**Comments Regarding Duke Green Level Hospital CON Application**
**Project No. J-12029-21**

**Submitted by WakeMed Health & Hospitals**
**March 31, 2021**

WakeMed appreciates the opportunity to provide the following comments opposing the certificate of need application filed by Duke University Health System to develop a hospital in western Wake County with 40 acute care beds and 2 operating rooms relocated from Duke Raleigh Hospital.

## Overview

While Duke maintains that the chief justification for the new hospital is to shift patients that would otherwise utilize an existing Duke Health System facility, it is not reasonable to assume that Duke would spend $235 million merely to improve accessibility to existing Duke patients. Aside from purported improvement in geographic accessibility, the Duke Green Level Hospital ("DGLH") application will offer nothing new to Wake County residents in terms of acute care service mix, cost effectiveness, or quality.

The proposed project should not be approved, as it does not conform with applicable certificate of need Review Criteria found in N.C.G.S. §131E-183, as described below.

## Review Criterion 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 DGLH project does not conform with Review Criterion 3. The applicant failed to demonstrate that that the project is needed for the following reasons:

- Volume projections and their underlying assumptions are unreliable;
- Justification for the proposed shift in cases to the new facility is unreasonable;
- The application failed to consider the impact of new acute care beds already under development in western Wake County;
- The proposed location does not materially improve access to acute care beds, surgical services, or emergency services in western Wake County;
- The project may have a detrimental effect on existing facilities in the Duke Health System.

On Application page 46, Duke states that "Existing DUHS facilities are responsible for approximately 16 percent of all Wake County acute care discharges. Many of these patients are treated either at [Duke University Hospital], a 960-bed quaternary care, academic teaching hospital, or at [Duke Raleigh Hospital]…". What this passage fails to note is that many Wake County residents who travel outside Wake County do so in order to access highly specialized tertiary health care services, such as the services that are available only at academic medical centers (AMCs). Wake County itself has no academic medical center, but two such AMCs are located in Durham and Orange Counties. The application provides no evidence that redistribution of acute care beds from Duke Raleigh to DGLH will alter referral patterns or the number of patients who seek care at facilities outside Wake County.

Assumptions Regarding Inpatient Volume Projections Not Reasonable

DGLH's projections are predicated on shifting inpatient cases that currently utilize existing Duke acute care hospitals in Durham and Wake Counties to a new facility in western Wake County. The DGLH "Catchment Area" is divided into three distinct "zones" around the DGLH site, defined by ZIP Code:

- Zone 1: 0-10 minutes' drive-time – Apex, Cary, and Morrisville ZIP Codes in Wake County;
- Zone 2: 10-20 minutes' drive-time – ZIP Codes in Wake, Durham and Chatham Counties, including Apex, Cary, Fuquay-Varina, Holly Springs, New Hill, Raleigh, Durham, and Pittsboro;
- Zone 3: 20-30 minutes' drive-time – ZIP Codes in Wake, Durham, Chatham, Orange, and Lee Counties, including Raleigh, Durham, Chapel Hill, Sanford and Moncure.

Despite its proposed location in Cary at the center of Zone 1, Duke hypothesizes that DGLH will attract significant proportions of patients from Zones 2 and 3, despite offering fewer specialized services and being located further away than existing/proposed acute care hospitals in Wake, Durham, Lee and Orange Counties to residents of Zones 2 and 3.

While the DGLH application notes that no acute care hospitals are located within Zone 1, based on the Catchment Area map on Application page 52, there are three existing or approved acute care hospitals already located within Zone 2: WakeMed Cary Hospital, UNC Rex Holly Springs Hospital, and UNC Rex Hospital. Central Carolina Hospital in Sanford is located in Zone 3.

Although they were shown outside the Catchment Area map on Application page 53, four additional acute care hospitals, WakeMed North Hospital, Duke Raleigh Hospital, Duke University Hospital (not shown on map on page 52), and UNC Medical Center (not shown on map on page 52) appear to be within 30 minutes' drive-time of DGLH on the map provided on Application page 52, and should be considered to be located in Zone 3. Thus, the notion that DGLH will improve geographic access to acute care hospital services is false.

Assumptions Regarding Inpatient Case Shift Not Reasonable

The DGLH projections include a lengthy discussion regarding Duke Health System cases originating in the "Catchment Area", broadly defined as a region within 30 minutes' drive-time of DGLH, and specifies the patients that fit certain diagnosis criteria appropriate for the service mix to be developed at DGLH. These selection criteria were described generally on Application pages 51 and 55, but no details were provided regarding specific MS-DRGs used in the analysis in the Application or Exhibits. Without this detail, it is impossible to evaluate the reasonableness of the methodology.

Although the DGLH project would be located in Wake County, and will ostensibly be developed to shift cases primarily from Duke Raleigh Hospital (DRAH), the facility's utilization projections rely heavily on patients from Durham County, discharged from Duke University Hospital (DUH) or Duke Regional Hospital (DRH). On Application pages 55 and 127, Duke provided the FYs 2017-2019 Duke Health System discharges originating from the Catchment Area that it deemed were appropriate to potentially shift to DGLH. Duke identified 9,971 cases in FY 2019 originating from the Catchment Area, and the Duke facilities from which they were discharged. Please see the following table, which provides additional detail for Application Table Q.1.

**Table 1**
**Historic Duke Health System Cases from Catchment Area by Facility - ZIP Code City and County Added**
**Excerpted from DGLH Application, Table Q.1, Page 127**

| | | | | FY 2017 | | | | FY 2018 | | | | FY 2019 | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Zone** | **Zip Code** | **Zip Code City** | **Zip Code County** | **DUH** | **DRH** | **DRAH** | **Total** | **DUH** | **DRH** | **DRAH** | **Total** | **DUH** | **DRH** | **DRAH** | **Total** | **% Total DUHS FY 19 Cases by Zip** |
| Zone 1 | 27502 | Apex | Wake | 100 | 17 | 27 | **144** | 118 | 18 | 30 | **166** | 122 | 8 | 28 | **158** | 2% |
| Zone 1 | 27513 | Cary | Wake | 139 | 19 | 53 | **211** | 142 | 26 | 36 | **204** | 127 | 30 | 32 | **189** | 2% |
| Zone 1 | 27519 | Cary | Wake | 317 | 39 | 44 | **400** | 304 | 48 | 43 | **395** | 272 | 44 | 31 | **347** | 3% |
| Zone 1 | 27523 | Apex | Wake | 27 | 8 | 5 | **40** | 52 | 8 | 4 | **64** | 52 | 16 | 10 | **78** | 1% |
| Zone 1 | 27560 | Morrisville | Wake | 153 | 31 | 20 | **204** | 180 | 29 | 25 | **234** | 176 | 48 | 24 | **248** | 2% |
| | | | Total Zone 1 | 736 | 114 | 149 | **999** | 796 | 129 | 138 | **1,063** | 749 | 146 | 125 | **1,020** | **10%** |
| | | | % Total Zone 1 by Facility | 74% | 11% | 15% | 100% | 75% | 12% | 13% | 100% | 73% | 14% | 12% | 100% | |
| Zone 2 | 27312 | Pittsboro | Chatham | 77 | 43 | 9 | **129** | 95 | 50 | 3 | **148** | 83 | 47 | 5 | **135** | 1% |
| Zone 2 | 27511 | Cary | Wake | 82 | 20 | 53 | **155** | 66 | 10 | 55 | **131** | 98 | 14 | 45 | **157** | 2% |
| Zone 2 | 27518 | Cary | Wake | 53 | 13 | 25 | **91** | 54 | 11 | 22 | **87** | 61 | 10 | 19 | **90** | 1% |
| Zone 2 | 27526 | Fuquay-Varina | Wake | 101 | 19 | 81 | **201** | 117 | 27 | 79 | **223** | 157 | 35 | 69 | **261** | 3% |
| Zone 2 | 27539 | Apex | Wake | 68 | 13 | 18 | **99** | 50 | 11 | 33 | **94** | 66 | 10 | 26 | **102** | 1% |
| Zone 2 | 27540 | Holly Springs | Wake | 74 | 22 | 31 | **127** | 96 | 12 | 36 | **144** | 93 | 16 | 35 | **144** | 1% |
| Zone 2 | 27562 | New Hill | Wake | 19 | 6 | 3 | **28** | 5 | 2 | 1 | **8** | 9 | 1 | 0 | **10** | 0% |
| Zone 2 | 27603 | Raleigh | Wake | 92 | 20 | 199 | **311** | 82 | 14 | 153 | **249** | 81 | 20 | 176 | **277** | 3% |
| Zone 2 | 27606 | Raleigh | Wake | 68 | 15 | 92 | **175** | 68 | 14 | 82 | **164** | 72 | 11 | 82 | **165** | 2% |
| Zone 2 | 27607 | Raleigh | Wake | 40 | 4 | 39 | **83** | 26 | 9 | 57 | **92** | 33 | 6 | 46 | **85** | 1% |
| Zone 2 | 27617 | Raleigh | Wake | 125 | 28 | 60 | **213** | 155 | 28 | 45 | **228** | 118 | 23 | 62 | **203** | 2% |
| Zone 2 | 27709 | Durham | Durham | 6 | 3 | 0 | **9** | 14 | 5 | 1 | **20** | 15 | 5 | 4 | **24** | 0% |
| Zone 2 | 27713 | Durham | Durham | 1,003 | 426 | 9 | **1,438** | 977 | 439 | 9 | **1,425** | 1,069 | 449 | 10 | **1,528** | 15% |
| | | | Total Zone 2 | 1,808 | 632 | 619 | **3,059** | 1,805 | 632 | 576 | **3,013** | 1,955 | 647 | 579 | 3,181 | **32%** |
| | | | % Total Zone 2 by Facility | 59% | 21% | 20% | 100% | 60% | 21% | 19% | 100% | 61% | 20% | 18% | 100% | |
| Zone 3 | 27330 | Sanford | Lee | 103 | 20 | 13 | **136** | 85 | 18 | 13 | **116** | 91 | 20 | 23 | **134** | 1% |
| Zone 3 | 27517 | Chapel Hill | Orange | 177 | 79 | 2 | **258** | 192 | 60 | 2 | **254** | 191 | 61 | 3 | **255** | 3% |
| Zone 3 | 27559 | Moncure | Lee | 7 | 3 | 1 | **11** | 9 | 3 | 1 | **13** | 7 | 2 | 2 | **11** | 0% |
| Zone 3 | 27612 | Raleigh | Wake | 84 | 11 | 143 | **238** | 77 | 17 | 154 | **248** | 81 | 18 | 141 | **240** | 2% |
| Zone 3 | 27613 | Raleigh | Wake | 134 | 38 | 212 | **384** | 153 | 23 | 195 | **371** | 127 | 18 | 190 | **335** | 3% |
| Zone 3 | 27615 | Raleigh | Wake | 104 | 21 | 408 | **533** | 111 | 27 | 345 | **483** | 105 | 26 | 360 | **491** | 5% |
| Zone 3 | 27703 | Durham | Durham | 1,225 | 980 | 38 | **2,243** | 1,219 | 1,021 | 48 | **2,288** | 1,281 | 1,068 | 72 | **2,421** | 24% |
| Zone 3 | 27707 | Durham | Durham | 1,262 | 597 | 7 | **1,866** | 1,315 | 606 | 12 | **1,933** | 1,259 | 619 | 5 | **1,883** | 19% |
| | | | Total Zone 3 | 3,096 | 1,749 | 824 | **5,669** | 3,161 | 1,775 | 770 | **5,706** | 3,142 | 1,832 | 796 | **5,770** | **58%** |
| | | | % Total Zone 3 by Facility | 55% | 31% | 15% | 100% | 55% | 31% | 13% | 100% | 54% | 32% | 14% | 100% | |
| **Total** | | | | 5,640 | 2,495 | 1,592 | **9,727** | 5,762 | 2,536 | 1,484 | **9,782** | 5,846 | 2,625 | 1,500 | **9,971** | **100%** |
| | | | Overall Percent Total | 58% | 26% | 16% | 100% | 59% | 26% | 15% | 100% | 59% | 26% | 15% | 100% | |

Analysis of the FY 2019 data by <u>discharge facility</u> within the Catchment Area revealed that Duke Raleigh Hospital comprised:

- 12 percent of Zone 1 discharges;
- 19 percent of Zone 2 discharges;
- 14 percent of Zone 3 discharges;
- Only 15 percent of total discharges *across all three zones*, in contrast with 59 percent from DUH and 26 percent from DRH.

Also, approximately 59 percent of the total Catchment area discharges in Application Table Q.1 originated from four *Durham County* ZIP Codes: 27703, 27707, 27709 and 27713.

WakeMed also summarized data in Application Table Q.1 by patient county by facility, which is provided in the following table.

**Table 2**
**Historic Duke Health System Cases Summarized by Facility by Patient County by Zone**
**Excerpted from DGLH Application, Table Q.1, Page 127**

| | | FY 2017 | | | | | FY 2018 | | | | | FY 2019 | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Zone | Zip Code County | DUH | DRH | DRAH | Total | % Total by County | DUH | DRH | DRAH | Total | % Total by County | DUH | DRH | DRAH | Total | % Total by County |
| Zone 1 | Wake | 736 | 114 | 149 | 999 | 100% | 796 | 129 | 138 | 1,063 | 100% | 749 | 146 | 125 | 1,020 | 100% |
| | Total Zone 1 | 736 | 114 | 149 | 999 | 100% | 796 | 129 | 138 | 1,063 | 100% | 749 | 146 | 125 | 1,020 | 100% |
| | | | | | | | | | | | | | | | | |
| Zone 2 | Chatham | 77 | 43 | 9 | 129 | 4% | 95 | 50 | 3 | 148 | 5% | 83 | 47 | 5 | 135 | 4% |
| | Durham | 1,009 | 429 | 9 | 1,447 | 47% | 991 | 444 | 10 | 1,445 | 48% | 1,084 | 454 | 14 | 1,552 | 49% |
| | Wake | 722 | 160 | 601 | 1,483 | 48% | 719 | 138 | 563 | 1,420 | 47% | 788 | 146 | 560 | 1,494 | 47% |
| | Total Zone 2 | 1,808 | 632 | 619 | 3,059 | 100% | 1,805 | 632 | 576 | 3,013 | 100% | 1,955 | 647 | 579 | 3,181 | 100% |
| | | | | | | | | | | | | | | | | |
| Zone 3 | Durham | 2,487 | 1,577 | 45 | 4,109 | 72% | 2,534 | 1,627 | 60 | 4,221 | 74% | 2,540 | 1,687 | 77 | 4,304 | 75% |
| | Lee | 110 | 23 | 14 | 147 | 3% | 94 | 21 | 14 | 129 | 2% | 98 | 22 | 25 | 145 | 3% |
| | Orange | 177 | 79 | 2 | 258 | 5% | 192 | 60 | 2 | 254 | 4% | 191 | 61 | 3 | 255 | 4% |
| | Wake | 322 | 70 | 763 | 1,155 | 20% | 341 | 67 | 694 | 1,102 | 19% | 313 | 62 | 691 | 1,066 | 18% |
| | Total Zone 3 | 3,096 | 1,749 | 824 | 5,669 | 100% | 3,161 | 1,775 | 770 | 5,706 | 100% | 3,142 | 1,832 | 796 | 5,770 | 100% |
| All Zones | | | | | | | | | | | | | | | | |
| | Chatham | 77 | 43 | 9 | 129 | 1% | 95 | 50 | 3 | 148 | 2% | 83 | 47 | 5 | 135 | 1% |
| | Durham | 3,496 | 2,006 | 54 | 5,556 | 57% | 3,525 | 2,071 | 70 | 5,666 | 58% | 3,624 | 2,141 | 91 | 5,856 | 59% |
| | Lee | 110 | 23 | 14 | 147 | 2% | 94 | 21 | 14 | 129 | 1% | 98 | 22 | 25 | 145 | 1% |
| | Orange | 177 | 79 | 2 | 258 | 3% | 192 | 60 | 2 | 254 | 3% | 191 | 61 | 3 | 255 | 3% |
| | Wake | 1,780 | 344 | 1,513 | 3,637 | 37% | 1,856 | 334 | 1,395 | 3,585 | 37% | 1,850 | 354 | 1,376 | 3,580 | 36% |
| | Total All Zones | 5,640 | 2,495 | 1,592 | 9,727 | 100% | 5,762 | 2,536 | 1,484 | 9,782 | 100% | 5,846 | 2,625 | 1,500 | 9,971 | 100% |

Analysis of the FY 2019 data by patient county showed that Wake County residents comprised:

- 100 percent of the Zone 1 discharges (nearly the entire Zone is located within Wake);
    - Zone 1 accounts for about 10 percent of FY 2019 total cases in the Catchment Area;
- 47 percent of the Zone 2 discharges;
    - Zone 2 represents 32 oof total cases in the Catchment Area;
- 18 percent of the Zone 3 discharges;
    - Zone 3 comprises 58 percent of total cases in the Catchment Area;
- Only 36 percent of discharges *across all three Zones*, compared with 59 percent from Durham County.

While DGLH projected 85.5 percent of acute care patients will originate from Wake County and 10.5 percent from Durham County in Project Year 1 (Application page 36), the bed need methodology in Section Q actually indicates that DGLH is heavily dependent on Durham County residents for much of its projected inpatient utilization, which does not benefit Wake County residents. On Application page 131, Duke projects 50 percent of Duke Raleigh patients appropriate for DGLH, from Zone 1, will shift to DGLH in Project Year 1, increasing to 70 percent by Project Year 3. This shift is expected to occur despite the DGLH site being geographically

closer to Duke University Hospital (21.0 road miles) than to Duke Raleigh (24.7 road miles). By contrast, only 10 percent of Zone 1 patients will shift from DUH to DGLH in Year 1, increasing to 17 percent by Year 3.

Therefore, without a significant infusion of patients originating in Durham County, the DGLH projections provided in Sections C and Q are overstated and insupportable. With two acute care hospitals in Durham County already under Duke's oversight, and most Durham County physicians already affiliated with the Duke system, it is not clear why Durham County residents would seek care outside Durham County. Likewise, with no material improvement in access, it is not clear why residents of Wake County, outside Zone 1, would seek care at DGLH as opposed to more nearby hospitals. With 59 percent of the Catchment Area originating from Durham County, it can be argued that approval of DGLH would actually decrease access to care for Wake County residents.

Impact of New Acute Care Beds Under Development in Western Wake County

A total of 80 new licensed acute care beds are slated to open in western Wake County during Calendar Year 2021: 30 beds at WakeMed Cary Hospital, bringing its licensed capacity to 208 beds, as well as 50 beds at UNC Rex Holly Springs Hospital. These new beds will add 29,220 available patient days to Wake County. Although acute care beds are allocated by county and not by subservice area, the inventory of licensed acute care beds located in western Wake County will increase by 45 percent in 2021, from 178 to 258 beds. The impact of these new beds on overall acute care utilization patterns in Wake County is not yet known.

Approval of DGLH would increase the acute care bed inventory in western Wake County by an additional 15 percent. Duke's claims that DGLH will improve geographic accessibility do not take these new acute care beds into account.

Emergency Department Projections Based on Unreasonable Assumptions

DGLH proposes a full-service emergency department, which would be the *fifth* ED located within a 20-minute drive from the DGLH site. As such, the DGLH will not materially improve access to emergency services.

On Application pages 45-46, DGLH characterizes WakeMed Cary Hospital as having "long wait times to be seen at the emergency department" as well as having wait times "among the longest of any of WakeMed's ED facilities", citing observed wait times on *five* days at *five* separate points between February 4-10, 2021. This is not a representative sample of wait times, due to its small size and the fact that observations were taken at different times of day during a single week. Further, it cannot be concluded from the data provided whether these wait times are excessive. It is likely that Duke chose these dates/times to further their narrative that additional ED capacity is needed in western Wake County. Because ED wait times at other Wake County facilities were not noted for the dates/times provided, Duke's claim that WakeMed Cary has unreasonably long wait times is unfounded.

UNC Rex Holly Springs Hospital, slated to open in late 2021, will have its own full-service ED and will be located less than 20 minutes from the DGLH site. The impact of this additional point of entry, and its associated additional capacity on ED utilization, cannot be known until after the facility has opened. It would be unreasonable to continue to approve new ED capacity in a region of the county that is already served by two stand-alone EDs and two acute care hospitals offering 24/7 emergency services.

Duke's reasoning for developing an emergency department at DGLH is, in part, to shift ED volume at Duke Raleigh Hospital originating in the Catchment Area to the new hospital. In FY 2019, Duke Raleigh treated 8,997 ED visits from Catchment Area ZIP Codes, or approximately 24 visits per day. Analysis of data provided in Application Table Q.43, organized by Catchment Area Zone, is provided below.

**Table 3**
**Duke Raleigh Hospital FY 2019 Emergency Visits by ZIP Code**
**Grouped by DGLH Catchment Area Zone – ZIP Code City and County Added**
**Excerpted from Application Table Q.43, Page 153**

| Zone | Zip Code | Zip Code City | Zip Code County | FY 2019 ED Visits | Percent of Total Visits |
|---|---|---|---|---|---|
| Zone 1 | 27502 | Apex | Wake | 124 | 1% |
| Zone 1 | 27513 | Cary | Wake | 223 | 2% |
| Zone 1 | 27519 | Cary | Wake | 190 | 2% |
| Zone 1 | 27523 | Apex | Wake | 24 | 0% |
| Zone 1 | 27560 | Morrisville | Wake | 145 | 2% |
| | | | Total Zone 1 | 706 | 8% |
| Zone 2 | 27312 | Pittsboro | Chatham | 14 | 0% |
| Zone 2 | 27511 | Cary | Wake | 217 | 2% |
| Zone 2 | 27518 | Cary | Wake | 79 | 1% |
| Zone 2 | 27526 | Fuquay-Varina | Wake | 285 | 3% |
| Zone 2 | 27539 | Apex | Wake | 130 | 1% |
| Zone 2 | 27540 | Holly Springs | Wake | 157 | 2% |
| Zone 2 | 27562 | New Hill | Wake | 21 | 0% |
| Zone 2 | 27603 | Raleigh | Wake | 1,297 | 14% |
| Zone 2 | 27606 | Raleigh | Wake | 823 | 9% |
| Zone 2 | 27607 | Raleigh | Wake | 318 | 4% |
| Zone 2 | 27617 | Raleigh | Wake | 287 | 3% |
| Zone 2 | 27709 | Durham | Durham | 2 | 0% |
| Zone 2 | 27713 | Durham | Durham | 79 | 1% |
| | | | Total Zone 2 | 3,709 | 41% |
| Zone 3 | 27330 | Sanford | Lee | 38 | 0% |
| Zone 3 | 27517 | Chapel Hill | Orange | 4 | 0% |
| Zone 3 | 27559 | Moncure | Lee | 7 | 0% |
| Zone 3 | 27612 | Raleigh | Wake | 1,002 | 11% |
| Zone 3 | 27613 | Raleigh | Wake | 953 | 11% |
| Zone 3 | 27615 | Raleigh | Wake | 2,246 | 25% |
| Zone 3 | 27703 | Durham | Durham | 243 | 3% |
| Zone 3 | 27707 | Durham | Durham | 89 | 1% |
| | | | Total Zone 3 | 4,582 | 51% |
| **Total** | | | | 8,997 | 100% |

The table above shows that Duke Raleigh provided 706 ED visits in FY 2019 from Zone 1, representing only 8 percent of total visits and equating to less than 2 visits per day. Nearly one-half of Duke Raleigh's ED visits from the *entire* Catchment Area originated from *three ZIP Codes in north Raleigh*: 27612 (11%), 27613 (11%) and 27615 (25%), all of which are located in Zone 3 and are more proximate to the Duke Raleigh campus.

On Application page 37, Duke projects that 87.9 percent of Project Year 1 ED visits at DGLH will originate in Wake County, with Durham County residents comprising 8.2 percent of total. Analysis of Table Q.43 data indicates that Wake County ED visits from Zones 1 and 2 comprised

only 48 percent of total Duke Raleigh ED visits from the Catchment Area. Please see the following table.

**Table 4**
**Duke Raleigh Hospital FY 2019 Emergency Department Visits by Zone – Grouped by Patient County**
**Excerpted from DGLH Application, Table Q.43, Page 153**

| Zone | Zip Code County | FY 2019 Visits | Percent Zone Total Visits by County | Percent Total All Zone Visits by County |
|---|---|---|---|---|
| Zone 1 | Wake | 706 | 100% | 8% |
| | Total Zone 1 | 706 | 100% | 8% |
| | | | | |
| Zone 2 | Chatham | 14 | 0% | 0% |
| | Durham | 81 | 2% | 1% |
| | Wake | 3,614 | 97% | 40% |
| | Total Zone 2 | 3,709 | 100% | 41% |
| | | | | |
| Zone 3 | Durham | 332 | 7% | 4% |
| | Lee | 7 | 0% | 0% |
| | Orange | 4 | 0% | 0% |
| | Wake | 4,201 | 92% | 47% |
| | Total Zone 3 | 4,544 | 100% | 51% |
| | | | | |
| All Zones | Chatham | 14 | 0% | 0% |
| | Durham | 413 | 5% | 5% |
| | Lee | 45 | 1% | 1% |
| | Orange | 4 | 0% | 0% |
| | Wake | 8,521 | 95% | 95% |
| | Total All Zones | 8,997 | 100% | 100% |

It is unreasonable to assume that in an emergency, residents of Zone 3, which comprised the greatest proportion of ED visits to Duke Raleigh, and who are also the most distant from the DGLH location, would travel past several other existing hospital-based and stand-alone emergency departments in Wake, Durham, Lee, and Orange Counties to utilize the ED at DGLH.

For the reasons described above, it can be concluded that DGLH's ED projections are based on faulty and unreasonable assumptions.

Please also see the discussion for Review Criterion 6.

Projections for Surgical Services Not Reasonable

Operating room utilization at DGLH, like its acute care bed utilization, is predicated on the ability to shift volume from existing Duke hospitals to the new facility. Duke cites rapid historic

growth in surgical utilization at Duke Raleigh, particularly for inpatient surgery, as the chief catalyst and assumes that the shift of inpatient discharges from all DUHS facilities to DGLH will result in a proportionate shift in surgical cases to DGLH. Duke assumes that the ratio of inpatient surgery cases to inpatient discharges from each Duke location will be a constant ratio of 27 percent during Project Years 1-3. Because much of the inpatient discharge volume assumed to be shifted to DGLH is projected to originate from ZIP Codes geographically closer to Duke Raleigh, which is unreasonable as detailed above, the inpatient surgical volume generated by this case shift would also be unreasonable. Duke also assumes that 27 percent of inpatient discharges shifted to DGLH from DUH and DRH will result in inpatient surgery, although many of these cases will originate in Durham County, where patients are likely as geographically close, if not closer, to DUH and DRH.

For outpatient surgery, Duke assumes DGLH's cases will be shifted exclusively from Duke Raleigh, in addition to other outpatient cases projected to be shifted to Duke's approved ambulatory surgical facilities. The application provides no analysis of patient origin for the outpatient cases to be shifted; rather, it relies on a percentage of Duke Raleigh's total outpatient cases, ranging from 5-15 percent, that will shift to DGLH in Project Years 1-3. There is no discussion provided to justify these percentages, so it cannot determined if the proportions are reasonable or in the best interest of Wake County residents.

<u>Projections for Obstetric Services Not Reasonable</u>

Although not part of the proposed project, DGLH references Duke's planned freestanding birthing center to be developed on its Green Level campus, and DGLH's support for this center's patients and newborns who require hospital care. DGLH states that the proposed birthing center will be located "more than 10 miles from the nearest inpatient facility or birthing center…".

On Application pages 136-140, the DGLH application provides a need methodology to project Obstetric care and Newborns. Duke bases its OB projected births on a statewide "birth rate per 1000 population" method applied to the <u>total</u> service area population to project births in the market, rather than women in the 15-44 age group, which would be a more relevant method. After projecting total births in Wake, Durham, Chatham, Lee, Harnett and Johnston Counties, DGLH assumes that 3 percent of total projected births in the combined this six-county service area would *potentially* use a freestanding birthing center, such as the one proposed for the DGLH campus. DGLH cites The Advisory Board as its source, but provides no research paper or other reference to corroborate this claim. Duke then arbitrarily assigns market shares for each county to its freestanding birthing center, assuming that up to 50 percent of freestanding birthing center deliveries originating in Wake County would be performed at the DGLH campus by Project Year 3. As of the date of these comments were filed, there were no freestanding birthing centers in operation in Wake County or in the other five counties in the defined market area. The closest existing freestanding birthing center to the DGLH site is located in Orange County. DGLH projects, without justification, that it will obtain up to 50 percent market share

of freestanding birthing center births in Wake and Durham Counties by Project Year 3, and up to 25 percent market share in Chatham, Lee, Harnett and Johnston Counties.

DGLH projects that 15 percent of women who utilize a freestanding birthing center will require hospital care for an unscheduled c-section or complicated vaginal delivery. (The basis for this proportion is purportedly an unreferenced journal article.). Even assuming these proportions are reasonable, the underlying assumptions regarding utilization of the Duke freestanding birthing center are not.

The OB projections included in the DGLH application are not reasonable, because they are not based on local historic OB utilization and assume that a percentage of total deliveries will be performed in freestanding birthing centers. The N.C. Department of Health and Human Services does not regulate or collect data from freestanding birthing centers, thus there is no information regarding annual births or patient origins at these centers.

**Review Criterion 3a**

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

The DGLH application classifies the proposed project as redistribution of CON-regulated assets, and that a portion of Duke Raleigh Hospital's existing patient volume will shift to the new facility. The relocation of acute care beds will leave Duke Raleigh with very little available bed capacity, even with the proposed shift of patients to DGLH. The application proposes a 21.5 percent reduction in acute care bed capacity at Duke Raleigh, a facility that operated at 72.1 percent occupancy in FY 2020. Duke projects that Duke Raleigh's inpatient utilization will continue to increase by approximately 1.1449 percent per year through FY 2026, reaching 77.2 percent occupancy with 186 beds. In Project Year 1 (FY 2027), Duke Raleigh's inpatient utilization is projected to be 94.6 percent with 146 beds, leaving available capacity of only 2,890 patient days for the entire year, which equates to *fewer than eight available beds per day following the opening of DGLH*. Please see the following table.

**Table 5**
**Duke Raleigh Hospital – Historic and Projected Acute Care Utilization, 2017-2029**
**Showing Available Daily Bed Capacity**
**Excerpted from Application Tables Q.55 and Q.58, Pages 159-160**

| Row | Statistic | Calculation | FY 2017 | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 | FY 2023 | FY 2024 | FY 2025 | FY 2026 | FY 2027 | FY 2028 | FY 2029 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| A | Total Licensed Beds | | 186 | 186 | 186 | 186 | 186 | 186 | 186 | 186 | 186 | 186 | 146 | 146 | 146 |
| B | Discharges | | 9,588 | 9,484 | 9,627 | 9,921 | 10,035 | 10,149 | 10,266 | 10,383 | 10,502 | 10,622 | 10,170 | 10,159 | 10,146 |
| C | Patient Days | | 42,854 | 42,783 | 48,394 | 48,926 | 49,486 | 50,052 | 50,625 | 51,205 | 51,791 | 52,384 | 50,400 | 50,404 | 50,399 |
| D | ALOS | C ÷ B | 4.5 | 4.5 | 5.0 | 4.9 | 4.9 | 4.9 | 4.9 | 4.9 | 4.9 | 4.9 | 5.0 | 5.0 | 5.0 |
| E | Percent Occupancy | C ÷ (A * 365) | 63.1% | 63.0% | 71.3% | 72.1% | 72.9% | 73.7% | 74.6% | 75.4% | 76.3% | 77.2% | 94.6% | 94.6% | 94.6% |
| F | Average Daily Census | C ÷ 365 | 117.4 | 117.2 | 132.6 | 134.0 | 135.6 | 137.1 | 138.7 | 140.3 | 141.9 | 143.5 | 138.1 | 138.1 | 138.1 |
| | | | | | | | | | | | | | | | |
| G | Total Capacity-Patient Days | A * 365 | 67,890 | 67,890 | 67,890 | 67,890 | 67,890 | 67,890 | 67,890 | 67,890 | 67,890 | 67,890 | 53,290 | 53,290 | 53,290 |
| H | Available Patient Days *(Capacity minus Actual)* | C - G | 25,036 | 25,107 | 19,496 | 18,964 | 18,404 | 17,838 | 17,265 | 16,685 | 16,099 | 15,506 | 2,890 | 2,886 | 2,891 |
| I | Available Beds Per Day | H ÷ 365 or A - F | 68.6 | 68.8 | 53.4 | 52.0 | 50.4 | 48.9 | 47.3 | 45.7 | 44.1 | 42.5 | 7.9 | 7.9 | 7.9 |

Relocation of acute care beds to DGLH will eliminate nearly all available daily bed capacity at Duke Raleigh Hospital, a reduction from 42.5 available beds per day in FY 2026 to fewer than eight beds per day in DGLH Project Years 1-3. At the projected FY 2027-2029 levels of utilization, frequency of emergency department diversion and cancelled elective inpatient surgeries due to lack of available beds become more pronounced, and pressure will grow to discharge patients more quickly, resulting in greater risk of readmission and safety concerns. Additionally, as shown in Form D.1 (Application page 122), Duke Raleigh's ALOS is projected to increase from 4.9 to 5.0 days. This level of utilization at Duke Raleigh, and the resultant scarcity of available bed capacity, does not appear reasonable or sustainable.

The projected high utilization at Duke Raleigh following completion of DGLH is unrealistically and impractically high for a facility in a growing urban market that provides a full range of acute care and surgical services. The assumption that patients who have historically utilized Duke Raleigh will automatically shift to DGLH, located 26 miles from Duke Raleigh, is dubious. Likewise, the assumption that operations at Duke Raleigh will not be adversely impacted following the opening of DGLH is questionable.

For these reasons, the DGLH application does not conform with Review Criterion 3a.

## Review Criterion 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, the DGLH application describes alternatives to the proposed project, including maintaining status quo, developing an acute care hospital in another location, and developing a hospital with a different number of beds and ORs than the chosen alternative.

However, Duke did not discuss the merits of other viable alternatives to the proposed project, such as developing additional beds at Duke Raleigh Hospital or applying for acute care beds allocated to Wake County in an upcoming State Medical Facilities Plan. Developing additional bed capacity at Duke Raleigh would likely be far less expensive than the chosen alternative. Seeking additional acute care beds allocated to Wake County would not take bed capacity from Duke Raleigh, which was utilized at 72.1 percent in FY 2020 and is projected to have 77.2 percent occupancy by FY 2026, the year prior to DGLH's proposed opening. In DGLH Project Year 1, Duke Raleigh's utilization is projected to be 94.6 percent, leaving the facility with very little available inpatient capacity.

On Application page 76, Duke states that "If bed day growth at DRAH or DGLH is much larger than projected, then a Wake County acute care bed need determination will be established pursuant to the standard need methodology in the SMFP. DUHS may apply for additional bed capacity in Wake County should this scenario transpire." This passage would lead the casual reader to believe that obtaining additional new acute care beds is a simple matter. Historically, acute care bed allocations to the Wake County Service Area have been extremely competitive, usually with several applicants vying for approval, often requiring a lengthy time period for resolution.

Therefore, DGLH does not conform with Review Criterion 4.

**Review Criterion 5**

*Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges of providing health services by the person proposing the service.*

As described in Review Criterion 3, DGLH's volume projections not reasonable, reliable or adequately supported, particularly for the acute care beds and emergency department. Because projected revenues and expenses are based at least in part on projected volumes, then projected revenues and expenses in the DGLH application are also unreasonable. Therefore, DGLH does not conform with Review Criterion 5.

**Review Criterion 6**

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

DGLH would duplicate existing and approved acute care facilities and services in western Wake County. In particular, the project would result in unnecessary duplication of acute care beds, emergency department services, and surgical services.

Acute Care Beds

The DGLH project will be duplicative of acute care beds in western Wake County. Currently, WakeMed Cary Hospital, with 178 licensed beds, is the only acute care hospital located in western Wake County. WakeMed Cary will open 30 new licensed beds in April 2021 (Project No. J-11428-17), bringing its capacity to 208 licensed beds, which more immediately accommodates the increased demand DGLH projects. The DGLH site is located approximately 9 road miles from WakeMed Cary.

In addition, UNC Rex Holly Springs Hospital (Project No. J-8669-11) is slated to open in late 2021 with 50 new acute care beds. The Holly Springs Hospital site is located approximately 14 road miles from the proposed DGLH site.

Because 80 new acute care beds will open in western Wake County in Calendar Year 2021, it would be unreasonable for the Agency to approve additional acute care beds for this region until the impact of these new beds can be evaluated. Given recent moves toward telehealth and CMS-approved "hospital at home" programs, adopted by WakeMed, UNC and Duke health systems, it is likely that some undefined proportion of patients who might ordinarily have been admitted to an acute care hospital may now opt out of a hospital stay. The impact of these programs, which were spurred largely by the COVID-19 pandemic, is yet to be fully known.

Emergency Department

The DGLH project proposes to develop an emergency department with 15 treatment bays. If approved, DGLH would be the fifth emergency department in western Wake County. The following EDs are located in DGLH's Zone 1 and Zone 2 Catchment Areas:

**Table 6**
**Existing/Proposed Emergency Departments in DGLH Catchment Areas**

| Facility | Zone | Distance from DGLH Site | |
|---|---|---|---|
| | | Road Miles | Drive-Time (minutes) |
| WakeMed Apex Healthplex | 1 | 4.4 | 9 |
| WakeMed Brier Creek Healthplex | 2 | 15.3 | 16 |
| WakeMed Cary Hospital | 2 | 9.6 | 15 |
| UNC Rex Holly Springs Hospital *(under development)* | 2 | 14.7 | 18 |

Source: Google Maps, www.google.com/map, using shortest road mileages and drive-time options provided

All of these EDs are located within a 20-minute drive from the proposed DGLH location. WakeMed Apex, in particular, is located in DGLH's Zone 1. Approval of another ED in this area would duplicate existing and proposed emergency services, and would have little positive improvement in accessibility. With more patients now choosing less expensive options such as urgent care and telehealth for their emergent health needs, it would be unreasonable to approve another ED provider in this area.

Surgical Services

Western Wake County is already home to one existing acute care hospital, WakeMed Cary, and one approved facility, UNC Rex Holly Springs. Both hospitals currently or will offer inpatient and hospital-based surgical services. The impact of UNC Rex Holly Springs on surgical utilization in western Wake County has yet to be realized.

In addition, several dedicated ambulatory surgical facilities (ASFs) are currently in operation or proposed at locations within 20 minutes' drive of the DGLH site, including:

- Rex Surgery Center of Cary;
- Raleigh Orthopaedic Surgery Center-Panther Creek;
- Holly Springs Surgery Center;
- Triangle Orthopaedics Surgery Center;
- Duke Ambulatory Surgery Center-Arringdon;
- Southpoint Surgery Center (approved); and,
- WakeMed Cary Surgery Center (approved).

Given the presence of 2 acute care hospitals offering surgical services and 7 ASFs already located or under development in western Wake County and southern Durham County, it would be imprudent to continue to add ORs to this region of the county.

**Review Criterion 8**

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

The DGLH application included a number of letters of support for the project from a wide range of physicians and mid-level providers, all employed by Duke Health System. Duke noted on Application pages 56-57 that it has more than 900 providers based in the DGLH Catchment Area, which includes providers located within a 30-minute drive of the DGLH site; this would include most Duke providers based in Durham County. There were no letters of support provided from community-based physicians who are not employed by any health system, suggesting that the medical staff will be closed to non-Duke providers or may not be supported by community-based physicians. Only one additional letter of support was included, from the Town of Cary, which has previously approved the development of the Green Level site.

The application contained no support letters from local community advocacy groups, first-responder organizations, or employers. There is no evidence that groups that could affect the success of the project have indicated their backing of DGLH.

For these reasons, the DGLH project does not conform with Review Criterion 8.

**Review Criterion 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 total capital cost of the DGLH facility is $235 million, or approximately **$5.9 million per licensed bed**. This is the most expensive project proposed for CON approval in recent history. Although Wake County and the surrounding area are slated to experience significant population growth over the next decade, it would appear imprudent to approve such an expensive capital project when previously-approved projects and existing and proposed facilities have yet to open.

According to information provided in Application Section K, the DGLH facility will have 298,960 building gross square feet (BGSF). Line drawings in Exhibit K.1 show that the building will have 256,322 designed gross square feet (DGSF). Analysis of the stacking diagram provided on Exhibit page 291 indicates that 133,500 square feet, or approximately 52 percent of the total DGSF, will be unprogrammed (mechanical, storage, or administrative/support) or shell space. Only 48 percent of the building DGSF is devoted to programmed clinical or support space. See the table below.

**Table 7**
**Duke Green Level Hospital Designed Gross Square Footage (DGSF) by Function**
**Excerpted from Exhibit K.1, Page 291**

| | | | Unprogrammed DGSF | | | | | |
|---|---|---|---|---|---|---|---|---|
| Level | Total DGSF | Programmed Clinical or Support DGSF | Storage | Mechanical | Admin/ Support | Shell | Total | Percent of Total DGSF |
| B1 | 45,300 | 26,800 | 16,000 | 2,500 | 0 | 0 | 18,500 | 41% |
| 1 | 41,896 | 21,896 | 0 | 2,800 | 17,200 | 0 | 20,000 | 48% |
| 2 | 46,526 | 25,526 | 0 | 0 | 21,000 | 0 | 21,000 | 45% |
| 3 | 37,000 | 7,000 | 0 | 0 | 30,000 | 0 | 30,000 | 81% |
| 4 | 21,000 | 0 | 0 | 21,000 | 0 | 0 | 21,000 | 100% |
| 5 | 21,600 | 21,600 | 0 | 0 | 0 | 0 | 0 | 0% |
| 6 | 21,500 | 20,000 | 1,500 | 0 | 0 | 0 | 1,500 | 7% |
| 7 | 21,500 | 0 | 0 | 0 | 0 | 21,500 | 21,500 | 100% |
| Total DGSF | 256,322 | 122,822 | 17,500 | 26,300 | 68,200 | 21,500 | 133,500 | **52%** |

Over one-quarter of DGLH's square footage is listed as "Administrative/Support" space, with other large portions of the building labeled "Mechanical" or "Shell" space. Given the project's significant capital cost and enormous amount of unprogrammed space, the DGLH facility represents an excessive expense that could potentially increase health care costs. Depreciation expenses provided on Application page 178 total over $12 million per year, second-highest only to Salaries.

For these reasons, DGLH does not conform with Review Criterion 12.

**Review Criterion 18a**

*The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost effectiveness, quality and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition would not have a favorable impact.*

Duke's claim that the DGLH project will have a positive impact on competition is not compelling. On Application page 110, Duke makes a single statement in response to Question N.1:

> *The project will promote cost-effectiveness, quality, and access to services and therefore will promote competition in Wake County because it will allow DUHS to create a new point of access for hospital services and <u>to better meet the needs of its existing patient population</u> and to ensure the timely provision of services in a new convenient location.* [emphasis added]

This statement does not demonstrate any tangible effect on competition in Wake County. Missing from Section N is any specific description of how DGLH will improve cost effectiveness, quality and value for acute care services. The DGLH project proposes no new services to Wake County, and will simply duplicate services at existing and approved acute care hospitals in the service area. If anything, the statement is telling because it implies that Duke intends for DGLH to serve only Duke Health System patients and physicians.

For these reasons, the DGLH project does not conform with Review Criterion 18a.

**Summary**

The DGLH application is nonconforming with numerous CON Review Criteria. Because it is nonconforming with these criteria, WakeMed recommends that the Agency deny the application.