ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

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

DECISION DATE: August 28, 2014
FINDINGS DATE: September 5, 2014

PROJECT ANALYST: Julie Halatek
INTERIM CHIEF: Martha J. Frisone

PROJECT I.D. NUMBER: E-10261-14 / Caldwell Memorial Hospital, Inc. and SCSV, LLC / Relocate three existing dedicated outpatient operating rooms from Hancock Surgery Center to Caldwell Surgery Center, a new separately licensed ambulatory surgical facility with three operating rooms and one procedure room / Caldwell 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

Caldwell Memorial Hospital, Inc. (CMH) and SCSV, LLC (SCSV) propose to relocate three existing dedicated ambulatory or outpatient operating rooms (ORs) from Hancock Surgery Center (HSC) to develop Caldwell Surgery Center (CSC), a separately licensed ambulatory surgical facility (ASF) with three dedicated outpatient ORs and one procedure room. HSC is located approximately one-half mile from the CMH campus in the City of Lenoir, which is located in the center of the county. The three existing dedicated outpatient ORs are included on CMH's license. The proposed ASF would be located near the southern Caldwell county line.

The total inventory of licensed ORs in Caldwell County will not change as a result of this proposal. The applicants do not propose to add any new health services or acquire any equipment for which there is a need determination in the 2014 State Medical Facilities Plan (SMFP).

However, Policy GEN-4, on page 38 of the 2014 SMFP, is applicable to this review. Policy GEN-4: ENERGY EFFICIENCY AND SUSTAINABILITY FOR HEALTH SERVICE FACILITIES 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 55-56, the applicants state:

> *"Caldwell Surgery Center will develop and implement an Energy Efficiency and Sustainability Plan for the ASC project that conforms to or exceeds the energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. The Plan shall not adversely affect patient or resident health, safety or infection control.*
>
> *The project scope includes construction of an ambulatory surgery center. The facility plans and specifications for the project shall be researched and developed by the project architect, with input from facility engineering and administration, to include specific design features to ensure improved energy efficiency and water conservation.*
>
> *Caldwell Surgery Center will develop and implement an Energy Efficiency and Sustainability Plan that is specific to the project and will address the following systems and features:*
>
> *(1) Lighting Systems – Lighting systems will included* [sic] *within the scope of the areas of renovation* [sic] *for the project to provide energy efficiency in accordance with energy efficiency and water conservation standards*

incorporated in the latest editions of the North Carolina State Building Codes. The selection of lighting systems shall not adversely affect patient or resident health, safety or infection control.

(2) Water Systems – Water systems, hand wash facilities, and toilets will be included for the project to provide higher energy efficiency in accordance with energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. The selection of water systems shall not adversely affect patient or resident health, safety or infection control.

(3) Heating, Ventilation, and Air-conditioning (HVAC) Systems – HVAC systems will be included within the scope of the project to provide higher energy efficiency in accordance with energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. The HVAC system specification [shall] *not adversely affect patient or resident health, safety or infection control.*

(4) Insulation in the attic space of the building will be included in the scope of areas of renovation [sic] *to increase energy efficiency. New construction will include energy efficient windows, high value insulation in the walls and attic spaces and building envelope design features to conserve energy.*

(5) Minor Equipment such as ice machines will be evaluated prior to purchase and implementation based on energy efficiency and water conservation. The minor equipment shall not adversely affect patient or resident health, safety or infection control.

(6) Other potential energy conservation measures for the project will be researched and evaluated by the project engineer and architect as well as Caldwell Surgery Center' [sic] *administration."*

It is unclear why the applicants reference *"areas of renovation"* in paragraphs (1) and (4) above. The rest of the application indicates the building does not yet exist and must be built from scratch.

Nevertheless, the application includes an adequate written statement describing the project's plan to assure improved energy efficiency and water conservation. Therefore, the application is consistent with Policy GEN-4 and conforming to this criterion.

(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.

CMH and SCSV propose to relocate three existing dedicated outpatient ORs from HSC to develop CSC, a separately licensed ASF with three dedicated outpatient ORs and one procedure room. HSC is located approximately one-half mile from the CMH campus in the City of Lenoir, which is located in the center of the county. The three existing dedicated outpatient ORs are included on CMH's license. The proposed ASF would be located near the southern Caldwell county line. The total inventory of licensed ORs in Caldwell County will not change as a result of this proposal; however, the location of the three existing dedicated outpatient ORs will change as a result of this project.

In Section I, pages 3-5, the applicants state that SCSV will be a single-member North Carolina LLC wholly owned by CMH. In the future, physicians may become part owners of SCSV; however, CMH will retain majority control. CMH will purchase the land on which the ASF is to be developed and SCSV will own and operate the licensed ASF. Brackett Flagship Properties, LLC, an unrelated company, will construct and own the building and lease the building to SCSV.

Population to be Served

Because CSC does not exist, there is no historical patient origin for that facility on which to base projected patient origin. In Section III.5, page 56, the applicants state that the proposed service area for CSC is based on the service area for the existing licensed ORs and the OR inventory in the 2013 SMFP. The applicants state:

> *"The proposed project will be located in the primary service area of Caldwell County. This is consistent with the service area definition for the existing licensed operating rooms and the operating room inventory included in the 2013 State Medical Facilities Plan. The boundaries of Caldwell County service area are outlined in green. Secondary service area counties are those in the region that have historically obtained ambulatory surgical services at Caldwell Memorial Hospital as reflected in the patient origin data."*

Note: In the above quote, the applicants reference boundaries for the service area *"outlined in green."* The Project Analyst cannot determine to what this statement refers.

In Section III.7, page 59, the applicants provide the historical origin for patients undergoing outpatient surgery at CMH during Federal Fiscal Year (FFY) 2013 (October 1st to September 30th):

CMH Patient Origin for AS services FFY 2013		
County	**Patients**	**Percentage**
Caldwell	2,613	85.78%
Burke	125	4.10%
Wilkes	77	2.53%
Catawba	72	2.36%
Watauga	51	1.67%
Alexander	25	0.82%
Lincoln	22	0.72%
Other NC Counties	15	0.49%
Ashe	14	0.46%
Avery	10	0.33%
Other States	7	0.23%
Tennessee	6	0.20%
Gaston	5	0.16%
McDowell	4	0.13%
Totals	**3,046**	**100.00%**

Note: Table may not foot due to rounding

In Section III.6, page 57, the applicants provide projected patient origin at CSC during the first three operating years (OYs) following project completion, as shown in the following table:

CSC Projected Patient Origin				
County	**Percentage**	**Patients**		
		OY1	**OY2**	**OY3**
Caldwell	89.29%	2,685	2,976	3,269
Burke	4.10%	123	137	150
Catawba	2.40%	72	80	88
Wilkes*	1.50%	45	50	55
Wilkes*	1.00%	30	33	37
Alexander	0.52%	16	17	19
Lincoln	0.50%	15	17	18
Ashe	0.40%	12	13	15
Avery	0.20%	6	7	7
McDowell	0.09%	3	3	3
Totals	**100.00%**	**3,007**	**3,333**	**3,661**

* The applicants list Wilkes County twice in the table on page 57. The Project Analyst assumes that the applicants intended that one of the two Wilkes County listings be Watauga County.

In Section III.6, pages 57-58, the applicants state:

> *"The proposed project is expected to substantially decrease Caldwell resident outmigration. Therefore the patient origin percentage for Caldwell Surgery Center will have a higher percentage of Caldwell residents as compared to historical*

utilization for Caldwell Memorial Hospital. This will be reinforced by the marketing plan for the CSC that will focus primarily on residents of Caldwell County. Also, Caldwell Memorial Hospital has specific physician recruitment plans that will allow patients in Caldwell County to have greater access to surgical specialists in their home county.

Patients from Burke, Catawba, Alexander, Avery, Watauga, Ashe and Wilkes will have access to the proposed Caldwell Surgery Center. However, existing licensed ambulatory surgical facilities are located in Burke, Catawba and Wilkes Counties. The existing facilities in these counties will likely continue to serve the majority of ambulatory surgery patients that originate from within those counties.

To be conservative, patient origin for Ashe, Alexander, Avery, Lincoln and McDowell Counties are projected to be less than historical percentages. The new facility location in Granite Falls may result in longer travel distances for some patients. Changes in patient referral patterns from these counties may also occur over time.

Patient origin numbers and percentages for other counties and other states have not been included in the CSC projections because the historical numbers of patients are small. Also, these patients, who are more distant from their homes, may need to obtain ambulatory surgery procedures at the hospital if there is a chance they may require extended recovery or observation following surgery."

The applicants adequately identify the population to be served. However, see discussion below regarding the reasonableness of portions of the population proposed to be served.

Demonstration of Need

There are currently eight existing ORs located in Caldwell County and all of them are on CMH's license. One dedicated C-Section OR and four shared inpatient/outpatient ORs are located on the CMH campus. Three dedicated outpatient ORs are located at HSC, approximately one-half mile from the CMH campus in the City of Lenoir, which is located in the center of the county. The total complement of ORs in Caldwell County will not change as a result of this project; however, the location of the three existing dedicated outpatient ORs will change as a result of this project.

In Section II.6, page 11, the applicants state:

"The population of Caldwell County lacks access to a freestanding ambulatory surgical facility in their home county. Consequently, a large number of patients leave their home county to obtain access to surgical facilities elsewhere. The proposed freestanding ambulatory surgery center offers a tremendous opportunity to improve both patient satisfaction and cost savings. The need is great because demand for ambulatory surgery will continue to increase based on the growth of the senior population, changes in surgical techniques and advances in anesthesia.

The proposed ambulatory surgery center (ASC) will offer patients a new choice of ASC provider, one that offers exceptional quality and customer service, lower costs, more efficient scheduling and better teamwork. … ASCs can improve the quality of care received by the patients and delivered by the physicians. …"

In Section III.1, pages 30-41, and Sections III.2 and III.3, pages 50-52, the applicants discuss the factors that they state support the need for development of an ASF located near the southern Caldwell County line. On page 30, the applicants state:

"Many types of surgical procedures that previously required hospital admission can now be safely performed in a freestanding ambulatory surgery center. The proposed multispecialty ambulatory surgery center will offer tremendous cost savings and improved patient access. The need for the proposed freestanding ambulatory surgical facility in Caldwell County relates to multiple factors that are outlined as follows:

- *National survey data demonstrates that the utilization of freestanding ambulatory surgery centers has increased dramatically.*
- *Advances in surgical technologies and anesthesia techniques promote increased demand for ambulatory surgery.*
- *Demographic data for the service area shows that the growth in the senior population will increase demand for healthcare services, including ambulatory surgery procedures.*
- *With the lack of access to a freestanding ambulatory surgery center in their home county, Caldwell County patient outmigration for ambulatory surgery exceeds 62%.*
- *The proposed project reallocates the existing operating room inventory to improve access to high quality and more affordable ambulatory surgical services.*
- *Physician letters of support demonstrate that the proposed project is necessary to provide needed surgical capacity.*
- *The proposed project will support ongoing physician recruitment.*
- *The Center's projected numbers of surgical cases are based on reasonable assumptions and will exceed the regulatory performance standards.*
- *Project approval is justified based on compliance with the CON review criteria and the extensive list of community benefits."*

Each factor is discussed below.

"National survey data demonstrates that the utilization of freestanding ambulatory surgery centers has increased dramatically."

The applicants cite the 2006 National Survey of Ambulatory Surgery to support their assertion of increased utilization of ASFs. The 2006 National Survey tracked outpatient surgery performed in hospital based ORs, ASFs and specialized rooms (such as endoscopy suites). A graph provided by the applicants on page 31 represents that during the ten-year period between

1996 and 2006, the increase in visits to ASFs grew faster than the increase in visits to hospital based ORs.

On page 31, the applicants state:

> *"The report also explains that over the years Medicare reimbursement has expanded to cover ambulatory surgery procedures and has created strong financial incentives to shift less complex surgery cases to outpatient settings. Medicaid and commercial insurance also have adopted similar policies."*

However, the applicants provide insufficient information in the application as submitted to show a correlation, if any, between national trends and Caldwell County trends to adequately document an unmet need for an ASF located near the southern Caldwell County line.

"Advances in surgical technologies and anesthesia techniques promote increased demand for ambulatory surgery."

In Section III.1, page 32, the applicants state that due to advances in surgical and anesthesia technologies, a variety of procedures can be performed on an outpatient basis. The applicants further state that in recent years, Medicare and Medicaid have provided updated and expanded lists of procedures that will be reimbursed when performed in an ASF. The applicants state that, due to the expanding list of covered procedures, along with the increasing number of procedures that can be performed in an ASF, thousands of procedures can be performed safely and are more cost-effective in an ASF than in a hospital based OR.

On page 32, the applicants state:

> *"The surgeons and anesthesiologists who have interest in performing ambulatory surgery cases at Caldwell Surgery Center have extensive experience in the use of new surgical technologies and anesthesia."*

"Demographic data for the service area shows that the growth in the senior population will increase demand for healthcare services, including ambulatory surgery procedures."

The applicants state that the population of Caldwell County has a higher median age than the median age for the total North Carolina population. The applicants also state that future growth of the senior population in Caldwell County will increase demand for services, including outpatient surgical services. In Section III.1, page 33, the applicants provide the following information:

Median Age	2013	2018	Change
Caldwell County	42.52	43.67	N/A
NC Population	37.94	38.43	N/A
Caldwell County Population Age 45+	37,991	39,290	3.4%

Applicants' source: North Carolina Office of State Budget and Management (NC OSBM), 2013 & 2018 Population

However, the applicants provide insufficient information in the application as submitted to adequately document a correlation, if any, between the higher median age of the population of Caldwell County and an unmet need for an ASF located near the southern Caldwell County line. Additionally, the applicants provide insufficient information in the application as submitted to adequately document a correlation, if any, between a 3.4 percent increase in the population of Caldwell County aged 45 years and older, over a five-year period, and an unmet need for an ASF located near the southern Caldwell County line.

In Section III.1, page 34, the applicants state that the ambulatory surgery use rate for Caldwell County residents was 84.70 cases per 1,000 residents during FFY 2012. During the same time period, the statewide ambulatory surgery use was 65.71 cases per 1,000 residents, which means the Caldwell County rate was almost 30 percent higher than the statewide rate [84.7 – 65.71 = 18.99; 18.99 / 65.71 = 0.299]. The applicants state that Caldwell County residents' higher ambulatory surgery use rate *"supports the need for the proposed ambulatory surgical facility project."* However, the applicants do not adequately document in the application as submitted the basis for that conclusion. Indeed, it could be argued that the higher ambulatory surgery use rate for Caldwell County residents shows that those residents already have greater access to ambulatory surgery services than residents of the state as a whole. Furthermore, the applicants do not provide sufficient information in the application as submitted to adequately document that Caldwell County residents who required outpatient surgical services were unable to obtain those services. Indeed, information in CMH's last three LRAs on file at the Division of Health Service Regulation show that the three existing dedicated outpatient ORs at HSC have capacity to serve more patients, as shown in the following table.

HSC	FFY 2011	FFY 2012	FFY 2013
# of Dedicated Outpatient ORs *	3	3	3
Total Outpatient Surgical Cases *	689	802	774
Total Outpatient Surgical Hours (total cases x 1.5 hours per case**)	1,033.5	1,203	1,161
Average Surgical Hours per OR (total hours / # of ORs)	344.5	401	387
Percent of Capacity (average hours per OR / 1,872 hours per OR per year**)	18.4%	21.4%	20.7%

*From CMH's 2012, 2013 and 2014 LRAs

**From the standard OR need methodology in Chapter 6 of the 2014 SMFP

As shown in the table above, during the last three FFYs for which data is available, the three dedicated outpatient ORs at HSC have operated at less than 25% of capacity. In its 2014 LRA, CMH reported performing over 5,000 ambulatory infusions and pain management procedures in the ORs at HSC. However, these are not surgical cases and are not included when applying the standard OR need methodology in the 2014 SMFP.

"With the lack of access to a freestanding ambulatory surgery center in their home county, Caldwell County patient outmigration for ambulatory surgery exceeds 62%."

In Section III.1, page 35, the applicants state:

> *"As of September, 2013 there were 114 licensed ambulatory surgical facilities in North Carolina. Of the total 114 facilities, 68 facilities are licensed GI endoscopy centers and the remaining 46 are surgical centers. The majority of the freestanding ambulatory surgical centers are located in urban areas of the state.*
>
> *Caldwell County has no existing freestanding ambulatory surgical facilities. Also, the population has limited choice and access to freestanding ambulatory surgical centers ("ASCs") because there are only four freestanding surgical centers in adjoining counties."*

The applicants further state that two of the four ASFs in adjoining counties are single specialty ophthalmic ASFs, and that while Wilkes County has an ASF with one OR, it is physically located in the surgical suite of the hospital. The applicants state that Caldwell County residents have limited access to an ASF.

In Section III.1, page 35, the applicants identify three counties with a similar population size as Caldwell that have one or more freestanding ASFs in addition to hospital based ORs, as shown in the table below:

Existing ASFs in Counties with Similarly Sized Population			
County	**2012 Population**	**# of ASFs**	**# of ORs**
Moore	93,025	2	9
Burke	89,227	1	2
Wilson	83,100	1	4
Carteret	69,917	1	2

Applicants' source: 2013 State Medical Facilities Plan

The Project Analyst accessed the NC OSBM website on July 23, 2014. There are three other counties that are closer in size to Caldwell County than Carteret County: Lincoln; Surry; and Wilkes counties. The applicants identified Wilkes County to support their assertion, but not Lincoln or Surry counties. Neither Lincoln County nor Surry County have any ASFs. The applicants do not provide sufficient information in the application as submitted to adequately document that, just because other counties in North Carolina with a population size similar to that of Caldwell County have one or more ASFs, Caldwell County also needs an ASF.

In Section III.1, page 36, the applicants provide the total number of outpatient surgical cases performed on Caldwell County residents in FFY 2012 by facility. Of the 6,997 outpatient surgical cases performed on Caldwell County residents, 5,223 cases were performed in hospital based ORs and 1,774 cases were performed in ASFs. Of the 5,223 Caldwell County residents who received services in a hospital based OR, 2,626 residents received services at CMH. Thus, 37.5 percent of Caldwell County residents received services within Caldwell County (2,626 /

6,997 = 0.3753) while 62.5 percent of Caldwell County residents left the county for outpatient surgical services (4,371 / 6,997 = 0.6246).

In Section III.1, page 37, the applicants state:

> *"The proposed project is expected to create a substantial reduction in the numbers of Caldwell County patients leaving their home county to obtain ambulatory surgery. The proposed project is expected to shift some ambulatory surgery cases from hospitals in outlying communities as well as some utilization from Caldwell Memorial Hospital. ...*
>
> *...*
>
> *Caldwell Surgery Center is expected to reverse the historical trend of high outmigration for ambulatory surgery patients. The project will provide patients with access to high quality and more cost effective ambulatory surgery as compared to an ambulatory surgery procedure in the hospital setting. When the project is complete all of the outpatient surgery cases that are now performed at the Hancock Surgery Center will shift to the Caldwell Surgery Center. ..."*

While the applicants state that the project will shift some cases from hospitals from outlying communities, the applicants do not explain in the application as submitted what they mean by *"some."* Nor do the applicants identify in the application as submitted the *"hospitals in outlying communities."*

In Section III.1, page 38, the applicants state that there are cost savings for surgeries performed in ASFs as compared to surgeries performed in hospital based ORs. The applicants state:

> *"Over the years, the Center for Medicare and Medicaid (CMS) has continued to expand the range of procedures for which ASCs will be paid a facility fee. CMS currently pays the ASCs approximately 58% of the outpatient procedure fees paid to hospitals. Medicare currently reimburses the ASC providers less than the hospital providers because ASCs do not have the overhead related to ancillary services, such as Emergency Departments. Medicare co-payment rates are significantly lower for ASCs as compared to hospital facilities, saving the ASC patient 40 to 50%. In addition, patients typically pay less coinsurance for procedures performed in an ASC than for comparable procedures in the hospital setting...."*

"The proposed project reallocates the existing operating room inventory to improve access to high quality and more affordable ambulatory surgical services."

On page 39, the applicants state that there are eight ORs located in Caldwell County. All eight are currently on CMH's license. The applicants state that, upon completion of the proposed project, CMH would be licensed for five ORs—one dedicated C-section room and four shared inpatient/outpatient ORs. CSC would be licensed for the three dedicated outpatient ORs that are currently located at HSC. The applicants state that the proposed project does not change the current OR inventory for Caldwell County. However, the proposal results in a relocation

of the three existing dedicated outpatient ORs from the City of Lenoir in the center of Caldwell County to the southern Caldwell County line.

"Physician letters of support demonstrate that the proposed project is necessary to provide needed surgical capacity."

On page 40, the applicants provide a list of physicians who wrote letters of support for the proposed projected and the number of outpatient surgical cases they project to refer to CSC. The table lists 16 physicians who project to refer 3,745 to 4,910 cases to the CSC per year. The letters of support are located in Exhibit 10.

"The proposed project will support ongoing physician recruitment."

On page 41, the applicants state that according to the North Carolina Health Professions 2011 Data Book, Caldwell County is underserved, with only 9.7 physicians per 10,000 residents, as opposed to the statewide ratio of 22.1 physicians per 10,000 residents. The applicants state that CMH has an ongoing physician recruitment program and expects to recruit more. According to the applicants, the affiliation of CMH with the UNC Health System, along with the proposed ASF, will help strengthen the recruitment program. The applicants' state that the current plans are to recruit one general surgeon, one vascular/endovascular surgeon, one otolaryngologist and one urologist.

On page 41, the applicants state:

> *"These specialists will be encouraged to obtain medical staff privileges at Caldwell Memorial Hospital and Caldwell Surgery Center. This arrangement will enhance the physicians' productivity and improve patient access to high quality and affordable healthcare. Physician recruitment is expected to boost surgery utilization at the proposed ambulatory surgery center and contribute to future growth of inpatient surgery at Caldwell Memorial Hospital.*
>
> *Future physician recruitment is expected to add further utilization at the proposed ambulatory surgery center. Please see Exhibits 10 and 23 for documentation regarding physician recruitment. In Exhibit* [10] *Dr. Jenkins states that an additional Podiatrist will join his practice and will likely perform 150 to 250 procedures per year at the surgery center. In Exhibit 23, Caldwell Memorial Hospital officials outline their physician recruitment plans."*

The applicants state several times in the application that CMH plans to continue recruiting physicians. In Exhibit 23, the applicants provide a September 17, 2013 letter signed by the Vice President of Business Development, which states only that CMH plans to recruit one general surgeon, one vascular/endovascular surgeon, one otolaryngologist, and one urologist. Based on the date of the letter, it was written approximately six months before the application was submitted. Thus, it is not clear how current the information is. Moreover, the applicants do not state where these surgeons will locate their office or provide an estimate of when these surgeons may begin practicing in Caldwell County. Without this information, the applicants

do not adequately document in the application as submitted that the proposed physician recruitment supports an unmet need for the proposed ASF located near the southern Caldwell County line.

"The Center's projected numbers of surgical cases are based on reasonable assumptions and will exceed the regulatory performance standards."

On page 42, the applicants state that, 3,240 outpatient surgical cases were performed at CMH and HSC during FFY 2012. During FFY 2013, 3,046 outpatient surgical cases were performed at CMH and HSC, a decrease of 6 percent (3,240 – 3,046 = 194; 194 / 3,240 = 0.5987). Regarding the decrease, the applicants state:

> *"The most recent twelve months' utilization reflects a decline in total surgery cases that is due in part to the departure of one otolaryngologist and the retirement of an orthopedic surgeon. General surgery volumes decreased during the past year due to the shift of minimally invasive vascular surgery cases to a general surgeon's practice.*
>
> *Going forward, Caldwell Memorial Hospital expects that physician recruitment will result in a net gain of surgeons on the medical staff with modest growth in surgery utilization. The recent recruitment of a new otolaryngologist will increase surgery utilization in the short term. Also the UNC Health Care System is strongly committed to assisting with physician recruitment to Caldwell County."*

The methodology and assumptions used to project utilization of the ORs are discussed below under the **Projected Utilization – Operating Rooms** header.

"Project approval is justified based on compliance with the CON review criteria and the extensive list of community benefits."

The applicants list this factor as supporting the development of the proposed project. However, this statement appears to be an assertion by the applicants, not a factor, and the applicants do not provide sufficient information in the application as submitted to adequately support their assertion.

In Sections III.2 and III.3, pages 50-52, the applicants assert that the proposed location, with a higher population density, will improve access to affordable and high quality care. In Section III.2, pages 50-51, the applicants state:

> *"Locating the proposed ambulatory surgery center project in Granite Falls in the southern portion of the county will improve access for residents from Granite Falls, Hudson, Cajah's Mountain and Saw Mills. These municipalities in the southern region of Caldwell County have the highest population density with a current combined population of over 16,500 persons.*
>
> *The red star located in the lower right of the Caldwell County map is the approximate location of the proposed ASC located in Granite Falls.*

Highway 321 provides easy access to the proposed facility as it is the main thoroughfare that diagonally transverses the county. Future growth in the southern region of Caldwell County and along the Highway 321 corridor is expected to outpace other areas of the county. Local physicians and hospital leaders believe that the proposed location is the most effective option to reduce the outmigration of Caldwell residents to healthcare facilities in other counties. As seen in Exhibits 23 and 6, numerous physicians support the development of the proposed project."

In Section III.2, page 51, the applicants state, *"The proposed relocation of the three operating rooms to the southern area of the county is based on the applicant's analysis of the county population distribution and an analysis of traffic patterns."* Regarding distribution of the Caldwell County population, on page 51, the applicants provide a map. On the map is a star that the applicants state represents the approximate location of the proposed site. The applicants also provide three other maps in Exhibit 40. The Project Analyst made a site visit during the review and reviewed Google maps. Based on this analysis, it was determined that the location of the star on the map on page 51 of the application is misleading. To be accurate, the star on the map on page 51 should be located closer to the county line than it is. The map in Exhibit 40 which shows a red star marking the location of the proposed site and nearby roads is accurate. However, another map—showing approximate locations of major towns in Caldwell County—shows the center of Granite Falls, not the proposed site; and the third map, which uses a red pin to show the proposed location, is placed in the center of Granite Falls—not where the proposed freestanding ASF will be located. The Project Analyst used Google Maps to find the distance between the intersection of the plaza where CSC will be located and Pepsi Hickory (the closest identifiable place to Caldwell County on the map that was located in Catawba County). According to Google Maps, the distance between the intersection of the plaza where CSC will be located and Pepsi Hickory, just beyond the Catawba County line, is 2.1 miles.

Regarding the analysis of traffic patterns, the applicants state on page 51 that the North Carolina Department of Transportation *"…verifies that Highway 321 has the highest traffic counts."* The applicants conclude: *"Therefore, the proposed ambulatory surgery center is located near the major thoroughfare that provides superior access."* However, the applicants do not provide sufficient information in the application as submitted to adequately document a correlation, if any, between traffic counts and an unmet need for an ASF located near the southern Caldwell County line. Furthermore, the applicants state that Employment Security Commission data shows that 65 percent of Caldwell County workers commute to another county for work. The applicants do not provide sufficient information in the application as submitted to adequately document a correlation, if any, between traveling to another county for employment and an unmet need for an ASF located near the southern Caldwell County line.

In Exhibit 10, the applicants provide letters of support from 16 local providers who project to refer 3,745 to 4,910 procedures annually to the proposed ASF, as well as a letter from a provider who plans to recruit an additional podiatrist in his office, and projects that the podiatrist may perform 150 to 200 procedures annually at CSC. The letters have almost

identical language, and many were not on the provider's letterhead. Nevertheless, the Project Analyst was able to determine the office locations of the 16 providers proposing to perform procedures at CSC. Of these 16 providers, 4 practice with Horizon Surgical Specialists, located approximately one half mile from the existing HSC, and approximately 13.9 miles from CSC (the projected podiatrist, who may perform an additional 150 to 200 procedures annually, will also be with Horizon Surgical Specialists). Their letters of support indicate they project to perform 1,800 to 2,200 procedures annually at CSC. Four other providers practice with Carolina Orthopaedic Specialists. Carolina Orthopaedic Specialists has offices in various locations including one in the City of Lenoir. The Lenoir office is located approximately 1.8 miles from the existing HSC and 13.8 miles from the proposed CSC. Of those four providers, two practice exclusively in the Lenoir office and they project to perform 400 to 500 procedures annually at the proposed CSC. Thus, of the 16 providers, 6 providers, estimating that they will perform 2,200 to 2,700 annual procedures, more than half of the projected annual procedures, have offices located closer to the existing HSC and CMH than to the proposed CSC. Patients are free to choose their doctor and the facilities where they go for outpatient surgical services. However, the applicants do not provide sufficient information in the application as submitted to demonstrate that it is reasonable to assume that all of the estimated cases would be performed at the proposed ASF located approximately 14 miles from the City of Lenoir where some of these physicians have their offices. These physicians would have the option of performing the surgery in one of the four shared ORs at CMH closer to their office. Utilizing the closer ORs would reduce travel time, which would increase the amount of time available to perform surgery or to see patients in the office.

Finally, in Section III.2, page 50, the applicants state that the proposed project is needed in the proposed location because the four towns nearby have the highest population density in Caldwell County, with over 16,500 residents living in the area. According to the NC OSBM, as of July 2012, Caldwell County municipalities had the following populations:

July 2012 Caldwell County Municipality Population (Source: NC OSBM)	
Municipality	**Population**
Blowing Rock (part)	48
Cajah's Mountain	2,785
Cedar Rock	295
Gamewall	4,018
Granite Falls	4,671
Hickory (part)	19
Hudson	3,857
Lenoir	17,905
Rhodhiss (part)	364
Sawmills	5,177
Caldwell County*	**39,139**

*Population of Caldwell County residents living in a municipality

The population of the four municipalities in the southern part of the county—Cajah's Mountain, Granite Falls, Hudson, and Sawmills—have a combined population of approximately 16,500 (the number in the table is slightly lower; the data the Project Analyst

accessed may have been unavailable to the applicants at the time of the application preparation). However, population density is not the same as actual population. Population density is a measure of how many people live in a defined area such as a square mile. It is not a measure of the actual population, and a higher population density does not equate to a higher population. While the four municipalities in the southern part of the county may have the highest population density, Lenoir—where HSC and CMH are located currently—has a higher population. The applicants do not provide sufficient information in the application as submitted to adequately document a correlation, if any, between population density in southern Caldwell County and an unmet need for an ASF located near the southern Caldwell County line.

In summary, the applicants do not adequately demonstrate the need the population proposed to be served has for an ASF located near the southern Caldwell County line because the applicants do not provide sufficient information in the application as submitted to adequately document each of the following:

- A correlation, if any, between national ambulatory surgery trends and Caldwell County ambulatory surgery trends and an unmet need for an ASF located near the southern Caldwell County line.
- A correlation, if any, between the higher median age of the population of Caldwell County and an unmet need for an ASF located near the southern Caldwell County line.
- A correlation, if any, between a 3.4% increase in the population of Caldwell County aged 45 years and older, over a five-year period, and an unmet need for an ASF located near the southern Caldwell County line.
- That the higher ambulatory surgery use rate for Caldwell County residents, as compared to the statewide use rate, means that Caldwell County residents do not have adequate access to outpatient surgical services.
- That Caldwell County residents are unable to obtain outpatient surgical services in the facility of their choice.
- That because other counties in North Carolina with a population similar to Caldwell County's population have one or more ASFs, therefore, Caldwell County also needs an ASF located near the southern Caldwell County line.
- That the proposed physician recruitment supports an unmet need for an ASF located near the southern Caldwell County line.
- A correlation, if any, between high traffic counts and an unmet need for an ASF located near the southern Caldwell County line.
- A correlation, if any, between traveling to another county for employment and an unmet need for an ASF located near the southern Caldwell County line.
- A correlation, if any, between the density of the population in southern Caldwell County and an unmet need for an ASF located near the southern Caldwell County line.

Projected Utilization – Operating Rooms

In Section IV, pages 64-65, the applicants provide projected utilization during the first three operating years following project completion as shown in the table below:

CMH and CSC Projected Utilization – Outpatient Surgical Cases			
Location	**OY1**	**OY2**	**OY3**
CMH	1,536	1,652	1,739
CSC	3,007	3,333	3,661
Total Outpatient Surgical Cases	4,543	4,985	5,400

Note: Operating Year = July 1 to June 30

In Section III.1(b), pages 42-49, the applicants describe the assumptions and nine-step methodology used to project utilization, as summarized below.

Step 1: Calculate the Ambulatory Surgery Use Rate for Caldwell County

On pages 42-43, using data reported in the Hospital and ASF License Renewal Applications (LRAs) on file with the Division of Health Service Regulation and population data obtained from the NC OSBM, the applicants calculate an ambulatory surgery use rate for Caldwell County residents, as shown in the following table:

Outpatient Surgical Cases Caldwell County Residents FFY 2012	
Total cases—all facilities	6,997
2012 population	82,590
Use rate per 1,000 residents	84.7

Note: The applicants state that they used FFY 2012 data because 2013 data was unavailable.

On page 36, the applicants identify which facilities Caldwell County residents utilized in FFY 2012 based on information available in the 2013 Hospital and ASF LRAs. Of the 6,997 Caldwell County residents who had outpatient surgery in FFY 2012, 1,317 had their surgery performed in a single specialty ASF limited to ophthalmic surgical services. The applicants do not propose to offer ophthalmic surgical services at CSC. However, the Caldwell County ambulatory surgery use rate calculated by the applicants includes ophthalmic surgical cases. Excluding ophthalmic surgical cases, the Caldwell County ambulatory surgery use rate would be only 68.77 cases per 1,000 residents, not 84.7 cases per 1,000 residents (6,997 – 1,317 = 5,680; 5,680 / 82,590 = 0.06877 x 1,000 = 68.77 per 1,000).

Step 2: Calculate Projected Outpatient Surgical Cases Based on Projected Use Rates

On page 43, utilizing the ambulatory surgery use rates calculated in Step 1, the applicants project outpatient surgical cases for Caldwell County residents. The applicants state:

"… The applicants assume that the ambulatory surgery use rate will increase by 0.5% each year based on the aging of the population, changes in surgical technology and anesthesia, physician recruitment and increased patient access. (For example, the 2012 use rate of 84.7 is multiplied by 1.005 to calculate the 2013 rate of 85.13.)"

The applicants' calculations are shown in the following table:

Caldwell County Residents
Actual and Projected Outpatient Surgical Cases

	Actual		Interim			OY1	OY2	OY3
	7/1/11	7/1/12	7/1/13	7/1/14	7/1/15	7/1/16	7/1/17	7/1/18
	6/30/12	6/30/13	6/30/14	6/30/15	6/30/16	6/30/17	6/30/18	6/30/19
Caldwell County Residents	82,590	82,312	82,041	81,794	81,570	81,365	81,181	81,014
Ambulatory Surgery Use Rate / 1,000 Residents (actual)	84.7							
Ambulatory Surgery Use Rate / 1,000 Residents Assuming a 0.5% Increase Annually (projected)		85.12	85.55	85.98	86.41	86.84	87.27	87.71
Projected Outpatient Surgical Cases – Caldwell Residents	6,997	7,007	7,019	7,032	7,048	7,066	7,085	7,106

Other than the statement quoted above, there is nothing in the application to support the projected 0.5% annual increases in the Caldwell County ambulatory surgery use rates. The applicants do not provide sufficient information in the application as submitted to adequately document that aging of the population, changes in surgical technology and anesthesia, physician recruitment and increased patient access would result in an increase in the ambulatory surgery use rate for Caldwell County residents, particularly since the Caldwell County ambulatory surgery use rate is already higher than the statewide use rate.

Even if they had adequately documented the projected 0.5% annual increases, the Caldwell County ambulatory surgery use rates used by the applicants are overstated. The applicants did not exclude ophthalmic surgical cases in calculating the ambulatory surgery use rates. CMH and HSC do not currently perform and CMH and CSC are not projected to perform ophthalmic surgical cases. However, in the table above, the projected outpatient surgical cases for Caldwell County residents includes ophthalmic surgical cases. The following table illustrates projected outpatient surgical cases, excluding ophthalmic surgical cases.

Caldwell County Residents Actual and Projected Outpatient Surgical Cases (excluding ophthalmic surgical cases)								
	Actual		Interim			OY1	OY2	OY3
	7/1/11	7/1/12	7/1/13	7/1/14	7/1/15	7/1/16	7/1/17	7/1/18
	6/30/12	6/30/13	6/30/14	6/30/15	6/30/16	6/30/17	6/30/18	6/30/19
Caldwell County Residents	82,590	82,312	82,041	81,794	81,570	81,365	81,181	81,014
Ambulatory Surgery Use Rate / 1,000 Residents (actual)	68.77							
Ambulatory Surgery Use Rate / 1,000 Residents Assuming a 0.5% Increase Annually (projected)		69.11	69.46	69.81	70.16	70.51	70.86	71.21
Projected Outpatient Surgical Cases – Caldwell Residents	5,680	5,689	5,699	5,710	5,723	5,737	5,753	5,769

Step 3: Market Share Assumptions

On page 44, the applicants state that they assume CSC's Caldwell County market share will be 38 percent in the first operating year, 42 percent in the second operating year, and 46 percent in the third operating year. The applicants state they base projected market share on the following factors:

- Strong support from physicians, including volume projections
- Lack of an existing freestanding ASF in Caldwell County
- Shift of approximately one half of ambulatory surgery cases from CMH to the CSC
- Increased number of residents who will no longer have to leave Caldwell County for services
- Projected physician recruitment
- New facility choice with lower cost to the patients than procedures performed in hospitals on an outpatient basis

The following table illustrates the results of Step 3, as reported by the applicants on page 44:

Outpatient Surgical Cases Based on Market Share Assumptions			
Caldwell Surgery Center	OY1	OY2	OY3
	7/1/2016	7/1/2017	7/1/2018
	6/30/2017	6/30/2018	6/30/2019
Projected Outpatient Surgical Cases - Caldwell Residents (all facilities)	7,066	7,085	7,106
Projected Market Share – Caldwell Residents	38%	42%	46%
Projected Caldwell Surgery Center Cases	2,685	2,976	3,269

However, the applicants do not provide sufficient information in the application as submitted to adequately document how the factors listed above result in the market shares projected in the first three operating years.

Moreover, as previously discussed in Step 1 above, the projected ambulatory surgery use rates utilized by the applicants are overstated. The following table illustrates the results of the applicants' Step 3 using projected ambulatory surgery use rates that do not include ophthalmic surgical cases.

Outpatient Surgical Cases Based on Market Share Assumptions (Use rates exclude ophthalmic surgical cases)			
Caldwell Surgery Center	**OY1**	**OY2**	**OY3**
	7/1/2016	**7/1/2017**	**7/1/2018**
	6/30/2017	**6/30/2018**	**6/30/2019**
Projected Outpatient Surgical Cases – Caldwell Residents (all facilities)	5,737	5,753	5,769
Projected Market Share – Caldwell Residents	38%	42%	46%
Projected Caldwell Surgery Center Cases – Caldwell Residents	2,180	2,416	2,654

Step 4: Calculate Total Surgery Volume at CSC

On pages 44-45, the applicants state:

> *"Step 4 provides the ambulatory surgery cases for Caldwell patients plus the projected number of ambulatory surgery cases for patients in nearby counties that have historically been served by Caldwell Memorial Hospital and the participating surgeons. The projected number of surgery cases for patient in-migration is based on the assumption that 12% of ambulatory surgery cases will be from these counties that include Burke, Catawba, Watauga, Wilkes, Ashe, Lincoln, Alexander, Avery and McDowell. …*
>
> *…*
>
> *The 12% assumption for the calculation of the 'in-migration' numbers of ambulatory surgery patients is more conservative as compared to the historical percentage of 19% of ambulatory surgery patients from the other counties as reported in the 2013 license renewal applications. This change in future patient origin with a higher percentage of patients from Caldwell County and lower percentage from other counties reflects the overall goal of the project to reduce the outmigration of patients from Caldwell County. Also, future marketing efforts, physician recruitment and the location of the facility focus on enhancing services to residents of Caldwell County."*

The applicants provide the following information on page 44:

CSC Total Outpatient Surgical Cases (Including Patients from Other Counties)			
Caldwell Surgery Center	**OY1**	**OY2**	**OY3**
	7/1/2016	**7/1/2017**	**7/1/2018**
	6/30/2017	**6/30/2018**	**6/30/2019**
Projected Outpatient Surgical Cases – Caldwell Residents (all facilities)	7,066	7,085	7,106
Projected Market Share – Caldwell Residents	38.00%	42.00%	46.00%
Projected Caldwell Surgery Center Cases – Caldwell Residents	2,685	2,976	3,269
Projected Outpatient Surgical Cases from Other Counties Assuming 12% of Projected Caldwell Cases*	322	357	392
Total Caldwell Surgery Center Cases	3,007	3,333	3,661

*Other counties include Burke, Catawba, Watauga, Wilkes, Ashe, Lincoln, Alexander, Avery and McDowell counties

The applicants state that they assumed 12 percent of the total number of patients served would be residents of other counties. However, the applicants multiplied the number of Caldwell County residents projected be served at CSC by 0.12 to arrive at the projected in-migration (3,269 x 0.12 = 392.28). This results in an in-migration percentage of only 10.7 percent of the total, not 12 percent (392 + 3,269 = 3,661; 392 / 3,661 = 0.107).

Moreover, the applicants do not provide sufficient information in the application as submitted to adequately document that in-migration at CSC would be 12 percent of the total cases performed at CSC. Specifically, included in that 12% are residents of Watauga, Wilkes, Ashe, and Avery counties. However, the applicants do not provide sufficient information in the application as submitted to adequately document that residents of these counties would utilize the proposed ASF located near the southern Caldwell County line. See discussion in Step 5 below.

Additionally, as previously discussed in Step 1 above, the projected ambulatory surgery use rates utilized by the applicants are overstated. The following table illustrates the results of the applicants' Step 4 using projected ambulatory surgery use rates that do not include ophthalmic surgical cases.

CSC
Total Outpatient Surgical Cases (Including Patients from Other Counties)
(Use rates exclude ophthalmic surgery cases)

Caldwell Surgery Center	**OY1**	**OY2**	**OY3**
	7/1/2016	**7/1/2017**	**7/1/2018**
	6/30/2017	**6/30/2018**	**6/30/2019**
Projected Outpatient Surgical Cases – Caldwell Residents	5,737	5,752	5,769
Projected Market Share – Caldwell Residents	38%	42%	46%
Projected Caldwell Surgery Center Cases – Caldwell Residents	2,180	2,416	2,654
Projected Cases from Other Counties Assuming 12% of Projected Caldwell Cases*	262	290	318
Total Caldwell Surgery Center Cases	2,442	2,706	2,972

*Other counties include Burke, Catawba, Watauga, Wilkes, Ashe, Lincoln, Alexander, Avery and McDowell counties

Step 5: Provide Assumptions and Methodology for CSC Patient Origin

On page 46, the applicants provide the patient origin by county for CMH ambulatory surgery patients during FFY 2013:

CMH Outpatient Surgery Patient Origin FFY 2013		
County	**# Patients**	**Percentage**
Caldwell	2,613	85.78%
Burke	125	4.10%
Wilkes	77	2.53%
Catawba	72	2.36%
Watauga	51	1.67%
Alexander	25	0.82%
Lincoln	22	0.72%
Other NC Counties	15	0.49%
Ashe	14	0.46%
Avery	10	0.33%
Other States	7	0.23%
Tennessee	6	0.20%
Gaston	5	0.16%
McDowell	4	0.13%
Totals	**3,046***	**100.00%**

*The number of patients during FFY 2013 is lower than the number of patients during FFY 2012. The projections in the application are based on the FFY 2012 data because the applicants state that not all 2014 LRAs for other facilities were available at the time the application was prepared (see page 43). See page 42 for a list of reasons provided by the applicants to explain the decrease in surgeries that occurred during FFY 2013.

On pages 45 and 57, the applicants provide the following projected patient origin by county for CSC:

CSC Projected Patient Origin				
County	**%**	**OY1**	**OY2**	**OY3**
Caldwell	89.29%	2,685	2,976	3,269
Burke	4.10%	123	137	150
Catawba	2.40%	72	80	88
Wilkes*	1.50%	45	50	55
Wilkes*	1.00%	30	33	37
Alexander	0.52%	16	17	19
Lincoln	0.50%	15	17	18
Ashe	0.40%	12	13	15
Avery	0.20%	6	7	7
McDowell	0.09%	3	3	3
Totals	**100.00%**	**3,007**	**3,333**	**3,661**

*The applicants list Wilkes County twice in the table on page 45 and the same table on page 57 but do not list Watauga County in either table. Because the applicants specifically discuss serving Watauga County residents and CMH reports serving Watauga County residents, the Project Analyst concludes one of the two Wilkes County listings in each table should be Watauga County.

On page 45, the applicants state:

> *"The proposed project is expected to substantially decrease patient outmigration of Caldwell residents seeking ambulatory surgical services. The above percentages are based on the historical patient origin percentages…with adjustments to account for the decreased outmigration of Caldwell patients. …, the patient origin percentage for Caldwell Surgery Center would have a higher percentage of Caldwell resident utilization (89.29%) as compared to historical utilization for Caldwell Memorial Hospital (85.8%). Patients from Burke, Catawba, Watauga and Wilkes will have access to the proposed facility. However, existing licensed ambulatory surgical facilities are located in Burke, Catawba and Wilkes Counties. Therefore no significant gains in CSC patient origin percentages or market share are expected. Patient origin percentages for Ashe, Alexander, Avery, and Lincoln Counties are projected to be similar to the historical percentages served by Caldwell Memorial Hospital and rounded to the nearest 0.50%. McDowell patient origin is adjusted to 0.21% which is less than historical. Other counties and states are excluded."*

However, in FFY 2013, 51 Watauga County residents, 77 Wilkes County residents, 14 Ashe County residents, and 10 Avery County residents utilized the ORs at the hospital in Caldwell County. In Section III.1, page 45, and Section III.6, page 57, the applicants project that the following number of patients would utilize the proposed ASF located near the southern Caldwell County line:

- 53 or 55 Watauga County residents
- 35 or 37 Wilkes County residents
- 14 or 15 Ashe County residents
- 7 Avery County residents

However, the applicants do not provide sufficient information in the application as submitted to document that it is reasonable to assume residents of these counties would travel to the proposed ASF for outpatient surgery services. These counties all lie north or west of Caldwell County. Assuming residents of these counties would utilize main roads, they would have to travel more than 10 miles past the hospital and its four shared ORs to reach the proposed ASF.

Moreover, as previously discussed in Step 1 above, the projected ambulatory surgery use rates utilized by the applicants are overstated. The following table illustrates the results of the applicants' Step 5 using projected ambulatory use rates that do not include ophthalmic surgery cases.

CSC Projected Patient Origin (Use rates exclude ophthalmic surgical cases)				
County	**%**	**OY1**	**OY2**	**OY3**
Caldwell	89.29%	2,180	2,416	2,654
Burke	4.10%	100	111	122
Catawba	2.40%	59	65	71
Wilkes/Watauga	1.50%	37	41	45
Wilkes/Watauga	1.00%	24	27	30
Alexander	0.52%	13	14	15
Lincoln	0.50%	12	14	15
Ashe	0.40%	10	11	12
Avery	0.20%	5	5	6
McDowell	0.09%	2	2	3
Totals	**100.00%**	**2,442**	**2,706**	**2,972**

Step 6: Project Operating Room Need at CSC

On page 46, the applicants provide a table with calculations based on the standard OR need methodology in the 2014 SMFP (1,872 annual operating hours per OR; 1.5 hours per outpatient surgical case), as shown in the table below.

CSC Number of ORs Needed Based on the Standard OR Need Methodology in the 2014 SMFP			
Caldwell Surgery Center	**OY1** **7/1/2016** **6/30/2017**	**OY2** **7/1/2017** **6/30/2018**	**OY3** **7/1/2018** **6/30/2019**
Projected Outpatient Surgical Cases – Caldwell Residents (all facilities)	7,066	7,085	7,106
Projected Market Share – Caldwell Residents	38.00%	42.00%	46.00%
Projected Caldwell Surgery Center Cases – Caldwell Residents	2,685	2,976	3,269
Projected Cases from Other Counties Assuming 12% of Projected Caldwell Cases*	322	357	392
Total Caldwell Surgery Center Cases	3,007	3,333	3,661
Number of ORs Needed Based on OR Need Methodology in the 2014 SMFP	2.41	2.67	2.93

*Other counties include Burke, Catawba, Watauga, Wilkes, Ashe, Lincoln, Alexander, Avery, and McDowell counties

Additionally, as previously discussed in Step 1 above, the projected ambulatory surgery use rates utilized by the applicants are overstated. The following table illustrates the results of the applicants' Step 6 using projected ambulatory surgery use rates that do not include ophthalmic surgical cases.

CSC Number of ORs Needed Based on the Standard OR Need Methodology in the 2014 SMFP (Use rates exclude ophthalmic surgery cases)								
Caldwell Surgery Center	**Actual**		**Interim**			**OY1**	**OY2**	**OY3**
	FFY 12	**FY 13***	**FY 14****	**FY 15**	**FY 16**	**FY 17**	**FY 18**	**FY 19**
Caldwell County Population	82,590	82,312	82,041	81,794	81,570	81,365	81,181	81,014
Ambulatory Surgery Use Rate / 1,000 Residents (excluding ophthalmic surgery cases)	68.77	69.11	69.46	69.81	70.16	70.51	70.86	71.21
Annual Increase in Use Rate		0.5%	0.5%	0.5%	0.5%	0.5%	0.5%	0.5%
Projected Caldwell County Ambulatory Surgery Cases (all facilities)	5,680	5,689	5,699	5,710	5,723	5,737	5,752	5,769
CSC Market Share						38%	42%	46%
CSC Caldwell County Cases						2,180	2,416	2,654
In-migration (12% of Caldwell County Cases)***						262	290	318
Total CSC Cases						**2,442**	**2,706**	**2,972**
Total Hours (1.5 Hours per Case x Number of Cases)						3,662.3	4,058.9	4,458.5
Number of ORs Needed Based on 2014 SMFP Need Methodology for ORs (Number of Hours / 1,872 Hours per OR per Year)						2.0	2.2	2.4

* FY = July 1st to June 30th.

** FY 14 is annualized.

*** As discussed in Step 4 above, the applicants state that they assumed 12 percent of the total number of patients served would be residents of other counties. However, the applicants multiplied the number of Caldwell County residents projected to be served by CSC by 0.12 to arrive at the projected in-migration. This results in an in-migration percentage of only 10.7 percent of the total, not 12 percent.

Regardless of whether or not the ambulatory surgery use rates are adjusted by excluding ophthalmic surgery cases, projected utilization shows a need for three ORs at CSC using the standard OR need methodology in the 2014 SMFP. However, projected utilization at CSC is not based on reasonable and adequately supported assumptions regarding:

- Market share percentages
- In-migration percentages
- Patient origin

See discussion above in Steps 3, 4, and 5 respectively.

Step 7: Project Operating Room Need at CMH

On page 47, the applicants state:

> *"Step 7 forecasts the projected market share and surgery utilization for Caldwell Memorial Hospital (CMH) through the third year following completion of the project.*

The projected total ambulatory surgery cases for the Caldwell population (at all facilities) is provided consistent with Step 3 on previous pages. The Caldwell population ambulatory surgery patients at CMH from other counties is projected based on the patient origin data with a ratio of 16.57% from other counties (16.57% times the number of Caldwell patients).

…

These figures exclude the C-Section cases performed in the dedicated C-Section room. The number of C-Section cases in the dedicated C-Section room and the number of C-Section cases performed in the operating rooms in future years are assumed to remain at the same level as the most recent 12 months. The last row of the table shows the number of operating rooms needed based on the formula in the 2013 [sic] *State Medical Facilities Plan."*

On page 47, the applicants provide calculations of projected OR need at CMH (the table referenced in the quote above), as shown in the following table.

CMH
Projected Number of ORs Needed Following Completion of the Project

	Actual		Interim			OY1	OY2	OY3
	10/1/11	10/1/12	7/1/13	7/1/14	7/1/15	7/1/16	7/1/17	7/1/18
	9/30/12	9/30/13	6/30/14	6/30/15	6/30/16	6/30/17	6/30/18	6/30/19
Outpatient Surgical Cases – Caldwell County Residents (all facilities)	6,995	7,007	7,019	7,032	7,048	7,066	7,085	7,106
CMH Market Share	37.5%	37.3%	37.3%	37.3%	37.3%	18.65%	20.00%	21.00%
CMH Outpatient Surgical Cases – Caldwell County Residents	2,623	2,613	2,618	2,623	2,629	1,318	1,417	1,492
CMH Outpatient Surgical Cases From Other Counties (16.57% x Caldwell Patients)	614	433	434	435	436	218	235	247
Total CMH Outpatient Surgical Cases	3,237*	3,046	3,052	3,058	3,065	1,536	1,652	1,739
CMH Inpatient Cases (excluding C-Sections) Based on 2% Annual Growth	1,480	1,332	1,359	1,386	1,414	1,442	1,471	1,500
ORs Needed Per the Standard OR Need Methodology in the 2014 SMFP						**3.5**	**3.7**	**3.8**

*On page 47, the applicants state the total equals 3,240; however, 2,623 plus 614 equals 3,237, not 3,240.

On pages 47-48, the applicants state:

"In Year 1 following project completion, approximately half of the CMH market share of ambulatory surgery cases shifts from the hospital to Caldwell Surgery Center. The CMH Caldwell patient market share decreases from 36% to 18.65% for Caldwell patients; ambulatory surgery volumes drop to 1318 Caldwell patients and 218 patients from other counties. Ambulatory surgery cases at CMH slowly increase in Years 2 and 3 as reflected in the 20% and 21% market share assumptions. This growth is because not all outpatient surgery patients can be shifted to freestanding ambulatory surgery centers because not all patients meet the patient selection criteria and some patients may need observation for an extended period of time following surgery."

…

As seen in the table above, inpatient surgery cases at CMH are projected to increase at 2% per year beginning in 2013 based on the aging of the population and physician recruitment. Furthermore, all of the physicians who have expressed interest in performing surgeries at the proposed surgery center are committed to obtain hospital privileges at Caldwell Memorial Hospital.

…

In Year 3 following project completion, 3.9 operating rooms are needed at CMH to accommodate the 1739 outpatient cases times 1.5 hrs /case plus the 1579 inpatient cases times 3.0 hours per case assuming that each operating room is available 1872 annual hours per year."

Additionally, as previously discussed in Step 1 above, the projected ambulatory surgery use rates utilized by the applicants are overstated. The following table illustrates the results of the applicants' Step 7 using projected ambulatory surgery use rates that do not include ophthalmic surgical cases.

CMH
Number of ORs Needed Based on the Standard OR Need Methodology in the 2014 SMFP
(Use rates exclude ophthalmic surgery cases)

	Actual	Actual	Projections			OY1	OY2	OY3
	10/1/11	10/1/12	7/1/13	7/1/14	7/1/15	7/1/16	7/1/17	7/1/18
	9/30/12	9/30/13	6/30/14	6/30/15	6/30/16	6/30/17	6/30/18	6/30/19
Outpatient Surgical Cases – Caldwell County Residents	6,995	7,007	7,019	7,032	7,048	5,737	5,752	5,769
CMH Market Share	37.5%	37.3%	37.3%	37.3%	37.3%	18.7%	20.0%	21.0%
CMH Outpatient Surgical Cases – Caldwell County Residents	2,623	2,613	2,618	2,623	2,629	1,070	1,150	1,211
CMH Outpatient Surgical Cases – Other Counties	614	433	434	435	436	177	191	201
Total CMH Outpatient Surgical Cases	3,237	3,046	3,052	3,058	3,065	1,247	1,341	1,412
CMH Inpatient Surgery Cases (excluding C-Sections)	1,480	1,332	1,359	1,386	1,414	1,442	1,472	1,500
ORs Needed Per the Standard OR Need Methodology in the 2014 SMFP						**3.3**	**3.4**	**3.5**

Regardless of whether or not the ambulatory surgery use rates are adjusted by excluding ophthalmic surgery cases, projected utilization shows a need for four ORs at CMH using the standard OR need methodology in the 2014 SMFP.

However, projected utilization at CMH following completion of the project is not based on reasonable and adequately supported assumptions regarding market share for outpatient surgical services. On page 47, the applicants state that the hospital's market share for outpatient surgical services in FFY 2013 was 37.3 percent (including HSC). The applicants state that they assume the market share for outpatient surgical services performed at CMH will be 18.65 percent in OY1 of the proposed ASF, 20 percent in OY2 and 21 percent in OY3. However, in OY3, the projected market share for the proposed ASF is 46 percent. Thus, the applicants are in effect projecting a total market share for outpatient surgical services of 67 percent, which is an increase of 29.7 percent points and a 79.6 percent increase. See the calculations below for OY3.

- 7,106 Total Caldwell County resident outpatient surgical cases (all facilities)
- 3,269 Caldwell County residents served at CSC
- 1,492 Caldwell County residents served at CMH
- 4,761 Caldwell County residents served at CSC and CMH combined (3,269 + 1,492 = 4,761)
- 4,761 / 7,106 = 0.67 = 67 percent (total market share for CSC and CMH combined)
- 67 percent - 37.3 percent = an increase of 29.7 percentage points
- 29.7 percentage points / 37.3 percent = a 79.6 percent increase in market share

The applicants do not provide sufficient information in the application as submitted to adequately document that the combined projected market share increase for CMH and CSC (79.6 percent) is reasonable.

Step 8: Project Caldwell County Market Share (Combined) and Number of Patients for Other Providers

On page 48, the applicants project the market share percentage and number of Caldwell County residents who will continue to seek outpatient surgical services outside of Caldwell County. The applicants state on page 48:

> *"… This step is provided to show that some outmigration of patients from Caldwell County is reasonably expected to continue following project completion due to the fact that Caldwell Surgery Center does not include all surgical specialties, and patient preference for other surgeons or other facilities. …"*

The applicants provide their projections for market share percentage and number of Caldwell County residents who will continue to leave the county for ambulatory surgery services, as shown in the table below:

Caldwell County Residents Outpatient Surgical Cases Performed in Facilities in Other Counties								
	Actual		Interim			OY1	OY2	OY3
	10/1/11	10/1/12	7/1/13	7/1/14	7/1/15	7/1/16	7/1/17	7/1/18
	9/30/12	9/30/13	6/30/14	6/30/15	6/30/16	6/30/17	6/30/18	6/30/19
Projected Outpatient Surgical Cases – Caldwell Residents (all facilities)	6,995	7,007	7,019	7,032	7,048	7,066	7,085	7,106
CMH Market Share	37.5%	37.3%	37.3%	37.3%	36.0%	18.7%	20.0%	21.0%
CSC Market Share	0.0%	0.0%	0.0%	0.0%	0.0%	38.0%	42.0%	46.0%
Percentage Outmigration to Facilities in Other Counties	62.5%	62.7%	62.7%	62.7%	64.0%	43.3%	38.0%	33.0%
Outpatient Surgical Cases – Caldwell Residents – Performed in Facilities in Other Counties	4,372	4,394	4,401	4,409	4,511	3,063	2,692	2,345

However, as previously discussed in Step 1 above, the projected ambulatory surgery use rates utilized by the applicants are overstated. Moreover, as previously discussed in Step 7 above, the applicants do not provide sufficient information in the application as submitted to

adequately document that the combined projected market share increase for CMH and CSC is reasonable.

Step 9: Project Outpatient Surgical Cases by Surgical Specialty

On page 48, the applicants project the number of outpatient surgical cases by surgical specialty. The applicants state that the projections are based on the composition of the medical staff; the letters of support from physicians; and estimates for the specialties that are being recruited, as shown in the table below:

CSC Projected Outpatient Surgical Cases by Surgical Specialty				
Type of Surgical Specialty	*"Draft %"*	7/1/16 6/30/17 OY1	7/1/17 6/30/18 OY2	7/1/18 6/30/19 OY3
Orthopedic & Spine	75.0%	2,255	2,500	2,746
Podiatry	10.0%	301	333	366
General Surgery & Vascular	15.0%	451	500	549
Totals	**100.0%**	**3,007**	**3,333**	**3,661**

Projected Utilization – Procedure Room

On page 49, the applicants state that the proposed procedure room is necessary for the following reasons:

> *"1. The procedure room will enable the facility to accommodate low-acuity procedures quickly and efficiently and alleviate high demand for the operating rooms.*
> *2. The procedure room has lower operating cost that enable the overall facility to achieve greater cost effectiveness.*
> *3. Having a procedure room to complement the operating rooms enhances scheduling efficiency and flexibility for the total facility."*

No other information was included in the application as submitted to document the reasonableness of the statements quoted above.

In Section III.1, page 49, and Section IV, page 65, the applicants provide projected utilization of the proposed procedure room, as shown in the following table.

CSC Projected Utilization of the Proposed Procedure Room			
	OY1	**OY2**	**OY3**
# of Pain Management Procedures The applicants state that they assume this will equal 20% of projected Orthopaedic Surgical Cases.	660	725	797
# of Other Minor Surgical Procedures * The applicants state that they assume that this will equal 14% of Total Projected Surgical Cases.	421	467	513
Total # of Procedures	1,081	1,192	1,310

*The applicants state that these *"will include but not be limited to,* [sic] *removal of pins, removal of surgical staples, minimally invasive podiatric cases, destruction of skin lesions, removal of moles and cysts, and* [sic] *wound repair and* [sic] *some podiatry cases and vascular cases."*

As shown in the table above, the applicants assume that the number of pain management procedures will be 20% of the projected orthopaedic surgical cases and other minor surgical procedures will be 14% of total projected surgical cases. However, the applicants provide no other information in the application as submitted to document that these assumptions are reasonable. Moreover, because projected utilization of the ORs is questionable (see discussion above), projected utilization of the procedure room which is based on projected utilization of the ORs is also questionable.

Access

In Section III.3(d), page 53, the applicants state:

> *"The proposed project maintains the same total operating room inventory but provides patients with greater access to ambulatory surgical operating rooms with lower charges and patient copayments. The relocation of three operating rooms to the proposed Caldwell Surgery Center provides a better geographical distribution of operating room capacity with the new facility located near Highway 321. The municipalities in the southern area of Caldwell County are expected to show future population growth. Access by Medicare, Medicaid and charity care / low income patients will be enhanced with the availability of more cost effective ambulatory surgical services. The operating rooms that remain at Caldwell Memorial Hospital will have the capacity to serve the projected surgical volumes of inpatients and outpatients.*
>
> *Patient charges for hospital surgical services will have the same level of modest increases in future years regardless of the location of the operating rooms to the Caldwell Surgical* [sic] *Center. Patients at Caldwell Memorial Hospital will continue to have access to a broad range of surgical specialties, ancillary and support services."*

In Section VI.2, page 70, the applicants state:

> *"Caldwell Surgery Center is committed to provide services to all of the above-listed* [underserved] *categories of patients. In addition, CSC will not discriminate against anyone due to age, race, color, religion, ethnicity, gender, disability, or ability to pay. The proposed project will obtain Medicare certification and accreditation in support of expanded patient access."*

In Section VI.4, page 70, the applicants state:

> *"CSC will provide access to service to all patients regardless of their ability to pay. Patient co-payments and deductibles are requested at the time of services; however, no patient will be denied care or treatment due to an inability to pay. CSC will accept charity care referrals as documented in Exhibit 24."*

In Section VI.13, page 75, the applicants project that 62.8 percent of patients will have some or all of their care reimbursed by Medicare or Medicaid during OY2.

In Section III.2, page 50, the applicants state that the proposed project is needed in the proposed location because the four towns nearby have the highest population density in Caldwell County, with over 16,500 residents living in the area. According to the NC OSBM, as of July 2012, Caldwell County municipalities had the following populations and median family incomes:

Caldwell County Municipality Population / Median Family Income (Source: NC OSBM)

Municipality	Population (July 2012)	Median Family Income (2010 Federal Census Data)
Blowing Rock (part)	48	$47,426
Cajah's Mountain	2,785	$48,571
Cedar Rock	295	$103,229
Gamewell	4,018	$29,257
Granite Falls	4,671	$46,544
Hickory (part)	19	$37,289
Hudson	3,857	$45,296
Lenoir	17,905	$29,860
Rhodhiss (part)	364	$30,882
Sawmills	5,177	$43,878
Caldwell County*	**39,139**	**$37,261**

***Population of Caldwell County residents living in a municipality

The population of the four municipalities in the southern part of the county—Cajah's Mountain, Granite Falls, Hudson, and Sawmills—have a combined population of approximately 16,500 (the number in the table is slightly lower; the data the Project Analyst accessed may have been unavailable to the applicants at the time of the application preparation). However, population density is not the same as actual population. Population density is a measure of how many people live in a defined area such as a square mile. It is not a measure of the actual population, and a higher population density does not equate to a higher population. So, while the four municipalities in the southern part of the county may have the

highest population density, Lenoir—where HSC and CMH are located currently—has a larger population.

Additionally, the four municipalities in the southern part of Caldwell County have a higher median income than the whole of Caldwell County. If the municipalities that are only partially within Caldwell County are not included due to their low population numbers, the four municipalities have the highest median incomes in the county (except for the median income for Cedar Rock, which is significantly higher than any other municipality, but also has a relatively small population).

The applicants do not provide sufficient information in the application as submitted to adequately document that relocating the existing dedicated outpatient ORs from the City of Lenoir in the geographic center of the county where more low-income and medically underserved groups reside to a location near the southern Caldwell County line where fewer low-income and medically underserved groups reside would not negatively impact access by low-income and medically underserved groups.

Conclusion

The applicants adequately identify the population to be served but do not adequately demonstrate the need the population to be served has for the proposed project or adequately demonstrate the extent to which all residents, and in particular, the medically underserved, are likely to have access to the proposed freestanding ASF located near the southern county line. Therefore, the application is nonconforming 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.

NC

CMH and SCSV propose to relocate three existing dedicated outpatient ORs from HSC to develop CSC as a separately licensed ASF with three dedicated outpatient ORs and one procedure room. HSC is located approximately one-half mile from the CMH campus in the City of Lenoir in the center of the county. The three existing dedicated outpatient ORs are included on CMH's license. The proposed ASF would be located near the southern Caldwell county line. The total inventory of licensed ORs in Caldwell County will not change as a result of this proposal; however, the location of the existing dedicated outpatient ORs will change as a result of this project.

In Section IV.1, page 64, the applicants provide current and projected utilization of the ORs at CMH, as shown in the following table:

OR Utilization – Current & Projected - CMH									
	Prior FY 2012	Most Recent FY 2013	Change in Fiscal Year Time Period (previously October 1 – September 30; new dates July 1 – June 30)	FY 2014	FY 2015	FY 2016	OY1 2017	OY2 2018	OY3 2019
Surgery Suite									
# Dedicated IP ORs									
Open Heart	0	0		0	0	0	0	0	0
C-Section	1	1		1	1	1	1	1	1
Other	0	0		0	0	0	0	0	0
# Dedicated IP Surgery Cases									
Open Heart	0	0		0	0	0	0	0	0
C-Section	33	19		19	19	19	19	19	19
Other	1,480	1,332		1,430	1,459	1,488	1,518	1,548	1,579
# Shared ORs	4	4		4	4	4	4	4	4
# Dedicated OP ORs	3	3		3	3	3	0	0	0
# OP Surgery Cases	3,240	3,046		3,052	3,058	3,065	1,536	1,652	1,739

In Section IV.1, page 65, the applicants provide current and projected utilization of the ORs at CSC, as shown in the following table:

OR Utilization – Current & Projected - CSC									
	Prior FY 2012	Most Recent FY 2013	Change in Fiscal Year Time Period (previously October 1 – September 30; new dates July 1 – June 30)	FY 2014	FY 2015	FY 2016	OY1 2017	OY2 2018	OY3 2019
Surgery Suite									
# Dedicated IP ORs									
Open Heart	0	0		0	0	0	0	0	0
C-Section	0	0		0	0	0	0	0	0
Other	0	0		0	0	0	0	0	0
# Dedicated IP Surgery Cases									
Open Heart	0	0		0	0	0	0	0	0
C-Section	0	0		0	0	0	0	0	0
Other	0	0		0	0	0	0	0	0
# Shared ORs	0	0		0	0	0	0	0	0
# Dedicated OP ORs	0	0		0	0	0	3	3	3
# OP Surgery Cases	0	0		0	0	0	3,007	3,333	3,661

The applicants' assumptions and methodology used to project utilization at CSC and CMH are found in Section III.1, pages 42-49, of the application. See Criterion (3) for discussion regarding projected utilization which is incorporated hereby as if set forth fully herein.

Currently, the hospital is licensed for three dedicated outpatient ORs which are located at HSC. Presumably these ORs are not utilized by inpatients or ED patients. If these ORs are relocated to the proposed ASF located near the southern Catawba County line, the hospital would only be licensed for shared ORs and one dedicated C-Section OR. In OY3 of the proposed CSC, the applicants project that 1,492 patients will have outpatient surgery performed at the hospital in the shared ORs. One of the applicants' arguments for a separately licensed freestanding ASF is more efficient scheduling (see page 11 of the application). As a result of this project, the patients continuing to utilize the hospital would have to utilize the same ORs used by

inpatients and ED patients, which may cause the outpatient surgery procedure to be delayed or postponed.

Moreover, in Section III.7, page 59, the applicants provide historical patient origin data for outpatient surgery services provided at the hospital. In FFY 2013, 51 Watauga County residents, 77 Wilkes County residents, 14 Ashe County residents, and 10 Avery County residents utilized the ORs at the hospital in Caldwell County. In Section III.1, page 45, and Section III.6, page 57, the applicants project that the following number of patients would utilize the proposed ASF located near the southern Caldwell County line:

- 53 or 55 Watauga County residents
- 35 or 37 Wilkes County residents
- 14 or 15 Ashe County residents
- 7 Avery County residents

However, the applicants do not provide sufficient information in the application as submitted to document that it is reasonable to assume residents of these counties would travel to the proposed ASF for outpatient surgery services. These counties all lie north or west of Caldwell County. Assuming residents of these counties would utilize main roads, they would have to travel more than 10 miles past the hospital and its four shared ORs to reach the proposed ASF.

In Section III.3(d), page 53, the applicants state:

> *"The proposed project maintains the same total operating room inventory but provides patients with greater access to ambulatory surgical operating rooms with lower charges and patient copayments. The relocation of three operating rooms to the proposed Caldwell Surgery Center provides a better geographical distribution of operating room capacity with the new facility located near Highway 321. The municipalities in the southern area of Caldwell County are expected to show future population growth. Access by Medicare, Medicaid and charity care / low income patients will be enhanced with the availability of more cost effective ambulatory surgical services. The operating rooms that remain at Caldwell Memorial Hospital will have the capacity to serve the projected surgical volumes of inpatients and outpatients.*
>
> *Patient charges for hospital surgical services will have the same level of modest increases in future years regardless of the location of the operating rooms to the Caldwell Surgical* [sic] *Center. Patients at Caldwell Memorial Hospital will continue to have access to a broad range of surgical specialties, ancillary and support services."*

In Section VI.2, page 70, the applicants state:

> *"Caldwell Surgery Center is committed to provide services to all of the above-listed* [underserved] *categories of patients. In addition, CSC will not discriminate against anyone due to age, race, color, religion, ethnicity, gender, disability, or ability to pay.*

The proposed project will obtain Medicare certification and accreditation in support of expanded patient access."

In Section VI.4, page 70, the applicants state:

"CSC will provide access to service to all patients regardless of their ability to pay. Patient co-payments and deductibles are requested at the time of services; however, no patient will be denied care or treatment due to an inability to pay. CSC will accept charity care referrals as documented in Exhibit 24."

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In Section III.2, page 50, the applicants state that the proposed project is needed in the proposed location because the four towns nearby have the highest population density in Caldwell County, with over 16,500 residents living in the area. According to the NC OSBM, as of July 2012, Caldwell County municipalities had the following populations and median family incomes:

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Additionally, the four municipalities in the southern part of Caldwell County have a higher median income than the whole of Caldwell County. If the municipalities that are only partially within Caldwell County are not included due to their low population numbers, the four municipalities have the highest median incomes in the county (except for the median income for Cedar Rock, which is significantly higher than any other municipality, but also has a relatively small population).

The applicants do not provide sufficient information in the application as submitted to adequately document that relocating the existing dedicated outpatient ORs from the City of Lenoir in the center of the county where more low-income and medically underserved groups reside to a location near the southern Caldwell County line where fewer low-income and medically underserved groups reside would not negatively impact access by low-income and medically underserved groups. Therefore, the applicants do not adequately demonstrate that the needs of the patients currently utilizing CMH and HSC for outpatient surgery services will be adequately met following completion of the project. Consequently, the application is nonconforming to this criterion.

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

NC

In Section III.8, pages 59-61, the applicants describe the alternatives considered prior to submitting this application for the proposed project, which include:

- Maintain the Status Quo – The applicants state that HSC is 11 years old, has 3 dedicated outpatient ORs and 2 GI endoscopy rooms, and is currently licensed as part of CMH. CMH is also licensed for four shared ORs and one dedicated C-Section OR. The applicants state that maintaining the status quo is not an effective alternative due to high demand, Caldwell County resident outmigration, and hospital-baased ORs do not offer the lower charges and co-payments that a separately licensed ASF would offer.

- Convert HSC to a Separately Licensed ASF – The applicants state that the location of HSC is not in good proximity to the high traffic and projected growth areas of southern Caldwell County. The applicants also state that the facility is almost 12 years old and nearing one half of the life of the building. The applicants state that because of those two reasons, this alternative is not an effective long-term alternative. However, HSC is centrally located in the municipality with the largest population. Moreover, HSC still has approximately 12 years of remaining life left if the building is only at one half its expected life now.

- Develop a Smaller ASF with Fewer ORs – The applicants state that the demand for services far exceeds the capacity of one to two ORs and a procedure room. The applicants also state that this would decrease room turnover time and scheduling would be inefficient. The applicants state that for those reasons, and due to the lessened ability of a smaller ASF to achieve financial strength, this alternative was rejected.

- Develop the Project as Proposed – The applicants state that due to the increasing number of procedures that can be performed at an ASF; the medical and technological advances; and the lower costs, the proposed ASF is the best alternative. The applicants state that the *"strengths"* of the proposal include:

    - access to high quality surgery care in a patient-focused environment;
    - more affordable rates for surgical procedures;
    - improved access for Medicare, Medicaid, and indigent patients;
    - availability of resources and support of CMH; and
    - future opportunities for physician ownership to strengthen relationships and bolster recruitment.

    However, the applicants do not adequately demonstrate that these *"strengths"* could not be achieved by separately licensing HSC for a lower capital cost.

Regarding the existing ORs at CMH and HSC, in Section III.3(a), page 52, the applicants state:

> *"The existing operating rooms within Caldwell Memorial Hospital and Hancock Surgery center were constructed more than eleven years ago and will have increasing needs for maintenance and repairs. The existing operating rooms at the Hancock Surgery Center will likely require renovations and upgrades within the next few years. Relocating three operating rooms to the proposed new facility will enable the hospital-based GI endoscopy services and infusion service to remain at Hancock Surgery with the delicensed operating rooms to be converted to a classroom, conference room and storage."*

Regarding licensing HSC as an ASF, on page 60, the applicants state:

> *"*[Converting HSC from hospital-based to an ASF] *is not an effective long term alternative because the facility location is not in good proximity to the high traffic / growth areas of southern Caldwell County. Furthermore, the facility is approaching twelve years old, which is close to one half of the life of the building. Following completion of the ASF,* [HSC] *can continue to be utilized for GI endoscopy, pain management procedures and infusion therapy."*

However, according to the applicants, HSC has approximately 12 years of life left. Additionally, on the website[1] for HSC (accessed by the Project Analyst on August 7, 2014), the HSC is described as a *"…state-of-the-art facility…"* Also, in Section III.8, page 60, the applicant states:

> *"The applicants will evaluate the feasibility of utilizing the Hancock Surgery Center as the interim location for the ASC while the new facility is in development. Caldwell Memorial Hospital will submit necessary documentation to the Division of Health*

[1] http://caldwellmemorial.org/office/6-george-m-hancock-surgery-center; accessed 8/7/2014

Service Regulation and Certificate of Need Section for SCSV, LLC to lease the existing space now occupied by the Hancock Surgery Center pending availability of a new ASC location. The documents are schedule [sic] *to be submitted later in 2014."*

Thus, the applicants indicate that the existing HSC could be separately licensed as an ASF. Furthermore, the applicants do not provide sufficient information in the application as submitted to document their assertion that HSC would be more costly to renovate and utilize as an ASF than developing the proposed project. Therefore, the applicants do not adequately demonstrate that the proposed project is the least costly or most effective alternative.

Moreover, the application is not conforming to all other applicable statutory and regulatory review criteria, and thus, is not approvable. See Criteria (3), (3a), (4), (5), (6), (18a), and 10A NCAC 14C .2100: Criteria and Standards for Surgical Services and Operating Rooms. An application that cannot be approved cannot be an effective alternative.

In summary, the applicants do not adequately demonstrate that this proposal is the least costly or most effective alternative to meet the stated need. Therefore, the application is nonconforming to this criterion and cannot be approved.

(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.

NC

In Section VIII.3, pages 85-86, the applicants project a total capital cost of $4,186,089, which includes $1,746,089 for purchasing the land; $2,330,000 for acquisition of fixed and moveable equipment; $70,000 for office equipment; and $40,000 for contingencies. Exhibit 37 contains a list of the equipment to be acquired along with the estimated cost of each piece of equipment.

The applicants do not include the cost to construct the building in the total capital cost reported in Section VIII.1, page 85. However, on page 85, the applicants do include the capital costs necessary to develop an ASF in the new building. In Section I.10, page 3, the applicants state that Brackett Flagship Properties, LLC, an unrelated company, will construct the building and lease the building to SCSV. Exhibit 3 contains a letter from the managing partner of Brackett Flagship Properties, LLC, stating its commitment to construct the building and a list of the key elements of the proposed lease.

In Section IX.1, page 89, the applicants project $100,000 in start-up expenses and $500,000 in initial operating expenses for the first five months for a total working capital of $600,000.

In Section VII.3, page 86, the applicants state that $2,400,000 of the capital cost will be financed by a conventional loan and the remaining $1,786,089 will be financed with cash and cash equivalents from CMH. Exhibit 35 contains a letter from the Chief Financial Officer of

CMH, stating the availability of cash and cash reserves to finance the proposed project, as well as a commitment to supply the necessary funding. Exhibit 34 contains a letter from the Vice President of First Citizens Bank offering to finance the conventional loan for the acquisition of equipment.

In Section IX.2, page 89, the applicants state that the working capital costs will be financed by a commercial loan. Exhibit 34 contains a letter from the Vice President of First Citizens Bank offering to finance the commercial loan for the working capital costs.

Exhibit 33 contains the Consolidated Financial Statements and Supplemental Information for years ending September 30, 2012 and 2011 for CMH. As of September 30, 2012, CMH had $8,046,152 in cash and cash equivalents; $64,376,776 in total assets, and $41,484,885 in net assets [total assets minus total liabilities]. The applicants adequately demonstrate the availability of sufficient funds for the capital and working capital needs of the project.

The applicants project revenues will exceed operating expenses in the first three operating years of the project, as illustrated in the table below:

CSC	FY 2017	FY 2018	FY 2019
Net Revenue	$9,328,136	$10,525,733	$11,773,992
Expenses	$8,938,659	$9,571,257	$10,214,632
Net Income	$389,477	$954,476	$1,559,290

See the pro formas at the end of the application for the applicants' assumptions.

However, not all of the assumptions used in preparation of the pro formas are reasonable and adequately supported. Specifically, projected utilization is not reasonable and adequately supported. See Criterion (3) for discussion of projected utilization which is incorporated hereby as if set forth fully herein. Therefore, since projected revenues (charges) and costs are based in part on projected utilization, they are also questionable.

In summary, the applicants adequately demonstrate the availability of sufficient funds for the capital and working capital needs of this project. However, the applicants do not adequately demonstrate that the financial feasibility of the proposal is based on reasonable projections of costs and charges. Therefore, the application is nonconforming 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.

NC

CMH and SCSV propose to relocate three existing dedicated outpatient ORs from HSC to develop CSC as a separately licensed ASF with three dedicated outpatient ORs and one procedure room. HSC is located approximately one-half mile from the CMH campus in the City of Lenoir in the center of the county. The three existing dedicated outpatient ORs are

included on CMH's license. The proposed ASF would be located near the southern Caldwell county line.

There are currently eight existing ORs in Caldwell County—all of which are on CMH's license. One dedicated C-Section OR and four shared inpatient/outpatient ORs are located on the CMH campus. Three dedicated outpatient ORs are located at HSC.

The total number of ORs in Caldwell County will not change as a result of this project; however, the location of three ORs will change as a result of this project.

The applicants do not provide sufficient information in the application as submitted to document that the proposal would not result in unnecessary duplication of existing or approved health service facilities in Caldwell County as explained below:

- The three existing dedicated outpatient ORs are currently located in the City of Lenoir, which is located in the center of Caldwell County making them reasonably accessible to all residents of Caldwell County. In contrast, the proposed ASF would be located near the southern Caldwell County line. If these ORs are moved, access to dedicated outpatient ORs by Caldwell County residents living in and north of the City of Lenoir would be less convenient.

- The proposed project involves constructing a new building and upfitting it as a separately licensed ASF with three dedicated outpatient ORs and a procedure room. The capital cost to be incurred by the applicants is $4.2 million, which does not include the cost of constructing the building.

- The applicants do not adequately demonstrate that projected utilization is based on reasonable and adequately supported assumptions. See Criterion (3) for discussion of projected utilization which is incorporated hereby as if set forth fully herein.

- There are two licensed GI endoscopy rooms located at HSC and they will remain in operation where they are. Thus, CMH will continue to maintain HSC in addition to the new freestanding ASF.

- The applicants do not adequately demonstrate that developing the proposed ASF near the southern Caldwell County line is a less costly or more effective alternative than obtaining a separate license for HSC as a freestanding ASF. See Criterion (4) for discussion of alternatives which is incorporated hereby as if set forth fully herein.

Therefore, the application is nonconforming 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.

The following table illustrates the projected staffing at the proposed facility in the second operating year as reported by the applicants in Section VII.2, page 78:

CSC Proposed Staffing	
Employee Category	**# of Full Time Equivalent (FTE) Positions**
Director	1.0
Clinical Coordinator	2.0
CRNA	3.0
Anesthesia Tech	1.2
OR RNs	4.4
Peri-op RNs	5.4
Surgical/Radiology Tech	1.0
Surgical Tech	4.4
Support Tech	2.5
Materials Mgmt Specialist	1.0
Bus. Office Manager	1.0
Accounts Rep.	1.0
Biller/Coder	2.0
Receptionist	2.0
Scheduler	1.2
TOTAL	**33.1**

As shown in the table above, the applicants project to employ 33.1 FTEs in the second operating year. In Section VII.3(b), page 78, the applicants state that they will use a combination of recruiting, referrals from related entities, and local healthcare personnel training programs. Exhibit 27 contains a letter signed by Matthew Hannibal, M.D., which expresses his commitment to serve as Medical Director for the CSC.

The applicants adequately demonstrate the availability of sufficient health manpower and management personnel to provide the proposed surgery 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.1, page 9, the applicants provide a chart documenting the types of ancillary services they will provide. The chart shows that most of the ancillary services will be directly provided by the CSC. In that chart, and II.2(a), page 10, the applicants state that anesthesiology services will be provided by Unifour Anesthesia Associates; radiology services will be provided by Catawba Radiology Associates; and pathology/laboratory professional services will be provided by Western Carolina Pathology Associates. Exhibit 6 contains letters from each of the three providers above confirming their commitment to provide services to the CSC.

Exhibit 5 contains a draft management services agreement which discusses the role of management in setting up and providing ancillary services.

Exhibit 9 contains letters from members of the community expressing support for the proposed project. Exhibit 10 contains letters from providers, expressing support for the proposed project, and projections of patient referrals to the proposed facility.

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 have an unrelated developer construct a 22,000 square foot building on a 6.8 acre site located on New Farm Road in Granite Falls. In Section XI.8, pages 96-97,

the applicants discuss the features and methods that will be used to maintain energy efficient operations and contain costs of utilities. Exhibit 16 contains a letter from the President/CEO of CMH stating that the facility will be constructed in compliance with all laws and regulations pertaining to fire and safety equipment and physical environment.

Assuming that the applicants adequately demonstrated that the construction project was necessary, they adequately demonstrate that the cost, design and means of construction represent the most reasonable alternative for the proposed construction project. However, see Criteria (3) and (6) for discussion regarding need and unnecessary duplication. Furthermore, the applicants adequately demonstrate that the proposed construction project would not unduly increase the costs and charges of providing ambulatory surgery services. However, see Criterion (5) for discussion of the reasonableness of costs and charges. The applicants adequately demonstrate that applicable energy saving features have been incorporated into the construction plans. Therefore, the application is conforming to this criterion.

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

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

C

The proposed project, a new freestanding ASF, does not yet exist. In Section VI.13, page 75, one of the applicants, CMH, provides the payor mix for ambulatory surgery services provided by the hospital during FFY 2012:

CMH Ambulatory Surgery Payor Mix FFY 2012	
Payor	**Cases as % of Total Cases**
Self-Pay / Indigent	4.0%
Medicare / Medicare Managed Care	47.4%
Medicaid	15.4%
Commercial Insurance	31.6%
Other (Workers Comp, VA, Champus, TriCare, Other)	1.6%
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. More current data, particularly with regard to the estimated uninsured percentages, was not available.

County	2010 Total # of Medicaid Eligibles as % of Total Population	2010 Total # of Medicaid Eligibles Age 21 and older as % of Total Population	CY2008-2009 % Uninsured (Estimate by Cecil G. Sheps Center)
Caldwell	19%	8.6%	18.1%
Statewide	17%	6.7%	19.7%

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 percent for those age 20 and younger and 31.6 percent 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.

NC 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 CMH's 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, NC 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 CMH's existing ambulatory surgery services and 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 73, the applicant states that the proposed ASF will have no federal

obligation to provide uncompensated care. In Section VI.10(a), page 73, the applicants state that there have been no civil rights complaints filed against CMH in the last five years. The application is conforming to this criterion.

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

NC

In Section VI.14, page 76, the applicants provide the projected payor mix for CSC:

CSC Projected Payor Mix	
Payor	**Projected Cases as % of Total Cases**
Self-Pay / Indigent	4.0%
Medicare / Medicare Managed Care	47.4%
Medicaid	15.4%
Commercial Insurance	31.6%
Other (Workers Comp, VA, Champus, TriCare, Other)	1.6%
Total	100.0%

Exhibit 24 contains a copy of the proposed charity care and patient access policies for CSC.

The applicants state that one of the justifications for developing a freestanding ASF in the proposed location is because that area of the county has the highest population density and is continuing to grow. However, the area in the southern part of Caldwell County cited by the applicants as the area with the highest population density also has a higher median income than the whole of Caldwell County. The applicants do not provide sufficient information in the application as submitted to adequately document that relocating the existing dedicated outpatient ORs from the City of Lenoir in the center of the county where more low-income and medically underserved groups reside to a location near the southern Caldwell County line where fewer low-income and medically underserved groups reside would not negatively impact access by low-income and medically underserved groups. See Criteria (3) and (3a) for discussion regarding access to the proposed ASF which is incorporated hereby as if set forth fully herein.

The applicants do not adequately demonstrate that medically underserved populations will have adequate access to the proposed services at CSC. Therefore, the application is nonconforming 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 72, the applicants state:

> *"Physicians with privileges at the facility may refer and schedule patients for procedures. CSC physicians are expected to receive patient referrals from a large base of primary care physicians and other providers in the region. CSC and its physicians also expect to receive patient referrals from local community agencies and local hospitals. …"*

Exhibit 26 contains written statements establishing the policies of the CSC regarding patient referrals and non-discrimination.

The information provided by the applicants 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.1(a), page 66, the applicants state that CSC will provide scheduled access to the facility for nursing faculty, nursing students, and surgical technologist students. Exhibit 25 contains a letter from CMH to Caldwell Community College and Technical Institute, offering to provide opportunities for students to learn onsite at the proposed facility. The applicants state they also anticipate future relationships with UNC Chapel Hill Schools of Medicine and Pharmacy.

In Section V.1(b), page 66, the applicants state:

> *"Caldwell Surgery Center has offered to serve as a clinical training site for health professional students. Access to the facility will be offered to the programs during normal hours of operation when registered nurses or other clinical staff are available for appropriate student supervision."*

In Section V.1(c), page 66, the applicants state:

> *"… Participating surgeons have agreed to provide lectures and equipment demonstrations to students. Also, students will have the opportunity to observe surgical procedures at CSC."*

The information provided by the applicants 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.

NC

CMH and SCSV propose to relocate three existing dedicated outpatient ORs from HSC to develop CSC as a separately licensed ASF with three dedicated outpatient ORs and one procedure room. HSC is located approximately one-half mile from the CMH campus in the City of Lenoir, which is located in the center of the county. The three existing dedicated outpatient ORs are included on CMH's license. The proposed ASF would be located near the southern Caldwell county line.

There are currently eight existing ORs in Caldwell County—all of which are on CMH's license. One dedicated C-Section OR and four shared inpatient/outpatient ORs are located on the CMH campus. Three dedicated outpatient ORs are located at HSC.

The total number of ORs in Caldwell County will not change as a result of this project; however, the location of three ORs will change as a result of this project.

In Section V.7, page 69, the applicants discuss how any enhanced competition will have a positive impact on the cost effectiveness, quality, and access to the proposed ambulatory surgery services. 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 in the application regarding quality is reasonable and credible and adequately demonstrates that any enhanced competition in the service area includes a positive impact on the quality of the proposed services. This determination is based on the information in the application and the conclusion that the applicants demonstrate that CMH has provided quality care in the past.

However, the applicants do not adequately demonstrate that any enhanced competition includes a positive impact on the cost effectiveness and access to the proposed services based on the information in the application and the following analysis:

- The applicants do not adequately demonstrate the need the population proposed to be served has for a separately licensed ASF located near the southern Caldwell County line. See Criterion (3) for discussion regarding demonstration of need which is incorporated hereby as if set forth fully herein. Development of a facility that is not needed is not cost effective.
- The applicants do not adequately demonstrate that the proposal is financially feasible. See Criterion (5) for discussion regarding financial feasibility which is incorporated hereby as if set forth fully herein. A project that is not financially feasible is not cost effective.
- The applicants do not adequately demonstrate that moving the ORs from the geographic center of the county where more low-income and underserved groups reside to the southern Caldwell County line where fewer low-income and underserved groups reside would not negatively impact access by low-income and medically underserved groups. See Criteria (3) and (3a) for discussion regarding access which is incorporated hereby as if set forth fully herein.

Therefore, the application is nonconforming 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 three existing dedicated outpatient ORs from HSC, which is licensed as part of CMH, to a new ASF located near the southern Caldwell County line. CMH 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 CMH 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.

NC

The Criteria and Standards for Surgical Services and Operating Rooms, promulgated in 10A NCAC 14C .2100, are applicable to this review. The application is not conforming with all applicable criteria and standards. The specific criteria are discussed below.

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

.2102 INFORMATION REQUIRED OF APPLICANT

(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 16, the applicants identify the following specialty areas: general surgery, orthopedic surgery, podiatry, GI endoscopy, pain management, and otolaryngology.

(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- The applicants do not propose to increase the number of ORs in Caldwell County, to convert a specialty ambulatory surgical program to a multispecialty ambulatory surgical program, or to add a specialty to a specialty ambulatory surgical program.

(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- In Section II.10, page 18, the applicants provide the number and type of ORs at CMH and HSC, as shown below:

CMH Current Inventory of ORs			
	CMH Hospital Campus	**HSC**	**Total Licensed CMH**
Dedicated Open Heart	0	0	0
Dedicated C-Section	1	0	1
Other Dedicated Inpatient Surgery	0	0	0
Dedicated Ambulatory Surgery	0	3	3
Shared Inpatient/Ambulatory Surgery	4	0	4
Total Operating Rooms	**5**	**3**	**8**

(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, pages 18-19, and Section IV.1, pages 64-65, the applicants provide the number and type of ORs at CMH, HSC, and CSC upon completion of the proposed project, as shown below:

Projected Inventory of ORs – Caldwell County				
	CMH Hospital Campus	**HSC**	**CSC**	**Total Caldwell County**
Dedicated Open Heart	0	0	0	0
Dedicated C-Section	1	0	0	1
Other Dedicated Inpatient Surgery	0	0	0	0
Dedicated Ambulatory Surgery	0	0	3	3
Shared Inpatient/Ambulatory Surgery	4	0	0	4
Total Operating Rooms	**5**	**0**	**3**	**8**

(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 III.9, page 62, the applicants provide the number of inpatient surgical cases and outpatient surgical cases performed during the most recent 12 month period (October 1, 2012 to September 30, 2013) at the hospital, as shown below:

CMH Surgical Cases (including HSC)	
Inpatient	1,332
Outpatient / Ambulatory	3,046
Total Surgical Cases	4,378

(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- In Section IV, pages 64-65, 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 CSC and at CMH, as shown below:

Projected Surgical Cases at CMH and CSC – OYs 1-3			
	OY1 2017	OY2 2018	OY3 2019
CMH – Inpatient	1,518	1,548	1,579
CMH – Outpatient	1,536	1,652	1,739
CSC	3,007	3,333	3,661

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

-NC- See Section III, pages 30-63, for the assumptions and methodology used in the development of the projections required by this Rule. However, the applicants do not provide adequate documentation in the application as submitted to support their assumptions. See Criterion (3) for discussion regarding projected utilization which is incorporated hereby as if set forth fully herein. The application is not conforming to this Rule.

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

-C- In Section II.10, page 19, the applicants state that the CSC hours of operation will initially be 7:00 a.m. to 5:00 p.m., Monday through Friday. The applicants also state that hours and days of service, including potentially opening on Saturdays, may be expanded in the future.

(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;

-NC- In Exhibit 20, the applicants provide the 20 surgical procedures most commonly performed at CMH, along with the average reimbursement received per procedure. However, the applicants do not provide a list of all services and items included in the reimbursement. The application is not conforming to this Rule.

(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

-NC- In Exhibit 20, the applicants provide the 20 surgical procedures that the applicants project will be the most commonly performed at the CSC, along with the average reimbursement received per procedure. However, the applicants do not provide a list of all services and items included in the reimbursement. The application is not conforming to this Rule.

(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 20, the applicants state the pre-operative services and procedures which will not be covered in the facility charge are anesthesiology, which will be performed by Unifour Anesthesia Associates; radiology, which will be performed by Catawba Radiology Associates; and pathology/laboratory professional services, which will be performed by Western Carolina Pathology Associates.

(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

(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 23, the applicants state:

> *"Utilization projections for Caldwell Memorial Hospital and Caldwell Surgery Center are based on assumptions and calculations that the operating rooms shall be considered to be available for use five days per week and 52 weeks per year."*

(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

-NC- The applicants propose to establish a new freestanding ASF by relocating three existing dedicated ambulatory surgery ORs from HSC, which is licensed as a part of CMH, to the proposed CSC. However, the applicants do not adequately demonstrate the need for three ORs in the proposed CSC because projected utilization is not based on reasonable and adequately supported assumptions. See Criterion (3) for discussion regarding projected utilization which is hereby incorporated as if set forth fully herein. The application is not conforming to this Rule.

(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 ORs in Caldwell County.

(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 a dedicated C-Section OR.

(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- The applicants do not propose to convert a specialty ambulatory surgical program to a multispecialty ambulatory surgical program.

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

-NC- In Section III.1, pages 42-50, the applicants provide a description of the assumptions and methodology used in the development of the projections provided in this application. However, projected utilization is not based on reasonable and adequately supported assumptions and data. See Criterion (3) for discussion of projected utilization which is incorporated hereby as if set forth fully herein. The application is not conforming to this Rule.

.2104 SUPPORT SERVICES

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

-C- In Exhibits 12, 14, and 26, the applicants provide copies of the written policies and procedures to be used by the CSC for patient transfer and follow-up, the transfer agreement between the CSC and CMH; and patient referral.

(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.

-NC- In Section XI.3, page 94, the applicants state that emergency services are one mile from the proposed facility, and that support services and ancillary services are provided onsite. The applicants state:

> *"Public transportation in Caldwell County is available on a regional basis through Greenway Public transportation. Abby Cab Company provides non-emergency medical transportation to facilities within Caldwell County."*

However, the applicants fail to provide information about the proximity of public transportation to the proposed facility. The application is not conforming to this Rule.

.2105 STAFFING AND STAFF TRAINING

(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- In Section VII, pages 77-81, the applicants provide the projected staffing for the proposed ASF for each area listed above. Additionally, the applicants provide job descriptions for each staff position in Exhibit 31.

(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- The CSC is not an existing facility and therefore has no physicians who currently use the facility. In Sections VII.8 and VII.9, pages 81-83, the applicants provide the number of physicians expected to utilize the CSC based on letters of support and projected referrals: 3 general surgeons, 11 orthopedic physicians, and potentially 2 podiatrists (one has expressed support; the other has been recruited to the practice but has not yet begun). See Exhibit 18 for the by-laws and Exhibit 19 for criteria to be used in extending privileges to medical personnel.

(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- In Exhibit 8, the applicants provide a list of physicians who have committed to refer patients to the proposed facility; a list of facilities at which they currently have privileges; and whether they are in good standing. Additionally, Exhibit 8 provides a statement from the proposed Medical Director, which states that all physicians utilizing the CSC, per the medical by-laws, are required to obtain privileges at CMH and must maintain good standing.

(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.

.2106 FACILITY

(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.

(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- In Exhibit 16, the applicants provide a letter stating that CSC will pursue and obtain 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 proposed facility.

(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 Exhibit 16, the applicants provide a letter stating that the physical environment of the facility will be constructed in conformity with federal, state, and local requirements.

(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 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- In Exhibit 22, the applicants provide a floor plan of the proposed facility which identifies all of the above areas required by this Rule.

(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 do not propose 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.