REQUIRED STATE AGENCY FINDINGS

FINDINGS
C = Conforming
CA = Conforming as Conditioned
NC = Nonconforming
NA = Not Applicable

Decision Date: July 26, 2021
Findings Date: July 26, 2021

Project Analyst: Mike McKillip
Team Leader: Fatimah Wilson

Project ID #: J-12029-21
Facility: Duke Green Level Hospital
FID #: 210092
County: Wake
Applicant: Duke University Health System, Inc.
Project: Develop a new separately licensed 40-bed hospital by relocating no more than 40 acute care beds and two shared operating rooms from Duke Raleigh Hospital

REVIEW CRITERIA

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

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

C

Duke University Health System, Inc., hereinafter referred to as "DUHS" or "the applicant," proposes to develop a new separately licensed 40-bed hospital by relocating no more than 40 acute care beds and two shared operating rooms from Duke Raleigh Hospital.

Need Determination

The proposed project does not involve the addition of any new health service facility beds, services, or equipment for which there is a need determination in the 2021 State Medical Facilities Plan (SMFP). Therefore, no need determinations are applicable to this review.

Policies

There are two policies in the 2021 SMFP applicable to this review: Policy AC-5: *Replacement of Acute Care Bed Capacity*, and Policy GEN-4: *Energy Efficiency and Sustainability for Health Service Facilities*.

Policy AC-5: *Replacement of Acute Care Bed Capacity*, on page 20 of the 2021 SMFP, states:

> *"Proposals for either partial or total replacement of acute care beds (i.e., construction of new space for existing acute care beds) shall be evaluated against the utilization of the total number of acute care beds in the applicant's hospital in relation to utilization targets found below. For hospitals not designated by the Centers for Medicare & Medicaid Services as Critical Access Hospitals, in determining utilization of acute care beds, only acute care bed days of care shall be counted. For hospitals designated by the Centers for Medicare & Medicaid Services as Critical Access Hospitals, in determining utilization of acute care beds, only acute care bed days of care and swing bed days (i.e., nursing home facility days of care) shall be counted in determining utilization of acute care beds. Any hospital proposing replacement of acute care beds must clearly demonstrate the need for maintaining the acute care bed capacity proposed within the application. Additionally, if the hospital is a Critical Access Hospital and swing bed days are proposed to be counted in determining utilization of acute care beds, the hospital shall also propose to remain a Critical Access Hospital and must demonstrate the need for maintaining the swing bed capacity proposed within the application. If the Critical Access Hospital does not propose to remain a Critical Access Hospital, only acute care bed days of care shall be counted in determining utilization of acute care beds and the hospital must clearly demonstrate the need for maintaining the acute care bed capacity proposed within the application.*

Facility Average Daily Census	***Target Occupancy of Licensed Acute Care Beds***
1-99	*66.7%*
100-200	*71.4%*
Greater than 200	*75.2%"*

Policy AC-5 is applicable to this review because the applicant proposes to construct new space for 40 existing acute care beds. In Section B, page 24, the applicant provides acute care bed days of care for the proposed hospital, Duke Green Level Hospital (DGLH) in the third full fiscal years following project completion, based on the applicant's projections from Section Q, Form C1.b, page 118 of the application, as shown in the table below.

Duke Green Level Hospital	**Operating Year 3**
Days of Care	11,291
Licensed Beds	40
Occupancy Rate	77.3%

As shown in the table above, DGLH, which will have an average daily census of 1-99 patients, is projected to have an occupancy rate of 77.3 percent, which exceeds the applicable utilization target of 66.7 percent, in the third full fiscal year of operation following project completion. Also, in Section Q, page 160 of the application, the applicant projects that Duke Raleigh Hospital, which will have an average daily census of 100-200 patients, is projected to have an occupancy rate of 94.6 percent, which exceeds the applicable utilization target of 71.4 percent, in the third full fiscal year of operation following project completion. Therefore, the application is consistent with Policy AC-5.

Policy GEN-4: *Energy Efficiency and Sustainability for Health Service Facilities*, on page 29 of the 2021 SMFP, states:

> *"Any person proposing a capital expenditure greater than $2 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178 shall include in its certificate of need application a written statement describing the project's plan to assure improved energy efficiency and water conservation.*
>
> *In approving a certificate of need proposing an expenditure greater than $5 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178, Certificate of Need shall impose a condition requiring the applicant to develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. The plan must be consistent with the applicant's representation in the written statement as described in paragraph one of Policy GEN-4.*
>
> *Any person awarded a certificate of need for a project or an exemption from review pursuant to G.S. 131E-184 is required to submit a plan for energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation. The plan must be consistent with the applicant's representation in the written statement as described in paragraph one of Policy GEN-4. The plan shall not adversely affect patient or resident health, safety or infection control."*

The proposed capital expenditure for this project is greater than $5 million. In Section B, page 26, the applicant provides a written statement describing the project's plan to assure improved energy efficiency and water conservation. The applicant states,

> *"DUHS will ensure that DGLH will be developed in physical spaces that are designed to be in compliance with all applicable federal, state, and local building codes, and to meet or exceed requirements for energy efficiency and water conservation, including 2021 SMFP Policy GEN-4. The building codes apply to systems and equipment for electrical power, lighting, heating, ventilating, air condition service, energy management, water heating and water conservation. Water conservation design standards include the use of low-flow toilets throughout the facility. The new physical spaces will be constructed to ensure energy efficiency and cost-effective utilities, including water conservation. Also, DUHS anticipates*

using reclaimed water for irrigation when available from the Town of Cary. DUHS will closely monitor its utility usage and costs (including water utilization) in order to maintain efficient and environmentally responsible energy operations. Please refer to Section K.3.c. for additional details about energy saving features of the project. Subsequent to CON approval of this application, DUHS will submit any required Energy Efficiency and Sustainability Plan to the Agency's Construction Section that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes."

The applicant adequately demonstrates that the application includes a written statement describing the project's plan to assure improved energy efficiency and water conservation. The application is consistent with Policy GEN-4.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

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

- The applicant does not propose to develop any beds, services or equipment for which there is a need determination in the 2021 SMFP.
- The applicant adequately demonstrates the proposal is consistent with Policy AC-5 based on its projections that utilization of the acute care beds at the proposed and existing hospital will exceed the utilization thresholds required by the Policy.
- The applicant adequately demonstrates the proposal is consistent with Policy GEN-4 based on its representations that the project includes a plan for energy efficiency and water conservation.

(2) Repealed effective July 1, 1987.

(3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, … persons [with disabilities], the elderly, and other underserved groups are likely to have access to the services proposed.

C

The applicant proposes to develop a new separately licensed 40-bed hospital by relocating no more than 40 acute care beds and two shared operating rooms from Duke Raleigh Hospital. In Section C.1, page 27, the applicant describes the project as follows:

> *"DUHS proposes to relocate 40 existing licensed acute care beds and two (2) ORs from DRAH in Raleigh and develop a new acute care hospital, Duke Green Level Hospital ("DGLH"), on Green Level W Road in Cary. The proposed new acute care hospital will offer inpatient, emergency, and surgical services. To provide the identified services components, the initial complement of services at DGLH will consist of the following:*

Duke Green Level Hospital

BEDS/EQUIPMENT/SERVICES	***No.***
ICU Beds	*4*
Med/Surg Beds	*36*
Total Licensed Acute Care Beds (sum of total beds above)	***40***
Non-licensed Birthing Rooms (not IP)	*2*
Non-licensed Observation Rooms	*12*
Shared Operating Rooms	*2*
Procedures Rooms	*3*
Emergency Department Exam Rooms	*15*
CT Scanner	*1*
Portable Ultrasound Units	*2*
X-ray Units	*3**
Fluoroscopy Units	*2*
Nuclear Camera	*1*
Interventional Radiology	*1*
Echocardiogram	*1*
Electroencephalograph (EEG)	*1*
Laboratory Services	*Yes*
Pharmacy Services	*Yes*
PT/OT/ST/RT	*Yes*

*The table in Section A.5(f), page 21 of the application, indicates the proposed hospital will include two fixed X-ray units. However, this table in Section C.1, page 27, and the narrative description that follows on page 29, as well as the utilization tables in Section Q (Form C.2b), all indicate the proposed hospital will include three units of X-ray equipment.

Patient Origin

The 2021 SMFP defines the service area for acute care bed services and operating rooms as the planning area in which the acute care beds and operating rooms are located. Thus, the service area for this application is Wake County. Facilities may also serve residents of counties not included in their service area.

DGLH is not an existing hospital and has no historical patient origin. The following tables show the applicant's historical (FY2020) patient origin for the acute care beds and operating rooms at Duke Raleigh Hospital (DRAH).

DRAH FY2020 Acute Care Bed Patient Origin		
County	**Patients**	**% of Total**
Wake	6,039	61.9%
Franklin	511	5.2%
Johnston	330	3.4%
Nash	218	2.2%
Durham	182	1.9%
Cumberland	153	1.6%
Harnett	150	1.5%
Vance	128	1.3%
Pitt	105	1.1%
Wilson	101	1.0%
Virginia	178	1.8%
Other States	105	1.1%
Other NC Counties*	1,559	16.0%
Total	**9,759**	**100.0%**

Source: Table on page 33 of the application
*Applicant states "Other NC Counties" includes counties that represent less than 1 percent of patients.

DRAH FY2020 Operating Room Patient Origin		
County	**Patients**	**% of Total**
Wake	4,835	48.6%
Johnston	436	4.4%
Durham	375	3.8%
Franklin	373	3.8%
Cumberland	282	2.8%
Harnett	228	2.3%
Pitt	213	2.1%
Nash	204	2.1%
Vance	128	1.3%
Wilson	103	1.0%
Virginia	196	2.0%
Other States	108	1.1%
Other NC Counties*	2,463	24.8%
Total	**9,944**	**100.0%**

Source: Table on page 34 of the application
*Applicant states "Other NC Counties" includes counties that represent less than 1 percent of patients.

The following table shows the applicant's projected patient origin for the proposed facility in the first three full fiscal years (FYs) following project completion.

DGLH Projected Patient Origin						
County	OY 1 (SFY2027)		OY 2 (SFY2028)		OY 3 (SFY2029)	
	# Patients	% of Total	# Patients	% of Total	# Patients	% of Total
Wake	9,212	87.4%	13,045	86.9%	18,973	85.8%
Durham	911	8.6%	1,345	9.0%	2,142	9.7%
Chatham	200	1.9%	296	2.0%	544	2.5%
Lee	130	1.2%	198	1.3%	267	1.2%
Orange	83	0.8%	129	0.9%	178	0.8%
Other*	1	0.0%	2	0.0%	4	0.0%
Total	**10,537**	**100.0%**	**15,015**	**100.0%**	**22,108**	**100.0%**

Source: Section C, page 37
*The applicant states, *"Other includes obstetrics patients originating from Harnett and Johnston counties."*

In Section C.3, pages 35-37, the applicant provides the assumptions and methodology used to project patient origin. The applicant's assumptions are reasonable and adequately supported because they are based on the historical utilization of Duke University Health System hospitals (Duke University Hospital, Duke Raleigh Hospital and Duke Regional Hospital) by patients that originated from the proposed service area that would be appropriately treated at DGLH, and the utilization projections for DGLH's proposed services by the population in the applicant's defined service area, as described in the methodology in Section Q of the application, pages 126-156.

Analysis of Need

In Section C.4, pages 38-60, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below:

- The historical and projected population growth and economic development in the Green Level area in south and southwestern Wake County and the need for community-based healthcare services to serve those populations (pages 38-45).
- The benefits of enhanced access to DUHS acute care services in Wake County which the applicant states will enhance patient choice by offering patients another access point for DUHS acute care services in a growing area of Wake County (pages 45-46).
- The applicant states the project will improve coordination with DUHS services because DGLH will be developed on the campus of Duke Health at Green Level, a regional ambulatory care site (pages 46-47).
- The historical and projected population growth and aging in Wake County and the historical DUHS hospital discharges in the identified DGLH catchment area that could be appropriately treated at DGLH (pages 47-58).

The information is reasonable and adequately supported for the following reasons:

- The applicant uses publicly available data to demonstrate the projected population growth and aging in the identified service area.
- The applicant provides maps and data to support its statements about the location of the proposed facility and its proximity to major roads.

- The applicant relies on DUHS's historical hospital utilization by patients residing in the proposed service area for DGLH.

Projected Utilization

In Section Q, Form C, the applicant provides projected utilization for the proposed hospital as shown in the following tables.

DGLH Projected Acute Care Bed Utilization			
	OY 1 (SFY2027)	OY 2 (SFY2028)	OY 3 (SFY2029)
Total Acute Care Beds			
# of Beds	40	40	40
# Discharges	1,277	1,772	2,536
# of Patient Days	5,702	7,905	11,291
Average Length of Stay	4.5	4.5	4.5
Occupancy Rate	39.1%	54.1%	77.3%

DGLH Projected Medical Equipment Utilization			
	OY 1 (SFY2027)	OY 2 (SFY2028)	OY 3 (SFY2029)
CT Scanner			
# of Units	1	1	1
# of Scans	4,579	6,344	9,049
# of HECT Units	5,706	7,905	11,275
X-ray			
# of Units	3	3	3
# of Procedures	4,947	6,853	9,775
Fluoroscopy			
# of Units	2	2	2
# of Procedures	618	856	1,221
Nuclear Medicine			
# of Units	1	1	1
# of Procedures	286	396	565
Ultrasound			
# of Units	2	2	2
# of Procedures	2,120	2,937	4,189
Interventional Radiology			
# of Units	1	1	1
# of Procedures	406	562	801
Echocardiography			
# of Units	1	1	1
# of Procedures	606	840	1,198
EEG			
# of Units	1	1	1
# of Procedures	139	192	274

DGLH Projected Operating Room Utilization			
	OY 1 (SFY2027)	OY 2 (SFY2028)	OY 3 (SFY2029)
Operating Rooms			
Shared Operating Rooms	2	2	2
Total # of ORs – Planning Inventory	2	2	2
# of Inpatient Cases	332	439	585
# of Outpatient Cases	400	814	1,242
Total # Surgical Cases	732	1,253	1,828
Inpatient Case Times	113.8	113.8	113.8
Outpatient Case Times	71.5	71.5	71.5
Inpatient Surgical Hours	630	832	1,110
Outpatient Surgical Hours	477	970	1,480
Total Surgical Hours	1,107	1,802	2,591
Group Assignment	4	4	4
Standard Hours per OR per Year	1,500	1,500	1,500
ORs Needed (total hours / 1,500)	0.7	1.2	1.7
Procedure Rooms	3	3	3
Procedures	105	179	264
DGLH Other Hospital Services Utilization			
	OY 1 (SFY2027)	**OY 2 (SFY2028)**	**OY 3 (SFY2029)**
Emergency Department			
# of Treatment Rooms	15	15	15
# of Visits	8,422	11,810	17,481
Observation Beds			
# of Beds	12	12	12
Days of Care	1,601	2,219	3,169
Laboratory			
Tests	155,464	215,356	307,193
Physical Therapy			
Treatments	6,251	8,660	12,352
Speech Therapy			
Treatments	441	611	872
Occupational Therapy			
Treatments	2,194	3,040	4,336

In Section Q, the applicant provides the assumptions and methodology used to project utilization, which are summarized below.

Projected Acute Care Bed Utilization

<u>DUHS Hospital Discharges:</u> The applicant divided the identified service area ("catchment area") into three zones. See Table Q.1 on page 127 of the application. The applicant states the five ZIP Code areas in Zone 1 are 10 minutes or less driving time from the proposed site, the 13 ZIP Code areas in Zone 2 are 10 to 20 minutes driving time from the proposed

site, and the eight ZIP Code areas in Zone 3 are approximately 30 minutes driving time from the proposed site. The applicant reviewed the historical DUHS hospital discharges from Duke University Hospital (DUH), Duke Raleigh Hospital (DRAH), and Duke Regional Hospital (DRH) for patients in the identified service area from 2017 to 2019 that could be appropriately served at the proposed hospital, as summarized in the table below:

DUHS Discharges Appropriate to Shift to Duke Green Level Hospital, FY2017-FY2019 Summarized by Catchment Area Zone

	FY2017	FY2018	FY2019	CAGR
Zone 1	999	1,063	1,020	1.0%
Zone 2	3,059	3,013	3,181	2.0%
Zone 3	5,669	5,706	5,770	0.9%
Total	**9,727**	**9,782**	**9,971**	**1.2%**

Source: Table Q.2 on page 127 of the application.

In Section Q, page 126, the applicant states,

> *"DUHS reviewed the FY2017-FY2019 inpatient discharges from DUHS facilities that originated from the projected catchment area and that could appropriately be served at Duke Green Level Hospital. First, DUHS excluded any patient discharges that were related to services not planned to be provided at DGLH during the initial operating years, such as open heart surgery, transplant services, inpatient rehabilitation, and inpatient behavioral health, as patients will continue to access those services at DUHS's existing acute care hospitals. DUHS also excluded obstetric patients from historical discharges as this cohort would largely be accommodated by the future DUHS Free Standing Birthing Center (FSBC). 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. This limitation is a very conservative assumption that reflects the anticipated initial utilization and scope of services at a 40-bed community hospital."*

Population Growth Projections: The applicant calculated the projected population growth rate from 2020 to 2025 for each of the three zones identified above. See the tables on page 129. The applicant applied the projected population growth rate for each zone to the 2019 DUHS hospital discharges appropriate for DGLH identified above. See the table on page 130.

Percentage Shifts from Existing DUHS Hospitals: The applicant projects the percentages of hospital discharges from DUH, DRH and DRAH that will shift to DGLH in the first three operating years of the project, as summarized in the following table:

Percent of DUHS Discharges Appropriate to Shift to Duke Green Level Hospital

DRAH			
	FY2027	**FY2028**	**FY2029**
Zone 1	50.0%	60.0%	70.0%
Zone 2	50.0%	60.0%	70.0%
Zone 3	20.0%	25.0%	30.0%
DUH			
	FY2027	**FY2028**	**FY2029**
Zone 1	10.0%	15.0%	17.0%
Zone 2 (Except 27713)	10.0%	11.0%	12.0%
Zone 2: Zip 27713*	3.0%	4.0%	4.0%
Zone 3	0.0%	0.0%	0.0%
DRH			
	FY2027	**FY2028**	**FY2029**
Zone 1	15.0%	17.0%	20.0%
Zone 2	10.0%	11.0%	12.0%
Zone 3	0.0%	0.0%	0.0%

Source: Table Q.6 on page 131 of the application.
*On page 131, the applicant states, *"Note that to be conservative in projecting shift from DUH, DUHS reduced the number of 27713 discharges in Zone 2 projected to shift from DUH to DGLH. Specifically, DUHS applied 1/3 of the Zone 2 shift assumptions to project the number of DUH discharges that will shift from 27713. This assumes 3%, 4%, and 4% of 27713 discharges from DUH will shift to DGLH during initial project years, respectively. Zip code 27713 presents the highest number of DUH discharges appropriate for DGLH in Zone 2 (and the third highest for the DGLH catchment area) and spans a broad geographic range north-to-south with some portions of the zip code potentially closer to DGLH and some closer to DUH; thus, DUHS prudently reduced the shift assumptions for this zip code to more conservatively anticipate patient utilization throughout the DGLH catchment area."*

<u>Projected DGLH from Shifts:</u> The applicant applies the percentages of hospital discharges from DUH, DRH and DRAH that will shift to DGLH to the total projected hospital discharges identified in Step 2 above to project the total hospital discharges from the existing DUHS hospitals that will shift to the proposed hospital in the first three operating years of the project, as summarized in the table below:

Projected DGLH Discharges Based on Volume Shifts from DUHS Hospitals

DRAH			
	FY2027	**FY2028**	**FY2029**
Zone 1	71	87	103
Zone 2	327	398	472
Zone 3	176	223	270
Total	**574**	**708**	**845**
DUH			
	FY2027	**FY2028**	**FY2029**
Zone 1	86	131	151
Zone 2	141	157	174
Zone 3	0	0	0
Total	**227**	**288**	**325**
DRH			
	FY2027	**FY2028**	**FY2029**
Zone 1	25	29	35
Zone 2	39	44	49
Zone 3	0	0	0
Total	**65**	**73**	**83**
DUHS Total	**865**	**1,069**	**1,254**

Source: Table Q.7 on page 132 of the application.

In Section Q, page 132, the applicant states,

> *"DUHS believes the annual projected shifts in patient discharges are reasonable and supported based on several factors. The total shift of 1,257 DUHS discharges to Duke Green Level Hospital during FY2029 is equivalent to 10.9 percent of the total DUHS discharges appropriate to shift to Duke Green Level Hospital (1,257 ÷ 11,560), a small percentage of the total eligible volume. It is reasonable to anticipate a shift in patient utilization patterns based on qualitative several factors, including but not limited to:*
>
> - *Medical privileges for physicians who care for patients in the catchment area as well as other physicians who will seek privileges at Duke Green Level Hospital (see Exhibit I.2 for a letter from Paul Newman, Executive Director, PDC and Duke Health physicians),*
> - *DUHS efforts to decompress capacity constraints in tertiary and quaternary care settings,*
> - *reduced travel burden for patients,*
> - *modern facility design and layout,*
> - *ease of access,*
> - *proximity to complementary outpatient services at Duke Health at Green Level, and*
> - *convenient location for growing catchment area population"*

ED Admissions: The applicant projects additional hospital discharges that originate as admissions through the emergency department. See the tables on page 133. The applicant states,

> *"It is assumed that the projected shift of patient discharges from DUHS facilities implicitly includes patients whose hospitalization originated via the ED. However, the methodology to project DGLH ED visits includes two cohorts of patients: 1) ED visits based on a shift of DRAH patient volume and 2) additional ED visits based on incremental ED service area share gain within the DGLH catchment area due to the presence of a point of access for such services in a growing area. Thus, in addition to the projected inpatient discharges based on shifts from DUHS hospitals, DUHS projects DGLH will experience incremental discharges resulting from hospitalizations associated with incremental ED Service Area Share visits.*
>
> *It is reasonable and appropriate for DUHS to project patient discharges based on patients admitted to DGLH by way of its emergency department. According to the American College of Emergency Physicians (ACEP), approximately 70 percent of hospital inpatients nationwide are processed through the ED. In 2018, inpatient units were the site of disposition of emergency patients in about 17 percent of visits. … Historically, approximately 13 percent of DRAH's ED visits result in an inpatient admission. Likewise, DUHS reasonably anticipates similar utilization patterns at DGLH, although given the projected capacity of DGLH and scope of services, it had conservatively adjusted the admission rate downward, as some patients may be determined to be better served by transfer to a tertiary or quaternary care facility. …. Historically, approximately 13 percent of DRAH's ED visits result in an inpatient admission. Likewise, DUHS reasonably anticipates similar utilization patterns at DGLH, although given the projected capacity of DGLH and scope of services, it had conservatively adjusted the admission rate downward, as some patients may be determined to be better served by transfer to a tertiary or quaternary care facility."*

The applicant projections of the additional hospital discharges that will originate as admissions through the emergency department is summarized in the table below:

DGLH Discharges Based on Hospitalizations from Incremental ED Visits

	FY2027	FY2028	FY2029
ED Visits Based on Incremental Service Area Share	4,922	7,498	12,335
% Hospitalization from ED	8%	9%	10%
Discharges Based on Hospitalizations from Incremental ED Visits	**394**	**675**	**1,233**

Source: Table Q.9 on page 133 of the application.

ALOS and Patient Days: The applicant projects total patient days of care at the proposed hospital based on the historical (FY2019) average length of stay for DUHS hospital discharges considered appropriate for DGLH, which the applicant calculates as 4.5 days. See the tables on page 134 of the application.

ICU Patient Days: The applicant projects total ICU patient days of care at the proposed hospital based on the historical (FY2019) percentage of total patient days provided to ICU patients at DRAH. See the tables on page 135 of the application.

OB Discharges/C-Sections: The applicant projects the number of obstetric discharges and C-section procedures at the proposed hospital based on a projection of the number of patients that will transfer from the freestanding birth center (FSBC) at Green Level. See tables and discussion on pages 136-139. The applicant projects the total number OB discharges and patient days in the first three full fiscal years of operation in the table on page 139, which is summarized below:

DGLH OB Discharges and Days of Care

	FY2027	FY2028	FY2029
OB Discharges	18	28	48
OB ALOS	2.0	2.0	2.0
OB Total Days of Care	**36**	**57**	**96**

Source: Table Q.21 on page 139 of the application.

Total Acute Care Utilization: Based on the projected hospital discharges that will shift from existing DUHS hospitals to DGLH, admissions from the emergency department, and obstetric transfers from the DUHS FSBC at Green Level, the applicant projects the total acute care bed discharges at the proposed hospital through the first three full fiscal years of operation (SFY2027-2029), as summarized in the table below:

Duke Green Level Hospital Acute Care Discharges

	FY2027	FY2028	FY2029
Discharges based on DUHS Shift	865	1,069	1,254
Discharges based on Admissions from Incremental ED Visits	394	675	1,233
OB Discharges	18	28	48
Total Acute Care Discharges	**1,277**	**1,772**	**2,536**

Source: Table Q.23 on page 140 of the application.

Projected utilization for acute care bed utilization is reasonable and adequately supported for the following reasons:

- The applicant's projections of total hospital discharges that will shift from existing DUHS hospitals are supported by the historical utilization of those facilities by patients residing in the proposed service area for the DGLH facility.
- The applicant's projections are based on and supported by its historical experience with regard to its ALOS for acute care bed services and the percentage of patient admissions originating from the hospital's emergency department.
- The applicant's projections are supported by the projected population growth and aging in the Wake County service area.

- Exhibit I.2 contains copies of letters from physicians expressing support for the proposed project and their intention to seek privileges at the proposed hospital.

Projected Observation Bed Utilization

In Section Q, pages 141-142, the applicant projects observation bed utilization at the proposed hospital based on the historical utilization of observation beds (ratio of observation patients to acute care patient days) at DRAH from FY2017 to FY2019. See the tables on pages 141-142. The applicant states,

> *"From FY2017 to FY2019, DRAH encountered 25,083 observation days and 134,031 acute care days, or a ratio of 0.187 observation patients to acute care days. DRAH observation patients had an ALOS of 36 hours. DUHS projects the same ratio for Duke Green Level Hospital based on DRAH's historical experience."*

Projected utilization is reasonable and adequately supported because it is based on the historical utilization experience for the observation beds at DRAH.

Projected Surgical Services Utilization

In Section Q, pages 142-150, the applicant provides the assumptions and methodology used to project surgical services utilization at the proposed hospital, which is summarized below.

Historical surgical utilization at DRAH: The applicant reviewed the historical surgical case volumes at Duke Raleigh Hospital from FY2018 to FY2020. On page 143, the applicant states,

> *"DUHS notes its FY2021 annualized surgical volume may reflect a portion of FY2020 cases that were rescheduled and ultimately performed in FY2021. Therefore, in an abundance of conservatism, DUHS projects surgical utilization using annualized FY2020 data reflective of July 2019 through February 2020 as its baseline."*

Projected surgical utilization at DRAH: Based on the historical surgical case volumes from FY2018 to FY2020, growth and aging of the Wake County population and the applicant's physician recruitment plans, the applicant projects the annual growth rates and projected surgical case volumes for inpatient and outpatient surgical cases at DRAH from FY2021 to FY2029, as shown in the tables on page 143 of the application.

Surgical cases projected to shift to ASCs: The applicant summarized the outpatient surgical cases performed at DRAH that were projected to shift to the previously approved ambulatory surgery centers (ASCs), Arringdon ASC (Project I.D. # J-11508-18) and Green Level ASC (Project I.D. # J-11557-18), as well as the ASC operating rooms that were proposed in applications under review, including Garner ASC (Project I.D. # J-11966-20) and Green Level ASC (Project I.D. # J-11967-20) from FY2024 to FY2029. See the table on page 144 of the application.

Surgical cases at DRAH after the projected to shift to ASCs: Based on the surgical cases volumes projected to shift to Arringdon ASC, Green Level ASC and Garner ASC, the applicant projects the inpatient and outpatient surgical case volumes at DRAH through FY2029. See the table on page 145 of the application.

Projected inpatient surgical cases at DGLH: Based on the inpatient discharges projected to shift from DRAH, DUH and DRH, and the projected emergency department visits at DGLH, and the historical experience at DRAH with regard to the inpatient surgical cases as a ratio of inpatient discharges and emergency department visits, the applicant projects the inpatient surgical cases at DGLH in the first three full fiscal years of operation (FY2027-FY2029), as summarized in the following table, from the applicant's Table Q.32, page 146 of the application:

Duke Green Level Hospital Inpatient Surgery Cases

Acute Care Discharges and ED Visits				IP Surgery Cases			
	FY2027	**FY2028**	**FY2029**		**FY2027**	**FY2028**	**FY2029**
				Ratio Discharges: IP Surgery	27.0%	27.0%	27.0%
Discharge Shift from DRAH	574	708	845	IP Cases based on DRAH Discharge Shift	155	191	228
Discharge Shift from DUH	227	288	325	IP Cases based on DUH Discharge Shift	61	78	88
Discharge Shift from DRH	65	73	83	IP Cases based on DRH Discharge Shift	17	20	23
				Subtotal	234	289	339
				Ratio ED Visits: IP Cases	2%	2%	2%
ED Visits Based on Incremental ED Service Area Share	4,922	7,498	12,335	% IP Cases from Incremental ED Volume	98	150	247
				Total IP Cases	**332**	**439**	**585**

Source: Table Q.32 on page 146 of the application.

In Section Q, page 145, the applicant states,

> *"DUHS projects inpatient surgical cases at DGLH based on the ratio of inpatient discharges and ED visits that are anticipated to include inpatient surgery. First, DUHS reviewed the historical ratio of inpatient surgeries to inpatient discharges and ED visits at DRAH. During FY2019, DRAH performed 3,568 inpatient surgical cases and 9,605 inpatient discharges, or a ratio of 0.37 inpatient surgeries to inpatient discharges. During FY2019, DRAH performed 3,568 inpatient surgical cases and 47,140 ED visits, or a ratio of 0.08 inpatient surgeries to ED visits. As previously described, approximately 80 percent of DRAH's acute care inpatients were comprised of patients with a DRG weight less than or equal to 2.0. Therefore, DUHS determined DRAH is a reasonable proxy on which to project DGLH utilization. In an abundance of conservatism, to project the number of DGLH discharges that will include inpatient surgery, DUHS reduced the ratio of inpatient*

surgeries to inpatient discharges to 0.27 and the ratio of inpatient surgeries to ED admissions to 0.02. DUHS applied this ratio to the projected number of discharges projected to shift from DUHS facilities and ED visits based on incremental DGLH ED Service Area Share, to calculate the projected number of inpatient surgery cases."

Projected outpatient surgical cases at DGLH: The applicant projects the outpatient surgical cases at DRAH that will shift to DGLH in the first three full fiscal years of operation (FY2027-FY2029), as summarized in the following table;

Duke Green Level Hospital Ambulatory Surgery Cases

		FY2027	FY2028	FY2029
DRAH OP Cases		8,004	8,142	8,282
% Shift to DGLH		5%	10%	15%
DGLH OP Cases		**400**	**814**	**1,242**
% Shift from DRAH ORs*	64%	256	521	795
% Shift from DRAH PRs*	34%	144	293	447

Source: Table Q.33 on page 147 of the application.
*On page 147, the applicant states, *"DRAH currently performs ambulatory surgery cases in both ORs and procedure rooms. Thus, DUHS accounted for the surgical cases that will shift from DRAH's ORs and procedure rooms based on the FY2018 & FY2019 weighted average surgical procedures by location (i.e., OR v. procedure room). For example, based on FY2018 and FY2019 data, approximately 64 percent of DRAH's ambulatory surgery cases were performed in ORs and 34 percent of ambulatory surgery cases were performed in procedure rooms. Thus, DUHS projects 64 percent of the identified ambulatory surgery cases will shift from DRAH's ORs and 34 percent of the identified ambulatory surgery cases will shift from DRAH's procedure rooms."*

In Section Q, page 146, the applicant states,

"DUHS projects outpatient surgical cases at DGLH based a shift of patients historical served at DRAH to DGLH. This shift is in addition to the projected shift discussed above of outpatient surgeries to DUHS approved and proposed ASCs. As set forth in the methodologies for those projects, DUHS projected ASC volume based on those cases that were ASC appropriate, and excluded outpatient cases that needed to be performed in a hospital setting due to ASA level of other factors. It is reasonable to anticipate a shift in patient utilization patterns for hospital outpatient surgeries to the new facility based on qualitative several factors, including but not limited to:
• Medical privileges for physicians who care for patients in the catchment area as well as other physicians who will seek privileges at Duke Green Level Hospital (see Exhibit I.2 for a letter from Paul Newman, Executive Director, PDC and Duke Health physicians),
• reduced travel burden for patients,
• modern facility design and layout,
• ease of access, parking, and wayfinding,
• proximity to complementary hospital and outpatient services at Duke Health at Green Level, and
• convenient location for growing catchment area population."

Total projected surgical case volumes at DGLH: The applicant summarizes the total projected inpatient and outpatient surgical cases at DGLH in the first three full fiscal years of operation (FY2027-FY2029), as summarized in the following table:

Duke Green Level Hospital Inpatient and Outpatient Surgery Cases

	FY2027	FY2028	FY2029
Inpatient Cases	332	439	585
Outpatient Cases	400	814	1,242
Total Surgery Cases	**732**	**1,253**	**1,828**

Source: Table Q.34 on page 147 of the application.

Total procedure room volumes at DGLH: Based on the applicant's experience at DRAH, the applicant projects procedure room volumes through the first three operating years of the proposed project, as shown in the table on page 149 of the application. On page 149, the applicant states,

> *"To project utilization for the procedure rooms at DGLH, DUHS reviewed DRAH's historical procedure room utilization for procedures such as cystoscopy and pain management. Historically, DRAH's ratio of procedure room procedures such as cystoscopy and pain management to operating room cases is 0.14. DUHS applied this historical ratio to total operating room cases projected to be performed by Duke Green Level Hospital to determine projected procedure room utilization, as shown in the following table. … Based on its experience operating acute care hospitals, DUHS determined Duke Green Level Hospital needs two procedure room to accommodate the projected non-surgical cases. As described previously in Section C.1, DUHS will develop a third procedure room which will be prioritized for C-sections and other surgical/non-surgical procedures appropriate for labor and delivery/OB-GYN patients."*

Projected surgical services utilization is reasonable and adequately supported for the following reasons:

- The applicant's projections of total surgical case volumes by year at DRAH are supported by the historical growth rates of surgical case volumes at that facility and by projected population growth and aging in the Wake County service area.
- The applicant's projections of total surgical case volumes by year that will shift from DRAH to the proposed DGLH facility are supported by other factors such as patient convenience advantages, including improved geographic access, and the advantages to both physicians and patients of having access to a newer, more modern facility,
- Exhibit I.2 contains copies of letters from physicians and surgeons expressing support for the proposed project and their intention to seek privileges at the proposed hospital.

Projected Emergency Department (ED) Utilization

In Section Q, pages 150-156, the applicant provides the assumptions and methodology used to project emergency department (ED) utilization, which are summarized below.

Population Growth Projections: The applicant identifies the ED service area ("catchment area") and the projected population growth from 2020 to 2029. See the table on page 151.

ED visits based on statewide ED use rate: The applicant projects the total ED visits for the identified service area for the first three operating years of the proposed project (FY2027-FY2029) based on the statewide ED use rate (462 ED visits per 1,000 population) and projected population by ZIP Code Area, and summarized the projected ED visits into three zones within the applicant's proposed service area. See the tables on pages 152 and 153.

Projected DGLH ED volume shifted from DRAH: The applicant identified DRAH ED visits from the DLGH ED service area for FY2019 and projected future ED visit volumes at DRAH based on projected population growth. The applicant summarized the projected DRAH ED visits into three zones within the applicant's proposed service area, as shown in the table below:

Projected DRAH ED Visits by Zip Code
Summarized by DGLH Catchment Area Zone

	FY2027	FY2028	FY2029
Zone 1	806	820	833
Zone 2	4,172	4,234	4,297
Zone 3	5,056	5,119	5,182
Total	**10,035**	**10,173**	**10,313**

Source: Table Q.44 on page 154 of the application.

The applicant applies the percentages of ED visits from DRAH that will shift to DGLH based on three zones within the identified ED service area through first three operating years of the project, which is summarized in the following tables:

Percent of DRAH ED Visits Shift to Duke Green Level Hospital

	FY2027	FY2028	FY2029
Zone 1	50.0%	60.0%	70.0%
Zone 2	50.0%	60.0%	70.0%
Zone 3	20.0%	25.0%	30.0%

Source: Table Q.45 on page 154 of the application.

DRAH ED Visits Shift to Duke Green Level Hospital

	FY2027	FY2028	FY2029
Zone 1	403	492	583
Zone 2	2,086	2,541	3,008
Zone 3	1,011	1,280	1,555
Total	**3,501**	**4,312**	**5,146**

Source: Table Q.46 on page 154 of the application.

On page 154, the applicant states,

> *"DUHS projects ED visits at DGLH based a shift of patients historically served at DRAH to DGLH. It is reasonable to anticipate a shift in patient utilization patterns based on qualitative several factors, including but not limited to:*
> *• geographic access,*
> *• reduced travel burden for patients,*
> *• modern facility design and layout,*
> *• ease of access, parking, and wayfinding,*
> *• proximity to complementary outpatient services at Duke Health at Green Level, and*
> *• convenient location for growing catchment area population.*
>
> *DUHS projects the annual shift of ED visits from DRAH to DGLH will mirror the shift of inpatient discharges during the initial project years."*

ED visits based on incremental service area share: The applicant projects an additional share of ED visits at the proposed hospital from the identified service area, which is summarized in the following tables:

DGLH Incremental ED Visit Share in Catchment Area

	FY2027	FY2028	FY2029
Zone 1	2.0%	3.0%	4.0%
Zone 2	1.0%	1.5%	3.0%
Zone 3	0.5%	0.75%	1.0%

Source: Table Q.48 on page 155 of the application.

DGLH ED Visits Based on Incremental ED Visit Share in Catchment Area

	FY2027	FY2028	FY2029
Zone 1	2,006	3,060	4,149
Zone 2	2,116	3,222	6,544
Zone 3	800	1,215	1,642
Total	**4,922**	**7,498**	**12,335**

Source: Table Q.49 on page 154 of the application.

In Section Q, page 155, the applicant states,

> *"DGLH's estimated ED visit Service Area Share based on the shift of ED volume from DRAH is extremely modest. DUHS reasonably expects the presence of a new acute care hospital and emergency department in western Wake County will result in incremental ED visit service area share gain at DGLH."*

Total ED Utilization: Based on projected ED visits to shift from DRAH and incremental service area ED visits, the applicant projects the ED visits at the proposed hospital through the first three full fiscal years of operation (SFY2027-2029), which is summarized in the following table:

Duke Green Level Hospital Emergency Department Visits

	FY2027	FY2028	FY2029
Volume Shift from DRAH	3,501	4,312	5,146
Incremental ED Visit Service Area Share	4,922	7,498	12,335
Total ED Visits	**8,422**	**11,810**	**17,481**

Source: Table Q.50 on page 156 of the application.

In Section Q, page 156, the applicant states,

> *"The projected emergency department visits are reasonable and achievable based on the shift of ED volume from DRAH and ED visits based on DGLH incremental ED visit Service Area Share. For information purposes, the projected number of catchment area ED visits that will be served at DGLH reflect approximately 3.6 percent of the total catchment area ED visit demand during the third project year (17,481 DGLH ED visits ÷ 486,037 Total Catchment Area ED Visit Demand = .036). The catchment area ED visits that will be served at DGLH and DRAH combined approximates 4.7 percent of the total catchment area ED visit demand during the third project year (17,481 DGLH ED visits + 5,167 DRAH ED visits = 22,648 ED visits ÷ 486,037 Total Catchment Area ED Visits = .047)."*

Projected utilization is reasonable and adequately supported for the following reasons:

- The applicant's projections of total ED visits that will shift from DRAH are based on the statewide ED use rate and supported by the historical utilization of DRAH ED services by patients residing in the proposed service area for the DGLH facility.
- The applicant's projections are supported by the projected population growth and aging in the Wake County service area.

Projected Utilization for All Other Service Components

In Section Q, pages 157-158, the applicant projects utilization at the proposed hospital for imaging and other ancillary services. The applicant projects utilization of the inpatient and outpatient imaging and other ancillary services based on the historical (FY2019) utilization of the services at DRAH. See the tables on pages 157-158 of the application. The applicant states,

> *"A hospital is required to have imaging and other ancillary services to support its projected inpatients, emergency patients, and outpatients utilizing the facility. These services are typically needed to be available immediately onsite for patient care at a hospital with the emergency and inpatient services as proposed in this project regardless of their utilization. To project utilization for imaging and ancillary services, DUHS reviewed DRAH's FY2019 utilization of the respective services. … As described previously, approximately 80 percent of DRAH's annual discharges are comprised of patients with DRG weights less than or equal to 2.0. Thus, DUHS determined DRAH is a reasonable proxy for imaging and ancillary utilization for*

the proposed project. ... For outpatient imaging and ancillary services, DUHS reasonably assumes the DRAH ratio of outpatient procedures to inpatient procedures would be comparable to that of DGLH's patients."

Projected utilization is reasonable and adequately supported because are based on the historical utilization experience of DRAH.

Access

In Section C.6, page 65, the applicant states:

"All individuals including low-income persons, racial and ethnic minorities, women, persons with disabilities, persons 65 and older, Medicare beneficiaries, Medicaid recipients, and other underserved groups, will have access to DGLH, as clinically appropriate. DUHS does not discriminate based on race, ethnicity, age, gender, or disability. Policies to provide access to services by low income, medically indigent, uninsured, or underinsured patients are described and provided in Exhibit C.6. As set forth in the pro formas, a significant proportion of DGLH's proposed services will be provided to Medicare, Medicaid, and uninsured patients."

On page 65, the applicant provides the estimated percentage for the following medically underserved groups at the proposed hospital, as shown in the following table.

Medically Underserved Groups	Estimated Percentage of Total Services in the 3rd Full Year
Low income persons	14.9%
Racial and ethnic minorities	35.8%
Women	51.3%
Persons with disabilities	NA
Persons 65 and over	43.7%
Medicare	43.7%
Medicaid	14.9%

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

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

- The applicant adequately identifies the population to be served.
- The applicant adequately explains why the population to be served needs the services proposed in this application.
- Projected utilization is reasonable and adequately supported.
- The applicant describes the extent to which all residents, including underserved groups, are likely to have access to the proposed services.

(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, … persons [with disabilities], and other underserved groups and the elderly to obtain needed health care.

C

The applicant proposes to develop a new separately licensed 40-bed hospital by relocating no more than 40 acute care beds and two shared operating rooms from Duke Raleigh Hospital.

In Section D.1, page 71, the applicant provides the following table showing the acute care beds and operating rooms at DRAH before and after the proposed relocations.

Facility	Existing Licensed Beds	Existing ORs	Beds Upon Project Completion	ORs Upon Project Completion
Duke Raleigh Hospital	186	15	146	13
Duke Green Level Hospital	0	0	40	2

In Section D, pages 91-92, the applicant explains why it believes the needs of the population presently utilizing the services to be reduced, eliminated, or relocated will be adequately met following completion of the project. The applicant states:

"As described in Section C.4, DUHS proposes to redistribute its CON-regulated assets to enhance accessibility to its acute care services for residents of Wake County and surrounding communities. A portion of DRAH's existing inpatient, surgical, and emergency department volume is anticipated to shift along with the relocated assets. The needs of patients continuing to use DRAH following the relocation of beds and ORs to DGLH will be met. As shown in Form D.1 and D.3, utilization shows that DRAH will have the capacity needed to care for its projected patients after the relocation of capacity and projected shift of patients and to DGLH."

In Section Q, page 159, the applicant provides the projected utilization of the acute care beds at DRAH in the first full three fiscal years of operation of the proposed project, as summarized below:

DRAH Projected Acute Care Bed Utilization			
	OY 1 (SFY2027)	OY 2 (SFY2028)	OY 3 (SFY2029)
Total Acute Care Beds			
# of Beds	146	146	146
# Discharges	10,170	10,159	10,146
# of Patient Days	50,400	50,404	50,399
Occupancy Rate	94.6%	94.6%	94.6%

In Section D.2, page 72, the applicant states,

> *"Regarding surgical services, Form D.3 shows DRAH's equivalent total surgical hours/standard hours per OR per year in FY2029 will be similar to its FY2019 and FY2020 (annualized based on July-February data) experience. Therefore, its relative capacity will remain substantially the same and the surgical needs of the patients continuing to use DRAH will be met following the relocation of 2 ORs to DGLH."*

The applicant provides Form D.3, Historical and Projected OR Utilization for DRAH only through the first full fiscal year of the project (FY2027). However, the applicant includes a projection of surgical cases for Duke Raleigh Hospital for the first three full fiscal years of operation of the proposed project in Section Q, page 148 of the application. Those utilization projections are summarized in the table below.

DRAH Projected Operating Room Utilization			
Operating Rooms	**OY 1 (SFY2027)**	**OY 2 (SFY2028)**	**OY 3 (SFY2029)**
Shared Operating Rooms	13	13	13
Inpatient Surgical Cases	5,063	5,288	5,525
Outpatient Surgical Case	4,866	4,690	4,505
Total Surgical Cases	9,929	9,978	10,030
Inpatient Surgical Case Times*	213	213	213
Outpatient Surgical Case Times*	133	133	133
Inpatient Surgical Hours	17,974	18,772	19,614
Outpatient Surgical Hours	10,786	10,396	9,986
Total Surgical Hours	28,760	29,169	29,600
Group Assignment*	3	3	3
Standard Hours per OR per Year*	1,755	1,755	1,755
Total Surgical Hours/Standard Hours Per OR per Year	16.4	16.6	16.9

*Surgical case times, group assignment and standard hours per OR per year are from the table in Section D.4, page 72 of the application.

This information is reasonable and adequately supported because the applicant's utilization projections for DRAH indicate the facility will continue to have adequate acute care bed and operating room capacity through the first three full fiscal years of operation of the proposed hospital. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.

Access to Medically Underserved Groups

In Section D.3, page 72, the applicant states:

> *"The proposed relocation of acute care beds and operating rooms from DRAH and DGLH will not adversely impact the ability of underserved groups to access care at DRAH or DGLH. In fact, DUHS expects the relocation of beds and ORs from DRAH to DGLH will have a positive impact on the accessibility of healthcare services to patients, including the underserved, by relocating patients it has historically served to a site that is accessible and conveniently located in western Wake County. Please see Section C.4 for a discussion of population growth and aging in the Green Level area.*
>
> *All DUHS facilities provide services to persons in need of medical care including low-income persons, racial and ethnic minorities, women, persons with disabilities, persons 65 and older, Medicare beneficiaries, Medicaid recipients, and other underserved groups. DUHS does not discriminate based on race, ethnicity, age, gender, or disability. Policies to provide access to services by low income, medically indigent, uninsured, or underinsured patients are described and provided in Exhibit C.6 and L.4."*

The applicant adequately demonstrates that the needs of medically underserved groups that will continue to use the acute care beds and operating rooms at DRAH will be adequately met following completion of the project.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the applicant adequately demonstrates that:

- The needs of the population currently using the services to be reduced, eliminated, or relocated will be adequately met following project completion.

- The project will not adversely impact the ability of underserved groups to access these services following project completion.

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

CA

The applicant proposes to develop a new separately licensed 40-bed hospital by relocating no more than 40 acute care beds and two shared operating rooms from Duke Raleigh Hospital.

In Section E.1, pages 75-76, the applicant describes the alternatives considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

Maintain the status quo: The applicant states that maintaining the status quo is less effective because it would fail to expand geographic and timely access to community-based DUHS acute care services in Wake County.
Develop the hospital in another location: The applicant states that developing the hospital in another location is less effective because no other geographic location is superior to the proposed location of Green Level based on population need, growth and access to existing services. Also, the proposed location will allow coordination with other Duke Health services under development.
Develop the hospital with a different number of beds and operating rooms: The applicant states that developing the hospital with a different number of beds and operating rooms is less effective because relocating 40 acute care beds leaves sufficient capacity at DRAH and 40 beds was determined to be adequate to promote operational efficiencies and economies of scale at DGLH. The applicant states the proposed number of beds and operating rooms, as well as the number and type of equipment, and services represent the minimum scope to support the proposed complement of 40 acute care beds.

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

- The applicant provides credible information to explain why it believes the proposed project is the most effective alternative.
- The application is conforming to all statutory and regulatory review criteria.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments

- Responses to comments

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

1. **Duke University Health System, Inc. (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**

2. **The certificate holder shall develop a new separately licensed 40-bed hospital, Duke Green Level Hospital, by relocating no more than 40 acute care beds and two shared operating rooms from Duke Raleigh Hospital.**

3. **Upon completion of the project, Duke Raleigh Hospital shall be licensed for no more than 146 acute care beds and 13 shared operating rooms.**

4. **Progress Reports:**
   a. **Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: https://info.ncdhhs.gov/dhsr/coneed/progressreport.html.**
   b. **The certificate holder shall complete all sections of the Progress Report form.**
   c. **The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.**
   d. **Progress reports shall be due on the first day of every fourth month. The first progress report shall be due on December 1, 2021. The second progress report shall be due on April 1, 2022 and so forth.**

5. **The certificate holder shall not acquire as part of this project any equipment that is not included in the project's proposed capital expenditures in Section Q of the application and that would otherwise require a certificate of need.**

6. **No later than three months after the last day of each of the first three full fiscal years of operation following initiation of the services authorized by this certificate of need, the certificate holder shall submit, on the form provided by the Healthcare Planning and Certificate of Need Section, an annual report containing the:**

   a. **Payor mix for the services authorized in this certificate of need.**
   b. **Utilization of the services authorized in this certificate of need.**
   c. **Revenues and operating costs for the services authorized in this certificate of need.**

d. Average gross revenue per unit of service.
e. Average net revenue per unit of service.
f. Average operating cost per unit of service.

7. The certificate holder shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.

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

C

The applicant proposes to develop a new separately licensed 40-bed hospital by relocating no more than 40 acute care beds and two shared operating rooms from Duke Raleigh Hospital.

Capital and Working Capital Costs

On Form F.1a in Section Q, the applicant projects the total capital cost of the project as shown in the table below.

Site Preparation Costs	$13,600,000
Construction Costs	$161,700,000
Landscaping	$550,000
Architect/Engineering Fees	$15,050,000
Medical Equipment	$36,400,000
Non-Medical Equipment	$5,450,000
Furniture	$2,150,000
Consultant Fees	$50,000
Other (CON filing fee)	$50,000
Total	**$235,000,000**

The applicant provides its assumptions and methodology for projecting capital cost in Section Q and Exhibits F.1 and K.3. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based the information provided in Section F.1, page 77, Section Q, pages 161-162, and referenced exhibits.

In Section F.3, page 79, the applicant projects that start-up costs will be $6,499,325 and initial operating expenses will be $19,613,142, for total working capital of $26,112,467. The applicant adequately demonstrates that the projected working capital needs of the project are based on reasonable and adequately supported assumptions based on the information provided in Section F.3, pages 79-80 of the application.

Availability of Funds

In Section F.2, page 77, the applicant states the capital cost will be funded with accumulated reserves from DUHS. In Section F.3, page 81, the applicant states the working capital costs will also be funded with accumulated reserves from DUHS.

In Exhibit F.2, the applicant provides a letter dated February 11, 2021 from the Senior Vice President, Chief Financial Officer and Treasurer for DUHS stating its commitment of $300 million of its accumulated reserves to fund the capital cost and working capital costs of the proposed project.

Exhibit F.2 also contains a copy of the audited Annual Financial Report for DUHS for the years ending June 30, 2019 and 2020. According to the financial report, as of June 30, 2020, DUHS had adequate accumulated reserves to fund the projected capital and working capital requirements of the proposed project. The applicant adequately demonstrates the availability of sufficient funds for the capital and working capital needs of the project based the information provided in Section F and Exhibit F.2 of the application.

Financial Feasibility

The applicant provides pro forma financial statements for the first three full fiscal years of operation following completion of the project. In Section Q, Form F.2b, the applicant projects that, for the proposed hospital standing alone, operating expenses will exceed revenues in the first three full fiscal years of operation of the proposed hospital following project completion. However, the applicant provides a Form F.2b for the entire DUHS system that projects revenues will exceed operating expenses in the first three full fiscal years of operation of the proposed hospital following project completion, as shown in the table below.

DUHS Projected Revenues and Operating Expenses			
DUHS-System ('000s)	**OY 1 (SFY 2027)**	**OY 2 (SFY 2028)**	**OY 3 (SFY 2029)**
Total Gross Revenue	$16,043,881	$16,495,851	$16,572,540
Total Net Revenue	$4,863,975	$5,000,196	$5,026,891
Total Operating Expenses	$4,638,063	$4,760,057	$4,775,497
Net Income	$225,912	$240,139	$251,394

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q. The applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

- Projected charges and revenues are reasonable and adequately supported.
- Projected operating expenses are reasonable and adequately supported.
- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

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

- The applicant adequately demonstrates that the capital and working capital costs are based on reasonable and adequately supported assumptions.
- The applicant adequately demonstrates availability of sufficient funds for the capital and working capital needs of the proposal.
- The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

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

C

The applicant proposes to develop a new separately licensed 40-bed hospital by relocating no more than 40 acute care beds and two shared operating rooms from Duke Raleigh Hospital.

The 2021 SMFP defines the service area for acute care bed services and operating rooms as the planning area in which the acute care beds and operating rooms are located. Thus, the service area for this application is Wake County. Facilities may also serve residents of counties not included in their service area.

In Section G.1, page 86, the applicant identifies the existing and approved acute care hospitals in Wake County, as summarized in the following table.

Facility Name	Licensed Beds	Days of Care	Inpatient Surgery Cases	Outpatient Surgery Cases	ED Visits
Duke Raleigh Hospital	186	48,394	3,568	7,415	47,140
WakeMed Hospital	567	161,323	8,803	8,149	130,886
WakeMed North Hospital	61	6,976	569	3,127	42,745
WakeMed Cary Hospital	178	48,997	3,859	3,740	46,132
Rex Hospital	439	118,736	9,847	11,942	71,230
Rex Holly Springs Hospital*	0	0	0	0	0

*Currently under development.

In Section G.2, page 87, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved acute care hospitals in the Wake County service area. The applicant states:

> *"This project is for the relocation of existing beds and operating rooms, not for any increase in the inventory. DUHS historical utilization supports the need to develop a new acute care hospital in Western Wake County. As described in Section C.4, DUHS has identified over 9,700 DUHS patient discharges from the DGLH catchment area that could be appropriately served by the proposed hospital.*
>
> *There are no acute care hospitals at all located in Zone 1 of the DGLH catchment area, which is comprised of approximately 200,000 residents. Wake Med Cary, Rex Hospital, and the new Rex Holly Springs Hospital are located in Zone 2 of the DGLH catchment area. WakeMed North is located on the eastern border of Zone 3. Despite the proximity of these facilities to the residents in the catchment area, a significant number of patients are choosing to travel to DUHS facilities to access hospital services provided by physicians who practice there. The need for the proposed project is therefore based on DUHS's identified need to redistribute its existing CON-regulated assets to enhance geographic access to acute care services in Wake County for patients who seek out DUHS's world-renowned healthcare. No other provider can meet these needs. DUHS is expanding access to existing services, not unnecessarily duplicating any other facility… While freestanding ASCs and freestanding emergency departments may exist in western Wake County, they do not offer inpatient services; thus, they are not comparable in scope to the services proposed at DGLH.*
>
> *Patients will greatly benefit from the proposed project. As described previously in Section C, thousands of Wake County patients are currently served at DRAH, DRH, and DUH. Many of these low-acuity admissions that could be accommodated at a community hospital are currently at DUH, adding demands on the system's tertiary and quaternary resources. DUHS expects DGLH will help to alleviate inpatient capacity constraints limiting access and expansion at DUHS facilities and will make optimal use of available acute care bed capacity across the DUHS system. Shifting appropriate patient discharge volume from DUHS facilities to DGLH will improve patient convenience, thus reallocating capacity at DUHS hospital sites. The development of DGLH is a critical component in DUHS's long-term ability to provide patient-centered, accessible care to its population."*

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area for the following reasons:

- The applicant is not proposing to increase the inventory of acute care beds or operating rooms in the Wake County service area.
- The applicant adequately demonstrates that the proposed hospital is needed in the proposed location in addition to the existing or approved hospitals in the service area.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

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

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

C

The applicant proposes to develop a new separately licensed 40-bed hospital by relocating no more than 40 acute care beds and two shared operating rooms from Duke Raleigh Hospital.

In Section Q, Form H, the applicant provides the projected full-time equivalent (FTE) staffing for the proposed services, as shown in the tables on pages 185-188.

The assumptions and methodology used to project staffing are provided in Section Q. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.3, which is found in Section Q. In Section H, pages 89-90, the applicant describes the methods to be used to recruit or fill new positions and its proposed training and continuing education programs. In Exhibits H.2 and H.3, the applicant provides supporting documentation.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services based on the information provided in Section H, pages 89-90, Exhibits H.2 and H.3, and in Section Q, Form H, as described above.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

The applicant proposes to develop a new separately licensed 40-bed hospital by relocating no more than 40 acute care beds and two shared operating rooms from Duke Raleigh Hospital.

Ancillary and Support Services

In Section I.1, the applicant identifies the necessary ancillary and support services for the proposed services. On page 91, the applicant explains how each ancillary and support service will be made available. The applicant states,

> *"Based on its experience operating acute care hospitals, DUHS has determined the previously identified ancillary and support services are necessary to support clinical and operational functions at DGLH.… DGLH will staff an on-site administrator that be responsible for the day-to-day hospital operations. DGLH will also have on-site nurse managers, operational managers, human resources, clinical and clerical support staff. … Additional administrative and operational support services including patient accounting, marketing, credentialing, staff training, information technology, and continuing education will be provided by DUHS as part of its centralized operations support for all its hospital facilities."*

The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on the information provided in Section I.1, pages 91-92, and Exhibit I.1, as described above.

Coordination

In Section I.2, pages 92-93, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit I.2. The applicant states,

> *"DGLH will be part of the Duke University Health System, which includes inpatient acute care, outpatient surgery, psychiatric, and rehabilitation services, primary care, home health, and hospice services in Wake County, Durham County, and surrounding areas. DUHS works closely with the Private Diagnostic Clinic, PLLC, the Duke University School of Medicine faculty practice which provides a full range of specialty physician services across the Triangle. Duke Health primary care, specialty care, and ambulatory surgery will be provided on an adjacent ambulatory*

campus, and this project was developed in consultation with all of those providers to ensure that the proposed services would meet the needs of patients. ... Through specialty program affiliations including the Duke Heart Network, the Duke Cancer Network, and the Duke Telestroke Network, Duke Network Services links community-based specialty programs at hospitals throughout the region with Duke Centers of Excellence."

The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the information provided in Section I.2, pages 92-93, and Exhibit I.2, as described above.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

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

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

NA

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

(10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:

(i) would be available under a contract of at least 5 years duration;

(ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
(iii) would cost no more than if the services were provided by the HMO; and
(iv) would be available in a manner which is administratively feasible to the HMO.

NA

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

(11) Repealed effective July 1, 1987.

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

C

The applicant proposes to develop a new separately licensed 40-bed hospital by relocating no more than 40 acute care beds and two shared operating rooms from Duke Raleigh Hospital.

In Section K.1, page 95, the applicant states that the project involves construction of 298,960 square feet of space for the new hospital. Line drawings are provided in Exhibit K.1.

In Section K.4, pages 97-98, the applicant identifies the proposed site 3208 Green Level W Road in Cary. The applicant states DUHS is the current owner and provides documentation regarding zoning for the site, and the availability of water, sewer and waste disposal and power at the site. Supporting documentation is provided in Exhibit K.3. The site appears to be suitable for the proposed facility based on the applicant's representations and supporting documentation.

In Section K.3, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal based on the information and representations made by the applicant on pages 95-96, and Exhibit K.3.

In Section K.3, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services based on the information and representations made by the applicant on page 96 of the application.

On page 96, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

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

(13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and … persons [with disabilities], which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:

(a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C

In Section L.1, pages 99-100, the applicant did not respond to the question regarding historical payor mix for Duke Raleigh Hospital. However, the applicant reported the payor mix for Duke Raleigh Hospital for FY2020 in the *2021 Hospital License Renewal Application, Section E. Reimbursement Source*, which is summarized in the table below.

Payor Category	Inpatient Days of Care	Emergency Visits	Outpatient Visits	Inpatient Surgical Cases	Ambulatory Surgical Cases
Self-Pay	0.4%	1.2%	0.2%	0.1%	0.1%
Charity Care	11.1%	33.8%	4.8%	5.6%	4.8%
Medicare	61.9%	27.0%	51.8%	57.8%	33.9%
Medicaid	7.3%	14.8%	5.1%	3.0%	3.3%
Insurance	17.7%	21.1%	35.9%	29.3%	51.6%
Other	1.7%	2.1%	2.1%	4.2%	6.2%
Total	100.0%	100.0%	100.0%	100.0%	100.0%

Source: Duke Raleigh Hospital 2021 Hospital License Renewal Application, Section E. Reimbursement Source.

In Section L.1, page 100, the applicant did not respond to the question regarding comparison with the percentages of the population of the service area. However, as indicated in the application form, these percentages can be found online using the US Census Bureau's Quick Facts, as shown in the table below:

	Percentage of the Population of the Wake County Service Area
Female	51.4%
Male	48.6%
Unknown	NA
64 and Younger	88%.0
65 and Older	12.0%
American Indian	0.8%
Asian	7.7%
Black or African-American	21.0%
Native Hawaiian or Pacific Islander	0.1%
White or Caucasian	59.6%
Other Race	10.8%
Declined / Unavailable	NA

*The percentages can be found online using the United States Census Bureau's QuickFacts (https://www.census.gov/quickfacts/fact/table/US/PST045218).

The Agency reviewed the:

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

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

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

C

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 101, the applicant states,

"For information purposes, Duke University Health System hospitals have satisfied the requirements of applicable federal regulations to provide, on an annual basis, a certain amount of uncompensated care in return for Hill Burton funds previously received. Further, they comply with the provisions of section 501(r) of the Internal Revenue Code including provisions requiring a published financial assistance policy, limiting charges to self-pay patients, and periodically conducting a Community Health Needs Assessment. DUHS has no special obligation under applicable Federal regulations to provide uncompensated care, community service, or access by minorities and handicapped persons, other than those obligations which apply to private, not-for-profit, acute care hospitals that participate in the Medicare, Medicaid, VA, TRICARE and Title V programs. ... DUHS does not discriminate based on race, ethnicity, creed, color, sex, age, religion, national origin, handicap, or ability to pay. DUHS will continue to have a robust financial assistance policy to provide all services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, ability to pay, or any other factor that would classify a patient as underserved. DGLH will be available to and accessible by any outpatient, including the medically underserved, having a clinical need for the offered services."

In Section L.2, page 102, the applicant states that during the 18 months immediately preceding the application deadline, two patient civil rights access complaints have been filed against facilities owned by the applicant. The applicant has responded to the request for information from the Department of Justice, Civil Rights Division.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

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

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

C

In Section L.3, page 103, the applicant projects the payor mix during the third full fiscal year of operation (SFY2029) following completion of the project, as illustrated in the following table.

DGLH Projected Payor Mix – SFY2029	
Payor Category	**Entire Facility as Percent of Total**
Self-Pay	7.9%
Medicare*	45.0%
Medicaid*	13.1%
Insurance*	31.8%
Workers Compensation	0.4%
TRICARE	0.6%
Other	1.2%
Total	**100.0%**

*Including any managed care plans.

As shown in the table above, during the third full fiscal year of operation following completion of the project, the applicant projects that 7.9 percent of total services will be provided to self-pay patients, 45 percent to Medicare patients, and 13.1 percent to Medicaid patients.

On page 103, the applicant provides the assumptions and methodology used to project payor mix during the first three years of operation following completion of the project. The projected payor mix is reasonable and adequately supported because the applicant's proposed patient payor mix is based on DUHS's historical experience providing hospital services to the patients from the identified service area at its existing hospitals (DUH, DRH and DRAH).

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L.5, page 107, the applicant adequately describes the range of means by which patients will have access to the proposed services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

The applicant proposes to develop a new separately licensed 40-bed hospital by relocating no more than 40 acute care beds and two shared operating rooms from Duke Raleigh Hospital.

In Section M.1, page 109, the applicant describes the extent to which health professional training programs in the area will have access to the facility for training purposes. The applicant adequately demonstrates that health professional training programs in the area have access to the facility for training purposes based on the information provided in Section M, page 109, as described above.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

(15) Repealed effective July 1, 1987.
(16) Repealed effective July 1, 1987.
(17) Repealed effective July 1, 1987.
(18) Repealed effective July 1, 1987.

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

C

The applicant proposes to develop a new separately licensed 40-bed hospital by relocating no more than 40 acute care beds and two shared operating rooms from Duke Raleigh Hospital.

The 2021 SMFP defines the service area for acute care bed services and operating rooms as the planning area in which the acute care beds and operating rooms are located. Thus, the service area for this application is Wake County. Facilities may also serve residents of counties not included in their service area.

In Section G.1, page 86, the applicant identifies the existing and approved acute care hospitals in Wake County, as summarized in the following table.

Facility Name	Licensed Beds	Days of Care	Inpatient Surgery Cases	Outpatient Surgery Cases	ED Visits
Duke Raleigh Hospital	186	48,394	3,568	7,415	47,140
WakeMed Hospital	567	161,323	8,803	8,149	130,886
WakeMed North Hospital	61	6,976	569	3,127	42,745
WakeMed Cary Hospital	178	48,997	3,859	3,740	46,132
Rex Hospital	439	118,736	9,847	11,942	71,230
Rex Holly Springs Hospital*	0	0	0	0	0

*Currently under development.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 110, the applicant states:

> *"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 to better meet the needs of its existing patient population and to ensure the timely provision of services in a new convenient location."*

Regarding the impact of the proposal on cost effectiveness, in Section N, page 110, the applicant states:

> *"This project will not affect the cost to patients or payors for the services provided by DGLH because reimbursement rates are set by the federal government and commercial insurers. The capital expenditure for this project is necessary to ensure that DUHS will continue to provide high-quality services that are accessible to patients. As described previously, DUHS has identified over 9,700 patient discharges that could appropriately be served at DGLH. DUHS has adequately demonstrated the need the population has for the services proposed. DGLH will add a DUHS second hospital to Wake County, thereby, enhancing access to acute inpatient services in an efficient and accessible location. Many patients will benefit from reduced travel time by receiving care at DGLH which may be close to home or more conveniently located. … Also, DUHS will continue to participate in initiatives aimed at promoting cost-effectiveness and optimizing quality healthcare. For example, Duke Connected Care, the physician-led accountable care organization (ACO) formed by Duke Health to improve health outcomes and address the national challenge of rising healthcare costs, saved Medicare $21.1 million last year. Duke's ACO, which also exceeded evidence-based quality standards, generated the most cost savings among North Carolina ACOs*

> *participating in the Medicare Shared Savings Program, an initiative of the Centers for Medicare & Medicaid Services (CMS). The Duke ACO's participants include the health system and its three existing hospitals, Duke Primary Care, Private Diagnostic Clinic, and independent community providers in a seven-county region around the greater Triangle. Similarly, DGLH will participate in the ACO, as appropriate."*

See also Sections C, F, and Q of the application and any exhibits.

Regarding the impact of the proposal on quality, in Section N, page 111, the applicant states,

> *"DUHS is committed to delivering high-quality care at all of its facilities and will continue to maintain the highest standards and quality of care, consistent with the standards that DUHS has sustained throughout its illustrious history of providing patient care. DUHS has quality-related policies and procedures, and its quality management programs emphasize a customer-oriented perspective that is used to determine the needs of patients, physicians, and others who utilize hospital services."*

See also Sections C and O of the application and any exhibits.

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 111, the applicant states:

> *"As previously stated, DUHS will continue to have a policy to provide services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, ability to pay, or any other factor that would classify a patient as underserved. DUHS's financial assistance policy will apply to the proposed services. By bringing hospital services closer to a growing population, it also makes them more accessible for patients with transportation challenges."*

See also Section C and L of the application and any exhibits.

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would have a positive impact on cost-effectiveness, quality, and access because the applicant adequately demonstrates that:

1) The proposal is cost effective because the applicant adequately demonstrates: a) the need the population to be served has for the proposal; b) that the proposal would not result in an unnecessary duplication of existing and approved health services; and c) that projected revenues and operating costs are reasonable.
2) Quality care would be provided based on the applicant's representations about how it will ensure the quality of the proposed services and DUHS's record of providing quality care in the past.
3) Medically underserved groups will have access to the proposed services based on the applicant's representations about access by medically underserved groups and the projected payor mix.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

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

(19) Repealed effective July 1, 1987.

(20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C

In Section Q, Form O, the applicant identifies hospitals located in North Carolina owned, operated, or managed by the applicant or a related entity. The applicant identified Duke Raleigh Hospital (DRAH), Duke University Hospital (DUH) and Duke Regional Hospital (DRH).

In Section O.4, page 114, the applicant states that during the 18 months immediately preceding the submittal of the application, there were no incidents related to quality of care at DRAH, DUH or DRH. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, during the 18 months immediately preceding submission of the application through the date of this decision, there were no incidents related to quality of care that occurred in any of these facilities. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at both hospitals, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

(21) Repealed effective July 1, 1987.

G.S. 131E-183 (b): The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C

The Criteria and Standards for Computed Tomography Equipment, promulgated in 10A NCAC 14C .2300, are applicable to this review. The application is conforming with those Criteria and Standards. Each of the applicable Criteria and Standards are discussed below.

SECTION .2300 – CRITERIA AND STANDARDS FOR COMPUTED TOMOGRAPHY EQUIPMENT

10A NCAC 14C .2303 PERFORMANCE STANDARDS

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

(1) each fixed or mobile CT scanner to be acquired shall be projected to perform 5,100 HECT units annually in the third year of operation of the proposed equipment;

-C- In Section Q, Form C.2b, page 119 of the application, the applicant projects to perform more than 5,100 HECT units annually in the third year of operation following completion of the project.

(2) each existing fixed or mobile CT scanner which the applicant or a related entity owns a controlling interest in and is located in the applicant's CT service area shall have performed at least 5,100 HECT units in the 12-month period prior to submittal of the application; and

-C- In Section C.7, page 67 of the application, the applicant reports that the four CT scanners located at DRAH performed 51,848 HECT units in FY2020, or 12,962 HECT units per CT scanner. [Note: DRAH reports a fifth CT scanner on its *2021 Hospital License Renewal Application* that is located at Duke Women's Cancer Care in Raleigh. The applicant reported that the CT scanner performed 2,687 CT scans (4,718 HECT units) in FY2020. Therefore, the total HECT units for all five CT scanners would be 56,566, or 11,313 HECT units per CT scanner.]

(3) each existing and approved fixed or mobile CT scanner which the applicant or a related entity owns a controlling interest in and is located in the applicant's CT service area shall be projected to perform 5,100 HECT units annually in the third year of operation of the proposed equipment.

-C- In Section C.7, page 67 of the application, the applicant states, *"The project is not expected to have any negative impact on CT scanner utilization at DRAH. Thus, in a conservative scenario where utilization of the DRAH CT scanners remains flat through FY2029, DUHS satisfies this performance standard."*