

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: December 28, 2015

Findings Date: January 4, 2016

Project Analyst: Gregory F. Yakaboski

Assistant Chief: Martha J. Frisone

Project ID #: E-11054-15

Facility: Caldwell Surgery Center

FID #: 140087

County: Caldwell

Applicants: Caldwell Memorial Hospital, Inc.
SCSV, LLC

Project: Develop a separately licensed ambulatory surgical facility with three operating rooms and one procedure room by relocating the three dedicated outpatient operating rooms from the Hancock Surgery Center (licensed as part of Caldwell Memorial Hospital) to the proposed Caldwell Surgery Center

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 develop a freestanding separately licensed ambulatory surgical facility (AMSU) with three operating rooms (ORs) and one procedure room by relocating the three existing dedicated outpatient ORs from the Hancock Surgery Center (HSC) to Caldwell Surgery Center (CSC). HSC is licensed as part of CMH but at a separate location.

According to Table 6A, on page 67 of the 2015 SMFP, CMH owns and operates all eight ORs located in Caldwell County (includes the one dedicated C-section OR at CMH). There are no approved ORs in Caldwell County. There are no existing or approved AMSUs located

in Caldwell County. The total number of ORs (eight) will not increase as a result of this proposal, only how the eight ORs are licensed and where they are located within Caldwell County. The three dedicated outpatient ORs at HSC, which are licensed as part of the hospital, will be moved and licensed separately as an AMSU.

Need Determination

The proposed project does not involve the addition of any new health service facility beds, services or equipment for which there is a need determination in the 2015 SMFP.

Policies

There is one policy 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 120-121, the applicants provide a written statement describing the proposed project’s plan to assure improved energy efficiency and water conservation. The application is consistent with Policy GEN-4.

Conclusion

In summary, the applicant demonstrates that its proposal is conforming to all applicable policies in the 2015 SMFP. Therefore, the application is conforming to this criterion.

- (2) Repealed effective July 1, 1987.
- (3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C

CMH and SCSV propose to develop a freestanding separately licensed AMSU with three ORs and one procedure room by relocating the three existing dedicated outpatient ORs from HSC to CSC. HSC is licensed as part of CMH but at a separate location.

According to Table 6A, on page 67 of the 2015 SMFP, CMH owns and operates all eight ORs located in Caldwell County (includes the one dedicated C-section OR at CMH). There are no approved ORs in Caldwell County. There are no existing or approved AMSUs located in Caldwell County. The total number of ORs (eight) will not increase as a result of this proposal, only how the eight ORs are licensed and where they are located within Caldwell County. The three dedicated outpatient ORs at HSC, which are licensed as part of the hospital, will be moved and licensed separately as an AMSU.

Population to be Served

On page 60, the 2015 SMFP defines the service area for ORs as “*the operating room planning area in which the operating room is located. The operating room planning areas are the single and multicounty groupings shown in Figure 6-1 [on page 65].*” Figure 6-1 shows Caldwell County as a single county OR service area. Thus, the service area for this proposal is Caldwell County. Facilities may also serve residents of counties not included in their service area.

In Section III.6, page 123, the applicants provide the projected patient origin for the ORs during the first two operating years following completion of the project, as shown in the table below.

**Operating Rooms
Projected Patient Origin**

County	Operating Year (OY) 1	OY 2	%
Caldwell	1,514	1,695	50.20%
Catawba	573	642	19.01%
Burke	261	293	8.67%
Watauga	180	201	5.96%
Alexander	149	166	4.93%
Wilkes	124	139	4.11%
Lincoln	77	86	2.54%
McDowell	41	46	1.36%
Iredell	24	27	0.80%
Ashe	14	15	0.46%
Gaston	11	13	0.38%
Avery	7	8	0.23%
Cleveland	2	2	0.06%
TN and Other*	39	44	1.30%
Totals	3,015	3,377	100.00%

*TN and Other includes Tennessee, Virginia and Other States.

In Section III.6, page 124, the applicants provide the projected patient origin for the procedure room during OYs 1 and 2, as shown in the table below.

**Procedure Room
Projected Patient Origin**

County	OY 1	OY 2	%
Caldwell	250	278	38.52%
Catawba	117	130	17.96%
Burke	91	102	14.06%
Watauga	51	57	7.86%
Lincoln	37	41	5.71%
Wilkes	27	30	4.17%
Gaston	17	19	2.66%
Alexander	17	18	2.55%
Ashe	8	9	1.23%
McDowell	6	7	0.98%
Iredell	6	7	0.97%
Avery	6	6	0.88%
Cleveland	2	2	0.27%
TN and Other*	14	16	2.18%
Totals	650	722	100.0%

*TN and Other includes Tennessee, Virginia and Other States.

The applicants provide the assumptions and methodology used to project patient origin on pages 88-92; 93-96 and 124-125. On pages 124-125, the applicants state:

“The patient origin data for the proposed project is based on the historical patient origin data for the physicians. Please see the page [sic] 89, 90, 94 and 95. Patients from Burke, Catawba, Watauga, Wilkes and Alexander will have access

to the proposed Caldwell Surgery Center. Ambulatory surgery patients are expected to travel to CSC from these counties due to existing patient relationships, participating surgeons, primary care physicians, long term care facilities and patient relationships with Caldwell Memorial Hospital and its affiliates. It is also reasonable that some patients from these contiguous counties have family members who reside in Caldwell County and will be involved in the patient's post-operative care. Therefore, some patients that reside in counties adjacent to Caldwell County will travel to and from the homes of family members who live in Caldwell County and near the CSC facility location.

Other NC counties include Ashe, Avery, Lincoln and McDowell Counties because multiple patients from these counties have obtained ambulatory surgery at Caldwell Memorial Hospital in previous years. Ambulatory surgery patients from these other counties are expected to travel to CSC due to existing patient referral relationships between primary care physicians and the surgeons and Caldwell Memorial Hospital.

The applicants have reviewed the patient origin data for the freestanding ambulatory surgery facilities in Burke and Catawba Counties and confirmed that patients from Caldwell, Watauga, Wilkes, Alexander, Ashe, Avery, Lincoln and McDowell Counties have historically traveled to the ambulatory surgery facilities in Burke and Catawba Counties and that these patients likely traveled past existing hospital-based operating rooms to reach the ambulatory surgical facilities. The cost savings and convenience of ambulatory surgery centers is motivation for some patients to travel to obtain ambulatory surgery at freestanding centers.”

The applicants adequately identify the population to be served.

Analysis of Need

In Section III Need/Demand, pages 41-137, and referenced exhibits, the applicants document the need for the proposal.

On pages 41-79, the applicants discuss 16 factors which they state support the need for the proposal, which are listed below along with the pages where each factor is discussed in the application:

- *Enhancing Access through Physician Participation (Page 41)*
- *Expanding into the Southern Population Area (Pages 42-44)*
- *Ensuring Access to the Medically Underserved (Pages 44-46)*
- *Responding to Growth in Southern Caldwell County (Pages 47-48)*
- *Improving Caldwell County through Development (Pages 48-49)*
- *Addressing Community Needs for Care (Pages 49-51)*
- *Facing Key Health Concerns (Pages 52-58)*

- *Attracting Essential Physician Involvement* (Pages 58-59)
- *Offering Physician Investment Opportunity* (Pages 60-62)
- *Delivering Cost-Effective Care* (Pages 62-64)
- *Responding to Trends in ASC Use* (Pages 64-67)
- *Meeting Caldwell Residents' High Surgical Demand* (Pages 67-72)
- *Reversing High Outmigration* (Pages 72-73)
- *Proposed Project Involves Relocation of Existing Operating Rooms With No Increase in the Total Operating Inventory* (Pages 74-75)
- *Physician Support Data* (Pages 75-77)
- *Physician Recruitment* (Pages 77-79)

On pages 100-102, the applicants adequately document the need for the proposed procedure room and the portable C-arms.

On pages 102-104, the applicants summarize the points made on pages 41-79.

On pages 104-118, the applicants discuss why they believe that the proposed AMSU is needed in the southern part of Caldwell County and how the needs of the patients who will continue to use the ORs in the hospital in Lenoir will be met.

On pages 128-133, the applicants discuss the alternatives considered and why the proposal was chosen.

On pages 134-137, the applicants identify all providers of outpatient surgical services in the service area, which is Caldwell County.

Based on review of: 1) the information provided by the applicants in Section III Need/Demand, pages 41-137, including referenced exhibits; 2) comments received during the first 30 days of the review cycle; and 3) the applicants' response to the comments received at the public hearing, the applicants adequately document the need to relocate the three existing dedicated outpatient ORs from HSC to the proposed CSC, which will be licensed as an AMSU.

Projected Utilization – Operating Rooms

In Section IV.1, page 140, the applicants provide projected utilization of the ORs during the first three OYs [Calendar Years (CYs) 2018 – 2020], as illustrated in the table below:

Operating Rooms			
	OY 1 (CY 2018)	OY 2 (CY 2019)	OY 3 (CY 2020)
# of ORs	3	3	3
Total Cases	3,015	3,377	3,740

In Section III, pages 79-99, the applicants provide the assumptions and methodology used to project utilization, which are summarized below.

Step #1: The applicants started with physician estimates of the number of cases they believe they will perform in the ORs and the procedure room. See the Table on page 86 and Exhibit 10 for the physician letters.

Step #2: The applicants calculated the number of ORs needed in the proposed AMSU based on the utilization projections in the Table on page 86 of the application. The following table illustrates projected surgical cases at the proposed AMSU in OY 3.

	Inpatient Cases	Outpatient Cases	Total Hours (cases x 1.5 hours / case)	Hours / 1,872 hours per OR / Year	# of ORs Needed
OY 3	----	3,740	5,610	2.996	3.0

On pages 87-88, the applicants identify factors which they believe support the reasonableness of the utilization projections, summarized as follows:

- The physician letters which provide projections for OY 1 and state *“that increased numbers of cases would follow in subsequent years.”* See Exhibit 10.
- When the physician provided a range of projected cases, the applicants summed up the low range figures for OY 1, the high range figures for OY 2 and the midpoint for OY 3. Where no range of cases was provided, the applicants assumed the same number of cases for all three operating years.
- On page 87, the applicants state that physicians with established practices and offices located near the proposed facility document their intent to obtain privileges at CMH or CSC. See Exhibits 8 and 10.
- On page 87, the applicants state *“The physician estimates in the physician support letters are specifically for cases to be performed at CSC; for physicians historically performing surgeries at CMH and/or HSC, the applicants confirmed with each physician that his/her volume estimates for CSC take into account continued surgical volume at CMH consistent with the projections as described in this Application.”*
- Physician recruitment which is documented in Exhibit 23. On page 87, the applicants state that *“recruitment of a urologist, general surgeon, otolaryngologist and gastroenterologist would add further utilization at CSC.”*
- On page 87, the applicants state that the proposed location is on a major highway with high visibility in the area of the county where the majority reside. See Exhibits 42, 43, 44 and 45.
- On page 88, the applicants state that a *“large portion”* of the cases are ones that would have been performed at HSC [2,028 cases out of a total of 3,015 cases in OY 1].

- On page 88, the applicants state that vascular and spine surgery procedures are not currently offered at other freestanding AMSUs in the region but will be offered at the proposed CSC.
- The marketing plan for the proposed AMSU. See Exhibit 30.

In Section III, in the tables on pages 80-81, 87, 97 and 139-140, the applicants provide historical and projected utilization, as illustrated in the tables below.

	10/1/12-9/30/13 (Actual)	10/1/13-9/30/14 (Actual)	10/1/14-9/30/15 *	CY 2016** (Projected)	CY 2017 (Projected)	OY 1 (CY 2018) (Projected)	OY 2 (CY 2019) (Projected)	OY 3 (CY 2020) (Projected)
CMH / HSC								
# of ORs	7	7	7	7	7	4	4	4
OP Cases	3,046	2,876	3,216	3,458	3,724	1,867	1,950	2,036
CSC								
# of ORs	0	0	0	0	0	3	3	3
OP Cases	0	0	0	0	0	3,015***	3,377	3,740
Total ORs	7	7	7	7	7	7	7	7
Total OP Cases	3,046	2,876	3,216	3,458	3,724	4,882	5,327	5,776
Difference	NA	(170)	340	242	266	1,158	445	449
% change	NA	(5.6%)	11.2%	7.5%	7.7%	31.1%	9.1%	8.4%

* Annualized based on 8 months of actual data.

** The actual data is for fiscal years starting October 1st. Projected data is for calendar years.

*** Includes 2,028 cases shifted from CMH/HSC (see page 97 of the application).

As shown in the table above, in OY 3 (CY 2020), the applicants project that 3,740 outpatient cases will be performed in one of the three ORs at the proposed CSC, which documents a need for three ORs consistent with the OR Performance Standard promulgated in 10A NCAC 14C .2103(b), as illustrated in the table below:

	Inpatient Cases	Outpatient Cases	Total Hours (OP Cases x 1.5 Hours / Case)	Total Hours/ 1,872 Hours / OR / Year	# of ORs Needed
OY 3	----	3,740	5,610	2.9	3.0

Projected utilization is based on reasonable and adequately supported assumptions.

Moreover, the following analysis shows that three ORs would still be needed at the proposed CSC if the projected utilization was as low as 2,871 outpatient cases in OY 3. There are seven ORs in a licensed health service facility in Caldwell County (excluding the dedicated C-Section room at CMH). 10A NCAC 14C .2103(b)(2)(B) states *“The number of rooms needed is determined as follows....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...”* Only 2,871 outpatient cases would have to be projected to show a need for three ORs, as shown in the following table:

	Outpatient Cases *	Total Hours (OP Cases x 1.5 Hours /Case)	Total Hours / 1,872 Hours / OR / Year	# of ORs Needed
OY 3	2,871	4,306.5	2.300	3.0

* This is the number of cases at which the result of the formula equals at least 2.3, without any rounding.

As shown in the first table on the previous page, more than 2,871 outpatient cases were performed at CMH / HSC during each of the last two full fiscal years for which actual data is available. The proposed CSC will be a brand new state-of-the-art facility, located on a major traffic corridor only approximately 13 miles from the existing HSC, allowing for physician ownership and strongly supported by surgeons as evidenced by the letters in Exhibit 10. Moreover, the proposed CSC will be licensed as an AMSU with associated potential cost savings for patients not available at HSC, which is licensed as part of the hospital.

Projected Utilization – Procedure Room

In Section IV.1, page 140, the applicants provide projected utilization of the proposed procedure room during the first three operating years, as illustrated in the table below:

	Procedure Room		
	OY 1 (CY 2018)	OY 2 (CY 2019)	OY 3 (CY 2020)
# of Procedure Rooms	1	1	1
Total Procedure Room Cases	650	722	795

The applicants adequately demonstrate the need the population to be served has for the proposed project, which is to relocate three existing dedicated outpatient ORs to a new location still within Caldwell County and license them as an AMSU

Access

In Section VI.14, page 154, the applicants project Medicare or Medicaid would be the payor source for 63.11% of the cases performed at the proposed AMSU.

In Section VI.6, pages 148-149, the applicants outline their strategies to improve access to medically underserved groups, which includes development of a transportation fund to assist low income patients and family members to access both the proposed CSC and CMH. On page 154, the applicants state:

“The applicants are committed to provide high levels of access to the medically underserved population of Caldwell County. 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, and provide transportation assistance to patients and families if needed.”

Furthermore, the applicants adequately demonstrate that the proposed project will increase access for residents of Caldwell County in two additional ways:

1. Geographic: Currently, the seven ORs (excluding the dedicated C-section room at CMH) are all concentrated within approximately a half mile of each other in Lenoir (four shared ORs at CMH and three dedicated outpatient ORs at HSC). Upon project completion, there will be four ORs in Lenoir (three shared ORs and one dedicated outpatient OR) and three dedicated outpatient ORs in the southern part of Caldwell County.
2. Financial: Currently all seven of the ORs (excluding the dedicated C-section room at CMH) in Caldwell County are on the hospital's license. Upon project completion, there will be four ORs on the hospital's license and three ORs licensed as an AMSU with patients able to benefit from the cost savings associated with having outpatient surgery at an AMSU as opposed to having the same outpatient surgery performed in a hospital-based OR.

The applicants adequately demonstrate the extent to which all residents, including underserved groups, will have access to the proposed services.

Conclusion

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

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

C

CMH and SCSV propose to develop a freestanding separately licensed AMSU with three ORs and one procedure room by relocating the three existing dedicated outpatient ORs from HSC to CSC. HSC is licensed as part of CMH but at a separate location.

According to Table 6A, on page 67 of the 2015 SMFP, CMH owns and operates all eight ORs located in Caldwell County (includes the one dedicated C-section OR at CMH). There are no approved ORs in Caldwell County. There are no existing or approved AMSUs located in Caldwell County. The total number of ORs (eight) will not increase as a result of this proposal, only how the eight ORs are licensed and where they are located within Caldwell

County. The three dedicated outpatient ORs at HSC, which are licensed as part of the hospital, will be moved and licensed separately as an AMSU.

CMH is currently licensed for four shared ORs located in the hospital and three dedicated outpatient ORs located at HSC. CMH and HSC are both located in Lenoir only 0.6 miles or one minute from each other. The two main traffic corridors in Caldwell County, US-64 and US-321, intersect at Lenoir.

The proposed AMSU will be located approximately 13 miles from HSC. A main traffic corridor, US-321, connects the proposed facility and HSC. The proposed AMSU will be located in the same Operating Room Service Area as HSC (Caldwell County).

As part of the proposed project, CMH will turn one of the four shared ORs located in the hospital into a dedicated outpatient OR. Upon project completion, there will be no remaining ORs at HSC; however, the two existing gastrointestinal (GI) endoscopy rooms will remain at HSC.

In Section III, in the tables on pages 80, 97 and 139, the applicants provide actual and projected utilization at CMH, as illustrated in the tables below.

CMH / HSC	10/1/12-9/30/13 (Actual)	10/1/13-9/30/14 (Actual)	10/1/14-9/30/15 *	CY 2016** (Projected)	CY 2017 (Projected)	OY 1 (CY 2018) (Projected)	OY 2 (CY 2019) (Projected)	OY 3 (CY 2020) (Projected)
# of ORs	7	7	7	7	7	4	4	4
OP Cases	3,046	2,876	3,216	3,458	3,724	1,867	1,950	2,036
IP Cases ***	1,332	938	1,041	1,107	1,179	1,224	1,270	1,319

* Annualized based on 8 months of actual data.

** The actual data is for fiscal years starting October 1st. Projected data is for calendar years.

*** Excluding C-sections.

	A	B	C	D
Operating Year	Inpatient Cases	Hours per Case	Total Inpatient Hours (A x B)	# of ORs Needed (C / 1872 Hours / OR / Year)
OY 1 (CY 2018)	1,224	3.0	3,672	1.96
OY 2 (CY 2019)	1,270	3.0	3,810	2.03
OY 3 (CY 2020)	1,319	3.0	3,957	2.11
Operating Year	Outpatient Cases	Hours per Case	Total Outpatient Hours (A x B)	# of ORs Needed (C / 1872 Hours / OR / Year)
OY 1 (CY 2018)	1,867	1.5	2,801	1.5
OY 2 (CY 2019)	1,950	1.5	2,925	1.6
OY 3 (CY 2020)	2,036	1.5	3,054	1.6

As shown in the tables above, the applicants project that the three remaining shared ORs and one dedicated outpatient OR at CMH will provide adequate capacity to meet projected utilization of surgical services at CMH in Lenoir. The applicants note that both inpatient and outpatient surgeries can be performed in the three shared ORs at CMH.

In Section VI.6, pages 148-149, the applicants outline their strategies to improve access to medically underserved groups, which includes development of a transportation fund to assist low income patients and family members to access both the proposed CSC and CMH. On page 154, the applicants state:

“The applicants are committed to provide high levels of access to the medically underserved population of Caldwell County. 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, and provide transportation assistance to patients and families if needed.”

Furthermore, the applicants adequately demonstrate that the proposed project will increase access for residents of Caldwell County in two additional ways:

1. Geographic: Currently, the seven ORs (excluding the dedicated C-section room at CMH) are all concentrated within approximately a half mile of each other in Lenoir (four shared ORs at CMH and three dedicated outpatient ORs at HSC). Upon project completion, there will be four ORs in Lenoir (three shared ORs and one dedicated outpatient OR) and three dedicated outpatient ORs in the southern part of Caldwell County.
2. Financial: Currently all seven of the ORs (excluding the dedicated C-section room at CMH) in Caldwell County are on the hospital’s license. Upon project completion, there will be four ORs on the hospital’s license and three ORs licensed as an AMSU with patients able to benefit from the cost savings associated with having outpatient surgery at an AMSU as opposed to having the same outpatient surgery performed in a hospital-based OR.

The applicants demonstrate that the needs of the population presently served will be adequately met and that the proposal will not adversely affect the ability of medically underserved groups to obtain needed health care. Therefore, the application is conforming to this criterion.

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

CA

CMH and SCSV propose to develop a freestanding separately licensed AMSU with three ORs and one procedure room by relocating the three existing dedicated outpatient ORs from HSC to CSC. HSC is licensed as part of CMH but at a separate location.

According to Table 6A, on page 67 of the 2015 SMFP, CMH owns and operates all eight ORs located in Caldwell County (includes the one dedicated C-section OR at CMH). There

are no approved ORs in Caldwell County. There are no existing or approved AMSUs located in Caldwell County. The total number of ORs (eight) will not increase as a result of this proposal, only how the eight ORs are licensed and where they are located within Caldwell County. The three dedicated outpatient ORs at HSC, which are licensed as part of the hospital, will be moved and licensed separately as an AMSU.

In Section III.8, pages 128-133, the applicants describe the alternatives considered, which included maintaining the status quo, converting HSC from hospital-based to an AMSU, developing a smaller AMSU with fewer ORs or the proposed project. The applicants discuss the limitations of the current space occupied by HSC, the inadequacies of the existing ORs at HSC and the inefficiencies of developing a smaller AMSU.

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

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

1. **Caldwell Memorial Hospital, Inc. and SCSV, LLC shall materially comply with all representations made in the certificate of need application.**
2. **Caldwell Memorial Hospital, Inc. and SCSV, LLC shall develop an ambulatory surgical facility which shall be licensed for no more than three dedicated outpatient operating rooms and one procedure room by relocating the three dedicated operating rooms located at the Hancock Surgery Center.**
3. **Caldwell Memorial Hospital, Inc. and SCSV, LLC shall not perform gastrointestinal endoscopy procedures in the procedure room.**
4. **Upon completion of the project, Caldwell Memorial Hospital, Inc. shall take the steps necessary to delicense the three dedicated outpatient operating rooms located at the Hancock Surgery Center and shall be licensed for a total of no more than five operating rooms (three shared operating rooms, one dedicated outpatient operating room and one dedicated C-section operating room).**
5. **Procedures performed in the procedure room shall not be reported on the facility's license renewal application as procedures performed in an operating room.**
6. **The ambulatory surgical facility shall meet all criteria to receive accreditation of the ambulatory surgical facility from The Joint Commission, The Accreditation Association for Ambulatory Health Care or a comparable accreditation authority within two years following completion of the facility.**
7. **Caldwell Memorial Hospital, Inc. and SCSV, LLC shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditure in Section VIII of the application and that would otherwise require a certificate of need.**

8. **Caldwell Memorial Hospital, Inc. and SCSV, LLC shall develop a transportation fund to assist low income patients and family members to access both the proposed Caldwell Surgery Center and Caldwell Memorial Hospital.**
 9. **Caldwell Memorial Hospital, Inc. and SCSV, LLC shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Healthcare Planning and Certificate of Need Section in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

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Capital and Working Capital Costs

In Section VIII.1, page 165, the applicants project the total capital cost of the project will be \$3,650,000, which includes:

Site Costs- Contingency	\$ 100,000
Construction Costs- Contingency	\$ 650,000
Movable Equipment	\$2,563,000
Telephone, computers, furniture, other	\$ 102,000
Consultant Fees	\$ 150,000
Contingency for taxes, loan origination fees	<u>\$ 85,000</u>
Total:	\$3,650,000

Exhibit 37 contains a list of the equipment to be acquired along with the estimated cost of each piece of equipment. In Section IX.1-3, page 170, the applicants project the total working capital costs (start-up and initial operating expenses) will be \$700,000.

Availability of Funds

In Section VIII.3, page 166, the applicants state that the capital cost of the proposed project will be financed by a conventional loan for the equipment as well as cash and cash equivalents. In Section IX, page 170, the applicants state that the working capital costs of the proposed project will be financed by a commercial loan.

In Exhibit 35, the applicants provide a letter dated July 8, 2015 from T. Rahn Chase, Vice President of First Citizens Bank which has two term sheets of proposed financing for SCSV, LLC. One term sheet covers the capital cost of \$3,650,000 and the second term sheet covers the working capital costs of \$700,000.

In Exhibit 34, there are two letters, one dated July 8, 2015 from Laura Easton of SCSV, LLC stating the SCSV, LLC is committed to utilizing the funding provided by First Citizens Bank and CMH to cover the projected capital cost and working capital costs of the proposed project to develop CSC. The second letter in Exhibit 34 is dated July 6, 2015 from Stephen Rinaldi, Vice President and Chief Financial Officer of Caldwell Memorial Hospital, Inc. confirming that CMH is committed to finance a portion of the capital cost in the amount of \$150,000 and that the hospital has sufficient cash and cash equivalents to cover this contribution.

The applicants adequately demonstrate that sufficient funds will be available for the capital and working capital needs of the project.

Financial Feasibility

In the projected revenue and expense statement (Form B), pages 184-185, the applicants project revenues will exceed operating expenses in each of the first three operating years following completion of the proposed project, as shown in the table below.

	OY 1 (CY 2018)	OY 2 (CY 2019)	OY 3 (CY 2020)
Net Revenues	\$6,867,727	\$7,835,292	\$8,829,375
Total Operating Expenses	\$6,855,243	\$7,351,433	\$7,669,011
Net Income	\$12,484	\$483,859	\$1,160,364

In the Gross Revenue Worksheets (Form D), pages 186-188, and the Net Revenue Worksheets (Form E), pages 189-191, the applicants project the average gross and net revenues during the first three operating years following completion of the proposed project. The projections for the third operating year are shown in the table below.

OY 3 (CY 2020)	ORs	Procedure Room	Combined
Average Gross Revenue Per Case (All Payors)	\$5,922	\$3,742	\$5,539
Average Net Revenue Per Case (Self Pay/Indigent/Charity)	\$592	\$374	\$532
Average Net Revenue Per Case (Medicare/Medicare Managed Care)	\$2,221	\$1,619	\$2,076
Average Net Revenue Per Case (Medicaid)	\$1,096	\$711	\$1,003
Average Net Revenue Per Case (Commercial and Managed Care)	\$2,724	\$1,806	\$2,515
Average Net Revenue Per Case (Workers Comp, VA & Other Gov't)	\$1,303	\$1,160	\$1,258
Average Net Revenue Per Case (All Payors Combined)	\$2,144	\$1,494	\$2,030

The assumptions used by the applicants in preparation of the pro formas are reasonable including projected utilization, costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference. The applicants adequately demonstrate that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

Conclusion

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

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

C

CMH and SCSV propose to develop a freestanding separately licensed AMSU with three ORs and one procedure room by relocating the three existing dedicated outpatient ORs from HSC to CSC. HSC is licensed as part of CMH but at a separate location.

On page 60, the 2015 SMFP defines the service area for ORs as *“the operating room planning area in which the operating room is located. The operating room planning areas are the single and multicounty groupings shown in Figure 6-1 [on page 65].”* Figure 6-1 shows Caldwell County as a single county OR service area. Thus, the service area for this proposal is Caldwell County. Facilities may also serve residents of counties not included in their service area.

According to Table 6A, on page 67 of the 2015 SMFP, CMH owns and operates all eight ORs located in Caldwell County (includes the one dedicated C-section OR at CMH). There are no approved ORs in Caldwell County. There are no existing or approved AMSUs located in Caldwell County.

The total number of ORs (eight) will not increase as a result of this proposal, only how the eight ORs are licensed and where they are located within Caldwell County. The three dedicated outpatient ORs at HSC, which are licensed as part of the hospital, will be moved and licensed separately as an AMSU. The cost to the patient, for the same outpatient surgical procedure, is generally lower if the surgery is performed in an AMSU rather than in a hospital-based OR.

The discussions regarding analysis of need, alternatives and competition found in Criteria (3) (4) and (18a), respectively, are incorporated herein by reference.

The applicants adequately demonstrate that the proposed project would not result in the unnecessary duplication of existing or approved ORs in Caldwell County. Consequently, the application is conforming to this criterion.

- (7) The applicant shall show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided.

C

In Section VII.2, page 157, the applicants project staffing at the proposed facility in the second operating year, as illustrated in the following table:

Caldwell Surgery Center Proposed Staffing OY 2 (CY 2019)	
Position	# of Full Time Equivalent (FTE) Positions
Director	1.0
Clinical Coordinator	2.0
CRNA	3.5
Anesthesia Tech	1.2
OR RNs	4.4
Peri-op RNs	5.4
Surgical/Radiology Tech	2.0
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	34.6

As shown in the table above, the applicants project to employ 34.6 FTEs in the second operating year. In Section VII.3, pages 157-158, the applicants state that staffing will be

accomplished by transfers of staff from HSC and CMH, in addition to utilization of a combination of advertising, staff referrals from related entities, recruitment of new graduates from nursing and surgical training programs and contacts with other health professionals and institutions. Exhibit 27 contains a letter signed by Matthew Hannibal, M.D., which expresses his commitment to serve as Medical Director for the CSC.

Adequate costs for the health manpower and management positions proposed by the applicants are budgeted in the pro forma financial statements.

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

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

C

In Section II.1, page 10, the applicants identify the ancillary services that will be provided. Most of the ancillary services will be provided directly by CSC. In the chart on page 10 and in Section II.2(a), page 11, the applicants state that anesthesiology services will be provided by the Department of Anesthesia UNC School of Medicine, 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 two of these providers confirming their commitment to provide services to the CSC. Exhibit 5 contains a draft management services agreement which addresses 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 proposed 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 6.89 acre site located on New Farm Road in Granite Falls. In Section XI.8, pages 180-181, 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.

The applicants adequately demonstrate that the cost, design and means of construction represent the most reasonable alternative for the proposed construction project. Furthermore, the applicants adequately demonstrate that the proposed construction project would not unduly increase the costs and charges of providing ambulatory surgery services. The discussion regarding financial feasibility found in Criterion (5) is incorporated herein by reference. 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

CSC does not yet exist. The three dedicated outpatient ORs at HSC are on CMH's license. In Section VI.13, pages 152-153, the applicants provide the payor mix for ambulatory surgery services provided by CMH during FFY 2014, as shown in the following table:

CMH Ambulatory Surgery Payor Mix FFY 2012	
Payor	Cases as % of Total Cases
Self-Pay / Indigent	3.58%
Medicare / Medicare Managed Care	48.43%
Medicaid	14.68%
Commercial Insurance	31.85%
Other (Workers Comp, TriCare)	1.46%
Total	100.00%

The Division of Medical Assistance (DMA) maintains a website which offers information regarding the number of persons eligible for Medicaid assistance and estimates the percentage of uninsured for each county in North Carolina. More current data, particularly with regard to the estimated uninsured percentages, was not available. The following table illustrates those percentages for Caldwell, Catawba, Burke, Watauga, Alexander, Wilkes and Lincoln counties and statewide.

	2010 Total # of Medicaid Eligibles as % of Total Population *	2010 Total # of Medicaid Eligibles Age 21 and older as % of Total Population *	2008-2009 % Uninsured (Estimate by Cecil G. Sheps Center) *
Caldwell	19.4%	8.6%	18.1%
Catawba	16.6%	6.2%	19.1%
Burke	18.3%	7.7%	17.7%
Watauga	7.6%	3.5%	24.2%
Alexander	16.2%	6.6%	16.9%
Wilkes	19.5%	8.7%	19.1%
Lincoln	15.0%	6.2%	19.0%
Statewide	16.5%	6.7%	19.7%

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

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

The Office of State Budget & Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina. In addition, data is available by age, race and gender. However, a direct comparison to the applicants' current payor mix would be of little value. The population data by age, race or gender does not include information on the number of elderly, minorities, handicapped persons or women utilizing health services.

The applicants demonstrate that medically underserved groups currently have adequate access to the services offered at CMH. Therefore, the application is conforming to this criterion.

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

Recipients of Hill-Burton funds were required to provide uncompensated care, community service and access by minorities and handicapped persons. In Section VI.10(a), page 151, 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

C

In Section VI.14, pages 154, the applicants provide the projected payor mix for the services to be provided by CSC during for the first three operating years following completion of the project, as shown in the following table:

CSC Payor Mix OYs 1-3 (CYs 2018-2020)	
Payor	Cases as % of Total Cases
Self-Pay / Indigent	3.58%
Medicare / Medicare Managed Care	48.43%
Medicaid	14.68%
Commercial Insurance	31.85%
Other (Workers Comp, TriCare)	1.46%
Total	100.00%

As shown in the table above, the applicants project that 48.43% of all cases will be covered by Medicare and 14.68% of all cases will be covered by Medicaid. On pages 148-149, the applicants outline their strategies to improve access to medically underserved groups, which strategies include development of a transportation fund to assist low income patients and family members to access both the proposed CSC and CMH. On page 154, the applicants state:

“The proposed project is expected to have a payor mix similar to the historical patient percentages for ambulatory surgery at Caldwell Memorial Hospital because the proposed project will provide multiple surgical specialties which represent a large number of cases currently performed at CMH and Hancock Surgery Center. The applicants are committed to provide high levels of access to the medically underserved population of Caldwell County. 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, and provide transportation assistance to patients and families if needed.”

The applicants demonstrate that medically underserved groups would have adequate access to the proposed ambulatory surgical services. Therefore, the application is conforming to this criterion.

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

C

In Section VI.9, page 150, the applicants describe the range of means by which a person will have access to the proposed CSC. The applicants adequately demonstrate that they will offer a range of means by which a person will have access to the proposed services. Therefore, the application is conforming to this criterion

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

C

In Section V.1, page 141, the applicants describe how the proposed AMSU will accommodate the clinical needs of area health professional training programs. They state:

“Caldwell Surgery Center will provide access to the surgery center for health professional training. Anticipated relationships include:

- *Caldwell Community College Nursing Associate Degree*

Future relationships will also be established with:

- *UNC Chapel Hill, School of Medicine*
- *UNC Chapel Hill School of Pharmacy.”*

Exhibit 25 contains a letter from the President and CEO of CMH addresses to the Caldwell Community College and Technical Institute offering the proposed AMSU as a clinical training site for their students.

The information provided is reasonable and adequately supports a determination that the application is conforming to this criterion.

- (15) Repealed effective July 1, 1987.
(16) Repealed effective July 1, 1987.

- (17) Repealed effective July 1, 1987.
- (18) Repealed effective July 1, 1987.
- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

C

CMH and SCSV propose to develop a freestanding separately licensed AMSU with three ORs and one procedure room by relocating the three existing dedicated outpatient ORs from HSC to CSC. HSC is licensed as part of CMH but at a separate location.

According to Table 6A, on page 67 of the 2015 SMFP, CMH owns and operates all eight ORs located in Caldwell County (includes the one dedicated C-section OR at CMH). There are no approved ORs in Caldwell County. There are no existing or approved AMSUs located in Caldwell County. The total number of ORs (eight) will not increase as a result of this proposal, only how the eight ORs are licensed and where they are located within Caldwell County. The three dedicated outpatient ORs at HSC, which are licensed as part of the hospital, will be moved and licensed separately as an AMSU.

On page 60, the 2015 SMFP defines the service area for ORs as *“the operating room planning area in which the operating room is located. The operating room planning areas are the single and multicounty groupings shown in Figure 6-1 [on page 65].”* Figure 6-1 shows Caldwell County as a single county OR service area. Thus, the service area for this proposal is Caldwell County. Facilities may also serve residents of counties not included in their service area.

In Section V.7, pages 144-146, the applicants discuss how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services.

See also Sections II, III, V, VI and VII where the applicant discusses the impact of the project on cost-effectiveness, quality and access to the proposed services.

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

- The applicants adequately demonstrate the need for the proposed project and that it is a cost-effective alternative. The discussions regarding analysis of need and

alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.

- The applicants adequately demonstrate that they will provide quality services. The discussion regarding quality found in Criterion (20) is incorporated herein by reference.
- The applicants demonstrate that they will provide adequate access to medically underserved populations. The discussions regarding access found in Criteria (3) and (13) are incorporated herein by reference.

Therefore, the application is conforming to this criterion.

- (19) Repealed effective July 1, 1987.
- (20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C

CMH and SCSV propose to develop a freestanding separately licensed AMSU with three ORs and one procedure room by relocating the three existing dedicated outpatient ORs from HSC to CSC. HSC is licensed as part of CMH but at a separate location.

In Section I.13, page 7, the applicants state that SCSV does not currently own any health care facilities in North Carolina. Also on page 7, the applicants list the affiliates of CMH, all of which appear to be services offered under the hospital license, based on the 2015 Hospital License Renewal Application.

According to the files in the Acute and Home Care Licensure and Certification Section, DHRS, during the 18 months immediately preceding the submittal of the application through the date of the decision, CMH operated in compliance with all Medicare conditions of participation. After reviewing and considering information provided by the applicants and by the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at CMH, the applicants provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.
- (b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in

order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C

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

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

10A NCAC 14C .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 23, the applicants identified the following specialty areas listed above that will be provided at CSC: otolaryngology, general surgery and orthopedic. In addition, the applicants state urology will be offered based on physician recruitment. The applicants propose at least three of the specialties necessary to meet the definition of a multispecialty ambulatory surgical program found in G.S. 131E-176(15a).

(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 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 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, 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 (b)(1) and (b)(2) of this Rule;*
 - (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 (b)(1) and (b)(2) of this Rule;*
 - (5) *a 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 new 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 included 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 a service area (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, pages 25-26, the applicants provide the number and type of existing ORs at CMH (including HSC), as illustrated in the table below. There are no approved ORs in Caldwell County.

	CMH (Hospital Campus)	HSC	Total
Dedicated C-Section	1	0	1
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 26-27, the applicants provide the number and type of ORs to be located in each affected facility after completion of the proposed project and all previously approved projects related to these facilities, as illustrated in the table below.

	CMH (Hospital Campus)	HSC	CSC	Total
Dedicated C-Section	1	0	0	1
Dedicated Ambulatory Surgery	1	0	3	3
Shared Inpatient/ Ambulatory Surgery	3	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 II., page 27 and in Section III, page 81, the applicants provide the number of inpatient and outpatient surgical cases performed in the ORs at CMH, including HSC, during the most recent 12-month period for which data is available.

(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.1, pages 138-140, the applicants provide the number of inpatient and outpatient surgical cases projected to be performed at CMH and the proposed CSC in each of the first three operating years following completion of the proposed project.

Year	CMH		CSC	
	Inpatient	Outpatient	Inpatient	Outpatient
OY 1 (CY 2018)	1,224	1,867	0	3,015
OY 2 (CY 2019)	1,270	1,950	0	3,377
OY 3 (CY 2020)	1,319	2,036	0	3,740

- (5) *a detailed description of and documentation to support the assumptions and methodology used in the development of the projections required by this Rule;*
- C- In Section III.1, pages 79-99, the applicants provide a detailed description of and documentation to support the assumptions and methodology used in the development of the projections required by this Rule. The discussion regarding the applicants' projected utilization found in Criterion (3) is incorporated herein by reference.
- (6) *the hours of operation of the facility to be expanded;*
- C- In Section II.10, page 28, the applicants state that the hours of operation of the proposed AMSU will “initially be 7:00 am to 5:00 pm Monday through Friday. In future years, the facility may expand hours and days of service to include Saturdays.”
- (7) *the average reimbursement received per procedure for the 20 surgical procedures most commonly performed in each affected facility during the preceding 12 months and a list of all services and items included in the reimbursement;*
- C- In Exhibit 20, the applicants provide the average reimbursement received per procedure for the 20 surgical procedures most commonly performed at CMH, including HSC, during the preceding 12 months. In Section II.10, page 28, the applicants provide 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 to be expanded and a list of all services and items included in the reimbursement; and*
- C- In Exhibit 20, the applicants provide the projected average reimbursement to be received per procedure for the 20 surgical procedures which the applicants project will be performed most often at the proposed CSC. In Section II.10, pages 28-29 and Exhibit 20, the applicants provide a list of all services and items included in the reimbursement.
- (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 29, the applicants identify the providers of pre-operative services and procedures which will not be included in the facility's charge. Anesthesiology will be provided by the Department of Anesthesia UNC School of Medicine, radiology will be provided by Catawba Radiological Associates and pathology/laboratory professional services will be provided 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.

10A NCAC 14C .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 a year.*

-C- In Section II.10, page 32, the applicants state that the projected utilization for the ORs at CMH and the proposed CSC are *"based on assumptions and calculations that the operating rooms shall be considered 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 based on the following formula: {[(Number of facility's 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 facility's projected*

outpatient cases times 1.5 hours)] divided by 1872 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 or a positive 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, then 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 less than 0.2; and if the difference is a negative number or a positive number less than 0.2, then the need is zero.*

-C- In Section II.10, page 33, the applicants state that there are seven ORs in Caldwell County (excluding the dedicated C-section room at CMH). As shown in the table below, in OY 3 (CY 2020), the applicants project that 3,740 outpatient cases will be performed in one of the three ORs at the proposed CSC, which documents a need for three ORs consistent with this Rule.

	Inpatient Cases	Outpatient Cases	Total Hours (OP Cases x 1.5 Hours / Case)	Total Hours/ 1,872 Hours / OR / Year	# of ORs Needed
OY 3	----	3,740	5,610	2.9	3.0

The discussion regarding analysis of need, including projected utilization, found in Criterion (3) is incorporated herein by reference.

- (c) *A proposal to increase the number of operating rooms (excluding dedicated C-section 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 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 projected outpatient cases for all the applicant's or related entities' facilities times 1.5 hours)] divided by 1872 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, 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, then 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 less than 0.2; and if the difference is a negative number or a positive number less than 0.2, then the need is zero.*

-NA- The applicants do not propose to increase the number of ORs in the service area (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 are not proposing to develop an additional 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 1872 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 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 are not proposing to convert a specialty ambulatory surgical program or to add a specialty to a specialty ambulatory surgical program.

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

-C- In Section III, pages 79-99, the applicants document the assumptions and provide data supporting the methodology used for each projection in this Rule. The discussion regarding analysis of need, including projected utilization, found in Criterion (3) is incorporated herein by reference.

10A NCAC 14C .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, 26 and 29, the applicants provide copies of the written policies and procedures that will be used by the proposed facility for patient referral, transfer, and follow-up.

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

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

-C- In Section II.10, page 37, the applicants document the proximity of the proposed facility to each of the services listed above.

10A NCAC 14C .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 in the facility to be developed or expanded:*

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

-C- In Section VII, pages 159-160, the applicants document the projected staffing for the proposed AMSU for each of the above listed areas. See also Exhibit 31 which contains copies of the job descriptions.

(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- CSC does not currently exist, therefore no physicians currently utilize the facility. In Section VII, page 162, the applicants provide an estimate of the number of physicians expected to utilize the facility during the first operating year following completion of the project. The criteria to be used by the facility in extending surgical and anesthesia privileges to medical personnel is provided in Exhibits 18 and 19.

(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 Exhibits 8, 18 and 19, the applicants document 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 (Caldwell County) in which the proposed AMSU will be located. Exhibit 8 contains a copy of a letter from the President and CEO of CMH which identifies physicians who have submitted letters of support for the proposed AMSU. The letter further states that all of the listed physicians understand that the “*medical staff bylaws for the ambulatory surgery center will require that physicians are required to obtain medical staff privileges at Caldwell Memorial Hospital. ... Please accept this letter as documentation that physicians with privileges to practice in the ambulatory surgery center will be required to be active members in good standing at Caldwell Memorial Hospital.*”

(d) *The applicant shall provide documentation that physicians owning the proposed single specialty demonstration facility will meet Emergency Department coverage responsibilities in at least one hospital within the service area, or documentation of contacts the applicant made with hospitals in the service area in an effort to commit its physicians to assume Emergency Department coverage responsibilities.*

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

10A NCAC 14C .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.*

-C- In Section II.10, page 38, and in the facility plans in Exhibit 22, the applicants document that the proposed AMSU will not be physically located in a physician's or dentist's office or within a general acute care hospital.

(b) *An applicant proposing to establish 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 document that the proposed AMSU will seek 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) *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- Exhibit 22 contains a floor plan for the proposed AMSU. Exhibit 16 contains documents that show that the physical environment of the facility will be designed, developed and constructed such that it conforms to the requirements of federal, state, and local regulatory bodies.

(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- Exhibit 22 contains a floor plan for the proposed AMSU which identifies the areas listed in 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.