

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: July 25, 2018

Findings Date: July 25, 2018

Project Analyst: Bernetta Thorne-Williams

Assistant Chief: Lisa Pittman

Project ID #: J-11505-18

Facility: Duke Regional Hospital

FID #: 923142

County: Durham

Applicant: Duke University Health System, Inc.

Project: Acquire one additional fixed computed tomography (CT) scanner for a total of three fixed CT scanners upon project completion

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

Duke University Health System, Inc. proposes to acquire one additional computed tomography (CT) scanner to be located in renovated space on the campus of Duke Regional Hospital (DRH) for a total of three fixed CT scanners upon project completion.

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 2018 SMFP. Therefore, there are no need determinations applicable to this review.

Policies

There is one policy in the 2018 SMFP that is applicable to this review: Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities, on page 33.

Policy GEN-4 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, Certificate of Need 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 of 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.”

The proposed capital expenditure for this project is greater than \$2 million, but less than \$5 million. In Section B.11, page 12, the applicant describes the project’s plan to assure improved energy efficiency and water conservation. Exhibit F.1 contains a letter dated April 1, 2018 from the architect stating *“the renovation of these spaces will be in accordance with current efficiency and sustainability design standards of practice and construction will meet or exceed current energy and water conservation standards as indicated in the North Carolina Building and Energy Codes.”* The applicant adequately demonstrates that the application includes a written statement describing the project’s plan to assure improved energy efficiency and water conservation. Therefore, the application is consistent with Policy GEN-4.

Conclusion

The Agency reviewed the:

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

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

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

C

The applicant proposes to acquire one additional CT scanner to be located in 750 square feet of renovated space on the campus of Duke Regional Hospital (DRH) for a total of three fixed CT scanners upon project completion. DRH is a licensed acute care hospital operated by Duke University Health System, Inc.

Patient Origin

The 2018 SMFP does not define a service area for CT scanners. The Criteria and Standards for Computed Tomography Equipment (10A NCAC 14C .2301) state that the service area for a fixed CT scanner is defined as “a geographical area defined by the applicant from which the applicant projects to serve patients.” The applicant defines its service area based on its historical and projected patient origin, as shown in the two tables below. Facilities may also serve residents of counties not included in their service area.

In Section C.2, pages 13-14, the applicant provides the historical patient origin for its existing CT scanners for the last full fiscal year (July 1, 2016 - June 30, 2017), as shown below.

County	Number of Patients	Percent of Total
Durham	16,001	60%
Granville	2,609	10%
Person	1,741	7%
Orange	1,118	4%
Other counties*	3,448	13%
All other	1,698	7%
Total	26,615	100.00%

*Other counties include Wake, Unknown, Alamance, Franklin, Vance, Halifax, Caswell, Cumberland, Guilford, Nash, Chatham, Warren, Danville City, Mecklenburg, and Robeson.

In Section C.3, page 14, the applicant provides the projected patient origin for the first three years of the proposed service, as illustrated below.

County	Project Year 1 FFY (7/1/19-6/31/20)		Project Year 2 FFY (7/1/20-6/31/21)		Project Year 3 FFY (7/1/21-6/31/22)	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	# of Patients
Durham	17,086	61%	17,453	61%	17,828	61%
Granville	2,786	10%	2,846	10%	2,907	10%
Person	1,859	7%	1,899	7%	1,939	7%
Orange	1,194	4%	1,219	4%	1,245	4%
Other counties*	3526	12%	3526	12%	3526	12% %
All other	1,737	6%	1,737	6%	1,737	6%
Total	28,188	100%	28,680	100%	29,182	100%

*Other counties include Wake, Unknown, Alamance, Franklin, Vance, Halifax, Caswell, Cumberland, Guilford, Nash, Chatham, Warren, Danville City, Mecklenburg, and Robeson.

In Section 3.C, page 15, the applicant states that, “*only marginal change is projected in regard to patient origin ... Any minimal change is attributed to the eventual renovation and operation of an expanded emergency department ... which will allow Duke Regional to treat additional ED patients and offer needed CT imaging*”.

The applicant’s assumptions are reasonable and adequately supported.

Analysis of Need

In Section C, pages 15-16, the applicant describes the factors which it states support the need for the proposed project, including:

- DRH plans to expand its emergency department (ED) in the future which will allow for the treatment of additional ED patients and the offering of CT scans.
- DRH lists four counties in its primary service area which include Durham, Granville, Orange and Person County. The applicant projects that volume from these counties will grow at approximately 2.1% annually.
- DRH projects that volume in other counties that comprise its secondary service area will remain consistent with their historical volume.
- Volume is high and growing on DRH’s two dedicated CT scanners. The utilization of those two scanners rose 14% with 38,151 HECT units in FY 2016 and 43,575 HECT units in FY 2017. At the performance threshold of 5,100 HECT units per scanner, this volume would support eight CT scanners.
- Use of SPECT-CT equipment for CT-only procedures when not in use for scheduled nuclear medicine procedures to help accommodate the demand for CT scans. However, the use of the SPECT-CT equipment was a “*stop-gap*” measure with a limit to the additional capacity it created.

- Truven Health Analytics projects a population growth of 7.7% in Durham County alone in the next five years.

The applicant adequately demonstrates the need for one additional fixed CT scanner at DRH.

Projected Utilization

In Section C, page 21, the applicant projects that the three fixed CT scanners at DRH will perform a total of 47,733 HECT units in FY22, for an average of 15, 911 HECT units per scanner $[47,733/3 = 15,911]$ in Project Year 3 (PY 3). In Form C in Section Q, the applicant projects utilization of the existing and proposed fixed CT scanners at DRH as summarized below.

	HISTORICAL				INTERIM	PROJECTED		
	FY 2015	FY 2016	FY 2017*	FY 2018*	FY 2019	PY1 FY 2020	PY2 FY 2021	PY3 FY 2022
CT Scans	22,526	23,638	26,615	27,228	27,705	28,190	28,683	29,185
% Change	--	4.93%	12.59%	2.30%	1.75%	1.75%	1.75%	1.75%
# Change	--	1,112	2,977	613	477	485	493	502
# CT Scanners	2	2	2	2	3	3	3	3
# HECT Units	36,083	38,151	43,575	44,579	45,359	46,154	46,912	47,733
# HECT Units per scanner*		19,076	21,788	22,290	15,120	15,385	15,637	15,911

*Rounded up to nearest whole number

**Indicates the use of the SPECT-CT scanner

In Section Q, the applicant states that FY2018 volumes are annualized based on the first six months of the year which consist of 8,062 inpatient and 19,166 outpatient procedures $[8,062 + 19,166 = 27,288]$. Beginning in FY2019, the applicant projects procedure volumes will increase 1.75% per year. The applicant bases its utilization on the following assumptions:

- growth and aging within its identified primary service area of Durham, Granville, Orange and Person counties;
- expected growth in ED visits due to an expansion of the ED; and
- relief from capacity constraints which will allow DRH to accommodate the need for CT scans in a timely manner.

Based on its own utilization data, the applicant projects its proposed fixed CT scanner will perform in excess of the utilization threshold of 5,100 HECT units per year required under the Criteria and Standards for Computed Tomography Scanners promulgated at 10A NCAC 14C .2302(b). The applicant's projections are based on historical utilization and are supported by population growth projections in the service area. Additionally, the applicant is already performing in excess of the utilization threshold required by 10A NCAC 14C .2303. Average utilization of all the CT scanners in the entire service area as defined by the applicant is in excess of the utilization threshold required by this Rule. Projected utilization is thus based on reasonable and adequately supported assumptions. Therefore, the applicant adequately demonstrates the need to acquire one additional fixed CT scanner.

Access

In Section C.11, page 19, the applicant states DRH complies with its EMTALA obligations to patients regardless of their ability to pay. The applicant further states on page 19 that in FY 2017 24% of its ED visits were self pay, 27% were Medicare recipients and 26% were Medicaid recipients.

In Section L, page 48, the applicant projects the following payor mix during the second full fiscal year (2021) of operation following completion of the project, as illustrated in the following table.

Payor Source	Entire Facility or Campus	CT Services (Service Component)
Self-Pay	6.4%	10.5%
Medicaid*	11.7%	11.3%
Managed Care	26.9%	23.0%
Medicare*	47.2%	46.7%
TRICARE	0.7%	0.4%
Workers Compensation	0.3%	0.3%
Other (Specify)	6.8%	7.9%
Total	100.0%	100.0%

*Including any managed care plans (Commercial, Duke Select and other government payor).

The projected payor mix is reasonable and adequately supported.

Conclusion

The Agency reviewed the:

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

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

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

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

NA

The applicant does not propose to:

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

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

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

CA

The applicant proposes to acquire one additional CT scanner to be located in renovated space on the campus of DRH for a total of three fixed CT scanners upon project completion.

In Section E, page 27, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- Use of SPECT/CT scanner - the applicant obtained authorization to use its SPECT/CT camera for CT procedures when not scheduled for SPECT procedures. The applicant states the SPECT/CT scanner is needed for nuclear medicine procedures and does not provide full time access to additional CT capacity. Therefore, this alternative was rejected.
- Mobile CT scanner - The applicant states Alliance Imaging was contacted to discuss the possibility of mobile CT scanner services. The applicant states that mobile CT services requires an expensive monthly fee and is not cost effective. Mobile CT equipment would require the use of a trailer outside the hospital's walls, which creates a less efficient operation of service and is less satisfactory to patients who must travel outside for CT scanner services. Therefore, this alternative was rejected.

The applicant adequately demonstrates that the alternative proposed in this application is the most effective alternative to meet the need because,

“The existing volumes at Duke Regional Hospital would justify the operation of at least four full-time CT scanners. ... [N]either approach solves the long-term capacity need for these services.”

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

- the applicant adequately demonstrates a need for additional CT capacity,
- the use of the SPECT/CT equipment, when not scheduled for nuclear medicine procedures, is a temporary *stop-gap*” measure with a limit to the additional capacity it created, and
- the use of mobile CT equipment is expensive and ineffective to meet the existing and growing need for CT services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency.

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

- 1. Duke University Health System, Inc. shall materially comply with all representations made in the certificate of need application.**
- 2. Duke University Health System, Inc. shall acquire no more than one fixed CT scanner for a total of no more than three fixed CT scanners to be located at Duke Regional Hospital.**
- 3. Duke University Health System, Inc. shall not acquire as part of this project any equipment that is not included in the project’s proposed capital expenditures in Section F of the application and that would otherwise require a certificate of need.**
- 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. 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. 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

The applicant proposes to acquire one additional CT scanner to be located in renovated space on the campus of DRH for a total of three fixed CT scanners upon project completion.

Capital and Working Capital Costs

In Section Q, Form F.1(a) and Exhibit F.1, the applicant projects the total capital cost of the project as shown in the table below.

Construction/Renovation Costs	\$685,000
Architect/Engineering Fees	\$67,865
Equipment Costs	\$2,055,804
Miscellaneous Costs*	\$203,331
Total	\$3,012,000

*Includes non medical equipment (\$27,295), furniture (\$6,901), and other (\$169,135)

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

In Section F, page 29, the applicant projects no start-up costs or initial operating expenses for the proposed project as DRH is an existing acute care facility.

Availability of Funds

In Section F, page 28, the applicant states that the capital cost will be funded as shown in the table below.

Sources of Capital Cost Financing

Type	Duke University Health System	Total
Loans	\$	\$
Accumulated reserves or OE *	\$3,012,000	\$3,012,000
Bonds	\$	\$
Other (Specify)	\$	\$
Total Financing **	\$	\$

* OE = Owner's Equity

Financial Feasibility

The applicant provided pro forma financial statements for the first three full fiscal years of operation following completion of the project. On Form F.2, the applicant states that keeping with its historical practice, DUHS provided the balance sheet for the health system as a whole. DUH fiscal year operates from July 1-June 30 each year. In Form F.4, the applicant projects that revenues will exceed operating expenses in the first three operating years of the project for its CT services, as shown in the table below.

	1 st Full Fiscal Year 2020	2 nd Full Fiscal Year 2021	3 rd Full Fiscal Year 2022
Total Procedures	28,190	28,683	29,185
Total Gross Revenues (Charges)	\$91,403,269	\$93,002,827	\$94,630,376
Total Net Revenue	\$18,174,866	\$18,515,173	\$18,862,574
Average Net Revenue per procedure	\$644.73	\$645.51	\$646.31
Total Expenses (Costs)	\$3,281,665	\$3,626,631	\$3,826,809
Average Operating Expense per procedure	\$116.41	\$126.44	\$131.12
Net Income	\$14,893,200	\$14,888,542	\$15,035,765

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

Conclusion

The Agency reviewed the:

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

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

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

- The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal.
 - The applicant adequately demonstrates that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.
- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

C

The applicant proposes to acquire one additional CT scanner to be located in renovated space on the campus of DRH for a total of three fixed CT scanners upon project completion.

In Section G, page 35, the applicant states there are three facilities in Durham County that offer CT services, all are hospitals. Of those three facilities, two are operated by Duke University Health System. According to the 2018 LRA those facilities reported the following number of CT procedures.

Name of Facility	# of CT scanners	# of Procedures
Duke Regional Hospital	2	27,228
Duke University Hospital	15	97,784
Duke Specialty Hospital	1	213
Total	18	125,225

In Section G, page 35, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved CT services in Durham County. The applicant states:

“...additional capacity is needed to accommodate the high existing utilization at Duke Regional Hospital, including for inpatients and patients presenting through the emergency department. Expanding capacity to meet the existing demand for the facility’s patients will not unnecessarily duplicate any services provided elsewhere in the county.

The other CT scanners operated by Duke University Health System at Duke University Hospital are already fully utilized and not able to meet the need at Duke Regional Hospital. From FY2016 to FY2017, overall CT procedure volume at DRH grew by 11.5% (22,678 to 25,291). During the same time period, both Duke University Hospital (DUH) and Duke Raleigh Hospital (DRAH) experienced growth of 7.7 and 14.4%, respectively. North Carolina Specialty Hospital has announced its intention to develop and offer emergency department services for which it ... needs its own dedicated CT scanner.” [Emphasis in original]

In a No Review letter dated October 6, 2017, North Carolina Specialty Hospital was granted permission to develop an emergency department to provide level three emergency services.

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area because the applicant adequately demonstrates that the proposed CT scanner is needed in addition to the existing or approved CT scanners in Durham County.

Conclusion

The Agency reviewed the:

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

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

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

C

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

Position	Current	Projected		
	As of 12/31/2017	1 st Full Fiscal Year 2020	2 nd Full Fiscal Year 2021	3 rd Full Fiscal Year 2022
Registered Nurse	0.06	0.06	0.06	0.06
Technologists	16.95	17.95	17.95	17.95
Imaging Manager	1.00	1.00	1.00	1.00
TOTAL	18.00	19.00	19.00	19.00

Source: Form H in Section Q of the application.

The assumptions and methodology used to project staffing are provided in Section Q. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.2, which is found in Section Q. In Section H, page 37, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. In Section H, page 38, the applicant identifies Mark Neely as the current Chief of Radiology at DRH. Exhibit H.4 contains a letter from Dr. Neely expressing his support for the proposed project. In Exhibit H.3, the applicant provides supporting documentation.

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

Conclusion

The Agency reviewed the:

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

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

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

C

In Section I, page 39, the applicant states that the following ancillary and support services are necessary for the proposed services:

- Business office/registration
- Medical records
- Administration
- Materials management
- Quality control
- Clinical engineering
- Laundry/housekeeping

On page 39, the applicant adequately explains how each ancillary and support service is be made available.

In Section I, page 39, the applicant describes its existing and proposed relationships with other local health care and social service providers.

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

Conclusion

The Agency reviewed the:

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

Based on that review, the Agency concludes that the application is conforming to this criterion.

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

NA

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

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

NA

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

- (11) Repealed effective July 1, 1987.
- (12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

NA

The applicant does not propose to construct any new space, but rather to renovate 750 square feet of existing space. The proposed CT scanner will be located in existing space that was vacated by the replacement and relocation of an existing CT scanner. Therefore, Criterion (12) is not applicable to this review.

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

C

In Section L, page 47, the applicant provides the historical payor mix during FFY 2017 (7/1/2016-6/30/2017) for the entire hospital and its CT services, as illustrated in the following table.

Payor Source	Entire Facility or Campus	CT Services (Service Component)
Self-Pay	7.0%	10.5%
Medicaid*	11.7%	10.5%
Managed Care	29.1%	25.3%
Medicare*	44.9%	44.9%
TRICARE	0.6%	0.3%
Workers Compensation	0.4%	0.4%
Other (Specify)	6.3%	8.1%
Total	100.0%	100.0%

* Including any managed care plans

In Section L, page 46, the applicant provides the following comparison.

	Percentage of Total Patients Served by the Facility or Campus during the Last Full FY	Percentage of the Population of the Service Area
Female	62.6%	51.9%
Male	37.2%	48.1%
Unknown	0.2%	-%
64 and Younger	68.0%	86.3%
65 and Older	32.0%	13.7%
American Indian	0.2%	0.5%
Asian	0.9%	5.0%
Black or African-American	44.0%	29.4%
Native Hawaiian or Pacific Islander	0.1%	-%
White or Caucasian	47.5%	56.1%
Other Race	5.3%	9.0%
Declined / Unavailable	2.0%	-%

Conclusion

The Agency reviewed the:

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

Based on that review, the Agency concludes that the applicant adequately documents the extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved. Therefore, the application is conforming to this criterion.

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

C

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 47, the applicant states,

“Duke University Health hospitals have satisfied the requirements of applicable federal regulations to provide, on an annual basis, a certain amount of uncompensated care in return for Hill Burton funds previously received. ... They have no special 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 hospitals which participate in the Medicare, Medicaid, and Title V programs.”

In Section L, pages 47-48, the applicant states that during the last five years three patient civil rights access complaints have been filed against DUHS facilities in North Carolina. The applicant states on page 47 that none of those complaints were filed against Duke Regional Hospital. Of those three complaints filed, two were closed without further investigation. Regarding the third complaint, DUHS submitted the necessary response to the Department of Justice (DOJ). On page 48, the applicant states one additional complaint was filed and voluntarily dismissed.

Conclusion

The Agency reviewed the:

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

Based on that review, the Agency concludes that the application is conforming to this criterion.

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

C

In Section L, page 48, the applicant projects the following payor mix during the second full fiscal year of operation following completion of the project, as illustrated in the following table.

Payor Source	Entire Facility or Campus	CT Services (Service Component)
Self-Pay	6.4%	10.5%
Medicaid*	11.7%	11.3%
Managed Care	26.9	23.0%
Medicare*	47.2%	46.7%
TRICARE	0.7%	0.4%
Workers Compensation	0.3%	0.3%
Other (Specify)	6.8%	7.9%
Total	100.0%	100.0%

* Including any managed care plans (Commercial, Duke Select and other government payor).

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 10.5% of total CT services will be provided to self-pay patients, 46.7% to Medicare patients and 11.3% to Medicaid patients.

On page 49, the applicant provides the assumptions and methodology used to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported for the following reasons:

Conclusion

The Agency reviewed the:

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

Based on that review, the Agency concludes that the application is conforming to this criterion.

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

C

In Section L, page 49, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion.

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

C

In Section M, pages 50-53, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes.

The Agency reviewed the:

- Application
- Exhibits to the application

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

Based on that review, the Agency concludes that the applicant adequately demonstrates that the proposed services will accommodate the clinical needs of area health professional training programs, and therefore, the application is conforming to this criterion.

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

C

The applicant proposes to acquire one additional CT scanner to be located in renovated space on the campus of DRH for a total of three fixed CT scanners upon project completion.

The 2018 SMFP does not define a service area for CT scanners. The Criteria and Standards for Computed Tomography Equipment (10A NCAC 14C .2301) state that the service area for a fixed CT scanner is defined as *“a geographical area defined by the applicant from which the applicant projects to serve patients.”* The applicant defines its service area based on its historical patient origin, as shown in the two tables below. Facilities may also serve residents of counties not included in their service area.

In Section G, page 35, the applicant states there are three facilities in Durham County that offer CT services, all are hospitals. Of those three facilities, two are operated by Duke University Health System. According to the 2018 LRA those facilities reported the following number of CT procedures were completed.

Name of Facility	# of CT scanners	# of Procedures
Duke Regional Hospital	2	27,228
Duke University Hospital	15	97,784
Duke Specialty Hospital	1	213
Total	18	125,225

In Section N, page 54, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote cost-effectiveness, quality and access to the proposed services. On page 54, the applicant states, *“This project will not affect the cost of services to patients or payors, as the service is already provided and the additional capacity will not affect gross charges or*

reimbursement rates by government or private payors. However, this project will improve access to CT services and will potentially improve the timeliness of diagnosis and treatment, therefore enhancing the quality of care received by patients.”

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

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

Conclusion

The Agency reviewed the:

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

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

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

C

In Section A.1, page 6, the applicant states Duke University Health System is a controlled affiliate of Duke University. On page 6, the applicant states Duke Regional Hospital is an existing acute care facility located in Durham County. In Section O, page 55, the applicant identifies nine facilities located in North Carolina owned, operated or managed by the applicant or a related entity.

In Section O, page 55, the applicant states that, during the 18 months immediately preceding the submittal of the application, no incidents related to quality of care occurred in any of these facilities. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, during the 18 months immediately preceding submission of the application through the date of this decision, no incidents related to quality of care occurred in any of these facilities. 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.

C

The Criteria and Standards for Computed Tomography Equipment promulgated in 10A NCAC 14C .2300 are applicable to this review. The application is conforming to all applicable criteria. The specific criteria are discussed below.

10A NCAC 14C .2303 PERFORMANCE STANDARDS

An applicant proposing to acquire a CT scanner shall demonstrate each of the following:

- (1) *each fixed or mobile CT scanner to be acquired shall be projected to perform 5,100 HECT units annually in the third year of operation of the proposed equipment;*
- C- In Section C.12, page 21, the applicant projects that the three CT scanners will perform 47,733 HECT units in the third year of operation (FY2022) or 15,911 HECT units per CT scanner ($47,733/3 = 15,911$). This exceeds the minimum of 5,100 HECT units annually in the third year of operations as required by 10A NCAC 14C .2303. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.
- (2) *each existing fixed or mobile CT scanner which the applicant or a related entity owns a controlling interest in and is located in the applicant's CT service area shall have performed at least 5,100 HECT units in the 12 month period prior to submittal of the application; and*
- C- In Section C.12, page 21, the applicant states in FY2017 the 15 CT scanners at Duke University Hospital (DUH) performed 168,379 HECT units for an average total of HECT 11,225 units per CT scanner. On page 21, the applicant states Duke University Health System (DUHS has a total of 23 existing and approved CT scanners in Durham County. These scanners performed 7,320.8 HECTS units per scanner [$7,320.8 \times 23 = 168,378.4$] which is consistent with the information reported on the applicant's 2017 license renewal application.

- (3) *each existing and approved fixed or mobile CT scanner which the applicant or a related entity owns a controlling interest in and is located in the applicant's CT service area shall be projected to perform 5,100 HECT units annually in the third year of operation of the proposed equipment.*
- C- In Section C.12, page 22, the applicant states that DUHS assumes that all CT scanners operated or approved at all sites in both Durham and Wake counties will exceed 5,100 HECT units per CT scanner by the third year of operations for the proposed project. The applicant assumes that all sites in Wake County will have the same CT volumes as in FY2017 with no additional growth. The applicant identifies Granville, Person and Orange counties as being a part of its primary service area. DUHS through Duke LifePoint (DLP) is a related entity of DLP Person Memorial Hospital (Person County) and DLP Central Hospital (Granville County). According to the 2018 LRA each of those facilities operates one fixed CT scanner per hospital with DLP Person Memorial Hospital performing 5,149 and DLP Central Hospital performing 7,283 CT procedures, respectively. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.