ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

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

DECISION DATE: April 25, 2014
PROJECT ANALYST: Julie Halatek
INTERIM CHIEF: Martha J. Frisone

PROJECT I.D. NUMBER: P-10228-13 / Wayne Memorial Hospital, Inc. / Acquire fixed angiography equipment to create a dedicated angiography room / Wayne County

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

The applicant, Wayne Memorial Hospital, Inc. (WMH), proposes to acquire a Siemens Artis zee Ceiling Angiographic System (or equipment with similar capabilities) and install it in existing space located at the hospital to develop a dedicated angiography room. 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 State Medical Facilities Plan.

There is one policy in the 2013 SMFP applicable to the review of the application.

Policy GEN-4: ENERGY EFFICIENCY AND SUSTAINABILITY FOR HEALTH SERVICE FACILITIES states:

> *"Any person proposing a capital expenditure greater than $2 million to develop, replace, renovate, or add to a health service facility pursuant to G.S. 131E-178 shall include in its certificate of need application a written statement describing the project's plan to assure improved energy efficiency and water conservation.*

In approving a certificate of need proposing an expenditure greater than $5 million to develop, replace, renovate, or add to a health service facility pursuant to G.S. 131E-178, the Certificate of Need Section shall impose a condition requiring the applicant to develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. The plan must be consistent with the applicant's representation in the written statement as described in paragraph one of Policy GEN 4.

Any person awarded a certificate of need for a project or an exemption from review pursuant to G.S. 131E-184 are required to submit a plan for energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation. The plan must be consistent with the applicant's representation in the written statement as described in paragraph one of Policy-GEN 4. The plan shall not adversely affect patient or resident health, safety, or infection control."

WMH provides a statement regarding its compliance with Policy GEN-4 in Section III.2, pages 51-53:

"WMH is committed to energy efficiency and sustainability that balances the need for healthcare services and environmental sustainability in the communities it serves. The project's plan to assure improved energy and water conservation in accordance with Policy Gen-4 requirements is discussed below.

Energy and water conservation measures which meet all of the following criteria will be designed:

1. *Reasonable payback on net cost of project.*
2. *Expected life of the equipment exceeds the payback time.*
3. *Measures are easily maintained.*
4. *Measures are not overly complicated.*
5. *Measures are reliable.*
6. *Measures in no way contribute to a loss of system performance, increase of infection risk, or a decrease of comfort for patients and staff.*
7. *Measures must not compete for the same purported energy savings.*
8. *Measures which do not require legal easements or use of other's property such as the City reservoir for water source heat pump unless legal permission has been obtained.*

Please note that measures which do not meet these criteria will be included if so directed by WMH in writing.

Water conservation features will include:

1. *Condensate recovery from all AHUs will be recovered water being used first in the cooling towers and secondly in irrigation.*
2. *Low flow fixtures.*
3. *Meters for cooling tower, domestic hot water, boiler make up, and irrigation (if any).*

Energy conservation measures which normally meet the above criteria and will likely be specified include:

1. *VAV systems in non-sensitive areas.*
2. *Reduction of air flow during unoccupied periods in non-sensitive areas.*
3. *Enthalpy economizers using National Weather Service data.*
4. *VFDs for all pumps, AHU fans, cooling towers.*
5. *High efficiency chiller complying with optional path of 2012 NC Energy Conservation Code.*
6. *Full DDC building automation system with individual room thermostats.*
7. *Basic commissioning shall be provided by the design engineer.*
8. *Leakage test on all ductwork above 2" static pressure.*
9. *Extensive use of air flow monitors.*
10. *Power Logic breakers and switchgear to provide enhanced electrical metering.*
11. *Registration for EPA Energy Star Program.*
12. *Maximize use of water cooled equipment such as freezers and imaging systems."*

The applicant's statement adequately describes the project's plan to assure improved energy efficiency and water conservation. Therefore, the application is consistent with Policy GEN-4 and is conforming to this criterion.

(2) Repealed effective July 1, 1987.

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

C

WMH currently provides angiography services, but the hospital does not have a dedicated angiography room. The current arrangement allows only limited time for angiography procedures and often results in angiography cases getting bumped for emergency cardiac and vascular cases. Angiography procedures are currently scheduled on a first-come, first-served basis, on Mondays, Wednesdays, and Fridays, with other procedures that use the one existing cardiac catheterization laboratory. The applicant states that if an urgent interventional cardiac catheterization case presented on a Monday, Wednesday, or Friday, it would likely receive priority over other non-urgent procedures.

In Section II.1, page 21, the applicant describes the project as follows:

> *"The proposed project will allow WMH to continue providing state-of-the-art diagnostic imaging services to its patients on site at the hospital, while obviating the need to schedule time in the hospital's only licensed cardiac catheterization laboratory. As such, the development of a dedicated angiography room will improve patient access and decrease scheduling difficulties."*

Population to be Served

The applicant states in Sections III.5(a) and III.5(b), pages 56-57, that its primary service area will remain Wayne County. The applicant states that Duplin, Sampson, Lenoir, and Johnston counties will remain its secondary service area.

The following table illustrates the projected patient origin for WMH's dedicated angiography room as reported in Section II.8, page 35 and Section III.5, page 58:

Projected Origin by County—WMH Angiography Patients				
	Projected FY 2015-2016	**Projected FY 2015-2016**	**Projected FY 2016-2017**	**Projected FY 2016-2017**
County	**# of Total Patients**	**% of Total Patients**	**# of Total Patients**	**% of Total Patients**
Wayne	201	81.1%	202	81.1%
Duplin	13	8.3%	13	8.3%
Sampson	3	5.3%	3	5.3%
Johnston	6	2.4%	6	2.4%
Lenoir	21	1.2%	21	1.2%
Other*	4	1.8%	4	1.8%
TOTAL	**248**	**100.0%**	**249**	**100.0%**

Note: Tables do not foot due to rounding.
*"Other" includes Bladen, Greene, and Wake counties.

The applicant states on page 58 that it projects patient origin based on historical data and does not anticipate changes in patient origin resulting from the proposed project. The applicant adequately identifies the population to be served.

Demonstration of Need

The applicant states on pages 43-44 that, due to the commencement of interventional cardiac catheterization procedures at WMH during the past year, there has been a large amount of growth in the number of procedures performed in the sole cardiac catheterization laboratory. The applicant also states that due to the increased number of procedures, sharing of the space is no longer optimal, and physicians have requested a separate room dedicated to angiography procedures. The applicant supplies a table on page 44 that shows historical cardiac catheterization procedures performed at WMH and the Compound Annual Growth Rate (CAGR) for these procedures:

Historical Cardiac Catheterization Patients at WMH	
Fiscal Year	***Total Patients***
FY10	257
FY11	229
FY12	221
FY13	429
CAGR	18.6%

Source: WMH Internal Data

The applicant goes on to state on pages 44-45 that, as the number of interventional procedures performed continues to increase, there will be a corresponding increase in the number of diagnostic procedures. Reasons given by the applicant include the travel inconvenience of having diagnostic and interventional procedures performed at different hospitals and the physical difficulties (such as two catheterization insertions instead of one and difficulty with mobility when the femoral artery, the typical access point, is used) that come with performing diagnostic and interventional procedures in different hospitals.

The applicant states on page 43:

> *"Moreover, it is important to note that under the current arrangement, there is no back-up for the hospital's one licensed cardiac catheterization/angiography laboratory. As an example of the impact of this situation, the hospital recently experienced a leak on the roof which caused the laboratory to lose power. Since there was no back-up room, the hospital created a temporary space to perform angiography procedures with a mobile C-arm while the cardiac catheterization room was down. The temporary solution, which utilized mobile equipment, was not ideal. The development of the proposed dedicated angiography room will enable the existing cardiac catheterization laboratory to serve as a back-up for the non-cardiac procedures during such sentinel events. Moreover, the development of a dedicated angiography room will lower the volume on the existing piece of equipment located in the cardiac catheterization laboratory which will render breakdowns due to excessive use unlikely. Further, although the proposed angiography room will not be used for cardiac catheterization procedures, it is possible that the CON Section may allow the hospital to re-designate the angiography room as its cardiac catheterization laboratory in the future if the existing cardiac catheterization laboratory experienced extended downtimes. (Please note that such temporary designation has been approved by the CON Section relative to CMC-Union, Exhibit 13. At no time would WMH operate more than one cardiac catheterization laboratory which would provide cardiac catheterization services, nor is WMH proposing to use the angiography room for cardiac catheterization services.)"*

In Section III.1(a), pages 41-42, the applicant states:

> *"Although WMH has performed angiography procedures since the hospital's inception, no dedicated equipment or room has been developed. As noted previously, angiography procedures are currently performed in the hospital's cardiac catheterization laboratory. The hospital's licensed cardiac catheterization laboratory is used to perform diagnostic*

cardiac catheterization, interventional cardiac catheterization, vascular, and angiography procedures. As such, the following physician specialties primarily utilize the hospital's cardiac catheterization laboratory at present: cardiologists, vascular surgeons, radiologists, and nephrologists. Of note, not one, but two separate cardiology practices currently perform procedures in WMH's cardiac catheterization laboratory. These two groups are comprised of a total of five cardiologists. As the demand for diagnostic and therapeutic services has increased, so have scheduling difficulties amongst the previously mentioned physician specialties, all of whom are competing for time in the hospital's one licensed cardiac catheterization room. Much as a single operating room would be difficult to manage with several specialties seeking to use it for surgical cases, so, too, is a single cardiac catheterization laboratory increasingly difficult to manage with the number of specialists that require it for procedures. Such demand drives the need to develop a dedicated angiography room."

The applicant states on page 42 that the cardiac catheterization laboratory operates on Monday through Friday from 7:00 a.m. to 4:00 p.m. Tuesdays and Thursdays are blocked off specifically for interventional cardiac catheterization procedures. All physicians are able to use the laboratory on a first-come, first-served basis on Mondays, Wednesdays, and Fridays; however, the applicant states that if an urgent interventional cardiac catheterization case presented on a Monday, Wednesday, or Friday, it would likely receive priority over other non-urgent procedures.

In Section III.1(b), pages 46-48, the applicant states that angiography cases have been performed on the hospital's cardiac catheterization equipment. The applicant states that, while vascular surgeons can occasionally perform procedures on mobile equipment in an operating room, the use of an operating room is less cost-effective and subject to the same scheduling constraints that the current cardiac catheterization laboratory faces. The applicant states that it has recently hired an additional vascular surgeon and that it therefore expects vascular interventional cases to increase in the future. The applicant also states that it believes lack of growth in angiography cases is due to the lack of a dedicated angiography room. The applicant believes volumes will increase at a faster rate than the historical utilization would project.

In supplemental information, the applicant states:

"…in the three remaining days available for angiography cases, the equipment must be shared among multiple physician specialties and groups, as discussed on pages 42 and 43. As reimbursement has declined for most physicians, they have naturally sought to offset these decreases through an expansion in the services performed. As a result, physician groups that historically did not utilize the angiography equipment are now requesting time in the lab. Based on WMH's consultants' experience, in the past, the "turf battles" in the cath lab were predominately between cardiologists and radiologists. Today, not only radiologists, but nephrologists and vascular surgeons are utilizing the cath lab to perform non-cardiac procedures. While these procedures can be scheduled, since the lab must also be used for cardiac catheterization, and since urgent interventional cardiac catheterizations are often a live-saving procedure, they take

precedent over other non-cardiac cases. While this is appropriate for patient care, it nonetheless is frustrating to the physician whose case was delayed or cancelled, as well as to the patient, who typically must not eat after midnight the day of the case. This issue is of greatest concern to WMH's vascular surgeons. These physicians must schedule cases not only in the cardiac cath/angiography room, but also in the operating room. In order to balance time between their offices and cases performed in the hospital, they must have a reliable schedule for their angiography cases."

Projected Utilization

In Section IV.1, page 62, the applicant provides historical and projected utilization of the cardiac catheterization equipment by angiography patients, as shown in the following table:

Historical and Projected Utilization by Angiography Patients						
	FY 2012 (10/1/11-9/30/12)	**FY 2013 (10/1/12-9/30/13)**	**Interim FY 2014 (10/1/13-9/30/14)**	**FY 2015 (10/1/14-9/30/15)**	**FY 2016 (10/1/15-9/30/16)**	**FY 2017 (10/1/16-9/30/17)**
Total Angiography Patients	189	245	247	248	250	251

The applicant's assumptions and methodology used to project utilization are provided in Section III.1(b), pages 47-49, and are described as follows:

"…[T]*he number of angiography cases declined from 242 cases in FY 2011 to 189 cases in FY 2012, and rebounded strongly to 245 cases in FY 2013, representing a one-year growth of approximately 30 percent. Overall, the number of angiography cases has experienced a compound annual growth of 0.6 percent between FY 2011 and FY 2013. WMH believes that, but for the reasons discussed below among other factors, the number of angiography cases performed at the hospital has been suppressed by the lack of a dedicated room for these cases.*

As stated earlier, the hospital's angiography patients are currently treated on equipment located in the hospital's licensed cardiac catheterization laboratory, which is also used to treat not only cardiac but also patients with numerous conditions, thus creating competition for time on the equipment among the surgeons, radiologists, cardiologists and nephrologists that use the catheterization laboratory and equipment. The current arrangement allows only limited time for patients requiring angiography procedures. Moreover, while on occasion, vascular surgeons can utilize mobile equipment in an operating room setting when the cardiac catheterization laboratory is not available, use of an operating room is not only dependent on the operating room schedule, but also represents a less cost-effective setting to perform interventional cases which can be performed more efficiently in the hospital's cardiac catheterization room.

Further, WMH recently recruited an additional vascular surgeon to its medical staff, and therefore expects its number of vascular interventional cases to increase in the

future. This will in turn put additional pressure on the cardiac catheterization equipment currently used for these vascular cases.

As discussed above, although WMH believes the historical volume growth in angiography cases has been suppressed by the lack of a dedicated room for these cases, and though the most recent volume shows a 30 percent increase over the previous year, WMH is projecting modest utilization increases in the future. As physicians performing angiography cases are able to more easily schedule them and as additional physicians join the medical staff, angiography volume is likely to grow at a greater rate than the historical growth suggests. However, WMH has chosen a conservative methodology for its future utilization, driven solely by the historical growth rate, ….

…

To project future utilization of its angiography equipment, WMH utilized an annual growth rate of 0.6 percent, which represents the historical CAGR from FY11 to FY13. WMH believes this assumption is both conservative and reasonable given the discussion above.

…

Using the 0.6 percent annual growth rate and the FY13 number of cases as a base, the resulting utilization for the proposed dedicated angiography room is shown in the table below. Please note that utilization for interim fiscal year (FY14) will be achieved using the existing catheterization equipment since the proposed project will be operational the beginning of FY15, October 1, 2014.

Projected Angiography Patients at WMH

	Base Year	***Interim Year***	***PY1***	***PY2***	***PY3***	***CAGR^***
	FY13	***FY14***	***FY15***	***FY16***	***FY17***	
Total Patients	***245***	***247***	***248***	***250***	***251***	***0.6%***

Note: Numbers may not foot due to computer rounding.

Based on the above discussion and the projected utilization for the proposed angiography equipment, WMH believes the proposed equipment is needed in order to support its current patients needing the growing demand for angiography services. While the projected utilization does not result in 100 percent utilization of the proposed angiography equipment, it will enable ongoing growth to much-needed diagnostic and therapeutic services at WMH. Moreover, as discussed in detail above, the primary need for the project is not volume-driven, but is based on the need for separate procedure rooms for cardiac catheterization and angiography services."

In supplemental information, the applicant states:

"As shown on page 44 of the application, historical utilization growth for cardiac catheterization has been significant, particularly since the commencement of interventional services late in 2012. In less than a full year, the number of total patients nearly doubled, from 221 in FY 2012 to 429 in FY 2013. From 2010 to 2013, this represents a CAGR of 18.6 percent. If that growth rate were projected forward through the second operating year, the following utilization would result:

Fiscal Year	***Total Cases***
FY13	*429*
FY14	*509*
FY15	*604*
FY16	*716*
CAGR	*18.6%*

While this growth rate may seem extraordinary, it is only one-half the CAGR of weighted cardiac catheterization cases, shown below. Note that the weighting factor used for interventional cases was 1.75, with diagnostic cases being weighted as 1.0. Please note also that data for the tables below are from the respective HLRA for WMH, not internal data from a different database, which was used in the application. …

Fiscal Year	***Diagnostic Cases***	***Interventional cases***	***Total Cases (weighted)***
FY10	*258*	*0*	*258*
FY11	*237*	*0*	*237*
FY12	*229*	*0*	*229*
FY13	*481*	*96*	*649*
CAGR	*18.6%*	*NA*	*36.0%*

If the total weighted cases are projected forward through the second project year, but using the lower growth rate for unweighted cases (18.6%), the following utilization results:

Fiscal Year	***Total Cases***
FY13	*770*
FY14	*913*
FY15	*1,083*
FY16	*1,285*
CAGR	*18.6%*

The applicant, in supplemental information, further states:

"As shown, the CAGR for diagnostic, interventional and total weighted cases would be approximately (or less than) one-half the respective historical growth rates by case type experienced at WMH. … As such, WMH believes these projections are reasonable. Please also note that the SMFP need methodology for cardiac catheterization triggers the need for an additional unit when the county's average utilization reaches 900 weighted cases per unit, a threshold that WMH is projected to approach by FY 2016."

Projected utilization is based on reasonable, credible, and supported assumptions.

Access

The applicant projects 78.1% of its patients utilizing the proposed angiography equipment will be covered by Medicare (71.6%) and Medicaid (6.5%). The applicant adequately demonstrates that medically underserved groups will have access 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, pages 53-54, the applicant describes the alternatives considered prior to the submission of this application, which include:

Maintain the Status Quo: The applicant rejected this alternative because it did not serve the best interests of the hospital's patients; improve access to angiography services in the service area; and it was contrary to the applicant's mission of providing quality care.

Expand Hours of Operation in the Cardiac Catheterization Laboratory: The applicant rejected this alternative because it was not feasible with the competing demands of different programs; it could mean overnight stays for patients; impacting patient time of recovery; and it would not provide back-up for non-cardiac patients during equipment downtime.

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 its least costly or most effective alternative to meet the identified need. Therefore, the application is conforming to this criterion and approved subject to the following conditions:

1. **Wayne Memorial Hospital, Inc. shall materially comply with all representations made in its certificate of need application and supplemental information. In those instances where representations conflict, Wayne Memorial Hospital, Inc. shall materially comply with the last made representation.**

2. **Wayne Memorial Hospital, Inc. shall acquire no more than one angiography system to be installed in an existing procedure room.**

3. **Wayne Memorial Hospital, Inc. shall not use the angiography procedure room or equipment purchased in this project to provide cardiac catheterization services as defined in N.C.G.S. 131E-176(2g).**

4. **Wayne Memorial Hospital, Inc. 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 which would otherwise require a certificate of need.**

5. **Wayne Memorial Hospital, Inc. shall acknowledge acceptance of and agree to comply with all conditions stated herein in writing to the Certificate of Need Section.**

(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

The applicant projects the capital cost for the proposed project will be $2,079,864, including $426,580 for construction costs and $1,440,540 for the fixed angiography equipment. In Section VIII.1, page 91, the applicant states that WMH will fund the proposed project using its accumulated reserves. In Section IX.1, page 99, the applicant indicates that the proposed project is not a new facility or service and therefore will not have start-up and initial operating expenses. In Exhibit 20, the applicant provides a letter dated November 15, 2013 from the Vice President, Finance and Chief Financial Officer, which states:

> *"…As the Chief Financial Officer for Wayne Memorial Hospital, I am responsible for the financial operations of the hospital. As such, I am very familiar with the organization's financial position. The total capital expenditure amount for this project is estimated to be $2,079,864. There are no start-up costs related to this project.*
>
> *Wayne Memorial Hospital will fund the capital cost from existing accumulated cash reserves. This expenditure will not impact any other capital projects currently underway or planned for at this time. For verification of the availability of these funds*

and our ability to finance these projects internally, please refer to the audited financial statements included with this Certificate of Need application."

Exhibit 21 contains the most recent audited financial statements available (FY 2012) for WMH. On the fourth page of the exhibit (marked page 446), the line item "*Cash and cash equivalents*" shows a value of $4,167,989 as of September 30, 2012. The line item "*Total assets"* shows a value of $44,574,904, and the line item *"Total net assets"* shows a value of $244,355,180 as of September 30, 2012. The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the proposed project.

The applicant also provided pro forma financial statements for the first three project years for WMH. The applicant projects that revenues will exceed expenses in each of the first three project years, as shown below:

Revenue Projections for WMH			
	First Full FY 2015	**Second Full FY 2016**	**Third Full FY 2017**
Total Revenue*	$223,953,088	$230,671,681	$237,591,831
Total Expenses	$206,958,572	$212,994,760	$219,219,166
Net Operating Income	$16,994,516	$17,676,921	$18,372,665
Nonoperating Income	$3,438,589	$3,541,747	$3,647,999
Total Net Income	$20,433,105	$21,218,668	$22,020,665

*Total Revenue = Net Patient Revenue + Other Operating Revenue

Operating costs and revenues are based on reasonable, credible, and supported assumptions, including projected utilization. See the pro forma financial statements in the application for the assumptions. See Criterion (3) for discussion regarding utilization 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. Therefore, 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

WMH currently provides angiography services, but the hospital does not have a dedicated angiography room. The applicant does not propose any new health services, beds, or operating rooms. Currently, angiography services are provided in the hospital's existing cardiac catheterization laboratory. There are no other providers of cardiac catheterization or angiography services located in Wayne County.

On page 42, the applicant states that the cardiac catheterization laboratory operates on Monday through Friday from 7:00 a.m. to 4:00 p.m. Tuesdays and Thursdays are blocked off specifically for interventional cardiac catheterization procedures. All physicians are able to use the laboratory on a first-come, first-served basis on Mondays, Wednesdays, and Fridays; however,

the applicant states that if an urgent interventional cardiac catheterization case presented on a Monday, Wednesday, or Friday, it would likely receive priority over other non-urgent procedures.

WMH adequately demonstrates the need to acquire the proposed angiography equipment and create a dedicated angiography procedure room for greater efficiency and improved patient access to both services. 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(a), page 84, the applicant states that there are not currently dedicated staff for angiography procedures and that the angiography procedures are currently performed by cardiac catheterization staff on the existing cardiac catheterization equipment. In Section VII.1(b), page 84, the applicant provides projected staffing for angiography services:

Proposed Staffing for WMH Angiography		
Position	**FY 2016 FTEs**	**FY 2016 Average Annual Salary per FTE**
Supervisor*	.5	$77,234
Angio Techs	2.0	$64,508
Radiology RN	1.0	$65,383
Total	3.5	

*Position shared with cardiac catheterization service; FTE allocation represents allocation to angiography.

As illustrated in the above table, the applicant projects to add 3.5 full-time equivalent (FTE) positions by the second full fiscal year following completion of the proposed project. In Section VII.3(b), page 85, the applicant states that it does not expect to have difficulty in recruiting the additional FTE's following completion of the proposed project, as WMH is the only hospital provider in Wayne County and has numerous resources from which to obtain staff. In Section VII.8, page 88, the applicant identifies its Chief of Staff and Medical Director for WMH. Exhibit 23 contains physician letters of support, including letters from multiple cardiologists and radiologists practicing at WMH, 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

WMH is an existing acute care hospital and provides all necessary ancillary and support services for its patients. In Section II.2(b) & II.2(c), pages 22-23, the applicant states that existing ancillary and support services will continue to be provided. Exhibit 6 contains a letter dated November 15, 2013, from WMH's President and Chief Executive Officer, stating that WMH will continue to provide ancillary and support services as it has previously. In Section V, pages 64-72, and Exhibits 16 and 23, the applicant adequately documents that angiography services are coordinated with the existing health care system.

The applicant adequately demonstrated the availability of the necessary ancillary and support services and that the proposed services would continue to 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

The following table illustrates the current payor mix for WMH as reported by the applicant in Sections VI.12-VI.13, page 81.

Current Payor Mix for WMH		
Payor Category	**FY 2012 Entire Facility**	**FY 2012 Angiography**
Self Pay/Indigent/Charity/Other*	8.9%	10.7%
Medicare/Medicare Managed Care	57.7%	71.6%
Medicaid	18.1%	6.5%
TriCare/Managed Care/Commercial	15.2%	11.2%
TOTAL	100.0%	100.0%

Note: Totals may not foot due to rounding.
*"Other" includes workers comp and other government payors.

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 Wayne County and statewide. 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)
Wayne County	20.0%	8.3%	20.3%
Statewide	**17.0%**	**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 angiography 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. However, a direct comparison to the applicant's 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. In Section VI.4(a), page 75, the applicant states:

> "*…WMH provides access to care to all patients regardless of their ability to pay. The admission policies included in Exhibit 17 clearly state, 'Patients will be admitted and treated regardless of the patient's financial condition.' This practice will not change with the development of a dedicated angiography room as proposed in this application.*"

See also Exhibit 17 for a copy of WMH's policies on hospital admissions, credit, and collections.

The applicant demonstrates that medically underserved populations have adequate access to services available at WMH. Therefore, the application is conforming to this criterion.

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

Recipients of Hill-Burton funds were required to provide uncompensated care, community service and access by minorities and handicapped persons. In Section VI.11, page 80, the applicant states:

> "*WMH has no obligation to provide uncompensated care. As stated in Section VI.8, the hospital provides, without obligation, a considerable amount of charity care."*

In Section VI.10(a), page 80, the applicant states:

> "*No civil rights equal access complaints have been filed against WMH in the past 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

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The following table illustrates the projected payor mix for WMH as reported by the applicant in Sections VI.14-VI.15, pages 82-83.

Projected Payor Mix for WMH		
Payor Category	**FY 2016 Entire Facility**	**FY 2016 Angiography**
Self Pay/Indigent/Charity/Other*	8.9%	10.7%
Medicare/Medicare Managed Care	57.7%	71.6%
Medicaid	18.1%	6.5%
TriCare/Managed Care/Commercial	15.2%	11.2%
TOTAL	100.0%	100.0%

Note: Totals may not foot due to rounding.
*"Other" includes workers comp and other government payors.

In Section VI.6, page 77, the applicant states:

> *"WMH's services are and will remain accessible to Medicare and Medicaid recipients, the uninsured, and the underinsured. Financial counselors assist patients and families in understanding their ability for financial support. Further, in compliance with the federal EMTALA law, emergency services and care are provided to all patients who present to the hospital who request examination or treatment of a medical condition to determine if an emergency condition exists."*

The applicant demonstrates that medically underserved populations will have adequate access to the proposed services. Therefore, the application is conforming with 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.

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In Section VI.9(a), page 79, the applicant states:

> *"Persons have access to services at WMH through referrals from physicians who have admitting privileges at the hospital. Patients of WMH are also admitted through the emergency department."*

The applicant adequately identified the range of means by which patients will have access to the proposed services. Therefore, the application is conforming to this criterion.

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

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In Section V.1(a), page 64, the applicant states:

> *"The proposed project relates to the clinical needs of health professional training programs in the area because it will improve access to clinical areas, specifically the imaging department, for those programs currently aligned with WMH. As it has done in the past, WMH will continue to work with the health professional training programs already aligned with the hospital and is available to work with others who wish to use its facilities for clinical training purposes. Please see Exhibit 15 for a list of programs that currently use WMH as a training site and a sample agreement."*

In Section V.1(b), pages 64-65, the applicant states:

> *"WMH currently has several long-standing relationships with clinical training programs. …*
>
> *…*
>
> *Of note, WMH provides professional training for over forty clinical and allied health programs, including nurse and radiological technology training for Wayne Community College and Johnston Community College, respectively. These*

relationships are expected to continue following the completion of the proposed project."

The information provided is reasonable and credible. Therefore, the application is conforming with this criterion.

(15) Repealed effective July 1, 1987.
(16) Repealed effective July 1, 1987.
(17) Repealed effective July 1, 1987.
(18) Repealed effective July 1, 1987.

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

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WMH currently provides angiography services, but the hospital does not have a dedicated angiography room. The applicant does not propose any new health services, beds, or operating rooms. Currently, angiography services are provided in the hospital's existing cardiac catheterization laboratory. There are no other providers of angiography services located in Wayne County.

On page 42, the applicant states that the cardiac catheterization laboratory operates on Monday through Friday from 7:00 a.m. to 4:00 p.m. Tuesdays and Thursdays are blocked off specifically for interventional cardiac catheterization procedures. All physicians are able to use the laboratory on a first-come, first-served basis on Mondays, Wednesdays, and Fridays; however, the applicant states that if an urgent interventional cardiac catheterization case presented on a Monday, Wednesday, or Friday, it would likely receive priority over other non-urgent procedures.

In Section V.7, pages 69-72, 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:

*"**MAXIMIZING HEALTHCARE VALUE***

The proposed project is indicative of WMH's commitment to containing healthcare costs and maximizing healthcare benefit per dollar expended. By locating the proposed equipment in existing space, the cost of the project is significantly lower than if the hospital were to develop new construction to house the proposed equipment. WMH has reduced expenses by utilizing existing space and avoiding new construction and has thus

proposed the most value-conscious alternative for the installation of the proposed equipment. …

SAFETY AND QUALITY

The proposed project will serve to improve access to state-of-the-art angiography services provided at WMH. At present, WMH provides exceptional angiography services. However, implementation of the proposed project will enable WMH to increase its capacity and therefore access to state-of-the-art services. In particular, as noted previously, the proposed system's advanced imaging capabilities will enhance the decision making of clinicians and facilitate faster and more effective procedures. Through the proposed project, WMH will raise the bar for quality of care in the service area and motivate other providers to deliver the highest quality of care in order to compete.

EQUITABLE ACCESS

WMH has historically provided services to all persons in need of medical care, regardless of race, sex, creed, age, national origin, handicap, or ability to pay. The hospital will continue to serve this population upon completion of the proposed project. By developing a dedicated angiography room, the proposed project will foster competition for radiology services in Wayne County and propel other providers to maximize the level of access to their services, regardless of the patient's payor source.

… By enhancing access to state-of-the-art diagnostic imaging services, the proposed project will naturally enhance competition in Wayne County and surrounding areas.

…

For these reasons, WMH believes the proposed project will promote safety and quality in the delivery of healthcare services while promoting equitable access and maximizing healthcare value for resources expended for the residents of Wayne and surrounding counties." (emphasis in original)

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 the 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 for its proposal 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

WMH is accredited by the Joint Commission and certified for Medicare and Medicaid participation. According to the files in the Acute Care Licensure and Certification Section, Division of Health Service Regulation, no incidents occurred within the eighteen months immediately preceding the date of this decision, for which any sanctions or penalties related to quality of care were imposed by the State. Therefore, the application is conforming to this criterion.

(21) Repealed effective July 1, 1987.

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

C

WMH is conforming to all applicable Criteria and Standards for Major Medical Equipment as required by 10A NCAC 14C .3100. See discussion below.

SECTION .3100 - CRITERIA AND STANDARDS FOR MAJOR MEDICAL EQUIPMENT

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- The applicant defines the service area for angiography services in Section III.5, pages 56-58, which is similar to the service area identified for the applicant's other health services.

(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 I.12(e), pages 11-13, and Section IV.1, page 62, the applicant provides documentation of its current experience providing angiography 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 10, the applicant provides documentation that the proposed angiography 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 proposed angiography suite 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 31, and Exhibit 6, 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 angiography suite.

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, pages 31-34, the applicant provides the projected number of patients that will use the angiography equipment for the first three years following completion of the proposed project, classified by diagnosis.

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

-C- In Section II.8, page 35, the applicant provides the following table showing the number of patients who will use the service by county of residence:

County	Historical Distribution	Projected Patients		
		FY 2015	FY 2016	FY 2017
Wayne	81.1%	201	202	204
Duplin	8.3%	21	21	21
Sampson	5.3%	13	13	13
Johnston	2.4%	6	6	6
Lenoir	1.2%	3	3	3
Other*	1.8%	4	4	4
TOTAL	**100.0%**	**248**	**249**	**251**

*"Other" includes Bladen, Greene, and Wake counties in North Carolina.
Note: Totals may not foot due to computer rounding.
Source: WMH Internal Data

(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- In Section II.8, page 35, the applicant states,

> *"WMH currently performs angiography procedures in the hospital's cardiac catheterization laboratory. At present, angiography procedures are scheduled on a first come, first serve basis from 7:00 a.m. to 4:00 p.m. on Mondays, Wednesdays, and Fridays. These hours of operation yield a capacity equaling approximately 1,350 angiography procedure hours per year. This capacity is based on the*

assumption of 50 weeks per year with angiography procedures presenting on a first come, first serve basis (which would not be the case 100 percent of the time as assumed). WMH's experience is that the angiography procedures take on average 1.5 hours. Therefore, the maximum number of procedures that can be performed under WMH's current angiography time in the hospital's licensed cardiac catheterization laboratory is 900 procedures (1,350 total operating hours ÷ 1.5 hours per procedure)."

(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 36, the applicant provides a table showing the quarterly projected utilization of WMH's proposed angiography room 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 III.1(b), pages 46-49.

(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- In Section II, page 37, the applicant states, *"WMH is not proposing to acquire new major medical technology as defined by 10A NCAC 14C .3102(4)."*

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- WMH is an existing acute care hospital and provides ancillary and support services for its patients. In Section II.2(b) & II.2(c), pages 22-23, the applicant states that existing ancillary and support services will continue to be provided. Exhibit 6 contains a letter dated November 15, 2013, from WMH's President and Chief Executive Officer, stating that WMH will continue to provide ancillary and support services.

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 VII.1(b), page 84, and Exhibits 5, 6, and 11, 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 angiography 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- Exhibit 6 contains a letter from the President and Chief Executive Officer stating that WMH will ensure that physicians who will use the equipment have had relevant residency training, formal continuing medical education courses, and prior on-the-job experience with the same or similar medical equipment. Exhibit 12 contains the curricula vitae of the physicians who currently perform angiography procedures at WMH.

(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, page 39, 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, page 39, and Exhibit 11, the applicant provides documentation of an organized program of staff education and training.