

October 1, 2024

Ms. Michaela Mitchell, Chief
Mr. Greg Yakaboski, Project Analyst
Healthcare Planning and Certificate of Need Section
Division of Health Service Regulation
Via Electronic Mail to:

DHSR.CON.Comments@dhhs.nc.gov

greg.yakaboski@dhhs.nc.gov

RE: Comments on September 1, 2024 Wake County Operating Rooms and Acute Care Bed CON Review

Project ID#	Facility	Project Description
J-12533-24	WakeMed North Hospital	Add 2 operating rooms
J-12534-24	Novant Health Knightdale Medical Center	New hospital with 36 acute beds and 1 operating room
J-12535-24	WakeMed	Add 2 operating rooms
J-12536-24	WakeMed North Hospital	Add 25 acute beds (Change in scope for J-12419-23)
J-12537-24	WakeMed Cary Hospital	Add 24 acute beds (Change in scope for J-12418-23)
J-12538-24	WakeMed	Add 21 acute beds
J-12542-24	UNC Health Rex Hospital	Add 20 acute care beds and 2 operating rooms
J-12543-24	UNC Health Rex Wake Forest Hospital	New hospital with 50 acute care beds and 2 operating rooms
J-12546-24	Duke Raleigh Hospital	Add 41 acute beds
J-12547-24	Duke Raleigh Hospital	Add 3 operating rooms
J-12548-24	Duke Cary Hospital	Add 17 acute beds (Change in scope/cost overrun for J-12029-21)
J-12549-24	Duke Garner Hospital	New hospital with 12 beds and 1 operating room

Dear Mr. Yakaboski and Ms. Mitchell:

Thank you for considering WakeMed's comments regarding the 12 applications for the 70 acute care beds and 4 operating rooms allocated to Wake County in the September 1, 2024 CON Review. This is a challenging review not only for the number of applications, but also because the projects fundamentally differ so greatly from one another. Specifically, acute care bed and operating room requests range from creation of a new micro-hospital to additions to a Level I Trauma Center. The differences render many of the Comparative Review Factors typically used by the Agency inconclusive in this review.

Financial proformas are not comparable across such inherently different projects, not only because of the profound differences in scope, but also due to the lack of commonality. Attachment A illustrates differences among the proformas.

The following Comparative Review Factors do not allow for consistent analysis across applicants:

- Net Revenue and Net Operating Expense per unit, as illustrated on Attachment A:
 - Surgical proformas range from the operating rooms alone to entire surgical departments.

- Bed proformas revenue and expense presentations range from beds alone to the entire acute inpatient stay.
- Medicaid and Medicare percentages of patients served: Though a traditional measure of service to underserved groups, the factor does not compare like types of patients in each of these applications.
 - o Some facilities, like UNC Rex Wake Forest, propose a disproportionate proportion of obstetrics and cancer. Medicaid is a dominant payor for both service lines. Medicaid covered 38 percent of births in North Carolina in 2022; and rates among certain ethnic and racial groups are as high as 64 percent. (ACC) Cancer patients are disproportionately represented in UNC Rex Wake Forest and Duke Garner. Cancer patients are disproportionately older; thus, Medicare will disproportionately cover cancer patients. Duke Garner also proposes to focus on cancer patients and the Duke Cary application proposes an increase in obstetrics patients.
- Geographic Access does not provide an equal playing field in a review with such differences and complexities as this batch.
 - Some applicants propose acute care beds and operating rooms in one application, while some propose only beds or only operating rooms.
 - O Unlike an MRI, ESRD, or nursing home application review, the applications for beds and operating rooms in this review do not propose the same level of services to patients. Access to a small, 12- to 50-bed community hospital is vastly different from access to the services offered in a Trauma Center or even a hospital that has a significant, established base of specialists. Duke Garner and WakeMed Raleigh propose immensely different levels of service in Wake County; these two applications cannot be fairly compared to each other.
 - Wake County is a service center for more than Wake County. Residents of surrounding Franklin, Nash, Lee, and Wilson counties, along with eastern Chatham and northern Harnett counties must travel hours to alternate sources of specialist acute inpatient and operating room care in Durham, Chapel Hill, Greenville, and Winston Salem.
 - When the Competition metric is applied to acute care beds, it relegates Wake County to a future of no growth in specialty hospital centers. Only small hospitals in micro geographies would qualify.
 - Competition is similar to Geographic Access –The Agency should balance development of new acute care facilities with the need for timely capacity in existing facilities. Existing facility need for beds in 2026 generated the need determination in this review. If it applies the Competition factor, the Agency would be establishing an unwritten policy that small new hospital market entrants are preferred to specialized service centers in Wake County. Applied in every review, this factor could result in Wake County having many very small hospitals that are unable to support the infrastructure required to treat highly acute patients. Ultimately, this is a disservice to Wake County residents. Wake County is already the most competitive acute care hospital service area in North Carolina. Wake is the only county with three competing health care systems who operate hospitals in the same county.

- If the Agency applies the Competition metric to acute care beds in every review, it could relegate Wake County to a future of no growth in specialty hospital capacity. Only small hospitals in micro geographies would be comparatively superior.
- Carving up the county into small markets for beds will ultimately mean that many residents east of Durham and Chapel Hill will be forced to use specialty services in Orange and Durham Counties because facilities located there will have the only available specialty capacity.
- The Agency has issued CONs for two small Wake County acute care hospitals that are not yet open (Duke Green Level, aka Duke Cary, and WakeMed Garner). Encouraging more new, small hospitals could have unintended consequences:
 - More acute care beds being delayed past the year the SMFP projects the beds are needed;
 - High transfer rates and related extra costs associated with transfers from these small hospitals to larger existing regional referral and tertiary hospitals;
 - Increasing capacity constraints at existing tertiary hospitals, as the decentralization of beds eliminates their ability to expand access.

Unfortunately, eliminating these comparative factors leaves the Agency with few metrics on its standard list. However, WakeMed believes the following factor is still valid.

For Beds and Operating Rooms:

- Scope of Services
- Access by Service Area Residents
- Historical Utilization

Scope of Services ensures development of specialty services. **Access by Service Area Residents** recognizes that Wake County residents should benefit from the competitive project. **Historical Utilization** acknowledges patient choices as well as where the current delivery system is stressed.

WakeMed also believes that this review merits two other metrics for consideration in the Comparative Analysis: **Availability and Workforce Impact**.

Service Availability is the proposed date of service provided in Section P. *Service Availability* is important because Wake County has a desperate shortage of inpatient resources at **existing facilities**. The *2024 SMFP* clearly states in Tables 5A and 6A that the need for beds and operating rooms occurs in **2026**. Several applications confirm immediacy of need, mentioning Diversion Hours, times when local EMS providers must play the game of "find a bed," because beds in hospitals with needed specialties are full. See the comparison table in Attachment B.

Workforce Impact measures the net new employees required for the services proposed in each application. *Workforce Impact* is important because health care workforce shortages are a well-documented issue that affects Wake County. Lowest is best because the applicant can develop the service with the least impact on the workforce. In three applications in the review, this requires deducting the net from previously approved projects. Please see Attachment C. The impact of approving many small hospitals has the effect of requiring unnecessary duplication of staff. These include support

staff, as well as nursing, therapists, and physicians. Such unnecessary duplication may deplete the available staff for existing hospitals that require only a fraction of those staff to bring the same bed and operating room assets online.

WakeMed is the safety net provider for Wake County. It operates the only two designated trauma centers in the county, at WakeMed Raleigh and WakeMed Cary. It has shortages of operating rooms and acute care beds, and those shortages drive most of the need calculations for acute care beds and operating rooms in the 2024 SMFP. Moreover, WakeMed can bring four of its proposed projects online within two years after approval, at low cost, and can bring all projects online with minimal impact on the county workforce.

Finally, WakeMed has received additional letters of support for applications during the Public Comment Period. Several in particular have competitive bearing on this review. We ask the Agency to carefully read letters in the respective applications as well as these recent letters submitted separately from these comments.

Thank/ou for your consideration

Rick Shrum

Vice President & Chief Strategy Officer

Attachments:

A.	Applicants' Financial Statement Presentations Compared
В.	Start Date of Services Compared
C.	Workforce Impact Comparison
D.	J-012534-24 Novant Health Knightdale Medical Center, 36 Acute Care Beds and 1 Operating Room
Ε.	Salary Comparison: Novant Knightdale vs WakeMed North
F.	J-012543-24 UNC Health REX Wake Forest, 50 Acute Care Beds and 2 Operating Rooms
G.	J-012546-24 Duke Raleigh Hospital, 41 Acute Care Beds
Н.	J-012547-24 Duke Raleigh Hospital, 3 Operating Rooms
I.	J-012548-24 Duke Cary Hospital, 17 Acute Care Beds Change of Scope4
J.	J-012549-24 Duke Garner Hospital, 12 Acute Care Beds and 1 Operating Room5
K.	National Demographer Clarita, Population Data, 10-min Drive Time from Duke Garner Hospital 63
ı	I-012452-24 LINC REX Hospital 20 Acute Care Reds and 2 Operating Rooms

ATTACHMENT A

Applicants' Financial Presentations Compared

Application	0 5	souto tropped.	otion suggest	Moode Notes	Inpay.	Acure Alsonices	Core Book on,	Salaries Co.	Ga Hoothean ED	wine facility.	"mire License Em.	Time System
Novant Health Knightdale, 36 beds 1 OR	х	х			х				х		x	
UNC Health REX Hospital, 20 beds, 2 ORs			х			х				х		
UNC REX Wake Forest, 50 beds, 2 OR	х	х			х			х				
Duke Raleigh Hospital, 41 Beds						х					х	
Duke Raleigh Hospital, 3 ORs			х								x	
Duke Cary Hospital, 17 Beds	х		х	х			х	x	х		x	
Duke Garner Hospital, 12 Beds, 1 OR	х		х	x				x	x		x	
WakeMed North, 2 ORs			х						х		х	
WakeMed Raleigh Campus, 2 ORs			х						х		х	
WakeMed North, 25 Beds						х			х		х	
WakeMed Cary, 21 Beds						х			х		х	
WakeMed Raleigh Campus, 24 Beds						х			х		x	

Some applicants have filed separately for beds and operating rooms, while others have combined these services in a single application. Furthermore, some applications bundled all inpatient services in one set of proforma financial statements (including surgical services), with scant assumptions, making it impossible to isolate the financial performance of just the beds and operating rooms.

ATTACHMENT B

Applicants' Proposed Start Date of Services Compared

Acute Care Beds

Application	2025	2026	2027	2028	2029	2030
WakeMed Cary, 24 beds	х					
UNC Health REX Hospital, 20 beds, 2 ORs		х				
WakeMed Raleigh Campus, 21 beds		х				
Duke Raleigh Hospital, 41 Beds				х		
Duke Garner Hospital, 12 Beds, 1 OR				х		
WakeMed North, 25 beds				х		
Duke Cary Hospital, 17 Beds					х	
Novant Health Knightdale, 36 beds 1 OR					х	
UNC REX Wake Forest, 50 beds, 2 OR						х

Operating Rooms

Application	2025	2026	2027	2028	2029	2030
WakeMed Raleigh Campus, 2 ORs	х					
UNC Health REX Hospital, 20 beds, 2 ORs		x				
WakeMed North, 2 ORs		х				
Duke Garner Hospital, 12 Beds, 1 OR				х		
Duke Raleigh Hospital, 3 ORs					х	
Novant Health Knightdale, 36 beds 1 OR					х	
UNC REX Wake Forest, 50 beds, 2 OR						х

ATTACHMENT C

Applicants' Healthcare Workforce Impact Compared

Application	Proposed	Approved Net New Staff (2021 / 2023)	Net New Staff Proposed 2024	New Staff Net of Current and Approved CONs	Adjustment for Prior CONs
WakeMed Raleigh Campus	21 Beds		-	-	none
WakeMed Raleigh Campus	2 ORs		-	-	none
WakeMed North	2 ORs		15.0	15.0	none
Duke Raleigh Hospital	3 ORs		30.2	30.2	none
Duke Raleigh Hospital	41 beds		32.8	32.8	none
WakeMed Cary	24 beds	7.7	70.8	63.1	removed net WakeMed Cary 2023
Duke Garner Hospital	12 beds, 1 OR		122.1	122.1	none
Duke Cary Hospital	17 beds	429.0	561.9	132.9	removed net Duke Cary 2021
WakeMed North	25 beds	155.7	297.8	142.1	removed net WakeMed North 2023
UNC Health REX Hospital	20 beds, 2 ORs		216.5	216.5	none
Novant Health Knightdale	36 beds, 1 OR		222.0	222.0	none
UNC REX Wake Forest	50 beds, 2 ORs		545.4	545.4	none

Sources and Notes:

- From Form H Current Staff minus Total Staff Project Year 03.
- Adjustment column calculated by same formula applied to the referenced CON application.

Competitive Review of – Novant Health Knightdale Hospital / Project ID #J-12534-24

Overview

Novant Health ("Novant") proposes to develop a new hospital with 36 acute care beds and 1 operating room at a site in Knightdale called Novant Health Knightdale ("NH Knightdale"), in response to the determinations for 70 acute care beds and 4 operating rooms in the 2024 State Medical Facilities Plan ("SMFP"). Novant fails to adequately demonstrate the need for the proposed project. The application is nonconforming with multiple Review Criteria and should be denied.

CON Review Criteria

 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, ambulatory surgery operating rooms, or home health offices that may be approved.

Overview

The proposed project is in response to a need determination for 70 acute care beds and four operating rooms in Wake County. It is therefore subject to Policy <u>GEN-3</u>: <u>Basic Principles</u>, which states:

"A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area."

As described in Criterion 3 below, Novant does not demonstrate that its proposal's, "projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area." The Novant application should therefore be found non-conforming to Review Criterion 1.

Value

NH Knightdale's total capital cost is \$286,941,626; this equates to \$7,970,600 per bed. The proposed project's construction is \$168,205,593, or \$4,672,377 per bed. Although capital cost has not been a comparative factor in recent years, there is a stark contrast between applicants proposing new acute care hospitals, and applicants who propose to utilize existing or approved space for beds and/or operating rooms. Given the alternatives proposed by various applicants in the Wake County acute care bed and operating room review cycle, approval of applicants proposing new acute care hospital campuses seems superfluous.

The NH Knightdale project requires an entirely new infrastructure of ancillary and support services. According to Form H, it will require hiring 122 FTEs. Section H describes a plan for recruiting physicians in Exhibit C-4.3. However, it does not describe where or how it will obtain the 122 other FTEs. This is important, because Wake County, like the rest of North Carolina has a shortage of direct care health care workforce members.

Novant salaries are not credible. Compared to WakeMed North for the same Fiscal Years, the table in Attachment E illustrates the operating shortfall required for Novant to make salaries for key positions comparable to WakeMed North, a community hospital that is only minutes away from the proposed NH Knightdale. Salaries for other staff are similarly below market. Attachment E shows it is entirely possible that when salaries are adjusted, the project will not have positive revenue, even by the third year.

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.

Novant proposes to develop its new hospital in Knightdale in eastern Wake County, citing the lack of acute care services in its defined primary service area ("PSA") as the principal reason for choosing this location – on page 62, the application states "There is a need for improved access to acute care services in the eastern part of the county." However, Novant provides no evidence to support this claim.

NH Knightdale's PSA is defined on page 50 as "a set of zip codes in which the majority of residents live closer to NH Knightdale than any other hospital." Its secondary service area ("SSA") is described as "two zip codes for which portions, but not the majority, or residents live closer to NH Knightdale than any other hospital." Simply proposing to develop a hospital in closer proximity to service area residents is a thin justification for a proposed capital outlay of \$268 million.

On page 36, the Novant application states: "Some hospitals are designed to be larger and offer tertiary services, and some hospitals are designed as community hospitals. A metropolitan area should have both to meet the needs of all patients." It should be noted that Wake County is already well-served by tertiary hospitals, regional referral facilities, and community hospitals that have either recently opened or which are approved and actively under development.

Unrealistic Market Share Projections

Novant projects that its Knightdale Hospital will garner 20 percent market share of the PSA and 10 percent share of the SSA by Project Year 3. Most of the population to be served is outside of the PSA which Novant claims is the underserved area. Novant provided market shares for comparable community hospitals' PSAs and SSAs as justification for its projections in Wake County. There are multiple issues with Novant's methodology, which will be discussed in turn below.

1. Service Area Definition and Drive Time Analysis

On page 156, Novant states:

"NH used ArcGIS to determine the primary service area of these hospitals, using the same method used to determine NH Knightdale's primary service area—the zip codes for which most residents live closer to that hospital than to any other, as determined by drive time and the population centroid of the zip code. Exhibit C-4.4 consists of maps for each hospital in the tables below as well as NH Knightdale, showing the areas closest to them by drive time and the population centroids of the area zip codes. Secondary service areas include zip codes for which some, but not most, area residents live closer to each facility than to any other. Some zip codes that only had a small portion closest to the hospital were not included in the secondary service area (which was also done for NH Knightdale's service area)."

The drive time analysis provided in Exhibit C-4.4 lacks several critical details:

- There are no specific drive time thresholds provided that explain how the service areas were delineated (e.g., 0-15 minutes for PSA, 15-29 minutes for SSA). The shaded area highlighted in the exhibit is only described as "area closest to hospital, as determined by drive time."
- There is no clear explanation for how population centroids were used in conjunction with drive times to determine service area boundaries.

Without a more specific description of how its service area was defined, the NH Knightdale projections cannot be substantiated and are unreasonable.

2. <u>Data Transparency</u>

The Novant application cites "HIDI Inpatient Database, 2023" as its source for the discharge data, but fails to provide any supporting documentation. The application lacks transparency in presenting the underlying data used for its projections, including the criteria for its selection of "limited acute care" MS-DRGs.

Without this information, it is impossible to independently verify the reasonableness of the service area definitions and the apparent market share of the respective service areas. This lack of transparency casts doubts on the foundation of the market share projections and subsequent utilization forecasts.

3. Use of Comparable Hospitals to Justify Market Share Shift

On pages 156-157, Novant provides examples of community hospitals in the Mecklenburg, Forsyth, and Wake Counties that were successful in growing inpatient market share, to justify its assumption that NH Knightdale will "conservatively" achieve 20 percent market share from its PSA and 10 percent share of the SSA by Project Year 3. Assuming the market share data described in the application are correct, these examples do not translate to NH Knightdale:

- NH Mint Hill, located in Mecklenburg County, took *six* years to achieve market shares of 19% and 8% in its primary and secondary service areas, respectively.
- NH Kernersville, open since 2011 in Forsyth County, has achieved 43% and 25% market shares after *over a decade* of operations.
- UNC Rex Holly Springs, which opened in November 2021 in Wake County, has achieved 31% and 14% market shares by 2023, but is a larger 50-bed community hospital that includes obstetric and neonatal services not proposed for NH Knightdale.

The hospitals listed above are in counties where the parent system has both a tertiary facility and a longstanding physician presence in the same county, both of which are vital to establishing a strong referral base. NH Knightdale will have neither of these built-in advantages at opening. Simply developing and opening a hospital does not guarantee that it will capture substantial market share.

The applicant has not provided sufficient justification for why NH Knightdale would capture market share more rapidly than these comparable facilities. The application lacks a detailed analysis of local market dynamics, competitor responses, or other factors that would support **immediately** achieving such aggressive market penetration by Project Year 3.

Use of Limited Acute Care Patient Data Not Justified

On pages 55-56, Novant provides information on "limited acute care" ("LAC") patient days that originate in the PSA and SSA. While Novant provides a list of the limited acute care MS-DRGs in Exhibit C-1.2, there is no discussion provided regarding the criteria for selection of these MS-DRGs.

While LAC patient days in the PSA ZIP Codes increased 27.8 percent from CY 2019-2023, the actual number of LAC patient days is greater in the SSA in both tables on pages 55 and 56. On page 56, Novant excludes patient days for patients with a primary COVID-19 diagnosis from its analysis – it is not immediately clear why this table is included in the application. The removal of 1,156 patient days translates to approximately 3.1 beds per day.

Payor Mix Projections Not Realistic

Novant's inpatient payor mix projections are based on the same questionable market share assumptions and service area definitions discussed above. Additionally, the application describes the methodology for calculating the payor mix but provides no supporting data or intermediate calculations. Its outpatient payor mixes are based on "2023 HIDI data" which is not provided, nor is it publicly available.

Average Length of Stay is Unreasonably High

On page 159, Novant provides CY 2023 limited acuity care discharges, patient days and average length of stay ("ALOS") for hospitals in Wake, Johnston, and Nash Counties, which is calculated at 5.02 days. To calculate NH Knightdale's projected ALOS, Novant chose to remove information for UNC Rex Healthcare and WakeMed Raleigh Campus, with the explanation that "[t]hese two hospitals are likely to serve more higher-acuity patients who require a longer length of stay."

Applying this logic, Novant should have also removed data for Duke Raleigh Hospital (186 beds) and WakeMed Cary Hospital (200 beds), both of which are regional referral centers, as well as UNC Johnston Health (126 beds) and Nash UNC Health Care (250 beds), which are largest/only acute care hospitals in their respective counties. The remaining facilities, UNC Rex Holly Springs (50 beds), Johnston Health Clayton (50 beds) and WakeMed North Hospital (71 beds), are true community hospitals and more analogous to NH Knightdale. The CY 2023 ALOS for these 3 facilities is provided below.

Table 1: CY2023 Average Length of Stay for Community Hospitals in NH Knightdale Service Area

Facility	Discharges	Patient Days	ALOS
Johnston Health Clayton	381	1,591	4.18
UNC Rex Holly Springs	8	24	3.00
WakeMed North Hospital	689	2,290	3.32
Total	1,078	3,905	3.62

Source: NH Knightdale application, page 159

The ALOS of 3.62 days is significantly lower than Novant's calculation of 4.39 on page 159, and more accurately reflects the ALOS for "LAC patients" at area community hospitals.

When this ALOS is applied to NH Knightdale's projected cases in PYs 1-3, utilization rates are far lower and do not meet the Performance Standard in 10A NCAC 14C .3803 in Year 3. Please see the table below.

57.7%

Metric **Partial PY** PY1 PY2 PY3 a. Total Discharges 499 2,017 2,059 2,100 b. ALOS 3.62 3.62 3.62 3.62 7,302 c. Patient Days 1,806 7,454 7,602 d. ADC 19.8 20.0 20.4 20.8 e. Capacity 3,312 13,140 13,140 13,176

Table 2: NH Knightdale Percent Utilization Using ALOS from Area Community Hospitals

Notes:

a. Source: NH Knightdale application, p. 160

54.5%

b. ALOS for community hospitals in NH Knightdale service area, see Table 1 above

55.6%

c. a * b

f. % occupancy

- d. c / number of days in period; Partial PY=92 days, PYs 1-2: 365 days; PY3: 366 days
- e. 36 beds * number of days in period
- f. c/e

For the reasons described above, the NH Knightdale application does not conform with Review Criterion 3, as its projections are unsupported and unreasonable, and do not meet the Performance Standard for Acute Care Hospitals.

56.7%

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.

In Section E, Novant provided the alternatives it considered to the proposed project. Given that the 2024 SMFP allocated 70 beds and 4 ORs to Wake County, Novant could have proposed to develop an ambulatory surgery center in the county, or to develop an acute care hospital in a region of Wake County experiencing more rapid growth or not located in such close proximity to existing acute care hospitals and freestanding emergency departments.

For this reason, NH Knightdale should be found non-conforming to Criterion 4.

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.

Novant Health's application for NH Knightdale lacks the critical financial details necessary to thoroughly evaluate its projections and compare it with other applications. Specifically, the application fails to provide adequate information on charges, contractual adjustments, and reimbursement rates for the proposed services. This omission is particularly concerning given the wide range of services NH Knightdale plans to offer, including:

Inpatient acute care services

- Emergency department services
- Outpatient surgery
- Imaging services (CT, MRI, X-ray, ultrasound, nuclear medicine)
- Laboratory services
- Pharmacy services
- Therapy services (physical, occupational, speech)
- Observation services

The lack of detailed financial information regarding charges, contractual adjustments, and reimbursement rates for NH Knightdale's proposed services represents a significant deficiency in Novant Health's application. This omission not only makes it impossible to thoroughly assess the reasonableness of the financial projections but also prevents meaningful comparison with other certificate of need applications in this review.

For this reason, NH Knightdale should be found non-conforming to Criterion 5.

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

On page 50, the Novant application states that "NH Knightdale will offer improved geographic access to patients in the eastern part of Wake County. The PSA is a set of zip codes in which the majority of residents live closer to NH Knightdale than any other hospital." In reality, the Novant proposal is duplicative of existing hospital and emergency providers in Wake County. While no acute care hospital is physically located within Novant's identified primary service area, eastern Wake County and the remainder of the PSA are well-served by existing providers.

The Novant site identified in its application is only 5.6 road miles from WakeMed Raleigh Campus and 7.7 miles from Duke Raleigh Hospital – each facility is approximately a 10-minute drive from the proposed site and offers a full complement of inpatient, outpatient and emergency services. In reviewing the Novant service area, there are likely residents who live closer to WakeMed Raleigh, WakeMed North Hospital, and Duke Raleigh Hospital, than NH Knightdale.

Novant failed to acknowledge the presence of WakeMed Wendell Healthplex, located at 2021 Wendell Valley Boulevard, Wendell, NC 27591, which opened in January 2024 and is near the center of the PSA, approximately 5.9 road miles, or a 7-minute drive from Novant's proposed site. WakeMed Wendell offers a 24/7/365 freestanding emergency department and outpatient imaging services. NH Knightdale's emergency department would be duplicative of the WakeMed Wendell ED. Please see the following map.

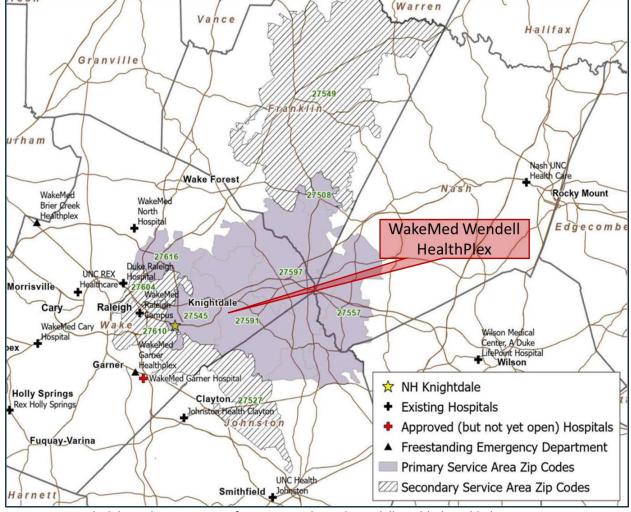


Figure 1: NH Knightdale Service Area Map Showing WakeMed Wendell Healthplex

Source: NH Knightdale application, p43, reference to WakeMed Wendell HealthPlex added

Novant proposes a mobile MRI that is based in Norfolk, Virginia, but fails to acknowledge the full time freestanding MRI that will replace an existing Akumin mobile MRI in Knightdale at Raleigh Radiology (Project ID# J-12393-23). The hospital-based Novant MRI will be more costly to patients and payors than the approved freestanding MRI at 1101 Great Falls Court, Knightdale 27545, only 3.9 miles, or 8 minutes away, according to Google Maps.

For these reasons, the NH Knightdale application is nonconforming with Review Criterion 6.

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.

Novant does not provide a specific plan for recruiting staff for the hospital. Instead, Section H provides generic references to Novant's recruiting success in other areas. The lack of a recruiting plan is a significant omission, given that Novant will be employing staff in a county where it has no existing acute care hospital and will be competing for FTEs with three established health care systems already present in Wake County. The Novant application is nonconforming with Review Criterion 7.

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.

Because NH Knightdale will be a community hospital with 36 beds, Novant proposes to provide inpatient and outpatient care to "limited acute care" patients. It identified a subset of MS-DRGs who would be likely candidates for admission, citing its experience operating similarly sized facilities in the Triad, Charlotte, and Wilmington markets. Notwithstanding the methodology used to create the list of diagnoses, there is nothing inherently erroneous with this approach, provided the facility can refer critically ill and other higher acuity patients to a regional referral or tertiary medical center.

Unlike other areas in North Carolina where Novant already operates tertiary medical centers, namely Novant Health Presbyterian Medical Center in Charlotte, Novant Health Forsyth Medical Center in Winston-Salem, and Novant Health New Hanover Medical Center in Wilmington, Novant has no acute care hospital presence in Wake County or the greater Research Triangle area. This raises an obvious question: where would NH Knightdale patients requiring specialized medical care not available at that facility be referred for that care? Novant will essentially be starting from scratch in Wake County to develop a medical staff. The application described two Novant-owned primary care physician practices in Wake County, both of which are located in Wake Forest, an area not included in the proposed service area. A third primary care group, whose physicians provided letters of support, has three offices in Wake County, none of which are in the proposed service area.

On page 112, Novant states: "NH maintains existing transfer agreements among NH facilities and would establish similar agreements for NH Knightdale." Novant did not describe any discussions or provide correspondence with existing hospitals in Wake County or the surrounding area to provide specialized services such as invasive cardiology, neonatology, or neurosciences. The closest Novant tertiary facility to NH Knightdale is Novant Health Forsyth Medical Center in Winston-Salem, which is 116 road miles and 1 hour 46 minutes' away. The Novant application did not explain how its services will be coordinated with the existing health system.

On page 113, Novant includes Novant clinics that would support the facility. The map and supporting narrative list only six primary care physicians and they are located in Wake Forest. None of these are specialists who would be needed to treat the neurology and pulmonology DRGs identified in Exhibit C.1-2

For these reasons, the NH Knightdale proposal does not conform with Review Criterion 8.

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.

The statement in Section K.3b that costs will not affect payment rates is ingenuous. CMS uses actual costs in cost reports to develop payments for subsequent years. Novant indicates that Knightdale costs will be incorporated in Novant's system overhead costs. Novant is not an insignificant system. It has 850 locations in four states, according to its website. As such a large player, it does affect national rates.

The application does not address how design and means of construction represent the most reasonable alternative and is nonconforming with Review Criterion 12.

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

In Section M, Novant describes its relationships with health professional training programs and states that it is "currently working to establish a relationship with area training programs and will continue to evaluate new education training programs and institutions as clinically appropriate." Exhibit H-2.1 provides a list of schools and universities with Novant has existing training agreements. However, there was no description provided in the application of specific efforts to work with training programs in the Wake County market. Novant provided no correspondence from local schools and universities expressing their interest in working with Novant, or correspondence to these programs to seeking to initiate such relationships.

The Novant application does not conform with Criterion 14.

a. 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 the service for which competition will not have a favorable impact.

Competition

Wake County is already the most competitive health care market in the state, being served by three large health systems, WakeMed Health & Hospitals, UNC Health, and Duke Health, all of whom operate or are approved to operate two or more acute care hospitals in the county. In addition, all three systems have a well-established physician presence. No other North Carolina county has more than two health systems with acute care hospitals.

The development of a fourth health system in Wake County would likely have a <u>detrimental</u> impact on competition, as four systems would be competing for patients, physician referrals, and finite clinical staff. This would also create unnecessary duplication for acute care hospital and emergency services. See the discussion for Criterion 6.

Quality

NH Knightdale would be a new Wake County hospital provider. However, at this time, Novant's track record indicates difficulty maintaining quality as it expands. Recent CMS 2024 2-star CMS ratings at Novant New Hanover Regional Medical Center appear to be related in some part to staffing difficulties¹. Novant's proposed staffing plan for Knightdale, which is discussed above in Criterion 1 and elaborated in Attachment E suggest that the problem could repeat at this proposed new Knightdale hospital.

Access

The NH Knightdale application purports increased access to health care services for residents of eastern Wake County but does not demonstrate that these residents are not currently being served. Novant's proposed service area consists of ZIP Codes that include portions of Wake, Johnston, Franklin and Nash Counties, and includes ZIP Codes where existing acute care services already exist. The primary service area appears carefully drawn to exclude existing hospitals in Raleigh and Clayton.

For this reason, NH Knightdale should be found non-conforming to Criterion 18a.

¹ https://www.whqr.org/local/2023-08-04/federal-agency-again-rates-novant-nhrmc-two-out-of-five-stars

ATTACHMENT E

Salary Comparison: Novant Health Knightdale Medical Center vs WakeMed North

Metric	FY2030 (PY1)	FY2031 (PY2)	Source / Notes
Registered Nurse		-	
a. WakeMed North Hourly per FTE	61.97	63.83	Form H Wake Med North Application
b. WakeMed North Annual	\$128,898	\$132,766	2080 Hours * a
c. Novant Form H Annual	\$100,951	\$103,980	Form H Novant Application
d. Novant / WakeMed North	78%	78%	c/b
e. Novant RN FTE	59	61	Form H Novant Application
Aides / Orderlies			
f. WakeMed North Hourly per FTE	22.75	23.44	Form H Wake Med North Application
g. WakeMed North Annual	\$ 47,320	\$48,755	2080 Hours * f
h. Novant Form H Annual	\$40,607	\$41,825	Form H Novant Application
i. Novant / WakeMed North	86%	86%	h/g
j. Novant FTE	28.4	28.4	Form H Novant Application
Radiology Techs			
k. WakeMed North Hourly per FTE	46.6	48	Form H Wake Med North Application
I. WakeMed North Annual	\$96,928	\$99,840	2080 Hours * k
m. Novant Form H Annual	\$ 74,617	\$76,856	Form H Novant Application
n. Novant / WakeMed North	77%	77%	m/I
o. Novant FTE	23	23	Form H Novant Application
Cost to Reach WakeMed Rate			
p. RNs	\$1,648,849	\$1,755,970	(b - a) * e
q. Aides/Orderlies	\$190,649	\$196,818	(g - h) * j
r. Radiology Techs	\$513,153	\$528,632	(I - m) * o
s. Total	\$2,352,652	\$2,481,420	p + q + r
t. Benefits Percentage	22%	22%	Form F.3 Novant Application
u. Total Staffing Shortfall	\$2,876,835	\$3,034,294	(1 + t) * s
v. Novant Net Income Form F.2	\$(455,566)	\$2,640,905	Form F.2 Novant Application
w. Adjusted Net	\$(3,332,401)	\$(393,389)	u - v

Note: Fiscal years for WakeMed North Project ID# J-12536-24, for 25 Acute Care Beds, are October 1, 2029, through September 30, 2031. Comparisons in the table above do not include Novant's PY3 because WakeMed North data were not available for that year for comparison.

Competitive Review of – UNC Rex Wake Forest Hospital / Project ID #J-12543-24

Overview

UNC Health Rex ("UNC Rex") proposes to develop a new acute care with 50 acute care beds and 2 operating rooms in Wake Forest, in response to the determinations for 70 acute care beds and 4 operating rooms for Wake County in the 2024 State Medical Facilities Plan ("SMFP"). UNC Rex fails to adequately demonstrate the need for the proposed project. The application is nonconforming with multiple Review Criteria and should be denied.

CON Review Criteria

 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, ambulatory surgery operating rooms, or home health offices that may be approved.

Overview

The proposed project is in response to a need determination for 70 acute care beds and four operating rooms in Wake County. It is therefore subject to Policy <u>GEN-3</u>: <u>Basic Principles</u>, which states:

"A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area."

As described in Criterion 3 below, UNC does not demonstrate that its proposal's, "projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area." The application should therefore be found non-conforming to Criterion 1.

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.

UNC Health proposes to develop a new hospital campus in Wake Forest, citing the lack of acute care services in northern Wake County and in Franklin County.

Number of Hospital Campuses in Wake vs. Mecklenburg County is Not Relevant

On page 46, the application makes a claim that is not supported by the 2024 SMFP. The header states "NEED FOR A NEW HOSPITAL AS DEMONSTRATED BY THE SMFP ACUTE CARE BED NEED DETERMINATION." The 2024 SMFP contains no such statement. The application acknowledges that three new hospitals have been approved recently and that only one, UNC Holly Springs, is open. The Agency approved Holly Springs in 2011, and it opened ten years later, on November 1, 2021.¹

UNC compares Wake County to Mecklenburg County in population and number of hospital campuses, noting "Wake County – while the largest county in North Carolina by population...still has fewer overall hospital campuses than Mecklenburg County," citing Mecklenburg's ten existing and approved campuses, versus Wake County's eight. This is an unfair comparison and does not indicate that additional hospital campuses are justified. Mecklenburg County has an acute care bed planning inventory of 2,128 beds, or 17.9 beds per 10,000 population, compared with 1,428 beds or 11.8 beds per 10,000 in Wake County. The greater issue is the disparity in beds per population, which recent bed allocations in the SMFP have sought to correct. Approval of a new hospital campus in Wake County will have the same effect as approving an applicant or applicants that proposed to add beds at an existing facility, albeit at significantly higher cost.

The discussion omits the fact that the <u>267-bed deficit for Wake County is for FY 2026</u>. Rex Wakefield does not propose to open until FY 2030. Recent UNC Rex history indicates it will be even later.

Acute Care Bed Need in Wake County in Proposed 2025 SMFP

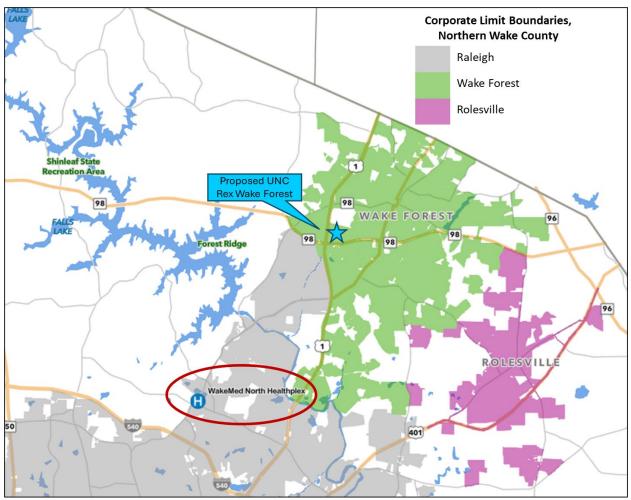
On pages 46-47, UNC Rex notes the planned allocation of 267 acute care beds to Wake County in the Proposed 2025 SMFP, and states that "...the portion of the bed need based on UNC Health Rex's projected days equate to 118 of the 267 acute care beds as determined by the acute care bed need methodology." UNC Rex includes an excerpt from Table 5A in the Proposed 2025 SMFP, highlighting UNC Health Rex's bed need. The highlighting masks the total need of 215 beds generated by the WakeMed System. Regardless, this discussion of acute care beds that will be allocated to Wake County in 2025 should have no bearing on the 2024 review.

¹ https://www.rexhealth.com/rh/about/news-media/2021/unc-rex-healthcare-to-open-new-holly-springs-hospital-on-nov-1/

Acute Care Services in Raleigh vs. Northern Wake County

On page 50, UNC Rex states that "...there is a large and growing portion of Wake County that currently does not have any acute care service located within it...." UNC Rex conveniently ignores the presence of WakeMed North Hospital, which is located in an adjacent ZIP Code and has provided emergency department services to northern Wake County since 2005 and inpatient hospital services since 2015. WakeMed North is located within the Raleigh city limits, whose boundary reaches as far north as N.C. Highway 98, approximately one mile from UNC Rex Wake Forest site. Please see the map below.

Figure 1: Map of Northern Wake County Showing Proximity of UNC Wake Forest to WakeMed North and Corporate Limits



Source: Wake County Planning Department, iMaps; UNC Rex Wake Forest site marker added

The fact that WakeMed North is the Raleigh city limits <u>does not mean</u> that residents of northern Wake County are going unserved. City limits are regularly extended to give fringe communities lower cost access to critical city infrastructure services. Using Rex's definition, any ZIP Code or township in the county without an acute care hospital is underserved.

UNC Rex Wake Forest Service Area Definition Overlaps WakeMed North Hospital

The UNC Rex Wake Forest service area is defined as a subset of ZIP Codes including and contiguous to Wake Forest ZIP 27587. Included in the definition is ZIP Code 27614, which is the location of WakeMed North Hospital, located only 7.2 miles from the proposed UNC Rex Wake Forest site. The service area is projected to grow by 28,807 residents from 2024-2029, or approximately 8.4 percent. The highest growth is projected to occur in ZIP Code 27587.

UNC Rex Wake Forest's proposed service area overlaps significantly with that of WakeMed North Hospital. As shown in the CON application for 25 additional acute care beds that WakeMed North filed in this review cycle (Project ID# J-12536-24), the largest concentrations of WakeMed North's patients currently originate in ZIP Codes 27587, 27614, and 27616. In FY 2023, 59.2 percent of WakeMed North's acute care bed discharges originated from the UNC Rex Wake Forest proposed service area, and over 35 percent of discharges originated from ZIPs 27587, 27616, and 27614. Please see the table below.

Table 1: FY 2023 WakeMed North Acute Care Bed Patient Origin by ZIP Code, from Proposed UNC Rex Wake Forest Service Area

ZIP Code-City	Acute Care Discharges	Percent of Total		
27587-Wake Forest	1,021	18.7%		
27616-Raleigh	486	8.9%		
27614-Raleigh	435	8.0%		
27596-Youngsville	374	6.9%		
27525-Franklinton	282	5.2%		
27549-Louisburg	217	4.0%		
27613-Raleigh	163	3.0%		
27597-Zebulon	153	2.8%		
27571-Rolesville	71	1.7%		
Total	3,202	59.2%		

Source: Project ID# J-12536-24, p. 37

The rest of the REX Wake Forest application does not identify patients to be served by ZIP code. It instead uses an inflated average length of stay to estimate patients. See discussion below in section "Average Length of Stay at UNC Rex Wake Forest Unreasonably High."

<u>Travel Time Standard to Emergency Departments is Arbitrary</u>

UNC Rex cites a 2022 article regarding travel times to hospital-based emergency departments, which suggests that patients "have been shown to travel 17.3 minutes on average for such services." Worth noting is that the cited article is based on a survey of emergency patients across the nation – the study is not specific to Wake County, or even North Carolina. On page 59, the UNC Rex Wake Forest application provides a map showing the radius for a 17.3-minute drive time from the UNC Rex Wake Forest site.

Although UNC Rex defined its service area on ZIP Codes, the map on page 59 appears to show Census Tract data obtained from the Town of Cary. The significance of this drive time as justification for the proposed project, is not clear. What is clear is that both WakeMed North and DLP Maria Parham Franklin's ED are each within that 17.3-minute drive time.

Use of Assumptions from 2023 Acute Care Bed Applications

On page 170, UNC Rex notes that there are 468 acute beds currently on the Rex license -418 beds at Rex Main Campus and 50 beds at Rex Holly Springs, and that it filed two applications for a total of 70 beds from the 2024 SMFP need determination for Wake County. On page 171, UNC Rex states: "With the addition of the 44 beds from the 2023 SMFP, under appeal, the UNC Health Rex license would have 600 beds in FY 2033." At first glance, it is unclear how UNC Rex reaches this total (418 + 50 + 44 = 480).

On page 173, UNC Rex states:

In 2023, UNC Health Rex proposed to develop 44 additional acute care beds at UNC Health Rex Hospital; that application, while denied, was found fully conforming with statutory and regulatory criteria by the Agency. Given that this application — and therefore its methodology — was found to be conforming and therefore reasonable and adequately supported by the Agency, UNC Health Rex has chosen to utilize some assumptions used that application's methodology, specifically regarding expected volume shifts to UNC Health Rex Holly Springs Hospital...

In the assumptions for its acute care bed projections, UNC Rex presumes that the beds in its 2023 application (Project ID# J-12417-23) will be approved and developed; then it counts these in its future bed total. Because the beds proposed in J-12417-23 are counted in the UNC Rex license bed total, UNC Rex assumed that the projected utilization developed for that project are also counted in the need methodology for J-12543-24. Given that the project in question was denied and cannot be counted in utilization projections, UNC Rex has overstated its acute care bed capacity, as well as its projections for inpatient utilization.

<u>Growth Projections at UNC Rex Holly Springs Unrealistic</u>

On page 171, UNC Rex provides historic patient days for facilities on the total UNC Rex license, and notes a CAGR of 5.7 percent for FY 2019-2024, which includes UNC Rex Holly Springs' utilization for FY 2022-2024. In Table 2-2 on page 174, UNC Rex provides projected acute care utilization at UNC Rex Holly Springs from FY 2024-2033, which is projected to increase by 4.8 percent per year from FY 2025-2029, and by 2.8 percent per year from FY 2030-2033. The projections contain a large increase of 47.6 percent in patient days between FY 2024 and 2025 – it is not clear what will precipitate such a large one-time jump in volume. In fact, UNC Rex states that "...the actual acute care days at UNC Rex Health Holly Springs for FY 2023 were slightly lower than what was projected in the previous application. Moreover, the projected days for FY 2024 are expected to be less than what was projected in last year's application," (p174, Section Q p5).

In Project ID# J-12417-23, UNC Rex projected that UNC Rex Holly Springs will have 11,577 patient days in FY 2024. In the application under review (J-12543-24), UNC Rex simply carries the projected UNC Rex Holly Springs patient days from J-12417-23 forward, so that UNC Rex Holly Springs will have 11,577 days in FY 2025. Without the 47.6 percent increase in patient days from FY 2024-2025, it is doubtful that UNC Rex Holly Springs would meet its target occupancy level of 66.7 percent, found in 10A NCAC 14C.3803, by FY 2033. If UNC Rex Holly Springs' patient days are increased by a more modest 4.8 percent per year through FY 2033, it does not reach the target occupancy. See the following table.

Table 2: UNC Rex Holly Springs Utilization, FY 2022-2033 Using 4.8 Percent Growth Rate from FY 2024 Forward

Metric	FY22	FY23	FY24	FY25	FY26	FY27	FY28	FY29	FY30	FY31	FY32	FY33
Patient Days	2,984	6,870	7,841	8,217	8611	9,024	9,457	9,911	10,387	10,886	11,409	11,957
Percent Occupancy	16.4%	37.6%	43.0%	45.0%	47.2%	49.4%	51.8%	54.3%	56.9%	59.6%	62.5%	65.5%

Source: Patient days for FYs 2022-2024 – UNC Rex Wake Forest application, p76

<u>Use of "Acuity-Appropriate" Diagnoses for Projecting Utilization at UNC Rex Wake</u> <u>Forest</u>

On page 178, UNC Rex describes its method for identifying likely candidates for admission to UNC Rex Wake Forest:

In order to approximate the acuity of patients expected to be treated at UNC Health Rex Wake Forest Hospital, UNC Health Rex analyzed the historical services rendered by UNC Health Rex Holly Springs Hospital and extrapolated the "acuity-appropriate" acute care days to be provided at UNC Health Rex Wake Forest Hospital based on services there. Given that UNC Health Rex Holly Springs is also a 50-bed acute care community hospital, is also located in Wake County, and is also a UNC Health Rex facility, UNC Health Rex believes it is reasonable to use it as a reasonable proxy for the acuity of patients to be treated at UNC Health Rex Wake Forest Hospital...

Missing from the application and exhibits is a list of the "acuity-appropriate" MS-DRGs used to develop utilization projections at UNC Rex Wake Forest. There is no description provided regarding what constitutes acuity-appropriate diagnoses or the criteria for their selection. UNC Rex provides acuity-appropriate patient days originating from the service area for "select DRGs" in Tables 2-6, 2-7 and 2-8, but there is no way to independently verify how these patient days were derived or if they are accurate. The reader is expected to accept UNC Rex's assertion at face value. Because UNC Rex's projections for UNC Rex Wake Forest cannot be confirmed, they are unsupported and unreasonable.

In Table 2-7 on page 179, UNC Rex provides historical patient days originating from the proposed UNC Rex Wake Forest service area ZIP Codes. Patient days for "select DRGs" at <u>all</u> UNC Rex facilities increased by 2.6 percent per year from FY 2019-2024 – this is the basis for projecting utilization at UNC Rex Wake Forest. In the same table, patient days for presumably the same "select DRGs" at UNC Rex Hospital grew 2.0 percent per year. Rather than using the more conservative growth rate of 2.0 percent for UNC Rex patient days, UNC Rex opted to base its projections on a growth rate of 2.6 percent per year.

Had UNC Rex used a 2.0 percent growth rate instead of 2.6 percent and projected a more conservative "ramp-up rate" it is unlikely that UNC Rex Wake Forest would meet the 66.7 percent target occupancy found in 10A NCAC 14C.3803. While UNC Rex Wake Forest is projected to reach 71.4 percent occupancy by Project Year 3, this may be an overly optimistic forecast. By comparison, UNC Rex Holly Springs was utilized at only 43 percent in FY 2024, its third year of operation.

Later, on page 179, UNC Rex states:

"Utilizing this growth rate is reasonable and conservative, as it is the historical growth rate of acuity-appropriate days for UNC Health Wake Forest Hospital's select ZIP codes across all facilities, shown in Table 2-7 – none of which is as proximate to these nine ZIP codes as UNC Health Rex Wake Forest Hospital will be, which, likely, will result in a more rapid rate of growth for the patient days that UNC Health Rex Wake Forest Hospital will treat." [emphasis added]

UNC Rex fails to acknowledge that the service area for UNC Rex Wake Forest overlaps significantly with that of WakeMed North Hospital, including ZIP Code 27614, where WakeMed North is located, as well as other ZIPs, namely 27613, 27616 and 27597, where WakeMed North will be at least as close as UNC Rex Wake Forest. It also fails to acknowledge that proposed UNC Rex Wake Forest will not have the same capabilities as UNC Rex Main Campus.

No Projections for OB Deliveries That Drive LDRP Utilization

UNC Rex Wake Forest proposes eight labor/delivery/recovery/postpartum ("LDRP") beds, which will be located on the third floor, alongside two C-section ORs, a Newborn Nursery, and two Level II neonatal beds. The application does not specifically project utilization of the LDRPs, whose use is limited to women in active labor and post-delivery; other types of patients are not admitted to these beds. UNC Rex provides no specific methodology step for projecting utilization of the LDRP beds — they are simply included in the forecast for medical-surgical and ICU beds. The number of projected deliveries is not discussed or projected. In short, UNC Rex does not demonstrate need for these eight beds.

On page 203 (Section Q page 34), the UNC Rex Wake Forest application projects volume for C-section OR cases as a percent of projected total acute care patient days, rather than as a percent of total deliveries. In fact, the UNC Rex Wake Forest application makes no mention of deliveries or births, which drives utilization of C-section ORs, LDRPs, and NICU beds. This is a flaw in the UNC Rex projections, making them unreasonable and unsupported. The application fails the test of Criterion 3, to demonstrate need of the population to be served for the service proposed.

Average Length of Stay at UNC Rex Wake Forest Unreasonably High

On page 184 (Section Q p15), UNC Rex describes its method for projecting discharges at UNC Rex Wake Forest:

"UNC Health Rex utilized the historical ALOS for acuity-appropriate patients served by UNC Health Rex Hospital who originated from the select ZIP codes listed in Table 2-4. This ALOS, in FY 2024, was 4.2. UNC Health Rex has therefore maintained this ALOS in order to project total discharges for UNC Health Rex Wake Forest Hospital through FY 2033..."

UNC Rex provided no description of "acuity-appropriate" patients or how they are defined anywhere in the application or exhibits, making it impossible to determine the veracity of the volumes presented. See the discussion in Criterion 3. UNC Rex uses an ALOS for UNC Rex Wake Forest which is very similar to that for the entire UNC Rex Hospital License, despite being a community hospital that will "provide services with lower overall acuity than those provided at UNC Health Rex Hospital in Raleigh..." (page 178). Although UNC Rex used ALOS to calculate discharges instead of patient days, the similarity of ALOS's between UNC Rex and UNC Rex Wake Forest seems unreasonable. UNC Rex's Main Campus is a tertiary hospital serving higher acuity patients with significantly more beds, it is realistic to expect that it would have a much higher ALOS than UNC Rex Wake Forest. A more reasonable comparison for ALOS would be UNC Rex Holly Springs Hospital, but this was not provided.

For the reasons listed above, the UNC Rex Wake Forest Hospital application does not conform with Review Criterion 3.

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.

In Section E, UNC Rex provided the alternatives it considered to the proposed project. Given that the 2024 SMFP allocated 70 beds and 4 ORs to Wake County, UNC Rex could have opted to propose fewer beds for Wake Forest, thereby reducing capital costs, or developing more beds at the UNC Rex campus in Raleigh. Given the extraordinary capital cost of UNC Rex Wake Forest, it is clear that the proposal does not demonstrate that the least costly or most effective alternative was proposed. Therefore, the UNC Rex Wake Forest application is nonconforming with Review Criterion 4.

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.

Given the multiple inconsistencies associated with utilization projections for UNC Rex Wake Forest, the financial projections, are unreliable and unsupported, and do not demonstrate the financial feasibility of the project. Please see the discussion for Review Criterion 3. Therefore, the UNC Rex Wake Forest application does not conform with Review Criterion 5.

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

On page 121, the UNC Rex Wake Forest application states: "...UNC Health Rex believes there is currently a lack of accessible acute care services in northern Wake and Franklin counties...". However, UNC Rex's only explanation of this claim is a sentence on page 121 that says, "...the most northern acute care facility in Wake County is still within the Raleigh city limits...". The application omits the fact that the proposed UNC Rex Wake Forest facility site is 7.2 road miles, or a 14-minute drive, from WakeMed North Hospital, which offers a full array of inpatient, outpatient and emergency services. WakeMed North is currently licensed for 77 acute care beds, including 6 Level III neonatal beds, and has Agency approval to develop 35 additional acute care beds (Project No. J-12419-23).

Statutory Finding of Fact in N.C.G.S. 131E-175(3a) calls attention to preserving rural health care facilities. The discussion in Section C.4 overlooks the DLP Maria Parham Franklin. The statement on page 51 that "[Franklin County] ... currently does not have any acute care providers within it," is wrong. DLP Maria Parham Franklin has an emergency department. The map on UNC Rex Wake Forest application page 51 shows Wake Forest immediately adjacent to Franklin County. Google Maps says Wake Forest is 29 minutes from DLP Maria Parham Franklin. That means the two would have overlapping emergency department service areas. On page 58, the application indicates intent to draw emergency patients from a 17.3-minute drive time. Many of those patients would be closer to Franklin Hospital emergency room (29-17.3 = 11.7 minutes).

UNC Rex proposes no services at Wake Forest that are not currently available at WakeMed North. The proposed UNC Rex Wake Forest Hospital requires duplication of ancillary and support services that are in place at WakeMed North. Approval of UNC Rex Wake Forest will unnecessarily duplicate hospital services already provided in northern Wake County. Please see the discussion regarding Review Criterion 3, which provides WakeMed North Hospital's FY 2023 discharges from the proposed UNC Rex Wake Forest service area ZIP Codes.

For the reasons listed above, the UNC Rex Wake Forest application does not conform with Review Criterion 6.

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.

The UNC Rex project proposes to hire **545 FTEs** by Project Year 3, which is a significantly larger number of FTEs than any other applicant in the review. Section H of the application provides no information about how UNC Rex will achieve such a large recruitment task in the face of a large and growing healthcare workforce shortage. For reference See Attachment C with these Comments.

For the reasons listed above, the UNC Rex Wake Forest application does not conform with Review Criterion 7.

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.

UNC Rex Wake Forest's total capital cost, \$462,130,986 equates to \$9,242,620 per bed. The proposed project's construction contract is \$304,886,139, or \$6,097,272 per bed. Section K.1 indicates intent to build 308,467 Square feet. Hence the forecast construction cost is \$988.39 per square foot. By contrast, RS Means/Gordian, a national construction cost tracking company, reports 2024 hospital construction at \$402.45 in the Atlanta region in 2024².

Although capital cost has not been used as a comparative factor in recent reviews, there is a stark contrast in this review between applicants proposing to develop acute care beds and/or operating rooms in new hospital campuses, and applicants who propose to utilize existing or approved space for beds and/or operating rooms. Like other applicants in the review who propose to develop new acute care hospital campuses, the UNC Rex Wake Forest project will require creation of expensive infrastructure, including site work, central plant, parking, and ancillary and support space, which are necessary for this new hospital, but they add significantly to the project cost. The application fails to explain the cost, design, and means of construction proposed represent the most reasonable alternative, or that the construction project will not unduly increase the costs of providing health services.

The exorbitant capital cost of UNC Rex Wake Forest Hospital is nearly double the cost of Novant Health's proposal (Project No. J-12534-24), the project with the next-highest capital cost in the 2024 Wake County Acute Bed and Operating Room review. It suggests that UNC Rex made little effort to contain the project's capital costs with regard to design and construction approach. Section K.3 contains no such information. In fact, the response to K.3.b. acknowledges that "the proposed project is capital intensive," (p. 124).

Because the project elements are not justified and the project requires duplication of ancillary and support infrastructure and construction cost savings are not explained, the UNC Rex Wake Forest application is nonconforming with Review Criterion 12.

² https://www.bdcnetwork.com/hospital-construction-costs-2024

a. 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 the service for which competition will not have a favorable impact.

On page 144, the UNC Rex Wake Forest application states that the project "is expected to enhance competition in the service area by promoting cost effectiveness, quality and access to acute care services." There is no discussion in Section N beyond referring to Question B.20. The project is nonconforming with Review Criterion 18a, particularly with regard to enhance competition, cost-effectiveness, and access.

Project Does Not Enhance Competition

UNC Rex is not a new competitor in Wake County. The application does not provide any information demonstrating that UNC Rex Wake Forest Hospital will offer competitive services or add cost effective features. The UNC Rex Wake Forest project will not enhance competition for acute care hospital services in Wake County and is duplicative of services currently operational and approved at WakeMed North Hospital. Please see the discussion for Review Criterion 6.

Cost Effectiveness

Please see the response to Review Criterion 12. The UNC Rex Wake Forest project proposes, by far, the highest capital cost in the review, and very high cost per square foot.

Access Not Improved

The UNC Rex Wake Forest project would create another point of access for acute care hospital services in Wake County, at great cost. The Agency must weigh the value in an additional point of entry, whose proposed service area overlaps significantly with an existing provider, against the cost of developing such a facility.

Because the project claims it will increase competition but provides no evidence to show how it will enhance competition, the project should be found non-conforming to Criterion 18a.

Competitive Review of – Duke Raleigh Hospital / Project ID #J-012546-24

Overview

Duke University Health System (DUHS) proposes to add 41 acute care beds to Duke Raleigh Hospital ("DRaH"), in response to the need determination for 70 acute care beds in the 2024 SMFP. DUHS fails to adequately demonstrate the need for the proposed services and should be found non-conforming with multiple Review Criteria and the Performance Standard for Acute Care Beds and should be denied.

CON Review Criteria

 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, ambulatory surgery operating rooms, or home health offices that may be approved.

Overview

The proposed project is in response to a need determination for 70 acute care beds. It is therefore subject to Policy GEN-3: Basic Principles, which states:

"A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area."

As described in Criterion 3 below, Duke's application for 41 beds at DRaH does not demonstrate that its proposal's, "projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area." The DRaH application should therefore be found non-conforming to Criterion 1.

<u>Value</u>

DRaH's total capital cost is \$15,250,000; practically, this equates to \$15,250,000 for a net of one additional bed. The proposed project to "backfill" existing and operational beds while only realizing one additional bed is, both, the most costly and least effective way to provide added capacity to Wake County residents.

For these reasons DRaH should be found non-conforming to Criterion 1.

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.

DUHS submitted three (3) applications proposing to add beds at three Wake County hospitals: DRaH, Duke Cary Hospital ("DCH"), and Duke Garner Hospital ("DGH"). The methodologies provided in each application are virtually identical. However, since each application utilizes the same first four steps, Duke's methodology renders <u>each</u> application non-conforming as it ultimately fails to demonstrate conformity with the <u>system-level</u> performance standards of 10A NCAC 14C .3803(5). The discussion below outlines each error that contributes to the methodology's non-conformity with the required performance standards.

Step 1:

Each application's methodology begins with Historical Utilization of DRaH, from its License Renewal Applications from FY 2015 through FY 2024.

	Duke Raleigh Hospital									
			Inpatie	nt Utilizat	ion, FY20	15-FY202	4			
	FY2015	FY2016	FY2017	FY2018	FY2019	FY2020	FY2021	FY2022	FY2023	FY202
Discharges	7,767	8,174	9,588	9,484	9,605	9,921	9,833	9,386	10,222	10,77
Days of Care	33,759	34,979	42,854	42,783	48,394	48,926	51,311	54,279	54,969	54,73
ALOS	4.3	4.3	4.5	4.5	5.0	4.9	5.2	5.8	5.4	5.
Beds	Beds 186 186 186 186 186 186 186 186 186 204									
63.0% Occupancy 49.7% 51.5% 63.1% 63.0% 71.3% 72.1% 75.6% 80.0% 81.0% 73.5%										

Source: DRaH Application, Section Q, Page 148

Fiscal Year 2024 provides the base of 10,778 discharges for Step 2, however, in the application Duke states it will reduce that number three times:

- 1. "First, DUHS excluded any patient discharges that were related to services not planned to be provided at DCH during the initial operating years, such as cardiac catheterization, open-heart surgery, transplant services, inpatient rehabilitation, and inpatient behavioral health, as those patients will continue to access those services at DUHS's existing acute care hospitals." (Source: DRaH Application, Section Q, page 152.
- 2. "DUHS also excluded obstetric patients from **historical discharges** as this facility will not provide labor and delivery services (other than emergencies)." [Emphasis added] Source: DRaH Application, Section Q, page 152.
- 3. "DUHS made a second adjustment to only include the historical DUHS discharges of patients in DRGs with weights less than or equal to 2.0." DRaH Application, Section Q, page 152.

<u>Error #1</u> - None of these "adjustments" described above were ever made in the historical discharges, or any mathematical step prior to, or after, Duke begins to apply a growth factor and shift these patients from DRaH to DCH and DGH. This error overstates both the number and acuity of patients appropriate to shift to these proposed facilities.

Step 2:

Duke calculates a Compound Annual Growth Rate (CAGR) based on discharges from the table in Step 1. Duke states it will utilize the CAGR of discharges from FY 2019-FY 2024 and provides the below table to justify the 2.9 percent growth rate.

DRAH Trends in Discharges and Patient Days								
DRAH CAGR Time Period Patient Days Discharges								
FY2015-FY2019	9.4%	5.5%						
FY2015-FY2024	5.5%	3.7%						
FY2019-FY2024	3.1%	2.9%						

Source: DRaH Application, Section Q, page 149

<u>Error #2</u> - when the CAGR for FY 2019-FY 2024 discharges from page 148 is accurately calculated, it is 2.3 percent, <u>not</u> 2.9 percent. Calculation: $((10,778 / 9605) ^ (1/5)-1 = 0.0233$. This calculation error has profound impact on projected utilization.

Step 3:

Duke then utilizes the over- inflated discharges due to the errors in Step 1, and the over-inflated CAGR from Step 2 to provide the below table:

Duke Raleigh Hospital Projected Baseline Utilization									
Dane National Projection Dubonile Chinzarion									
	Actual	Interim	Interim	Interim	Interim	Project	Project	Project Veer 2	
	FY 2024	Year FY2025	Year FY2026	Year FY2027	Year FY2028	Year 1 FY2029	Year 2 FY2030	Year 3 FY2031	FY2032
Discharges	10,778	11,093	11,417	11,751	12,094	12,448	12,811	13,186	13,57
ALOS	5.1	5.1	5.1	5.1	5.1	5.1	5.1	5.1	5.:
Inpatient Days of Care	54,733	56,333	57,979	59,673	61,417	63,212	65,059	66,961	68,91
Licensed Beds	204	204	225	225	225	245	205	205	20
% Occupancy	73.5%	75.7%	70.6%	72.7%	74.8%	70.7%	86.9%	89.5%	92.19

Source: DRaH Application, Section Q, page 150

Error #3 -

- 1. There is no way to determine how many discharges should be excluded from the FY 2024 discharges of 10,778 to account for all the specialty services and DRGs greater than 2.0.
- 2. The overstated CAGR of 2.9 percent was applied to the overstated FY 2024 discharges.

The table below provides a partly corrected table. Since Error 1 cannot be quantified, the below table utilizes the overinflated FY2024 discharges of 10,778 but utilizes the <u>correct</u> CAGR of 2.3 percent.

Table 1: DRaH Discharges Using Corrected CAGR

Metric	Actual		Interin	n Years		PY1	PY2	PY3	FY32
Weth	FY24	FY25	FY26	FY27	FY28	FY29	FY30	FY31	F132
a. Discharges	10,778	11,026	11,279	11,539	11,804	12,076	12,354	12,638	12,928
b. ALOS	5.1	5.1	5.1	5.1	5.1	5.1	5.1	5.1	5.1
c. Inpatient Days of Care	54,968	56,233	57,523	58,849	60,200	61,588	63,005	64,454	65,933
d. Licensed Beds	204	204	225	225	225	245	205	205	205
e. % Occupancy	73.82%	75.52%	70.04%	71.66%	73.10%	68.87%	84.20%	86.14%	87.88%

Notes and Sources:

- a. FY24 actual per Section Q p150, DRaH application; projections: previous year discharges * (1+ 2.3%)
- b. FY24 actual per Section Q p150, DRaH application
- c. a * b
- d. FY24 actual per Section Q p150, DRaH application
- e. c/(d * 365); FY28 and FY32 calculated at 366 annual days

Step 4:

Duke then begins to shift a portion of these patients, which include all services and MS-DRGs, to DGH and DCH without their stated exclusions. After these shifts, Duke provides the below table to project DRAH's occupancy rate.

Projected Utilization of DRAH with Proposed 41 Beds After Shifts in Days of Care to DCH and DGH								
	FY 2025	FY 2026	FY 2027	FY 2028	FY 2029	FY 2030	FY 2031	FY 2032
Projected Days of Care	56,333	57,979	59,673	61,417	62,383	59,917	60,748	61,753
Average Daily Census	154.3	158.8	163.5	168.3	170.9	164.2	166.4	169.2
Baseline Beds*	204	204	204	204	204	164	164	164
Proposed Beds	0	21	21	21	41	41	41	41
Total Beds at DRAH	204	225	225	225	245	205	205	205
Projected Occupancy Rate	75.7%	70.6%	72.7%	74.8%	69.8%	80.1%	81.2%	82.5%
*Baseline beds reflects the approved relocation of 40 beds to DCH, which is expected to come on line in FY2030.								

Source: DRaH Application, Section Q, page 151

<u>Error #4 – DRAH's</u> occupancy rate is overly inflated due to the incorrect CAGR in Error #2 and shifting an inappropriate number of patients outlined in Error #3.

Calculating the System-Level Occupancy Rate

A number of Duke's errors cannot be quantified, derived, or otherwise corrected as it relates to the exclusion of patients. As such, the only correction that can be made is the projected CAGR. The table below illustrates that when the correction is made to the CAGR, the entirety of the Duke System does not meet the performance standard. Because the corrected exclusion of patients cannot be determined, the below table includes the unadjusted FY2024 discharges and the unadjusted shifts to DCH and DGH. If those corrections were made, it is highly likely that both DCH and DGH would also, independently, no longer meet the performance standards of 75.2 percent in FY2031 the third project year.

Table 2: DRaH System Utilization, FY 2031 (PY3) *Includes DRaH, DCH, and DGH*

Metric	FY31	Notes / Sources					
DRaH Adjusted Inpatient Days of Care							
a. FY31 Adjusted Projection	64,454	Table 1 above					
b. Shift to DCH	5,078	pg151 DRaH application					
c. Shift to DGH	1,135	pg151 DRaH application					
d. Total Adjusted FY31 DRaH	58,241	a - b - c					
Total Duke System Days of Care							
e. Total Adjusted FY31 DRaH	58,241	see d					
f. DCH	13,565	Form C.1b, p144					
g. DGH	3,073	Form C.1b, p143					
h. Total Duke System	74,879	e + f + g					
Licensed Beds by Site							
i. DRaH	205	Form C.1b, p142					
j. DCH	57	Form C.1b, p144					
k. DGH	12	Form C.1b, p143					
I. Duke System	274	i + j + k					
Available Bed Days							
m. DRaH	74,825	i * 365					
n. DCH	20,805	j * 365					
o. DGH	4,380	k * 365					
p. Duke System	100,010	m + n + o					
FY31 Percent Occupancy							
q. DRaH	77.84%	e/m					
r. DCH	65.20%	f/n					
s. DGH	70.16%	g/o					
t. Duke System	74.87%	h/p					

Summary:

Four major errors contribute to the non-conformity of <u>all three</u> of Duke's applications for acute care beds:

- 1. Use of an overinflated CAGR;
- 2. Failing to exclude specialties as determined by Duke;
- 3. Failing to exclude DRGs <2.0 as determined by Duke;
- 4. Failing to reach the Acute Care Bed Performance Standards as a System.

Due to compounding effects of these errors, the shift of patients from DRaH to DGH and DCH are inflated and inaccurate. Since these errors cannot be corrected with publicly available data, these inaccurate shifts also render the DRaH application nonconforming with Review Criterion 3 as there is no way to determine whether the correct number of patients has been attributed to DRaH.

These shared and critical errors made in the foundation of Duke's calculations, which are used in all of their three acute care bed applications, not only renders their entire methodology unreasonable and unsupported, but cast doubt on any and all other assertions and hardships Duke purports to experience. Duke's methodology is unreliable, unsupported, and irreparable – for these reasons, all of Duke's acute care bed applications are non-conforming.

For these reasons, the DRaH application is nonconforming with Review Criterion 3.

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.

While the DRaH application for additional beds does not, itself, propose to eliminate acute care beds, it underscores the unreasonableness of relocating 40 beds to DCH, purportedly pushing DRaH to an unsustainable occupancy level – the very definition of reducing services to an irresponsible and unreasonable level. Duke asserts that the relocation is still necessary to provide additional beds in Cary, however, this shell game is additional duplication of services, as WakeMed Cary was recently approved to develop acute care beds and WakeMed Cary has applied to add more beds at a lower cost. Due to the passage of time since DCH was approved, and because construction has not yet started (per Duke Green Level Progress Report – June 2024), Duke had the responsibility to reproject for all 57 of the proposed DCH beds (40 relocated from DRaH + 17 from current review) to demonstrate that this reduction of beds was still reasonable.

For these reasons, the DRaH application is non-conforming with Criterion 3a.

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.

Duke's application for 41 acute care beds at DRaH both exposes and underlines that <u>none</u> of their applications are the most cost-effective alternative for the 70 acute care beds allocated to Wake County in the 2024 SMFP. In fact, the combination of the DRaH application and the Duke Green Level/Cary Hospital applications shows that shifting beds, backfilling beds, adding beds, is the costliest, lengthiest, and most burdensome way to implement these beds. Duke would save the entirety of this project's capital cost of \$15,250,000 if it opted not to relocate those same beds to Duke Green Level/Cary as approved Project ID# J-12029-21. The DRaH application proposes a \$15,250,000 spend for a net increase of only one (1) acute care bed.

For these reasons, the DRaH application is non-conforming with Criterion 3a.

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.

For reasons outlined in Criterion 3, all of Duke's volume projections were inaccurate and irreparable, and, when partially corrected with publicly available information, the Duke system no longer meets the performance standards. The multitude of errors in the projections render the financial and operational projections unreliable and therefore non-conforming.

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

Duke Green Level/Cary was originally represented to open on 7/1/2026; since approval, little development appears to have occurred. This change of scope extends the opening date to 7/1/2029. It is not possible to consider the DRaH and Duke Green Level/Cary applications independently. Taken together, they precisely outline how they duplicate available services, and show the enormous cost associated with that duplication.

The DRaH application for 41 beds is proposed to backfill 40 beds that are approved for relocation to Duke Green Level/Cary. The cost to duplicate these existing and operational licensed acute care beds will really be much more than \$15,250,000 if the Agency considers the full costs of DCH as proposed in Project ID# J-012548-24.

For these reasons, the DRaH application is non-conforming with Criterion 6.

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.

As outlined in Criterion 4, this project proposes one of the costliest plans to implement the acute care beds available in the 2024 SMFP, costing \$15,250,000 for a net of one (1) new bed at DRAH. Only the DGH application, which proposes to develop 12 beds at a cost of nearly \$18 million per bed, is more expensive. For this reason, the DRaH is nonconforming with Review Criterion 12.

Competitive Review of – Duke University Health System, Inc. / Project ID #J-012547-24

Overview

The Applicant, Duke University Health System, Inc., proposes to add three operating rooms to Duke Raleigh Hospital ("DRaH") from the September 1, 2024, batch for the Wake County need determination for four operating rooms. This application requests approval for a total capital expenditure of \$1,000,000.

As detailed below DRaH should be found non-conforming on Criterion 1, 3, 6, 7, and 12.

CON Review Criteria

 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, ambulatory surgery operating rooms, or home health offices that may be approved.

The proposed project is in response to a need determination for 70 acute care beds and four operating rooms in Wake County. It is therefore subject to Policy <u>GEN-3</u>: <u>Basic Principles</u>, which states:

"A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area."

As described in Criterion 3 below, DRaH does not demonstrate that its proposal's, "projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area." DRaH should therefore be found non-conforming to Criterion 1.

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.

The proposed project includes a request for three operating rooms at DRaH. Two are a backfill of an approved relocation to Duke Green Level (now Duke Cary), and the third is conversion of an existing procedure room. The proposed project is set to open in FY2030.

Duke Cary cannot be completed without approval of Change of Scope, Cost Overrun in CON Project ID J-012548-24. There will be no space for two of the requested rooms if Project ID J-012548-24 is not approved. The project utilization forecasts and proformas assume that Project ID J-012548-24 will be approved and Duke Cary Hospital will open on time.

On page 156, DRaH surgical cases are increasing, before operating rooms at Duke Cary ASC (1), Duke Cary Hospital (2) or Duke Garner ASC (1) are open. Methodologies for all of the new facilities involve "shifts" of surgical cases away from DRaH. Using a growth rate of 5% a year – faster than population, the application adds about 3,000 annual cases to DRaH by FY 2029 (page 158) which means DRaH proposes to serve 21,260 cases in 15 operating rooms. That requires 2,996 annual hours for 15 operating rooms. To accomplish this, <u>DRAH will have to run all 15 operating rooms 12 hours per day, for the 253 days per year</u> it reports offering operating services in its LRA. See Table 1 below.

Table 1: DRaH Proposed Operating Room Capacity, FY2029, Final Interim Year

Metric	FY2029	Sources / Notes
a. Inpatient Cases	4,449.0	Page 157
b. Outpatient Cases	16,811.0	Page 157
c. Inpatient Hours per Case	3.0	Page 160, inpatient case time in minutes / 60
d. Outpatient Hours per Case	1.9	Page 160, outpatient case time in minutes / 60
e. Total Surgical Hours	44,933.6	(a * c) + (b * d)
f. Total ORs	15.0	Page 149, Form C.3b
g. Surgical Hours per OR	2,995.6	e/f
h. OR Operating Days / Year	253.0	per DRaH 2024 Hospital LRA, Exhibit B.1, p19
i. Operating Hours per Day	11.8	g/h

There is nothing in the application to show this plan. In fact, page 160 shows only the OR performance in the first three project years, starting in FY2030. Thus, there is no credibility in the total case forecast for the interim years prior to the proposed project years. Because the interim years lack credibility, the forecast years built on those interim years, also lack credibility.

Moreover, the application has no evidence that the proposed population to be served needs the full complement of proposed DUHS operating rooms in Wake County, which include DRAH. Inpatient surgical cases depend on inpatient acute care beds. See discussion of issues with inpatient bed forecast in comments on Project ID# J-012546-24.

Because it fails to demonstrate the need of the for the project by the proposed population to be served it should be found nonconforming to Criterion 3.

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

This application proposes to change the license of a procedure room to an operating room and backfill two relocated operating rooms. This project results in a net new of one operating room. However, the application asserts that surgical procedures are occurring in that procedure room today (page 84). By definition, the application demonstrates that this project is not needed in order to provide the services proposed. This capital expenditure adds no new capacity to Wake County.

For these reasons, the DRaH application is nonconforming with Criterion 6.

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.

The project requires 30 more staff according to Form H with no increase in capabilities. Page 37 reports that the several of the nine procedure rooms "provide a high level of surgical volume appropriate for their physical standards." The table on page 84 says that 7,060 surgical cases were performed in nine procedure rooms. This equates to 784 cases per procedure room. Page 85 suggests that including the surgical cases done in procedure rooms, DRAH needs 21 operating rooms. The fallacy in this analysis is that DRAH managed to provide those cases in procedure rooms without an operating room licenses. Thus, any increase in staff associated with the conversion of one procedure room to an operating room is an unnecessary expenditure of health manpower.

For these reasons, the DRaH application is nonconforming with Criterion 7.

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.

The proposed additional "vacuum outlet" could be added to procedure room 28 without a CON and without licensing it as an operating room. The proposed \$1M expenditure is not the most reasonable alternative for accomplishing this maintenance improvement.

For these reasons, the DRaH application is nonconforming with Criterion 12.

Competitive Review of – Duke Cary Request for 17 Beds as Change of Scope for Project ID J-12029-21 / Project ID# J-012548-24

Overview

The applicant, Duke University Health System, Inc. ("DUHS"), requests a Change of Scope to add 17 beds from the September 1, 2024, batch for Wake County need determinations for 70 beds and 4 operating rooms. This application requests approval for a total additional capital expenditure of \$208,100,000 would increase the acute care beds for a new named Duke Cary Hospital ("DCH") from 40 to 57 including 4 ICU beds. The total Capital cost of \$443,100,000, also includes full ancillary and support services for this proposed new hospital campus of Duke Raleigh Hospital ("DRaH"). The project requests approval to almost double the capital investment associated with the original CON application. The project also involves a change in the approved timeline for the project. The original CON calls for opening July 1, 2026.

Because this project involves such a major change in scope and timeline, this change of scope application should contain a full justification for the total capital expenditure for the entire project scope. Moreover, the costs are described as a cost overrun in Exhibits, but the application fails to address cost overrun questions.

Exhibit F.1 cost justification shows that only \$59,900,000 of the Fixed Capital Cost is associated with the cost of the beds. The remaining proposed costs include construction cost increases that start in the year of the original application, 2021. The cost justification also references "slight redesign "of patient floors. In fact, Exhibit K.2 shows a completely different hospital design.

The application is non-conforming to Criteria 3, 3a, 4, 5, 6, 7, 12, and Performance Standard as described in the following paragraphs.

CON Review Criteria

 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, ambulatory surgery operating rooms, or home health offices that may be approved.

The proposed project is in response to a need determination for 70 acute care beds and four operating rooms in Wake County. It is therefore subject to Policy <u>GEN-3</u>: <u>Basic Principles</u>, which states:

"A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients

with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area."

As described in Criterion 3 below, DCH does not demonstrate that its proposal's, "projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area." DCH should therefore be found non-conforming to Criterion 1.

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.

The application asks the Agency to assume that all original assumptions still apply to the 40-bed hospital need. It states that the only change is cost associated with the delayed opening and cost inflation.

The Section Q Utilization methodology indicates that forecast bed use excludes heart, neonatal, transplant, inpatient rehab, behavioral health, and Ob services (page 184). It limits historical discharges to those with DRG weights less than or equal to 2 but provides no supporting worksheets. It provides a table showing 8,740 discharges that were candidates for a shift in FY2024, most of which, 5,193, are associated with Duke University Hospital (page 185), and about 40 percent of those are associated with Durham ZIP codes that are closer to DUHS than to DCH, ZIP codes 27703 and 27707 (per Google maps).

Zip code	Miles to DUH	Miles to DCH
27703	11.9	17
27707	5 (11 minutes)	23

Source: Google Chrome, accessed September 19, 2024

The methodology increases these discharges at the population rate of growth. Then on page 188, it forecasts that 5,727 of these Durham County Zone 3 patient discharges will shift away from quaternary Duke University Hospital to the proposed small DCH. The same table indicates that 2,299 Durham County patients could shift from Durham Regional Hospital to DCH. The calculation seems pointless, because on page 190, it shows no Zone 3 patients shifting from Duke University Hospital or Durham Regional Hospital to DCH. However, Zone 3 is used in the incremental ED visits related admissions. The Zone 3 calculation also serves to overstate the percentage shift. Without Zone 3, the percentage Shift is closer to 20 percent than the stated 15%.

The methodology makes no effort to show that patients in the selected ZIP codes need more acute care beds in Cary. It only assumes that that the bed need will grow with population and that patients will choose to shift.

In fact, as discussed in Criterion 3a, the methodology shows that the 40 beds shifted from DRaH will cause a shortage of beds for patients served by DRaH.

An even bigger flaw in the methodology is the calculation of extra DCH discharges based on "incremental emergency room visits." The methodology ignores the fact that these discharges incorporated in the shifted discharges. A portion of the shifted discharges originated as emergency room patients from the ZIP codes that the project proposes to serve.

The application provides no information to show that the population to be served needs more access to community level emergency room visits. On page 191, the methodology refers to a "separate methodology ED Utilization methodology below." On page 213, the methodology. Describes a shift of emergency department visits. This methodology relies on the entire catchment area, including ZIP codes in Durham City to generate 13,985 more ED visits than are shifted from existing facilities, just because the facility will be there (page 217).

The methodology claims that the forecast is reasonable because the market share is small, and the use rate is consistent with Wake County ED use rates. However, the reasoning is flawed. The applicant uses its Zones to assert that this proposed 57 bed hospital that starts out with minimal medical staff, will serve an area covering most of Durham and Wake Counties and large parts of Orange, Chatham, and Lee Counties (page 77), and will initially be just a freestanding ED. This area is served by larger, more sophisticated EDs and Trauma Centers (DUH, WakeMed Cary, WakeMed North, WakeMed Raleigh, DRaH, UNC Chape Hill, and Chatham Hospital). The 13,985 visits proposed would represent a much larger market share if the ED service area were more realistically described.

This is important because these unsupported "incremental ED patient discharges" account for most – 52 to 54 percent – of projected DCH discharges in the first three project years.

Table 1: DCH Acute Care Discharges As Forecast with Percentage of Total Discharges

	2030	2031	2032	Page Reference
Discharges Based on DUHS Shift	1,142	1,407	1,647	190
Discharges Based on Admits from Incremental ED Visits	1,221	1,567	1,958	191
Subtotal Non-OB Discharges	2,363	2,975	3,605	
OB Discharges	19	30	51	196
Total Acute Care Discharges	2,382	3,005	3,655	
Discharges Based on DUHS Shift	48%	47%	46%	190
Discharges Based on Admits from Incremental ED Visits	52%	53%	54%	191
Subtotal Non-OB Discharges	100%	100%	100%	
OB Discharges	19	30	51	196
Total Acute Care Discharges	2,382	3,005	3,655	

Without these Incremental ED discharges and related patient days, the project does not meet the required Special Rule performance standard.

Table 2: DCH Days of Care with Incremental ED Days of Care Removed

	FY2030	FY2031	FY2032
a. Non-OB Discharges	1,142	1,408	1,647
b. Non-OB ALOS	4.5	4.5	4.5
c. Non-OB Days of Care	5,139	6,336	7,412
d. OB Discharges	19	30	51
e. OB ALOS	2.0	2.0	2.0
f. OB Days of Care	39	60	101
g. Total Days of Care	5,178	6,396	7,513
h. Beds	57	57	57
i. % Occupancy	24.9%	30.7%	36.1%

Notes:

- a. p192
- b. p192
- c. a * b
- d. p196
- e. p196
- f. d*e
- g. c+f
- h. 40 approved + 17 proposed
- i. g/(h * 365)

Table 3: Adjusted Performance Standard Analysis DCH and All DRAH Campuses with Duke Garner Hospital in and DCH Incremental ED Discharges Removed

		FY2030	FY2031	FY2032
a.	Reduced days	5,587	7,169	8,954
b.	Original Total days p 198	73,010	77,385	81,338
c.	Adjusted Days	67,423	70,216	72,385
d.	ADC	185	192	198
e.	Total beds	274	274	274
f.	% occupied	67.4%	70.2%	72.4%
g.	Performance Standard			75.10%

Notes:

- a. Days associated with Incremental ED visits
- b. As noted in methodology for DRAH license
- c. b-a
- d. c/365
- e. Per application
- f. d/e
- g. Per Category 3 hospital the license category for the licensee DRAH

On page 192, the methodology asserts that these incremental ED Discharges will come from "other parts of the service area. This part of the methodology is inconsistent and overstated. Starting on page 216, the application proposes to increase market share of the ED visits and related admissions from all zones, including Zone 3, by 800 percent and more (4.0% / 0.5% = 800%). This is not only a substantial increase, but it also contradicts an earlier statement that Zone 3 discharges were excluded from the shift for reasons of proximity.

To add discharges, page 199 adds 51 more OB discharges from the freestanding birthing center. Are these discharges double counted? Were they in the original shift calculations? The freestanding birthing center does not yet exist. The methodology indicates that the proposed Birthing Center will serve half of the birthing center candidates in Wake County. It provides no point of reference comparison to the history of Wake County's existing Cary Birthing Center, Haven.1

Because the application fails to show need of the population for the services proposed, it should be non-conforming to Criterion 3.

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.

This total project involves the original scope relocation of 40 beds from DRaH. However, the methodology on page 177 shows that following relocation 40 beds from DRaH to DCH, DRaH will not have enough beds to serve projected patients. Insufficient capacity will affect all patients including low-income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

Because of the adverse effects on key populations, this project is non-conforming to Criterion 3a.

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.

The application demonstrates on page 177 that the population of Wake County would be better served if DUHS leaves 40 beds at DRaH. Forecast admissions require a shift from DRaH and are insufficient to support proposed beds.

Because of the adverse effects on key populations, this project us non-conforming to Criterion 4.

¹ https://www.havenhealthandbirth.com/

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.

As discussed in Criterion 3, utilization projections are unreasonable. Therefore, all financial projections for the project are also unreasonable. Therefore, the project cannot be found conforming to Criterion 5.

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

The application depends on admissions from a yet not opened Birthing Center and fails to recognize Haven Birthing Center that is only 14 minutes away. The application double counts admissions related to Emergency Department visits as discussed in Criterion 3. As a result, the application over counts admissions and proposes to build more capacity than needed by the population to be served.

As a result, the project cannot be found conforming to Criterion 6.

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.

The project will require 561.9 new FTE's (p 245). This represents a significant challenge to the already strained health care workforce supply in Wake County. The application does not explain plans to recruit these employees.

The proposed DCH project will also require more travel for Duke physicians. No Duke physicians are located on this proposed campus at the time of this application.

As a result, the project cannot be found conforming to Criterion 7.

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.

The application provides information in Exhibit F.2, showing a different hospital design from the original proposal. It cites construction cost increases as the reason for requesting to almost double the expenditure. The proposed 17 bed addition estimated is only \$59 million. The application on page 177 shows that relocating beds from DRaH will leave DRaH unable to meet patient demand after the relocation, even with patients sifted away. By implication, the project is requesting to spend \$443.1 million to serve patients who might have been well served by a \$59 million (page 224) addition to DRaH.

In this case, the applicant has not demonstrated that the cost, design and means of construction will not unduly increase the costs of providing health services by the person proposing the construction project and should be found non-conforming to Criterion 12.

CON Rules

10A NCAC 14C .3801(a) Acute Care Beds, Performance Standard

See discussion in Criterion 3. The proposed project involves a shift of patients from Duke Regional and Duke University Hospitals. It does not show that those hospitals will meet required performance standards by project year 03.

The application relies on bed shifts from Durham Regional and Duke University Hospitals, both located in Durham. The application fails to show utilization of those hospitals after construction. Form C.1b shows only Wake County hospitals. See p 159.

Competitive Review of – Duke Garner Request for 12 Beds & 1 Operating Room / Project ID# J-12549-24

Overview

Duke University Health System (DUHS) proposes to develop a new hospital with 12 acute care beds and one operating room in Garner called Duke Garner Hospital ("DGH"), in response to the need determination for 70 acute care beds and four operating rooms in the 2024 SMFP. DUHS fails to adequately demonstrate the need for the proposed services and should be found non-conforming with multiple Review Criteria and the Performance Standard for Acute Care Beds and should be denied.

CON Review Criteria

 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, ambulatory surgery operating rooms, or home health offices that may be approved.

Policy GEN-3 requires that applicants in competitive batches demonstrate how the projected volumes demonstrate value. The DGH project does not.

Micro-hospitals are intended to be lower-cost facilities¹. This project involves an enormous capital investment-- \$205 million to build and equip the proposed 12-bed healthcare facility and \$3 million more for estimated start-up and initial operating expenses. Projected volumes depend on additional undefined "CON-exempt" expenditures for a cancer therapy center (page 31). This project's capital cost -- \$18 million per bed – is completely out of line with national averages. Form F.1a proposes \$115 million for construction. According to Fixr, the cost of a new micro-hospital in the US in 2022 was \$52.2 million².

The proposed beds and operating room volumes are only possible if the applicant invests in an emergency room that duplicates one only 1.7 miles away at WakeMed Garner, as well as hospital ancillary and support departments that duplicate those approved and in design at WakeMed Garner, as well as those existing at DRAH. The application is non-conforming to Policy Gen-3 on the value component alone.

The project indicates on page 31, that DUHS will transfer many Garner ED patients to other DUHS hospitals. However, the application does not include costs associated with the ambulance transfers. Patients will incur charges for these transfers. As residents discover this, they and local EMS providers may decide to by-pass this facility in favor of facilities that can provide them with full care upon arrival.

DGH should therefore be found nonconforming to Criterion 1.

¹ Eagle, Amy, op cit.

² https://www.fixr.com/costs/build-hospital#

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.

Contrived Catchment Areas vs Patient Origin

Patient origin for DGH in Section C.4 indicates that 97 percent of patients will come from Wake and Johnston Counties. This application and methodology do not focus on the needs of the population to be served.

Patient origin in Section C.4 indicates that 97% of patients will come from Wake and Johnston Counties, but the application fails to adequately address the specific needs of that population. Instead, it relies on an elaborate plan to shift patients from other Duke facilities, combined with unsupported assumptions that twice as many additional patients will travel from far outside the immediate area to use the proposed DGH micro-hospital simply because it is a modern facility.

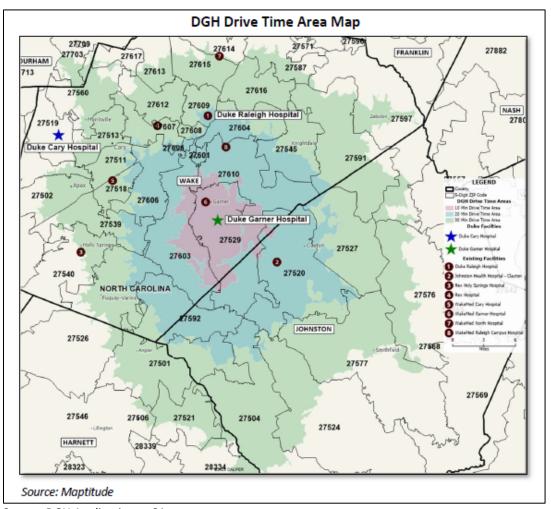
Page 63 describes a "catchment area" drive time map that extends into Durham and Johnston Counties. The application highlights a primary service area that is a 10-minute drive time from the proposed site and uses Claritas Spotlight for population estimates. However, rather than using the Claritas Spotlight population tool that provides population estimates for a 10-minute drive time, the application uses populations of ZIP Codes like 27603, that cover a much larger geography, including an area that extends minutes from Duke Raleigh into Johnston County; and 27610, which includes WakeMed Raleigh Campus. For clarification, Attachment K provides Claritas Spotlight total population forecasts in a 10-minute drive time of the proposed DGH. The entire population is 45,140 in 2024 and will be 47,996 in 2029 (Attachment K). Moreover, the Claritas Spotlight map accompanying the data shows that most of that population is on the outside boundaries of that area (Attachment K). That puts the population closer to other existing hospitals.

The narrative in Section C.4 is confusing. A second map on page 63 shows a "catchment area" for the 12-bed hospital extending into Wayne County. The resulting claim that this proposed micro-hospital will serve a population of 415,445 people in 2024 and 452,404 people in 2029 is clearly overstated. The Claritas Spotlight 10-minute estimates are more realistic.

DUHS used another mapping technique called a Drive Time Influenced Area that shows the 20-minute boundary between patients closer to DCH and closer to DGH as shown below these ZIP codes include: 27626, 27603, 27606, and 27539 (ZIP Codes are indicated in yellow text in the map below). The following map shows the drive time influenced area:

On page 64, the narrative describes a **Drive Time Influence Area Catchment Area.** This Influence Area provides the foundation for estimating the size of the population to be served by the proposed new hospital and goes far beyond 30 minutes' drive time. The application mentions a "tool" for these Drive Time Influence Area calculations, but like the Shift DRG methodology, the application does not provide supporting data or methodology for the calculations. Hence, it is impossible to evaluate.

Moreover, the overlap of catchment geography for the proposed hospital with WakeMed Raleigh Campus and other Wake County acute care hospitals, is implied in the Keys to DGH maps like the one below, but the overlap is notably excluded from narratives that reference the maps. WakeMed Garner, which has received CON approval and is in design, is not even mentioned in the map keys.



Source: DGH Application p. 64

The proposed DGH would be a micro-hospital with 12 beds and one operating room. The application explains its choice of a more than one-hour drive time geographic Influence Area because of Duke's reputation as a "world-class healthcare provider (page 62)." That discussion, too, does not mention the needs of the population that resides in that area for the proposed micro-hospital.

Shifts and Other Forecasts

The bed need justification is based on "shift" and expected incremental emergency department discharges, (p 177). However, the proposed Emergency Department visits on which the discharged are based are entirely speculative. The methodology overlooks the presence of **WakeMed Garner's existing licensed hospital emergency room, which is in operation and is only 7 minutes away.** UNC Health Johnston – Clayton Campus, is also within the proposed catchment area. The application provides no information to show that the population of this geography needs more emergency department services, especially an emergency department that would open in July 2028 and does not yet have a medical staff, or a building in which to house them. Maps of the catchment areas notably *include* UNC Health Johnston and *exclude* mention of WakeMed Garner Hospital, which has a CON and is under construction, only 1.7 miles away. See maps in Criterion 6 below.

Shifts from patterns of use of existing DRAH and other DUHS facilities represent about half of the estimated acute bed discharges. The methodology relies on "additional Incremental Emergency Department visits" for more than half of the inpatient discharges (See Table on page 179). Yet, the application also indicates that not all these Incremental Emergency patients would remain at DGH for inpatient care. Specialty patients would be transferred to other DUHS facilities (page 31). The extra cost of that transfer and the related reduction in length of stay are not included in the calculations of DGH inpatient days. The following tables include Discharges as presented in the application on page 179 and illustrate the percentage associated with shifts and Incremental Emergency Department visits.

Table 1: DGH Acute Care Discharges (Application p179)

	2030	2031	2032
a. Discharges Based on DUHS Shift	305	371	377
b. Discharges Based on Admits from Incremental ED Visits	277	397	403
c. Total Discharges	582	768	780

Source: DGH Application page 179

Table 2: Percentages of Discharges by Patient Source

	2030	2031	2032
a. Discharges Based on DUHS Shift	52%	48%	48%
b. Discharges Based on Admits from Incremental ED Visits	48%	52%	52%
c. Total Acute Care Discharges	100%	100%	100%

Notes:

- a. Table 1 row a / row d
- b. Table 1 row b / row d
- c. a+b

Without the extra discharges and related patient days associated with the Incremental Emergency Visits, the project is not financially feasible and does not meet Performance Standards for Acute Care Beds. Moreover, on page 179, the methodology uses a 4.0-day average length of stay for these discharges. According to the American Hospital Association, microhospitals average length of stay is half that—48 hours³.

Besides size, the primary difference between a microhospital and a larger community or tertiary care hospital is that micro hospitals do not provide services like intensive care. "Microhospitals cater toward the noncritical patients," Harney says. "If a patient's going to be there more than 48 hours [emphasis added], the provider will transfer [him or her] to a larger hospital. They're trying to take the less-acute patient who needs a hospital stay and needs to be cared for but who doesn't need to go to the larger tertiary hospital.

On page 62, the application speaks of plans to develop <u>non-reviewable cancer therapy services</u> on the proposed DGH campus, but the application includes no evidence that such services have DHSR approval.

On page 71, the application describes plans for "cancer patients who need 24-hour observation to ensure that there are no negative reactions from the start of therapy." First, the application makes no attempt to quantify these patients, and second, the application is not clear – are these "would be" individuals observation outpatients who would not qualify for inpatient acute care admissions? There is a difference. Observation outpatients need oversight. They do not need full inpatient care. And, finally, and most importantly, there is no Duke or any other sponsored cancer program at this location at the time of this CON application.

In the methodology on page 174, the application shows DUHS Discharges from Zone 3 declining, but it forecasts, without explanation, which use of DUHS services by residents of Zone 3 will increase with population, for the next five years; and the methodology proceeds to show 15 percent of the increased patents shifting from DRAH to DGH.

DUHS Discharges Appropriate to Shift to Duke Garner Hospital FY2022-FY2024 Annualized Summarized by Catchment Area Zone

			FY2024	
	FY2022	FY2023	Annualized	CAGR
Zone 1	476	518	577	10.1%
Zone 2	1,257	1,297	1,446	7.3%
Zone 3	812	783	811	-0.1%
Total	2,545	2,598	2,834	5.5%

Source: DUHS Internal Data

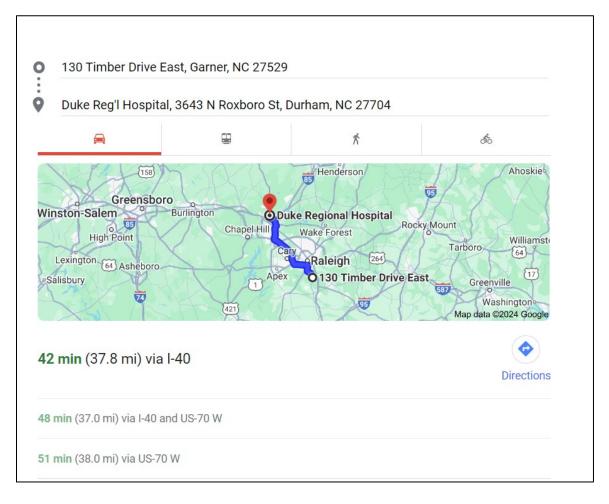
Source: DGH Application page 174.

³ Eagle, Amy, Care close to home, AHA Trustee Services, 2024, on line at https://trustees.aha.org/articles/1327-microhospitals-are-helping-to-meet-the-health-care-needs-of-communities accessed September 24, 2024.

55

The application clearly fails to justify need of the population to be served for the proposed beds. That shortcoming alone should make it non-conforming with Review Criterion 3. In North Carolina, an acute care hospital license requires inpatient beds (10A NCAC 13B). CMS Certification for Acute Care Hospitals also requires licensed acute inpatient beds. Hence, if the beds cannot be approved, there is no need for hospital-based operating rooms, because there is no need for a hospital. The campus is already approved for an ambulatory surgical center (Project No. J-11966-20). Moreover, the surgery ratios in the methodology on page 200 are based on the discharges in the flawed bed need methodology. They cannot be correct.

More surprising in the DGH bed methodology is the proposed shift of patients from Duke University Hospital and Durham Regional Hospital, which have very robust and complex medical staffs. According to N.C. Hospital Licensure rules, only physicians can admit patients to hospital beds. It is important to note that the physicians associated with Durham Regional and Duke University Hospitals are almost one hour away from the proposed DGH, according to Google Maps. It would be inefficient for any of these physicians to leave busy practices in Durham to care for one or two patients in Garner, when the round trip could take up to two to four hours for travel and care.



Because the application fails to demonstrate the need of the proposed population for the services proposed, It is non-conforming to criterion 3.

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.

Section H provides no recruitment plan for physicians who would staff the proposed microhospital. The closest statement on page 60, indicates that DUHS plans to add at least 142 providers serving Wake County within the next three years. It does not say whether these providers will be in Wake County or whether they will be physicians. The application indicates that physicians employed by DUHS would shift time from existing DUHS facilities to DGH. This implies that patients at those existing hospitals will have less physician coverage. This will affect all patients, including low-income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly. Thus, the application is non-conforming to Review Criterion 3a.

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.

The project involves an expenditure of \$211 million for the micro-hospital alone. The application indicates this expenditure is only the beginning. Other expenditures for cancer infusion therapy will be essential to providing for patients that are needed to support the project.

As noted in the discussion of Criterion 3, half of the patients would shift from other DUHS facilities that have the capacity to serve them. The remaining half of patients will require taking market share away from other existing hospitals.

Forms F.2 and F.3a together indicate that the project will lose money for at least the first three full project years. The application indicates that on a cash basis, it will break even in the second year. However, a hospital without funded depreciation will encounter problems when it is time to replace and upgrade equipment.

The proposed DGH project does not account for the existence of an alternate hospital under development only 1.7 miles away. However, the project depends for more than half of its income on incremental use of DUHS programs from that hospital's immediate geographic service area

A blog from the MHA program at USC reports:

Micro-hospitals are priced higher than urgent care centers, but far less than a full-service hospital emergency center or inpatient facility. So, their prices are relatively average. They can accommodate patients suffering from diseases and conditions such as acute abdominal pain, sprained and broken bones, dehydration, heart attacks, pneumonia, seizures, minor trauma, bladder infections, lacerations, and more.⁴

⁴ https://healthadministrationdegree.usc.edu/blog/micro-hospitals

As a campus of DRAH, this facility will use the DRAH charge master. Charges will be the same as at larger DRAH.

The application fails to demonstrate that the proposed facility is the least costly alternative available to the applicant or to the proposed population to be served. It does not demonstrate that this is the most effective or least costly alternative and should be found non-conforming to Criterion 4.

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.

As discussed in Criterion 3, the DGH need methodology fails to justify 12 acute care beds. Without beds, the proposed facility cannot be licensed or certified for Medicare and Medicaid participation. Without licensure and certification, the project will have little or no revenue. Most private insurers condition inclusion in network facilities on State licensure and CMS certification.

As a result, the project cannot be found conforming with Review Criterion 5.

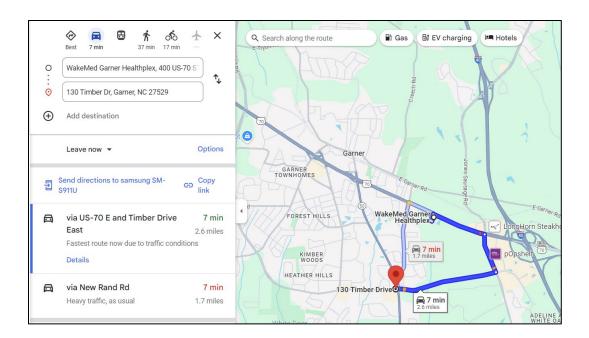
6. The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

The application fails to mention WakeMed Garner Hospital (Project ID J-12264-22), for which a Certificate of Need was issued in 2023. WakeMed Garner Healthplex emergency department is open. The rest of the hospital is under construction. WakeMed Garner Hospital will be larger and offer more services than the proposed DGH

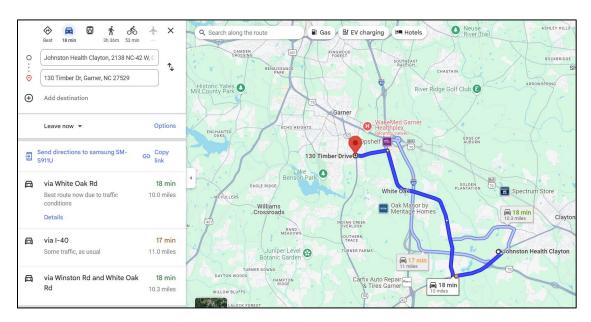
The application fails to differentiate any needed role the proposed population to be served has for a micro-hospital. By emphasizing the large catchment area and MS-DRGs with weights as high as 2.0, the application suggests that the intent is to make DGH like any other community hospital.

DRGs with a relative weight of less than 1.0 are less resource-intensive to treat and are generally less costly to treat. DRGs with a relative weight of more than 1.0 generally require more resources to treat and are more expensive to treat. The higher the relative weight, the more resources are required to treat a patient with that DRG⁵. [emphasis added]

⁵ Elizabeth Davis, How a DRG Determines How Much a Hospital Gets Paid, on line updated February 8, 2024 Verywellhealth, Health Insurance/ Medicare https://www.verywellhealth.com/how-does-a-drg-determine-how-much-a-hospital-gets-paid-1738874



And there are other community hospital options nearby. In addition to WakeMed Garner Hospital, proposed DGH is only 10 miles from Johnston UNC Clayton Hospital, another existing hospital with an active emergency department.



Because DGH will result in unnecessary duplication of services, it should be found nonconforming to Criterion 6.

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.

According to Form H, the project will require 122 new healthcare employees by the third project year, including 4.2 hospitalists and 0.9 Physician assistants. History shows that new entrants staff their new hospitals by offering staff of existing facilities higher salaries to relocate. This approach will stress the workforce for all existing Wake and Johnston County health care providers. In response to question H.2, DUHS admits that it has not been immune from its own workforce staffing stress.

The application provides no specific information about plans for physician staffing, other than the four hospitalists.

Absent recruiting plans for critical health manpower, the project should be found non-conforming to Criterion 7.

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.

The application fails to demonstrate that the exorbitant capital cost of nearly \$18 million per bed is the most reasonable alternative. The flaws in utilization forecasts indicate that utilization estimates could be half the applicant's forecasts. That would mean that unit costs are twice as high as forecast in the financial forms. The project will require substantial investment in infrastructure because it is on land with no development other than the medical office building being developed by an independent party. Roads, sewer, and power are described, but the application does not indicate they are adequate to support the proposed project. For these reasons, the DGH application is nonconforming with Review Criterion 12.

a. 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 the service for which competition will not have a favorable impact.

The narrative on DGH page 141 indicates the project will not adversely affect cost-effectiveness because the Federal government sets reimbursement rates. This is disingenuous. The Federal government uses data on operating costs from prior years' Medicare cost reports to set reimbursement rates for subsequent years.

Moreover, costs, as demonstrated in the operating room proformas in Form F.3b and in Tables 3 and 4 below, the DGH cost per discharge at the inflated utilization rates is \$29,576 per discharge, which is more than DRAH reports in its application for 41 beds. Applying the smaller number of shifted DGH discharges to DGH Form F.3.b, to calculate cost per discharge, shows the project would not have a positive impact on cost effectiveness. Unit costs would be double those of DRAH (FY 2031, \$61,192 compared to \$24,907 per discharge)

Table 3: Garner Cost per Discharge Before and After Removing Incremental ED Discharges

	FY 2029	FY 2030	FY 2031
Total Expense Form F.3.b	\$16,293,173	\$19,519,473	\$23,069,203
Total Discharges	582	768	780
Cost per Discharge	\$27,995	\$25,416	\$29,576
Discharges without Increment ED	305	371	377
Cost per Discharge without Incremental ED	\$ 53,420	\$ 52,613	\$ 61,192

Table 4: Duke Raleigh Cost per Discharge

	FY 2029	FY 2030	FY 2031
Total Expense Form F.3.b p 184	\$281,455,429	\$282,494,616	\$293,499,934
Total Discharges Form C.1b p 142	12,241	11,650	11,784
Cost per Discharge	\$22,993	\$24,248	\$24,907

Source: Form F3b and C.1b from Project ID J-012546-24

Because it fails to demonstrate it will be cost-effective it should be found nonconforming to Criterion 18a.

CON Rules

10A NCAC 14C .2103(a) Surgical Services and Operating Rooms, Performance Standard

According to Form F.3b, page 223, project Year 3 is FY 3031. Because the application fails to support the need for all proposed inpatient acute care beds, the surgical inpatient cases and hours associated with the unsupported beds are unjustified. Page 203 reports 95 inpatient cases at 106.9 minutes in FY 2031, Year 3. This translates to 167.5 hours not justified. Without those hours, the operating room hours will be below the standard for a Category 4 hospital, 1500 hours, and the operating room cannot be approved. The following calculations demonstrate that the project does not meet the Performance Standard until Year 4.

Table 5: Impact of Removing Inpatient Surgical Cases on DGH Patient Days

Metric	FY 2029 YR 01	FY 2030 Yr 02	FY 2031 YR 03	FY 2032 YR 04
a. IP Cases shifted	48	61	74	75
b. Unjustified ED extra IP cases	5	11	20	20
c. Total IP	53	72	94	96
d. Min / case	106.9	106.9	106.9	106.9
e. Hours not Justified	94.4	128.3	167.5	169.3
f. Original Hrs.			1,448	1,772
g. Adjusted Hours			1,280.5	1,602.7
h. Required Hours Category 4 hospital			1,500	1,500

Notes:

- a. Table in application, p201
- b. Incremental Cases associated with Incremental ED visits per application, p201
- c. a+b
- d. Inpatient minutes per table, p202
- e. c * d / 60 minutes per hour
- f. Per application, p202
- *g*. *f*−*e*

Because DGH fails to meet the performance standard by Project Year 3, it should be found nonconforming to the CON Rules.

Pop-Facts® Census Demographics | Summary



Trade Area: 130 Timber Drive East - 10 min

	Total	%
Population		
2010 Census	37,715	100.00
2020 Census	42,428	100.00
2024 Estimate	45,140	100.00
2029 Projection	47,996	100.00
Population Growth	,	
Percent Change: 2010 to 2020		12.50
Percent Change: 2020 to 2024	_	6.39
Percent Change: 2024 to 2029		6.33
1 d Call Change. 2024 to 2029	_	0.33
	Total	%
Households	Total	75
2010 Census	14,245	100.00
2010 Census	16,465	100.00
2024 Estimate	17,737	100.00
	19,006	100.00
2029 Projection	19,000	100.00
Household Growth		45.50
Percent Change: 2010 to 2020	-	15.58
Percent Change: 2020 to 2024		7.72
Percent Change: 2024 to 2029	-	7.16
	T	2/
	Total	%
Family Households	0.770	100.00
2010 Census	9,773	100.00
2020 Census	10,859	100.00
2024 Estimate	12,119	100.00
2029 Projection	12,974	100.00
Family Household Growth		
Percent Change: 2010 to 2020		11.11
Percent Change: 2020 to 2024	_	11.60
Percent Change: 2024 to 2029	_	7.05

Benchmark: USA

© 2024 Claritas, LLC. All rights reserved. Source: ©Claritas, LLC 2024. (https://claritas.easpotlight.com/Spotlight/About/3/2024)

Pop-Facts® Demographics | Population & Race



Trade Area: 130 Timber Drive East - 10 min

POPULATION

45,140

HOUSEHOLDS

17,737

ETHNICITY



15.6%

Index:78

Hispanic/Latino

HISPANIC ORIGIN*



52.3%

Index:88

Mexican

HOME LANGUAGE*

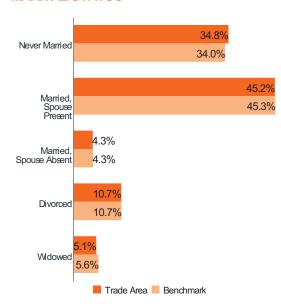


85.6%

Index:109

Only English

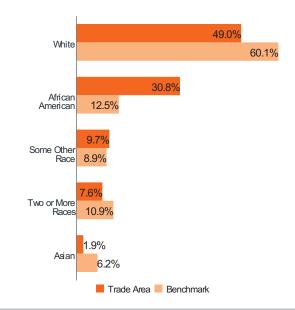
MARITAL STATUS



POPULATION BY AGE

Age	Count	%	Index
0 - 4	2,509	5.6	102
5 - 9	2,442	5.4	96
10 - 14	2,610	5.8	94
15 - 17	1,766	3.9	101
18 - 20	1,748	3.9	88
21 - 24	2,186	4.8	90
25 - 34	6,142	13.6	105
35 - 44	6,168	13.7	106
45 - 54	5,959	13.2	110
55 - 64	5,837	12.9	103
65 - 74	4,618	10.2	94
75 - 84	2,397	5.3	92
85+	759	1.7	84

POPULATION BY RACE**



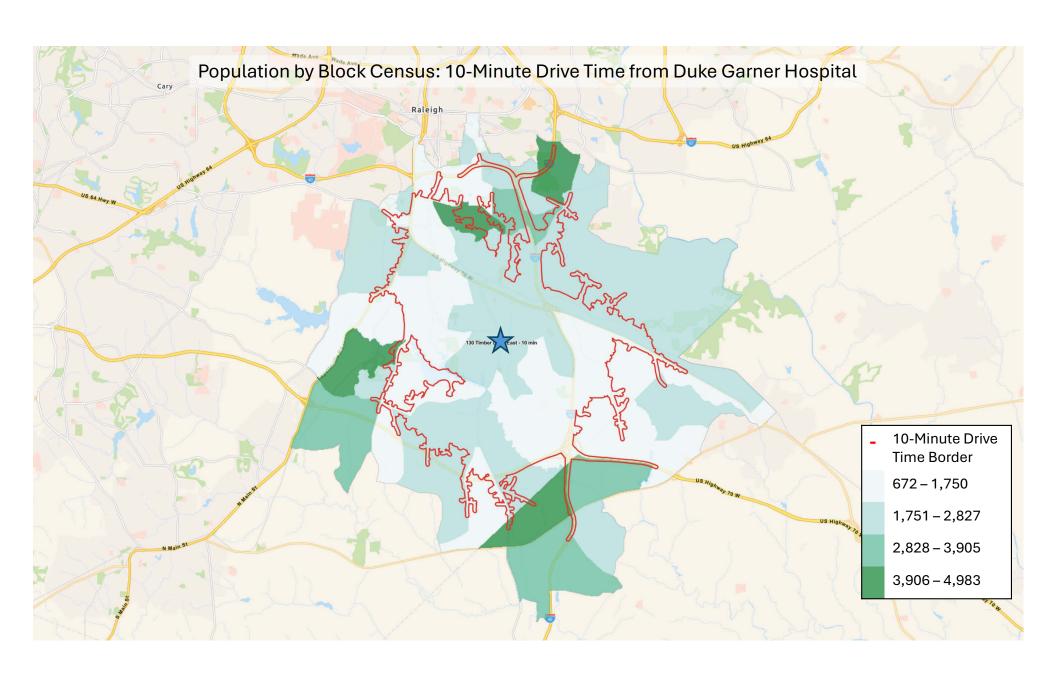
Benchmark:USA

© 2024 Claritas, LLC. All rights reserved. Source: ©Claritas, LLC 2024. (https://claritas.easpotlight.com/Spotlight/About/3/2024)

Index Colors:	<80	80 - 110	110+

^{*}Top variable chosen from percent composition ranking

^{**}Top 5 variables chosen from percent composition ranking



Report Details

Name: Executive Dashboard
Date / Time: 9/26/2024 8:52:32 AM

Workspace Vintage: 2024

Trade Area

Name	Level	Geographies
130 Timber Drive East - 10 min		N/A

Benchmark

Name	Level	Geographies
USA	Entire US	United States

DataSource

Product	Provider	Copyright
Claritas Pop-Facts® Premier 2024	Claritas	©Claritas, LLC 2024 (https://claritas.easpotlight.com/Spotlight/Aboul
SPOTLIGHT Pop-Facts® Premier 2024, including 2010 US Census, 2024 estimates and 2029 projections	Claritas	©Claritas, LLC 2024 (https://claritas.easpotlight.com/Spotlight/Aboul

Competitive Review of – UNC Rex Hospital / Project ID #J-012542-24

Overview

UNC Rex Hospital ("UNC Rex") proposes to add 20 acute care beds and two operating rooms to its main campus hospital in Raleigh, NC in response to the need determinations for 70 acute care beds and four operating rooms for Wake County in the 2024 SMFP. UNC Rex fails to adequately demonstrate the need for proposed services by the population, it should be found non-conforming to Criterion 1, 3, 3a, 6, and the Performance Standard for Operating Rooms.

CON Review Criteria

 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, ambulatory surgery operating rooms, or home health offices that may be approved.

The proposed project is in response to a need determination for 70 acute care beds and four operating rooms in Wake County. It is therefore subject to Policy <u>GEN-3</u>: <u>Basic Principles</u>, which states:

"A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area."

As described in Criterion 3 below, UNC Rex does not demonstrate that its proposal's, "projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area." UNC Rex should therefore be found non-conforming to Criterion 1.

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.

UNC Rex failed to demonstrate that the proposed population is in need of the proposed services; specifically with regard to the portion of population it proposes to serve, the implied change in need for Observation beds, and the need for additional operating rooms at UNC Health Rex Hospital.

Proposed Service Area

Beginning on page 52 of its application, UNC Rex discusses the "Need for Additional Acute Care and Surgical Capacity for Patients Originating from **Central Wake County**" [emphasis added]. Using data from the Wake County Planning Department, the Applicant suggests that Raleigh is the fastest growing portion of Wake County because between 2021 and 2022 it had the largest growth in number of residential building permits. UNC Rex also states on page 53 that "while Central Wake County is already densely populated, its growth continues to account for a significant portion of overall growth in the Wake County and attracts more new development than anywhere else in the county."

However, this argument is unsubstantiated. First, UNC Rex fails to define "Central Wake County." It suggests that, based on Wake County Planning Department data, Raleigh is "Central Wake County," but provides no map, boundaries, or other data to support this definition. Given that the city of Raleigh is, by far, the largest township in Wake County, both in land area and population, it stands to reason that its number of building permits would be high.

Second, while the raw number of residential buildings permits in the Raleigh Jurisdiction may be the largest in the county, not even the Applicant's source material from the Wake County Planning Department agrees that Raleigh has the highest concentration of building permits. In fact, updated data for 2023 – which was released in February 2024 – shows that Raleigh's growth in building permits is declining. Furthermore, the source data does not differentiate the types of residential permits issued. For instance, **one** permit is issued for building a single family home and **one** permit is issued for an apartment building. Therefore, while there may be more permits, without additional information it does not necessarily correlate with more net new residents. See Figure 1 and Table 1 below.

Table 1: Wake County Building Permit Data, 2021 vs 2022 vs 2023

Wake County	Residen	tial Permits Issued	Growth / (Decline) of Residential Permits Issued			
Jurisdiction	CY21	CY22 CY23		CY21 to CY22	CY22 to CY23	
Angier	47	3	39	(44)	36	
Apex	1,052	884	897	(168)	13	
Cary	858	532	303	(326)	(229)	
Clayton	-	-	-	-	-	
Durham	-	-	63	-	63	
Fuquay-Varina	1,561	1,569	906	8	(663)	
Garner	616	600	1,048	(16)	448	
Holly Springs	623	485	592	(138)	107	
Knightdale	145	210	261	65	51	
Morrisville	139	37	7	(102)	(30)	
Raleigh	1,267	1,848	1,756	581	(92)	
RDU	-	-	-	-	-	
Rolesville	172	281	184	109	(97)	
RTP	-	-	-	-	-	
Wake Forest	359	623	615	264	(8)	
Wendell	484	374	887	(110)	513	
Zebulon	308	383	470	75	87	
Wake County (other)	775	619	462	(156)	(157)	
Total	8,406	8,448	8,490	42	42	

Source: Wake County Planning, Permit Density Maps; https://s3.us-west-1.amazonaws.com/wakeqov.com.if-us-west-1/s3fs-public/documents/2024-02/Development%20Permit%20Density_cy2023.pdf

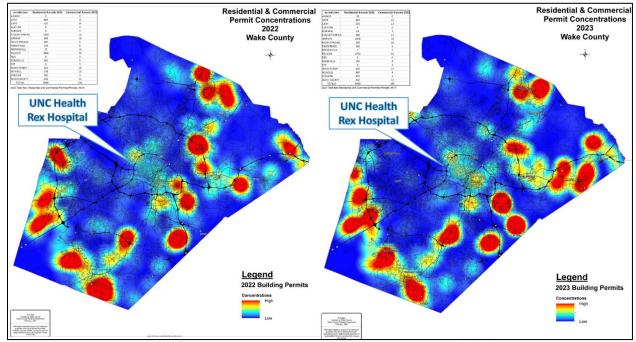


Figure 1: Wake County Residential & Commercial Permit Concentrations, 2022 vs 2023

Source: Wake County Planning, Permit Density Maps; https://s3.us-west-1.amazonaws.com/wakeqov.com.if-us-west-1/s3fs-public/documents/2024-02/Development%20Permit%20Density cy2023.pdf

The Applicant's provided information does not support that "Central Wake County" is the portion of Wake County with the greatest population growth.

Finally, even if UNC Rex's argument that Central Wake County has the highest growth were correct, they do not demonstrate that UNC Health Rex Hospital will serve more patients from this "high growth area." Projected patient origin for both acute care beds and operating rooms beginning on page 39, show that it plans to serve patients from "Wake County." By using the entire county in its patient origin, the reader must assume that UNC Health Rex Hospital is equally as likely to serve patients from the ambiguous Central Wake County as they are to serve patients from Morrisville, Zebulon, or Fuquay-Varina, all cities on the far edges of Wake County. They do not clearly demonstrate how Central Wake County will have access to the proposed services.

Unreasonable Surgical Case Volume Projections

UNC Rex proposes to add two operating rooms to UNC Health Rex Hospital. On page 163, UNC Rex says "the proposed surgical services are needed within the UNC Health System and are specifically needed at UNC Health Rex Hospital in Raleigh." However, the Applicant fails to show adequate need for additional surgical services at the main campus.

UNC Rex fails to address the fact that surgical cases have been on a steady decline at UNC Health Rex Hospital for the last five years. Data in the methodology show a history for the UNC Rex License, which beginning in SY22 includes UNC Health Rex Holly Springs Hospital (Table 1-4, p158). The Applicant then provides the individual surgical case history for UNC Health Rex Holly Springs Hospital (Table 3-1, p163). The Applicant never provides the individual historical surgical case data for UNC Health Rex Hospital.

Because UNC Health Rex Hospital and UNC Health Rex Holly Springs Hospital are on the same license, it is reasonable to assume that total surgical cases for UNC Health Rex Hospital can be determined by subtracting the UNC Health Rex Holly Springs Hospital cases from the total UNC Rex license cases. See Table 2 below.

Table 2: Estimated Surgical Cases at UNC Health Rex Hospital, SY19-SY24

Historical OR Utilization	SY19	SY20	SY21	SY22	SY23	SY24	CAGR (d)
a. UNC Rex Health License, Inpatient	8,624	7,643	7,204	6,716	6,909	6,884	
b. UNC Health Rex Holly Springs Hospital, Inpatient				138	216	277	
c. UNC Health Rex Hospital Difference, Inpatient	8,624	7,643	7,204	6,578	6,693	6,607	-5.2%
a. UNC Rex Health License, Outpatient	11,705	10,901	12,892	14,265	14,772	14,658	
b. UNC Health Rex Holly Springs Hospital, Outpatient				952	1,584	2,081	
c. UNC Health Rex Hospital Difference, Outpatient	11,705	10,901	12,892	13,313	13,188	12,577	1.4%
a. UNC Rex Health License, Total Cases	20,329	18,544	20,096	20,981	21,681	21,542	
b. UNC Health Rex Holly Springs Hospital, Total Cases				1,090	1,800	2,358	
c. UNC Health Rex Hospital Difference, Total Cases	20,329	18,544	20,096	19,891	19,881	19,184	-1.2%

Notes:

- a. Table 1-4, p158
- b. Table 3-1, p163
- c. a-b
- d. UNC Health Rex Hospital Compound Annual Growth Rate, SY19-SY24

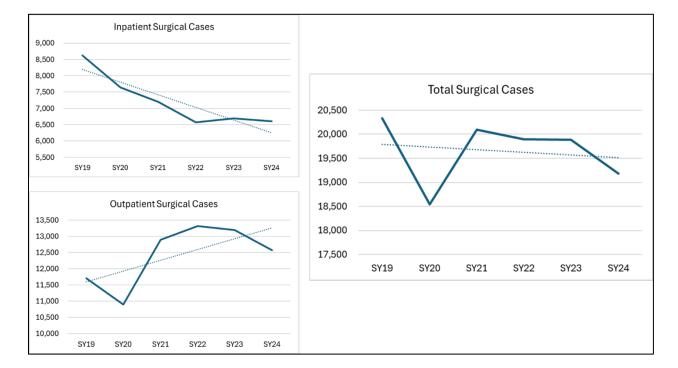


Figure 2: Estimated UNC Health Rex Hospital Surgical Cases, SY19-SY24

UNC Rex's own data show surgical cases at UNC Health Rex Hospital are declining, and not all of that decline can be attributed to a shift of patients to the new UNC Health Rex Holly Springs Hospital. As Table 2 and Figure 2 demonstrate, the decline in volume began before UNC Health Rex Holly Springs Hospital began operations.

Furthermore, by using the "trend" from UNC Health Rex Holly Springs Hospital, the Applicant would like the reader to believe that the increase in outpatient cases more than offsets the decline in inpatient cases and therefore overall growth can be achieved. However, when isolated, UNC Health Rex Hospital's decline in inpatient surgical case volume is so much more severe than the slight increase of outpatient surgical case volumes, that total surgical case volumes cannot recover.

To cover up this obvious flaw, UNC Rex relies on the growth pattern of newly opened UNC Health Rex Holly Springs Hospital to justify growth for UNC Health Rex Hospital because they are on the same license. It recognizes the decline of inpatient cases at both hospitals, but in the case of outpatient cases, growth at UNC Health Rex Holly Springs Hospital surpasses the decline of inpatient cases therefore creating an overall growth pattern.

UNC Health Rex Holly Springs Hospital is a new community hospital designed to serve southern Wake County. It has only been operational for approximately 34 months (November 2021 through September 2024), which, because UNC Rex operates on a state fiscal year (July to June), means they truly have only two full fiscal years of data. Basing surgical case volume growth for an established tertiary hospital on a barely opened community hospital is unreasonable.

Unsupported Acute Care Bed Need

Inpatient surgical cases account for approximately 20 to 40 percent of all acute care bed patients^{1,2}. As detailed in the previous section, operating room projections are unsubstantiated. Without the addition of new operating rooms, and an obvious decline in inpatient surgical cases at UNC Health Rex Hospital, projections for acute care beds days is overstated.

UNC Rex is therefore non-conforming with Review Criterion 3.

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.

UNC Rex fails to demonstrate how observation patients will continue to be adequately served once the existing 20 observation beds are converted to acute care beds.

As detailed on page 34 of its application, UNC Rex proposes to convert 11,185 square feet of space which currently houses unlicensed observation beds into the proposed new 20 acute care bed unit. However, beginning on page 60, the Applicant explains that over the last five years, the number of observation patients have been on a steady increase. In fact, in FY23 the average daily census of observation patients was 46.2. UNC Rex explains that while these patients' needs may mimic that of acute care patients, they are unable to be classified as inpatients because of limitations set by insurers.

This would suggest that the need for observation beds is significant and increasing. For reference, UNC Rex's 2024 LRA shows 59 unlicensed observation beds. If 20 are converted to acute care, and their average daily census is 46, then this project will leave UNC Rex Hospital **short** at least seven unlicensed observation beds (59-20=39,39-46=(7)). As population increases, the deficit will increase. Conversion of these beds to licensed status would thus reduce access to observation beds for low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups.

UNC Rex Hospital application does not address how it will continue to provide adequate access to Observation beds for this growing group of patients and should therefore be found non-conforming to Criterion 3a.

¹ Knowlton, Lisa M et al. "The economic footprint of acute care surgery in the United States: Implications for systems development." The journal of trauma and acute care surgery vol. 86,4 (2019): 609-616. doi:10.1097/TA.000000000002181

² Project ID#J-012548-24, Duke University, Inc., Duke Cary Hospital Application p205

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

As described in Criterion 3 above, projected surgical case volumes at UNC Health Rex Hospital are unreasonable and unsupported. Therefore, approval of this application would in fact duplicate surgical services at UNC Health Rex Hospital.

UNC Rex is therefore non-confirming to Criterion 6.

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.

The project involves a substantial capital investment, +\$16.5 million. The only supporting documentation in Exhibit F.1 says construction cost estimate is +\$8.7 million.

Form F.1a indicates that \$11.7 million is for acute care beds. The very high cost for converting existing Observation beds is not explained.

The very high costs associated with both the bed and operating room expansions are not explained, therefore the Agency cannot determine that these are the most reasonable alternative and should therefore be found non-conforming to Criterion 12.

CON Rules

10A NCAC 14C .2103(a) Surgical Services and Operating Rooms, Performance Standard

The performance standard requires the Applicant to "...demonstrate the need for the number of proposed operating rooms in addition to the existing and approved operating rooms in the applicant's health system...." As described in Criterion 3, UNC Rex did not adequately demonstrate the need for additional operating rooms at UNC Health Rex Hospital, it therefore cannot be found conforming with the performance standard.