

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: April 19, 2018

Findings Date: April 19, 2018

Project Analyst: Julie M. Faenza

Assistant Chief: Lisa Pittman

Project ID #: E-11446-18

Facility: Caldwell Memorial Hospital

FID #: 933051

County: Caldwell

Applicant: Caldwell Memorial Hospital, Inc.

Project: Acquire one unit of shared fixed cardiac catheterization equipment

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

N.C. Gen. Stat. §131E-183(a) The Agency 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. proposes to acquire one unit of shared fixed cardiac catheterization equipment to be located on the campus of Caldwell Memorial Hospital (CMH), pursuant to the adjusted need determination in the 2018 State Medical Facilities Plan (2018 SMFP), for a total of one unit of shared fixed cardiac catheterization equipment upon project completion.

Need Determination

The 2018 SMFP includes an Adjusted Need Determination for one unit of shared fixed cardiac catheterization equipment in the Caldwell County Cardiac Catheterization Service Area. The applicant does not propose to develop more units of shared fixed cardiac catheterization equipment than are determined to be needed in the 2018 SMFP for the Caldwell County

Cardiac Catheterization Service Area. Therefore, the application is consistent with the need determination.

Policies

There is one policy in the 2018 SMFP that is applicable to this review: Policy GEN-3: Basic Principles, on page 33.

Policy GEN-3: Basic Principles states:

“A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area.”

In Section B, pages 21-23 (and referenced exhibits), the applicant explains why it believes its application is conforming to Policy GEN-3. The applicant states that:

- CMH is committed to maintaining accreditation by The Joint Commission, which will promote patient safety and quality of care, as well as maintaining transfer agreements with hospitals that provide advanced cardiac services (pages 21-22).
- CMH currently provides these services to Medicare and Medicaid patients, low-income patients, and other medically underserved patients, and plans to continue to do so (page 22).
- CMH will be able to reduce operating costs, improve efficiency, and enhance quality in the provision of services by acquiring a unit of shared fixed cardiac catheterization equipment (pages 22-23).
- CMH projects utilization based on historical data, increases in staff, and other factors directly related to Caldwell County patient population and utilization. The acquisition of the unit of shared fixed cardiac catheterization equipment will enable lower operating expenses, provide more advanced treatment and early detection for patients, and improve patient outcomes (page 23).

Conclusion

The Agency reviewed the:

- Application

- Exhibits to the application
- Supplemental information requested by the Agency
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant does not propose to acquire more units of cardiac catheterization equipment than are determined to be needed in the service area.
 - The applicant adequately demonstrates that the proposal is consistent with Policy GEN-3 for the following reasons:
 - The applicant adequately demonstrates that it will promote safety and quality, provide access for medically underserved and low-income patients, and maximize healthcare value for resources expended. The discussion regarding access found in Criteria (6), (13c), and (18a) are incorporated herein by reference.
 - The applicant adequately demonstrates how its projected utilization meets the need identified in the 2018 SMFP, incorporates the concepts in Policy GEN-3, and addresses the need for residents of Caldwell County. The discussions regarding need and projected utilization found in Criterion (3) are incorporated herein by reference.
- (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

Caldwell Memorial Hospital, Inc. proposes to acquire one unit of shared fixed cardiac catheterization equipment to be located on the campus of CMH, pursuant to the adjusted need determination in the 2018 SMFP, for a total of one unit of shared fixed cardiac catheterization equipment upon project completion. The adjusted need determination found in the 2018 SMFP was a result of a petition submitted by CMH on July 24, 2017, and approved by the State Health Coordinating Council for inclusion in the 2018 SMFP on October 4, 2017.

Patient Origin

On page 166, the 2018 SMFP defines the service area for shared fixed cardiac catheterization equipment as “...the cardiac catheterization equipment planning area in which the equipment is located. The cardiac catheterization equipment planning areas are the same as the Acute Care Bed Service Areas defined in Chapter 5, Acute Care Beds, and shown in Figure 5.1. The

cardiac catheterization equipment service area is a single county, except where there is no licensed acute care hospital located within the county.” Figure 5.1 shows Caldwell County as a single county Acute Care Bed Service Area. Thus, the service area for this proposal is Caldwell County. Facilities may also serve residents of counties not include in their service area.

In Section C.2, page 27, the applicant provides the historical patient origin for cardiac catheterization for the last full fiscal year, as shown in the table below.

CMH Patient Origin – Cardiac Catheterization – FY 2017 (7/1/2016 – 6/30/2017)		
County	Number of Patients	Percent of Total
Caldwell	497	95.58%
Burke	9	1.73%
Catawba	3	0.58%
Watauga	2	0.38%
Wilkes	4	0.77%
Other counties*	3	0.58%
Other states**	2	0.38%
Total	520	100.00%

*Other counties where patients have historically originated from include Alexander, Ashe, Avery, Forsyth, Gaston, Lincoln, McDowell, Nash, Rowan, Rutherford, Wake, and others.

**Other states where patients have historically originated from include Georgia, Tennessee, Virginia, and others.

In Section C.3, page 29, the applicant projects the origin of the patient population it proposes to serve during the first three years of operation following project completion, as shown in the table below.

CMH Projected Patient Origin – Cardiac Catheterization – FYs 1-3						
County	FY 1 (7/1/19 – 6/30/20)		FY 2 (7/1/20 – 6/30/21)		FY 3 (7/1/21 – 6/30/22)	
	# Patients	% of Total	# Patients	% of Total	# Patients	% of Total
Caldwell	721	95.6%	829	95.6%	953	95.6%
Burke	13	1.7%	15	1.7%	17	1.7%
Catawba	4	0.5%	5	0.6%	6	0.6%
Watauga	3	0.4%	3	0.3%	4	0.4%
Wilkes	6	0.8%	7	0.8%	8	0.8%
Other counties*	4	0.5%	5	0.6%	5	0.5%
Other states**	3	0.4%	3	0.3%	4	0.4%
Total	754	100.0%	867	100.0%	997	100.0%

*Other counties where patients may originate from include Alexander, Ashe, Avery, Forsyth, Gaston, Lincoln, McDowell, Nash, Rowan, Rutherford, Wake, and others.

**Other states where patients may originate from include Georgia, Tennessee, Virginia, and others.

In Section C.3, page 29, the applicant provides the assumptions and methodology used to project its patient origin. The applicant’s assumptions are reasonable and adequately supported.

Analysis of Need

In Section C.4, pages 31-35, and in supplemental information, the applicant discusses the need for the project. The applicant states that the need for the project is based on the following factors:

- Adjusted Need Determination in the 2018 SMFP (page 31)

On page 31, the applicant states that it submitted a petition for an adjusted need determination for one unit of shared fixed cardiac catheterization equipment for Caldwell County, and the State Health Coordinating Council approved the petition, resulting in the present adjusted need determination for Caldwell County.

- Population Growth and Aging (page 31)

On page 31, the applicant provides population data from the NC Office of Budget and Management for Caldwell and contiguous counties, which shows the population in Caldwell County and all but one contiguous county increasing over the next five years. The applicant also states that the Caldwell County population of those age 65 and older will increase over the next five years and that the median age for Caldwell County population will also increase over the next five years.

- Incidence of Heart Disease (page 32)

On page 32, the applicant provides data from the State Center for Health Statistics showing the incidence of heart disease deaths between 2001-2015, adjusted by age, for Caldwell County as well as the North Carolina average. While the death rates went down over time for both Caldwell County and North Carolina as a whole, Caldwell County's rates of death from heart disease were consistently higher than the state average, and the difference in the Caldwell County rate versus the state average rate also increased during that same time period.

- Constraints with Current Service Arrangement (pages 32-33)

On pages 32-33, the applicant states that it has provided cardiac catheterization services since 1990, first through use of mobile equipment provided by an outside vendor, and since 2007 through equipment installed at CMH and operated by an outside vendor with a contract for services. The vendor operating the equipment provides the equipment and the staff for the equipment. The applicant states that if the contract is not renewed or extended, the equipment could be removed from CMH. The applicant further states that due to the nature of the contract, it cannot cross-train staff to assist in other areas during low-volume times; cardiologists prefer a consistent team of staff, and the vendor staff is frequently rotated; and it cannot realize potential benefits such as cost savings or adjustments to operation and hours of service due to the necessity of coordinating with a vendor.

- Addition of Cardiologists to the Medical Staff (pages 34-35)

On page 34, the applicant states that two cardiologists performed most of the cardiac catheterization procedures at CMH during the past year. The applicant states that in November and December of 2017, six additional cardiologists obtained privileges at CMH and expressed a willingness to begin performing cardiac catheterization procedures at CMH in January 2018. In supplemental information, the applicant confirmed that the six cardiologists did begin performing procedures at CMH in January 2018. On page 35, the applicant states that the addition of the six cardiologists will support stability and growth in future utilization because of the increase in physician support and broader base of referring physicians.

- Historical Utilization Growth (supplemental information)

In supplemental information, the applicant provides historical utilization for the last three fiscal years (July 1 – June 30), and states that despite a high degree of variability, which is experienced by hospitals with lower utilization totals due to the changes that the arrival or departure of a single cardiologist can cause, utilization has increased at a Compound Annual Growth Rate (CAGR) of 12.48 percent.

The information is reasonable and adequately supported for the following reasons:

- The applicant cites appropriate data that correlates to Caldwell County.
- The applicant cites future projections of staff increases which were later verified.
- The applicant relies on historical utilization to justify the need.

Projected Utilization

In Section Q, the applicant provides historical and projected utilization as illustrated in the table below.

CMH Historical/Projected Utilization – Cardiac Catheterization Procedures					
	Current	Intervening	Year 1	Year 2	Year 3
	7/1/17-6/30/18*	7/1/18-6/30/19	7/1/19-6/30/20	7/1/20-6/30/21	7/1/21-6/30/22
Diagnostic	348	400	460	529	609
Interventional**	222	255	294	338	388
Total	570	656	754	867	997

*Annualized

**Throughout the application, the applicant uses “interventional” and “therapeutic” interchangeably.

In Section Q and in supplemental information, the applicant provides the assumptions and methodology used to project utilization, which are summarized below.

- Operating Year 1/Fiscal Year 1 = July 1, 2019 – June 30, 2020
- Operating Year 2/Fiscal Year 2 = July 1, 2020 – June 30, 2021

- Operating Year 3/Fiscal Year 3 = July 1, 2021 – June 30, 2022
- The applicant bases its projected mix of 61 percent diagnostic and 39 percent interventional procedures on the combined average of the three most recent years of data provided on its License Renewal Applications (LRAs), as shown in the table below.

CMH Historical Diagnostic/Interventional Procedure Mix				
	10/1/14-9/30/15	10/1/15-9/30/16	10/1/16-9/30/17	Average
Diagnostic	332	308	288	309
Interventional	149	215	221	195
Totals	481	523	509	504
% Diagnostic	69%	59%	57%	61%
% Interventional	31%	41%	43%	39%

- The applicant states that the total number of procedures during the last three full fiscal years (July 1 – June 30) results in a Compound Annual Growth Rate (CAGR) of 12.48 percent. The Project Analyst obtained a different result, as shown in the table below.

CMH Historical Utilization Growth				
	7/1/14-6/30/15	7/1/15-6/30/16	7/1/16-6/30/17	Average
Total Procedures	411	513	520	
Difference	-	+102	+7	
Average Rate	24.8%			
Average Rate	1.4%			
CAGR				13.1%

Despite being different than the applicant’s results, the Project Analyst’s results demonstrate that relying on a CAGR of 12.48 percent as part of the applicant’s utilization projections is reasonable.

- The number of cardiac catheterization providers at CMH remained stable during the three fiscal years used by the applicant in the calculation of the CAGR.
- The applicant states that six cardiologists have received privileges to perform cardiac catheterization procedures at CMH, and in fact did begin performing cardiac catheterization procedures at CMH during January 2018.
- The applicant projects utilization for the current fiscal year (FY 18) by using actual utilization for the last six months of 2017, and then projects that utilization will increase by approximately 20 percent for the first six months of 2018, as a result of the six additional cardiologists beginning to perform procedures at CMH, for a FY 2018 increase of 9.6 percent over FY 2017.
- The applicant projects the number of cardiac catheterization procedures will increase in each subsequent year by 15 percent, due to the existing 12.48 percent CAGR that CMH has seen and due to the addition of the six cardiologists.

- In supplemental information, the applicant provides a letter signed by Dr. John Edmunds, the Medical Director for the Cardiac Catheterization service, stating that he has personally reviewed the utilization projections provided by the applicant and finds them to be reasonable with regard to past utilization increases and the capability of cardiologists to perform the number of cardiac catheterization procedures projected.

The applicant’s utilization projections, found in Section Q of the application, are shown in the table below.

CMH Cardiac Catheterization Projected Utilization: Current through OYs 1-3*					
	Q1	Q2	Q3	Q4	Total
Current (July 1, 2017 – June 30, 2018)**					
Diagnostic	68	90	90	100	348
Interventional	44	58	58	63	222
Combined	112	148	148	162	570
Interim (July 1, 2018 – June 30, 2019)					
Diagnostic	92	97	103	108	400
Interventional	58	62	66	69	255
Combined	150	159	168	178	656
Operating Year 1 (July 1, 2019 – June 30, 2020)					
Diagnostic	111	114	116	119	460
Interventional	71	73	74	76	294
Combined	182	186	191	195	754
Operating Year 2 (July 1, 2020 – June 30, 2021)					
Diagnostic	128	131	134	137	529
Interventional	81	83	85	87	338
Combined	209	214	219	225	867
Operating Year 3 (July 1, 2021 – June 30, 2022)					
Diagnostic	147	150	154	158	609
Interventional	94	96	98	101	388
Combined	240	246	252	258	997

*In this table in Section Q, the applicant makes several mathematical errors which result in an increase or decrease of procedures by a single procedure. These mathematical errors do not have any effect on the final decision about this application and are not included in the table above.

**Current FY utilization is based on actual utilization from the first six months of the fiscal year and projected utilization for the second six months of the fiscal year.

As shown above, the applicant projects to perform 258 cardiac catheterization procedures in the fourth quarter of the third year following project completion. This exceeds the requirement that the applicant must reasonably project to perform at least 225 cardiac catheterization procedures in the fourth quarter of the third year following project completion, as promulgated in 10A NCAC 14C .1603(d)(1).

Projected utilization is reasonable and adequately supported for the following reasons:

- The applicant relies on historical utilization to determine projected utilization rates.
- The applicant provides information to support a projected increase in utilization based on additional cardiologists performing cardiac catheterization procedures at CMH.

Access

In Section C.11, page 47, the applicant states:

“Caldwell Memorial Hospital consistently serves a wide variety of patient groups...

...

CMH is Medicare and Medicaid certified and accredited by The Joint Commission. The applicant complies with all federal and state regulations and does not exclude people or treat them differently due to race, color, national origin, religion, age, disability, or sex. The facility is designed and constructed for use by handicapped persons in compliance with local, local [sic] and federal building requirements. Also, CMH provides qualified interpreters and information written in other languages for people whose primary language is not English.

...

The proposed project will increase access for the medically underserved and hold down operating costs; this enables CMH to have the financial capacity to continue to provide discount services and uncompensated care.”

In Section L.3, page 86, the applicant projects the following payor mix during the second full fiscal year of operation following completion of the project, as illustrated in the following table.

Payor Source	Entire Hospital (Patient Days)	Cardiac Catheterization (Procedures)
Self-Pay	9.0%	9.0%
Charity Care	1.2%	1.2%
Medicare*	63.2%	73.0%
Medicaid*	15.5%	6.8%
Insurance*	9.5%	8.7%
Workers Compensation	0.1%	0.0%
TRICARE	0.1%	0.0%
Other	1.4%	1.3%
Total	100.0%	100.0%

* Including any managed care plans

The projected payor mix is reasonable and adequately supported.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Supplemental information requested by the Agency

- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately identifies the population proposed to be served.
- The applicant adequately explains why the population proposed to be served needs the services proposed in this application.
- Projected utilization is reasonable and adequately supported.
- The applicant projects the extent to which all residents, including underserved groups, will have access to the proposed services (payer mix) and adequately supports its assumptions.

- (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.

NA

The applicant does not propose to:

- Reduce a service
- Eliminate a service
- Relocate a facility or service

Therefore, Criterion (3a) is not applicable to this review.

- (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 proposes to acquire one unit of shared fixed cardiac catheterization equipment.

In Section E.2, page 61, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- Maintain the Status Quo
- Pursue the Proposed Project

On pages 61-62, the applicant states that its proposal is the most effective alternative because it allows for cross-training of staff; removes limitations on its ability to provide cardiac catheterization services; provides operational cost savings; increases physician satisfaction; and supports expanded access for the growing patient population.

The applicant provides supporting documentation in Exhibit C.4.

The applicant adequately demonstrates that the alternative proposed in this application is the most effective alternative to meet the need for the following reasons:

- The application is conforming to all statutory and regulatory criteria.
- The applicant provides credible information to explain why it believes the proposed project is the most effective alternative.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Supplemental information requested by the Agency
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above. Therefore, the application is approved subject to the following conditions:

- 1. Caldwell Memorial Hospital, Inc. shall materially comply with all representations made in the certificate of need application and any supplemental responses. In the event that representations conflict, Caldwell Memorial Hospital, Inc. shall materially comply with the last made representation.**
- 2. Caldwell Memorial Hospital, Inc. shall acquire no more than one unit of shared fixed cardiac catheterization equipment.**
- 3. Upon completion of the project, Caldwell Memorial Hospital shall be licensed for no more than one unit of shared fixed cardiac catheterization equipment.**
- 4. Caldwell Memorial Hospital, Inc. shall not acquire as part of this project any equipment that is not included in the project's proposed capital expenditures in Section F of the application and that would otherwise require a certificate of need.**
- 5. No later than three months after the last day of each of the first three full years of operation following initiation of the services authorized by this certificate of need, Caldwell Memorial Hospital, Inc. shall submit, on the form provided by the**

Healthcare Planning and Certificate of Need Section, an annual report containing the:

- a. **Payor mix for the services authorized in this certificate of need.**
 - b. **Utilization of the services authorized in this certificate of need.**
 - c. **Revenues and operating costs for the services authorized in this certificate of need.**
 - d. **Average gross revenue per unit of service.**
 - e. **Average net revenue per unit of service.**
 - f. **Average operating cost per unit of service.**
6. **Caldwell Memorial Hospital, Inc. shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency 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

CMH proposes to acquire one unit of shared fixed cardiac catheterization equipment.

Capital and Working Capital Costs

In Section Q, on Form F.1a on page 106, the applicant projects the total capital cost of the project will be \$1,620,651, which includes:

CMH – Capital Expenditures	
Construction/Renovation	\$200,000
Medical Equipment	\$1,291,501
Taxes/Contingency	\$129,150
Total	\$1,620,651

In Section Q, the applicant provides the assumptions used to project the capital cost.

In Section F.3, page 65, the applicant projects no working capital costs (start-up and initial operating expenses) as the proposed service is an existing service.

Availability of Funds

In Section F.2, page 63, the applicant states that the capital cost will be funded as shown in the table below.

Sources of Capital Cost Financing

Type	Caldwell Memorial Hospital, Inc.
Loans	\$0
Accumulated reserves or OE *	\$1,620,651
Bonds	\$0
Other (Specify)	\$ 0
Total Financing **	\$1,620,651

* OE = Owner's Equity

The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project.

Financial Feasibility

The applicant provides pro forma financial statements for the first three full fiscal years of operation following completion of the project. In Form F.4, the applicant projects that revenues will exceed operating expenses in the first three operating years of the project, as shown in the table below.

	OY1	OY2	OY3
Number of Cardiac Catheterization Procedures	754	867	997
Total Gross Revenues (Charges)	\$20,070,726	\$23,078,673	\$26,539,143
Total Net Revenue	\$5,274,974	\$6,095,848	\$7,044,923
Average Net Revenue per procedure	\$6,996	\$7,031	\$7,066
Total Operating Expenses (Costs)	\$2,669,831	\$3,096,787	\$3,401,807
Average Operating Expense per procedure	\$3,541	\$3,572	\$3,412
Net Income	\$2,605,143	\$2,999,060	\$3,643,116

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Supplemental information requested by the Agency
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions.

- The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal.
 - The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.
- (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

Caldwell Memorial Hospital, Inc. proposes to acquire one unit of shared fixed cardiac catheterization equipment to be located on the campus of CMH, pursuant to the adjusted need determination in the 2018 SMFP, for a total of one unit of shared fixed cardiac catheterization equipment upon project completion.

On page 166, the 2018 SMFP defines the service area for shared fixed cardiac catheterization equipment as “...*the cardiac catheterization equipment planning area in which the equipment is located. The cardiac catheterization equipment planning areas are the same as the Acute Care Bed Service Areas defined in Chapter 5, Acute Care Beds, and shown in Figure 5.1. The cardiac catheterization equipment service area is a single county, except where there is no licensed acute care hospital located within the county.*” Figure 5-1 shows Caldwell County as a single county Acute Care Bed Service Area. Thus, the service area for this proposal is Caldwell County. Facilities may also serve residents of counties not include in their service area.

Table 9X in the 2018 SMFP shows that CMH has the only unit of cardiac catheterization equipment in the service area of Caldwell County. Utilization at CMH would not result in a need determination for an additional unit of cardiac catheterization equipment based on the standard methodology in the SMFP. However, CMH submitted a petition requesting an adjusted need determination for one unit of shared fixed cardiac catheterization equipment for Caldwell County on July 24, 2017, and the petition was approved by the State Health Coordinating Council for inclusion in the 2018 SMFP on October 4, 2017.

In Section G, pages 71-72, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved cardiac catheterization services in Caldwell County. The applicant states that it is the sole provider of cardiac catheterization services in the Caldwell County service area, and that it intends to replace an existing mobile unit of cardiac catheterization equipment, which would then be free to be located at a different facility, and which would keep the existing inventory of cardiac catheterization equipment in Caldwell County at one unit of shared fixed unit of cardiac catheterization equipment.

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area for the following reasons:

- There is an adjusted need determination in the 2018 SMFP for the proposed unit of shared fixed cardiac catheterization equipment.
- The proposal would not result in an increase in units of cardiac catheterization equipment located in Caldwell County.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Supplemental information requested by the Agency
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

- (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 Q, Form H, the applicant provides current and projected staffing for the proposed services as illustrated in the following table.

CMH Current and Projected Staffing				
Position	Current	Projected		
	As of 1/15/2018	1st Full FY	2nd Full FY	3rd Full FY
Director of Nursing	NA	0.10	0.10	0.10
Cardiovascular Director	NA	0.25	0.25	0.25
Nurse Manager	NA	1.00	1.00	1.00
Registered Nurses	NA	5.00	5.00	5.00
Certified Cardiovascular Technician	NA	2.00	2.00	2.00
Scrub Technician	NA	1.00	1.00	1.00
Radiology Technologists	NA	1.50	1.50	1.50
TOTAL	NA	10.85	10.85	10.85

Source: Form H in Section Q of the application.

In Section H.1, page 73, the applicant states that current staffing is provided by the outside vendor through a services agreement, which is comprehensive and covers the equipment, staff, and salary for contract staff.

The assumptions and methodology used to project staffing are provided in Section Q. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.4, which is found in Section Q. In Section H, pages 73-74, the applicant describes the methods used to recruit or fill new positions and its existing training and

continuing education programs. In Section H.4, page 74, the applicant identifies the current medical director. In Exhibit C.1, the applicant provides a letter from the existing medical director indicating his support for the proposed services. In Section H, page 75, the applicant describes its physician recruitment plans. In Section H.4, page 74, the applicant states that it has recently recruited six additional cardiologists to begin performing cardiac catheterization procedures at CMH beginning in January 2018, and in supplemental information the applicant confirms that the six additional cardiologists did in fact begin performing procedures at CMH in January 2018.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Supplemental information requested by the Agency
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

- (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 I, page 77, the applicant states that the following ancillary and support services are necessary for the proposed services:

- Laboratory
- Pharmacy
- Radiology/Imaging
- Dietary
- Housekeeping
- Laundry and Linen
- Medical Records
- Maintenance
- Security
- Hospital Administration

On page 77, the applicant adequately explains how each ancillary and support service will continue to be made available and provides supporting documentation in Exhibit I.1.

In Section I, page 78, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit I.2.

The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Supplemental information requested by the Agency
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that 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

The applicant does not project to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which the services will be offered. Furthermore, the applicant does not project to provide the proposed services to a substantial number of persons residing in other states that are not adjacent to the North Carolina county in which the services will be offered. Therefore, Criterion (9) is not applicable to this review.

- (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

The applicant is not an HMO. Therefore, Criterion (10) is not applicable to this review.

- (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.

NA

The applicant does not propose to construct any new space or make more than minor renovations to existing space. Exhibit K.4 contains a letter from a licensed architect, which states the following:

“Based on my assessment of the existing facility space, the installation of the proposed new cardiac catheterization equipment will not require renovation or new construction to the existing cardiac catheterization procedure or control room.

For the purpose of establishing a capital cost estimate for the project I recommend a budget of \$200,000 for contingencies to allow for equipment installation, electrical system modification, inspections and unforeseen changes in local, state or federal building requirements while the CON application is under review and the project is being developed.”

Therefore, Criterion (12) is not applicable to this review.

- (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

In Section L.1, page 85, the applicant provides the historical payor mix during the last full fiscal year (July 1, 2016 – June 30, 2017) for the proposed services, as shown in the table below.

CMH Historical Payor Mix – FY 2017 (7/1/2016 – 6/30/2017)		
Source	Entire Hospital – % Patient Days	Cardiac Catheterization - % of Procedures
Self-Pay	9.0%	9.0%
Charity Care	1.2%	1.2%
Medicare	63.2%	73.0%
Medicaid	15.5%	6.8%
Insurance	9.5%	8.7%
Worker’s Compensation	0.1%	0.0%
Tricare	0.1%	0.0%
Other	1.4%	1.3%
Total	100.0%	100.0%

Source: CMH Financial Records

In Section L.1, page 84, the applicant provides the following comparison.

	Percentage of Total Patients Served by the Facility or Campus during the Last Full FY	Percentage of the Population of the Service Area
Female	59.2%	50.4%
Male	40.8%	49.6%
Unknown	0.0%	0.0%
64 and Younger	69.0%	81.4%
65 and Older	31.0%	18.6%
White or Caucasian	85.6%	92.2%
Racial Minorities	14.4%	7.8%
Declined / Unavailable	0.0%	0.0%

Sources: CMH Records; US Census Bureau

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Supplemental information requested by the Agency
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the applicant adequately documents 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. Therefore, the application is conforming to this criterion.

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

C

Regarding any obligation to provide uncompensated care, community service, or access by minorities and persons with disabilities, in Section L, page 85, the applicant states that it has no such obligations.

In Section L, page 85, the applicant states that during the last five years no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Supplemental information requested by the Agency
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that 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 L.3, page 86, the applicant projects the following payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as shown in the table below.

CMH Projected Payor Mix – FY 2021 (7/1/2020 – 6/30/2021)		
Source	Entire Hospital – % Patient Days	Cardiac Catheterization - % of Procedures
Self-Pay	9.0%	9.0%
Charity Care	1.2%	1.2%
Medicare	63.2%	73.0%
Medicaid	15.5%	6.8%
Insurance	9.5%	8.7%
Worker’s Compensation	0.1%	0.0%
Tricare	0.1%	0.0%
Other	1.4%	1.3%
Total	100.0%	100.0%

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 9 percent of cardiac catheterization services will be provided to self-pay patients, 1.2 percent to charity care patients, 73 percent to Medicare patients, and 6.8 percent to Medicaid patients.

On page 86, the applicant provides the assumptions and methodology used to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported for the following reasons:

- The applicant states on page 86 that the projected payor mix is assumed to be the same as the historical payor mix for FY 2017.
- The applicant states that there are no major changes expected to the scope of services provided by CMH or by the cardiac catheterization service.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Supplemental information requested by the Agency
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that 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 L.4, page 87, the applicant adequately describes the range of means by which patients will have access to the proposed services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Supplemental information requested by the Agency
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that 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 M, page 88, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M.1.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Supplemental information requested by the Agency
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the applicant adequately demonstrates that the proposed services will accommodate the clinical needs of area health professional training programs, and therefore, 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

Caldwell Memorial Hospital, Inc. proposes to acquire one unit of shared fixed cardiac catheterization equipment to be located on the campus of CMH, pursuant to the adjusted need determination in the 2018 SMFP, for a total of one unit of shared fixed cardiac catheterization equipment upon project completion.

On page 166, the 2018 SMFP defines the service area for shared fixed cardiac catheterization equipment as “...*the cardiac catheterization equipment planning area in which the equipment is located. The cardiac catheterization equipment planning areas are the same as the Acute Care Bed Service Areas defined in Chapter 5, Acute Care Beds, and shown in Figure 5.1. The cardiac catheterization equipment service area is a single county, except where there is no licensed acute care hospital located within the county.*” Figure 5-1 shows Caldwell County as a single county Acute Care Bed Service Area. Thus, the service area for this proposal is Caldwell County. Facilities may also serve residents of counties not include in their service area.

Table 9X in the 2018 SMFP shows that CMH has the only unit of cardiac catheterization equipment in the service area of Caldwell County. Utilization at CMH would not result in a need determination for an additional unit of cardiac catheterization equipment based on the standard methodology in the SMFP. However, CMH submitted a petition requesting an adjusted need determination for one unit of shared fixed cardiac catheterization equipment for Caldwell County on July 24, 2017, and the petition was approved by the State Health Coordinating Council for inclusion in the 2018 SMFP on October 4, 2017.

In Section N, pages 89-92, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality, and access to the proposed services. On page 89, the applicant states:

“CMH is the sole provider of cardiac catheterization services in the Caldwell County service area. The proposed cardiac catheterization equipment will be used to serve residents from Caldwell County and other counties. While CMH is the only provider of cardiac catheterization service in the service area, patients will continue to have choices and may elect to travel to facilities out of the service area.

The proposed project will enable CMH to compete more effectively with other hospitals in the region in terms of quality of care, timeliness of service and cost effectiveness.”

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates:

- The cost-effectiveness of the proposal (see Sections F and Q of the application and any exhibits).
- Quality services will be provided (see Section O of the application and any exhibits).
- Access will be provided to underserved groups (see Section L of the application and any exhibits).

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Supplemental information requested by the Agency
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

- (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

In Section O.3, page 93, the applicant identifies the hospitals located in North Carolina owned, operated, or managed by the applicant or a related entity. The applicant identifies a total of ten hospitals located in North Carolina.

In Section O.3, page 94, the applicant states that, during the 18 months immediately preceding the submittal of the application, no incidents related to quality of care occurred in any of these facilities. After reviewing and considering information provided by the applicant and considering the quality of care provided at all ten facilities, the applicant 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 Cardiac Catheterization Equipment and Cardiac Angioplasty Equipment promulgated in 10A NCAC 14C .1600 are applicable to this review. The application is conforming to all applicable criteria. The specific criteria are discussed below.

10A NCAC 14C .1603 PERFORMANCE STANDARDS

(a) *An applicant proposing to acquire cardiac catheterization equipment shall demonstrate that the project is capable of meeting the following standards:*

(1) *each proposed item of cardiac catheterization equipment, including mobile equipment but excluding shared fixed cardiac catheterization equipment, shall be utilized at an annual rate of at least 60 percent of capacity excluding procedures not defined as cardiac catheterization procedures in 10A NCAC 14C .1601(5), measured during the fourth quarter of the third year following completion of the project;*

-NA- The applicant proposes to acquire shared fixed cardiac catheterization equipment.

(2) *if the applicant proposes to perform therapeutic cardiac catheterization procedures, each of the applicant's therapeutic cardiac catheterization teams shall be performing at an annual rate of at least 100 therapeutic cardiac catheterization procedures, during the third year of operation following completion of the project;*

-C- In Section Q, the applicant projects to perform 388 interventional/therapeutic cardiac catheterization procedures during the third year of operation following completion of the project. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

(3) *if the applicant proposes to perform diagnostic cardiac catheterization procedures, each diagnostic cardiac catheterization team shall be performing at an annual rate of at least 200 diagnostic-equivalent cardiac catheterization procedures by the end of the third year following completion of the project;*

-C- In Section Q, the applicant projects to perform 609 diagnostic cardiac catheterization procedures during the third year of operation following completion of the project. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

- (4) *at least 50 percent of the projected cardiac catheterization procedures shall be performed on patients residing within the primary cardiac catheterization service area;*
- C- In Section C.3, page 29, the applicant projects that 95.6 percent of cardiac catheterization procedures will be performed on patients residing within Caldwell County. The discussion regarding patient origin found in Criterion (3) is incorporated herein by reference.
- (b) *An applicant proposing to acquire mobile cardiac catheterization equipment shall:*
- (1) *demonstrate that each existing item of cardiac catheterization equipment, excluding mobile equipment, located in the proposed primary cardiac catheterization service area of each host facility shall have been operated at a level of at least 80 percent of capacity during the 12 month period reflected in the most recent licensure form on file with the Division of Health Service Regulation;*
 - (2) *demonstrate that the utilization of each existing or approved item of cardiac catheterization equipment, excluding mobile equipment, located in the proposed primary cardiac catheterization service area of each host facility shall not be expected to fall below 60 percent of capacity due to the acquisition of the proposed mobile cardiac catheterization equipment;*
 - (3) *demonstrate that each item of existing mobile equipment operating in the proposed primary cardiac catheterization service area of each host facility shall have been performing at least an average of four diagnostic-equivalent cardiac catheterization procedures per day per site in the proposed cardiac catheterization service area in the 12 month period preceding the submittal of the application;*
 - (4) *demonstrate that each item of existing or approved mobile equipment to be operating in the proposed primary cardiac catheterization service area of each host facility shall be performing at least an average of four diagnostic-equivalent cardiac catheterization procedures per day per site in the proposed cardiac catheterization service area in the applicant's third year of operation; and*
 - (5) *provide documentation of all assumptions and data used in the development of the projections required in this Rule.*
- NA- The applicant does not propose to acquire mobile cardiac catheterization equipment.
- (c) *An applicant proposing to acquire cardiac catheterization equipment excluding shared fixed and mobile cardiac catheterization shall:*

- (1) *demonstrate that its existing items of cardiac catheterization equipment, except mobile equipment, located in the proposed cardiac catheterization service area operated at an average of at least 80 percent of capacity during the twelve month period reflected in the most recent licensure renewal application form on file with the Division of Health Service Regulation;*
- (2) *demonstrate that its existing items of cardiac catheterization equipment, except mobile equipment, shall be utilized at an average annual rate of at least 60 percent of capacity, measured during the fourth quarter of the third year following completion of the project; and*
- (3) *provide documentation of all assumptions and data used in the development of the projections required in this Rule.*

-NA- The applicant proposes to acquire shared fixed cardiac catheterization equipment.

(d) *An applicant proposing to acquire shared fixed cardiac catheterization equipment as defined in the applicable State Medical Facilities Plan shall:*

- (1) *demonstrate that each proposed item of shared fixed cardiac catheterization equipment shall perform a combined total of at least 225 cardiac catheterization and angiography procedures during the fourth quarter of the third year following completion of the project; and*

-C- In Section Q, the applicant projects to perform 258 cardiac catheterization procedures during the fourth quarter of the third year of operation following completion of the project. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

- (2) *provide documentation of all assumptions and data used in the development of the projections required in this Rule.*

-C- The applicant provides all assumptions and data used in the development of the projections required in this Rule in Section Q and supplemental information.

(e) *If the applicant proposes to perform cardiac catheterization procedures on patients age 14 and under, the applicant shall demonstrate that it meets the following additional criteria:*

- (1) *the facility has the capability to perform diagnostic and therapeutic cardiac catheterization procedures and open heart surgery services on patients age 14 and under; and*
- (2) *the proposed project shall be performing at an annual rate of at least 100 cardiac catheterization procedures on patients age 14 or under during the fourth quarter of the third year following initiation of the proposed cardiac catheterization procedures for patients age 14 and under.*

-NA- In Section C, page 53, the applicant states it is not proposing to perform cardiac catheterization procedures on patients age 14 and under.