ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

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

DECISION DATE: May 31, 2013

PROJECT ANALYST: Michael J. McKillip
ASSISTANT CHIEF: Martha J. Frisone

PROJECT I.D. NUMBER: D-10089-13 / Watauga Medical Center / Acquire a peripheral vascular lab / Watauga County

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

G.S. 131E-183(a) The Department shall review all applications utilizing the criteria outlined in this subsection and shall determine that an application is either consistent with or not in conflict with these criteria before a certificate of need for the proposed project shall be issued.

(1) The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service, health service facility, health service facility beds, dialysis stations, operating rooms, or home health offices that may be approved.

NA

Watauga Medical Center **[WMC]** proposes to acquire a peripheral vascular lab to be located in renovated space within the hospital. 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 2013 SMFP. There are no policies in the 2013 SMFP that are applicable to this review. Therefore, this criterion is not applicable.

(2) Repealed effective July 1, 1987.

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

C

The applicant, WMC, proposes to acquire a peripheral vascular lab to be located in renovated classroom space within the hospital. In Section II.1, page 14, the applicant describes the project as follows:

> *"Because of the increase in the demand for interventional and diagnostic cardiac catheterization to be performed at WMC, and the introduction of electrophysiology, device insertions and peripheral vascular procedures in 2012, as well as the increase in special procedures including the introduction of balloon kyphoplasty, WMC proposes to develop and operate a peripheral vascular lab, to be located in renovated space within WMC. Specifically, WMC proposes to renovate an existing classroom that is located adjacent to the cardiac catheterization unit. … WMC's existing cardiac catheterization unit is used to perform all cardiac and vascular procedures. The peripheral vascular lab will be used for all types of vascular procedures with the specific exception of cardiac catheterization procedures."*

Population to be Served

In Section III.5, page 66, the applicant provides projected patient origin for WMC's cardiovascular service in the first two years of operation (FY2015 and FY2016), as shown in the table below.

County	Percent of Total
Watauga	51.1%
Ashe	25.5%
Avery	17.6%
In-Migration*	5.9%
TOTAL	**100.0%**

*The applicant provides a complete list of the counties included in its service area on page 63 of the application.

The applicant projects patient origin will remain unchanged from its historical (FY2012) patient origin for cardiovascular services, as shown in Section III.4(b), page 64 of the application. The applicant adequately identified the population proposed to be served.

Need for the Project

In Section IV.1, page 69, the applicant provides a table showing the historical and projected utilization for the existing cardiac catheterization equipment and the proposed peripheral vascular lab equipment at WMC through the first three years of operation for the proposed project, which is summarized below:

Watauga Medical Center-Cardiac Catheterization Equipment Utilization

Year	Cardiac Catheterization Procedures	Peripheral Vascular Procedures	Total Procedures	Percent Change
FY2011 – Actual	11	257	268	---
FY2012 – Actual	238	529	767	186%
FY2013 – Projected	420	636	1,056	38%
FY2014 – Projected*	516	189	705	-33%
FY2015 – Year 1	528	NA	528	-25%
FY2016 – Year 2	540	NA	540	2%
FY2017 – Year 3	553	NA	553	2%

*The applicant projects that 25% of total peripheral vascular cases will be performed on the cardiac catheterization equipment in FY2014.

Watauga Medical Center-Peripheral Vascular Lab Equipment Utilization

Year	Cardiac Catheterization Procedures	Peripheral Vascular Procedures	Total Procedures	Percent Change
FY2011 – Actual	NA	NA	NA	---
FY2012 – Actual	NA	NA	NA	---
FY2013 – Projected	NA	NA	NA	---
FY2014 – Projected*	NA	567	567	---
FY2015 – Year 1	NA	773	773	36%
FY2016 – Year 2	NA	792	792	3%
FY2017 – Year 3	NA	809	809	2%

*The applicant projects that 25% of total peripheral vascular cases will be performed on the cardiac catheterization equipment in FY2014.

The following table shows the applicant's historical and projected cardiac catheterization utilization by procedure types, including diagnostic and interventional cardiac catheterization procedures, on the existing cardiac catheterization equipment at WMC through the first three years of operation for the proposed project, as shown in the table on page 69 of the application.

Watauga Medical Center-Cardiac Catheterization Utilization

Year	Diagnostic Cardiac Catheterization Procedures	Interventional Cardiac Catheterization Procedures	Total Cardiac Catheterization Procedures	Percent Change
FY2011 – Actual	11	0	11	---
FY2012 – Actual	238	0	238	2063%
FY2013 – Projected	244	176	420	76%
FY2014 – Projected	299	217	516	23%
FY2015 – Year 1	306	222	528	2%
FY2016 – Year 2	313	227	540	2%
FY2017 – Year 3	321	232	553	2%

On page 71 of the application, the applicant states its cardiac catheterization utilization projections are based on the assumption that cardiac catheterization cases will increase from 20 cases per month in FY2012 to 35 cases per month in FY2013, and then to 43 cases per month in FY2014. Thereafter, the applicant assumes total cardiac catheterization cases at WMC will continue to increase at the *"adjusted population growth"* rate (approximately 2-3 percent per year) through the first three years of the project (FY2015 – FY2017).

The following table shows the applicant's historical and projected peripheral vascular lab utilization by procedure types, including special procedures, peripheral vascular procedures, and electrophysiology (EP)/device insertion procedures, on both the existing cardiac catheterization equipment and the proposed peripheral vascular lab equipment at WMC through the first three years of operation for the proposed project, as shown in the table on page 70 of the application.

Watauga Medical Center-Peripheral Vascular Lab Utilization

Year	Special Procedures	Peripheral Vascular Procedures	EP/Device Insertion Procedures	Total Procedures	Percent Change
FY2011 – Actual	257	0	0	257	---
FY2012 – Actual	444	18	67	529	106%
FY2013 – Projected	480	36	120	636	20%
FY2014 – Projected*	540	60	156	756	19%
FY2015 – Year 1	552	61	160	773	2%
FY2016 – Year 2	566	63	163	792	3%
FY2017 – Year 3	578	64	167	809	2%

*The applicant projects that 25% of total peripheral vascular cases will be performed on the cardiac catheterization equipment in FY2014. In the years prior to FY2014, the applicant assumes all peripheral vascular cases will be performed on its existing cardiac catheterization equipment, and in the years subsequent to FY2014, the applicant projects all peripheral vascular cases will be performed on the proposed peripheral vascular lab equipment.

On page 70 of the application, the applicant states its peripheral vascular lab (PVL) utilization projections are based on the assumption that special procedure cases will increase from 37 cases per month in FY2012 to 40 cases per month in FY2013, and then to 45 cases per month in FY2014. The applicant assumes peripheral vascular cases will increase from about 2 cases per month in FY2012 to 3 cases per month in FY2013, and then to 5 cases per month in FY2014. The applicant assumes EP/device insertion cases will increase from about 6 cases per month in FY2012 to 10 cases per month in FY2013, and then to 13 cases per month in FY2014. Thereafter, the applicant assumes total PVL cases (all three types) at WMC will continue to increase at the *"adjusted population growth"* rate (approximately 2-3 percent per year) through the first three years of the project (FY2015 – FY2017).

In Section III.1(b), the applicant states the need for the proposed peripheral vascular lab is based on historical and projected population growth in the service area counties, particularly in the older population segments (pp. 48-51), the age-adjusted heart disease death rates for residents of the service area (pp. 52-55), and changes in the physician referral patterns and support for cardiac catheterization and peripheral vascular services (pp. 56-57). On page 56, the applicant states

"For over a decade, WMC has had an affiliation agreement with the Sanger Clinic at Carolinas Medical Center in Charlotte, NC. During this period, the number of cardiac catheterizations performed at WMC was restricted based on the schedule of Sanger Clinic cardiologists at WMC. The majority of cardiac catheterizations from Watauga and Avery counties were performed at Carolinas Medical Center and cardiac catheterizations from Ashe County were sent to several distant hospitals, including hospitals in Tennessee.

In 2011 and 2012, knowing that its affiliation agreement with Sanger Clinic would be altered, ARHS [Appalachian Regional Health System] *and WMC began taking steps to offer those services that had been shifted to Carolina* [sic] *Medical Center, back to WMC. WMC has recruited experienced cardiologists to expand Cardiovascular Services. In 2012, WMC began offering diagnostic cardiac catheterizations on a full-time basis and its cardiologists also began offering interventional cardiac catheterizations. Electrophysiology and device insertions have increased, which* [sic] *the offering of kyphoplasty has increased the number of special procedures performed at WMC.*

Also, in 2012, WMC cardiologists began offering office hours in Ashe County and have begun referring Ashe County resident [sic] *to WMC, decreasing the number of referrals going out-of-state to Tennessee.*

As the following graph illustrates [on page 57 of the application], *WMC is projected and on target to perform more cardiac catheterization cases in FY2013, than it performed in the previous four years combined. This volume and the continued growth of cardiac catheterization cases and other cardiac cases will require the development of the PVL to accommodate peripheral vascular cases, as well as special procedures."*

The applicant provided the following table summarizing its projected Year 3 utilization for both the existing cardiac catheterization equipment and proposed peripheral vascular equipment:

Year 3 Utilization

Vascular	Cases	Hours	Total Hours
Special procedures	578	1.0	578.0
Peripheral procedures	64	3.0	192.0

EP/Device Insertion	167	3.5	584.5
Turn Over Time	809	0.33	267.0
Total Room Hour Utilization			1,621.5
Utilization Rate			**81.1%**
Cardiac Catheterization	**Cases**	**Weight**	**Total Weight**
Diagnostic	321	1.0	321.0
Interventional	232	1.75	406.0
Total Weighted Utilization			727.0
Utilization Rate			**48.5%**

With regard to the above table, the applicant states

> *"The Year 3 Utilization table shows that when using reasonable volume capacities for the dedicated peripheral vascular lab and for the cardiac catheterization unit that the dedicated peripheral vascular lab will be utilized at a rate of 81.1% [(1,621.5 hours / 2,000 hours) x 100 = 81.1%] and the cardiac catheterization lab will be utilized at a rate of 48.5% [(727 weighted procedures / 1,500 weighted procedures) x 100 = 48.5%]. Separately, both pieces of equipment can accommodate their projected Year 3 volumes; however, if all projected volumes had to be performed only on the existing cardiac catheterization unit, then the cardiac catheterization unit would operate at nearly 130.0 percent of capacity [81.1% utilization + 48.5% utilization = 129.6%].*
>
> *WMC is not* [sic] *be able to accommodate a projected 129.6% utilization without providing "scheduled" procedures on a second shift starting after 5:00pm, which is not acceptable from a patient's, staff's, or physician's view point. Many patients must remain immobile for up to 5 hours before they can* [sic] *discharged, which would require additional staff working recovery until after mid-night, or increasing the number of observation beds needed to accommodate patients that could not be admitted as an inpatient, but observed until discharge in the morning."*

With regard to travel and accessibility of cardiovascular services, on page 46, the applicant states

> *"It is common knowledge that when the weather is bad in the High Country area of NC, travel essentially stops or at a minimum becomes dangerous. This has always been an issue with medical cases that need treatment outside of the High Country area. Depending on snowfall and/or fog, both ground and air transportation can be halted. Even on relatively clear days, the amount of time it takes ground transportation in the mountains to get to a tertiary center can be unacceptable, requiring the need for air transportation.*
>
> *The development of the PVL will not only increase capacity for peripheral vascular procedures and special procedures, but also the available capacity on the existing cardiac catheterization unit, decreasing the possibility of costly transportation to Charlotte or Winston-Salem for cardiac catheterization or other cardiovascular procedures."*

The applicant reports that its peripheral vascular cases increased from 257 in FY2011 to 529 in FY2012, or by approximately 106 percent. The applicant projects its peripheral vascular utilization will grow from 529 cases in FY2012 to 809 cases by the third project year (FY2017), which is an average of 9.0 percent per year over the five-year period. Exhibit 17 of the application contains a copy of a letter from The Cardiology Center of Appalachian Regional Healthcare System, WMC's cardiology physician group, expressing support for the proposed project. Based on the projected population growth in the applicant's service area and the historical utilization of the applicant's existing cardiac catheterization equipment, the applicant's utilization projections are reasonable. WMC adequately demonstrates that the existing cardiac catheterization lab will no longer be able to accommodate cardiac catheterization procedures and peripheral vascular, EP and special procedures. Therefore, the applicant adequately demonstrated the need to acquire a peripheral vascular lab.

Access

The applicant projects 72.6% of its patients will be covered by Medicare (64%) and Medicaid (8.6%). The applicant demonstrates adequate access for medically underserved groups to the proposed services.

In summary, the applicant adequately identified the population to be served, adequately demonstrated the need the population projected to be served has for the proposed project, and demonstrated all residents of the service area, and, in particular, underserved groups, are likely to have access to the services proposed. 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.

NA

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

CA

In Section III.3, page 61, the applicant describes the alternatives considered, including maintaining the status quo, developing a joint venture, referring patients to other facilities, and developing a freestanding or mobile lab.

- The applicant states it rejected the status quo alternative due to the need to refer increasing numbers of patients to other facilities as far away as Mecklenburg and Guilford counties (100 and 112 miles, respectively).

- The applicant considered the alternative of developing a joint venture with a physician practice, but rejected it because of concerns with regard to "Stark regulations" and other complications regarding the location of the equipment, cost-sharing, and potential loss of productivity if the WMC cardiologists were required to cover two separate locations rather than just one.
- The applicant considered the alternative of developing either a freestanding or mobile lab, but rejected it because of the need to incur higher capital costs and higher operating costs due to the need to hire a larger number of staff for the mobile or additional freestanding lab than will be required if the lab is developed at WMC.

The applicant adequately demonstrated that the proposal is its least costly or most effective alternative to meet the need.

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

In summary, the applicant adequately demonstrates that its proposal is the least costly or most effective alternative to meet the need. Therefore, the application is conforming to this criterion and approved subject to the following conditions:

1. **Watauga Medical Center shall materially comply with all representations made in the certificate of need application.**

2. **Watauga Medical Center shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditure in Section VIII of the application and that would otherwise require a certificate of need.**

3. **Watauga Medical Center shall not use the peripheral vascular procedure room or equipment purchased in this project to provide cardiac catheterization services as defined in N.C.G.S. 131E-176 (2g).**

4. **Watauga Medical Center shall acknowledge acceptance of and agree to comply with all conditions stated herein to the 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

In Section VIII.1, the applicant projects its capital cost for the project to be $1,862,951. In Section VIII.3, the applicant states the capital cost will be financed with accumulated

reserves of WMC and Appalachian Regional Healthcare System, Inc. (ARHS), which is WMC's parent company. In Section IX.1, the applicant projects $14,792 in start-up expenses and $30,000 in initial operating expenses, for total working capital required of $44,792. In Exhibit 24 of the application, the applicant provides a letter from the Chief Executive Officer for Watauga Medical Center, which states

> *"Watauga Medical Center will provide $1.9 million through Cash and Cash Equivalents to fund acquisition and development of the dedicated peripheral vascular lab. … Watauga Medical Center will provide up to $500,000 through Cash and Cash Equivalents to fund the working capital associated with the operation of the dedicated peripheral vascular lab."*

Exhibit 25 of the application contains audited financial statements for ARHS for the year ended September 30, 2012, which documents that ARHS had $29.4 million in cash and cash equivalents as of September 30, 2012. The applicant adequately demonstrated the availability of sufficient funds for the capital and working capital needs of the proposal.

In pro forma financial statements for WMC's cardiovascular services (Form C), the applicant projects revenues will exceed expenses in the second and third operating years, as shown below:

Watauga Medical Center Cardiovascular Services

	FY2015 Year 1	**FY2016 Year 2**	**FY2017 Year 3**
Total Net Revenue	$4,035,457	$4,277,533	$4,529,129
Total Expenses	$4,063,741	$4,253,415	$4,450,251
Net Income (Loss)	($28,284)	$24,118	$78,888

Operating costs and revenues are based on reasonable assumptions including projected utilization. See the pro forma financial statements in the application for the assumptions. See Criterion (3) for discussion regarding utilization assumptions which is incorporated hereby as if set forth fully herein. The applicant adequately demonstrated that the financial feasibility of the proposal is based upon reasonable projections of operating costs and revenues, and the application is conforming with 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

WMC proposes to acquire a peripheral vascular lab. WMC currently utilizes its cardiac catheterization lab to perform special procedures, peripheral vascular procedures, and electrophysiology procedures. There are no other providers of peripheral vascular services in the applicant's proposed service area.

In Section IV.1, page 70, the applicant provides a table showing the historical and projected utilization for peripheral vascular services at WMC through the first three years of operation for the proposed project, which is summarized below:

Watauga Medical Center-Peripheral Vascular Lab Utilization

Year	Special Procedures	Peripheral Vascular Procedures	EP/Device Insertion Procedures	Total Procedures	Percent Change
FY2011 – Actual	257	0	0	257	---
FY2012 – Actual	444	18	67	529	106%
FY2013 – Projected	480	36	120	636	20%
FY2014 – Projected*	540	60	156	756	19%
FY2015 – Year 1	552	61	160	773	2%
FY2016 – Year 2	566	63	163	792	3%
FY2017 – Year 3	578	64	167	809	2%

*The applicant projects that 25% of total peripheral vascular cases will be performed on the cardiac catheterization equipment in FY2014. In the years prior to FY2014, the applicant assumes all peripheral vascular cases will be performed on its existing cardiac catheterization equipment, and in the years subsequent to FY2014, the applicant projects all peripheral vascular cases will be performed on the proposed peripheral vascular lab equipment.

WMC projected utilization for the cardiac catheterization and peripheral vascular services, and demonstrated the need to acquire a dedicated peripheral vascular lab, given that the cardiac catheterization lab would no longer be able to accommodate both the cardiac catheterization procedures and the peripheral vascular, EP and special procedures. In Section IV.2, page 72, the applicant projects the proposed peripheral vascular lab will operate at 81.1% of its capacity by the third year of operation (FY2017). Consequently, the applicant adequately demonstrates the proposed project would not result in the unnecessary duplication of existing or approved health service capabilities or facilities in the applicant's service area. Therefore, the application is conforming with 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.1, pages 86-87, the applicant provides the current and proposed staffing for WMC's cardiovascular services, as shown in the table below.

WMC Cardiovascular Services Staffing	Current FTEs	Proposed FTEs
Licensed Practical Nurse	1.0	1.0
Registered Nurse	5.8	6.8
Cardiovascular Technologists	0.0	3.0
Director	1.0	1.0
Clerical	4.0	4.0

Total	**11.8**	**15.8**

The applicant states the proposed project will result in the addition of one registered nurse and three cardiovascular technologists. In Section VII.3, page 89, the applicant states that it does not anticipate any difficulties identifying, hiring, and retaining qualified staff for the proposed project. In Section VII.8, page 92, the applicant identifies Nicholas Placentra, M.D. as the Medical Director for WMC. Exhibit 17 of the application contains a copy of a letter from The Cardiology Center of Appalachian Regional Healthcare System, WMC's cardiology physician group, expressing support for the proposed project. The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services. Therefore, the application is conforming to this criterion.

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

C

In Section II.2, page 26, and Exhibit 5, the applicant states that all of the necessary ancillary and support services for the proposed services are currently provided at WMC. In Exhibit 16 of the application, the applicant provides a copy of a sample transfer agreement and Section V.2, page 74, contains a list of facilities with which WMC has transfer agreements. In Exhibit 17 of the application, the applicant provides a letter from the Cardiology Center of ARHS, the cardiology physician group for WMC, supporting the proposed project. The applicant adequately demonstrates that necessary ancillary and support services will be available and that the proposed project will be coordinated with the existing health care system. Therefore, the application is conforming with 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.

NA

(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 VI.13, page 84, the applicant provides the payer mix during FY2012 for the cardiovascular services at WMC, as shown in the table below.

WMC Cardiovascular Services Payer Category	**Procedures as % of Total**
Self Pay/Indigent/Charity	4.6%
Medicare/Medicare Managed Care	64.8%
Medicaid	8.5%
Commercial Insurance	9.8%
Other (Government)	12.3%
Total	**100.0%**

The Division of Medical Assistance (DMA) maintains a website which offers information regarding the number of persons eligible for Medicaid assistance and estimates of the percentage of uninsured for each county in North Carolina. More current data, particularly with regard to the estimated uninsured percentages, was not available.

County	Total # of Medicaid Eligibles as % of Total Population June 2010	Total # of Medicaid Eligibles Age 21 and older as % of Total Population June 2010	% Uninsured CY 2008-2009 (Estimate by Cecil G. Sheps Center)
Ashe	18%	9.1%	19.2%
Avery	16%	7.6%	21.0%
Watauga	8%	3.5%	24.2%
Statewide	**17%**	**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 peripheral vascular 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 or gender. However, a direct comparison to the applicants' current payer mix would be of little value. The population data by age, race or gender does not include information on the number of elderly, minorities or women utilizing health services. Furthermore, OSBM's website does not include information on the number of handicapped persons.

The applicant demonstrates that medically underserved populations currently have adequate access to the applicant's existing services and is conforming to this criterion.

(b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access

by minorities and handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C

Recipients of Hill-Burton funds were required to provide uncompensated care, community service and access by minorities and handicapped persons. On page 83, the applicant states:

> *"WMC fulfilled its Hill-Burton obligations and does not have any related obligation under any applicable federal regulations to provide uncompensated care, community service, or access to minorities and the handicapped. As a 501(c)(3) tax-exempt entity, WMC is a charity organized, among other things, to promote the health of the community. Accordingly, WMC provides charity care. However, there are no federal regulations per se applicable to WMC that requires the provision of uncompensated care. Nevertheless, WMC strives to provide services to all persons in need of health care services. Please refer to Exhibit 19 for a copy of WMC's FY2011 Community* [Benefit] *Report."*

In Section VI.10 (a), page 82, the applicant states that no Office of Civil Rights complaints have been filed against WMC in last five years. Therefore, 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.15, page 85, the applicant provides the projected payer mix for the second full fiscal year following completion of the proposed project (FY2016) for the cardiovascular services at WMC, as shown in the table below.

WMC Cardiovascular Services Payer Category	**Procedures as % of Total**
Self Pay/Indigent/Charity	5.4%
Medicare/Medicare Managed Care	64.0%
Medicaid	8.6%
Commercial Insurance	9.7%
Other (Government)	12.2%
Total	**100.0%**

On page 85, the applicant states, *"ARHS and WMC assume a slight change in payer mix due to volume projections."* The applicant demonstrates that medically underserved populations will have adequate access to the proposed 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(a), page 82, the applicant describes the range of means by which a person will have access to its services. The information provided is reasonable and credible and supports a finding of conformity 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 73, the applicant states WMC has established relationships with area health professional training programs, including Duke University, East Tennessee State University, Wake Forest University Baptist Medical Center, Asheville Buncombe Technical Community College, UNC Chapel Hill, and Appalachian State University. Exhibit 15 contains copies of WMC's training program affiliation agreements. The information provided in Section V.1 is reasonable and credible and supports a finding of conformity 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

WMC proposes to acquire a peripheral vascular lab to be located in renovated space at the hospital. There are no other existing providers of the peripheral vascular services in the applicant's service area.

In Section V.7, page 78, the applicant discusses the impact of the proposed project on competition in the service area as it relates to promoting cost-effectiveness, quality and access. The applicant states

> *"WMC attempts to address every barrier to access its services. … The state-of-the-art equipment that is proposed will enhance cost-efficiency and scheduling of Cardiovascular Services by increasing capacity for non-cardiac catheterization related cases. … The WMC Cardiovascular Service will provide patients of the service area with quality care in the most patient-friendly setting."*

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

The information provided by the applicant in those sections is reasonable and credible and adequately demonstrates that the expected effects of the proposal on competition in the service area include a positive impact on cost-effectiveness, quality and access to the proposed services. This determination is based on the information in the application and the following analysis:

- The applicant adequately demonstrates the need to acquire a peripheral vascular lab and that it is a cost-effective alternative;
- The applicant adequately demonstrates that it will continue to provide quality services; and
- The applicant demonstrates that it will continue to provide adequate access to medically underserved populations.

The application is conforming to this criterion.

(19) Repealed effective July 1, 1987.

(20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C

WMC is certified by CMS for Medicare and Medicaid participation, and licensed by the NC Department of Health and Human Services. According to files in the Acute and Home Care Licensure and Certification Section in the Division of Health Service Regulation, no incidents have occurred at WMC within the eighteen months immediately preceding the date of the decision for which any sanctions or penalties related to quality of care were imposed by the State. Therefore, the application is conforming to this criterion.

(21) Repealed effective July 1, 1987.

(b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and

may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C

WMC proposes to acquire a peripheral vascular lab to be located in renovated space at the hospital. In Section II.1, page 14, the applicant states, *"The peripheral vascular lab will be used for all types of vascular procedures with the specific exception of cardiac catheterization procedures."* In Section II.8, page 31, the applicant states, *"Neither ARHS nor WMC proposes the acquisition or operation of cardiac catheterization equipment that will increase the inventory of cardiac catheterization equipment in Watauga County."* Therefore, the Criteria and Standards for Cardiac Catheterization Equipment promulgated in 10A NCAC 14C .1600, are not applicable to this review. However, the Criteria and Standards for Major Medical Equipment promulgated in 10A NCAC 14C .3100, are applicable to this review. The application is conforming to all applicable criteria and standards. The specific criteria are discussed below.

10A NCAC 14C .3103 INFORMATION REQUIRED OF APPLICANT
(a) An applicant proposing to acquire new major medical technology or major medical equipment shall use the Acute Care Facility/Medical Equipment application form.

-C- The applicant used the Acute Care Facility/Medical Equipment application form.

(b) An applicant shall define a proposed service area for the major medical equipment or new major medical technology which shall be similar to the applicant's existing service area for other health services, unless the applicant documents that other providers outside of the applicant's existing service area are expected to refer patients to the applicant.

-C- In Section II.8, page 33, the applicant defines the proposed service area as Watauga, Ashe, and Avery counties, which is similar to the service area identified for the applicant's existing services in Section III.4(a), page 63.

(c) An applicant shall document its current experience in providing care to the patients to be served by the proposed major medical equipment or new major medical technology.

-C- In Section II.8, pages 35-36, the applicant documents its current experience in providing cardiovascular and peripheral vascular services.

(d) An applicant shall document that the proposed new major medical technology or major medical equipment, its supplies, and its pharmaceuticals have been approved by the U.S. Food and Drug Administration for the clinical uses stated in the application, or that the equipment shall be operated

under protocols of an institutional review board whose membership is consistent with the U. S. Department of Health and Human Services' regulations.

-C- In Exhibit 9, the applicant provides documentation that the proposed peripheral vascular lab equipment has been approved for use by the U.S. Food and Drug Administration.

(e) An applicant proposing to acquire new major medical equipment or new major medical technology shall provide a floor plan of the facility in which the equipment will be operated that identifies the following areas:

(1) receiving/registering area;
(2) waiting area;
(3) pre-procedure area;
(4) procedure area or rooms;
(5) post-procedure areas, including observation areas; and
(6) administrative and support areas.

-C- In Exhibit 4, the applicant provides a floor plan of the cardiovascular services department and proposed peripheral vascular lab which identifies the areas listed in this Rule.

(f) An applicant proposing to acquire major medical equipment or new major medical technology shall document that the facility shall meet or exceed the appropriate building codes and federal, state, and local manufacture's standards for the type of major medical equipment to be installed.

-C- In Section II.8, page 38, the applicant provides documentation that the facility meets or exceeds the appropriate building codes and federal, state, and local manufacture's standards for the proposed peripheral vascular lab.

10A NCAC 14C .3104 NEED FOR SERVICES

(a) An applicant proposing to acquire major medical equipment shall provide the following information:

(1) the number of patients who will use the service, classified by diagnosis;

-C- In Section II.8, page 39, the applicant provides the following table showing the number of patients who will use the service by diagnosis:

Diagnosis	FY2015 Year 1	FY2016 Year 2	FY2017 Year 3
Vascular disease	614	628	643
Total Patients	**614**	**628**	**643**

(2) the number of patients who will use the service, classified by county of residence;

-C- In Section II.8, page 39, the applicant provides the following table showing the number of patients who will use the service by county of residence:

County	FY2015	FY2016	FY2017

	Year 1	Year 2	Year 3
Watauga	314	320	328
Ashe	156	160	164
Avery	108	111	113
In-Migration	36	37	38
Total Patients	**614**	**628**	**643**

(3) documentation of the maximum number of procedures that existing equipment that is used for similar procedures in the facility is capable of performing;

-C- WMC does not have an existing peripheral vascular lab. In Section IV.2, page 72, the applicant identifies the capacity of the existing cardiac catheterization equipment as *"1,500 weighted cases."* In Section II.8, page 39, the applicant states

"Currently, WMC performs all cardiac and vascular procedures on its existing cardiac catheterization unit. Previous capacity on that equipment was adequate to accommodate peripheral vascular cases and special procedures, as a majority of cardiac catheterizations were being performed by Sanger Clinic cardiologists at Carolinas Medical Center in Charlotte. Excess capacity on this equipment dramatically decreased when the affiliation agreement between the Sanger Clinic and WMC ended in 2012 and WMC began providing both diagnostic and interventional cardiac catheterizations at the medical center."

(4) quarterly projected utilization of the applicant's existing and proposed equipment three years after the completion of the project; and

-C- In Section II.8, page 40, the applicant provides tables showing the quarterly projected utilization of WMC's existing cardiac catheterization equipment and proposed peripheral vascular lab for the first three years following completion of the project.

(5) all the assumptions and data supporting the methodology used for the projections in this Rule.

-C- The applicant provides the assumptions and data supporting the methodology used for the projections in Section IV.2(b), pages 69-71.

(b) An applicant proposing to acquire new major medical technology shall provide the following information:

(1) the number of patients who will use the service, classified by diagnosis;
(2) the number of patients who will use the service, classified by county of residence;
(3) quarterly projected utilization of the applicant's proposed new major medical technology three years after the completion of the project;
(4) documentation that the applicant's utilization projections are based on the experience of the provider and on epidemiological studies;
(5) documentation of the effect the new major medical technology may have on existing major medical technology and procedures offered at its facility and other facilities in the proposed service area; and

(6) all the assumptions and data supporting the methodology used for the projections in this Rule.

-NA- The applicant does not propose to acquire new major medical technology.

10A NCAC 14C .3105 SUPPORT SERVICES

An applicant proposing to acquire major medical equipment or new major medical technology shall identify all ancillary and support services that are required to support the major medical equipment or new major medical technology and shall document that all of these services shall be available prior to the operation of the equipment.

-C- In Section II.8, page 42, the applicant identifies all ancillary and support services required to support the proposed peripheral vascular lab. In Exhibit 5, the applicant provides a copy of a letter from the Chief Executive Officer of WMC documenting that all of these services are currently available at WMC.

10A NCAC 14C .3106 STAFFING AND STAFF TRAINING

(a) An applicant proposing to acquire major medical equipment or new major medical technology shall document that:

(1) trained and qualified clinical staff shall be employed, and

(2) trained technical staff and support personnel to work in conjunction with the operators of the equipment shall be employed.

-C- In Section II.8, page 43, the applicant provides documentation that trained and qualified staff will be employed and that trained technical staff and support personnel will work with the manufacturer and operators of the peripheral vascular lab equipment.

(b) An applicant proposing to acquire major medical equipment or new major medical technology shall provide documentation that physicians who will use the equipment have had relevant residency training, formal continuing medical education courses, and prior on-the-job experience with this or similar medical equipment.

-C- In Exhibit 3, the applicant provides copies of the curriculum vitae of the cardiologists and radiologists who will treat patients in the peripheral vascular lab documenting that they have the required education and training.

(c) An applicant shall demonstrate that the following staff training will be provided to the staff that operates the major medical equipment or new major medical technology:

(1) certification in cardiopulmonary resuscitation and basic cardiac life support; and

-C- In Section II.8, page 44, and Exhibit 11, the applicant provides documentation that staff training is and will continue to be provided for certification in cardiopulmonary resuscitation and basic cardiac life support (BCLS).

(2) an organized program of staff education and training which is integral to the operation of the major medical equipment and ensures improvements in technique and the proper training of new personnel.

-C- In Section II.8, page 44, and Exhibit 10, the applicant provides documentation of an organized program of staff education and training.