 cases. As discussed earlier, in "Demonstration of Need, Demand for Ambulatory Surgical Services" and reported on its 2013 LRA, SPSC operated at 120% of capacity in FY2012.

The table above also shows that 10% of the projected Randolph Surgery Center surgical cases will be shifted from both CMC-Main and CMC-Union; with another 6% shifting from both CMC-Huntersville and CMC-University; and 4.5% shifting from CMC-Pineville. The following table shows that CMC-Main, CMC-Union and CMC-Pineville each operated at 80% or above capacity during FY2012, per reported cases on the 2013 LRAs. CMC-University and CMC-Huntersville operated at 63% and 79% capacity, respectively.

Facility	Total OR Capacity Hours	2012 Inpatient Cases	2012 AmSu Cases	Inpatient Utilization Hours	AmSu Utilization Hours	Total Utilization Hours	Percent of Capacity
SPSC	11,232	0	9,005	0	13,508	13,508	120%
CMC-Main	87,984	15,867	15,298	47,601	22,947	70,548	80%
CMC-Mercy*	28,080	3,910	5,036	11,730	7,554	19,284	69%
CMC-Pineville*	18,720	2,610	5,377	7,830	8,066	15,896	85%
CMC-Huntersville	3,744	0	1,971	0	2,957	2,957	79%
CMC-University	18,720	1,372	5,127	4,116	7,691	11,807	63%
CMC-Union	11,232	1,766	4,846	5,298	7,269	12,567	112%

* As of October 2013, CMC-Mercy was removed from CMC-Pineville's license and added to CMC-Main's license. The applicants do not project shifting any cases from CMC-Mercy. Adjusting the numbers of ORs and cases performed for CMC to include CMC-Mercy on CMC-Main's licensure, brings CMCs total utilization down to a combined 77% of capacity.

The following table projects each of the above facilities' surgical utilization forward to March 31, 2018, assuming the status quo and continued growth at the CEENTA physicians' 4.1% CAGR since 2011. As shown below, each facility will be operating at 80% capacity or above. All but two facilities will be operating at 100% capacity, with SPSC and CMC-Union operating at 153% and 142%, respectively, assuming the surgeries are not shifted as proposed.

Facility	Total OR Capacity Hours	2018 Surgical Hours	Percent of Capacity
SPSC	11,232	17,190	153%
CMC-Main	87,984	89,782	102%
CMC-Mercy	28,080	24,542	87%
CMC-Pineville	18,720	20,229	108%
CMC-Huntersville	3,744	3,763	100%
CMC-University	18,720	15,025	80%
CMC-Union	11,232	15,993	142%

In Section III, page 77, relative to the projected utilization at the proposed Randolph Surgery Center, the applicants state:

> *"Rather than assume that these cases will continue to grow as they have historically, Randolph Surgery Center, LLC conservatively projects the volume to remain static and to be achieved in the third project year, not the first, following a ramp-up period. Randolph Surgery Center, LLC has therefore assumed that its volume will ramp up from PY1 to PY3, using conservative estimates of 80 and 90 percent of the total PY3 volume for PY1 and PY2, respectively."*

The following table shows Randolph Surgery Center projections based on the physician referrals, with the total 4,742 referrals of outpatient eye and ENT cases projected in PY3.

	PY1 Cases	PY2 Cases	PY3 Cases
Outpatient Cases	3,794	4,268	4,742
Outpatient Hours @ 1.5 per case	5,690	6,402	7,113
ORs Needed @ 1,872 per OR	3.0	3.4	3.8
ORs Proposed	2	2	2

The projections above are for eye and ENT surgical cases and no other types of surgical cases. The applicants state that any additional case volumes, either in ophthalmology and otolaryngology or other specialties or by non-CEENTA physicians, will only further increase the utilization of the facility.

The applicants are also proposing one procedure room to perform YAG laser and other minor procedures and state that the need is both quantitative and qualitative. In Section III, page 79, the applicants state:

> *"As YAG procedures are often adjunct to surgical treatments for conditions such as cataracts, having the ability to perform these procedures in the same facility is reasonable and improves access for both the physician and the patient. Moreover, due to the unique equipment needs as it relates to YAG laser procedures, Randolph*

Surgery Center, LLC believes it is reasonable to include a procedure room in its proposed ASC to accommodate patients needing these minor procedures."

Based on the historical experience of CEENTA physicians who will practice at the proposed facility, the applicants project Randolph Surgery Center, LLC *"will perform approximately 300 YAG laser procedures in PY3, and this volume is expected to shift from SPSC, which performed 1,366 YAG laser procedures in FFY 2012, according to its 2013 Hospital License Renewal Application."* This is a ratio of YAG laser cases to surgical cases of 0.06 at Randolph Surgery Center compared to SPSC's ratio of 0.14, as shown below.

	Randolph Surgery Center PY3	**SouthPark Surgery Center FFY2012**
Surgical Cases	4,742	9,905
YAG Laser Procedures	300	1,366
Ratio of YAG to Surgical Cases	6%	14%

Note: the number of SPSC surgical cases shown above appears to be a typographical error. The number of surgical cases reported on the 2013 LRA was 9,005, not 9,905; thus the ratio for SPSC YAG procedures was 15%.

The above PY3 projected ratio of YAG laser procedures to surgical cases appears to be a reasonable assumption based on the CEENTA physicians' experience at SPSC. In projecting the utilization for YAG procedures in the first two years of operation, the applicants once again project performing 80% and 90% of PY3 cases in PY1 and PY2, respectively, resulting in the following number of procedures.

Year	**YAG Laser Procedures**
PY1	240
PY2	270
PY3	300

The applicants state that the above projections are conservative because, although the CEENTA physicians perform other minor procedures, the only procedures projected for Randolph Surgery Center are YAG laser procedures and any additional procedures, either in these or other specialties will only further increase the utilization of the facility.

Thus 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 two existing outpatient operating rooms and the addition of one procedure room.

Access

In Section III, page 66, the applicants state the proposed project will increase access to timely, clinically appropriate and high quality surgical services in Mecklenburg County with

an 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, thus improving access for patients. "*Moreover*", state the applicants on page 67, in reference to serving all payor types, "*CHS facilities and CEENTA physicians have historically demonstrated a commitment to ensuring equitable access and will continue to provide such access upon completion of the proposed project.*" In Section VI, page 107, the applicants state, "*Randolph Surgery Center will provide services to all persons in need of medical care, regardless of race, color, religion, natural* [sic] *origin, sex, age, disability, or source of payment.*" Exhibit 27 contains Randolph Surgery Center's Non-Discrimination Policies.

In summary, the applicants adequately identify the population to be served, adequately demonstrate the need the population to be served has for the proposed project and demonstrate the population will have adequate 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 two existing dedicated ambulatory ORs from CMC-Main to develop a new ASC (Randolph Surgery Center) with two ORs and one procedure room for YAG laser and other minor procedures. The ORs to be relocated are 2 of the 11 dedicated outpatient ORs in the CMC-One Day Surgery unit on the main floor of the CMC Medical Center Plaza. CMC-Main and Randolph Surgery Center are both located inside the I-485 Beltline and less than 4 miles from one another.

In Section III.1, page 75, the applicants provide a table demonstrating the number of cases by existing facility that the CEENTA physicians expect to eventually shift to the proposed facility in project year three, April 1, 2017 to March 31, 2018, as shown below.

Projected Case Shift in PY3

Facility	Cases	Percent
SouthPark Surgery Center	2,982	62.9%
CMC-Main	483	10.2%
CMC-Pineville	213	4.5%
CMC-Huntersville	268	5.7%
CMC-University	284	6.0%
CMC-Union	512	10.8%
Total	**4,742**	**100.0%**

The majority of the cases, 62.9% are expected to shift from SouthPark Surgery Center, the ASC in Charlotte, owned by CEENTA physicians. As discussed on pages 73-75, and in Criterion (3), SPSC is operating well above capacity and the development of Randolph Surgery Center is expected to alleviate capacity constraints at SPSC. On page 94 of the application, the applicants provide the expected impact on SPSC of shifting cases to the new ASC. Based on reported 2012 fiscal year cases totaling 9,005, the applicants project SPSC surgery cases forward to FFY2018 using the NC OSBM Mecklenburg County projected population CAGR of 2.1%, as shown in the following table.

Projected SPSC Utilization

	FFY13	FFY14	FFY15	FFY16	FFY17	FFY18
Total Cases	9,195	9,389	9,587	9,789	9,995	10,206
Hours @ 1.5/case	13,794	14,083	14,380	14,683	14,993	15,309
OR Need (hours/1,872)	7.4	7.5	7.7	7.8	8.0	8.2
Exisitng ORs	6	6	6	6	6	6
OR Deficit	1.4	1.5	1.7	1.8	2.0	2.2

Source: Page 94 of the application and Exhibit 20

As the table above demonstrates, SPSC will be operating far above capacity by 2018 with a projected annual increase limited to the population increase of 2.1%, when the CEENTA eye and ENT physicians experienced a compound annual growth rate of 4.1% between CY2011 and annualized CY2013.

If approved, Randolph Surgery Center is projected to be operational April 1, 2015. The applicants provide the assumptions for conversion of SPSC's projected surgical utilization from calendar years to Randolph Surgery Center's proposed project years on page 94 of the application as follows:

PY1 = 4/1/15-3/31/16 = 0.75*CY15 Cases + 0.25*CY16 Cases
PY2 = 4/1/16-3/31/17 = 0.75*CY16 Cases + 0.25*CY17 Cases
PY3 = 4/1/17-3/31/18 = 0.75*CY17 Cases + 0.25*CY18 Cases

The applicant states, *"The projected shift of 2,982 cases from SPSC to Randolph Surgery Center is expected to occur in PY3, with 80 and 90 percent ramp up in PY1 and PY2, respectively."*

Based on the assumptions above, the following table converts SPSC's projected surgical utilization by calendar year to Randolph Surgery Center's proposed project years, deducts the cases from SPSC's projected cases, and illustrates SPSC still maintains a need for its six licensed operating rooms.

Impact on SouthPark Surgery Center after Conversion from CY to PY and Shift of Cases

	PY1	PY2	PY3
Total Cases before Shift	9,637	9,840	10,048
Projected Shift to RSC	2,386	2,684	2,982
Total Cases after Shift*	7,251	7,156	7,062
Hours @ 1.5/case	10,877	10,735	10,599
OR Need (hours/1,872)	5.8	5.7	5.7
Exisitng ORs	6	6	6

*PY3 total cases after shift calculate to be 7,066; however, the error in calculation makes the projection more conservative.

Ten percent of the total case volume shift projected for the third project year at Randolph Surgery Center comes from CMC-Main. Exhibit 18 outlines the applicants' step by step methodology for determining the current and projected surgical utilization at CMC-Main both before and after the relocation of the two ORs from the CMC-One Day Surgery program at CMC-Main and the shift in the surgery cases from CMC-Main to Randolph Surgery Center.

Step 1. Examine historical OR utilization at CMC-Main.

CMC Historical OR Utilization

CY	IP Cases	OP Cases	Total Cases
2010	12,955	14,496	27,451
2011	13,421	14,805	28,226
2012	13,494	15,112	28,606
2013*	13,305	15,670	28,976
CAGR	0.9%	2.6%	1.8%

*Annualized using YTD July 2013 data
Note: cases exclude cases in dedicated trauma, open heart and C-section rooms.

On page 347 of Exhibit 18, the applicants state that CMC achieved continued growth, a three-year CAGR of 0.9% and 2.6% for inpatient and outpatient cases, respectively, despite the dedicated shift of surgical cases to other CHS facilities as part of CHS's operating room master plan to develop specialty surgical programs at CMC-Mercy and CMC-Pineville. The

applicants further state a belief that the shift in cases to Mercy and Pineville, based on the master plan, has taken place and future changes will develop organically based on growth of the population.

Step 2. Project CMC-Main's future utilization prior to the Fort Mill and Randolph Surgery Center shift.

CMC Projected OR Utilization Prior to Future Shifts

CY	IP Cases	OP Cases	Total Cases
2013	13,305	15,670	28,976
2014	13,424	16,082	29,507
2015	13,544	16,506	30,050
2016	13,665	16,940	30,605
2017	13,787	17,385	31,173
2018	13,911	17,843	31,753
CAGR	0.9%	2.6%	1.8%

Totals may not sum due to rounding.

The table above and on page 348 uses the historical CAGR for inpatient and outpatient cases to project future growth at CMC-Main. The applicants state the projection is reasonable and conservative because they are based on historical growth at CMC-Main during a time when CHS was purposely shifting surgical volume from CMC-Main to CMC-Mercy and CMC-Pineville.

Step 3. Impact of CMC-Fort Mill on CMC-Main Utilization.

The applicants project the proposed shift of inpatients and surgical cases to CMC-Fort Mill, based on the approved Certificate of Need application to develop CMC-Fort Mill, which was still under appeal at the time of this application's filing. The following calculations assume CMC-Fort Mill becomes operational January 1, 2015 with 24% of its total discharges being surgical patients based on the medical/surgical mix of the CMC-Fort Mill service area. The calculations also assume an outpatient to inpatient surgery ratio of 1.5.

CMC-Main Projected Shifts to CMC-Fort Mill

CY	Shift of Total Discharges	IP Surgical Shift	OP Surgical Shift
2015	1,314	313	469
2016	1,351	321	482
2017	1,388	330	495
2018	1,427	339	509

Because the project is still under appeal, the cases may not actually shift to Fort Mill and if they do, the likelihood of meeting the January 1, 2015 deadline would be questionable; thus the projections are conservative using this assumption.

Step 4. Summary of CMC-Main Projected Utilization Prior to the shift of cases to Randolph Surgery Center.

CMC-Main Projected Utilization After CMC-Fort Mill Shift and Prior to Randolph Surgery Center Shift

CY	Inpatient Cases	Outpatient Cases	Inpatient Case Shift	Outpatient Case Shift	Total CMC IP Cases after CMC-FM Shift	Total CMC OP Cases after CMC-FM Shift
2013	13,305	15,670	0	0	13,305	15,670
2014	13,424	16,082	0	0	13,424	16,082
2015	13,544	16,506	313	469	13,232	16,037
2016	13,665	16,940	321	482	13,344	16,458
2017	13,787	17,385	330	495	13,457	16,890
2018	13,911	17,843	339	509	13,571	17,334

Step 5. Convert CMC-Main CY volume to Randolph Surgery Center project year volume

The applicants use the same conversion assumptions as discussed above and outlined on page 350 of Exhibit 18 to convert CMC-Main's projected surgical utilization from calendar years to Randolph Surgery Center's proposed project years. Based on those assumptions, the following table converts CMC-Main's projected surgical utilization by calendar year to Randolph Surgery Center's proposed project years.

CMC-Main Surgical Volume Conversion from CY to PY

Project Year	IP Cases	OP Cases	Total Cases
PY1	13,260	16,142	29,403
PY2	13,372	16,566	29,939
PY3	13,486	17,001	30,487

Step 6. Shift of surgical cases from CMC-Main to Randolph Surgery Center

As the table earlier in this Criterion and on page 75 of the application demonstrates, 483 surgical cases are expected to shift from CMC-Main to the proposed ASC in PY3. On page 77, the applicants state the assumption of a ramp-up with PY1 achieving 80% and PY2 achieving 90% of PY3's volume as the following table shows.

CMC-Main Surgical Volume
Conversion from CY to PY

Project Year	Ramp Up	Cases Shifted from CMC-Main
PY1	80%	387
PY2	90%	435
PY3	100%	483

Step 7. Impact - Final projected utilization for CMC-Main after shift of cases to Randolph Surgery Center

CMC-Main Projected Surgical Volume
After Shift to Randolph Surgery Center

Project Year	IP Cases	OP Cases	Surgical Hours*	OR Need^
PY1	13,260	15,755	63,412	33.9
PY2	13,372	16,132	64,313	34.4
PY3	13,486	16,518	65,234	34.8

*Surgical hours = 3.0 hours x inpatient case + 1.5 hours x outpatient case
^OR Need = surgical hours / 1,872 hours per room

On page 351 of Exhibit 18, the applicants state:

> *"In accordance with the special CON rules and criteria for operating rooms, 10A NCAC 14C .2100, CMC's projected utilization is related to 35 operating rooms (35 operating rooms = 45 total excluding five dedicated open heart, four dedicated C-section, and one room for Level I trauma). As a result of these shifts, CMC's 65,234 total surgical hours in PY3, the third project year of the proposed project, justifies the need for 35 operating rooms as shown above."*

In Section II, page 41, the applicants state:

> *"It is important to note that the relocation does not affect CMC's core surgical operations which are very well utilized. Rather, the two operating rooms are being relocated from CMC-One Day Surgery, which is a relatively old facility, has smaller rooms and does not operate 24 hours a day."*

The applicants further state that CMC-One Day Surgery has been historically less well utilized than CMC's core operating rooms. On page 42, the applicants demonstrate CMC-One Day Surgery's 2013 need for only eight of its 11 licensed operating rooms. The two ORs will be relocated to a newer facility with larger rooms in a state-of-the-art ASC. On page 43, the applicants state:

> *"As such, CMC believes that the relocation of the two operating rooms from CMC-One Day Surgery to Randolph Surgery Center allows for better utilization of the existing operating rooms, particularly for outpatient cases in a dedicated ASC*

environment, while also allowing for more efficient utilization of the remaining nine operating rooms and associated resources at the CMC-One Day Surgery facility."

Nonetheless, the applicants demonstrate that after relocating the two operating rooms from CMC to the proposed ASC and shifting the projected number of surgical cases to the new ASC, CMC is projected to be operating at capacity as shown in the table above (65,234 surgical hours / (1,872 hours x 35 ORs) = 0.996 or 99.6%).

In Section III.9(d), pages 95-97, the applicants discuss the impact of the shift in surgery cases from the other existing surgical facilities as listed on page 75. On page 95, the applicants state:

"The table below shows the historical (FFY12) surgical hours and OR need, and projected (FFY17 and FFY18) surgical hours for the remaining affected facilities. Randolph Surgery Center has projected future surgical hours based on assumed 2.1 percent annual growth rate, equivalent to the Mecklenburg County projected population growth rate for 2013 to 2018 as determined by the NC OSBM (see Exhibit 20). None of the facilities listed below are directly involved in the proposed project and their projections do not encompass programmatic or physician changes. Randolph Surgery Center believes the assumed population growth rate is a reasonable basis to project future volumes."

Facility	FFY12 Inpatient Cases*	FFY12 Outpatient Cases*	FFY12 Surgical Hours**	FFY12 OR Need^	FFY17 Surgical Hours	FFY18 Surgical Hours
CMC-Pineville	1,809	5,377	13,493	7.2	14,976	15,292
CMC-Huntersville	-	1,971	2,957	1.6	3,282	3,351
CMC-University	875	5,127	10,316	5.5	11,450	11,691
CMC-Union	1,766	4,846	12,567	6.7	13,949	14,243

*Source: LRA
**Surgical Hours = 3.0 x IP Cases + 1.5 x OP Cases
^OR Need = Surgical Hours / 1,872

The following table shows the total number of cases and corresponding surgical hours that will be shifted from each facility in PY3 (after the conversion from fiscal year to project year, based on the same assumptions stated on page 94) and the resulting impact on those facilities' utilization, per the applicants' methodology.

Impact on Affected Facilities of Shifting Surgical Cases to Randolph Surgery Center

Facility	PY3 Surgical Hours	PY3 OP Cases Shifted to RSC	Shifted Surgical Hours	PY3 Surgical Hours after Shift	PY3 OR Need^ after Shift	FFY12 Current OR Need^	Difference in PY3 and FFY12 OR Need
CMC-Pineville	15,055	213	320	14,735	7.87	7.2	0.66
CMC-Huntersville	3,299	268	402	2,897	1.55	1.6	(0.03)
CMC-University	11,510	284	425	11,084	5.92	5.5	0.41
CMC-Union	14,022	512	767	13,255	7.08	6.7	0.37

*PY3 Hours = (0.75 x FFY17 hours) + (0.25 x FFY18 hours)
^OR Need = surgical hours / 1,872

On page 97, the applicants state,

> *"As shown above, all of the impacted facilities, with the exception of CMC-Huntersville, are projected to have a greater need for operating rooms in Randolph Surgery Center's PY3 than they do currently. CMC-Huntersville's need is only slightly impacted; however, its volume is still expected to demonstrate a need to maintain both of its operating rooms."*

The analyst questioned the reasonableness of using Mecklenburg County's population CAGR of 2.1% as the assumption factor for projecting growth in Union County surgical cases when Union County's population CAGR is only 1.2%. However, recalculating the surgical cases for Union County with the assumption of 1.2% annual growth in surgical cases makes a neglible difference as the table below shows.

County CAGR	PY3 Surgical Hours	PY3 OP Cases Shifted to RSC	Shifted Surgical Hours	PY3 Surgical Hours after Shift	PY3 OR Need^ after Shift	FFY12 Current OR Need^	Difference in PY3 and FFY12 OR Need
2.1% Annual Growth	14,022	512	767	13,255	7.08	6.7	0.37
1.2% Annual Growth	13,379	512	767	12,611	6.74	6.7	0.02
Difference	642	0	0	643	0	0	0.34

The above table shows that CMC-Union is still projected to have a greater need for operating rooms in Randolph Surgery Center's PY3 than it currently has.

In Section II, page 43, the applicants state:

> *"Finally, the project does not change the total number of operating rooms in the service area and is expected to result in more efficient utilization of these operating rooms, particularly those at CMC and Randolph Surgery Center."*

The applicants include a discussion of CMC-Mercy's OR utilization before and after the proposed relocation of the operating rooms because CMC-Mercy now operates as part of CMC-Main's license, effective October 1, 2013. However, because CMC-Mercy is not located at CMC-Main and is not impacted by the OR relocation or the shift in surgical cases, the analyst chose not to include any further discussion of CMC-Mercy's OR utilization, other than that included in "projected utilization at status quo" discussed in Criterion (3).

In summary, the applicants adequately demonstrate that the needs of the population presently served will be adequately met following the relocation of the two existing outpatient operating rooms from CMC-Main to the proposed Randolph Surgery Center.

(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, page 90, 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 goals: to facilitate physician collaboration, provide more convenient and accessible capacity for outpatient surgical services, and more appropriately utilize the existing operating room capacity within CHS.

2) Relocate two operating rooms from another CHS facility - The applicants state they briefly considered relocating operating rooms from CMC-Mercy instead of CMC-One Day Surgery. However, the applicants determined that this alternative was not the most effective or least costly because, CMC-Mercy's operating rooms have been recently renovated and, as part of CHS's operating room master plan to develop specialty surgical programs, are home to the following specialized surgical programs: the Bariatric Center, Hip & Knee Center, Foot & Ankle Institute, and robotic surgery. The applicants state that these programs have been designed to take full advantage of the capacity and configuration of CMC-Mercy's ORs.

3) Construct new space - The applicants immediately rejected the alternative of new construction as cost-prohibitive, given the proposed project could be developed in existing space designed for an ambulatory surgery center.

4) Renovate existing space and relocate two licensed ORs from CMC-One Day Surgery at CMC-Main - In Section III, page 91, the applicants state that after much consideration, they determined that developing a multispecialty two-room ASC in Charlotte, in renovated existing space, is cost-effective and best meets community needs. The applicants further state:

> *"The proposed ownership structure – a joint venture between CHS and CEENTA Surgery II, LLC – aligns the incentives of all parties involved. As such, the ownership structure facilitates collaboration and fosters a synergistic relationship between the healthcare system and physicians. The proposed facility will benefit from the clinical, operational, and facility management experience of CHS, combined with the surgical expertise of the CEENTA surgeons."*

The applicants also discussed timeliness as a concern and determined that the chosen alternative can be developed in considerably less time than necessary to develop new construction.

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 best 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 for the following reasons:

- The proposed project does not increase the number of licensed operating rooms in Mecklenburg County or the proposed service area,
- The proposed project fosters better utilization of the two dedicated operating rooms being relocated from CMC-Main,
- The proposed project responds to the projected population growth and expected increase in outpatient surgery utilization, and
- The existing vacated operating room space can be efficiently and cost-effectively renovated to house the proposed ASC.

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 applicants' identified need. Therefore, the application is conforming to this criterion and approved subject to the following conditions:

1. **Randolph Surgery Center, LLC and The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center shall materially comply with all representations made in its certificate of need application and the clarifying supplemental information dated December 19, 2013. In those instances where representations conflict, Randolph Surgery Center, LLC and The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center shall materially comply with the last-made representation.**

2. **Randolph Surgery Center, LLC and The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center shall develop an**

ambulatory surgical facility which shall be licensed for no more than two dedicated outpatient operating rooms and one procedure room.

3. **Randolph Surgery Center, LLC and The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center shall develop no more than two rooms in the facility that meet licensure requirements for an operating room under the ambulatory surgical facility rules.**

4. **Randolph Surgery Center, LLC and The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center shall relocate no more than two dedicated outpatient operating rooms from CMC-One Day Surgery at Carolinas Medical Center.**

5. **Upon completion of the project, The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center shall take steps necessary to de-license two dedicated outpatient operating rooms located at Carolinas Medical Center and Carolinas Medical Center shall be licensed for a total of no more than 15 shared operating rooms at CMC-Mercy; and 45 operating rooms at CMC-Main, including one dedicated inpatient, four dedicated C-Section, five dedicated Open Heart, 26 shared operating rooms and nine dedicated outpatient operating rooms.**

6. **The procedure room shall not be used for procedures that should be performed only in an operating room based on current standards of practice.**

7. **Procedures performed in the minor procedure rooms shall not be reported for billing purposes as having been performed in an operating room and shall not be reported on the facility's license renewal application as procedures performed in an operating room.**

8. **Randolph Surgery Center, LLC and The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center shall not perform gastrointestinal endoscopy procedures in the procedure room.**

9. **Randolph Surgery Center, LLC and The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center shall meet all criteria to receive accreditation of the ambulatory surgical facility from The Joint Commission, The Accreditation Association of Ambulatory Health Care or a comparable accreditation authority within two years following completion of the facility.**

10. **Randolph Surgery Center, LLC and The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center 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.

11. Randolph Surgery Center, LLC and The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center 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

In Section VIII.1, page 126, the applicants project that the total capital cost of the project will be $3,174,299 as shown in the table below.

Project Cap ital Costs

Construction Contract	$632,047
Equipment/Furniture	$2,110,310
Architect & Engineering Fees	$75,000
Legal / Consultant /Other	$115,000
Contingency	$241,942
Total Capital Cost	**$3,174,299**

Exhibit 34 contains a letter from the architect which states that total estimated construction costs are $632,047, which is consistent with the information in Section VIII. CHS will finance $1,745,864 of the total capital cost from accumulated reserves and CEENTA II will use proceeds from a SunTrust term loan to finance $1,428,435 of the capital costs.

In Section IX.1-3, pages 132-133, the applicants state start-up and initial operating expenses required for the project will total $1,214,073 and that the source of the working capital will be $667,740 from unrestricted cash of CHS and $546,333 from CEENTA II via the SunTrust loan.

Exhibit 30 contains a letter dated October 15, 2013 from the Executive Vice-President and CFO of Carolinas Healthcare System, which states CHS's intent to provide capital in the amount of $1,745,864 and working capital of $667,740 for an estimated total of $2,413,605 from accumulated cash reserves for the development of the proposed project. Exhibit 30 also contains a letter dated October 15, 2013 from CEENTA II representative physicians documenting intent to contribute up to $2,715,459 funded through a term loan for CEENTA Surgery II, LLC's portion of capital and working capital for the proposed project development. A letter from SunTrust, dated October 3, 2013, documents its willingness to extend a term loan not to exceed $2,715,459 to CEENTA Surgery II, LLC.

Exhibit 32 contains the financial statements for The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas HealthCare System for the years ending December 31, 2012 and 2011. As of December 31, 2012, CHS had $85,603,000 in Cash and Cash Equivalents and Funded Depreciation of $2,205,144,000 on its Combined Balance Sheet (application page 484).

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 4/1/15-3/31/16**	**PY2 4/1/16-3/31/17**	**PY3 4/1/17-3/31/18**
Projected # of Eye Surgical Cases	1,947	2,191	2,434
Projected Average Charge Eye Cases	$ 3,565	$ 3,672	$ 3,787
Projected # of ENT Surgical Cases	1,846	2,077	2,308
Projected Average Charge ENT Cases	$ 4,465	$ 4,599	$ 4,737
Projected Total Surgical Cases	3,793	4,268	4,742
Projected Average Charge Surgical Cases	$ 4,004	$ 4,123	$ 4,247
Gross Patient Revenue Surgical Cases	$ 15,185,541	$ 17,596,246	$ 20,137,926
Projected # of YAG Laser Procedure Room Cases	240	270	300
Projected Average Charge PR Cases	$ 1,628	$ 1,677	$ 1,727
Gross Patient Revenue Procedure Room	$ 390,659	$ 452,676	$ 518,062
Projected Total ASC Cases	4,033	4,538	5,042
Projected ASC Average Charge	$ 3,862	$ 3,977	$ 4,097
Gross Patient Revenue	$ 15,576,200	$ 18,048,922	$ 20,655,988
Deductions from Gross Patient Revenue	$ 9,660,924	$ 11,246,085	$ 12,929,046
Net Patient Revenue	$ 5,915,276	$ 6,802,836	$ 7,726,942
Total Expenses	$ 5,893,811	$ 6,053,009	$ 6,517,105
Net Income	$ 21,465	$ 749,827	$ 1,209,837

However, the applicants fail to include interest expense on the CEENTA II loan as an operating expense. In Section VIII.4, page 128, the applicants state, *"Please note that CEENTA Surgery II, LLC will incur the interest expense for this loan, not Randolph Surgery Center, LLC. CEENTA Surgery II, LLC is not an applicant, and as such, no interest expense is included in the financial statements following Section XII."* CEENTA Surgery II, LLC has a 45% membership/ownership in Randolph Surgery Center, LLC. As such, the interest expense should be considered as an operational expense for the surgery center. The applicants provide the amortization schedule showing principal and interest payments for a loan of $2,715,459 in Exhibit 31. Interest expense is not included on Form B & C in the pro formas; however, the interest expense associated with the total CEENTA II loan of $1,974,768 is considered part of the total cost of this project, regardless of what entity pays it. The interest expense in the first three years of the project is less than $50,000 in PY1, $40,000 in PY2 and $30,000 in PY3. Reducing the net income by the additional interest

expense incurred in PY1 results in a net loss in the first operating year; however, the additional interest expense becomes inconsequential in PY2 and PY3, with net incomes of more than $700,000 and $1.2 million, respectively. The $1,500 loan fee and the interest on the loan during the construction period should also be included as part of the total capital cost, increasing the total capital cost and the amount due from CEENTA II. However, the total loan fee plus the "interest during construction" for the projected seven month construction period would fall well within the range of the limit that SunTrust is willing to finance on behalf of CEENTA II. Therefore, failure of the applicants to include the cost of financing CEENTA II's portion of the capital and working capital does not impact the project's financial feasibility.

Except for the erroneous assumption associated with the interest on the loan, the assumptions used by the applicants in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See the pro formas in the Financials section of the application, following Tab 12 for the assumptions regarding costs and charges. See Criteria (3) and (4) for discussion regarding projected utilization which is incorporated hereby as if fully set forth herein. The applicants adequately demonstrate that the financial feasibility of the proposal is based upon reasonable projections of costs and charges, and 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, Randolph Surgery Center, LLC and CMC propose to relocate two existing dedicated outpatient ORs from CMC-Main to a new, separately licensed ASC, to be known as Randolph Surgery Center, LLC. Randolph Surgery Center, LLC is a newly formed joint venture comprised of CEENTA II physicians and CHS.

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 2013 SMFP. The total number of operating rooms in the CMC system and in Mecklenburg County will not change as a result of the proposed project. The applicants adequately demonstrate that relocation of the existing dedicated outpatient ORs is necessary and the least costly or most effective alternative to meet the applicants' identified need – "*better utilization of the existing operating rooms, particularly for outpatient cases in a dedicated ASC environment, while also allowing for more efficient utilization of the remaining nine operating rooms and associated resources at the CMC-One Day Surgery facility*". See Criterion (3) for further discussion regarding need demonstration which is incorporated hereby as if set forth fully herein. The applicant adequately demonstrates that the OR relocation project will not result in an unnecessary duplication of existing or approved health service capabilities or facilities. 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 117.

Employee Category	# of Full Time Equivalent (FTE) Positions
Facility Manager	1.0
RNs	16.0
Sterile Processing	2.0
OR Assistant	2.0
Surgical Techs	5.0
Transcription	1.5
Bookkeeper	1.0
Non-health personnel	5.0
TOTAL	33.5

As shown in the table above, the applicants propose a total of 33.5 FTE positions in project year two. On page 118, the applicants state that as existing healthcare providers in the Charlotte area, CEENTA and CHS have numerous resources from which to obtain staff and do not anticipate difficulty in recruiting staff because of CEENTA's recognition as offering family-friendly working environments, CEENTA's strong relationships with local training programs, and CHS's provision of its facilities as clinical training sites for so many different professional healthcare programs.

Exhibit 15 contains a letter signed by James H. Antoszyk, MD and Michael W. Sicard, MD, which states their commitment to serve as Co-Medical Directors for the proposed facility. Exhibit 26 contains both physicians' 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(a), pages 27-28, the applicants identify the ancillary and support services required for the proposed project. They state:

"The following ancillary and support services will be included: patient reception, medical records, billing and insurance, laboratory support, diagnostic imaging, housekeeping, and maintenance."

The applicants further state that ancillary services, such as lab tests, diagnostics and other services, will be provided through the patients' physicians, at CMC, or are available elsewhere throughout the community. Anesthesia services will be provided by physicians and CRNAs, both of which will bill directly to the patient. Support services, such as reception, medical records, billing and insurance, housekeeping and maintenance will be provided by the facility's support staff or through contract with the facility manager, CHS. Exhibit 9 contains a copy of the proposed Management Services Agreement between Randolph Surgery Center and CHS.

Exhibit 36 contains letters from physicians stating their support for the proposed project and stating the number of surgical procedures they intend to refer to Randolph Surgery Center.

The applicants adequately demonstrate that all necessary ancillary and support services will be available and that the services will be coordinated with the existing health care system. Therefore, the application is conforming to 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 an existing surgical facility and renovate that space to meet the needs of the proposed two-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. The existing facility (leased space) is 18,200 square feet. The applicants propose to renovate 3,051 square feet and occupy a total of 13,488 square feet as the proposed ASC. Exhibit 13 contains the line drawings, identifying the functional areas of the ASC and its boundaries shaded orange. Renovations include the development of a procedure room and reconfiguration of storage, clean/soiled linen, and sterile processing in two of the four decommissioned operating rooms; and the development of a break room in space currently used as a corridor. The break room will serve to physically separate the proposed ASC leased space from the remaining leased space not involved in the proposed project and identified in the line drawings as CS Center LLC and shaded yellow.

On page 24, the applicants state,

> *"As currently configured, the area shaded orange in the second floor line drawing included in Exhibit 12 already includes the following necessary areas: receiving / registering, waiting, pre-operative, operating rooms, recovery, and observation. Of note, the existing facility design includes the following pre- and post-operative spaces:*

Space	***# of Bays***
Preparation	*8*
Phase I Recovery	*10*
Phase II Observation	*8*

> *These spaces are existing as they were formally used by CSC-Randolph to support more than just the two operating rooms proposed by Randolph Surgery Center, LLC. These areas are roughly located in the areas marked by the red stars in the drawing on the previous page* [page24]. *Although this number of spaces would not typically be developed if the facility were being newly constructed, Randolph Surgery Center, LLC does not believe it would be prudent to expend capital to alter these spaces, since they already exist. … Randolph Surgery Center, LLC maintains that utilizing this space as is, rather than completely reconfiguring the space in order to reduce the overall project area, is the more cost-effective and timely alternative.*

> …

The areas subject to renovation include various support space areas such as: a break room, staff lockers, storage areas, office areas, and the waiting room."

On page 26, the applicants state that the remaining 10,347 square feet of the proposed ASC, which encompasses the operative areas, administrative and other support areas, will not be subject to renovation and will remain the same. In addition to the renovated areas discussed above, at completion, the facility will include 2 multi-specialty dedicated outpatient operating rooms, one procedure room, eight prep bays, 10 recovery bays and eight observation bays. Exhibit 34 contains the architect's estimate of construction costs at $632,047, which is consistent with Section VIII, page 126.

In Section XI.6, page 142, the applicants estimate the following construction costs per square foot:

Estimated Construction Cost per Square Foot			
	Estimated Square Feet	**Construction Cost/ Square Foot**	**Total Cost / Square Foot**
Total	13,488	$46.86	$235.34

In Section III.4, pages 84-85, and Section XI.8, pages 143-145, the applicants discuss the project's plan to assure improved energy and water conservation, stating,

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

The applicants list the following as Randolph Surgery Center's "*Guiding Principles* [emphasis in original]

1. *Implement environmental sustainability to improve and reduce our environmental impact.*
2. *Integrate sustainable operational and facility best practices into existing and new facilities.*
3. *Encourage partners to engage in environmentally responsible practices.*
4. *Promote environmental sustainability in work, home and community.*
5. *Deliver improved performance to provide a long term return on investment that supports our mission and values."*

The applicants state that CHS and Randolph Surgery Center will work with a design team, experienced with Energy Star, Leadership in Energy and Environmental Design (LEED) and Hospitals for a Healthy Environment Green guide for HealthCare (GGHC), to ensure energy efficient systems are an inherent part of the proposed project to the degree appropriate with the proposed renovations. The design team will design for maximum efficiency and life cycle benefits within each mechanical system: heating, cooling water, sewer, and irrigation. The applicants further state:

"CHS and Randolph Surgery Center, LLC will work with experienced architects and engineers to develop this proposed project to ensure energy efficient systems are an inherent part of the proposed project to the degree appropriate with the proposed renovations."

The applicants adequately demonstrate that the cost, design and means of construction represent the most reasonable alternative for the project as proposed and that the renovation project will not unduly increase the costs and charges of providing health services. See Criterion (5) for discussion of costs and charges which is hereby incorporated as if set forth fully herein. 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

Randolph Surgery Center will be a new ambulatory surgery facility and as such has no history of service. In Section VI.13, page 114, the applicants provide the payor mix for CMC's surgical program for CY2012, as illustrated in the table below.

Payor	**Cases as % of Total Cases**
Self Pay/ Indigent/ Charity	5.7%
Medicare/ Medicare Managed Care	24.9%
Medicaid	19.5%
Commercial Insurance / Managed Care	46.0%
Other (Work Comp and Other government)	3.9%
Total	100.0%

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. The following table illustrates those percentages for the proposed North Carolina service area counties and statewide.

	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%

* More current data, particularly with regard to the estimated uninsured percentages, was not available.

The majority of Medicaid eligibles are children under the age of 21.

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 or women utilizing health services. Furthermore, OSBM's website does not include information on the number of handicapped persons.

The applicants demonstrate that medically underserved populations currently have adequate access to services available at Carolinas Medical 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

Recipients of Hill-Burton funds were required to provide uncompensated care, community service and access by minorities and handicapped persons. In Section

VI.11, page 113, 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, as documented in the Non-Discrimination policies included in Exhibit 27. In Section VI.2, page 107, the applicants state:

> *"Randolph Surgery Center, LLC will not discriminate based on age, race, national or ethnic origin, disability, sex, or source of income. 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 113, in reference to civil rights complaints, the applicants state, *"Not applicable. Randolph Surgery Center is not an existing facility."* On page 17 of the application, the applicants state, *"Please note that CEENTA Surgery II, LLC, the other member, does not currently own any healthcare facilities in North Carolina or other states."* The application did not provide any information relative to Randolph Surgery Center's other owner, CHS and any civil rights access complaints. Nor did the application provide civil rights access complaints information on the co-applicant, CMC. The applicant provided supplemental information dated December 19, 2013, as requested during the expedited review, stating:

> *"No complaints have been filed against Carolinas Medical Center regarding civil rights equal access in the last five years.*
>
> …
>
> *No complaints have been filed against Carolinas HealthCare System or any affiliated entity of Carolinas HealthCare System regarding civil rights equal access in the last five years."*

(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

On page 114, the applicants state: *"The tables on the following page show the payor mix by volume for the service components, eye, ENT and YAG Laser, proposed in this project. They are based on the experience of both CHS and CEENTA physician investors who are joint owners of the new venture, Randolph Surgery Center, LLC."*

The following tables illustrate the projected payor mix at Randolph Surgery Center during the second operating year, as reported by the applicants in Section VI.14, page 115.

Randolph Surgery Center Project Year Two
Projected Payor Mix for Eye Cases

Payor 4/1/16-3/31/17	Projected Number of cases as Percent of Total Cases
Self Pay / Indigent/ Other*	2.0%
Medicare / Medicare Managed Care	88.0%
Medicaid	5.0%
Commercial Insurance / Managed Care	5.0%
Total	**100.0%**

*Other includes workers comp and other government payors

Randolph Surgery Center Project Year Two
Projected Payor Mix for ENT Cases

Payor 4/1/16-3/31/17	Projected Number of cases as Percent of Total Cases
Self Pay / Indigent/ Other*	13.0%
Medicare / Medicare Managed Care	13.0%
Medicaid	6.0%
Commercial Insurance / Managed Care	68.0%
Total	**100.0%**

*Other includes workers comp and other government payors

Randolph Surgery Center Project Year Two
Projected Payor Mix for YAG Laser Procedures

Payor 4/1/16-3/31/17	Projected Number of cases as Percent of Total Cases
Self Pay / Indigent/ Other*	2.0%
Medicare / Medicare Managed Care	88.0%
Medicaid	5.0%
Commercial Insurance / Managed Care	5.0%
Total	**100.0%**

*Other includes workers comp and other government payors

Exhibit 27 contains a copy of Randolph Surgery Center's proposed Non- Discrimination policies. Pages 111-112 provide Randolph Surgery Center's projected charity care of 5.3% of net revenue and bad debt of 5.2% of net revenue in the first two project years.

The applicants demonstrate that medically underserved populations will have adequate access to the proposed services and 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 112, the applicants state, *"Patients will gain access to Randolph Surgery Center via physician referral."* The applicants state expectation that the majority of referrals will initially come from physicians who practice at CMC-Mercy and CMC to the CEENTA surgeons. The information provided is reasonable and credible and supports a finding of conformity with 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, page 100, the applicants state that the proposed ASC will be managed by CHS and will benefit from CHS's extensive existing relationships. CHS has existing relationships with numerous health professional training programs, including Central Piedmont Community College, Queens University of Charlotte, University of North Carolina At Charlotte, Gardner-Webb university, Presbyterian School of Nursing and Mercy School of Nursing. The applicants discuss components of these relationships and list a few as follows:

- CHS houses 14 Accreditation Council for Graduate Medical Education (ACGME) accredited residency programs, including general surgical residency.
- CHS, along with Cabarrus College of Health Sciences and Carolinas College of Health Sciences, provides educational environments for more than 1,000 residents, medical, physician extender, nursing, radiology, and other allied health professional students annually.
- CHS and the University of North Carolina at Charlotte offer a collaborative program for registered nurses with a Master's degree to obtain professional nurse anesthetist training.
- CHS has a contractual agreement with the University of North Carolina at Chapel Hill to mange the Charlotte Area Health Education Center (AHEC). This agreement deems CHS facilities as a clinical rotation training site for several physician extender programs including Duke University, UNC at Chapel Hill, and Wake Forest Baptist Medical Center.

On page 101, the applicants state, *"Students from these clinical programs will have access to the services at the proposed ASC for clinical rotations following completion of the proposed project."*

Exhibit 23 contains a copy of the standard educational affiliation agreement used by CHS facilities and a list of current educational affiliations. The information provided is reasonable and credible and supports a finding of conformity with 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 propose to relocate two existing dedicated ambulatory ORs from CMC-Main to develop a new, separately licensed Mecklenburg County ASC, with two ORs and one procedure room for YAG laser and other minor procedures. The proposed project does not increase the number of operating rooms at CMC or in Mecklenburg County.

Per the Proposed 2014 SMFP, as sent to the Governor in mid-November 2013, Mecklenburg County has a total of 166 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				4	4
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
Novant Health Presbyterian Medical Center	6	6	22		34
CMC-Mercy-Pineville	2		25		27
CMC	10	11	26		47
Novant Health Charlotte Ortho Hospital			12	-2	10
CMC-University-Huntersville	1	4	7		12
Novant Health Matthews Medical Center	2		6		8
Novant Health Huntersville Medical Center	1		4	1	6
Total	22	42	102	3	169

Note: As of October 2013, CMC-Mercy is on CMC's license, not Pineville's. CMC-Mercy has 15 shared ORs and CMC-Pineville has 2 Inpatient and 10 Shared ORs.

In Section III.1, pages 65-68, 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 the proposed project will serve to increase access to timely, clinically appropriate and high quality surgical services in Mecklenburg County. In Section V.7, page 106, the applicants discuss the impact of the proposed project on competition in the service area as it relates to promoting cost-effectiveness, quality and access, stating, *"Competition will be enhanced because the proposed facility will improve access to high-quality 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 those sections is reasonable and credible and adequately demonstrates that the expected effects of the proposal on competition in the service area include a positive impact on 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 two dedicated outpatient operating rooms from CMC-Main to a newly licensed ASC and that it is a cost-effective alternative;
- The applicants adequately demonstrate that they will continue to provide quality services; and

- The applicants demonstrate that they will continue to provide adequate access to medically underserved populations.

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 two existing dedicated outpatient ORs from CMC-Main to a new, separately-licensed ambulatory surgery center to be known as Randolph Surgery Center. Randolph Surgery Center is not an existing facility. However, upon completion of the project, the applicants state Randolph Surgery Center will seek accreditation from the Joint Commission or another appropriate accrediting organization. CMC is accredited by the Joint Commission and certified for Medicare and Medicaid participation. According to the records in the Acute and Home Care Licensure and Certification Section of the Division of Health Service Regulation, no incidents have occurred at Carolinas Medical Center within the eighteen months immediately preceding the date of this decision for which any sanctions or penalties related to quality of care were imposed by the State. 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 37, the applicants state,

> *"The proposed multispecialty ASC expects to perform outpatient ophthalmology (eye), otolaryngology/ear, nose and throat (ENT), as well as plastics 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 38, the applicants state: *"As noted previously, Randolph Surgery Center, LLC is proposing to relocate existing operating rooms from an existing licensed facility, CMC, 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. The applicants plan to relocate two existing dedicated ambulatory ORs from CMC-Main to Randolph Surgery Center. On page 39, the

applicants provide operating room data for CMC-Main and Randolph Surgery Center, prior to the proposed relocation of the ORs. OR data from CMC-Mercy is also included because CMC-Mercy is on CMC's license, as of October 1, 2013.

	CMC-Main	Randolph Surgery Center	CMC-Mercy
Dedicated Inpatient ORs	1	0	0
Dedicated Outpatient ORs	11	0	0
Shared ORs	26	0	15
Dedicated Open Heart Surgery ORs	5	0	0
Dedicated C-Section ORs	4	0	0
Total ORs	**47**	**0**	**15**

(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 39, 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-Main	Randolph Surgery Center	CMC-Mercy
Dedicated Inpatient ORs	1	0	0
Dedicated Outpatient ORs	9	2	0
Shared ORs	26	0	15
Dedicated Open Heart Surgery ORs	5	0	0
Dedicated C-Section ORs	4	0	0
Total ORs	**45**	**2**	**15**

(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 40, the applicants provide the number of inpatient surgical cases and outpatient surgical cases performed in the most recent 12 month period (August 2012 to July 2013) in the operating rooms in each facility listed in Subparagraphs (c)(1) and (c)(2) of this Rule:

	Inpatient Surgical Cases*	Outpatient Surgical Cases	Total Surgical Cases
CMC	13,593	15,324	28,917
CMC-Mercy	3,559	5,420	8,979
Randolph Surgery Center	N/A	N/A	N/A
Total	**17,152**	**20,744**	**37,896**

*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 page 41, 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 Randolph Surgery Center and CMC, as listed in (c)(1) and (c)(2) of this Rule:

Facility	PY1	PY2	PY3
Inpatient			
CMC	13,260	13,372	13,486
CMC-Mercy	3,966	4,043	4,120
Randolph Surgery Center	N/A	N/A	N/A
Total Inpatient Cases	17,226	17,415	17,606
Outpatient			
CMC	15,755	16,131	16,518
CMC-Mercy	5,347	5,406	5,466
Randolph Surgery Center	3,794	4,268	4,742
Total Outpatient Cases	24,896	25,805	26,726
Total Surgical Cases	**42,122**	**43,220**	**44,331**

See Criterion (3) for discussion regarding projected utilization, which is hereby incorporated as if set forth fully herein.

(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- 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. See Criterion (3) for discussion regarding utilization, which is hereby incorporated as if set forth fully herein. 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 44, the applicants state that the proposed ASC's hours of operation will be 7:00 am to 7:00 pm, Monday through Saturday, 52 weeks per year.

(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- The applicants provide tables with the average reimbursement for the 20 most commonly performed surgical procedures at CMC and CMC-Mercy in Section II.10, pages 45-46. The applicants state that reimbursement 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. On page 46, the applicants state that "*Randolph Surgery Center, LLC does not currently exist so no reimbursement is provided.*"

(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- The table in Section II.10, page 47 contains the projected average reimbursement to be received per procedure for the surgical and non-surgical procedures projected to be performed in the proposed ASC, including YAG laser procedures.

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 47, 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 50, 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 two dedicated outpatient operating rooms from CMC to Randolph Surgery Center, a new ambulatory service center. See the need discussion in Criterion (3) which is hereby incorporated as if set forth fully herein. On page 51, the applicants demonstrate the need for the two ORs at Randolph Surgery Center as shown below.

Project Year 3 Total Cases	4,742
Project Year 3 Total Hours	7,113
ORs Needed = Hours/1,872	3.8
ORs Proposed	2

The applicants are not proposing to increase the number of operating rooms in the proposed service area. Rather, the applicants propose to relocate two existing ORs to a new ambulatory surgery center. On page 64, the applicants state that CMC-One Day Surgery is a relatively old facility, has smaller rooms, and does not operate 24 hours a day. The applicants further state,

"…CMC believes that the relocation of the two operating rooms from CMC-One Day Surgery to Randolph Surgery Center will allow for better utilization of the existing operating rooms, particularly for outpatient cases in a dedicated ASC environment, while also allowing for more efficient utilization of the remaining nine operating rooms and associated resources at the CMC-One Day Surgery facility."

.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 29, the applicants state: "*The proposed project does not plan 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, 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. See Criterion (3) for discussion of the need which is hereby incorporated as if fully set forth herein. Therefore, the application is conforming to this Rule.

.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.*

-CA- The applicants refer to Exhibit 14 for the above policies. Exhibit 14 contains a copy of Randolph Surgery Center's transfer policy and transfer log. Exhibit 24 contains a letter from CMC President documenting willingness to accept all transfers from the proposed ASC, along with a sample patient transfer agreement. Exhibit 14 also contains a copy of its Blood Transfusion and Jehovah's Witness policy. In supplemental information requested by the Project Analyst during the expedited review, and dated December 19, 2013, the applicant provided adequate further explanation of the proposed Randolph

Surgery Center policies and procedures for patient referral, transfer and follow-up.

.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, page 54, 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, CHS. 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 bus stop located at the intersection of Randolph Road and Billingsley Road, 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 117 and state that the proposed staffing is based on the experience of CHS and CEENTA physicians, 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 56, 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 38 CEENTA physicians who intend to utilize the facility. Additionally, Exhibit 19 contains copies of the proposed ASC's privileging and credentialing policies.

.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 the Co-Medical Directors of the proposed ASC which states their willingness to serve as Medical Directors 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 Co-Medical Directors of the proposed ASC 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 58, 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 CHS VP, Facilities Management, 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 13 contains copies 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 two existing dedicated outpatient operating rooms.