

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: September 28, 2017

Findings Date: September 28, 2017

Project Analyst: Bernetta Thorne-Williams

Team Leader: Fatimah Wilson

Project ID #: J-11354-17

Facility: Duke University Hospital

FID #: 943138

County: Durham

Applicant(s): Duke University Health System, Inc.

Project: Acquire Synaptive Brightmatter surgical equipment at Duke University Hospital

### REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

NA

Duke University Health System, Inc. (DUHS) d/b/a Duke University Hospital (DUH) proposes to acquire one unit of Synaptive Brightmatter surgical equipment to be located in The Preston Robert Tisch Brain Tumor Center in the Duke Cancer Center (DCC) located on the Duke University Hospital campus.

#### **Need Determination**

The proposed project does not involve the addition of any new health service facility beds, services, or equipment for which there is a need determination in the 2017 State Medical Facilities Plan (SMFP). Therefore, there are no need determinations applicable to this review.

#### **Policies**

There are no policies in the 2017 SMFP applicable to this review.

### **Conclusion**

In summary, there are no need determinations or policies applicable to this review. Therefore, this criterion is not applicable to this review.

- (2) Repealed effective July 1, 1987.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

In this application, DUH proposes to acquire Synaptive Brightmatter surgical equipment to be located in The Preston Robert Tisch Brain Tumor Center in the DCC located on the Duke University Hospital campus.

### **Patient Origin**

In Section B.3(a), the applicant identifies itself as an Academic Medical Center Teaching Hospital, thus, DUH provides services for patients not only in NC, but other states. As such, on page 21, the applicant provides historical patient origin for neurosurgery cases performed at DUH in fiscal year 2016 (FY2016) that would be eligible for the proposed equipment. The applicant identifies 19 counties in North Carolina, Virginia and other states as its service area.

In Sections C.2 and C.3, pages 21-23, the applicant provides the historical patient origin for FY2016 and the projected patient origin for the first three fiscal years by number of neurosurgery cases, by county of residence, as summarized below.

County	Historical (FY2016)		OY1 (FY2019)		OY2 (FY2020)		OY3 (FY2021)	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Alamance	16	2%	8	1%	8	1%	8	1%
Caswell	1	0%	-	0%	-	0%	-	0%
Chatham	6	1%	2	0%	2	0%	2	0%
Cumberland	25	3%	32	4%	32	4%	32	4%
Durham	65	8%	67	7%	67	7%	67	7%
Franklin	6	1%	6	1%	6	1%	6	1%
Granville	14	2%	8	1%	8	1%	8	1%
Guilford	14	2%	15	2%	15	2%	15	2%
Harnett	9	1%	17	2%	17	2%	17	2%
Johnson	16	2%	6	1%	6	1%	6	1%
Lee	7	1%	2	0%	2	0%	2	0%
Nash	9	1%	12	1%	12	1%	12	1%
Orange	15	2%	14	2%	14	2%	14	2%
Person	13	2%	14	2%	14	2%	14	2%
Robeson	9	1%	12	1%	12	1%	12	1%
Vance	12	1%	14	2%	14	2%	14	2%
Wake	108	13%	137	15%	137	15%	137	15%
Warren	1	0%	9	1%	9	1%	9	1%
Wilson	6	1%	220	24%	220	24%	220	24%
Other NC Counties	243	28%	249	27%	249	27%	249	27%
Other States	217	25%	249	27%	249	27%	249	27%
Virginia	51	6%	66	7%	66	7%	66	7%
<b>Total</b>	<b>863</b>	<b>100%</b>	<b>910</b>	<b>100%</b>	<b>910</b>	<b>100%</b>	<b>910</b>	<b>100%</b>

On page 20, the applicant states the patient origin is by category of neurosurgery cases for which the proposed equipment is anticipated to be used, as defined by CPT codes, excluding outpatient, non-neurosurgery, and spine cases. On pages 23-24 and Exhibit C.4, the applicant provides the assumptions and methodology used to project patient origin. The applicant projects that the proposed equipment would be used in twenty percent of the cases above, thus the total number of patients in each county would be twenty percent of the number identified for the specified neurosurgery cases in each county.

The applicant adequately identifies the population it proposes to serve.

**Analysis of Need**

In this application, DUH proposes to acquire Synaptive Brightmatter surgical equipment to be located in The Preston Robert Tisch Brain Tumor Center in the DCC located on the Duke University Hospital campus. In Section C, page 25, the applicant states that the proposed equipment does not provide stand-alone procedures, rather, is a tool used in the course of neurosurgery.

In Section C.4, page 24, the applicant describes the factors which it states support the need for the proposed project, including:

- The Preston Robert Tisch Brain Tumor Center has one of the best pediatric and adult neuro-oncology programs in the world; combining research breakthroughs, clinical trials and the newest therapies. (page 24)
- The Preston Robert Tisch Brain Tumor Center sees up to 800 new adult and 75 new pediatric brain tumor patients per year from across the country and around the world. (page 24)
- A key component to The Preston Robert Tisch Brain Tumor Center is its multidisciplinary approach to state-of-the-art neurosurgery. (page 24)
- DUH's neurosurgeons project to use the proposed equipment on a significant proportion of open craniotomy cases. (page 25)

The applicant states in Section Q, that DUH is reaching its practical capacity for its inpatient neurology units and unless inpatient capacity is increased, DUH will have limits on additional surgical volumes as patients would have to be admitted to an inpatient bed following their surgery.

On page 56, the applicant states that as an AMCTH, DUH serves as a primary teaching site for medical students, residents, fellows, nurses, and other health care professionals, thus, the proposed project will enhance DUH's ability to fulfill its educational mission.

The applicant adequately demonstrates the need DUH has for the Synaptive Brightmatter surgical equipment.

#### Projected Utilization

In Section C, page 23, the applicant states that the proposed equipment is projected to be used in 20 percent of neurosurgery cases, therefore, the total number of projected patients that would use the proposed new neurosurgical equipment would be 20 percent of the total identified neurosurgery cases in each county, as shown in the table below. Additionally, in Section C, page 25, the applicant states that the proposed equipment does not provide stand-alone procedures, rather, it is a tool used in the course of neurosurgery. Thus, the total number of neurosurgery cases that might be performed using the proposed equipment in a single day is 2-3, depending on the procedure. Therefore, the projected maximum capacity for the proposed neurosurgery equipment would be 12.5 cases per week or 625 cases per year depending on the nature of the cases, the surgeon's schedule, and operating room constraints. (pages 25-26)

In Section Q, the applicant provides the following table which illustrates the historical utilization of neurosurgery procedures performed and the projected utilization of neurosurgery procedures to be performed on the proposed equipment, as illustrated below.

	Historical	Interim		Projected		
	FFY 2016	FFY 2017	FFY 2018*	OY1 FFY 2019	OY2 FFY 2020	OY3 FFY 2021
# Brightmatter Units			1	1	1	1
# of Cases	863	897	910	910	910	910
# of Procedures	1,316	1,338	1,357	1,357	1,357	1,357
Procedures/Case	1.52	1.49	1.49	1.49	1.49	1.49
Case Growth	17.4%	3.9%	1.4%	0.0%	0.0%	0.0%
Procedure Growth	18.9%	1.7%	1.4%	0.0%	0.0%	0.0%
# of Cases w/ Brightmatter Equipment			61	182	182	182
# of Procedures w/ Brightmatter Equipment 20% of total procedures			91	271	271	271
Procedures/Case			1.49	1.49	1.49	1.49

As illustrated above, the applicant projects that 20 percent of all neurosurgery procedures would be performed on the Synaptive Brightmatter surgical equipment, for a total of 271 procedures ( $1,357 \times .20 = 271$ ) in each of the first three fiscal years of the proposed project.

In Section Q, Form C, the applicant states that the assumptions regarding projected utilization is based on inpatient and research cases as a portion of the following procedures:

- Cranial Navigation – Intradural
- Cranial Navigation – Extradural
- 3D Rendering w/ Interpretation and Reporting of CT, MRI, Ultrasound, or other Tomographic
  - Modality; Requiring image post-processing on an independent Workstation (planning)
- Microsurgical Techniques, requiring use of operating microscope

The applicant states that case volume and procedure volume are calculated using the FY2017 case/procedure ratio. Cases reflect patient encounters, which can have multiple procedures per encounter. The applicant then applied a 20 percent ratio to the projected neurosurgery cases and procedures in which the proposed equipment could be used. [**Emphasis added reflects language in the application**]. The applicant states in Section Q, that neurosurgery cases are projected to increase overall by 1.4% in FY2018 over FY2017 and assumes this growth rate to be reasonable in light of historic growth. The applicant states that the volume for the procedures on the proposed equipment in FY2018 is expected to increase at the same rate (1.4%). DUH projects that volumes will be held flat after FY2018 at 910 cases per year for the specified procedure categories listed above. (Section Q)

The assumptions include factors such as surgeon preference, scheduling constraints, and procedure specific factors that will affect which equipment is the most useful as the proposed equipment can only be used in one procedure at a time. The applicant states that for FY2018,

DUH assumes that the proposed equipment will be used in 20 percent of the eligible cases beginning in March 2018, when the equipment is put into service (910 annual cases x 4 months/12 x .2). (Section Q)

Based on DUH's internal data, the applicant demonstrates that the proposed Synaptive Brightmatter surgical equipment will perform a total of 271 procedures by OY3 (2021). The applicant states that DUH is reaching its practical capacity for its inpatient neurology units and unless inpatient capacity is increased, DUH will have limits on additional surgical volumes as patients would have to be admitted to an inpatient bed following their surgery.

Projected utilization is based on reasonable and adequately supported assumptions.

### **Access**

In Section C.10, page 27, the applicant states DUH is opened to all residents and non-area residents of North Carolina and surrounding areas. The applicant states DUH does not discriminate based on race, ethnicity, age, gender, or disabilities. In Section L, page 51, the applicant provides a table which illustrates that DUH (entire hospital) provided services to women (43.4%), those 65+ (31.9%) and racial minorities (23.7%) during the last fiscal year. The applicant also provides the historical comparison by percentage for its neurosurgery services, as follows, women (51.3%), those 65+ (23.9%) and racial minorities (22.9%) during the last fiscal year. In Section L.3, page 53, the applicant projects that 46.66 percent of patients will have some or all of their neurosurgery services paid for by Medicare and/or NC Medicaid during the second FY (2020).

### **Conclusion**

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

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

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 E, page 32, the applicant discusses the alternatives considered for meeting the needs for the proposed project. The applicant states that the only other alternative to the proposed project is to maintain the status quo. The applicant states that by applying for the equipment, DUH hopes to improve patient care, research and teaching of best practices procedures. Therefore, the proposed alternative is the most effective alternative.

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

In summary, the applicant adequately demonstrates that this proposal is the 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. Duke University Health System, Inc. d/b/a Duke University Hospital shall materially comply with all representations made in the certificate of need application.**
  - 2. Duke University Health System, Inc. d/b/a Duke University Hospital shall acquire no more than one unit of Synaptive Brightmatter surgical equipment to be located at The Preston Robert Tisch Brain Tumor Center in the Duke Cancer Center.**
  - 3. Duke University Health System, Inc. d/b/a Duke University Hospital as part of this project, shall not acquire any equipment that is not included in the project's proposed capital expenditures in Section F of the application and that would otherwise require a certificate of need.**
  - 4. No later than three months after the last day of each of the first three full years of operation following initiation of the services authorized by this certificate of need, Duke University Health System, Inc. d/b/a Duke University Hospital shall submit, on the form provided by the Healthcare Planning and Certificate of Need Section, an annual report containing the:**
    - a. Payor mix for the services authorized in this certificate of need.**
    - b. Utilization of the services authorized in this certificate of need.**
    - c. Revenues and operating costs for the services authorized in this certificate of need.**
    - d. Average gross revenue per unit of service.**
    - e. Average net revenue per unit of service.**
    - f. Average operating cost per unit of service.**
  - 5. Duke University Health System, Inc. d/b/a Duke University Hospital shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

DUH proposes to acquire one unit of Synaptive Brightmatter surgical equipment to be located in The Preston Robert Tisch Brain Tumor Center in the Duke Cancer Center located on the Duke University Hospital campus.

**Capital and Working Capital Costs**

In Form F.1a in Section Q, the applicant projects the total capital cost of the proposed project to be \$1,700,000 as follows:

<b>Projected Capital Costs</b>	
Medical Equipment	\$1,450,000
Other (contingency and filing fee)	\$250,000
<b>Total</b>	<b>\$1,700,000</b>

In Section F.3(a) and (b), pages 34-35, the applicant projects no start-up or initial operating expenses for the proposed project.

**Availability of Funds**

In Section F.2, page 33, the applicant states the capital cost of the project will be funded with accumulated reserves or owner’s equity. Exhibit F.2 contains a letter dated June 1, 2017 from the Senior Vice President, Chief Financial Officer and Treasurer of DUHS committing up to \$2,000,000 in accumulated reserves to the capital costs of the proposed project. Exhibit F.2 also contains the Duke University Health System, Inc. and Affiliates consolidated balance sheets for the years ending June 30, 2016 and 2015. As of June 30, 2016, DUHS had \$281,143,000 in cash and cash equivalents, \$5,164,925,000 in total assets, and \$2,394,892,000 in net assets. The applicant adequately demonstrates that sufficient funds will be available for the capital needs of the project.

**Financial Feasibility**

The applicant provides pro forma financial statements for the first three full fiscal years of operation following completion of the project on Form F.2. In the pro forma financial statements (Form F.4), the applicant projects that operating expenses will exceed revenues in the second and third operating years of the proposed project, as shown in the table below.

<b>DUH Neurosurgery Projected Revenues &amp; Expenses – FYs 2019-2021</b>			
	<b>OY 1 – FY 2019</b>	<b>OY 2 – FY 2020</b>	<b>OY 3 – FY 2021</b>
Total Neurosurgery Cases	910	910	910
Total Gross Revenues (Charges)	\$64,111,941	\$64,111,941	\$64,111,941
Total Net Revenue	\$25,191,864	\$25,320,370	\$25,450,174
Total Operating Expenses (Costs)	\$25,123,730	\$26,393,561	\$27,666,972
Projected Average Charge per Case	\$70,453	\$70,453	\$70,453
Average Operating Expense per Case	\$27,608	\$29,004	\$30,403
Net Income	\$68,134	(\$1,073,191)	(\$2,216,798)



However, the applicant projects in Form F.2 that revenues will exceed operating expenses in the first three operating years of the project for DUHS as a whole. The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section Q of the application for the assumptions used regarding costs and charges. The discussion regarding analysis of need and projected utilization found in Criterion (3) is incorporated herein by reference. The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

### **Conclusion**

In summary, the applicant adequately demonstrates the financial feasibility of the project is based upon reasonable and adequately supported assumptions regarding projected utilization, revenues (charges) and operating costs. Therefore, the application is conforming to this criterion.

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

### C

In Section B.3(a), page 13, the applicant states DUH is an AMCTH, as such, DUH provides services for patients from multiple counties in North Carolina and other states. The applicant identifies 19 counties in North Carolina, Virginia and other states in its service area. In Section G, page 39, the applicant states that as an AMCTH, DUH is not required to document or project the utilization of any other facility in the service area, including related entities, pursuant to N.C. Gen. Stat. §131E-183(b). However, DUH states that it is not aware of any other providers in the state who currently use the proposed equipment for neurosurgery procedures.

On page 39, the applicant provides a list of hospitals in Durham and Wake counties that reported inpatient neurosurgery volumes on their 2017 license renewal application (LRA), as follows:

- UNC Hospitals 1,403
- WakeMed 789
- WakeMed Cary 78
- Rex Hospital 739
- Duke Regional Hospital 159
- Duke Raleigh Hospital 560

The applicant further states on page 39, that it is impossible to determine what kinds of neurosurgery procedures were performed based on the data contained in the LRAs. The applicant does not seek to offer new services, but rather to enhance existing neurosurgery services currently offered at DUH in The Preston Robert Tisch Brain Tumor Center in the Duke Cancer Center.

The applicant adequately demonstrates that its projected utilization is based on reasonable and adequately supported assumptions. The discussion regarding analysis of need and projected utilization found in Criterion (3) is incorporated herein by reference.

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in its proposed service area. Therefore, the application is conforming to this criterion.

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

C

In Section Q, on Form H, the applicant states that it currently employs 9.95 FTE positions for its neurosurgery operating room (OR) services. The applicant projects no additional FTE positions will be needed. The applicant provides its assumptions for staffing on Form H. In Section H.2, page 41, the applicant discusses its process for recruiting staff. In Section H.4, the applicant states that Dr. Lisa Pickett is the Medical Director for DUH and that Dr. John H. Sampson is the chair of the Neurosurgery Department. The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services. Therefore, the application is conforming to this criterion.

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

C

In Section I, page 44, the applicant states that as an Academic Medical Center Teaching Hospital the necessary ancillary and support services are currently available including DUH's clinical engineering and support through a service agreement with the vendor of the proposed equipment. The applicant further states that DUH is a part of DUHS which includes inpatient acute care, psychiatric, and rehabilitation services, primary care, home health and hospice services and DUH works closely with Private Diagnostic Clinic, PLLC, which provides a range of specialty physician services across the Triangle. In Exhibit I.1, the applicant provides a summary of the support services that will be offered for the Synaptive Brightmatter equipment.

The applicant adequately demonstrates that necessary ancillary and support services are available and that the proposed services will be coordinated with the existing healthcare 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

DUH purposes the acquisition of movable surgical equipment which does not require construction or renovations to any of its existing operating rooms.

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:
- (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C

In Section L.1(b), page 52, the applicant provides the payor source for DUH and for its neurosurgery services for FY 2016, as follows.

<b>DUH Historical Payor Mix FY 2016</b>		
<b>Payor Source</b>	<b>Entire Facility</b>	<b>Neurosurgery Services</b>
Private Pay/Managed Care*	39.73%	51.68%
Medicare	41.26%	30.94%
NC Medicaid	13.11%	12.91%
TRICARE	1.67%	2.70%
Worker Comp.	0.14%	0.00%
Other** Manage Care Plans	1.75%	1.36%
Self-Pay	2.33%	0.40%
<b>Total</b>	<b>100.0%</b>	<b>100.0%</b>

\*Includes Commercial (DUH 1.09%), (Neurosurgery 1.72%), Duke Select (DUH 3.15%), (Neurosurgery 1.42%) and Managed Care (DUH 35.49%), (Neurosurgery 48.54%). \*\*Includes out of state Medicaid, VA, International, other Government and non-specified payor sources.

The United States Census Bureau provides demographic data for North Carolina and all counties in North Carolina. The following table contains relevant demographic statistics for the applicant's service area.

<b>Percent of Population</b>						
<b>County</b>	<b>% 65+</b>	<b>% Female</b>	<b>% Racial &amp; Ethnic Minority*</b>	<b>% Persons in Poverty**</b>	<b>% &lt; Age 65 with a Disability</b>	<b>% &lt; Age 65 without Health Insurance**</b>
Durham	11%	52%	58%	17%	7%	18%
Wake	10%	51%	39%	12%	5%	14%
Statewide	15%	51%	36%	17%	10%	15%

Source: <http://www.census.gov/quickfacts/table>, 2014 Estimate as of December 22, 2015.

\*Excludes "White alone" who are "not Hispanic or Latino"

\*\*"This geographic level of poverty and health estimates are not comparable to other geographic levels of these estimates. Some estimates presented here come from sample data, and thus have sampling errors that may render some apparent differences between geographies statistically indistinguishable...The vintage year (e.g., V2015) refers to the final year of the series (2010 thru 2015). Different vintage years of estimates are not comparable."

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, women or handicapped persons utilizing health services.

The applicant demonstrates that it currently provides adequate access to medically underserved populations. Therefore, the application is conforming to this criterion.

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

C

Recipients of Hill-Burton funds were required to provide uncompensated care, community service and access by minorities and handicapped persons. In Section L.2, page 52, the applicant states DUH has satisfied its requirements of applicable federal regulations for uncompensated care in return for the Hill-Burton funds previously received. The applicant states on page 52, that DUH has no obligation under applicable federal regulations to provide uncompensated care, community service, or access by minorities and handicapped persons other than those obligations which apply to private, not-for-profit, acute care hospital which participate in Medicare, Medicaid and Title V programs. On page 53, the applicant states no civil rights access complaints were filed against the hospital in the last five years. Therefore, the application is conforming to this criterion.

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

C

In Section L.3, page 53, the applicant projects its payor mix for the second operating year following project completion (FY2020) for the entire hospital and its neurosurgery services, as shown below.

<b>DUH Projected Payor Mix FY 2020</b>		
<b>Payor Source</b>	<b>Entire Facility</b>	<b>Neurosurgery Services</b>
Private Pay/Managed Care*	38.04%	47.69%
Medicare	42.68%	29.24%
NC Medicaid	12.76%	17.42%
TRICARE	1.75%	1.73%
Worker Comp.	0.16%	0.00%
Other** Manage Care Plans	1.97%	3.44%
Self-Pay	2.64%	0.48%
<b>Total</b>	<b>100.0%</b>	<b>100.0%</b>

\*Includes Commercial (DUH 1.03%), (Neurosurgery 2.67%), Duke Select (DUH 3.23%), (Neurosurgery 1.13%) and Managed Care (DUH 33.78%), (Neurosurgery 43.89%). \*\*Includes out of state Medicaid, VA, International, other Government and non-specified payor sources.

The applicant projects that 44.66 percent of its neurological services patients will have all or some of their services paid for by Medicare and/or NC Medicaid. The applicant provides its assumptions and methodology used for the projected payor mix on page 54. The applicant demonstrates that medically underserved populations will continue to have adequate access to neurosurgery services offered at DUH. Therefore, the application is conforming to this criterion.

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

C

In Section L.5, page 54, the applicant states that patients are referred for neurological services by physician or are admitted through the emergency department. The applicant adequately demonstrates that the facility will offer a 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.

C

In Section M, page 56, the applicant states that as an AMCTH, DUH serves as a primary teaching location for medical students, residents, fellows, nurses, and other health care professionals. The applicant further states on page 56, that the proposed project will enhance DUH's ability to fulfill its educational mission. The applicant states that members of Duke University Schools of Medicine and Nursing and DUH's staff work closely with faculties of other schools and universities, community colleges and clinics in the area to provide health professional training programs including specialized training. The information provided is reasonable and credible and supports a finding of conformity to this criterion.

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

C

The applicant proposes to acquire one unit of Synaptive Brightmatter surgical equipment to be located in The Preston Robert Tisch Brain Tumor Center in the DCC located on the Duke University Hospital campus.

In Section B.3(a), page 13, the applicant states DUH is an Academic Medical Center Teaching Hospital, as such, DUH provides services for patients from multiple counties in North Carolina

and Virginia. The applicant identifies 19 counties as its primary and secondary service area. In Section G, page 39, the applicant states that as an AMCTH, DUH is not required to document or project the utilization of any other facility in the service area, including related entities, pursuant to N.C. Gen. Stat. §131E-183(b). However, DUH states that it is not aware of any other providers in the state who currently use the proposed equipment for neurosurgery procedures.

In Section N, page 57, the applicant states that the proposed project will promote cost-effectiveness, quality, and access to services and thereby promote competition in the service area because it will allow DUH to better meet the needs of its existing patient population, respond to emergencies and ensure timely provision of services. The applicant further states on page 57 that the proposed project will not directly affect cost effectiveness in that the new equipment will be used in conjunction with existing services for which charges and reimbursement will not change.

See also Sections C, E, F, G, H, I, L, and O, where the applicant discusses the impact of the project on cost-effectiveness, quality, and access.

The information in the application is reasonable and adequately demonstrates that any enhanced competition in the service area includes 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 the project and that it is a cost-effective alternative. The discussions regarding the analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.
- The applicant adequately demonstrates it will continue to provide quality services. The discussions regarding quality found in Criterion (20) is incorporated herein by reference.
- The applicant demonstrates that it will continue to provide adequate access to medically underserved populations. The discussions regarding access found in Criteria (3) and (13) are incorporated herein by reference.

Therefore, the application is conforming to this criterion.

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

## C

In Section O.3, page 58, the applicant states that it currently owns, leases, or manages nine facilities in North Carolina. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, during the 18 months immediately preceding the submittal of the

application through the date of the decision one facility, Duke Raleigh Hospital, was found to be out of compliance with one or more Medicare conditions of participation. The hospital submitted a plan of correction in February 2016 and is back in compliance as of February 24, 2016. At this time, all nine facilities are in compliance with all Medicare conditions of participation. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at all nine facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

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

NA

The proposed neurosurgery equipment does not provide stand-alone procedures, rather it is a tool to be used to assist with enhancing the quality of neurosurgery procedures. Therefore, procedures are not scheduled on the proposed equipment, as such, determining capacity is not feasible. Therefore, there are no performance standards that are applicable to the proposed equipment or to this review.