

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

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

DECISION DATE: September 27, 2012
PROJECT ANALYST: Bernetta Thorne-Williams
TEAM LEADER: Lisa Pittman

PROJECT I.D. NUMBER: Q-8845-12/ Pitt County Memorial Hospital, Incorporated d/b/a Vidant Medical Center/ Acquire one replacement gamma knife to operate on the existing hospital campus/ Pitt 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

According to the 2012 State Medical Facilities Plan (SMFP) there are two gamma knife systems in North Carolina, one at West Forest University Baptist Medical Center which serves the western region (HSA's I, II and III) and one at Pitt County Memorial Hospital which serves the eastern region (HSA's IV, V and VI). In this application, Pitt County Memorial Hospital, Incorporated (PCMH) d/b/a Vidant Medical Center (VMC), proposes to replace its existing gamma knife, in the eastern region, to be operated on the existing hospital campus. The total cost for the replacement gamma knife is \$4,671,700 (after all applicable discounts and trade in value for the existing equipment). There is one policy in the 2012 SMFP that is applicable to this review.

Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities, on page 40 states:

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

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

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

In Section III.2, page 23, the applicant states how the proposed project will be energy efficient. The applicant states:

"VMC is committed to constructing facilities that are energy efficient and promote water conservation. Because of the limited extent of the actual equipment replacement included in this project, the ability to significantly alter the parameters of the existing systems to increase energy will be limited. The existing Gamma Knife facility was completed in 2006."

The applicant adequately demonstrates that in the past Vidant Health has been committed to promoting water conservation and being energy efficient. The applicant states the proposal will continue to provide energy efficiency and a sustainability plan.

In summary, the application is consistent with Policy GEN-4. Consequently, the application is conforming to this criterion.

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

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Pitt County Memorial Hospital, Incorporated d/b/a Vidant Medical Center, whose parent company is University Health Systems of Eastern Carolina, Inc. (UHS) d/b/a Vidant Health

(VH), proposes to replace its existing gamma knife to be operated on the main hospital campus. PCMH, in Project I.D. # Q-6936-03, was approved to acquire one Gamma Knife System to operate in eastern North Carolina, pursuant to a need determination identified in the 2003 SMFP. The existing gamma knife equipment has been operational since October 2005. The applicant proposes to operate the replacement gamma knife in the existing 2,702 square foot gamma knife suite, after de-installation of the current gamma knife.

Population to be Served

In Section III.4(b) and Section III.5(c), pages 26-28, the applicant provides the current and projected patient origin for outpatient and inpatient gamma knife services at VMC, as illustrated in the table below:

| County | FY11 Percent of Total | OY1 – FY 2014 Percent of Total | OY2 – FY 2015 Percent of Total |
|---------------|--------------------------------------|---|---|
| Pitt | 16.0% | 14.4% | 15.1% |
| Wilson | 14.0% | 11.9% | 11.9% |
| Craven | 14.0% | 11.9% | 11.9% |
| Edgecombe | 10.0% | 8.5% | 8.7% |
| Onslow | 6.0% | 6.8% | 7.1% |
| Lenoir | 6.0% | 5.1% | 5.6% |
| Chowan | 6.0% | 6.8% | 7.1% |
| Perquimans | 4.0% | 5.1% | 4.8% |
| Wayne | 4.0% | 3.4% | 3.2% |
| Duplin | 4.0% | 5.1% | 4.8% |
| Nash | 4.0% | 3.4% | 3.2% |
| Northampton | 4.0% | 5.1% | 4.8% |
| Sampson | 2.0% | 2.5% | 2.4% |
| Halifax | 2.0% | 1.7% | 1.6% |
| Johnston | 2.0% | 2.5% | 2.4% |
| Martin | 2.0% | 1.7% | 1.6% |
| All Other* | - | 4.2% | 4.0% |
| Total | 100.0% | 100.0% | 100.0% |

As illustrated in the table above, the applicant projects a slight change in the patient origin for gamma knife services, including the addition of an “All Other” category which the applicant states will include the fringe service area for other counties not listed.

The applicant adequately identified the population to be served.

Need Analysis

VMC currently owns and operates one existing gamma knife system. In Section III.1, the applicant states that the need for the proposed replacement gamma knife at VMC is based on the following factors:

1. The age of the existing gamma knife system has affected quality and procedure time,
2. The need for advanced gamma knife capabilities,
3. The need to continue to provide efficient, high quality gamma knife services in eastern North Carolina.

In Section III.1, page 19, the applicant discusses the need for a replacement gamma knife based on the age of the existing gamma knife at VMC. The applicant states:

“With the source of the Gamma Knife at VMC decayed beyond its half-life, and with this unit being an inferior, older model, patients living in the eastern half of the State that require gamma knife services lack the access to the efficient and state-of-the-art services available in the western half of NC. Because of the time required for certain procedures as a result of the decayed source at VMC, some patients must either be referred to the facility in Winston-Salem, be referred to another facility outside North Carolina, or forego this procedure in lieu of other treatment options. Those patients simply cannot currently be provided with gamma knife services of adequate quality.”

In Section III.1, page 19, the applicant discusses the advanced capabilities of the proposed replacement gamma knife. The applicant states:

“The replacement gamma knife device utilizes the same radiation source (Cobalt-60) and the same mechanism of tumor destruction through the focused application of radiation. However, the new Perfexion Gamma Knife device offers the following additional features:

- *Treatment delivery to one or more tumors in a single session*
- *The potential to treat lesions in the paranasal sinuses, orbits and upper cervical spine – even paraspinal metastases and laryngeal tumors*
- *Enhanced radiation protection*
- *One-button automation and robotic helmet system to reduce treatment times”*

In Section II.5, page 14, the applicant states, *“The new technology will enhance patient safety and comfort, decrease treatment time ...”*

In Section III.1, pages 18-19, the applicant states the importance for maintaining gamma knife services for patients of eastern North Carolina. The applicant states:

“The Gamma Knife can be used as an alternative to standard neurosurgical operations or as an additional therapy in the treatment of residual or recurrent lesions left by conventional surgery. Radiosurgery can be especially useful for those patients who are not suitable for standard surgical techniques due to illness or advanced age. In many neurosurgical cases, the Gamma Knife is the only feasible treatment. Conditions for which application of the Gamma Knife is considered most effective are:

1. *Intracranial tumors such as:*

- *Acoustic neuromas,*
- *Pituitary adenomas,*
- *Pinealomas,*
- *Craniopharyngiomas,*
- *Meningiomas,*
- *Chordomas,*
- *Chondrosarcomas,*
- *Metastases, and*
- *Glial tumors.*

2. *Vascular malformations including arteriovenous malformations.*

3. *Functional disorders such as trigeminal neuralgia, intractable pain, Parkinson's disease, and epilepsy."*

Further in Section III.1, pages 19-20, the applicant states:

"VMC believes that eastern North Carolinians, as they have since October 2005, should have access to the same level of gamma knife services as other state residents who are closer to Winston Salem. ..."

In Section IV.1, pages 31-32 the applicant discusses the historical and projected utilization and provides its assumptions. The applicant states:

"The SMFP currently does not define the annual maximum capacity for a gamma knife. VMC assumes the annual maximum capacity of one gamma knife is 468 procedures annually. The specific formula to determine capacity is:

(2 procedures/9 hour day x 5 days/ week x 52 weeks/year x.9 (10% downtime due to routine maintenance) = 468)"

Table IV.1: VMC Historical and Projected Gamma Knife Utilization

| <i>Historical</i> | <i>Projected</i> |
|-------------------|------------------|
|-------------------|------------------|

| | FY 2006 | FY 2007 | FY 2008 | FY 2009 | FY 2010 | FY 2011 | FY 2012* | FY 2013 | FY 2014 | FY 2015 | FY 2016 |
|---------------|------------|------------|------------|------------|------------|------------|-----------------|------------|------------|------------|------------|
| PSA | 73 | 83 | 76 | 76 | 52 | 36 | 59 | 62 | 73 | 79 | 86 |
| Mkt. Share | 36.4% | 41.2% | 37.6% | 37.4% | 25.4% | 17.5% | 28.6% | 30.0% | 35.0% | 38.0% | 41.0% |
| SSA | 27 | 34 | 30 | 27 | 19 | 14 | 21 | 26 | 40 | 42 | 44 |
| Mkt. Share | 4.8% | 5.9% | 5.1% | 4.5% | 3.1% | 2.2% | 3.3% | 4.0% | 6.1% | 6.3% | 6.4% |
| Fringe | 7 | 3 | 5 | 3 | 0 | 0 | 0 | 5 | 5 | 5 | 5 |
| Mkt. Share | 1.6% | 0.7% | 1.1% | 0.7% | 0.7% | 0.0% | 0.0% | 1.0% | 1.0% | 1.0% | 1.0% |
| Totals | 107 | 120 | 111 | 106 | 71 | 50 | 80 | 93 | 118 | 126 | 135 |
| | | | | | | | % change | 16.3% | 26.9% | 6.8% | 7.1% |

Table IV.1 Assumptions

Methodology and Assumptions:

- Fiscal years run from October 1 through September 30
- PSA = Primary Service Area. This market includes the following NC counties:

| | | |
|-----------|---------|------------|
| Beaufort | Halifax | Pamlico |
| Bertie | Jones | Pitt |
| Craven | Lenoir | Washington |
| Edgecombe | Martin | Wayne |
| Greene | Nash | Wilson |

- SSA = Secondary Service Area. This market includes the following NC counties:

| | | |
|------------|-------------|------------|
| Camden | Gates | Pender |
| Carteret | Granville | Perquimans |
| Chowan | Harnett | Sampson |
| Cumberland | Hertford | Tyrrell |
| Currituck | Hyde | Vance |
| Dare | Johnston | Wake |
| Duplin | Northampton | Warren |
| Durham | Onslow | |
| Franklin | Pasquotank | |

- “Fringe” volumes come from other counties not mentioned above.
- FY07 through FY11 is based on actual historical data from the hospital’s internal database.
- FY12 is estimated based on 3 months actual historical data from the hospital’s internal database. As the current equipment’s source is already beyond its half-life, the procedure time is increasing, reducing volume capacity. Because of the

time currently needed for certain procedures, those patients are referred elsewhere, further reducing volumes.

- *FY13 assumes the new Perfexion Gamma Knife will only be in operation for 3 months (July through Sept). Even for only three months, the improved efficiency related to the new equipment should allow for volumes, in total, to be greater in FY13 than in FY12.*
- *The total market for Gamma Knife services are [sic] assumed to increase with population in projected years.*
- *Conservatively, VMC expects slight market share gains as the additional efficiencies and functionalities of the Perfexion Gamma Knife are realized. Because FY14 is the first full year of service with Perfexion, the most significant increase in market share and volume occurs between FY13 and FY14.*
- *Additional market share gains, not to significantly exceed historical figures, are assumed in FY15 and FY16. Volume growth for those years will hover around 6%.”*

Based on these assumptions, the applicant projects it will perform 135 gamma knife procedures in the third project year which is reasonable given VMC is the only provider of gamma knife services in eastern North Carolina providing services to over 40 counties.

Projected utilization is based on reasonable, credible and supported assumptions regarding projected market share growth due primarily to better efficiencies and functionalities in gamma knife procedures.

In summary, the applicant adequately identified the population to be served and adequately demonstrated the need the population has for the proposed replacement gamma knife. Consequently, 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.

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In Section III.3, pages 24-25, the applicant describes three alternatives considered which include the following:

1) Maintain the Status Quo – which the applicant concluded would not be in the best interest of its patients for the following three reasons.

I. Decayed Source – The gamma knife uses a radioactive ionizing source which has a half-life of approximately 5 years. Meaning that after this point 50% of the radioactive source has decayed and is not available for patient treatment. This requires additional treatment times to deliver the same dose of radiation.

II. External Fixation Adjustment – Patient movement during treatments can not be allowed. The existing gamma knife requires external fixation of the patient's head through the use of a metal frame affixed to the patient's skull that prevents movement. Manual adjustments are required, which introduces human error and increased procedure times.

III. Beam Targeting and Monitoring Technology – this technology has improved since the existing gamma knife was installed and is highly accurate.

2) Reloading the existing machine with a new radioactive source – this option was discarded based on patient care and financial return issues. This option would still have required the manual external fixation of the patient's head and the replacement Cobalt-60 core is over one million dollars.

3) Acquire a replacement gamma knife – the applicant concluded that replacing its existing gamma knife would provide for optimal patient care, improved technology and functionality, thus making this option its least costly and most effective alternative.

Furthermore, the application is conforming to all other applicable statutory and regulatory review criteria, and therefore, the application is approved. The application is conforming to this criterion and is approved subject to the following conditions:

- 1. Pitt County Memorial Hospital, Incorporated d/b/a Vidant Medical Center shall materially comply with all representations made in its certificate of need application.**
- 2. Pitt County Memorial Hospital, Incorporated d/b/a Vidant 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 or that would otherwise require a certificate of need.**
- 3. Pitt County Memorial Hospital, Incorporated d/b/a Vidant Medical Center shall de-install and use as trade-in the existing gamma knife equipment system prior to the acquisition of the new gamma knife system.**
- 4. Pitt County Memorial Hospital, Incorporated d/b/a Vidant 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.

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In Section VIII.1, page 61, the applicant states that the total capital cost of the project will be \$4,671,700, including \$121,000 for the construction contract, \$4,530,000 for equipment/furniture lease/purchase, \$19,000 for architect/engineering fees, and \$1,700 other (DHSR) fee. In Section IX, page 62, the applicant states that there will be no start up or initial operating expenses associated with the proposed project. In Section VIII.3, page 57, the applicant states that the project will be funded by VMC's accumulated reserves (\$2,941,700) and trade in discounts (\$1,730,000). Appendix O contains a June 14, 2012 letter signed by the Chief Financial Officer for Vidant Health (VH) and Vidant Medical Center (VMC), which states:

“VH and VMC will commit \$3,000,000 in accumulated reserves to complete the proposed replacement of an existing gamma knife at the hospital.

VH's accumulated reserves as of April 30, 2012 are \$424.6 million and can support this project.”

Appendix P of the application contains the audited financial statements for University Health Systems of Eastern Carolina, Inc. (UHS) for the years ending September 30, 2011 and September 30, 2010. As of September 30, 2011, UHS had \$101,492,000 in cash and cash equivalents, \$599,225,000 in unrestricted net assets and \$694,310,000 in net assets (total assets less total liabilities). The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project.

The applicant provided pro forma financial statements for the first three years of the project for the entire facility and the proposed gamma knife service in Section X, pages 63-76. For the replacement gamma knife system, the applicant projects revenues will exceed operating expenses in each of the first three operating years of the project. Furthermore, the applicant projects a positive net income for the entire hospital in each of the first three operating years of the project. The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization and cost and charges. See Section X of the application for the pro formas and assumptions. See Criterion (3) for discussion of projected utilization which is hereby incorporated by reference as if fully set forth herein. The applicant adequately demonstrated that the financial feasibility of the proposal is based upon reasonable projections of costs and revenues, and therefore, the application is conforming to this criterion.

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

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The 2012 SMFP identifies two gamma knife systems in North Carolina; one which is located at West Forest University Baptist Medical Center which serves the western region (HSA's I, II and III) and one which is located at Pitt County Memorial Hospital and serves the eastern region (HSA's IV, V and VI). In this application, Pitt County Memorial Hospital, Incorporated d/b/a Vidant Medical Center proposes to replace its existing gamma knife. The proposed gamma knife would be operated in the existing gamma knife suite on the hospital's campus. The applicant adequately demonstrates the need to replace the existing gamma knife system at VMC with a replacement gamma knife system that provides improved technology and functionality. The applicant adequately demonstrates the need for its proposed replacement gamma knife system is based on reasonable, credible and supported projected utilization (which is based on historical utilization as the only provider of gamma knife services in eastern North Carolina). See Criterion (3) for discussion which is hereby incorporated as if fully set forth herein. Thus, the applicant adequately demonstrates the replacement of the gamma knife system at VMC will not result in the unnecessary duplication of gamma knife services in eastern North Carolina. Consequently, the application is conforming to this criterion.

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

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In Section VII.1(a), page 50, the applicant states:

“Staffing tables include only the staff directly related to the operation of the Gamma Knife service. Staffing tables do not include staff related to ancillary and support services not identified as a component of the proposed project.”

VMC currently provides gamma knife services in eastern North Carolina. As such, in Section VII.1(b), page 50, the applicant states, *“VMC intends to hire no additional staff as a direct result of the proposed project.”*

In Section VII.1(a) and (b), page 50, the applicant states that one registered nurse is needed for the operation of the gamma knife service.

In Section VII.8(a), page 54, the applicant identifies the Chief of Staff/Medical Director and provides a copy of his curriculum vitae in Appendix J.

The applicant adequately demonstrated the availability of adequate health manpower and management personnel for the provision of 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.

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The applicant is an existing hospital and provider of gamma knife services and the necessary ancillary and support services are currently available. In Section II.2(a), pages 13-14, the applicant states:

“All ancillary and support services required for efficient and effective utilization of the proposed replacement project are already in place at VMC as this is an existing service. A patient requiring a gamma knife procedure must be fitted with a Leskell head frame prior to the procedure. Placing this frame requires a MRI scan. The MRI is conveniently located immediately adjacent to the gamma knife vault.

The radiation physicist associated with the existing radiation oncology services provides coverage for the existing gamma knife services and will continue to provide this coverage for the replacement equipment. No additional support for the radiation physicist will be needed to provide the gamma knife service. The existing radiation oncology program has adequate capacity to meet the existing and anticipated support needs of the proposed project.

VMC currently has 9 neurosurgeons, 20 radiation oncologists, 1 medical physicist, 64 diagnostic radiologists, 22 anesthesiologists, 2 otolaryngologists, and 11 medical neurologists on its medical staff. All of these physicians currently provide medical coverage and consultation services to VMC patients and will continue to do so with the replacement of the existing gamma knife. ...

One fully trained gamma knife nurse provides necessary nursing support for the existing machine and will continue that support for the proposed replacement project.

No additional administrative or support staff will be needed for the proposed replacement project. Support functions such as management, billing, transcription, radiation safety, patient transport, etc. currently support the existing gamma knife and will continue to do so after the existing machine is replaced.”

In Section V.2(a), page 36, the applicant states:

“As the tertiary referral center for all of eastern North Carolina, VMC already has formal transfer agreements with all of the acute care hospitals in the region and with several military hospitals and nursing homes. ...”

Appendix H, contains a list of facilities with which VMC has transfer agreements. Appendix I contains copies of letters of support from area physicians.

The applicant adequately demonstrated the availability of the necessary ancillary and support services and that the proposed services would be coordinated with the existing health care system. Therefore, the application is conforming to this criterion.

- (9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:
- (i) would be available under a contract of at least 5 years duration;
 - (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
 - (iii) would cost no more than if the services were provided by the HMO; and
 - (iv) would be available in a manner which is administratively feasible to the HMO.

NA

- (11) Repealed effective July 1, 1987.

- (12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

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;

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In Section VI.12 and VI.13, pages 47-48, the applicant provides the payor mix during Fiscal Year 2011 for the entire hospital and its gamma knife services, as illustrated in the tables below:

| VMC FY 2011 Payor Mix As a % of Total Procedures | | |
|--|-----------------|------------------------|
| | Entire Hospital | Gamma Knife Procedures |
| Commercial Insurance | 1.3% | 2.8% |
| Medicaid | 27.7% | 8.5% |
| Medicare/Medicare Managed Care | 45.3% | 52.0% |
| Managed Care | 16.7% | 25.4% |
| Other (CHAMPUS / Workman Comp) | 4.2% | 9.9% |
| Self Pay/Indigent/Charity | 4.8% | 1.4% |
| Total | 100.0% | 100.0% |

In Section VI.2, page 42, the applicant states:

“As eastern North Carolina’s only academic medical center and tertiary care provider, Vidant Medical Center (VMC) has an obligation to accept any eastern NC resident requiring medically necessary treatment. No eastern NC resident is denied access to non-elective care at VMC based on race, color creed, age, sex, national origin, religion, disability status, sexual preference, source of payment for care or lack of medical insurance.”

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. The following table illustrates those percentages as of June 2010 and CY 2009, respectively. The data in the table was obtained on September 7, 2012. More current

data, particularly with regard to the estimated uninsured percentages, was not available.

| | Total # of Medicaid Eligibles as % of Total Population | Total # of Medicaid Eligibles Age 21 and older as % of Total Population | % Uninsured CY 2009 (Estimate by Cecil G. Sheps Center) |
|-----------|---|--|--|
| Pitt | 16% | 6.7% | 21.0% |
| 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 services offered by Vidant Medical Center.

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 applicant's current payor mix would be of little value. The population data by age, race or gender does not include information on the number of elderly, minorities or women utilizing health services. Furthermore, OSBM's website does not include information on the number of handicapped persons.

The applicant demonstrated that medically underserved populations currently have adequate access to Vidant Medical Center and its gamma knife services. 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 47, the applicant states:

“VMC is bound by the Civil Rights Act, Hill-Burton Community Services obligation as well as its admissions policy to provide equal access to care without discrimination and without regard to race, color, creed, national origin, or source of payment. VMC has fulfilled its required volume of uncompensated care services in compliance with Hill-Burton regulations. However, there exists into perpetuity the Hill-Burton requirement that VMC provide access to all those in need. In fact, over the last four fiscal years, VMC has provided almost \$306.2 million in charity care services. Below is the four year breakout.

*FY08 = \$41,776,646
FY09 = \$74,044,506
FY10 = \$99,545,120
FY11 = \$90,795,365”*

Further, the applicant states in Section VI.2, pages 42-43, that VMC does not discriminate on the basis of race, age, income, etc. The applicant states:

“The hospital is a major participant in the Community Care Plan (CCP) program that operates throughout eastern North Carolina. CCP is a partnership between entities that include VMC, other charitable organizations, other health care providers, and county organizations. The program is designed to provide health care services at little to no cost to residents who have no health insurance and are considered medically indigent. These programs allow the medically underserved to have access to essential inpatient and outpatient services.

VMC has traditionally provided services to a variety of patient populations. In FY11, the distribution of patients treated at VMC that received a gamma knife appropriate procedure was as follows.

| | % of Total |
|---------------------------------------|-------------------|
| <i>Racial & Ethnic Minorities</i> | <i>24.0%</i> |
| <i>Seniors (65+)</i> | <i>30.0%</i> |
| <i>Female</i> | <i>62.0%</i> |
| <i>Medically Underserved</i> | <i>14.0%</i> |

Source: VMC Internal Data”

In Section VI.10(a), page 47, the applicant states:

“There have been no civil rights equal access complaints filed against the hospital within the past five years.”

The application is conforming to this criterion.

- (c) That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services; and

C

In Section VI.14(a) and Section VI.15(b), pages 48-49, the applicant provides the projected payor mix for the second full fiscal year (2015) of operations for the proposed replacement gamma knife procedures, as illustrated in the table below.

| VMC FY 2015 Payor Mix As a % of Total Procedures | | |
|---|------------------------|-----------------------------------|
| | Entire Hospital | Gamma Knife Procedures |
| Commercial Insurance | 1.3% | 2.8% |
| Medicaid | 27.7% | 8.5% |
| Medicare/Medicare Managed Care | 45.3% | 52.0% |
| Managed Care | 16.7% | 25.4% |
| Other (CHAMPUS / Workman Comp) | 4.2% | 9.9% |
| Self Pay/Indigent/Charity | 4.8% | 1.4% |
| Total | 100.0% | 100.0% |

In Section VI.14, page 48, the applicant states, “*VMC assumes FY15 payor mix would approximate FY11.*”

The applicant demonstrated that medically underserved populations will have adequate access to the proposed replacement gamma knife 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.

C

In Section VI.9(a), page 46, the applicant states:

“As in the past, patients will have access to the proposed Perfexion Gamma Knife primarily through medical staff referrals, emergency department admissions and patient transfers and referrals from other institutions. The services are available through normal operating hours.”

The applicant demonstrated the means by which patients will have access to the proposed services. Therefore, the application is conforming with 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(a) and (c), pages 34-35, the applicant provides documentation that VMC will continue to accommodate the clinical needs of area health professional training programs. The information provided is reasonable and credible and supports a finding of conformity 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.

C

The applicant currently owns and operates the only gamma knife system serving eastern North Carolina. In Section V.7, page 40, the applicant discusses how the replacement gamma knife will foster competition by promoting cost effectiveness, quality, and access to services in the proposed service area. The applicant states:

“The proposed replacement of an existing gamma knife will foster competition by promoting high quality, delivering cost effective services, and providing continued access to gamma knife services. ...”

Further, in Section V.7, page 40, the applicant provides a bullet point list which explains why VMC believes the replacement gamma knife is critical to its mission to provide quality care to patients in eastern North Carolina. See also Sections II, III, VI and VII of the application for additional discussion by the applicant about the impact of its proposal on cost effectiveness, quality and access to gamma knife services in eastern North Carolina.

The applicant adequately demonstrates that its proposal would enhance competition by promoting cost effectiveness, quality and access to gamma knife services based on the following analysis:

- 1) Projected utilization of the replacement gamma knife is based on reasonable, credible and supported assumptions which are based on historical utilization. See Criterion (3) for discussion regarding projected utilization which is hereby incorporated as if fully set forth herein. The applicant adequately demonstrates the financial feasibility of the proposal is based upon reasonable projections of costs and charges. See the Pro Formas. See Criterion (5) for discussion regarding financial feasibility which is hereby incorporated as if fully set forth herein. Therefore, the applicant adequately demonstrates the cost effectiveness of its proposal.
- 2) The applicant projects to provide adequate access to medically underserved groups, including self pay / charity care patients, Medicare beneficiaries and Medicaid recipients. See Section VI of the application. See Criterion (13c) for discussion regarding projected access by these groups which is hereby incorporated as if fully set forth herein.
- 3) The applicant adequately documents that it will provide quality care. See Sections II and VII of the application.

Therefore, the applicant adequately demonstrates that its proposal 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

VMC is accredited by the Joint Commission and certified for Medicare and Medicaid participation. According to the files in the Acute and Home 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

The applicant proposes to replace an existing gamma knife, not to acquire an additional gamma knife. Therefore the Criteria and Standards for Major Medical Equipment, promulgated in 10A NCAC 14C.3100, are not applicable to this review.