

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: June 28, 2017

Findings Date: June 28, 2017

Project Analyst: Jane Rhoe-Jones

Team Leader: Lisa Pittman

Project ID #: J-11301-17

Facility: WakeMed North Family Health & Women's Hospital

FID #: 990974

County: Wake

Applicant(s): WakeMed

WakeMed Property Services

Project: Expand the Emergency Department and acquire a second CT Scanner

### 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

The applicants, WakeMed and WakeMed Property Services (WakeMed), propose to expand the Emergency Department (ED) and acquire a second computerized tomography (CT) scanner at WakeMed North Family Health & Women's Hospital (WakeMed North).

#### 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**

Policy GEN-4: ENERGY EFFICIENCY AND SUSTAINABILITY FOR HEALTH SERVICE FACILITIES, on page 33 of the 2017 SMFP, is applicable to this review. 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 applicants propose to renovate 11,270 square feet in the ED and expand it from 19 beds to 32 beds. No new construction is proposed as existing space will be reconfigured to accommodate the expanded services. The second component of the project is to acquire a second fixed CT scanner. The total projected capital cost for the proposed project is \$9,196,579.

In Section B-11, pages 24-25, the applicants provide a written statement describing the project’s plan for energy efficiency and water conservation. On page 24, the applicants state:

*“WakeMed develops all capital projects with the goal of maximizing energy efficiency and water conservation. In both new construction and renovations, WakeMed uses energy- efficient windows and insulation to maximize energy efficiency. Heating and HVAC systems are high-efficiency units, and reflect the best technology available on the market. The design of the renovated areas will incorporate additional HVAC ‘zones’ whereby systems will have an improved sensitivity to the temperature and humidity in the areas served taking into account people and equipment loads as well as peripheral loads (e.g., exterior walls and windows, internal wall, etc.). The installation of a state of the art building management system will provide the necessary air monitoring devices to ensure temperature, humidity and room pressurization criterial are optimized.”*

On page 25, the applicants state:

*“WakeMed is committed to designing its new and renovated facilities, with the goal of meeting the Leadership in Energy and Environmental Design (LEED) certification criteria, as established by the U.S. Green Building Council.”*

The applicants adequately demonstrate that the proposal has 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, subject to Condition #4 in Criterion (4).

### **Conclusion**

In summary, the applicants adequately demonstrate that the proposal is consistent with Policy GEN-4 and conforming to this criterion, subject to Condition #4 in Criterion (4).

- (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 applicants propose to renovate 11,270 square feet in the ED at WakeMed North to add 13 treatment bays for a total of 32 treatment bays upon project completion. Existing space will be reconfigured to accommodate the additional treatment bays. The second component of the project is to acquire a second fixed CT scanner. (See Section C-1, pages 26-27.)

In Section C-1, pages 28-29, the applicants state that the existing CT scanner and the proposed second CT scanner will be located in space near the ED at WakeMed North.

### **Population to be Served**

#### **WakeMed North ED**

The 2017 SMFP does not define a service area for emergency departments. The applicants define their market area in Section C-4(a), pages 43-44, as nine zip codes in northern Wake County, which includes north Raleigh, Wake Forest and Rolesville, plus Franklin County. Facilities may also serve residents of counties not included in their market area.

In Section C-2(a), page 32, the applicants state that historically 74.4% of visits in the ED in FY2016 were from Wake County, while 18.1% were from Franklin County for a total of 92.6%. Eighty-six other NC counties comprise 5.6% of visits, while 1.9% of the visits are from out of state. The historical patient origin is provided in the application pages 32-34 and is illustrated below in the table.

<b>WAKEMED NORTH ED VISITS Patient Origin FY2016</b>		
<b>County</b>	<b>Visits</b>	<b>% Total Visits</b>
Wake	31,478	74.4%
Franklin	7,668	18.1%
Other NC Counties	2,328	5.6%
Out of State	810	1.9%
<b>Total Visits</b>	<b>42,284</b>	<b>100.0%</b>

In Section C-3(a), pages 37-40, the applicants provide the projected patient origin, by county for the WakeMed North ED during the first three operating years following project completion. On page 43, the applicants state that patient origin has remained “*relatively constant*” over the last several years and is not expected to change significantly in the future, as shown below in the table.

<b>WAKEMED NORTH ED VISITS PROJECTED PATIENT ORIGIN FYs 2019-2021</b>						
	<b>PY1 2018-2019</b>		<b>PY2 2019-2020</b>		<b>PY3 2020-2021</b>	
<b>County</b>	<b>Visits</b>	<b>% Total Visits</b>	<b>Visits</b>	<b>% Total Visits</b>	<b>Visits</b>	<b>% Total Visits</b>
Wake	36,270	74.4%	37,501	74.4%	38,665	74.4%
Franklin	8,835	18.1%	9,134	18.1%	9,418	18.1%
Other NC Counties*	2,672	5.6%	2,767	5.6%	2,850	5.6%
Out of State	935	1.9%	966	1.9%	996	1.9%
<b>Total Visits</b>	<b>48,712</b>	<b>100.0%</b>	<b>50,368</b>	<b>100.0%</b>	<b>51,929</b>	<b>100.0%</b>

\*Other NC counties = 85 and less than 1% of the total ED visits.

### WakeMed North CT Scanner

The 2017 SMFP does not define a service area for CT scanner services. The applicants define their market area in Section C-4(a), pages 43-44, as nine zip codes in northern Wake County, which includes north Raleigh, Wake Forest and Rolesville, plus Franklin County. Facilities may also serve residents of counties not included in their market area.

In Section C-2(a), pages 35-36, the applicants state that historically 71.2% patients using CT in FY2016 were from Wake County, while 12.5% were from Franklin County, 8.1% were from Vance County and 1.1 % were from Granville County for a total of 92.9%. The remaining 7.1% of the CT patient origin is comprised of other NC counties and out of state. The historical patient origin is illustrated below in the table.

<b>WAKEMED NORTH CT VISITS Patient Origin FY2016</b>		
<b>County</b>	<b>CT Scans</b>	<b>% Total Scans</b>
Wake	7,917	71.2%
Franklin	1,390	12.5%
Vance	905	8.1%
Granville	119	1.1%
Other NC Counties*	522	4.7%
Out of State	269	2.4%
<b>Total Visits</b>	<b>11,122</b>	<b>100.0%</b>

\*Other NC counties = 71 and individually less than 1% of the total CT scans.

In Section C-3(a), pages 40-42, the applicants provide the projected patient origin, by county for WakeMed North CT during the first three operating years following project completion, as shown below in the table.

<b>WAKEMED NORTH CT SCANS PROJECTED PATIENT ORIGIN FYs 2019-2021</b>						
<b>County</b>	<b>PY1 2018-2019</b>		<b>PY2 2019-2020</b>		<b>PY3 2020-2021</b>	
	<b>CT Scans</b>	<b>% Total Scans</b>	<b>CT Scans</b>	<b>% Total Scans</b>	<b>CT Scans</b>	<b>% Total Scans</b>
Wake	8,908	71.2%	9,265	71.2%	9,632	71.2%
Franklin	1,564	12.5%	1,627	12.5%	1,692	12.5%
Vance	1,018	8.1%	1,059	8.1%	1,102	8.1%
Granville	134	1.1%	139	1.1%	145	1.1%
Other NC Counties*	584	5.6%	745	5.6%	777	5.6%
Out of State	303	2.4%	315	2.4%	328	2.4%
<b>Total Visits</b>	<b>12,511</b>	<b>100.0%</b>	<b>13,011</b>	<b>100.0%</b>	<b>13,531</b>	<b>100.0%</b>

\*Other NC counties = 71 and individually less than 1% of the total CT scans.

In Section C-3(c), page 43, the applicants state that assumptions regarding projected patient origin are based on existing historical patient origin percentages for CT scanner services at WakeMed North which have remained consistent over the past several years.

The applicants adequately identify the ED and CT populations they propose to serve.

**Analysis of Need - WakeMed North ED**

In Section C-4(a), pages 43-50, and referenced exhibits, the applicants state the following factors support the need to expand the capacity of the WakeMed North ED, as discussed below:

- Northern Wake County population growth (primary market area);
- Franklin County population growth (secondary market area);
- Growth in WakeMed North ED utilization;
- ED utilization in the State and Wake County
- National trends in the utilization of EDs
- Impact of the Affordable Care Act (ACA) on utilization of EDs

Northern Wake County population growth (primary market area)

On pages 43-44, the applicants discuss the “*rapid pace*” in population growth in their primary market which is comprised of North Raleigh, Wake Forest and Rolesville – a total of nine ZIP Codes. The table on page 44 shows the population data, for years 2012-2016 and 2016-2021. The primary market population in 2016, was about one-third of the total Wake County population. The applicants state that in their primary market area, the population is estimated to have grown by 8.4% from 2012-2016 and projected to grow 12.5% [11.4%] in 2016-2021, or over 386,000 residents. This would mean a total percentage change of 20.8% from 2012-2021, which equals a growth in population from 320,000 to 386,000 persons. (Applicants’ Source: *Esri*)

Franklin County population growth (secondary market area)

On pages 44-45, the applicants discuss the population growth in their secondary market – Franklin County. The applicants state that the growth in population is not at the pace of Wake County, but it is growing. There was an estimated population growth of 5% from 2012 to 2016; approximately 62,000 to approximately 65,000 persons. The percent change from 2016-2021 is projected to be 6.0%; approximately 65,000 persons to approximately 69,000. (Applicants’ Source: NC Office of State Budget and Management (OSBM))

The applicants also note that as of February 15, 2017, Franklin County had no 24 hour/seven day per week emergency department.

Growth in WakeMed North ED utilization

WakeMed North ED utilization - On pages 45-47, the applicants discuss development and evolution of WakeMed North, which in 2005 was the first “stand-alone” twenty-four hour, seven days a week ED in North Carolina. WakeMed North as reported by the applicants, experienced “*robust*” growth in ED volume immediately. The applicants correlate several years of negative growth with the opening of another WakeMed ED in another part of Wake County, then with the construction of the inpatient tower at WakeMed North, which resulted in a temporary relocation of the ED entrance.

The applicants provide the following table from page 46 to illustrate the growth in utilization at the WakeMed North ED, which experienced volume increases of 6.5% from FY2014-2015, and 17.2% from FY2015-2016.

WAKEMED NORTH ED Visits FYs 2007-2016				
Fiscal Year	Visit Volume	% Change from Prior Year	% Change 2007-2016	% Change 2012-2016
2007	28,140	---		
2008	32,047	13.9%		
2009	34,881	8.8%		
2010	34,019	-2.5%		
2011	34,978	2.8%		
2012	34,738	-0.7%		
2013	34,918	0.5%		
2014	33,866	-3.0%		
2015	36,081	6.5%		
2016	42,284	17.2%	50.3%	21.7%

The applicants attribute much of the recent growth at WakeMed North to greater public awareness when it changed from an outpatient healthplex only to a full-service acute care hospital in 2015. The applicants state that in order to accommodate times of peak patient volume, the hospital must use five to eight pre-admission testing rooms for patient overflow; which occurs seven days per week. In the absence of using the pre-admission testing rooms, the ED wait times and patients leaving without care would be “unacceptably” high.

Emergency Department Capacity – Nineteen treatment bays are currently in operation. In FY2016 the hospital treated 42,284 ED patients which is a yearly average of 2,225.5 patients per treatment bay. The applicants state that this average is “significantly” higher than recommended by the Emergency Department Benchmarking Alliance (EDBA). Per the EDBA, most EDs are designed to treat 1,300-1,700 visits per patient per year and when volumes are greater than 1,900 visits per patient per year, patients who leave untreated, increases. For its ED planning WakeMed uses a standard metric of 1,800 visits per patient per year. The applicants state that using the WakeMed metric, the WakeMed North ED operated as follows at 123.6 percent of capacity:  $[42,284 \text{ visits} / (19 \text{ bays} \times 1800 \text{ visits/bay/year}) = 1.236 = 123.6\%]$ . (Applicants’ source: “*Emergency Department Performance Measures, 2014 Data Guide*,” published by the EDBA, Denver CO, page 16).

Franklin Medical Center Closed – The applicants state that the October 2015 closing of Franklin Medical Center (FMC) in Louisburg is likely another contributing factor to the increased volume at WakeMed North. The former site for FMC is approximately 28 miles from WakeMed North and had the only full-service ED in Franklin County. WakeMed North’s ED volume increased 17.2% or by 6,403 visits from 2015 to 2016.

ED utilization in the State and Wake County

The applicants state that hospital license renewal applications indicate that statewide ED utilization has been increasing. In 2013, hospitals in the state are reported to have treated more than 4.7 million ED visits for a use rate of 480 visits per 1,000 population. By 2015, the number treated increased to almost 5 million visits, for a use rate of almost 496 visits per 1,000.

In 2015, Wake County residents comprised 10% of the state’s population, but only accounted for 6.8% of total statewide ED visits. Wake County ED visits increased 8.8% from 2013-2015, more rapidly than the statewide increase of 5.4%. The applicants attribute this growth in ED visits to Wake County population growth (4.5%), which is higher than the state’s (2.0%); as shown below in the following table. See Table C-9, page 48, of the application.

<b>EMERGENCY DEPARTMENT VISITS                      at NORTH CAROLINA EMERGENCY DEPARTMENTS                      EMERGENCY DEPARTMENT VISITS by WAKE COUNTY RESIDENTS                      EMERGENCY DEPARTMENT USE RATES                      2013-2015</b>					
	2013	2014	2015	% Change 2013-2015	CAGR 2013-2015
Total Visits in NC EDs	4,731,833	4,710,500	4,987,924	5.4%	2.7%
Total Wake Co ED visits	312,634	318,872	340,276	8.8%	4.3%
% Wake Co ED of total	6.6%	6.8%	6.8%		
NC population	9,856,664	9,951,630	10,056,683	2.0%	1.0%
<b>NC ED use rate/1,000</b>	<b>480.6</b>	<b>473.34</b>	<b>495.98</b>	<b>3.3%</b>	
Wake County population	964,642	985,386	1,007,631	4.5%	2.2%
<b>Wake Co ED use rate/1,000</b>	<b>324.09</b>	<b>323.60</b>	<b>337.70</b>	<b>4.2%</b>	
% Wake Co population of total NC population	9.8%	9.9%	10.0%		

Source- ED visit volume: Hospital License Renewal Applications, DHSR. Source – population data: NCOSBM.

National Trends in ED Utilization – The applicants state that population growth and an aging population are driving ED utilization. The applicants state that the highest ED visit rates occur in children under age one (900 visits per 1,000 population) and in adults over age 75 (619 visits per 1,000 population). The applicants discuss “Baby Boomers” and that by 2030, when the last of the baby boomers reach age 65, the United States will have more than 74 million persons aged 65 and older, and that many of these older persons will utilize ED services. (See pages 48-49.)

Impact of the Affordable Care Act (ACA) on utilization of EDs

The applicants state that the American College of Emergency Physicians (ACEP) surveyed its membership as to the impact of the ACA on ED utilization. The applicants report the results as follows:

- 75% of respondents indicated that ED patient volume has increased since the ACA took effect;



- 56% of emergency physicians indicated that the Medicaid ED patient volume increased; and
- 70% of respondents stated their beliefs that their EDs were not prepared for “significant” increases in volumes of visits.

The applicants adequately demonstrate the need for the renovation of the ED and additional treatments bays.

Projected Utilization - ED

In Section Q, Form C-1, pages 143-149, the applicants provide the assumptions and methodologies to project ED utilization. In Section Q, Form C-1, pages 150-154, the applicants provide the assumptions and methodologies used to project CT scanner utilization.

On page 146, the applicants state that their primary service area consists of nine ZIP Codes in northern Wake County and the current population is approximately 347,000 which is an 8.4% increase since 2012 (See Table C-6, page 44). According to the applicants, the primary service area population is growing at approximately 2.2% per year, which would yield approximately 7,626 additional northern Wake County residents in 2017 [ $346,657 \times 0.222 = 7,626$ ]. If the 2.2% population growth rate continues to the interim project years, and through Project Years 1-3, would yield 386,304 residents in 2021 [See Table Q-4, page 146].

On page 147, the applicants state that WakeMed has demonstrated that the 2015 ED utilization rate for Wake County was 337.7 visits per 1,000 population. The applicants state that they conservatively assume that the rate will remain constant through PY3. Projected ED visits for the applicants’ primary service area are calculated by applying the 2015 ED utilization rate to the projected WakeMed North ED primary service area population for 2017 (119,816 ED visits) through 2021 (130,395 ED visits). The applicants assume that population growth will be the principal cause of future ED utilization.

<b>PROJECTED ED VISITS in PRIMARY SERVICE AREA USING 2015 WAKE COUNTY ED UTILIZATION RATE</b>		
<b>Fiscal Year</b>	<b>ED Visits Primary Service Area</b>	<b>Change in ED Visits by Year</b>
2016	117,086	2,315
2017	119,816	2,575
2018	122,226	2,632
2019	124,890	2,690
2020	127,613	2,749
2021	130,395	2,810

At the time the application was submitted, the applicants estimated that the WakeMed North ED would treat approximately 1,000 of the 2,315 visits in FY 2016, which represented 15 percent of the total FY2016 ED volume increase at WakeMed North.

*Utilization Projections*

The applicants’ ED utilization assumptions include:

- Some of the above growth events will continue through PY3, but at a decreasing level in each successive year
- The FY2017-2021 ED projections for WakeMed North is assumed to have a base of 2.2 percent annual growth resulting from population increases.
- Assumptions are based on:
  - projected population CAGR
  - additional percentage growth factor derived from ongoing growth and development of WakeMed North Hospital over the next five to seven years
  - WakeMed North ED volume will continue to be impacted by factors such as additional service development at WakeMed North and county in-migration; although at a smaller percentage each year
  - The visit volume increase from FY2016-FY2017 is projected to be 6.0 percent and taper to 3.1 percent by PY3 (FY2021). See the following table:

Fiscal Year	Annual ED Visits	Change per Year in Visit Volume	% Change per Year	ED Treatment Bays	ED Visits per Bay per Year
2014	33,866	---	---	19	1,782.43
2015	36,081	2,215	6.5%	19	1,899.0
2016	42,284	6,203	17.2%	19	2,225.5
2017 interim	44,824	2,537	6.0%	19	2,359.2
2018 interim	46,838	2,017	4.5%	19	2,465.2
2019 Y1	48,717	1,874	4.0%	32	1,522.4
2020 Y2	50,368	1,656	3.4%	32	1,574.0
2021 Y3	51,929	1,561	3.1%	32	1,622.8

The applicants state:

*“Assuming a metric of 1,800 visits per bed per year, the WakeMed North ED will have a practical visit capacity of 57,600 annual visits following project completion [calculation: 32 treatment beds x 1800 visits/bed/year = 57,600]. The projection model shows that that [sic] WakeMed North ED will be utilized at 1622.8 visits per bed per year in Project Year 3 [calculation: 51929 visits/32 treatment beds = 1622.78], well within industry standards recommended by the Emergency Department Benchmarking Alliance and WakeMed’s own planning standard. The additional capacity will improve patient throughput, help minimize wait times, and improve patient and staff satisfaction.”*

The applicants adequately demonstrate that projected utilization of ED services is based on reasonable and adequately supported assumptions regarding continued growth in the patient population in northern Wake County.

**Analysis of Need - WakeMed North CT Scanner**

In Section C-4(a), pages 50-51, and related exhibits, the applicants discuss growth in the CT volume at WakeMed North and the need to acquire a second CT scanner. The applicants state that CT is the preferred imaging method for emergency patients because there are not the adverse issues that MRI presents when it comes to metal objects that may be in a patient’s body. On pages 50, 150-151 the applicants discuss the growth of the CT service as at WakeMed North.

The growth in volume of the CT service for the past four years, which is reported in the 2013-2017 LRAs, is depicted in the following table.

<b>WAKEMED NORTH CT SCANNER VOLUME FYs 2012-2016</b>				
<b>FY</b>	<b># CT Scans</b>	<b>% Change</b>	<b>HECT Units</b>	<b>% Change from Previous Year</b>
2012	8,666	---	13,135.50	
2013	8,585	-0.9%	12,166.50	-7.4%
2014	8,540	-0.5%	12,238.00	0.6%
2015	9,151	7.2%	12,530.50	2.4%
2016	11,222	21.5%	15,766.25	25.8%
<b>2012-2016 CAGR</b>				<b>6.4%</b>

Source – WakeMed internal CT scan volume submitted for 2013-2017 Hospital LRAs.

The CT volume at WakeMed North grew at a Compound Annual Growth Rate (CAGR) of 6.4% from 2012-2016. The majority of the growth was from 2014-2016 when utilization increased 31.4% (See page 150). The applicants attribute historical and projected growth in CT volume to the following:

- Growth in ED volume (pp. 46, 51)
- Admitting inpatients in 2015 (p.51)
- Opening additional acute care beds in 2017 (p.51)
- Starting a hospitalist program to treat medical-surgical patients in 2017 (p.51)
- Offering additional inpatient services which would make it feasible to treat more patients requiring admission from the ED versus transferring those patients to the WakeMed Raleigh facility
- Increasing ED visits will result in more patients being admitted
- Growing patient volume indicates additional need for CT capacity

- Franklin County had no fixed CT scanner services as of February 15, 2017 (Section C-4, page 45)

The applicants adequately demonstrate the need for an additional CT scanner at WakeMed North.

*Projected Utilization – CT Scanner*

In Section Q, pages 150-153, the applicants discuss the proposed expansion of their WakeMed North Emergency Department. The Emergency Department at WakeMed North operates one fixed CT scanner. The scanner performed 11,222 scans (15,766.25 equivalent HECT units) in FY2016.

CT utilization at WakeMed North in the most recent five fiscal years and as reported on its annual licensure renewal application, is as shown below in the table:

<b>WAKEMED NORTH CT UTILIZATION FYs 2012-2016</b>						
<b>Fiscal Year</b>	<b># CT Scans</b>	<b>% Change from Previous Year</b>	<b>CT Scans CAGR 2012-2016</b>	<b>HECT Units</b>	<b>% Change from Previous Year</b>	<b>HECTs CAGR 2012-2016</b>
2012	8,666	---	6.4%	13,135.50	---	4.7%
2013	8,585	-0.9%		12,166.50	-7.4%	
2014	8,540	-0.5%		12,238.00	0.6%	
2015	9,151	7.2%		12,530.50	2.4%	
2016	11,122	21.5%		15,766.25	25.8%	

CT scan volume average annual growth was 6.4 percent from 2012-2016. Utilization increased 30.2 percent occurred during 2014-2016 with the majority of volume increase. The applicants state:

*“... Because CT utilization among all Wake County providers is not fully known, it would be virtually impossible to develop a projection methodology based on use rates per population for market shares. WakeMed examined various methods of using historical scanner volume at WakeMed North to project future volume. Among these were:*

- *CT volume as percentage of emergency department visit volume;*
- *Linear growth modeling;*
- *Constant annual percentage growth.*

*Projecting volume using CT scans as a percent of ED visit volume was not selected because WakeMed North continues to transition from an outpatient-only facility to a hospital with licensed acute care beds. Historically, approximately 25 percent of ED visits at WakeMed North result in a CT scan. As North’s inpatient business continues to grow, this proportion will change as more inpatients are admitted who will require a CT scan. The difficulty involved in projecting the total CT scans as a percentage of*

*ED visits was such that WakeMed opted not to utilize this method. Likewise, applying a linear growth model to historic CT volume, given that recent volume has experienced rapid growth, created a growth trendline that was deemed overly aggressive, one that resulted in unrealistically high procedure volumes.*

*WakeMed determined that the most conservative method for projecting CT volume at WakeMed North was to apply a constant annual percentage growth rate to the interim years and Project Years 1-3. CT volume at WakeMed North grew by an average of 6.4 percent from 2012-16 – most of this growth occurred in the two most recent full fiscal years, with a CAGR of 14.1 percent. Because use of these growth rates were [sic] considered unrealistically high going forward, WakeMed opted to apply a constant growth of 4.0 percent per year through Project Year 3 – this is a more conservative than using the historic compound annual growth rates from 2012-16 or 2014-16. This growth rate also tracks more closely to projected ED volume growth. ...”*

The applicants further stated that their projections for interim years and project years use a constant growth rate of 4.0 percent per year for CT scan volumes.

Regarding calculation of HECT units for the CT scanner, the applicants state:

*“To compute HECT units for the interim years and Project Years 1-3, WakeMed analyzed the percentage of scans in each HECT category at WakeMed North for FYs 2014-2016 and utilized the following averages in its projections:”*

<b>WAKEMED NORTH HECT UNITS by CONVERSION FACTOR CATEGORY</b>			
	<b>CT Scan Type</b>	<b>Conversion Factor</b>	<b>Average % of HECT Units 2014-2016</b>
1	Head without contrast	1.00	39.6%
2	Head with contrast	1.25	2.3%
3	Head without & with contrast	1.75	0.7%
4	Body without contrast	1.50	22.8%
5	Body with contrast	1.75	32.4%
6	Body without & with contrast	2.75	2.2%
7	Biopsy in addition to body scan without & with contrast	2.75	0.0%
8	Abscess drainage in addition to body scan without & with contrast	4.0	0.0%
	<b>Total</b>		<b>100.0%</b>

The applicants apply the above percentages going forward to calculate the following CT scans and HECT units for PYs 1-3 / FYs 2019-2021, as shown below in the table.

<b>WAKEMED NORTH CT SCANS &amp; HECT UNITS PROJECT YEARS 1 - 3</b>								
	<b>CT Scan Type</b>	<b>Conversion Factor</b>	<b>FY2019</b>		<b>FY2020</b>		<b>FY2021</b>	
			<b>Scans</b>	<b>HECTS</b>	<b>Scans</b>	<b>HECTS</b>	<b>Scans</b>	<b>HECTS</b>
1	Head without contrast	1.00	4,957	4,957.00	5,156	5,156.00	5,362	5,362.00
2	Head with contrast	1.25	288	360.00	299	373.75	311	388.75
3	Head without & with contrast	1.75	82	143.50	85	148.75	88	154.00
4	Body without contrast	1.50	2,846	4,269.00	2,960	4,440.00	3,078	4,617.00
5	Body with contrast	1.75	4,058	7,101.50	4,220	7,385.00	4,389	7,680.75
6	Body without & with contrast	2.75	280	770.00	291	800.25	303	833.25
7	Biopsy in addition to body scan without & with contrast	2.75	0	0.00	0	0.00	0	0.00
8	Abscess drainage in addition to body scan without & with contrast	4.0	0	0.00	0	0.00	0	0.00
	<b>TOTALS</b>		<b>12,511</b>	<b>17,601.00</b>	<b>13,011</b>	<b>18,303.75</b>	<b>13,531</b>	<b>19,035.75</b>

The applicants adequately demonstrate that projected utilization of CT services is based on reasonable and adequately supported assumptions. Furthermore, the current (2016) CT scanner volume at WakeMed North of 15,766.25 HECT units is more than three times the performance standard of 5,100 HECT units annually.

### Access

In Section L-1(a), page 107, the applicants state:

*“In FY 2016, WakeMed Health and Hospitals served a significant proportion of its patients from many historically underserved groups. ...”*

The applicants provide a table on page 108 that depicts the various demographic groups, and their proportion of total patients served at WakeMed and WakeMed North from Wake and Franklin counties (market area). The table shows the following for WakeMed North: 64% women, 13% elderly, 45% racial and ethnic minorities, 25% low income/uninsured, and 18% children (0-17).

In Section L-1(b), page 109, the applicants provide the payor mix for the entire WakeMed North, the ED and the CT service components for FY 2016. The applicants report that 90.3% of all patients who received services at the WakeMed North facility, 36.7% of the ED patients and 34.4% of the CT patients had some or all of their services paid by Medicare and/or Medicaid. Additionally, on page 110, the applicants provide the payor mix for the entire WakeMed North facility, the ED and the CT service components in FY 2020. The applicants do not project a change in their payor mix from their historical payor mix.

The applicants adequately demonstrate the extent to which all residents of the area, including underserved groups, are likely to have access to the proposed services.

### Conclusion

In summary, the applicants adequately identify the population to be served, adequately demonstrate the need that population has for the proposed services and the extent to which all residents of the area, including underserved groups, are likely to 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-2, pages 70-72, the applicants describe the alternatives considered to meet the needs of the proposed project, which include:

- Maintain the Status Quo

ED - the applicants state that this option is not an effective alternative for the ED because based on current volume, the capacity is not adequate to meet the emergency care needs of a growing population.

CT scanner - the applicants state that this option is not an effective alternative for the CT service component because the procedural volume for the scanner continues to grow and is already beyond the standard of 5,100 HECT units per year as set forth by the Agency.

- Expand Emergency Departments at Other WakeMed Locations - The applicants state that this option is not an effective alternative because expanding capacity at the other WakeMed locations would not alleviate the demand at WakeMed North, making it difficult for patients in northern Wake County and from Franklin County to get emergency care closer to home.
- Construct Additional Space at WakeMed North for ED Expansion - The applicants state that this option is not an effective alternative because it would not be cost effective, would be disruptive to existing operations and not necessary. The applicants state that the existing space can be redesigned to meet the needs as proposed in this application, without being too costly and disruptive to operations.

After considering those alternatives, the applicants state that the alternative represented in the application is the most effective alternative to meet the identified need.

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

In summary, the applicants adequately demonstrate that the 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. WakeMed and WakeMed Property Services shall materially comply with all representations made in the certificate of need application.**
- 2. Prior to issuance of the certificate of need, WakeMed and WakeMed Property Services shall provide in writing, confirmation that the addition of a second CT scanner at WakeMed North will not reduce the number of HECT units performed at WakeMed Brier Creek Healthplex below 5,100 HECT units during the third year of operation of this project.**
- 3. WakeMed and WakeMed Property Services shall not acquire, as part of this project at WakeMed North, any equipment that is not included in the project's proposed capital expenditure in Section VIII of the applicant and which would otherwise require a certificate of need.**



4. **WakeMed and WakeMed Property Services shall 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.**
  5. **WakeMed and WakeMed Property Services 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 applicants propose to renovate the WakeMed North ED and acquire a second fixed CT scanner. Existing space will be reconfigured to accommodate additional treatment bays.

**Capital and Working Capital Costs**

In Section F-2(a), page 75 and Section Q, Form F-1a, page 155, the applicants state the total projected capital cost is to be as follows:

<b>WAKEMED NORTH CAPITAL COST</b>	
<b>Item</b>	<b>Cost</b>
Construction Contract	\$4,162,950
Medical Equipment (CT scanner, ED treatment beds, bedside monitoring equipment & related instrumentation)	2,036,500
Other Equipment	\$425,000
Furniture	\$102,106
Architect & Engineering	\$416,295
Consultant Fees (Fire Testing)	\$10,000
Information Technology	\$284,000
Financing Costs *	\$173,524
Interest During Construction	\$347,048
Other (Permitting, Testing, Contingency)	\$1,239,336
<b>Total</b>	<b>\$9,196,759</b>

\*If bond financing is determined to be more feasible, F-2(d), page 77.

Exhibit F-1 contains a certified cost estimate from the Vice President of Facilities and Construction at WakeMed which mirrors the projected project cost of **\$9,196,759** as stated by the applicants.

In Section F-3(a), pages 77-78, the applicants state there will be no start-up or initial operating expenses associated with the proposed project.

**Availability of Funds**

In Section F-2(d), page 77, the applicants state the entire capital cost of the project will be funded with accumulated reserves from WakeMed. Exhibit F-2.1, contains a letter dated February 6, 2017 from the Acting Chief Financial Officer of WakeMed Health and Hospitals documenting the availability of sufficient funds for the capital costs of the proposed project.

Exhibit F-2.2 contains the audited financial statements for the WakeMed system. As of September 30, 2016, WakeMed had \$100,620,000 in cash and cash equivalents, \$1,579,208,000 in total assets and \$907,284,000 in total net position. The applicant adequately demonstrates that sufficient funds will be available for the capital needs of the project.

**Financial Feasibility**

The applicants provide pro forma financial statements for the first three full fiscal years of operation following completion of the project. In the pro forma financial statements (Form F-4(a), page 163 - ED service component) and (Form F-4(b), page 166 - CT service component), the applicants project that revenues will exceed operating expenses in the first three operating years of the project, as shown in the tables below: (1) ED and (2) CT.

<b>WAKEMED NORTH ED</b>			
	<b>1<sup>st</sup> Full Fiscal Year FY 2018-2019</b>	<b>2<sup>nd</sup> Full Fiscal Year FY 2019-2020</b>	<b>3<sup>rd</sup> Full Fiscal Year FY 2020-2021</b>
Total Cases	48,712	50,368	51,929
Total Gross Revenues (Charges)	\$197,812,651	\$210,666,120	\$223,711,393
Total Net Revenue	\$35,809,175	\$37,026,116	\$38,173,741
Average Net Revenue per Case	\$735	\$735	\$735
Total Operating Expenses (Costs)	\$23,381,102	\$24,677,844	\$25,626,115
Average Operating Expense per Case	\$480	\$490	\$493
<b>Net Income</b>	<b>\$12,428,073</b>	<b>\$12,348,272</b>	<b>\$12,547,626</b>

<b>WAKEMED NORTH CT</b>			
	<b>1<sup>st</sup> Full Fiscal Year FY 2018-2019</b>	<b>2<sup>nd</sup> Full Fiscal Year FY 2019-2020</b>	<b>3<sup>rd</sup> Full Fiscal Year FY 2020-2021</b>
Total Procedures	12,511	13,011	13,531
Total Gross Revenues (Charges)	\$105,557,015	\$113,064,136	\$121,112,329
Total Net Revenue	\$17,860,446	\$18,575,906	\$19,317,813
Average Net Revenue per Procedure	\$1,428	\$1,428	\$1,428
Total Operating Expenses (Costs)	\$8,873,693	\$9,233,431	\$9,545,455
Average Operating Expense per Procedure	\$709	\$710	\$705
<b>Net Income</b>	<b>\$8,986,753</b>	<b>\$9,342,475</b>	<b>\$9,772,358</b>

The assumptions used by the applicants 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. The applicants

adequately demonstrate 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 applicants adequately demonstrate that sufficient funds will be available for the capital, working capital and operating needs of the project. Furthermore, the applicants adequately demonstrate that the financial feasibility of the proposal is based on reasonable projections of costs and charges. 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**

The applicants propose to renovate the 11,270 square feet in the ED at WakeMed North to add 13 treatment bays for a total of 32 treatment bays upon project completion. Existing space will be reconfigured to accommodate the additional treatment bays. The second component of the project is to acquire a second fixed CT scanner.

The 2017 SMFP does not define a service area for emergency departments or CT scanners. The applicants define their market area in Section C-1, page 26, as northern Wake County and Franklin County. Facilities may also serve residents of counties not included in their market or service areas. The number of ED treatment bays will increase by 13 for a total of 32 and the CT scanners will increase to a total of two as a result of this proposal.

In Section G-1, pages 83-85, the applicants provide a list of existing facilities that operate hospital-based 24/7 EDs services in their market area, as illustrated in the following table:

<b>ED LOCATIONS in NORTHERN WAKE COUNTY and FRANKLIN COUNTY FY2015</b>		
<b>Facility</b>	<b>Location/County</b>	<b>Number of Visits</b>
WakeMed North	10000 Falls of Neuse Rd. Raleigh 27614 / Wake	42,284
WakeMed Briar Creek Healthplex	8001 T.W. Alexander Dr. Raleigh 27617 / Wake	19,182
Duke Raleigh Hospital	3400 Wake Forest Rd. Raleigh 27609 / Wake	46,009
Franklin Medical Center (closed)	100 Hospital Dr. Louisburg 27549 / Franklin	15,290

Source: 2016 HLRAs, (FY2015 data) and FY2016 WakeMed internal data.

Additionally, on pages 83-85, the applicants provide a list of hospital-based facilities with CT scanners in northern Wake County and Franklin County, as illustrated in the following table:

<b>FIXED CT UTILIZATION in NORTHERN WAKE COUNTY and FRANKLIN COUNTY FY2015</b>				
<b>Facility</b>	<b>Location/County</b>	<b># Scanners</b>	<b>Total Scans</b>	<b>HECT Units</b>
WakeMed North	10000 Falls of Neuse Rd. Raleigh 27614 / Wake	1	11,122	15,766.25
WakeMed Briar Creek Healthplex	8001 T.W. Alexander Dr. Raleigh 27617 / Wake	1	3,959	5,577.00
Duke Raleigh Hospital	3400 Wake Forest Rd. Raleigh 27609 / Wake	3	23,455	38,135.25
Franklin Medical Center (closed)	100 Hospital Dr. Louisburg 27549 / Franklin	1	2,948	3,933.25

Source: 2016 HLRAs, (FY2015 data) and FY2016 WakeMed internal data.

Several non-hospital-based CT providers operate in the service area: WakeMed Briar Creek Healthplex (27609), Raleigh Radiology Briar Creek (27617), Raleigh Radiology Cedarhurst (27609), Wake Radiology Merton Drive (27609), Wake Radiology Wake Forest - Rogers Road (27587), and Raleigh Endoscopy Center North – Ambulatory Surgery (27615).

In a note at the bottom of page 85, the applicants state that the Division of Health Service Regulation does not report utilization statistics for non-hospital-based CT providers. As a result of the proposed project, WakeMed North would add 13 emergency department treatment bays and one CT scanner in Wake County. The applicants state that WakeMed North is the only acute care hospital located in northern Wake County and is the closest acute care hospital for many residents in Franklin County. Franklin County has had no local emergency department or CT scanner since 2015. WakeMed North is located in the center of its service area whose total population is growing at an average of 2% per year. Likewise, WakeMed North operates the only hospital-based CT scanner in northern Wake County and offers the closest CT scanner for many residents of Franklin County.

The applicants adequately demonstrate the need to renovate the ED, add 13 emergency department treatment bays and one CT scanner on the campus of WakeMed North. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

The applicants adequately demonstrate that the proposal will not result in the unnecessary duplication of existing or approved health service capabilities or facilities in Wake County or Franklin County. 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.

C

WakeMed North is an existing provider of emergency department and CT services in Wake County. In Section A-10, page 12 and in other sections in the application, the applicants state that the ED and CT scanner operate 24/7. The applicant proposes to maintain the same schedule of operations following completion of the proposed project. In Section Q, Form H, pages 175 and 176, the applicants provide the current and proposed staffing for the project,

and the assumptions, respectively. The applicants state that the ED at WakeMed North currently operates with 60.34 full time equivalent (FTE) staff and the CT scanner operates with 5.50 FTEs. Upon project completion, the applicants propose to operate the renovated and expanded ED with a total of 70.03 FTEs and operate the CT service component with a total of 8.30 FTEs in the second full federal fiscal year (FY2020), illustrated as follows:

<b>WAKEMED NORTH STAFFING ED and CT</b>		
	<b># FTEs</b>	
	<b>Current (as of 9.30.2016)</b>	<b>Projected 2<sup>nd</sup> Full Project Year FY 2020</b>
<b>EMERGENCY DEPARTMENT</b>		
Nursing		
Manager	1.00	1.00
Supervisor	2.00	3.00
RNs	35.21	41.30
Aides/Orderlies	13.15	15.75
<b>Total Nursing</b>	<b>51.36</b>	<b>61.05</b>
ED Registration		
Manager	.19	.19
Registration	8.68	8.68
Financial Acct. Rep.	.11	.11
<b>Total ED Registration</b>	<b>8.98</b>	<b>8.98</b>
<b>TOTAL ED</b>	<b>60.34</b>	<b>70.03</b>
<b>CT SCANNERS-Radiology</b>		
CT Technologists	3.75	4.70
CT Technologists (WEO)	1.80	3.60
<b>TOTAL CT SCANNERS</b>	<b>5.55</b>	<b>8.30</b>

In Section H-4, page 95, the applicants state that Dr. Seth Brody currently serves as the Executive Medical Director at WakeMed North. Exhibit H-4.1 contains a letter dated February 6, 2017 from Dr. Brody expressing his support for the project and his willingness to continue to serve as the Medical Director at WakeMed North.

On pages 93-94, the applicants list their medical staff by specialty. The applicants state that they have nearly 1,000 physicians on the medical staff at the WakeMed Raleigh campus who also have privileges at WakeMed North. Included in that number are 72 active emergency medicine physicians, all of whom are board certified in emergency medicine.

The applicants document the availability of adequate health manpower and management personnel, including the Medical Director, 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.

C

WakeMed North is an existing provider of the proposed services. In Section I-1 and 2, pages 97-99, the applicants describe the ancillary and support services that are currently available and that will continue to be available following completion of the proposed project. The applicants state that no new services are required to support the proposed project. Exhibit I-1 contains a letter dated February 6, 2017 from the Senior Vice President and Administrator of WakeMed North documenting the availability of all necessary ancillary and support services. Exhibit I-2.1 contains copies of sample transfer agreements, and page 98 contains a list of facilities with which WakeMed has transfer agreements. See Exhibit I-2.2 for copies of letters of support from physicians.

The applicants adequately demonstrate that they will continue to provide or have arrangements for the necessary ancillary and support services and that the proposed services will 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.

## C

The applicants propose to renovate 11,270 square feet in the ED at WakeMed North to add 13 treatment bays for a total of 32 treatment bays upon completion of the project. Existing space will be reconfigured to accommodate the additional 13 treatment bays. The second component of the project is to acquire a second fixed CT scanner. (In Section K, Footnote 16, page 102, the applicants state that on the line drawings in Exhibit K-2, the rooms with ED treatment beds are labeled “exam” rooms.). The new CT scanner will also be housed in existing space near the ED and existing CT scanner. See Section C-1, pages 26-29.

In Section K-4, page 103, the applicants state:

*“The option to renovate the existing space results in the most space-efficient and cost effective method in adding the requested emergency department treatment beds. Throughout the design process, Lean techniques are deployed to assure that patient and staff travel patterns are minimized, storage is held to a minimum while located at the point of service, and equipment is staged where it is most convenient for patient access. The proposed project will significantly increase the treatment room densities (treatment rooms per occupied square foot) and will optimize staff and equipment circulation.*

*The design of the space will result in an increased throughput for the delivery of care – optimizing patient-to-physician times, maximizing productive time for staff and physicians. ...”*

In Section B-11, pages 24-25, the applicants describe WakeMed North’s Energy Efficiency and Sustainability Plan; the methods that will be used by the facility to maintain efficient energy operations and contain the costs of utilities. The discussion regarding the applicants’ plan for energy efficiency and sustainability found in Criterion (1) is incorporated herein by reference.

The total projected capital costs for the proposed project is \$9,196,579. Exhibit F-1 contains a certified cost estimate of construction costs of \$4,162,950, which corresponds to the project capital cost projections provided by the applicant in Section Q, Form F-1(a), page 155, of the application. The discussion regarding costs and charges found in Criterion (5) is incorporated herein by reference. The applicants adequately demonstrate that the cost, design and means of construction represent the most reasonable alternative, and that the construction cost will not unduly increase costs and charges for health services. Therefore, the application is conforming to this criterion.

- (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 109, the applicants provide the payor mix for WakeMed North (entire facility), the ED and the CT service components, as illustrated in the following tables.

<b>WAKEMED NORTH HISTORICAL PAYOR MIX FY2016</b>			
<b>Payor Source</b>	<b>WakeMed North (entire facility)</b>	<b>ED</b>	<b>CT Scanner</b>
Self-Pay/Charity	8.5%	15.8%	13.9%
Medicare	37.5%	18.3%	24.1%
Medicaid	15.8%	18.4%	10.3%
Commercial /Managed Care	37.3%	43.5%	47.1%
Workers Comp/Other Gov't	0.9%	4.1%	4.6%
<b>Total</b>	<b>100%</b>	<b>100%</b>	<b>100%</b>

As illustrated above, 53.3% of all patients who received services WakeMed North, 36.7% of ED patients and 34.4% of CT patients had some or all of their services paid by Medicare and/or Medicaid. On page 108, the applicants provide a breakdown of the patients who received services at WakeMed North in 2016 by women, ages (65+ and 0-17), racial and ethnic minorities, low income and uninsured status; as well as the percentages of the aforementioned groups in the service area.

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 applicants' 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>
Wake	10%	51%	39%	12%	5%	14%
Franklin	15%	50%	37%	15%	11%	19%
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 applicants' 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 applicants demonstrate that they currently provide 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

In Section L-2, page 109, the applicants state that they have no obligation to provide uncompensated care, community service, or access by minorities, and handicapped persons under federal regulations. The applicants also state there have been no civil rights access complaints filed within the last five years against WakeMed. 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 110, the applicants provide the projected payor mix for WakeMed North and the ED and CT service components in FY 2020, as below illustrated:

<b>WAKEMED NORTH PROJECTED PAYOR MIX FY2020</b>			
<b>Payor Source</b>	<b>WakeMed North (entire facility)</b>	<b>ED</b>	<b>CT Scanner</b>
Self-Pay/Charity	8.5%	15.8%	13.9%
Medicare	37.5%	18.3%	24.1%
Medicaid	15.8%	18.4%	10.3%
Commercial /Managed Care	37.3%	43.5%	47.1%
Workers Comp/Other Gov't	0.9%	4.1%	4.6%
<b>Total</b>	<b>100%</b>	<b>100%</b>	<b>100%</b>

As illustrated above, 53.3% of all patients who received services WakeMed North, 36.7% of ED patients and 34.4% of CT patients had some or all of their services paid by Medicare and/or Medicaid. The applicants state on page 111 that they do not project a change in the payor mix from their historical payor mix. In Section L-5, pages 111-112, the applicants state:

*“WakeMed provides service to any person in need of medical care, regardless of his or her ability to pay. ...*

*Additionally, WakeMed’s formal admissions policy states that WakeMed will accept anyone seeking medical services.”*

The applicants adequately demonstrate that medically underserved populations will have adequate access to the proposed services. Therefore, the application is conforming to this criterion.

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

C

In Section L-5, pages 111-112, the applicants describe the range of means by which patients currently and will have access to WakeMed services. The applicants adequately demonstrate that they 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-1 and 2, pages 113-118, the applicants state how as an existing facility, WakeMed accommodates the clinical needs of area health professional training programs:

*“WakeMed has in place a number of training agreements with health professional training program [s] at colleges and universities, both inside and outside North Carolina.*

*...”*

In addition, WakeMed provides job-shadowing opportunities for students at some local high schools. WakeMed is home to Wake Area Health Education Center (AHEC), which brings valuable benefits to health professionals and community residents.

The applicants list the colleges and universities with whom they have training agreements on pages 113-116, and provide copies of sample training agreements in Exhibit M-1. The applicants state on page 118 that they are open to establishing agreements with additional programs, both locally and nationally.

The information provided in Section M and referenced exhibits is reasonable 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 applicants propose to renovate 11,270 square feet in the ED at WakeMed North to add 13 treatment bays for a total of 32 treatment bays upon project completion. Existing space will be reconfigured to accommodate the additional treatment bays. The second component of the project is to acquire a second fixed CT scanner.

The 2017 SMFP does not define a service area for emergency departments or CT scanners. The applicants define their market area in Section C-1, page 26, as northern Wake County and Franklin County. Facilities may also serve residents of counties not included in their market or service areas. The number of ED treatment bays will increase by 13 for a total of 32 and the CT scanners will increase to a total of two as a result of this proposal.

In Section G-1, pages 83-85, the applicants provide a list of existing facilities that operate hospital-based 24/7 EDs services in their market area, as illustrated in the following table:

<b>ED LOCATIONS in NORTHERN WAKE COUNTY and FRANKLIN COUNTY FY2015</b>		
<b>Facility</b>	<b>Location/County</b>	<b>Number of Visits</b>
WakeMed North	10000 Falls of Neuse Rd. Raleigh 27614 / Wake	42,284
WakeMed Briar Creek Healthplex	8001 T.W. Alexander Dr. Raleigh 27617 / Wake	19,182
Duke Raleigh Hospital	3400 Wake Forest Rd. Raleigh 27609 / Wake	46,009
Franklin Medical Center (closed)	100 Hospital Dr. Louisburg 27549 / Franklin	15,290

Source: 2016 HLRAs, (FY2015 data) and FY2016 WakeMed internal data.

Additionally, on pages 83-85, the applicants provide a list of hospital-based facilities with CT scanners in northern Wake County and Franklin County as illustrated in the following table:

<b>FIXED CT UTILIZATION in NORTHERN WAKE COUNTY and FRANKLIN COUNTY FY2015</b>				
<b>Facility</b>	<b>Location/County</b>	<b># Scanners</b>	<b>Total Scans</b>	<b>HECT Units</b>
WakeMed North	10000 Falls of Neuse Rd. Raleigh 27614 / Wake	1	11,122	15,766.25
WakeMed Briar Creek Healthplex	8001 T.W. Alexander Dr. Raleigh 27617 / Wake	1	3,959	5,577.00
Duke Raleigh Hospital	3400 Wake Forest Rd. Raleigh 27609 / Wake	3	23,455	38,135.25
Franklin Medical Center (closed)	100 Hospital Dr. Louisburg 27549 / Franklin	1	2,948	3,933.25

Source: 2016 HLRAs, (FY2015 data) and FY2016 WakeMed internal data.

Several non-hospital-based CT providers operate in the service area: WakeMed Briar Creek Healthplex (27609), Raleigh Radiology Briar Creek (27617), Raleigh Radiology Cedarhurst (27609), Wake Radiology Merton Drive (27609), Wake Radiology Wake Forest - Rogers Road (27587), and Raleigh Endoscopy Center North - Ambulatory Surgery (27615).

In a note at the bottom of page 85, the applicants state that utilization statistics for non-hospital-based CT providers is not publicly available. As a result of the proposed project, WakeMed North would add 13 emergency department treatment bays and one CT scanner in Wake County. The applicants state that WakeMed North is the only acute care hospital located in northern Wake County and is the closest acute care hospital for many residents in Franklin County. Franklin County has had no local emergency department or CT scanner since 2015. WakeMed North is located in the center of its service area whose total population is growing at an average of 21% per year. Likewise, WakeMed North operates the only hospital-based CT scanner in northern Wake County and offers the closest CT scanner for many residents of Franklin County.

In Section N-1 and 2, pages 119-121, the applicants discuss how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services. The applicants state:

*“WakeMed North Hospital is the only acute care facility in northern Wake County, and operates the only 24/7 emergency department in the North Raleigh/Wake Forest/Rolesville area. For residents of this area, as well as much of Franklin County, WakeMed North is the closest full-service emergency facility.*

*The proposed project represents a cost-effective alternative, one that will increase emergency department capacity and CT scanner capacity at WakeMed North Hospital without new construction.*

*WakeMed strives to provide high-quality services to all. ...*

*The proposed project will have a positive impact on quality at WakeMed North. ... this project represents a carefully planned expansion that will accommodate current and future volume and allow patients to be treated as quickly as possible. ...*

*WakeMed's emergency departments provide a significant proportion of total visits to Medicare, Medicaid, Charity Care, and other underserved groups. ..."*

See also Sections B, C, E, G, K, L and O and where the applicants discuss the impact of the project on cost-effectiveness, quality and access to the proposed services.

The information in the application is reasonable and credible and adequately demonstrates that any enhanced competition in the service area includes a positive impact on cost-effectiveness, quality and access to the proposed services. This determination is based on the information in the application and the following analysis:

- ◆ The applicants adequately demonstrate the need for the proposed project and that it is a cost-effective alternative. The discussions regarding analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.
- ◆ The applicants adequately demonstrate that they will continue to provide quality services. The discussion regarding quality found in Criteria (1) and (20) is incorporated herein by reference.
- ◆ The applicants adequately demonstrate that they 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(a), pages 132-133, the applicants state that they currently own and operate seven hospitals/acute care health services facilities and owns/manages eight health services properties in North Carolina. In Exhibit O-3.2, the applicants provide a February 8, 2017 letter from the President and CEO of WakeMed Health and Hospitals confirming that during the 18 months immediately preceding the submittal of the application, all facilities owned, operated and managed by WakeMed were in compliance with all Medicare conditions of participation. After reviewing and considering information provided by the applicants considering the quality of care provided at all seven hospital facilities, the applicants provide 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.

## CA

WakeMed and WakeMed Property Services propose to acquire an additional CT scanner at WakeMed North for the hospital Radiology Department. Therefore, 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 and Standards for Computed Tomography Equipment. See Criterion 4, Condition 2. The specific criteria are discussed below.

### **SECTION .2300 CRITERIA AND STANDARDS FOR COMPUTED TOMOGRAPHY EQUIPMENT**

#### **10A NCAC 14C .2302 INFORMATION REQUIRED OF APPLICANT**

#### **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-11(b), Rules, page 63, the applicants project that the proposed fixed CT scanner will perform a total of 9,517.88 HECT units in the third year of operation following completion of the project. Thus, the proposed CT scanner is projected to perform more than 5,100 HECT units in Project Year 3. The discussion regarding analysis of need and alternatives 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.*
- C- In Section C-11(b), Rules, page 64, the applicants state,

*“The existing fixed CT scanner at WakeMed North performed 15,766.25 HECT units in FY2016, well above the standard set forth in this Rule. ...”*

In Section G-2, Table G-2, page 85, the applicants provide the following table depicting the CT scanners in their identified service area, as illustrated below in the table:

<b>TABLE G-2 FIXED CT UTILIZATION in the SERVICE AREA FY2015</b>				
<b>Facility</b>	<b>Location/County</b>	<b># Scanners</b>	<b>Total Scans</b>	<b>HECT Units</b>
WakeMed North	10000 Falls of Neuse Rd. Raleigh 27614 / Wake	1	11,122	15,766.25
WakeMed Briar Creek Healthplex	8001 T.W. Alexander Dr. Raleigh 27617 / Wake	1	3,959	5,577.00

Source: 2016 HLRAs, (FY2015 data) and FY2016 WakeMed internal data.

The table found on page 85 and illustrated above demonstrates that each of the fixed CT scanners in the applicants' identified primary service area exceeded the 5,100 HECT units annually as required in this rule.

- (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.*

-CA- WakeMed North currently has one existing CT scanner and is proposing to add a second CT scanner. Briar Creek Healthplex currently has one existing CT scanner. The applicants project that in the third year of operation following completion of the project, the existing and proposed CT scanners at WakeMed North will perform 19,035.75 HECT units as illustrated below in the table.

<b>WAKEMED NORTH PROJECTED HECT UNITS FY2021/PY3</b>						
	Type of CT Scan	No. of Scans		Conversion Factor		HECT Units
1	Head without contrast	5,362	X	1.00	=	5,362.00
2	Head with contrast	311	X	1.25	=	388.75
3	Head without and with contrast	88	X	1.75	=	154.00
4	Body without contrast	3,078	X	1.50	=	4,617.00
5	Body with contrast	4,389	X	1.75	=	7,680.75
6	Body without contrast and with contrast	303	X	2.75	=	833.25
7	Biopsy in addition to body scan with or without contrast	0	X	2.75	=	0.00
8	Abscess drainage in addition to body scan with or without contrast	0	X	4.00	=	0.00
	<b>Total</b>	<b>13,531</b>				<b>19,035.75</b>

Section Q, Table Q-14, page 154 of the application.

However, the applicants did not provide the projected HECT units for the WakeMed Briar Creek Healthplex in the third year of operations of the proposed project to be developed at WakeMed North, as required by this Rule.

The Project Analyst compiled the information on the WakeMed Briar Creek Healthplex CT scans and HECT units for the past five years from hospital LRAs, as depicted in the following table. The CT scanner at WakeMed Briar Creek Healthplex has increased utilization each year for the past five years and has exceeded the minimum number of HECT Units for the past two years. Therefore, the Agency considers it reasonable to assume that due to the historical performance of the CT scanner at WakeMed Briar Creek Healthplex, that the addition of the proposed second CT scanner at WakeMed North will not negatively impact the performance of the CT scanner at WakeMed Briar Creek Healthplex. See Criterion 4, Condition #2 of these findings.

<b>WAKEMED BRIAR CREEK HEALTHPLEX HISTORICAL CT SCANS AND HECT UNITS FYs 2012 - 2016</b>		
<b>LRA</b>	<b>Total Scans</b>	<b>Total HECT Units</b>
2017	3,959	5,577.00
2016	3,766	5,119.00
2015	3,552	4,994.50
2014	2,944	4,124.25
2013	1,729	2,423.00

Source: WakeMed HLRAs, 2013-2017 = data for FYs 2012-2016.