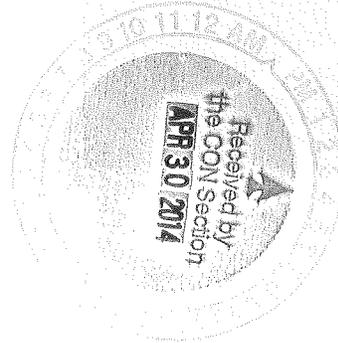


CATAWBA VALLEY MEDICAL CENTER

April 29, 2014

Ms. Martha Frisone, Interim Chief
Certificate of Need Section
Division of Health Service Regulation
2704 Mail Service Center
Raleigh, NC 27699-2704



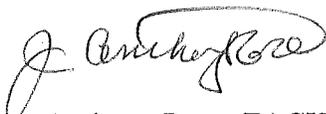
RE: Caldwell Memorial Hospital Certificate of Need Application to Relocate 3 Operating Rooms to an offsite location, Project ID# E-10261-14

Dear Ms. Frisone:

Catawba Valley Medical Center (CVMC) is providing written comments regarding the Certificate of Need application filed by Caldwell Memorial Hospital (Project ID E-10261-14) in the April 1, 2014 review cycle.

Thank you for your consideration of these comments. If you have questions or require additional information, please do not hesitate to contact us.

Sincerely,



J. Anthony Rose, FACHE
President and CEO

JAR:mme

Attachment

**Comments Regarding the Certificate of Need Application
Filed by Caldwell Memorial Hospital
Project No. E-10261-14**

**Submitted by: Catawba Valley Medical Center
April 30, 2014**

Overview

A Certificate of Need application was filed by Caldwell Memorial Hospital and SCSV, LLC for the April 1, 2014 review cycle to relocate three (3) operating rooms to an off-site location in southern Caldwell County.

The following comments will demonstrate that the application should not be approved as it fails to conform to all applicable review criteria as required by G.S. §131E-183.

CON Review Criterion 3

The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

The application does not conform to Criterion 3 for the following reasons.

- Volume projections for the proposed CSC are heavily dependent upon Caldwell County residents increasing their utilization of ambulatory surgery services in Caldwell County even though the population of Caldwell County and other counties in the proposed service area are experiencing declines in population.
- The secondary service area overestimates the number of “other counties” likely to utilize CSC, particularly counties for which the new location would actually increase the distance between resources currently available in Lenoir and the proposed new location.
- The assumptions regarding patient “in-migration” are not reasonable.
- The project location does not materially improve access to ambulatory surgical services in Caldwell County.
- Current utilization rates indicate that more than sufficient resources exist to meet need for ambulatory surgical services by Caldwell County residents.
- The 2014 SMFP clearly documents that the supply of operating rooms in Caldwell County exceeds the number needed by 2.09 rooms.

The application proposes the relocation of three (3) operating rooms from Caldwell Memorial Hospital’s Hancock Surgery Center to a site in Granite Falls, located approximately 9.5 miles south of Caldwell Memorial Hospital (page 26). The application indicates that the new location will improve accessibility

to ambulatory surgical services for Caldwell County residents, resulting in greater numbers of Caldwell County residents remaining in Caldwell County for these services. The application, however, fails to support the assumptions upon which projected volumes are based.

Primary Service Area

The Caldwell Surgery Center (CSC) CON application defines its primary service area as Caldwell County. The application states that one of the primary motivations for relocating three (3) operating rooms from Lenoir to Granite Falls is to increase the number of Caldwell County residents remaining in Caldwell County for ambulatory surgical services. However, the population of Caldwell County is projected to decline between 2012 and 2019, the third year of CSC’s operation as are the populations of a number of other counties included in the proposed secondary service area.

As the following table illustrates, the projected populations of five of the ten counties included in the primary and secondary service area of CSC are estimated to decline by 2019. In addition, three of the five counties with projected population increases would be required to travel longer distances to access the proposed CSC than currently required to access ambulatory surgery at either Caldwell Memorial Hospital or Hancock Surgery Center. Population growth is projected for Catawba County but according to the application should have virtually no impact on the cases projected for CSC. As the application explains on page 45, no significant gains in patient origin or market share are expected for Catawba County.

County	Estimate		Projections						Net Chng 2012-19
	Jul-12	Jul-13	Jul-14	Jul-15	Jul-16	Jul-17	Jul-18	Jul-19	
Alexander	37,361	37,183	37,012	36,853	36,714	36,585	36,471	36,367	-994
Ashe	27,326	27,464	27,446	27,524	27,528	27,590	27,608	27,657	331
Avery	17,795	17,856	17,748	17,790	17,712	17,729	17,670	17,673	-122
Burke	90,051	89,551	89,152	88,793	88,468	88,178	87,914	87,675	-2,376
Caldwell	82,590	82,312	82,041	81,794	81,570	81,365	81,181	81,014	-1,576
Catawba	155,353	156,181	156,919	157,659	158,399	159,137	159,877	160,615	5,262
Cleveland	97,800	97,276	96,901	96,568	96,272	96,010	95,775	95,568	-2,232
Lincoln	79,512	79,594	79,942	80,286	80,632	80,978	81,323	81,670	2,158
Watauga	52,472	52,954	53,614	54,272	54,931	55,588	56,250	56,908	4,436
Wilkes	69,625	70,046	70,359	70,671	70,984	71,298	71,608	71,923	2,298

Source: NC Office of State Budget and Management.

The application attempts to overcome its heavy reliance on Caldwell County population by projecting significant increases in the number of ambulatory surgery cases performed on residents of Caldwell County in any North Carolina licensed OR, resulting in a substantial increase of the ambulatory surgery use rate used to project future volume. However, this assumption is not supported by actual utilization data. See “Use Rate” discussion that follows in response to Criterion 3. Population declines make it unlikely that the number of ambulatory surgery cases for residents of Caldwell County will actually increase between 2012 and 2017, the first year of CSC’s operation. As a result, it is unlikely that the use rate can be expected to increase steadily throughout the projection period.

The applicant also contends that relocating the new CSC to the southern portion of Caldwell County will result in more Caldwell County residents remaining in Caldwell County for care. However, this ignores the fact that more persons reside in Lenoir than in the municipalities that make up the southern portion of the Caldwell County. A table comparing estimated municipality populations for 2011 is provided below. As the table indicates, Lenoir’s population exceeds the total of all municipalities located in the southern portion of the county (Cajah’s Mountain, Granite Falls, Hudson, and Sawmills).

County/Municipality	Apr-11 Population
Caldwell County	83,029
Blowing Rock(Part)	49
Cajah's Mountain	2,823
Cedar Rock	300
Gamewell	4,051
Granite Falls	4,722
Hickory(Part)	18
Hudson	3,776
Lenoir	18,228
Rhodhiss(Part)	370
Sawmills	5,240
Southern Municipalities	16,561

Source: North Carolina Office of State Management and Budget.

Established commuter patterns are likely to continue to result in a large percentage of Caldwell County residents seeking medical services in other counties, particularly if their employers’ health insurance networks include primarily local providers. To avoid out-of-network charges, Caldwell County residents employed outside Caldwell County will likely continue to seek medical services, including ambulatory surgery services, in counties other than Caldwell.

Secondary Service Area

The secondary service area defined in the application of Caldwell Surgery Center includes counties other than Caldwell that have historically received ambulatory surgery services at Caldwell Memorial Hospital. As supporting documentation the applicant provides patient origin data on page 59 of the application. The application also identifies a number of counties for which patient origin is assumed to be similar at the new CSC as at Caldwell Memorial Hospital. Counties other than Caldwell included in the projected volume at Caldwell Surgical Center are identified on the following page.

Caldwell Memorial Hospital Ambulatory Surgery Patient Origin October 1, 2012 to September 30, 2013	10/1/12-9/30/13 Total	Other Counties Included
Caldwell	2,613	
Burke	125	125
Catawba	72	72
Watauga	51	51
Wilkes	77	77
Ashe	14	14
Lincoln	22	22
Alexander	25	25
Avery	10	10
McDowell	4	4
Gaston	5	
Other NC Counties	15	
Out of State	13	
	3,046	400
% Other Counties of Caldwell County Use		15.31%

The application describes how the proposed location of the new CSC will improve geographic access to ambulatory surgery services presently received at Caldwell Memorial Hospital. However, this is not true for a number of the counties included in the volume projections for CSC. The new location in southern Caldwell County would increase travel times for residents of Avery, Ashe, Wilkes, Watauga, Alexander Counties. The projected patient origin for CSC assumes some reduction in the percent these counties make up of the total projected CSC volume. The physicians responsible for referring patients to CSC will be the same physicians presently treating these patients at Caldwell Memorial Hospital. Because the application contains no physician offices at the proposed site, patients from Avery, Ashe, Wilkes, Watauga, and Alexander Counties are likely to continue to visit these physicians at their offices in Lenoir. Without documentation that supports the patient origin for counties included in the proposed secondary services, including these counties in the projected service area of the new ambulatory surgery center inflates the percentage of "other counties" to be served at CSC. This, in turn, artificially inflates the volume projections for CSC. See the following table.

Caldwell Memorial Hospital Ambulatory Surgery Patient Origin October 1, 2012 to September 30, 2013	10/1/12-9/30/13 Total	Other Counties Included	Other Counties Closer to New Location
Caldwell	2,613		
Burke	125	125	125
Catawba	72	72	72
Watauga	51	51	
Wilkes	77	77	
Ashe	14	14	
Lincoln	22	22	22
Alexander	25	25	
Avery	10	10	
McDowell	4	4	4
Gaston	5		
Other NC Counties	15		
Out of State	13		
	3,046	400	223
% Other Counties of Caldwell County Use		15.31%	8.53%

The application assumes that 12 percent “in-migration” is more conservative than the 19 percent of ambulatory surgery patients represented by “other counties” on the 2013 license renewal application (2012 data, page 44). However, as illustrated above the percentage of patients from counties included in the projected secondary service area made up only 15.31 percent of ambulatory surgery patients originating from Caldwell County in 2013 ($400/2,613 = 15.31\%$, page 59). When cases from counties located farther from the new location than CMH are removed, the percentage drops to 8.53 percent. As a result the number of cases projected for the secondary service is not justified.

Projected Use Rate

The rate at which Caldwell County residents utilize ambulatory surgery services was cited as justification for the development of an additional ambulatory surgery location in Caldwell County. The map provided on page 33 of the application indicates that Caldwell County ranks in the top 21 counties in North Carolina for the number of ambulatory surgical visits (including endoscopy) per 1,000 population (2009-2010). Caldwell County’s higher than normal use rate for ambulatory surgery services indicates that resources are more than sufficient to meet residents’ needs for ambulatory surgery now and throughout the projection period.

The application ignores the fact that the population of Caldwell County is actually expected to decline throughout the projection period. The table below shows that a declining population in Caldwell County can be expected to result in reductions in the number of ambulatory surgical cases for Caldwell County residents, from 6,995 in 2012 to 6,862 in 2019, even assuming that use rates remain at the 2012 rate.

	2012	2013	2014	2015	2016	2017	2018	2019
Caldwell County Population	82,590	82,312	82,041	81,794	81,570	81,365	81,181	81,014
Actual/Proj. 2012 AS Cases	6,995	6,971	6,949	6,928	6,909	6,891	6,876	6,862
Actual 2012 Use Rate	84.70	84.70	84.70	84.70	84.70	84.70	84.70	84.70

Source: Population - OSBM

Declining population in Caldwell County will likely continue to place downward pressure on the volume of ambulatory surgery cases performed on Caldwell County residents. As the table below illustrates, the volume of ambulatory surgery cases performed at Caldwell Memorial Hospital has declined in all but one year since 2008-09. Most recently, Caldwell Memorial Hospital experienced a six percent decline in the number of ambulatory surgical cases between 2012 and 2013. Declines were also reported between 2009 and 2010 and between 2010 and 2011.

Caldwell Memorial Hospital Surgical Volume

	Inpatient Surgical Cases	Percent Chng from Previous Year	Outpatient Surgical Cases	Percent Chng from Previous Year	Total Surgical Cases	Percent Chng from Previous Year
2013	1,332	-10.0%	3,046	-6.0%	4,378	-7.2%
2012	1,480	12.9%	3,240	16.2%	4,720	15.1%
2011	1,311	-11.6%	2,789	-2.6%	4,100	-5.7%
2010	1,483	2.7%	2,863	-1.1%	4,346	0.2%
2009	1,444		2,894		4,338	

Source: NC Hospital License Renewal Applications.

The projected number of inpatient cases for Caldwell Memorial Hospital is not supported by evidence provided in the application. Utilization projections on page 47 of the application assume that inpatient surgery cases as CMH will increase by 2% annually between 2013 and 2019. However, as the data provided on page 47 indicates, the number of inpatient surgical cases (excluding C-sections performed in C-section rooms), fell by 10% between 2012 and 2013. One of the reasons given for the projected increase in the number of inpatient surgery cases is based on successful physician recruitment in the specialties of general surgery, urology, and otolaryngology. However, the vast majority of surgeries performed by otolaryngologists are performed on an outpatient basis. Given the decline in inpatient surgical procedures between 2012 and 2013 of 10%, it is unlikely that the number of inpatient cases will increase at an annual rate of 2%.

Utilization projections contained in the application are also overstated because the assumptions related to market share are incorrect. The percentage of Caldwell County residents projected to utilize the new CSC is assumed to increase from 37.5% in 2012 to 46% by Year 3 of the project (2019). However, the 38% market share assumed for CSC in Year 1 of the project is based on the Caldwell County market share for ambulatory surgery enjoyed by Caldwell Memorial Hospital ($2,626 / 6,997 = 37.5\%$). Although the application assumes that Caldwell County market share at the new CSC will be 38% in Year 1, page 44 includes the statement that, "...approximately one half of the ambulatory surgery cases from Caldwell Memorial Hospital and the Hancock Surgery Center..." will be shifted to CSC. This would result in

approximately 19% market share of Caldwell County residents shifting to the new CSC in Year 1, not the entire 38% of Caldwell County residents seeking ambulatory surgical services at CMH. The resulting volumes would be significantly less than those projected in the application. Applying the 19 percent market share to the projected number of ambulatory surgery cases above would result in 1,309, 1,306, and 1,304 ambulatory surgery cases at CSC in Years 1 through 3, respectively. As a result, the utilization projections are not feasible.

A primary reason given for developing the new surgery location is to allow a greater number of Caldwell County residents to remain in Caldwell County for ambulatory surgery services. However, the supply of ambulatory surgery resources is more than adequate to meet residents' need for ambulatory surgery. The use rate of ambulatory surgical services by Caldwell County residents ranks among the highest in North Carolina. This higher-than-average utilization of ambulatory surgery indicates that resources are easily accessible to Caldwell County residents. The number of operating rooms in Caldwell County already exceeds the need resulting from the SMFP need methodology for operating rooms by greater than two rooms according to the 2014 SMFP. In addition, relocating operating rooms from Lenoir, the most populous municipality in Caldwell County, to the southern portion of Caldwell County is unlikely to increase the number of Caldwell County residents remaining in the county for care.

Orthopedic Utilization

Orthopedic cases are projected to make up the majority of cases to be performed at Caldwell Surgery Center. The projected number of orthopedic cases to be performed at CSC is 2,255 in Year 1, 2,500 in Year 2 and 2,746 in Year 3 (page 48). However, based on license renewal applications for years ending September 2010, 2011, and 2012, orthopedic cases performed at Caldwell Memorial Hospital were well below those projected in the application and have actually declined in recent years, from 1,002 in 2010 to 828 in 2012.

	CMH Ortho Amb Cases	Hancock Ortho Amb Cases	Total Ortho Amb Cases
2010	481	521	1002
2011	557	323	880
2012	524	304	828

As the above table suggests, the number of orthopedic cases would need to more than triple to reach the volume projected in Year 3 of the CSC application. This will be difficult given the retirement of an orthopedic surgeon described in the application.

Recruitment efforts are cited as one way that the applicant plans to achieve the projected volumes. However, no specific recruitment efforts were described to address the number of orthopedic surgeons. In addition, letters were provided from orthopedic surgeons stating their intent to perform procedures at CSC along with estimated volumes for the first year of operation. The application includes letters from orthopedic surgeons estimating the number of cases they intend to perform in the first year of operation of CSC. Those estimates range from 1,945 to 2,730 (page 40). At present, four of the twelve orthopedic surgeons stating their intent to perform cases at CSC have privileges at Caldwell Memorial Hospital. However, the letters did not address the impact the projected volumes at CSC will have on CMH. Neither

did the letters describe how the physicians would achieve these volume increases, particularly those that currently perform cases at CMH as well as at multiple facilities in contiguous counties.

Given that the number of orthopedic surgeons is not expected to change significantly (in fact, one orthopedic surgeon retired during 2013, page 42) achieving the aggressive orthopedic projections is unlikely. In addition, as the table above illustrates, substantially more orthopedic cases are performed at CMH than at the Hancock Surgery Center. If, as the applicant states, approximately one-half of the cases will be shifted to the new CSC in Year 1, this would result in only 152 cases being performed at the new CSC (304 in 2012 / 2 = 152 orthopedic cases). This is significantly below the 2,255 orthopedic cases projected for Year 1 of project, further undermining the feasibility of the projected CSC volumes.

Orthopedic volume projections may also be difficult to achieve because the CSC Bylaws require that physicians receiving privileges at CSC must also have comparable privileges at Caldwell Memorial Hospital. This would require that existing orthopedic surgeons maintain privileges at Caldwell Memorial as well as the new CSC. Only eight of the twelve orthopedic surgeons that supplied letters with estimated first year volumes currently have privileges at Caldwell Memorial Hospital. Meeting the requirements of active medical staff membership and maintaining privileges at multiple hospitals and ASCs will make it difficult for these orthopedic surgeons to achieve the volume targets contained in the application. The inability of the existing supply of orthopedic surgeons to adequately cover cases at both CSC and CMH, as well as the other facilities where they currently maintain privileges, could seriously jeopardize the ability to reach the volumes projected at both CMH and CSC.

Need for Minor Procedure Room

The applicant states that a minor procedure room is needed to allow flexibility in determining whether minimally invasive surgical procedures will be performed in an operating room or in a procedure room. However, no documentation was provided to support the projected number of cases to be performed in the procedure room in any of the three years of the projection period. Based on statements made on page 49 of the application, it is likely that some percentage of those cases will actually be cases included in the volume projections for the CSC ORs. As a result it is impossible to determine what portion of the procedure room cases will actually be surgical cases which will reduce the number of cases performed in the licensed ORs. This not only calls into question the volume projections for the operating rooms but fails to justify the volume of cases projected for the procedure room.

There are other questions about the types of procedures to be performed in the minor procedure room. On page 12 of the application it states that the minor procedure room "will be used to perform minimally invasive pain management procedures and infusion care." However, page 49 of the application describes the types of procedures to be performed as minimally invasive surgical procedures and low complexity pain management procedures. It does not appear that staffing numbers included personnel for the provision of infusion care or that ancillary services to be provided are sufficient to support this service. As a result it is impossible to determine either the number of exact types of procedures to be performed in the minor procedure room.

The line drawing of the proposed CSC suggests that the minor procedure room will be laid out exactly as the three licensed operating rooms. It also appears to be the same size as the proposed operating rooms. The applicant clearly states that the availability of the procedure room will allow provide flexibility for surgeons wishing to perform minimally invasive surgery in the procedure room. This would indicate that the proposed CSC will have not three but four operating rooms.

A significant portion of cases to be performed in the CSC procedure room is expected to involve pain management procedures. Although not stated specifically, most pain management procedures are performed by anesthesiologists. Unifour Anesthesia Associates, PA provided a letter stating its intention to provide anesthesia services to CSC with a total of twenty (20) board-certified anesthesiologists. Because Unifour Anesthesia Associates also provides anesthesia and pain management procedures at Caldwell Memorial Hospital, it is assumed that UAA will also provide pain management procedures at CSC. The medical staff bylaws of CSC require that physicians granted privileges at CSC must maintain comparable privileges at Caldwell Memorial Hospital (unless they are only providing anesthesia services). (See CON Application Exhibit 6.)

Unifour Anesthesia Associates, PA already provide anesthesia services to multiple locations. According to its website, UAA provides anesthesia services for Caldwell Memorial Hospital, Hancock Surgery Center, Davis Regional Medical Center, Frye Regional Medical Center, Viewmont Surgery Center, and Unifour Surgery Center. UAA also provides pain management services at four office locations in addition to hospital and ASC locations in the region. The applicant did not provide documentation of how Unifour Anesthesia Associates will be able to supply the manpower necessary to support the projected volume at CSC as well as maintain comparable privileges are CMH and other area providers. Without sufficient anesthesia resources, the volume projections for both CSC and CMH are unreasonable.

CON Review 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.

The application does not conform to Criterion 3a for the following reasons

Demographic Data

An aging population is cited for one reason that the new CSC is required and for relocating the center to the southern portion of Caldwell County. However, the most persons over the age of 65 live in Lenoir, the current location of the Hancock Surgery Center and Caldwell Memorial Hospital. As seen in the table below, significantly more persons aged 65+ reside in Lenoir (zip code 28645) than in Granite Falls (zip code 28630) and Hudson (zip code 28638), both located in the southern portion of the county. A comparison of the median age of the county and service area zip codes is also provided.

Caldwell County Residents Aged 65+ for Select Zip Codes

Zip Code/County	City/County	Number Aged 65+	% Persons Aged 65+
Caldwell County	Total	12,847	100.00%
Zip Code 28645	Lenoir	7,793	60.66%
Zip Code 28638	Hudson	2,082	16.21%
Zip Code 28630	Granite Falls	2,611	20.32%

Source: US Census Bureau, American FactFinder 5-year survey, 2008-2012.

Caldwell County Median Age for County and Select Zip Codes

Zip Code/County	City/County	Median Age
Caldwell County	Total	41.2
Zip Code 28645	Lenoir	42.5
Zip Code 28638	Hudson	41.1
Zip Code 28630	Granite Falls	38.8

Source: US Census Bureau, American FactFinder 5-year survey, 2008-2012.

The applicant assumes that the relocation of three (3) ORs from the Hancock Surgery Center to the new CSC will reduce the number of Caldwell County residents leaving the county for ambulatory surgery services. However, as seen above the greatest number of persons residing in Caldwell County live in the Lenoir area, not the southern portion of the county. In addition, residents of Caldwell County must still travel to Lenoir to access the surgeons proposing to perform surgery at CSC. Caldwell County residents already have sufficient access to ambulatory surgery services at a convenient location in Lenoir with easy access to three major travel arteries, US 321, US 64, and NC 18.

Access to ambulatory surgery services will not be enhanced for the majority of Caldwell County residents. In 2013, Caldwell Memorial Hospital reported a total of 3,046 ambulatory surgical cases. By 2019, that number is projected to fall to 1,739. However, more than one-half of Caldwell County residents live in Lenoir (zip code 28645). As a result a significant proportion of Caldwell County residents living in Lenoir will be forced to travel to the new CSC for outpatient orthopedic, general surgery, and podiatry services. While the new location will improve convenience for persons living in the southern portion of the county, it will create new barriers for residents of Lenoir, the location of the majority of Caldwell County residents as well as for residents of Ashe, Avery, Alexander, Wilkes, and Watauga Counties.

The applicant further asserts that the new Caldwell Surgery Center will improve access in terms of hours of operation and access by all categories of payers, including charity care patients (page 13). Hours of operation of the new CSC will be 7:00 AM to 5:00 PM. However, no information was provided comparing the hours of operation of the Hancock Surgery Center. This makes it impossible to determine

whether the hours of operation will actually increase access to ambulatory surgery services as asserted in the CSC application.

These hours of operation are also unlikely to accommodate the needs of a significant portion of Medicare patients. Due to their age, co-morbidities and poly-pharmacy requirements, many of these patients will not meet selection criteria for surgery at CSC. Many will require post-surgical recovery times beyond 5:00 pm. Many will require extended observation prior to discharge. The lack of extended hours and staffing to accommodate the needs of these patients suggests that access will not be improved for a significant number of Medicare patients. It also suggests that the payer mix attributable to Medicare patients may be suspect.

The proposed location of the new CSC is also unlikely to achieve the same payer mix at ambulatory surgery services at Caldwell Memorial Hospital. As described in response to Criterion 13, the proposed location of the new CSC will be in the most affluent portions of Caldwell County. The majority of persons living in poverty and likely to require charity care or Medicaid coverage reside in Lenoir, not the municipalities located in the southern most portions of Caldwell County. This makes it unlikely that the payer mix will be the same for CSC as for CMH. In fact the complex health conditions faced by many Medicare patients will make them unlikely candidates for surgery at free-standing centers unable to accommodate extended post-surgical stays.

CON Review 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.

A number of alternatives were discussed and found inferior to the development of a new ambulatory surgery center in Caldwell County. One reason given was the age of the Hancock Surgery Center, approaching one-half of its useful life (page 60). However, the applicant states that its two GI endoscopy rooms will remain at Hancock Surgery Center as will its pain management services and its infusion therapy. The Hancock Surgery Center is conveniently located on Morganton Boulevard, separate from Caldwell Memorial Hospital. The location is just one mile off U.S. 321, the major transportation artery through Caldwell County making it easily accessible for the majority Caldwell County residents.

Maintaining the three operating rooms at the Hancock Surgery Center, even if renovations are required, is a more cost effective alternative than the relocation of existing operating rooms away from the greatest number of Caldwell County residents, particularly those identified as medically underserved. Caldwell County residents would be better served if the Hancock Surgery Center were converted to a separately licensed ambulatory surgical facility and hence charges reduced. This would represent a more cost effective alternative than the purchase of land and the long-term lease of a new ambulatory surgery center as proposed. In fact, the application essentially admits this by proposing to lease Hancock as a separately licensed facility while CSC is being developed.

The Hancock Surgery Center also provides a safer alternative than the proposed location in Granite Falls in the case of a patient emergency. The current location of Hancock Surgery Center is less than one mile from Caldwell Memorial Hospital. Google Maps gives the distance from the Granite Falls location to CMH as 13.5 miles via US 321, the most heavily travelled highway in Caldwell County. The increased distance, coupled with heavy traffic, will create new barriers to emergency care that do not exist at the

Hancock Surgery Center. In fact, the proposed location of CSC is only 5.2 miles to Frye Regional Medical Center in Hickory (Catawba County).

The application has not supported the contention that the development of the project represents the least costly or the most effective alternative. For this reason, application does not conform to Criterion 4.

The application also fails to support the need for the relocation of three (3) operating rooms from Hancock Surgery Center to the new CSC. The 2014 State Medical Facilities indicates that Caldwell County already has an excess of two operating rooms. Therefore, the most effective alternative would involve reducing the number of surplus operating rooms to better accommodate the needs of Caldwell County.

CON Review Criterion 5

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

As described in these comments, the application does not conform to Criteria 3, 3a, 4, on 5, 13, and 18a. Because the projected utilization is overstated, estimated costs and revenues are not supportable

CON Review 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.

The application does not conform to Criterion 6 for the following reason.

As described in response to Criterion 4, the State Medical Facilities indicates that the number of operating rooms in Caldwell County already exceeds the need for operating rooms by 2.09 rooms (2014 SMFP). Relocating three (3) operating rooms to the new CSC, along with a procedure room, will further duplicate existing ambulatory surgical resources in Caldwell County.

CON Review 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.

Because the application fails to justify the need for the project, it also fails to conform to Criterion 7.

CON Review 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.

The application does not conform to Criterion 8 for the following reasons.

On page 10 of the application the applicant states that the Pharmacy and biomedical equipment maintenance services will be provided through a services agreement as outlined in Exhibit 11. However, the table on page 9 indicates that the biomedical equipment maintenance will be provided by "Facility staff." No biomedical equipment maintenance services staff were identified in the proposed staffing for the new CSC (page 78). This discrepancy makes it impossible to determine whether sufficient arrangements are in place to provide the necessary ancillary and support services.

CON Review 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.

The application does not conform to Criterion 9 for the reasons provided in response to Criterion 3.

CON Review Criterion 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.

The application does not justify the need for the proposed project. As a result it does not conform to Criterion 12. In addition, costs for preparation of the Certificate of Need application were not included in the total project costs.

CON Review 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;*
- 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. 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*
- 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.*

The application does not conform to Criterion 13 for the following reasons. The relocation of three operating rooms from Hancock Surgery Center to Granite Falls can be expected to actually reduce the access to ambulatory surgery services for medically underserved groups. Persons residing in the southern portion of Caldwell County have incomes significantly above those of persons residing in Lenoir. In fact, the number of persons living in poverty in the municipality of Lenoir exceeds the total of all municipalities located in the southern portion of Caldwell County.

Municipality Name	Year	Median Family Income	Persons in Poverty	Percent Persons in Poverty	Persons 65+ in Poverty	Percent Persons 65+ in Poverty
Lenoir	2010	\$29,860	3,830	21.6	432	14.6
Granite Falls	2010	\$46,544	495	10.9	66	11.5
Hudson	2010	\$45,296	532	14.5	72	11.7
Cajahs Mountain	2010	\$48,571	328	11.8	37	7.8
Sawmills	2010	\$43,878	954	18.4	127	19.3

Source: Linc Report, OSBM.

As the above table illustrates, the number of persons living in poverty is much greater for Lenoir than for municipalities located in southern Caldwell County. The total number of persons living in poverty for these municipalities was 2,309 in 2010 as compared to 3,830 in Lenoir. The number of persons aged 65 and over living in poverty was also lower for southern Caldwell County municipalities than Lenoir, 302 as compared to 432. As the chart also illustrates, the median family incomes for residents of southern Caldwell County are well above those for Lenoir area residents. Relocating ambulatory surgery rooms to southern Caldwell County will reduce access for residents traditionally identified as medically underserved in favor of the more affluent population of southern Caldwell County.

The proposed relocation to the southern portion of Caldwell County will also hamper access for persons over the age of 65. The current location of the Hancock Surgery Center is Lenoir. The application proposes relocating the three (3) operating rooms from the Hancock Surgery to the proposed location in

Granite Falls. The application indicates that this will improve access for the rapidly growing senior population. However, as the table below illustrates, significantly more persons over the age of 65 reside in Lenoir than in municipalities located in the southern portion of Caldwell County.

Municipality/ County	Year	Total Population	Population 65+
Lenoir	2010	18,228	3,373
Granite Falls	2010	4,722	667
Hudson	2010	3,776	655
Cajahs Mountain	2010	2,823	519
Sawmills	2010	5,240	697
Caldwell County	2010	83,029	12,816

Source: LINC Topic Reports, NC OSBM.

The new location of CSC will also hamper access to the county's racial and ethnic minorities. Data compiled by the U.S. Census Bureau shows that the majority of racial and ethnic minorities live in Lenoir, not the southern portion of Caldwell County. Data represent zip code areas that extend beyond municipality boundaries. For example, Sawmills and Cajah's Mountain do not have individual zip codes. The only zip codes located south of Lenoir are Granite Falls and Hudson.

Race	Caldwell County	Lenoir	Hudson	Granite Falls
White	74,276	40,199	11,639	19,233
Black or African American	3,928	3,609	42	211
American Indian/Alaska Native	289	171	0	82
Asian	477	407	0	70
Native Hawaiian/Other Pacific	74	38	0	36
Some Other Race	2,295	1,825	224	246
Two or More Races	1,154	788	69	354
Hispanic	3,796	2,576	621	490

Source: U.S. Census Bureau, American FactFinder, 5-year study 2008 - 2012.

The new location of the proposed Caldwell Surgery Center cannot be expected to improve access for most Caldwell County residents. The majority of Caldwell County residents live in the Lenoir area, not the southern portion of the county. The majority of Caldwell County's residents living in poverty live in the Lenoir area. In addition, the majority of persons of racial and ethnic minorities reside in Lenoir, not the southern portion of Caldwell County. In fact the proposed site of CSC is located in the most affluent portion of Caldwell County and will not improve access for persons historically identified as medically underserved.

CON Review 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.

The application fails to justify the need for the project. As a result it does not conform to Criterion 14.

CON Review Criterion 18a

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

The application does not conform to Criterion 18a for the following reasons.

The application indicates that the proposed Caldwell Surgery Center will improve competition with other existing providers (page 69). The only existing provider of ambulatory surgery services currently located in the applicant's primary service area is Caldwell Memorial Hospital. According to the application, Caldwell Memorial Hospital will be the sole member of the limited liability partnership SCSV which will own the new ambulatory surgical facility. Therefore, Caldwell Memorial Hospital will continue to operate and own the only ambulatory surgical facilities in Caldwell County. As a result, competition will not improve as a result of this project.

This criterion is not applicable as the application fails to justify the need for the proposed project.

Summary

Based on the information provided in these comments, the Caldwell Memorial Hospital/SCSV application does not conform to all applicable review criteria and should not be approved.