Comments on Competing Applications for One Medicare-Certified Home Health Agency in Pitt County

December 1, 2023

Medicare-Certified Home Health Agency Applications

Submitted by

Five Points Healthcare of NC, LLC (Aveanna)

In accordance with N.C. GEN. STAT. § 131E-185(a1)(1), Five Points Healthcare of NC, LLC d/b/a Aveanna Home Health (Aveanna) hereby submits the following comments related to competing applications filed to develop a Medicare-certified home health agency in Pitt County based on the need identified in the *2023 State Medical Facilities Plan* (*SMFP*). Aveanna's comments include "*discussion and argument regarding whether, in light of the material contained in the application and other relevant factual material, the application complies with the relevant review criteria, plans and standards*." *See* N.C. GEN. STAT. § 131E-185(a1)(1)(c).[1] To facilitate the Agency's ease in reviewing these comments, Aveanna has organized its discussion by issue, specifically noting the general Certificate of Need (CON) statutory review criteria and regulations creating the non-conformity relative to each issue, as they relate to competing applications. Aveanna's comments relate to the following applications proposing to develop a Medicare-certified home health agency in New Hanover County. Aveanna's comments relate to the following applications:

- Well Care Home Health of New Hanover County (Well Care), Project ID # Q-12456-23
- BAYADA Home Health (BAYADA), Project ID # Q-12451-23

Given that all three applicants propose to meet the need for additional home health services in Pitt County, only one can be approved. The comments below include substantial issues that Aveanna believes render the competing applications by Well Care and BAYADA non-conforming with applicable statutory criteria and regulatory review criteria.

[1] Aveanna is providing comments consistent with this statute; as such, none of the comments should be interpreted as an amendment to its application filed on October 16, 2023 (Project ID # Q-12445-23).

GENERAL COMMENTS

The *2023 State Medical Facilities Plan (SMFP)* identifies a need for one additional Medicare-certified home health agency in Pitt County based on the application of the home health need methodology. The following section outlines general comments related to the applications for the new Medicare-certified home health agency.

Competition

In addition to Well Care's submission of an application for the Certificate of Need award in Pitt County, the Agency recently awarded Well Care two Certificates of Need for Medicare-certified home health agencies in Brunswick and Forsyth Counties.[2] Well Care is also an applicant for the pending Certificate of Need for a certified home health agency in New Hanover County, where it already has a licensed home health agency, and in Onslow County, a county where it had a 46.5 percent market share in FFY 2021, representing the highest share of any home health provider. Indeed, Well Care's certified home health agencies hold either the highest or second-highest market share in eight counties in southeastern North Carolina, as shown in the following table.

Well Care Southeastern NC Market Share by County

County	***2021 Patients***	***2021 Market Share***	***2021 Market Share Rank***
New Hanover	2,051	33.0%	2
Brunswick	1,506	32.9%	1
Onslow	1,440	46.5%	1
Columbus	893	45.8%	1
Duplin	728	42.1%	1
Pender	715	43.9%	1
Bladen	531	51.1%	1
Sampson	262	18.1%	2

Source: DHSR Chapter 12: Home Health Data by County of Patient Origin – 2021 Data

While Well Care has applied for all five home health need determinations in the *2023 SMFP*, there is no acknowledgement nor discussion of its 2022 Summer Petition[3] to remove all the need determinations in the state. This omission is relevant to the Pitt application because in its petition, Well Care argued quite clearly that the additional need determinations were a threat to its existing home health operations in North Carolina: "As a leading provider in multiple communities across the State, Well Care stands to face an onslaught of proposals from providers seeking entry into areas Well Care currently serves. Accordingly, such prospective new entrants would further increase competition for the precious limited clinical workforce resources available in the market…"[4] Well Care's petition, and subsequent applications for the five need determinations included in the final version of the *2023 SMFP,* are tactics to stifle competition

[2] State Agency Findings, 2023 Brunswick County Home Health Agency Review, July 24, 2023; 2023 Forsyth County Home Health Agency Review, September 20, 2023.

[3] https://info.ncdhhs.gov/dhsr/mfp/pets/2022/summer/L01-WellCare2023SMFPPetition.pdf. See attached Exhibit A.

[4] Well Care petition, page 2.

and limit home health provider choice in the markets it serves. In its petition, Well Care complains that having a relatively high number of need determinations in one year may hinder the ability of existing home health providers to apply for all the assets in the *SMFP*: "[existing providers] may be unable to do so because resources can only be stretched so thin."[5] This is quite plainly contradicts the Findings by the North Carolina General Assembly that government regulation is needed to ensure adequate geographic distribution of services and to ensure equal access for all population groups.[6] Well Care's initial attempt to restrict competition for home health services via its Summer petition was rejected last year; in response, it has shifted tactics by now applying for all the need determinations in the *2023 SMFP*, thereby consolidating its market share and blocking new entrants.

In all of its 2023 home health applications, Well Care has failed to explain why it reversed course less than one year later and now believes it can achieve the hiring and training of additional agency staff that it warned would be in scarce supply due to the "limited clinical workforce resources available in the market."[7] In fact, each of the Well Care applications, including the one for Pitt County, omits any mention of its previous petition. Well Care also fails to provide any justification for its intent to duplicate services in markets already served by existing Well Care Medicare-certified home health agencies, or provide any material changes that occurred since it filed its 2022 petition that claimed an "adjustment" to eliminate the entire list of need determinations for an additional certified home health agency in the *2023 SMFP* was necessary until the SHCC could convene a working group to review the home health need methodology and make recommendations affecting future drafts of the *SMFP*.

In the 2022 Durham-Caswell Acute Care Bed Review (see the attached Exhibit B) the Agency found Duke non-conforming with Criterion 3 as it had previously submitted a summer petition to the SHCC proposing to eliminate or defer the need determination for acute care beds in the service area. Less than a year after submitting the petition to the SHCC to remove the need, Duke did not explain in its application what circumstances, if any, had changed from when it filed the petition to when it applied for the same resources that were not removed from the *SMFP*.

The Agency made the same decision in the 2023 Service Area 20 (Wake-Franklin) LINAC Review (see the attached Exhibit C) when it found Duke non-conforming with Criterion 3. The Agency stated that Duke submitted comments in response to WakeMed's petition for an adjusted need determination for the LINAC stating there was no need for an additional LINAC. According to the Agency, Duke did not provide information in its submitted application explaining what had changed in the eight months between the deadline for comments and the application submission date that prompted it to believe a need existed for LINAC services.

The facts of those two findings are consistent with Well Care's application. Given that Well Care submitted a petition to remove the need for home health agencies in North Carolina and then did not address the circumstances that changed for it to now believe there is additional need for home health agencies, the Well Care application should be found non-conforming with Criterion 3.

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5 Ibid, page 9.

6 North Carolina G.S. § 131E-175(3)

7 Well Care petition, page 2.

1. The Well Care application understates net revenue and hides its actual profitability on Form F.2b.

Well Care claims in its Section Q assumptions on page 150 that "Contractual Adjustments by payor are the difference between gross and net revenue for commercial payors." However, in Form F.2b, the contractual adjustment is more than seven times greater than insurance gross charges in PY1 and PY2 and more than 15 times greater than the insurance gross charges in PY3. Well Care's contractual adjustments are related to Well Care's Medicare charges, as evidenced by the fact that the figure for contractual adjustments exceeds the sum of gross revenues for all payors excluding Medicare each year, as shown below. It is unreasonable to assume that Well Care's contractual allowances are so high as to result in negative net revenue. The following table summarizes the unreasonable figures with negative values for commercial net revenue in each project year based on this assumption:

Well Care Adjustments to Revenue by Project Year

	PY1	*PY2*	*PY3*
Total Gross Revenue	$952,971	$3,258,329	$4,272,319
Gross Revenue Excluding Medicare	$878,557	$354,698	$880,799
Commercial Gross Revenue	$26,958	$129,690	$464,258
Contractual Adjustments	$203,474	$979,846	$1,493,230
Commercial Net Revenue	-$176,516	-$850,156	-$1,028,972

Source: Form F.2b, p. 145

This error is more than a mere misstatement or typographical error; it is clearly an attempt to understate its net revenue, thereby diminishing profitability to compare more favorably with other applicants. According to Form F.2b, Well Care's total net revenue in Project Year 3 is $2,618,830. This amount is lower than the correct figure for Well Care's Medicare patients alone. Using Well Care's stated payments per episode for Medicare patients in Form F.5, it should receive $3,782,420 in reimbursement for Medicare patients, as calculated in the following table:

Well Care Revised Medicare Reimbursement, Project Year 3

Medicare Reimbursement	*Episodes*	*Reimbursement Per Episode*	*Total Reimbursement*
Full Episode without Outlier	1,355	$2,700	$3,658,500
Full Episode with Outlier	31	$3,000	$93,000
Partial Episode Payment (PEP)	2	$1,215	$2,430
Low-Utilization Payment Adjustment (LUPA)	154	$185	$28,490
Total Medicare Net Reimbursement	**1,542**		**$3,782,420**

Source: Well Care application, p. 131, p. 139.

Using only the revised figure for total Medicare reimbursement, Well Care's adjusted net revenue of $3,782,420 in Project Year 3 is more than $1.1 million higher than the total net revenue amount shown in Form F.2b. As such, the most reasonable explanation is that this $3.78 million figure is understated. Applying this corrected figure, Well Care's average net revenue per patient is much

higher and has a corresponding significant impact on Well Care's ranking for this comparative factor. This will be discussed later in the Comparative Factors analysis of these comments.

Well Care Revised Average Net Revenue Per Visit, Project Year 3

Medicare Reimbursement	***Well Care Application***	***Revised***
Total Net Revenue	$2,618,830	$3,782,420**
Total Patient Visits	22,016	22,016
Net Revenue per Patient	$119	$172

** Total Net Revenue for Medicare patients only.
Source: Well Care application, p. 135, p. 137.

Well Care's revenue assumptions are unreasonable and unsupported. As such, the application is non-conforming with N.C. Gen. Stat. § 131E-183(a) (5) and the application should be denied. Further, the Agency should not consider Well Care's revenue projections to be more favorable than Aveanna's in the comparative analysis because of this error.

2. Well Care's expenses are understated by $182,429 in Project Year 3 based on incorrect inflation assumptions.

   Well Care states in its Form F.3 Operating Costs Assumptions that its expenses are "consistent with current experience, [and] inflated 2.5 percent annually."[8] However, Well Care applies its same base year assumptions in Project Year 1 (2025), two years later, without accounting for the annual inflation occurring in 2024 and 2025. Well Care does not begin applying the 2.5 percent inflation rate until Project Years 2 and 3. This results in understated operating costs for multiple categories, and a Project Year 3 total operating cost that is $182,000 less than the correct amount. Additionally, Well Care misstates its rental expense; its Form F.3 Assumptions state that rent is $24,000 per year, while in Exhibit K.4 the lease terms agreement with the landlord states the base rental amount is $28,620 per year. Well Care also fails to include annual inflation during the interim years for this operating expense item. These understated expense categories are summarized in the following table, with the corrected figures for Project Year 3:

[8] Well Care application, p. 144.

Well Care Total Operating Cost Recalculation – Project Year 3

	Well Care Application	*Revised*
Net Revenue	**$2,618,830**	**$3,782,420****
Total Salaries (from Form H)	$1,709,281	$1,813,376
Taxes and Benefits	$347,326	$417,077
Travel Expense	$47,418	$48,603
Training	$5,043	$5,298
Medical Supplies	$82,981	$85,055
Office Supplies (including postage)	$3,782	$3,974
Rent	$30,069	$31,591
Utilities	$3,782	$3,974
Telephone	$16,740	$18,478
Maintenance	$1,839	$1,932
Insurance	$4,413	$4,636
Contracted Services (1)	$8,825	$9,934
Central Office Overhead	$78,565	$78,565
Equipment Depreciation	$5,000	$5,000
Other	$20,000	$20,000
Total Expense	**$2,365,064**	**$2,547,493**
Net Income	**$253,766**	**$1,234,927**

** Total Net Revenue for Medicare patients only.
Source: Well Care Application Form F.3b.

As shown in the table above, total operating costs on Form F.3b are understated by $182,429 based on Forms F.2 and F.3. Well Care also understates net revenue on Form F.2. These incorrect assumptions result in a $981,161 variance in net income. Although the Well Care application projects to be financially feasible, its financial projections are not adequately supported by its assumptions, nor does the proposed project apply reasonable assumptions for costs and contractual deductions.

Accordingly, the Well Care application should be found non-conforming with N.C. Gen. Stat. § 131E-183(a) (5) and the application should be denied. Further, the Agency should not consider Well Care's expense projections to be more favorable than Aveanna's in the comparative analysis because of this error.

1. <u>BAYADA's market share projections are unreasonable and include patient volume already allotted to existing home health providers in Pitt County.</u>

BAYADA uses unreasonably aggressive assumptions for projecting the number of patients it will serve from Pitt County. In BAYADA's Form C methodology, it assumes it will capture 95 percent of the need deficit for home health patients in Pitt County in the first project year, without incorporating a reasonable ramp up in volume. This assumption occurs despite BAYADA not currently serving Pitt County patients nor patients in any of the other seven counties it expects to serve through the proposed agency. BAYADA will need to establish referral relationships with physicians and referring institutions that it currently has no experience working with. It is unclear how this represents a conservative projection for the first project year, as BAYADA contends.[9]

BAYADA compounds this unreasonable methodology in its market share calculations. In Project Year 1, BAYADA calculates its market share at 13.71 percent, which represents its share of the total projected home health patients in Pitt County in 2024:

County	Projected FY2024 Home Health Patients	Home Health Patients Captured	FY2026 Market Share
Pitt	3,868	530	13.71%

Calculation: (Home Health Patients Captured / Projected FY2024 Home Health Patients) X 100

Source: BAYADA application, Form C Assumptions, Step 3.

A market share of 13.71 percent is reasonable because it represents patients that are not currently served by another provider. However, BAYADA errs in its subsequent assumption that it will capture an additional 75 percent of this initial market share in Project Year 2, and again in Project Year 3. This results in market share increases of 10.28 percent in both Project Years 2 and 3, with a resulting market share of 34.26 percent in Project Year 3.

Step 4. Projected FY2026 through FY2028 Home Health Market Share and Patients

BAYADA projects that its capture rate in Pitt County will increase in FY2027 and FY2028 by 75.0 percent of the FY2026 market share or by 10.28%, annually.

Year	FY2026	FY2027	FY2028	75% of FY2026 Market Share
Market Share	13.71%	23.99%	34.26%	10.28%

Calculation: Market Share Growth = FY2026 Market Share x 75%
Projected Market Share = Previous Year's Market Share + Market Share Growth

Source: BAYADA application, Form C Assumptions, Step 4.

BAYADA provides no justification for this unrestricted growth in market share, despite the obvious facts that in the second project year it will have effectively captured the need deficit it calculated

[9] BAYADA application, Form C Assumptions, Step 3.

in Pitt County, and that to grow market share it will be necessary to shift volume away from existing providers. BAYADA assumes its proposed Pitt agency will draw 1,397 patients from Pitt County in Project Year 3 (FFY 2028), nearly triple the *2023 SMFP* need deficit of 558 home health patients. Even if the need deficit in Pitt County continues to grow, as modeled in the following table, BAYADA will need to acquire 263 additional patients that are being served by existing home health agencies to meet its volume target.

BAYADA Pitt County Patient Projections, PY1 – PY3

	FFY 2025	*FFY 2026*	*FFY 2027*	*FFY 2028*
Pitt Patient Need Deficit**	**717**	**864**	**1,003**	**1,134**
BAYADA Patients		544	965	1,397
BAYADA Patients Above Deficit		-320	-38	263

** Need deficit calculated in future years using *2023 SMFP* methodology.

In addition, BAYADA's market share is unreasonable when compared with its historical experience in other North Carolina markets. BAYADA's in-county market shares for its existing locations are as follows:

BAYADA Market Share for Existing Locations

Location	*In-County Agencies*	*BAYADA In-County Patients*	*Patients Served by Other BAYADA Locations*	*Total BAYADA Patients*	*Total County Patients*	*BAYADA Market Share*
Scotland	1	314	-	314	723	43.4%
Person	2	238	-	238	1,024	23.2%
Rowan	4	486	1	487	3,875	12.6%
Davidson	5	753	7	760	3,889	19.5%
Cabarrus	2	475	406	881	4,031	21.9%
Cumberland	5	521	-	521	6,179	8.4%
Gaston	5	326	-	326	7,591	4.3%
Forsyth	10	1,403	18	1,421	10,422	13.6%
Guilford	8	1,694	302	1,996	11,593	17.2%
Mecklenburg	14	2,181	10	2,191	17,635	12.4%
Wake	16	2,043	1	2,044	18,897	10.8%

Source: DHSR Chapter 12: Home Health Data by County of Patient Origin – 2022 Data

As shown above, BAYADA's largest market shares are in Scotland County at 43.4 percent and Person County at 23.2 percent, a full 11 percent less than what it projects to serve in Pitt County. Notably, these two counties are the smallest markets and have roughly one-fourth the home health patient volume of Pitt County. BAYADA's market share in Cabarrus County includes two BAYADA locations serving the county: a Cabarrus County agency and a Mecklenburg County agency. Further, Scotland, Person, and Cabarrus counties have the least in-county competition of any of BAYADA's existing locations. Pitt County will most closely resemble Rowan and Davidson counties. These counties have four or five in-county agencies and serve a similar number of

patients. BAYADA's market shares of 12.6 in Rowan County and 19.5 percent in Davidson County do not support its Pitt County market share projection of 34.3 percent. Based on the market shares in North Carolina counties where BAYADA operates, a projected market share of 34.3 percent for Pitt County is overstated and unsupported.

BAYADA has not demonstrated that the population that would be served by its proposed Pitt agency has a need for this service and is non-conforming with N.C. Gen. Stat. § 131E-183(a) (3).

BAYADA does not demonstrate that patients from Pitt County have need for home health services by its proposed Pitt agency. BAYADA also fails to describe the impact on competition that will result from its capture of patients and market share from existing home health providers serving Pitt County. Accordingly, the BAYADA application should be found non-conforming with N.C. Gen. Stat. § 131E-183(a) (3), (5), (6) and (18a), as well as the performance standards for home health services, and the application should be denied.

2. BAYADA's visit projections are unreasonable and unsupported.

In addition to its Pitt County application, BAYADA applied for home health agencies in Brunswick and New Hanover counties earlier in 2023. The number of visits per unduplicated patient for Pitt County is extremely high and unreasonable when compared to its previous applications.

BAYADA Visits per Unduplicated Patient Comparison

	Brunswick	***New Hanover***	***Pitt***
Unduplicated Patients	1,041	507	1,491
Visits	22,935	8,178	38,938
Visits per Unduplicated Patient	22.0	16.1	26.1

Source: Project ID # O-012324-23 and Project ID # O-12404-23, Methodology

BAYADA utilized internal data to project visits for all three applications. As shown in the table below, the number of visits per episode for the Pitt County application far exceeds the visits per episode utilized in the previous applications, despite deriving its assumptions from a purportedly consistent internal data source for all three applications.

BAYADA Visits per Episode Comparison

Payor Category	***Brunswick***	***New Hanover***	***Pitt***
Medicare Full w/o Outliers	14.4	12.5	14.0
Medicare Full w Outliers	7.2	15.7	28.0
Medicare - PEPs	5.0	0.0	11.0
Medicare-LUPAs	10.1	8.4	5.0
Medicaid	7.4	10.0	18.0
Insurance	13.6	11.3	19.0
Indigent	3.6	5.0	15.0
Self	3.6	0.0	15.0

Source: Project ID # O-012324-23 and Project ID # O-12404-23, Methodology, Step 9 or 10

Further, BAYADA fails to demonstrate why it is appropriate to use a statewide North Carolina average in its Pitt application, especially given the various sizes of its North Carolina agencies and its use of data limited to a specific agency in other recent applications.

BAYADA will likely respond that it utilized different assumptions for the three applications (Rowan County, Guilford County, and all North Carolina). However, given that Rowan and Guilford data would be included in the North Carolina data and these two counties represent roughly 25 percent of BAYADA's North Carolina patients, it is unlikely that they would differ this significantly from BAYADA's other agencies in North Carolina, and BAYADA's assumptions remain unreasonable and unsupported.

BAYADA does not demonstrate that its visit per episode assumptions are reasonable or supported and should be found non-conforming with N.C. Gen. Stat. § 131E-183(a) (3).

COMPARATIVE ANALYSIS FOR CERTIFIED HOME HEALTH AGENCY

The Aveanna - Pitt (Project ID # Q-12445-23), BAYADA (Project ID # Q-12451-23), and Well Care (Project ID # Q-12456-23) applications all propose to develop an additional Medicare-certified home health agency in response to the *2023 SMFP* need determination for Pitt County. Given that all three applicants propose to meet the need for Pitt County, only one can be approved. To determine the comparative factors that are applicable in this review, Aveanna examined recent Agency findings for competitive home health reviews. The Agency completed similar reviews of competing applications for home health agencies in Brunswick and Forsyth counties in 2023. Based upon these analyses and the facts and circumstances of the competing applications in this review, Aveanna believes the following comparative factors will be helpful to the Agency in its review:

- Conformity with Review Criteria
- Competition (Patient Access to a New Provider)
- Access by Service Area Residents
- Access by Underserved Groups
  - Duplicated Medicare Patients
  - Unduplicated Medicaid Patients
- Average Number of Visits per Unduplicated Patient
- Projected Average Net Revenue per Visit
- Projected Average Net Revenue per Unduplicated Patient
- Projected Average Operating Expense per Visit
- Ratio of Net Revenue per Visit to Total Operating Expense per Visit
- Salaries for Clinical Staff

Aveanna believes that the factors presented above and discussed in turn below should be used by the Project Analyst in reviewing the competing applications.

Conformity with Review Criteria
As noted above, the Well Care application is non-conforming with Criterion 5 and others, while the BAYADA application is non-conforming with Criteria 3, 5, 6, 18a, and others. The Aveanna-Pitt application conforms with all review criteria.

Competition
Aveanna, BAYADA, and Well Care are all providers that neither operate home health agencies in Pitt County nor serve Pitt County patients requiring home health services from agencies in contiguous counties. However, there are other factors the Agency should consider in terms of competition.

As previously stated, Well Care filed a summer petition to remove the need for all home health agencies in the 2023 SMFP. Despite this petition, Well Care has submitted applications for all five home health reviews and has been approved in both competitive reviews completed by the Agency as of this date. Well Care should be found non-conforming just as the two Duke applications with similar facts were deemed non-conforming, as previously discussed.

In addition, while all three applicants are existing providers of home health services in North Carolina, they vary greatly in scale. As shown in the table below, Aveanna will have between one and three home health agencies in North Carolina, Well Care will have between seven and 10 home health agencies in North

Carolina, and BAYADA will operate between 11 and 14. BAYADA and Well Care are home health providers with a more widespread presence in North Carolina, while Aveanna represents a provider that competes in fewer markets. The application filed by Aveanna best enhances competition in the service area as well as the state as a whole.

Existing and Proposed Certified Home Health Agencies by Applicant

Agency	***Home County***	***Agency Type***
Aveanna		
Aveanna Home Health	Cumberland	Existing
Aveanna Home Health	New Hanover	Proposed
Aveanna Home Health	Pitt	Proposed
Total Aveanna		*1 Existing, 2 Proposed*
BAYADA		
BAYADA Home Health Care	Cabarrus	Existing
BAYADA Home Health Care	Cumberland	Existing
BAYADA Home Health Care	Davidson	Existing
BAYADA Home Health Care	Forsyth	Existing
BAYADA Home Health Care	Gaston	Existing
BAYADA Home Health Care	Guilford	Existing
BAYADA Home Health Care	Mecklenburg	Existing
BAYADA Home Health Care	Person	Existing
BAYADA Home Health Care	Rowan	Existing
BAYADA Home Health Care	Scotland	Existing
BAYADA Home Health Care	Wake	Existing
BAYADA Home Health Care	New Hanover	Proposed
BAYADA Home Health Care	Onslow	Proposed
BAYADA Home Health Care	Pitt	Proposed
Total BAYADA		*11 Existing, 3 Proposed*
Well Care		
Well Care Home Health of the Piedmont	Mecklenburg	Existing
Well Care Home Health, Inc.	New Hanover	Existing
Well Care Home Health of the Triad, Inc.	Davie	Existing
Well Care Home Health of the Triangle, Inc.	Wake	Existing
Well Care Home Health of the Southern Triangle, Inc.	Wake	Existing
Well Care Home Health of Brunswick	Brunswick	Approved
Well Care Home Health of Forsyth County	Forsyth	Approved
Well Care Home Health of New Hanover	New Hanover	Proposed
Well Care Home Health of Onslow	Onslow	Proposed
Well Care Home Health of Pitt	Pitt	Proposed
Total Well Care		*5 Existing, 2 Approved, 3 Proposed*

Access by Service Area Residents

Aveanna projects that it will serve 1,036 patients from Pitt County in Project Year 3, representing 73.6 percent of all unduplicated patients. BAYADA states that it will serve 1,397 Pitt County patients, or 93.7 percent of all unduplicated patients. Well Care projects it will serve 672 unduplicated Pitt County patients, or 65.0 percent of all unduplicated patients. Based on these figures, BAYADA is the most effective applicant for this factor, while Aveanna is more effective. However, the BAYADA application is non-conforming with Criterion 3 due to methodological flaws that result in overstated and unsupported volume. For this reason, the BAYADA application cannot be approved, and the Aveanna application is most effective for this factor.

Access by Service Area Residents – Project Year 3

Rank	*Applicant*	*Pitt County Residents Served*	*Total Unduplicated Patients*	*% of Patients from Pitt County*
1	BAYADA	1,397	1,491	93.7%
2	Aveanna - Pitt	1,036	1,407	73.6%
3	Well Care	672	1,034	65.0%

Source: Form C Methodologies and Assumptions of the respective applications.

Access by Underserved Groups

Projected Medicare – The following table compares access by Medicare patients in Project Year 3 for the three applicants. BAYADA has a higher volume of duplicated Medicare patients and percentage of Medicare patients as a percentage of total unduplicated patients, while Aveanna ranks second for both the number of unduplicated Medicare patients and percentage of total unduplicated patients. However, as described earlier, BAYADA's methodology includes market share assumptions that are unreasonable and unsupported. For this reason, the BAYADA application is non-conforming and is not approvable. Therefore, Aveanna is the most effective applicant for this factor.

Projected Access by Medicare Recipients – Project Year 3

Rank	*Applicant*	*Duplicated Medicare Patients*	*Total Duplicated Patients*	*Duplicated Medicare Patients as a % of Total*
1	BAYADA	2,526	2,726	92%
2	Aveanna - Pitt	1,791	2,375	75%
3	Well Care	1,028	1,270	81%

Source: Form C.5 and Form C Methodology Assumptions of the respective applications.

Projected Medicaid – The following table compares access by Medicaid patients in Project Year 3 for all three applicants. Aveanna has the highest total number of unduplicated Medicaid patients and has the highest percentage of Medicaid patients (payor mix percentage). Aveanna is therefore the most effective applicant for this factor.

Projected Access by Medicaid Recipients – Project Year 3

Rank	*Applicant*	*Unduplicated Medicaid Patients*	*Total Unduplicated Patients*	*Unduplicated Medicaid Patients as a % of Total*
1	Aveanna - Pitt	172	1,407	12.2%
2	BAYADA	149	1,491	10.0%
3	Well Care	124	1,034	12.0%

Source: Form C.5 of the respective applications.

Average Number of Visits per Unduplicated Patient

The following table shows the average number of visits per unduplicated patient in Year 3 for the respective applications. The Agency has historically reasoned that because Medicare reimburses home health providers on a per episode rather than a per visit basis, a higher visit total per patient is indicative of higher quality care.[10]

Average Visits per Unduplicated Patient – Project Year 3

Rank	*Applicant*	*Total Unduplicated Patients*	*Total Visits*	*Average # of Visits per Unduplicated Patient*
1	BAYADA	1,491	38,938	26.1
2	Aveanna - Pitt	1,407	32,787	23.3
3	Well Care	1,034	22,016	21.3

Source: Form C.5 of the respective applications.

Although Aveanna ranks second for the average number of visits per unduplicated patient, the BAYADA application is non-conforming with at least Criterion 3 as its visits are unreasonable and unsupported, and thus is not approvable. Therefore, Aveanna is the most effective applicant for this factor.

Average Net Revenue per Patient Visit

The following table shows the projected average revenue per patient visit in the third year of operation based on the information provided in each applicant's pro forma financial statements (Forms C and F.2). The Agency has previously favored applicants with a lower revenue per visit as evidence of greater financial accessibility for patients and insurers.[11]

As noted in the specific comments on the Well Care application, Well Care has inappropriately applied a contractual deduction to its Medicare reimbursement per episode. This results in lower net revenue and a corresponding decrease in the average net revenue per visit. Applying the revised Total Net Revenue of $3,782,420, representing the amount of Medicare net revenue that Well Care would receive according to Form F.5 of its application, results in the following comparison ranking.

[10] See 2021 Mecklenburg County Home Health Agency Review Findings, p. 91.

[11] See 2021 Mecklenburg County Home Health Agency Review Findings, p. 92.

Average Net Revenue per Patient Visit – Project Year 3

Rank	*Applicant*	*Total Net Revenue*	*Total Visits*	*Average Net Revenue per Visit*
1	Aveanna - Pitt	$4,240,458	32,787	$129
2	BAYADA	$5,258,854	38,938	$135
3	Well Care	$3,782,420	22,016	$172

Source: Forms C.5 and Form F.2b of the respective applications.

Aveanna projects the lowest average net revenue per visit of the three applicants, while Well Care has the highest average net revenue per visit. Furthermore, Aveanna is the only applicant that is conforming with the review criteria. Aveanna is therefore the most effective applicant for this factor.

Average Net Revenue per Unduplicated Patient

The following table shows the projected net revenue per unduplicated patient in the third year of operation based on the information provided in each applicant's pro forma financial statements (Forms C and F.2).

As noted in the specific comments on the Well Care application, Well Care has inappropriately applied a contractual deduction to its Medicare reimbursement per episode. This results in lower net revenue and a corresponding decrease in the average net revenue per visit. Applying the revised Total Net Revenue of $3,782,420, representing the amount of Medicare net revenue that Well Care would receive according to Form F.5 of its application, results in the following comparison ranking.

Average Net Revenue per Unduplicated Patient – Project Year 3

Rank	*Applicant*	*Total Net Revenue*	*Total Unduplicated Patients*	*Average Net Revenue per Unduplicated Patient*
1	Aveanna - Pitt	$4,240,458	1,407	$3,014
2	BAYADA	$5,258,854	1,491	$3,527
3	Well Care	$3,782,420	1,034	$3,658

Source: Forms C.5 and Form F.2b of the respective applications.

Aveanna projects the lowest average net revenue per unduplicated patient of the three applicants, while Well Care has the highest average net revenue per visit. Furthermore, Aveanna is the only applicant that is conforming with the review criteria. Aveanna is therefore the most effective applicant for this factor.

Projected Average Operating Expense per Visit

The following table shows the projected average operating expense per patient visit in the third year of operation for each of the applicants, based on the information provided in applicants' pro forma financial statements (Forms C and F.3). The Agency has included this comparative factor in previous competitive reviews, stating that a lower average operating expense per visit may "indicate a lower cost to the patient or third-party payor or a more cost-effective service."[12]

[12] See 2021 Mecklenburg County Home Health Agency Review Findings, p. 93.

Well Care's operating expenses in project year 3 have been revised to reflect its incorrect assumption regarding annual inflation increases. Well Care's average operating expense is $116 per visit when this correction is included.

Average Operating Expense per Patient Visit – Project Year 3

Rank	*Applicant*	*Total Operating Expenses*	*Total Visits*	*Average Operating Expense per Visit*
1	Well Care	$2,547,493	22,016	$116
2	Aveanna - Pitt	$4,078,334	32,787	$124
3	BAYADA	$5,129,552	38,938	$132

Source: Forms C.5 and Form F.3b of the respective applications.

BAYADA projects the highest average operating expense per visit of the three applicants, while Well Care has the lowest average operating expense per visit. However, Aveanna is the only applicant that is conforming with the review criteria and that has a reasonable methodology for projecting patient visits. Aveanna has the second-lowest average expense per visit of the three applicants and is the only conforming applicant; thus, it is the most effective applicant for this factor.

Ratio of Average Net Revenue per Visit to Average Total Operating Expense per Visit

Generally, the application proposing the lowest ratio is the more effective alternative for this comparative factor. The ratios for each applicant were calculated by dividing the average net revenue per visit in the third full fiscal year of operation by the average total operating expense per visit. The ratio must be equal to or greater than 1.0 for the proposal to be financially feasible. The ratios are shown in the following table:

Ratio of Average Net Revenue/Visit to Average Total Operating Expense/Visit – Project Year 3

Rank	*Applicant*	*Average Net Revenue per Visit*	*Average Operating Expense per Visit*	*Ratio*
1	BAYADA	$135	$132	1.03
2	Aveanna - Pitt	$129	$124	1.04
3	Well Care**	$172	$116	1.48

** Well Care averages are calculated using corrected Total Net Revenue and Total Operating Expenses, as explained earlier in the comments.

BAYADA and Aveanna are essentially tied for the lowest ratio of net revenue per visit to average expense per visit. However, Aveanna has a lower average net revenue per visit and lower average operating expense per visit than BAYADA. In addition, BAYADA has unreasonable utilization projections that result in an understated ratio. Aveanna is the only conforming applicant and is thus the most effective applicant for this factor.

Nursing and Home Health Aide Salaries

The Agency has stated that applicants with relatively higher annual salaries are more effective alternatives, as this can promote employee retention and an increased ability to attract job candidates.[13] The tables below compare the proposed annual salary for registered nurses, licensed practical nurses, and home health aides in the first year of operation, as reported by the applicants in Form H of their respective

[13] See 2017 Mecklenburg County Home Health Agency Findings, p. 49.

applications. Using the Project Year 1 figure eliminates any discrepancies in assumptions about inflation, job promotion, employee turnover, etc. The applicants are listed in the tables below in decreasing order.

Average Annual Base Salaries by Position – Project Year 1

Rank	*Applicant*	*Registered Nurse*
1	BAYADA	$111,824
2	Aveanna - Pitt	$110,125
3	Well Care	$108,726

Rank	*Applicant*	*Licensed Practical Nurse*
1	Well Care	$71,843
2	Aveanna - Pitt	$70,232
3	BAYADA	$69,566

Rank	*Applicant*	*Home Health Aide*
1	Aveanna - Pitt	$55,062
2	BAYADA	$48,026
3	Well Care	$46,987

Source: Form H of the respective applications.

There is variability in the rankings by position type. Aveanna has the highest average salary for home health aides, and the second-highest salaries for RNs and LPNs. BAYADA has the highest average salary for RNs, the second-highest salary for home health aides and the lowest salary for LPNs. Well Care has the highest average LPN salary and the lowest salary for both RNs and Home Health Aides. Taken together, Aveanna has the best average rank score for the three positions ((1 + 2 + 2) ÷ 3 = 1.67; BAYADA's average rank is 2.0 and Well Care's is 2.33). For these reasons, Aveanna is the most effective applicant for this factor.

Summary of Comparative Analysis

The following table summarizes the comparative analysis for the Pitt County Medicare-certified home health agency applications:

Comparative Factor	*Aveanna*	*BAYADA*	*Well Care*
Conformity with Review Criteria	Conforming	Non-Conforming	Non-Conforming
Competition (Access to a New Provider)	Most Effective	Less Effective	Less Effective
Access by Service Area Residents	More Effective	Non-Conforming	Less Effective
Access by Underserved Groups – Duplicated Medicare Patients	More Effective	Non-Conforming	Less Effective
Access by Underserved Groups – Duplicated Medicare Patients as % of Total Duplicated Patients	Effective	Non-Conforming	Non-Conforming
Access by Underserved Groups – Unduplicated Medicaid Patients	Most Effective	Non-Conforming	Less Effective
Access by Underserved Groups – Unduplicated Medicaid Patients as % of Total Unduplicated Patients	Most Effective	Non-Conforming	Less Effective

Average Number of Visits per Unduplicated Patient	More Effective	Non-Conforming	Less Effective
Projected Average Net Revenue per Visit	Most Effective	Non-Conforming	Less Effective
Projected Average Net Revenue per Unduplicated Patient	Most Effective	Non-Conforming	Less Effective
Projected Average Operating Expense per Visit	More Effective	Less Effective	Non-Conforming
Ratio of Net Rev/Visit to Avg. Operating Expense/Visit	More Effective	Non-Conforming	Less Effective
Base Salaries for Nurses and Home Health Aides	Most Effective	Non-Conforming	Less Effective

SUMMARY

Aveanna believes that its application is the most effective alternative for the unmet need for home health services in Pitt County. Aveanna's application is also the only application that fully conforms with all applicable statutory and regulatory review criteria. If the Agency should find the other two applications to be conforming, Aveanna compares favorably on the historical comparative factors for home health reviews. Aveanna is the most effective applicant for six criteria. BAYADA is most effective for three, while Well Care is most effective for one criterion. As such, the Agency should approve Aveanna's proposal.

Exhibit A

Petition for An Adjustment to Eliminate the 2023 SMFP Home Health Agency Need Determinations and Call for Further Study of the Data & Methodology

Via E-Mail Only: DHSR.SMFP.Petitions-Comments@dhhs.nc.gov

The following Petition is submitted on behalf of Well Care Health by its Chief Executive Officer:

Name:	Zac Long, JD, MHA, Chief Executive Officer Well Care Health, LLC ("Well Care" or "Petitioner")
Address:	8025 Creedmoor Road, Suite 200, Raleigh, NC 27613
Email Address:	zlong@wellcarehealth.com
Phone Number:	919-846-1018 x321

Background

With approximately 35 years of operating experience, Well Care Health ("Well Care") is a family-owned and operated home-based care provider that serves more than 50 counties in North Carolina. As a patient-centered and mission-driven organization, Well Care has grown from seven to over 1,000 team members and expanded our care delivery model to offer a full spectrum of home-based care services, including home health, private duty nursing, personal care services, and hospice home care.

Today, Well Care proudly serves patients from seven licensed Home Care offices, six Medicare-certified home health branches, and a Medicare-certified Hospice Home Care center.

Well Care operates the following Medicare-certified home health agencies in North Carolina:

• Well Care Home Health of the Triangle, Inc.	HC0074	Wake
• Well Care Home Health of the Southern Triangle, Inc.	HC5229	Wake
• Well Care Home Health, Inc.	HC1231	New Hanover
• Well Care Home Health of the Triad, Inc.	HC0496	Davie
• Well Care Home Health of the Piedmont, Inc.	HC5130	Mecklenburg

Through operating these home health agencies across North Carolina, Well Care has built deep experience as a provider of industry-leading home health patient care. In fact, Well Care today cares for a home health patient census of more than 3,800 patients and has been consistently recognized by CMS as a 5-star rated home health provider in quality of patient care, which corresponds nationally with the top 4-5% of providers nationally.

Well Care is a strong supporter of the SMFP process and the state's Certificate of Need regulations which provide critical safeguards that ensure quality and access, while avoiding costly duplication of services. Well Care applauds the work of the Healthcare Planning staff in developing and presenting the information in support of each Chapter of the annual SMFP.

Historically, Well Care has responded in multiple instances to SMFP Need Determinations as an applicant for CON approvals for new agencies in various Counties of our State. As examples:

- In 2017, Well Care was approved to develop a new agency in Mecklenburg County in a competitive review involving three applicants; Well Care's approval was challenged by a denied applicant, requiring Well Care to expend significant resources in successfully defending the Agency approval in a multi-week contested case hearing.

- In 2019, Well Care was approved to develop its second home health agency in Wake County
- in 2021, Well Care applied in a field of five applicants vying for another Mecklenburg County agency but was not approved.

Statement of Requested Change / Citation to Need Determination(s)

Well Care petitions the State Health Coordinating Council to remove the announced Home Health Need Determinations from Chapter 12 of the 2023 State Medical Facilities Plan ("SMFP") and, instead establish a working group to study the methodology for determining home health needs in our State.

Well Care respects the overarching healthcare planning process which both generates proposed Need Determinations based on a standard methodology, while also empowers SHCC with the authority and responsibility to make adjustments to such need determinations when special or extraordinary circumstances are present. **Due to the plainly anomalous and inconsistent nature of the 12 Proposed 2023 Need Determinations and considering the clear foreseeable adverse impacts that such Need Determinations would have on the state's home health provider community and continuity of patient care across North Carolina, Well Care requests an adjustment to remove the Proposed 2023 need determinations and the establishment of a workgroup to examine and revise the home health need methodology to ensure a workable methodology governs future need determinations**. In light of the issues and concerns identified by Well Care and the broader home health industry (as expressed in AHHC's prior public hearing comments) and the urgent need for modernization of the methodology, Well Care believes that a workgroup can update the home health need methodology to help ensure the methodology can be relied upon to consistently produce reliable projections of the need for new home health agencies in our State.

Moreover, the 2023 SMFP's extraordinary and unprecedented proposal of Need Determinations for 12 home health agencies would foreseeably have profound impacts on Well Care, its staff, and the patients it serves, as well as similarly situated home health providers across the state. As a leading provider in multiple communities across the State, Well Care stands to face an onslaught of proposals from providers seeking entry into areas Well Care currently serves. Accordingly, such prospective new entrants would further increase competition for the precious limited clinical workforce resources available in the market, in the context of a worsening clinical workforce shortage across North Carolina. Conversely, the Need Determinations would offer a myriad of opportunities for Well Care to apply for CON approvals and potentially expand its operations in North Carolina.

Reasons for the Proposed Change

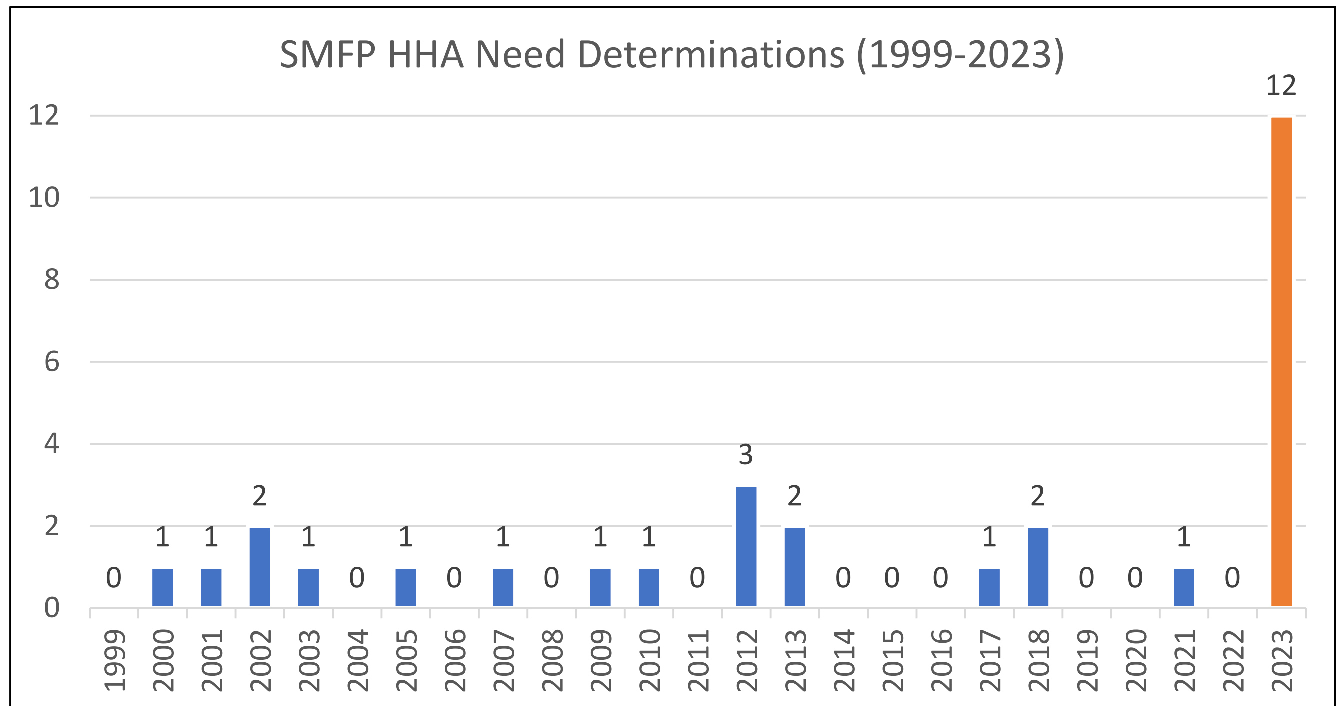
Earlier this year, the 2023 Proposed SMFP was released, revealing for a surprising and unprecedented showing of Need Determinations for 12 additional Medicare-Certified Home Health Agencies or Offices in locations throughout North Carolina.

Well Care respectfully requests (a) an adjustment to remove the 12 Need Determinations in Chapter 12 of the 2023 Proposed SMFP for Home Health Agencies; and (b) the creation of a working group to update and modernize the home health methodology. The requested adjustment is justified and necessary because the result of 12 Need Determinations is extraordinary, unprecedented, inconsistent with SMFP Need Determinations for similar healthcare services

(including those for Hospice Home Care offices), a by-product of a years-old and unique methodology, and risks substantial disruption for health care providers and continuity of patient care in North Carolina.

1. *The Proposed 2023 Need Determinations are Unprecedented and Extraordinary*

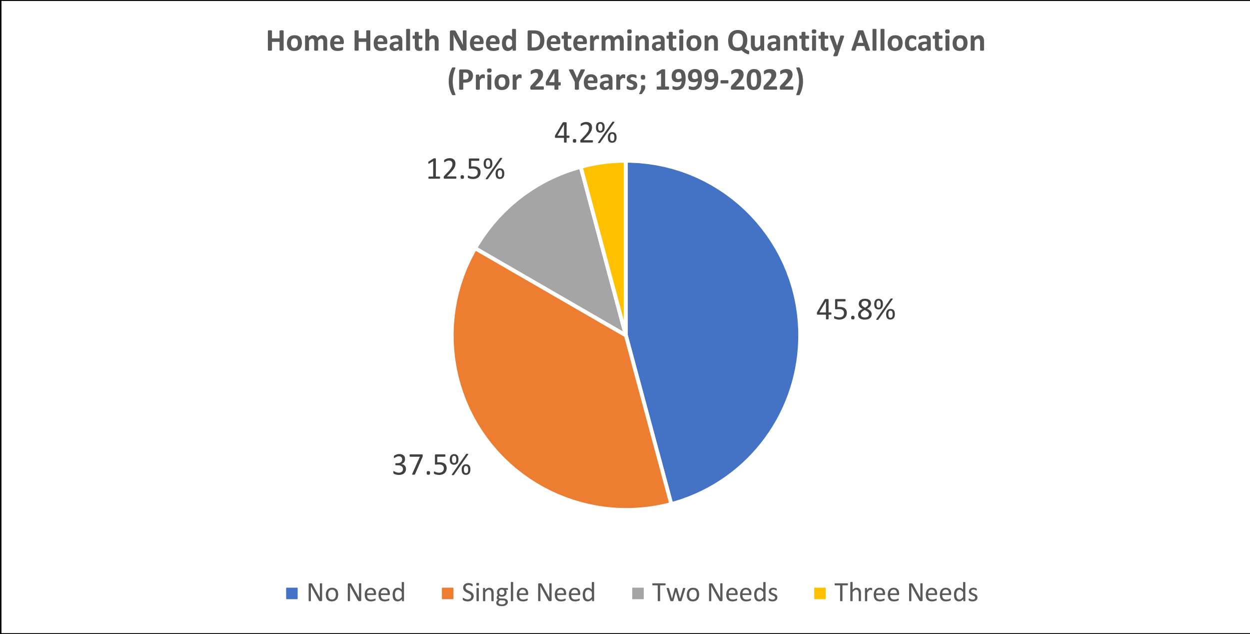
To compare the 12 HHA Need Determinations in the 2023 Proposed SMFP to prior years, Petitioner accessed the HHA Need Determinations from every SMFP from 1999 through 2023, as is summarized in the following table:



Source: Public SMFP Data
**Proposed 2023 Home Health Need Determination in Orange*

This striking historical backdrop illuminates the extent to which this proposed result is anomalous, unprecedented, inconsistent, and extraordinary – especially given the following key insights:

- The 12 proposed HHA need determinations in 2023 is equivalent to the total HHA need determinations found over the **prior 16 years combined**
- The 12 proposed HHA need determinations in 2023 is equivalent to **four times** the prior annual record (3) for need determinations during this time period
- The 12 proposed HHA need determinations in 2023 is equivalent to **sixteen times** the average annual need determinations (0.75) found during this time period
- From 1999 to 2022, each SMFP has shown either 0, 1, or 2 HHA Need Determinations, except one year (2012) in which 3 HHA Need Determinations were identified
- The most recent plan year (2022) produced **zero** Need Determinations, while the prior 5 years produced a total of **3** Need Determinations.



Source: Public SMFP Data

The yearly Need Determination allocation further supports the incongruent and concerning nature of the 12 Proposed 2023 Home Health Need Determinations – especially given the following key insights from the prior 24 year time period:

- In **more than 83%** (83.3%) of plan years, **one or fewer** need determinations were found
- In **nearly 96%** (95.6%) of plan years, **two or fewer** need determinations were found
- In **only one year** (2012) did the SMFP show a need for **more than two** new home health agencies
- In **no plan years** were more than 3 need determinations found

As shown, the 12 Proposed 2023 Home Health Need Determinations do not present an incremental increase or relatively high number of Need Determinations, it represents a highly anomalous departure from historical home health planning outcomes. The striking magnitude of this extraordinary departure and inconsistency clearly signals that some type of material abnormality has occurred, and hence this result deserves heightened scrutiny by SHCC.

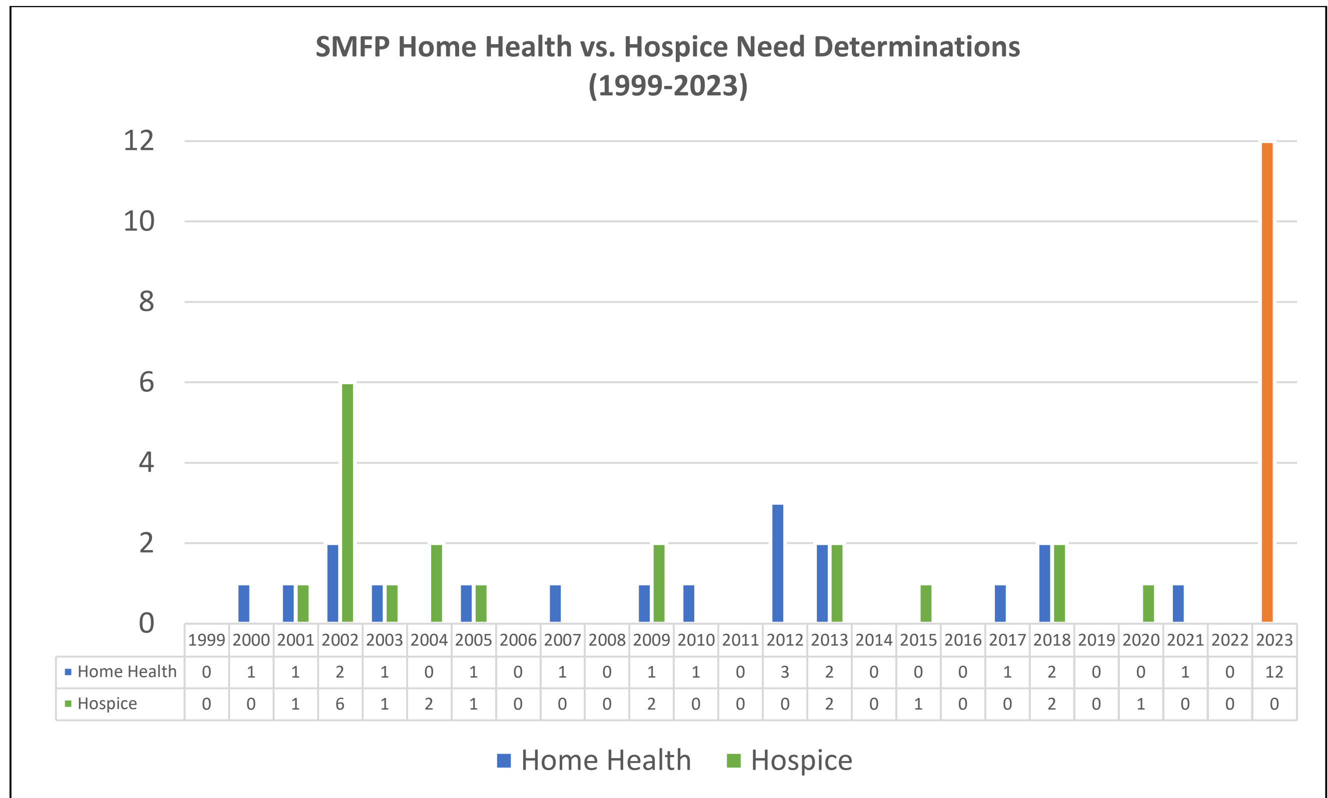
2. *The Proposed 2023 Home Health Need Determinations are Incongruent and Inconsistent with Historical SMFP Need Determinations for Related Healthcare Services*

The 12 Proposed Home Health Need Determinations in the 2023 SMFP are not only extreme and inconsistent with historical home health need determinations, but also glaringly incongruent with the SMFP's need determinations for similar healthcare services, particularly for new hospice home care offices.

Home Health and Hospice Home Care are in many ways adjacent "sister" service offerings, as both are Medicare-certified home care services and involve health care professionals delivering care in patient residences to meet their health care needs. Home health and hospice home care

serve similar patient profiles (largely Medicare-aged patients), and regularly work closely together in coordinating patient care. While needs for home health and hospice are based on distinct methodologies, the respective methodologies are applied to same the geographic area and are based on similar principles of service use rate, population data, and growth trends.

To compare the historical Home Health Need Determinations with the Need Determinations for Hospice Home Care offices, Petitioner accessed the Need Determinations for both services from every SMFP from 1999 through 2023.

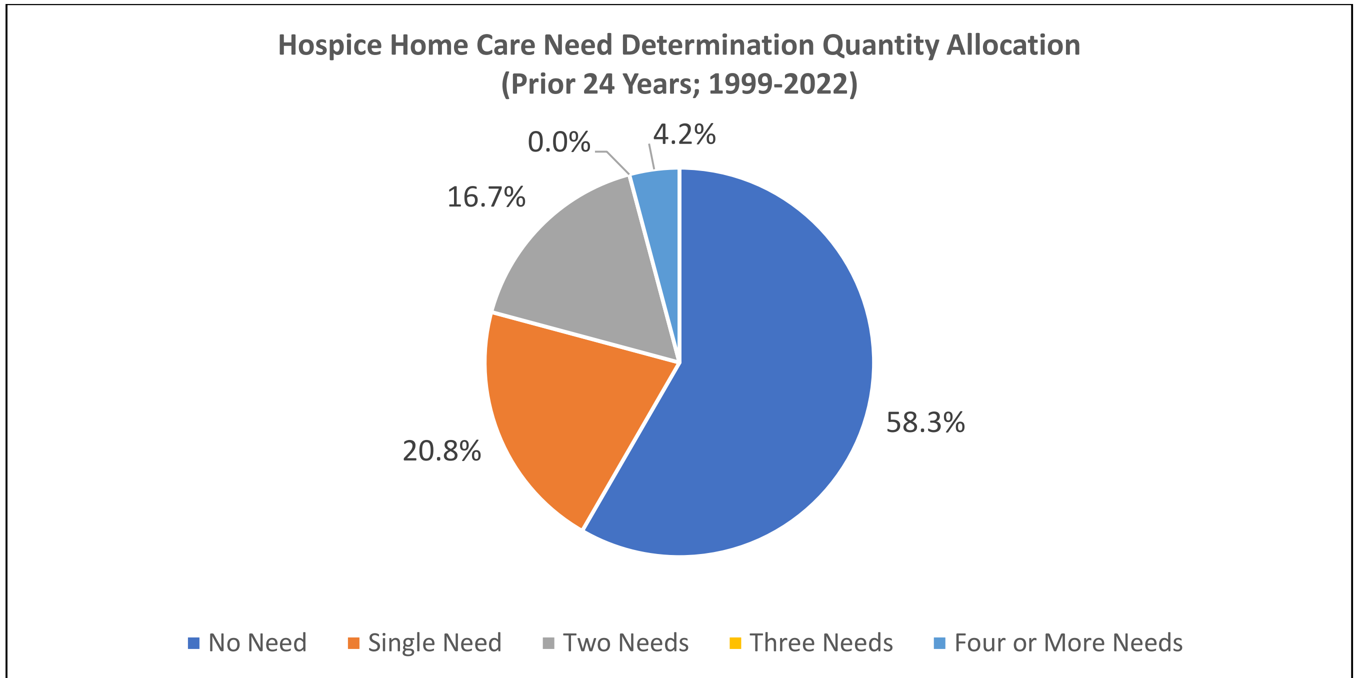


Source: Public SMFP Data
**Proposed 2023 Home Health Need Determination in Orange*

As shown above, over the years, the home health and hospice methodologies have historically produced quantitatively similar Need Determinations. Several key takeaways emerge from this analysis with respect to the prior 24 year time period of 1999-2022:

- The SMFP has established **a nearly identical total number of Need Determinations** for Home Health (18) and Hospice Home Care (19)
- The SMFP has produced a **tightly aligned annual average number of Need Determinations** for Home Health (0.75) and Hospice Home Care (0.79)
- The 12 proposed HHA need determinations in 2023 is equivalent to the total need determinations found for **both Home Health and Hospice combined over the prior 10 years**
- The average annual need determinations found for Hospice Home Care was 0.79, meaning that the 12 proposed HHA need determinations in 2023 is equivalent to **more than 15 (15.15) times this average annual need determination**

- The **three most recent plan years** (2020, 2021, 2022) produced **zero** need determinations for Hospice Home Care
- The Need Determination in every year but one has shown a need for 0, 1, 2 or 3 for both home health and hospice agencies.
- In all but three years (2002, 2004, and 2012), there has been a discrepancy between Hospice Home Care and Home Health need determinations of one or less.



Source: Public SMFP Data

As shown in the graph above, historical Hospice Home Care and Home Health need determination results are highly aligned and similar.

- In **almost 80%** (79.2%) of plan years, one or fewer need determinations were found for Hospice Home Care
- In **nearly 96%** (95.8%) of plan years, two or fewer need determinations were found for Hospice Home Care
- In **only one year** (2002) did the SMFP show a need for more than two Hospice Home Care agencies
- In **no plan years** were more than 6 need determinations for Hospice Home Care found, and that result was from twenty years ago (2002).

Assessing this comparative Home Health and Hospice Home Care data clearly shows the striking inconsistency and incongruency of the Proposed 2023 Home Health Need Determinations. This extraordinary result is especially concerning given that Home Health and Hospice Home Care are similar service offerings in the core patient demographics served, in addition to sharing the same geographic area and corresponding population characteristics and trends.

Particularly perplexing also is that the 2023 Proposed SMFP shows **no** Need Determinations for hospice home care offices anywhere in the State. This result is in sharp contrast to the 2023 Proposed SMFP's 12 HHA Need Determinations and a dramatic departure from the decades of

relatively aligned results in which the two methodologies generated comparable Need Determinations.

Furthermore, looking beyond Hospice Home Care to other healthcare services governed under the SMFP, the 2023 Proposed SMFP Need Determinations for 12 new home health agencies is similarly markedly inconsistent with the Need Determinations for numerous other healthcare services. Home health agencies in North Carolina serve a high percentage of senior age patients and patients with chronic conditions such as diabetes and heart disease, a patient demographic often associated with nursing home and hospital level care settings. Yet the 2023 Proposed SMFP does **not** identify unusually high Need Determinations for hospital (acute care) beds **nor** for long-term care (nursing home or adult care home) beds.

For these methodologies to be effectively working in tandem, if the home health methodology produced 12 Need Determinations, one would expect to see at least some correlated spike in the need for hospital or nursing home beds, hospice home care agencies, and other health care services. To the contrary, the 2023 Proposed SMFP does **not** incorporate any out-of-ordinary Need Determinations for these related service offerings. In fact, the 2023 Proposed SMFP shows **no** need for new nursing home beds or hospice home care agencies anywhere in the State.

3. *The HHA Need Methodology is Antiquated, Inconsistent with the Need Methodologies in place for Similar Healthcare Services, and in Urgent Need of Modernization*

Having now been in place many years, the HHA Need Methodology has become outdated and antiquated, as well as inconsistent with methodologies used to evaluate need for similar health services. The use of "Council of Governments" or COG data is an especially arcane feature of the HHA methodology. North Carolina COGs were established by the General Assembly in 1972 as an avenue for local governments across the state to collaborate regionally around issues affecting their region. North Carolina's 16 regional COGs focus on areas such as state programs, economic development, geographic information systems (GIS) planning, grants, and other services. While COGs may have been born for the purposes of county and municipal government collaboration, it is difficult to understand its value or relevance to **county-specific** healthcare planning for home health services. In fact, **no other service category methodology in the SMFP Long-Term Care Section relies on use rates for COG regions**.

Also concerning is the potential disconnect between use of regional COG territories in identifying county-based healthcare planning need determinations. The home health methodology identifies need by County but nonetheless relies on the historical utilization trends by COG region. The methodology, as written, incorporates an inherent inconsistency between planning on a County-by-County basis and use of data from broader COG regions.

For these reasons, Well Care supports the recent public hearing comments made by the Association for Home & Hospice Care of North Carolina (AHHC of NC) expressing concern about the current home health methodology and the urgent need for a workgroup to be formed to modernize the methodology.

Well Care acknowledges that three (3) of the 12 need determinations are based on Criterion 1 or Criterion 2 of the HHA methodology, *i.e.*, Edgecombe, Granville, and Montgomery counties. The Proposed 2023 SMFP is the first year that the provisions of Policy HH-3 have been incorporated into the HHA methodology. Well Care believes that it is responsible and appropriate to defer these Need Determinations based on Criterion 1 or Criterion 2 of the HHA methodology until the efforts of a SHCC methodology workgroup are complete. Until this process is completed, Edgecombe,

Granville, and Montgomery counties would continue to be served by a substantial pool of existing home health agencies. According to Chapter 12: Home Health Data by County of Patient Origin - 2021 Data:

- Edgecombe County is served by 13 individual home health agencies
- Granville County is served by 17 individual home health agencies
- Montgomery County is served by 9 individual home health agencies

Especially in light of the extraordinary Proposed 2023 Home Health Need Determinations and the substantial public policy implications for the state's home health provider community, pausing to thoughtfully and carefully evaluate the HHA methodology is timely, appropriate, and responsible.

4. *Approving the Anomalous 2023 HHA Need Determinations Would Deal a Significant Blow to North Carolina's Home Health Provider Community During a Period of Unprecedented Change and Challenge*

Unquestioningly accepting the 12 Proposed HHA Need Determinations, thereby likely opening North Carolina to a tsunami of additional HHAs collectively poses real and substantial public policy concerns that would directly impact patient care continuity. For Home Health providers in North Carolina and across the country, far and away, the primary constraint on service capabilities and growth is a worsening supply shortage in clinical workforce. In fact, North Carolina is one of the most severely impacted states nation-wide in workforce shortages, which was recently highlighted by WRAL article that reported **more than <u>2,500 nurse openings</u> in Research Triangle-area hospitals alone**.[1] This pressing clinical workforce shortage impacts providers across the care continuum, including Home Health providers, leading to intense competition for clinical staff, ongoing staffing shortages, and increased reliance on travel nurses (when available).

Proceeding with these anomalous, outlier Need Determinations, and the likely resulting material influx in new market applicants/entrants would risk further strain on the limited existing clinical workforce resources relied upon by the state's HHA providers. The disruptive impact of this tsunami would hit the state's HHA providers at an especially difficult and precarious time, when such providers are still reeling not only from delivering needed home care services during a global pandemic, but also from the transformative changes in the industry's regulatory and payment framework. Effective in January 2020, CMS's shift to the Patient Driven Groupings Model ("PDGM") represented a complete overhaul of the payment structure for Home Health organizations and the most significant industry change in the past 20 years. The impact of this recent payment change is further exacerbated by the recently proposed Federal Rule for Calendar Year 2023 in which CMS has proposed substantial permanent rate reductions. In addition, Review Choice Demonstration ("RCD") is a pilot program from CMS designed to reduce fraud, waste and abuse, while imposing significant added administrative burden and resource investments to ensure compliance. North Carolina has been included in the demonstration as one of 5 pilot states, effective in 2021.

In summary, the disruptive impact of proceeding with an unprecedented 12 Need Determinations in the context of this broader industry transformation would serve to "pile

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[1] WRAL, "Nursing shortage: With over 2,500 openings, local hospitals feel the strain," Posted and Updated July 26, 2022. https://www.wral.com/nursing-shortage-with-over-2-500-openings-local-hospitals-feel-the-strain/20390878/.

on" the state's home health providers at a critical time when agencies need stability and support more than ever in fulfilling their patient care focused missions.

Statement of the Adverse Effects on Providers/Consumers Absent Change

Well Care believes that retaining 12 HHA Need Determinations in the Plan could adversely affect North Carolina providers and consumers/patients of home health agency services.

It is difficult to envision how providers will respond to 12 HHA Need Determinations. Well Care is one of the largest and most well-respected home health providers in the State. Notwithstanding Well Care's strong interest in serving the home health needs of the residents of North Carolina, the prospect of applying for 12 new CON approvals in a single year is without comparison in NC's home health planning history. With each Need Determination giving rise to a CON approval, once the 12 new home health agencies are authorized for operation in Counties throughout the State of North Carolina, such new offices will operate in perpetuity.

Some existing providers that otherwise would have applied to serve the home health needs in a community may be unable to do so because resources can only be stretched so thin. Although home health does not involve the same capital demands as other bricks-and-mortar health care services, investment in a new home health agency operation is a significant undertaking. Having 12 HHA opportunities in a single year skews the normal dynamics under which *bona fide* providers budget and plan based on logical growth expectations based on the history of Need Determinations in our State. If experienced providers opt out of certain filing opportunities because of the enormous scope of HHA Need Determinations across the State, it is possible that some needs will be met by smaller, less-experienced agencies that may win approvals without the typical CON competition.

For health care consumers, the potential for 12 new home health agency reviews in a single CON year raises a sizable concern over how the CON Section will be able to receive and meaningfully review such an influx of CON proposals with its existing staff and resources, and how it will be able to issue decisions and author detailed Agency Findings within the statutory deadlines. As a reference, the proposed 2023 influx of home health need determinations is **four times** the magnitude of the previous annual high mark in need determinations.

The typical CON Review Schedule creates only four filing opportunities for new home health agencies in a year. If each review attracts multiple applicants – which is entirely common – the CON Section could receive 30 or 40 HHA CON Applications or more within 2023. By way of example, in response to the 2020 Rowan County hospice Need Determination, eight (8) different providers submitted CON Applications and, predictably, and litigation followed the Agency's approval of a single Applicant.

To balance all the HHA reviews across the year, the CON Section would have to simultaneously conduct three competitive HHA reviews on proposals for different Counties, starting in each of the four review cycles. Findings would have to be issued in multiple reviews at the same time other reviews were starting or on-going based on earlier filings. Decisions in reviews with multiple Applicants could lead to litigation and associated demands on the time of Agency personnel. For the consumer, such a scenario raises doubt over the scrutiny that can be applied to each HHA applicant.

There is good reason that the SMFP process does not automatically or mechanically finalize Need Determinations based on a formulaic algorithm. The process has justifiably

incorporated a safeguard against clearly inconsistent and extraordinary results, whereby the SHCC can evaluate and consider the totality of the circumstances where heighted scrutiny is necessary. Well Care asks the SHCC to exercise this important safeguard to avoid an unprecedented and potentially damaging result.

As shown above, in the vast majority (83.3%) of prior SMFPs plan years, need determinations for Home Health have been limited to zero or one. Limiting the 2023 Plan to show no home health need and allowing for a workgroup evaluation of the HHA methodology would be consistent with this historical approach and result set, and would represent a far more responsible course given the likely disruptive impact of unquestioningly approving this unprecedented Need Determination.

Statement of Alternatives to the Proposed Change Considered & Rejected

Well Care considered standing silent in the face of the 12 Need Determinations but, considering the significance of these Need Determinations for patients and providers, Well Care rejected this option in favor of filing this Petition asking that the Need Determinations be removed and that a workgroup be installed to address the methodology for identifying home health agency needs in North Carolina.

Evidence the Proposed Change will Not Result in Unnecessary Duplication

Well Care is asking that the 12 HHA Need Determinations be removed which, obviously, will forestall the development of new agencies and the potential for unneeded duplication until a workgroup can address the home health methodology.

Evidence the Proposed Change is Consistent with the SMFP Basic Principles

Well Care's request that the Need Determinations be removed and the HHA methodology be studied is a request that is consistent with the objective of ensuring that only quality providers are approved for operation in our State. While the request will not add new agency access, it will allow for a proper evaluation of the extent of access called for in each community. And the request will ensure North Carolina avoids approving an onslaught of new agencies that could strain State resources for the administration of comprehensive CON reviews and result in the approval of a host of additional agencies which could raise charges to fund their operations in the face of competition.

Safety and Quality Basic Principle

The delivery of safe, high-quality home health services is critically important to the residents of North Carolina.

If left unaddressed, the HHA Need Determinations in the 2023 Proposed SMFP will lead to a proliferation of new home health agencies unlike anything the State of North Carolina has experienced over the last two decades (or longer).

For the last twenty years, the CON Section has been called upon to conduct no more than a few HHA reviews each year. If left in the Plan, the 12 HHA Need Determinations would require the CON Section to foreseeably undertake the evaluation of 30 or 40+ competing home health agency CON proposals in a single year, under strict statutory time deadlines. In some instances, the decisions of the CON Section could give rise to challenges at the Office of Administrative Hearings ("OAH"). If 12 HHA Need Determinations remain in place, decisions

on the first round of CON Section filings could be under challenge at OAH at the same time CON Section personnel are expected to be conducting reviews on the subsequent rounds of HHA CON Application filings. All this unprecedented and extraordinary activity creates a risk that each CON proposal will not receive the usual scrutiny as it relates to the proponent's intended service offerings and its quality record under Criterion 20 (N.C. Gen. Stat. § 131E-183(a)(20)).

Access Basic Principle

Well Care respectfully requests that the HHA Need Determinations be removed from the SMFP, and a work group be commissioned to examine the home health need methodology. While a dozen new agencies would create a significant amount of new home health agency access, increased access is not a metric to be evaluated in a vacuum. The CON process is intended to provide a meaningful assessment of potential providers in terms of their quality track records and their specific agency proposals. The central objective of the healthcare planning process is to ensure North Carolina has the "right" amount of access based on the populations and health care needs of its communities. **Considering the unprecedented and extraordinary nature of the HHA Need Determinations and the uncertain impacts such an onslaught of agencies could have on the clinical workforce and the delivery of care in North Carolina, Well Care urges a more cautious approach**.

Value Basic Principle

Home Health is an essential health care service because of the value it offers patients in need of health care, particularly as compared to accessing care in an institutional setting.

However, if North Carolina approves fully a dozen new home health agencies in one year, the competition for patients will correspondingly escalate. With 12 new agencies in the landscape, agencies will be vying to serve the available patient population and provide sufficient levels of service to support their operational demands.

This radical change could lead some HHA providers to charge more to cover the costs of agency operations. Charging more reduces the cost-efficiencies normally associated with home health. Considering the unprecedented and extraordinary nature of the HHA Need Determinations, the number of agencies could be misaligned with the demand for services, leaving too many agencies serving not enough patients. In that situation, agencies may charge more to improve their financial pictures and detract from the value typically associated with home health services.

Conclusion

In conclusion, Well Care seeks an adjustment to remove the HHA Need Determinations because these Need Determinations are markedly inconsistent with both past HHA Need Determinations and Need Determinations for similar healthcare services, are a by-product of a years-old and unique methodology in urgent need of reevaluation and modernization, and risks substantial disruption for health care providers and continuity of patient care in North Carolina.

For the reasons outlined above, Well Care respectfully asks that the SHCC exercise its vested authority and responsibility to protect the state healthcare planning process from anomalous results, as well as adverse policy consequences, by adjusting the 2023

Proposed SMFP to show no Need Determinations for new home health agencies and calling for a working group to be formed to update and modernize the home health methodology.

Thank you for your consideration of this petition,

Zac Long
CEO and General Counsel
Well Care Health

100746249.1

Exhibit B

REQUIRED STATE AGENCY FINDINGS

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

Decision Date: September 23, 2022
Findings Date: September 23, 2022

Project Analyst: Julie M. Faenza
Co-signer: Gloria C. Hale

COMPETITIVE REVIEW

Project ID #:	J-12211-22
Facility:	Duke University Hospital
FID #:	943138
County:	Durham
Applicant:	Duke University Health System, Inc.
Project:	Develop no more than 68 additional acute care beds pursuant to the 2022 SMFP need determination for a total of no more than 1,130 acute care beds upon completion of this project and Project ID #J-11717-19 (add 34 beds)

Project ID #:	J-12214-22
Facility:	UNC Hospitals-RTP
FID #:	210266
County:	Durham
Applicants:	University of North Carolina Hospitals at Chapel Hill University of North Carolina Health Care System
Project:	Develop no more than 34 additional acute care beds pursuant to the 2022 SMFP need determination which is a change of scope to approved Project ID #J-12065-21 (develop a new acute care hospital) for a total of no more than 74 acute care beds upon project completion

Each application was reviewed independently against the applicable statutory review criteria found in G.S. 131E-183(a) and the regulatory review criteria found in 10A NCAC 14C. After completing an independent analysis of each application, the Healthcare Planning and Certificate of Need Section (CON Section) also conducted a comparative analysis of all the applications. The Decision, which can be found at the end of the Required State Agency Findings (Findings), is based on the independent analysis and the comparative analysis.

Given the complexity of this review and the nuances of the types of care proposed, the Project Analyst created the tables below listing acronyms or abbreviations used in the findings.

Acronyms/Abbreviations Used	
Acronym/Abbreviations Used	**Full Term**
ADC	Average Daily Census (# of acute care days / 365 days in a year)
ALOS	Average Length of Stay (average number of acute care days for patients)
CAGR	Compound Annual Growth Rate
CY	Calendar Year
ED	Emergency Department
FFY	Federal Fiscal Year (October 1 – September 30)
FY	Fiscal Year
HSA	Health Service Area
ICU	Intensive Care Unit
IP	Inpatient
LRA	License Renewal Application
NC OSBM	North Carolina Office of State Budget and Management
SHCC	State Health Coordinating Council
SFY	NC State Fiscal Year (July 1 – June 30)
SMFP	State Medical Facilities Plan

REVIEW CRITERIA

G.S. 131E-183(a): The Department 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.

NC – Duke University Hospital
C – UNC Hospitals-RTP

Need Determination – Chapter 5 of the 2022 State Medical Facilities Plan (SMFP) includes a methodology for determining the need for additional acute care beds in North Carolina by service area. Application of the need methodology in the 2022 SMFP identified a need for 68 additional acute care beds in the Durham/Caswell multicounty service area. Two applications were submitted to the Healthcare Planning and Certificate of Need Section ("CON Section" or "Agency") proposing to develop a total of 102 new acute care beds in Durham County. However, pursuant to the need determination, only 68 acute care beds may be approved in this review for the Durham/Caswell multicounty service area. See the Conclusion following the Comparative Analysis for the decision.

Only qualified applicants can be approved to develop new acute care beds. On page 37, the 2022 SMFP states:

"A qualified applicant is a person who proposes to operate the additional acute care beds in a hospital that will provide:

(1) a 24-hour emergency services department,
(2) inpatient medical services to both surgical and non-surgical patients, and
(3) if proposing a new licensed hospital, medical and surgical services on a daily basis within at least five of the following major diagnostic categories (MDC) recognized by the Centers for Medicare & Medicaid services (CMS) listed below… [listed on page 37 of the 2022 SFMP]*."*

Policies – There are two policies in the 2022 SMFP which are applicable to this review.

Policy GEN-3: Basic Principles, on page 30 of the 2022 SMFP, states:

"A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina

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

Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities, on pages 30-31 of the 2022 SMFP, states:

> *"Any person proposing a capital expenditure greater than $4 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."*

Policy GEN-3 applies to both applications. Policy GEN-4 applies to Project ID #**J-11214-22** but does not apply to Project ID #**J-12211-22**.

Project ID #J-12211-22/Duke University Hospital/Add 68 acute care beds

Duke University Health System, Inc. (hereinafter referred to as "Duke" or "the applicant") proposes to add 68 new acute care beds to Duke University Hospital

(DUH), a hospital with 1,062 existing and approved acute care beds, for a total of 1,130 acute care beds upon completion of this project and Project ID #J-11717-19 (add 34 beds).

Need Determination. The applicant does not propose to develop more acute care beds than are determined to be needed in the Durham/Caswell multicounty service area. In Section B, page 22, the applicant adequately demonstrates that it meets the requirements of a "qualified applicant" as defined in Chapter 5 of the 2022 SMFP.

Policy GEN-3. In Section B, page 25, the applicant explains why it believes its proposal is consistent with Policy GEN-3.

However, the applicant does not adequately demonstrate how its projected volumes incorporate the concept of maximizing healthcare value for resources expended. The applicant does not adequately demonstrate the need to develop 68 new acute care beds and does not adequately demonstrate that developing 68 new acute care beds would not be an unnecessary duplication of existing and approved services. The discussions regarding analysis of need (including projected utilization) and unnecessary duplication found in Criterion (3) and Criterion (6), respectively, are incorporated herein by reference. An applicant that does not demonstrate the need for the proposed project (including projected utilization that is reasonable and adequately supported) and does not demonstrate that the proposed project is not an unnecessary duplication of existing and approved health care services in the service area cannot demonstrate that it will maximize healthcare value for resources expended in meeting the need identified in the 2022 SMFP. Thus, the application is not consistent with Policy GEN-3.

Conclusion – The Agency reviewed the:

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

Based on that review, the Agency concludes that the application is not conforming to this criterion based on the following:

- The applicant does not adequately demonstrate the need to develop 68 new acute care beds or that developing 68 new acute care beds would not be an unnecessary duplication of existing and approved health care services.

- Therefore, the applicant does not adequately demonstrate how its projected volumes incorporate the concept of maximum healthcare value for resources expended as required in Policy GEN-3.

Project ID #J-12214-22/UNC Hospitals-RTP/Add 34 acute care beds

University of North Carolina Hospitals at Chapel Hill and University of North Carolina Health Care System (hereinafter referred to as "UNC" or "the applicant") was approved by the Agency on September 21, 2021, to develop a new hospital with 40 acute care beds and 2 operating rooms (ORs) pursuant to need determinations in the 2021 SMFP. The decision to approve Project ID #J-12065-21 is currently under appeal and no certificate of need (CON) has been issued. In this project, UNC proposes a change of scope to Project ID #J-12065-21, by proposing to add 34 acute care beds and additional hospital-based services. If a CON is issued to UNC for Project ID #J-12065-21, UNC would have a total of 74 acute care beds upon approval of this project and Project ID #J-12065-21.

Need Determination. The applicant does not propose to develop more acute care beds than are determined to be needed in the Durham/Caswell multicounty service area. In Section B, page 25, the applicant adequately demonstrates that it meets the requirements of a "qualified applicant" as defined in Chapter 5 of the 2022 SMFP.

Policy GEN-3. In Section B, pages 27-31, the applicant explains why it believes its proposal is consistent with Policy GEN-3.

Policy GEN-4. The proposed capital expenditure for this project is greater than $4 million. In Section B, page 32, the applicant describes the project's plan to improve energy efficiency and conserve water.

Conclusion – The Agency reviewed the:

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

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

- The applicant does not propose to develop more acute care beds than are determined to be needed in the Durham/Caswell multicounty service area.

- The applicant adequately demonstrates it is a "qualified applicant" as defined in Chapter 5 of the 2022 SMFP.

- The applicant adequately demonstrates that the proposal is consistent with Policy GEN-3 and Policy GEN-4 for the following reasons:

- The applicant adequately documents how the project will promote safety and quality in the delivery of acute care bed services in the Durham/Caswell multicounty service area.

- The applicant adequately documents how the project will promote equitable access to acute care bed services in the Durham/Caswell multicounty service area.
- The applicant adequately documents how the project will maximize healthcare value for the resources expended.

- The applicant adequately demonstrates that the application includes a written statement describing the project's plan to assure improved 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.

NC – Duke University Hospital
C – UNC Hospitals-RTP

Project ID #J-12211-22/Duke University Hospital/Add 68 acute care beds

The applicant proposes to add 68 new acute care beds to DUH, a hospital with 1,062 existing and approved acute care beds, for a total of 1,130 acute care beds upon completion of this project and Project ID #J-11717-19 (add 34 beds).

The applicant was part of a competitive review for acute care beds in the Durham/Caswell multicounty service area based on a need determination in the 2021 SMFP. The Agency issued a decision on that competitive review on September 21, 2021, awarding 40 acute care beds to the other applicant for acute care beds in that competitive review. Duke has appealed that decision. As of the date of these findings, that decision is still under appeal, and no CON has been issued. In Section C, page 27, and in Section Q, the applicant states that if the Agency decision is reversed and the 40 acute care beds are awarded to DUH, the applicant plans to develop those 40 acute care beds in addition to the 68 acute care beds it is proposing to develop as part of the current application. Thus, DUH would potentially have 1,170 acute care beds upon completion of this project and other associated projects.

Patient Origin – On page 33, the 2022 SMFP defines the service area for acute care beds as *"... the single or multicounty grouping shown in Figure 5.1."* Figure 5.1, on

page 38, shows Durham and Caswell counties in a multicounty grouping. Thus, the service area for these facilities is the Durham/Caswell multicounty service area. Facilities may also serve residents of counties not included in their service area.

The following table illustrates historical and projected patient origin. Duke's fiscal year is July 1 – June 30, which is also North Carolina's state fiscal year (SFY).

Historical and Projected Patient Origin – Adult Acute Care Services								
Area	SFY 2021		FY 1 (SFY 2024)		FY 2 (SFY 2025)		FY 3 (SFY 2026)	
	# Patients	% of Total	# Patients	% of Total	# Patients	% of Total	# Patients	% of Total
Alamance	1,389	3.9%	1,578	4.2%	1,602	4.2%	1,626	4.2%
Caswell	172	0.5%	190	0.5%	192	0.5%	195	0.5%
Chatham	230	0.6%	206	0.5%	209	0.5%	212	0.5%
Cumberland	837	2.3%	880	2.4%	893	2.4%	906	2.4%
Durham	10,153	28.2%	10,412	28.0%	10,567	28.0%	10,727	28.0%
Franklin	588	1.6%	488	1.3%	496	1.3%	503	1.3%
Granville	1,361	3.8%	1,479	4.0%	1,502	4.0%	1,524	4.0%
Guilford	586	1.6%	606	1.6%	615	1.6%	624	1.6%
Harnett	328	0.9%	406	1.1%	412	1.1%	418	1.1%
Johnston	471	1.3%	424	1.1%	431	1.1%	437	1.1%
Lee	282	0.8%	321	0.9%	326	0.9%	331	0.9%
Nash	336	0.9%	309	0.8%	314	0.8%	318	0.8%
Orange	1,456	4.0%	1,405	3.8%	1,426	3.8%	1,448	3.8%
Person	1,095	3.0%	1,228	3.3%	1,246	3.3%	1,265	3.3%
Robeson	552	1.5%	509	1.4%	517	1.4%	524	1.4%
Vance	988	2.7%	973	2.6%	987	2.6%	1,002	2.6%
Wake	4,522	12.6%	4,782	12.9%	4,854	12.9%	4,927	12.9%
Warren	338	0.9%	328	0.9%	333	0.9%	338	0.9%
Wilson	248	0.7%	266	0.7%	270	0.7%	274	0.7%
Other NC Counties	5,790	16.1%	6,155	16.5%	6,247	16.5%	6,341	16.5%
Virginia	2,405	6.7%	2,365	6.4%	2,401	6.4%	2,437	6.4%
Other States	1,892	5.3%	1,906	5.1%	1,934	5.1%	1,964	5.1%
International	2	0.0%	6	0.0%	6	0.0%	6	0.0%
Total	**36,021**	**100.0%**	**37,222**	**100.0%**	**37,780**	**100.0%**	**38,347**	**100.0%**

Source: Section C, pages 28 and 30

In Section C, page 30, the applicant provides the assumptions and methodology used to project patient origin. The applicant's assumptions are reasonable and adequately supported based on the following:

- The applicant's projected patient origin is based on historical patient origin at the same facility.

- The applicant states it does not project any material change to its historical patient origin as a result of the proposed project because it is expanding the existing services that it is using to project future patient origin.

Analysis of Need – In Section C, pages 32-38, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below:

- The applicant states that the need determination in the 2022 SMFP for 68 beds is entirely the result of utilization at DUH, and the other two hospitals in Durham County both have surpluses. The applicant states the actual acute care bed need for DUH is 141 acute care beds, but the total is offset by the surplus of acute care beds at Duke Regional Hospital (DRH) and the 2021 SMFP need determination of 40 acute care beds (which is currently under appeal).

- The applicant states that between SFY 2016 and SFY 2021, inpatient days of care increased by 14%, or at a Compound Annual Growth Rate (CAGR) of 2.6%. The applicant states that growth in discharges was lower than inpatient days of care which reflects longer inpatient stays over time. The applicant states the longer inpatient stays cause capacity constraints and limit Duke's ability to serve more patients.

- The applicant states DUH is the state's *"preeminent academic medical center"* and provides specialized quaternary care across a range of service lines. The applicant states DUH is ranked nationally by US News and World Report and the same report ranks DUH as the best hospital in the state. The applicant states that the need for this specialized level of care is demonstrated by the fact that less than 30% of their patient origin is from Durham County. The applicant states that due to the level of care provided, providers often request to transfer high acuity patients to DUH, and capacity constraints can prevent the ability to transfer patients to DUH.

- The applicant states that, according to information from the North Carolina Office of State Budget and Management (NC OSBM), population growth in the Durham/Caswell multicounty service area is expected to grow by a total of 13.4% between July 2020 and July 2030 (a CAGR of 1.4%). The applicant states that population in nearby counties from which it has historically served patients is projected to increase by varying amounts, and that statewide population is projected to increase by 10.2% between July 2020 and July 2030 (a CAGR of 1.1%). The applicant states that the counties from which DUH draws most heavily are among the fastest growing in the state and will contribute, along with the overall statewide increase in population, to demand for specialized services at DUH.

- The applicant states that Duke's medical staff and referral network have grown by almost 3% during the past year. The applicant states its physicians with admitting privileges rely on access to surgical services at DUH and that the Private Diagnostic Clinic (PDC), the practice for Duke's School of Medicine faculty, is implementing a recruitment plan to grow further.

However, the information is not reasonable or adequately supported for the following reasons:

- In Section C, pages 32-34, Duke states the need for 68 acute care beds in the Durham/Caswell multicounty service area was generated entirely by DUH. However, anyone may apply to meet the need, not just Duke. Duke has the burden of demonstrating the need for the proposed acute care beds in its application as submitted.

  In early 2022, Duke submitted a spring petition to the State Health Coordinating Council (SHCC) proposing to eliminate neonatal intensive care unit (NICU) beds (Levels II-IV) and days of care from the planning inventory and need methodology calculations of acute care beds. The petition was widely supported, including by UNC, who submitted comments in support of the petition. Duke stated that NICU beds are so unlike every other kind of acute care bed that it is impossible to treat them as interchangeable with other acute care bed inventory, because of the specialized equipment and spaces needed to support NICU patients. The Agency evaluated the petition and recommended the removal of the NICU beds and acute care days from the acute care bed planning inventory and need methodology calculations. The Agency's recommendation was accepted by the Acute Care Services Committee at its meeting on April 12, 2022 and accepted by the entire SHCC at its meeting on June 1, 2022.

  In the Agency Report evaluating the impact of removing NICU beds and days of care from the acute care bed planning inventory and need methodology calculations, analysis of the data showed there would be no new need determinations in the 2022 SMFP as a result of the proposed change. The data also showed that while two service areas would have a slight increase in the number of beds in the need determination in the 2022 SMFP, four other service areas would have declines in the number of beds in the need determination in the 2022 SMFP. On page 4 of the Agency Report, it states:

  > *"In sum, in particular service areas, NICU beds accounted for a large portion of the bed need, suggesting that the actual need for new general acute care beds was not as high as the need determination indicated."*

  On page 5 of the Agency Report, a table displays the changes in need determinations in the 2022 SMFP that would have occurred if the proposed elimination of NICU beds and days of care from the acute care bed need methodology had been in effect. The table is reproduced in part below.

Acute Care Bed Need Determinations, 2022 SMFP			
Service Area	**With NICUs**	**Without NICUs**	**Change**
Buncombe/Graham/Madison/Yancey	67	75	8
Cumberland	29	43	14
Durham/Caswell	***68***	***28***	***-40***
Mecklenburg	65	26	-39
Pitt	43	28	-15
Wake	45	44	-1
Total	**317**	**244**	**-73**

As shown in the table above, with the NICU beds and days of care removed from the planning inventory and need methodology calculations, the Durham/Caswell multicounty service area would have had the largest reduction out of all acute care bed need determinations in the state and would have had a need determination of 28 beds – less than half of the current need determination the applicant states demonstrates the need for the proposed project.

The applicant is not proposing to add new NICU beds to their inventory as part of the proposed project. The applicant submitted the petition in late February or early March of 2022, at least a month prior to the submission date of this application which suggests there was overlap in the time developing the petition and this application. The data and methodology Duke used in its application does not take into account its own facts and data as presented in its petition. The application as submitted does not address why the applicant needs 68 non-NICU acute care beds when the applicant's own historical data shows more than half of that need determination is due to NICU utilization.

- In July 2021, Duke submitted a summer petition to the SHCC proposing to eliminate or defer the need determination for acute care beds in the Durham/Caswell multicounty service area and to adjust the Wake County need determination that appeared in the Proposed 2022 SMFP. Duke stated that because there were so many acute care bed need determinations in Durham County over the past five years, and because a significant number of those beds had been brought online in June 2021, it proposed to eliminate or defer the need determination in the Durham/Caswell multicounty service area until the utilization patterns of the newly licensed acute care beds could be determined. Duke stated this was consistent with other approved petitions for adjustments to bed needs submitted in the past.

  On page 4 of the petition, Duke stated:

  > *"…in Durham County, there are already significant number* [sic] *of beds under development or review.* ***Further adding to the inventory may lead to the unnecessary duplication of existing and approved services, at least until the effects of the additional capacity are known.****"* (emphasis added)

While the petition seems at times to tie the reduction of the acute care bed need determination in the Durham/Caswell multicounty service area to the adjusted need determination proposed for Wake County in the same petition, need determinations in separate acute care bed service areas are calculated independently of any other acute care bed service areas. Duke does not state the proposed elimination or deferral of the need determination in Durham County is contingent upon an adjusted need determination for more acute care beds in Wake County; rather, it states the beds are not needed or should be deferred.

On page 6 of the petition, Duke stated:

> *"Given the large number of beds already under development or review in Durham County, eliminating the need in Durham County is consistent with ensuring appropriate utilization of existing and approved assets as well as those under review."*

On pages 3-4 of the Agency Report in response to the Duke petition, the Agency stated that Duke had not shown in its petition how an adjustment of the need determination in Wake County would be the most effective alternative to the actual need determination for Wake County.

With regard to the Durham/Caswell multicounty service area, on page 4 of the Agency Report, the Agency stated:

> *"Historically, the Agency has recommended removal of an acute care bed need determination when the actual conditions in a service area are not adequately reflected in a component of the methodology, thereby causing a need determination. The Petitioner does not present evidence that this has occurred in the Durham/Caswell service area for the 2022 SMFP cycle."*
>
> …
>
> *…the Agency emphasizes that the Durham/Caswell service area's need determination is an appropriate projection of bed need because it is based on the service area's total planning inventory and a GRM* [Growth Rate Multiplier] *that accounts for any growth in actual bed utilization. Finally, while the utilization by Duke Health System hospitals created the need in the service area, another entity in the service area is eligible to apply for the beds."*

On September 14, 2021, the Acute Care Services Committee voted to accept the Agency's recommendation and rejected the petition for an adjusted need determination in Wake County and elimination of the need determination in Durham County. The SHCC accepted the Committee's recommendations at its September 29, 2021 meeting.

However, less than a year after Duke submitted the petition to the SHCC, before all of its approved beds were brought online and in use, and despite its stated need to eliminate or defer the 2022 need determination for acute care beds, Duke filed this application to develop 68 new acute care beds. Comments received during the public comment period pointed out Duke's 2021 petition to remove the acute care bed need determination for the Durham/Caswell multicounty service area.

Duke did not explain in its application as submitted what circumstances changed between July 2021, when Duke stated its concern that the need determination of 68 acute care beds in the Durham/Caswell multicounty service area would potentially be an unnecessary duplication, and when Duke submitted the current application. Further, Duke provided no response to comments submitted during the public comment period that pointed out the discrepancy in Duke's positions.

Projected Utilization – On Forms C.1a and C.1b in Section Q, the applicant provides historical and projected utilization, as illustrated in the following table.

DUH Historical & Projected Utilization – Acute Care Beds				
	SFY 2021	**FY 1 (SFY 2024)**	**FY 2 (SFY 2025)**	**FY 3 (SFY 2026)**
# of Beds	960	1,130	1,130	1,130
# of Discharges	40,906	44,254	44,917	45,591
# of Patient Days	311,279	333,559	338,558	343,639
ALOS*	7.61	7.54	7.54	7.54
Occupancy Rate	88.8%	80.9%	82.1%	83.3%

*ALOS = Average Length of Stay

In the Form C.1 Assumptions subsection of Section Q, the applicant provides the assumptions and methodology used to project utilization for DUH, which are summarized below.

- The applicant discussed the impact of the COVID-19 pandemic on historical data. Specifically, the applicant discussed the decline in discharges in SFYs 2020 and 2021 compared to prior years. The applicant states this was due to reductions in elective surgeries and other procedures, restrictions in place at DUH, patient reluctance to seek non-emergency healthcare, and decreases in ED admissions due to injuries to children involved in sports and other activities.

- The applicant states that despite the reduction in discharges, there has been a significant increase in days of care during SFYs 2020 and 2021 due to longer average length of stay (ALOS).

- The data for SFY 2022 annualized is based on the first six months of utilization for SFY 2022 (July 2021 through December 2021).

- The applicant projected a 1.5% annual growth rate in adult patient discharges beginning in SFY 2023. The applicant assumed the ALOS would be 7.25 days, which is an average of the ALOS from SFYs 2021 and 2022 annualized.

- The applicant projected a 1.5% annual growth rate in pediatric patient discharges (excluding neonatal) beginning in SFY 2023. The applicant assumed the ALOS would remain consistent at the SFY 2022 annualized level of 6.50 days.

- The applicant projected a 10% increase in NICU discharges between SFY 2022 annualized and SFY 2023. The applicant states it has 14 approved NICU beds that will begin serving patients in SFY 2023 and because of the increased capacity, there will be a temporary large increase in discharges. The applicant projects growth for NICU discharges at 1.5% per year after SFY 2023. The applicant assumed the ALOS would be 30 days, which is an approximate average of the ALOS for SFY 2021 and SFY 2022 annualized.

- The applicant states that its projections are reasonable and conservative because of the need previously discussed, historical growth trends where days of care increased by more than 1.5% each year, and the anticipated increases in volume that DUH will be able to serve with increased capacity.

The applicant's assumptions, methodology, and projected utilization of acute care beds at DUH during the first three full fiscal years following project completion are summarized in the table below.

DUH Projected Utilization						
	SFY 2021	**SFY 2022***	**SFY 2023**	**SFY 2024**	**SFY 2025**	**SFY 2026**
Adult Discharges	36,021	36,130	36,672	37,222	37,780	38,347
Adult ALOS	7.13	7.37	7.25	7.25	7.25	7.25
Adult Days of Care	256,841	266,186	265,872	269,860	273,905	278,016
Pediatric Discharges	5,419	6,082	6,173	6,266	6,360	6,455
Pediatric ALOS	6.32	6.50	6.50	6.50	6.50	6.50
Pediatric Days of Care	34,222	39,526	40,119	40,721	41,331	41,951
Neonatal Discharges	717	686	755	766	777	789
Neonatal ALOS	31.62	29.04	30.00	30.00	30.00	30.00
Neonatal Days of Care	22,675	19,924	22,638	22,978	23,322	23,672
Total Discharges	40,906	42,898	43,600	44,254	44,917	45,591
Total ALOS	7.53	7.59	7.54	7.54	7.54	7.54
Total Days of Care	311,279	325,636	328,629	333,559	338,558	343,639
ADC**	853	892	900	914	928	941
Total Licensed Beds	960	1,048	1,062	1,130	1,130	1,130
Utilization	88.9%	85.1%	84.7%	80.9%	82.1%	83.3%

*SFY 2022 is annualized based on July-December 2021 data.
**Average Daily Census = Number of days of care / 365 days per year

Duke University Health System

The Duke System for acute care beds in the Durham/Caswell multicounty service area consists of DUH and DRH. Pursuant to 10A NCAC 14C .3803(a), an applicant proposing to add new acute care beds to a service area must reasonably project that all acute care beds in the service area under common ownership will have a utilization of at least 75.2 percent when the projected Average Daily Census (ADC) is greater than 200 patients in the third operating year following completion of the proposed project.

However, pursuant to G.S. 131E-183(b):

> *"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."*

In Appendix F on page 423 of the 2022 SMFP, DUH is defined as an academic medical center teaching hospital. Therefore, projected utilization at DRH is not included as part of determining whether DUH meets the performance standard promulgated under 10A NCAC 14C .3803(a).

As shown in the table above, in the third full fiscal year following project completion, the applicant projects the utilization for all acute care beds at DUH will be 83.3%. This meets the performance standard promulgated in 10A NCAC 14C .3803(a), which requires an applicant proposing to add new acute care beds to a service area to reasonably project that all acute care beds in the service area under common ownership will have a utilization of at least 75.2% when the projected ADC is greater than 200 patients.

However, projected utilization is not reasonable and adequately supported based on the following analysis:

- The applicant projects discharges at DUH based on a projected growth rate that is not reasonable and adequately supported.

  The applicant projects adult and pediatric discharges will increase at a rate of 1.5% each year, and that after an initial increase of 10% in one year, neonatal discharges will increase by 1.5% per year. The applicant states its projections are reasonable because of the historical growth rate of acute care days along with the factors it identified as supporting the need for the proposed project. However, the applicant does not explain in the application as submitted what, if any, correlation exists between an increase in acute care days and an increase in discharges. In Section C, page 34, the applicant states that acute care days between SFY 2016 and SFY 2021 increased by a total of 14% and had a CAGR of 2.6%. However, based on the

applicant's License Renewal Applications (LRAs), discharges between SFY 2016 and SFY 2021 decreased by a total of -0.2% and by a CAGR of -0.03%. The applicant does not provide a reasonable basis in the application as submitted for applying a 1.5% growth rate to any of the categories of discharges when its historical growth rate for discharges was essentially flat.

- Duke uses an ALOS which is not reasonable or adequately supported in its utilization projections.

In the Form C.1 Assumptions subsection of Section Q, the applicant states:

> *"…, FY 2021 inpatient days of care reflect a significant increase not only over FY 2020 but also over previous years due to longer average length of stay."*

In Section C, page 34, Duke provides historical information about days of care, discharges, and ALOS, consistent with the information found on its historical LRAs submitted to the Agency. Information about DUH and historical utilization is shown in the table below.

DUH Historical Utilization – Acute Care Days, Discharges, & ALOS						
	SFY 2016	**SFY 2017**	**SFY 2018**	**SFY 2019**	**SFY 2020**	**SFY 2021**
Acute Care Days	273,758	284,052	292,286	303,409	296,466	311,279
Discharges	40,975	42,083	42,469	43,055	40,715	40,906
ALOS (in days)	6.68	6.75	6.88	6.98	7.24	7.61

Source: Section C, page 34; Agency records

Between SFY 2016 and SFY 2019, the ALOS for DUH increased by 0.3 days, a total increase of 4.5% and a CAGR of 1.5%. Between SFY 2019 and SFY 2020, the ALOS for DUH increased by 0.26 days, a 3.7% increase in a single year and more than double the CAGR for the previous four SFYs. Between SFY 2020 and SFY 2021, the ALOS for DUH increased by 0.37 days, a 5.1% increase in a single year and more than the entire cumulative increase in ALOS between SFYs 2016 and 2019.

In its utilization projections, Duke assumes that adult inpatient ALOS will remain at an average of the ALOS for SFYs 2021 and 2022 annualized (based on July – December 2021 data) and assumes that pediatric inpatient ALOS will remain at the ALOS for SFY 2022. Duke does not provide any information in the application as submitted as to adequately support the ALOS' it uses. The applicant does not adequately address why the ALOS has increased more in the last two years compared to the historical ALOS or why use of the more recent ALOS (or an average ALOS of two recent years) is reasonable and adequately supported compared with historical utilization.

Comments submitted during the public comment period state that the ALOS used by Duke is artificially inflated due to the effects of COVID-19 and creates an unreasonably high number of acute care days. In its response to those comments, the applicant states:

> *"…, Duke University Hospital has experienced a higher ALOS in recent years, but DUHS did not identify that this increase was solely due to COVID-19. DUHS documented that even pre-COVID, its ALOS had increased significantly…, reflecting ongoing evolution in care, such as the shift of some surgical procedures from requiring short inpatient stays to outpatient encounters."*

However, as quoted above from the Form C.1 Assumptions subsection of Section Q, Duke discusses the impact of COVID-19 on both its discharges and its ALOS for SFY 2020 <u>and</u> SFY 2021. Moreover, the ALOS used by Duke in its utilization projections is far higher than the historical "significant increase" in ALOS prior to COVID-19.

Moreover, while Duke states that it did not identify that COVID-19 was the "sole" reason for the increase in acute care days, statewide data provided to the Agency indicates that hospitals statewide are reporting a much higher ALOS than would be expected normally. The written summary of recommendations of the Acute Care Services Committee to the SHCC published on June 1, 2022, states:

> *"…, the Committee addressed continuing effects of the COVID-19 pandemic on bed need. Initial calculations showed that the state had a need for 1,481 additional beds. This number is about three to four times more than in a typical year. Analysis showed that the large number of needs was partly due to the fact that the overall average length of stay increased by about 20-25% from 2020 to 2021. This increase is unprecedented, but not expected to be permanent. Rather, it is most likely related to the lengthier stays of COVID patients."*

The recommendation of the Acute Care Services Committee was to offset this seemingly artificial increase for the 2023 SMFP by using county growth rate multipliers from the 2021 SMFP, reflecting pre-pandemic years. The SHCC accepted that recommendation at the June 1, 2022 meeting.

While Duke is not required to provide utilization projections that are consistent with historical utilization, Duke does not demonstrate that the utilization projections it provides are reasonable and adequately supported.

<u>Access to Medically Underserved Groups</u> – In Section C, page 43, the applicant describes how it will provide access to medically underserved groups. On page 43, 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 DUH, as clinically appropriate. DUHS does not discriminate on the basis of 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 DUH's proposed services will be provided to Medicare, Medicaid, and uninsured patients."*

On page 43, the applicant provides the estimated percentage for each medically underserved group, as shown in the following table.

Medically Underserved Groups	% of Total Patients
Low-income persons	18%
Racial and ethnic minorities	39%
Women	59%
Persons aged 65 and older	34%
Medicare beneficiaries	38%
Medicaid recipients	12%

In Section C, page 43, the applicant states that "low-income persons" is not defined and estimates the percentage based on projected Medicaid beneficiaries and charity or reduced cost recipients. The applicant also states it does not keep data on persons with disabilities but emphasizes that disabled people have not and will not be denied access to care.

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 based on the following:

- The applicant provides its Notice of Nondiscrimination in Exhibit C.6 and its financial assistance policies in Exhibit L.4.

- The applicant provides a statement clearly stating that all residents of the service area, including underserved groups, are not discriminated against or turned away from the proposed services based on belonging to an underserved group.

<u>Conclusion</u> – The Agency reviewed the:

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

Based on that review, the Agency concludes that the application is not conforming to this criterion for all the reasons described above.

Project ID #J-12214-22/UNC Hospitals-RTP/Add 34 acute care beds

The applicant proposes a change of scope to Project ID #J-12065-21, which approved the development of UNC Hospitals-RTP with 40 acute care beds (currently under appeal; no CON has been issued). The applicant proposes to add 34 acute care beds and additional hospital-based services for a total of 74 acute care beds upon approval of this project and Project ID #J-12065-21.

The applicant was part of a competitive review for acute care beds and operating rooms (ORs) in the Durham/Caswell multicounty service area based on need determinations in the 2021 SMFP. The applicant proposed to develop a new hospital with 40 acute care beds and 2 ORs. The Agency issued a decision in that competitive review on September 21, 2021, approving the applicant's proposal to develop a new hospital with 40 acute care beds and 2 ORs. That decision was appealed. As of the date of these findings, that decision is still under appeal, and a CON has not been issued.

The applicant assumes the Agency's decision will be upheld and proposes a change of scope to its previously approved project. The applicant proposes to develop 34 acute care beds pursuant to the need determination in the 2022 SMFP. If the Agency decision is upheld in the appeal of the original application to develop UNC Hospitals-RTP, the facility will have 74 acute care beds upon completion of that project and the project under review.

UNC also proposes to add two additional labor and delivery room (LDR) beds, two additional procedure rooms, ten additional observation beds, eight additional emergency department (ED) bays, one additional CT scanner, and one additional ultrasound unit. The applicant proposes to more than double the original square footage of the facility as part of this proposed project.

Patient Origin – On page 33, the 2022 SMFP defines the service area for acute care beds as *"... the single or multicounty grouping shown in Figure 5.1."* Figure 5.1, on page 38, shows Durham and Caswell counties in a multicounty grouping. Thus, the service area for these facilities is the Durham/Caswell multicounty service area. Facilities may also serve residents of counties not included in their service area.

UNC Hospitals-RTP is not an existing facility and thus has no historical patient origin to report. The table below shows the projected patient origin for the entire facility. UNC's fiscal year is July 1 – June 30, which is also the North Carolina SFY.

Projected Patient Origin – UNC Hospitals-RTP – Entire Facility						
County	FY 1 – SFY 2030		FY 2 – SFY 2031		FY 3 – SFY 2032	
	# Patients	% of Total	# Patients	% of Total	# Patients	% of Total
Durham	192,416	85.0%	267,223	85.0%	306,385	85.0%
Wake	31,239	13.8%	43,384	13.8%	49,742	13.8%
Chatham	2,037	0.9%	2,829	0.9%	3,244	0.9%
Caswell	679	0.3%	943	0.3%	1,081	0.3%
Total	**226,371**	**100.0%**	**314,379**	**100.0%**	**360,452**	**100.0%**

Source: Section C, page 69

The following tables illustrate projected patient origin for the proposed project's stated service components.

Projected Patient Origin – UNC Hospitals-RTP – Acute Care Discharges						
County	FY 1 – SFY 2030		FY 2 – SFY 2031		FY 3 – SFY 2032	
	# Patients	% of Total	# Patients	% of Total	# Patients	% of Total
Durham	2,084	85.0%	2,877	85.0%	3,279	85.0%
Wake	338	13.8%	467	13.8%	532	13.8%
Chatham	22	0.9%	30	0.9%	35	0.9%
Caswell	7	0.3%	10	0.3%	12	0.3%
Total	**2,451**	**100.0%**	**3,384**	**100.0%**	**3,858**	**100.0%**

Source: Section C, page 67

Projected Patient Origin – UNC Hospitals-RTP – Outpatient Surgical Services						
County	FY 1 – SFY 2030		FY 2 – SFY 2031		FY 3 – SFY 2032	
	# Patients	% of Total	# Patients	% of Total	# Patients	% of Total
Durham	1,649	85.0%	2,356	85.0%	2,776	85.0%
Wake	268	13.8%	382	13.8%	450	13.8%
Chatham	17	0.9%	25	0.9%	29	0.9%
Caswell	6	0.3%	8	0.3%	10	0.3%
Total	**1,940**	**100.0%**	**2,771**	**100.0%**	**3,265**	**100.0%**

Source: Section C, page 67

Projected Patient Origin – UNC Hospitals-RTP – Emergency Department						
County	FY 1 – SFY 2030		FY 2 – SFY 2031		FY 3 – SFY 2032	
	# Patients	% of Total	# Patients	% of Total	# Patients	% of Total
Durham	9,131	85.0%	12,608	85.0%	14,372	85.0%
Wake	1,483	13.8%	2,047	13.8%	2,333	13.8%
Chatham	97	0.9%	133	0.9%	152	0.9%
Caswell	32	0.3%	44	0.3%	51	0.3%
Total	**10,743**	**100.0%**	**14,832**	**100.0%**	**16,908**	**100.0%**

Source: Section C, page 67

Projected Patient Origin – UNC Hospitals-RTP – Imaging						
County	FY 1 – SFY 2030		FY 2 – SFY 2031		FY 3 – SFY 2032	
	# Patients	% of Total	# Patients	% of Total	# Patients	% of Total
Durham	22,996	85.0%	31,938	85.0%	36,622	85.0%
Wake	3,733	13.8%	5,185	13.8%	5,946	13.8%
Chatham	243	0.9%	338	0.9%	388	0.9%
Caswell	81	0.3%	113	0.3%	129	0.3%
Total	**27,053**	**100.0%**	**37,574**	**100.0%**	**43,085**	**100.0%**

Source: Section C, page 68

Projected Patient Origin – UNC Hospitals-RTP – Therapy						
County	FY 1 – SFY 2030		FY 2 – SFY 2031		FY 3 – SFY 2032	
	# Patients	% of Total	# Patients	% of Total	# Patients	% of Total
Durham	28,086	85.0%	39,008	85.0%	44,729	85.0%
Wake	4,560	13.8%	6,333	13.8%	7,262	13.8%
Chatham	297	0.9%	413	0.9%	474	0.9%
Caswell	99	0.3%	138	0.3%	158	0.3%
Total	**33,042**	**100.0%**	**45,892**	**100.0%**	**52,623**	**100.0%**

Source: Section C, page 68

Projected Patient Origin – UNC Hospitals-RTP – Lab						
County	FY 1 – SFY 2030		FY 2 – SFY 2031		FY 3 – SFY 2032	
	# Patients	% of Total	# Patients	% of Total	# Patients	% of Total
Durham	128,471	85.0%	178,436	85.0%	204,607	85.0%
Wake	20,858	13.8%	28,970	13.8%	33,218	13.8%
Chatham	1,360	0.9%	1,889	0.9%	2,166	0.9%
Caswell	453	0.3%	630	0.3%	722	0.3%
Total	**151,142**	**100.0%**	**209,925**	**100.0%**	**240,713**	**100.0%**

Source: Section C, page 68

In Section C, page 69, the applicant provides the assumptions and methodology used to project patient origin. The applicant states projected patient origin assumes 85% of patients will originate from Durham County and 15% of patients will originate from surrounding counties. The applicant provides an explanation of the Durham County service area by ZIP code in the Form C Utilization – Assumptions and Methodology subsection of Section Q. The applicant's assumptions are reasonable and adequately supported based on the following:

- The applicant states it did not significantly adjust its patient origin from the previously approved application because the types of services it will offer are the same, even if there will be more capacity for those services.

- The applicant's projected patient origin is similar to the patient origin it projected in Project ID #J-12065-21, which was found to be reasonable and adequately supported, and nothing in the current application as submitted would affect that determination.

Analysis of Need – In Section C, pages 52-65, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below:

- The applicant states many of the same conditions documented by the applicant in Project ID #J-12065-21 are still relevant in this review:
  - the projected population increase in Durham County overall;
  - the projected population increase in southern Durham County, where UNC Hospitals-RTP will be located; and
  - more than half of the population of Durham County is concentrated in southern Durham County.

- The applicant states acute care days in Durham County hospitals grew at a CAGR of 2.7% between CY 2017 and CY 2019. The applicant explains its choice to exclude utilization data from CY 2020 and the first half of CY 2021 and describes the analysis it used in determining to exclude that data.

- The applicant states there is a greater need for "basic community (non-tertiary) services," which it defines as low acuity services needed in high frequencies by a significant portion of the population. The applicant states that, based on its analysis of "basic community (non-tertiary) services" using data from IBM Watson Health, acute care days for "basic community (non-tertiary) services" at Durham County hospitals grew at a CAGR of 3.7% between CY 2017 and CY 2019, compared with growth of higher acuity acute care days at a CAGR of 1.2%. The applicant states that at both DRH and DUH, "basic community (non-tertiary) services" grew at a higher rate than other services.

- The applicant states that, based on its analysis of data from IBM Watson Health, Durham County residents from the southern part of Durham County had higher utilization rates for "basic community (non-tertiary) services" than the central/west and northern parts of Durham County. The applicant further states that when comparing data for all Durham County residents served at any hospital – not just Durham County hospitals – utilization of "basic community (non-tertiary) services" grew at a CAGR of 3.4% between CY 2017 and CY 2019, while utilization of higher acuity services by Durham County residents at any hospital decreased by a CAGR of 1.0% between CY 2017 and CY 2019.

- The applicant states that despite not having an existing hospital in Durham County, its hospitals in Wake and Orange counties served more Durham County residents than any other hospital system except Duke. The applicant states that utilization of "basic community (non-tertiary) services" by Durham County residents at UNC hospitals in Orange and Wake counties increased at a CAGR of 2.9% between CY 2017 and CY 2019, and that in each of those three years, utilization by residents of the southern part of Durham County exceeded utilization by residents of both the central/west and northern areas of Durham County.

- The applicant states that it proposes to add additional services such as ED treatment bays, procedure rooms, imaging equipment, and other ancillary and support services to accommodate the projected increase in patients it will serve with more acute care beds.

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

- The applicant uses data collected by IBM Watson Health to analyze utilization patterns.

- The applicant provides reasonable explanations and thorough analysis of why it chose to use CY 2017 to CY 2019 for historical utilization patterns.

- The applicant uses assumptions consistent with those it used in Project ID #J-12065-21, which the Agency found to be reasonable and adequately supported, and there are no changes to the specific conditions in the proposed service area or in the application as submitted which would affect that determination.

Projected Utilization – On Forms C.1b-4b in Section Q, the applicant provides projected utilization as illustrated in the following tables.

UNC Hospitals-RTP Projected Utilization Acute Care Services			
	FY 1 – SFY 2030	**FY 2 – SFY 2031**	**FY 3 – SFY 2032**
Acute Care Beds			
# of Beds	74	74	74
# of Patient Days	11,847	16,455	18,869
# of Discharges	2,451	3,384	3,858
ALOS	4.8	4.9	4.9
Occupancy Rate	43.9%	60.9%	69.9%
CT Scanner			
# of Units	2	2	2
# of Scans	7,646	10,620	12,177
# of HECT Units	12,708	17,651	20,240
Fixed X-ray (including fluoroscopy)			
# of Units	3	3	3
# of Procedures	11,903	16,532	18,957
Mammography			
# of Units	1	1	1
# of Procedures	3,006	4,175	4,787
Nuclear Medicine			
# of Units	1	1	1
# of Procedures	360	500	574
Ultrasound			
# of Units	3	3	3
# of Procedures	4,138	5,747	6,590
Emergency Department			
# of Bays (Rooms)	20	20	20
# of Visits	10,743	14,832	16,908
Observation Beds			
# of Beds	20	20	20
Days of Care	1,230	1,709	1,959
Laboratory			
# of Tests	151,142	209,925	240,713
Therapy			
PT Treatments	18,271	25,377	29,099
ST Treatments	1,641	2,279	2,613
OT Treatments	13,130	18,236	20,910

NOTE: Totals may not sum due to rounding.

UNC Hospitals-RTP Projected Operating Room and Procedure Room Services			
	FY 1 – SFY 2030	**FY 2 – SFY 2031**	**FY 3 – SFY 2032**
ORs - # of Rooms by Type			
# of Dedicated C-Section ORs	2	2	2
# of Shared ORs	2	2	2
Total ORs	4	4	4
# of Excluded ORs	2	2	2
Adjusted Planning Inventory	2	2	2
Surgical Cases			
# of Inpatient Cases (excludes C-Section)	867	1,238	1,459
# of Outpatient Cases	1,317	1,034	689
Total # Surgical Cases	2,184	2,273	2,148
Case Times (Section C, Question 5(c))			
Inpatient	113.7	113.7	113.7
Outpatient	72.7	72.7	72.7
Surgical Hours			
Inpatient	1,643	2,347	2,765
Outpatient	1,596	1,253	835
Total Surgical Hours	3,239	3,600	3,600
# of ORs Needed			
Group Assignment	4	4	4
Standard Hours per OR per Year	1,500	1,500	1,500
ORs Needed*	2.2	2.4	2.4
Procedure Rooms			
Rooms	4	4	4
Procedures	623	1,737	2,576

NOTE: Totals may not sum due to rounding
* ORs Needed = Total Surgical Hours / Standard Hours per OR per Year

In the Form C Utilization–Assumptions and Methodology subsection of Section Q, the applicant provides the assumptions and methodology used to project utilization, which are summarized below.

Acute Care Services

- The applicant obtained days of care for Durham County residents from IBM Watson Health for CY 2017 through CY 2019 and calculated a CAGR of 2.1% for medicine, 6.4% for surgery, -3.8% for obstetrics, and 1.9% for total days of care. (page 3)

- The applicant states that certain higher acuity services will not be provided at UNC Hospitals-RTP and reduced the number of acute care days provided to Durham County residents based on the excluded higher acuity services. (page 4)

- The applicant calculated potential days of care for Durham County residents between CY 2017 and CY 2019 after excluding the higher acuity services and

calculated a CAGR of 2.9% for medicine, 7.1% for surgery, -0.9% for obstetrics, and 3.4% for total days of care. (page 4)

- The applicant assumes the identified potential days of care will grow through 2032 at a rate equal to the CY 2017 through CY 2019 CAGR for each service. The table below shows the projected potential days of care for Durham County residents during CYs 2029 through 2032. (pages 4-5)

Durham County Resident Potential Days of Care CYs 2029-2032				
	CY 2029	CY 2030	CY 2031	CY 2032
Medicine	72,920	75,031	77,203	79,438
Surgery	44,144	47,288	50,655	54,263
Obstetrics	10,486	10,387	10,289	10,191
Total Days	**127,550**	**132,706**	**138,147**	**143,892**

- The applicant converted calendar years to the hospital's fiscal year (SFY 2030 = 0.5 * CY 2029 + 0.5 * CY 2030), resulting in the following potential days of care for Durham County residents. (pages 5-6)

Durham County Resident Potential Days of Care SFYs 2030-2032			
	SFY 2030	SFY 2031	SFY 2032
Medicine	73,976	76,117	78,321
Surgery	45,716	48,971	52,459
Obstetrics	10,436	10,338	10,240
Total Days	**130,128**	**135,426**	**141,020**

- The applicant used the same historical market share analysis as in Project ID #J-12065-21. The percentages it calculated represented UNC's average market share of Durham County residents between CY 2017 and CY 2019. The applicant calculated an average of 8.5% of medicine patients, 12.1% of surgery patients, and 15.6% of obstetrics patients. These percentages reflect UNC Health's market share of Durham County residents in facilities outside of Durham County. (pages 6-7)

- The applicant states that because the project will take three years longer to develop than the previously approved project, and have nearly double the amount of beds as the previously approved project, it now projects it will serve 110% of its historical market share. The applicant states that the additional time to develop the proposed project will also give it more time to broaden its patient base and further support its projected market share. (page 7)

- The applicant states it projects utilization will ramp up over the first three full fiscal years of operation, with 75% of historical market share utilization in its first fiscal year, 100% of historical market share utilization its second fiscal year, and 110% of historical market share utilization in its third fiscal year. The applicant states that while it projects a 10% increase from its previous market share, the actual increase

in the overall market share will be minimal. The increase in percentage of market share is shown below. (page 7)

UNC Hospitals-RTP Market Share of Durham County Potential Days of Care				
	SFY 2030 (75%)	SFY 2031 (100%)	SFY 2032 (110%)	CYs 2017-2019 Avg
Medicine	6.3%	8.5%	9.3%	8.5%
Surgery	9.1%	12.1%	13.3%	12.1%
Obstetrics	11.7%	15.6%	17.2%	15.6%

- The applicant applied the percentages above to the projected potential days of care for Durham County residents to calculate projected utilization, as shown in the table below. (pages 7-8)

UNC Hospitals-RTP Projected Acute Care Days – Durham County Residents			
	SFY 2030	SFY 2031	SFY 2032
Medicine	4,697	6,444	7,294
Surgery	4,149	5,926	6,983
Obstetrics	1,224	1,617	1,762
Total Days	**10,070**	**13,987**	**16,038**
ADC	**27.6**	**38.3**	**43.9**

- The applicant then projected in-migration. The applicant states that it examined the in-migration of all 116 North Carolina acute care hospitals (Exhibit C.5-2) to determine a reasonable and appropriate in-migration rate for the proposed facility. The applicant states that while it used an in-migration projection of 10% in Project ID #J-12065-21, based on the additional time it will take to develop and the higher number of beds, it projects in-migration will be 15%. The applicant states that out of all 116 acute care hospitals in North Carolina, only 15 had in-migration rates of 15% or less. The applicant applied an assumed 15% in-migration rate to its previous utilization projections. (pages 9-10)

- The applicant based its projected discharges on its projected days of care, including the in-migration, and the CY 2019 ALOS for Durham County residents at UNC hospitals. (page 10)

The applicant's projected utilization calculations are summarized in the table below.

UNC Hospitals-RTP Projected Utilization – Acute Care Beds			
	SFY 2030	**SFY 2031**	**SFY 2032**
Medicine	4,697	6,444	7,294
Surgery	4,149	5,926	6,983
Obstetrics	1,224	1,617	1,762
Total Durham County Days	10,070	13,987	16,038
In-migration (15%)	1,777	2,468	2,830
Total Acute Care Days	11,847	16,455	18,869
ADC	32.5	45.1	51.7
Total Acute Care Beds	74	74	74
Occupancy Rate	43.9%	60.9	69.9%
Total Discharges	2,451	3,384	3,858

UNC does not currently have any acute care beds in the Durham/Caswell multicounty service area. Pursuant to 10A NCAC 14C .3803(a), an applicant proposing to add new acute care beds to a service area must reasonably project that all acute care beds in the service area under common ownership will have a utilization of at least 66.7 percent when the projected Average Daily Census (ADC) is fewer than 100 patients in the third operating year following completion of the proposed project.

As shown in the table above, in the third full fiscal year following project completion, the applicant projects the utilization for all acute care beds at UNC Hospitals-RTP will be 69.9%. This meets the performance standard promulgated in 10A NCAC 14C .3803(a), which requires an applicant proposing to add new acute care beds to a service area to reasonably project that all acute care beds in the service area under common ownership will have a utilization of at least 66.7% when the projected ADC is fewer than 100 patients.

The applicant states that it projects to serve a portion of the projected growth in acute care days for Durham County residents. The applicant states that, based on the historical growth rate of acute care days for the selected services it proposes to offer, there will be 143,892 potential days of care during CY 2032 for Durham County residents receiving the selected services proposed by the applicant – an increase of 55,358 days of care over CY 2019. The applicant states that since it proposes to serve only a portion of the projected growth in days of care for Durham County residents, it does not expect the development of UNC Hospitals-RTP to impact other hospitals that serve residents of Durham County, because those hospitals are expected to serve the same number of patients or more than they currently do. The applicant also notes that UNC Hospitals-RTP does not project to serve higher acuity patients and growth in those days of care are not included in the applicant's analysis of projected utilization. (pages 11-12)

Surgical Services

- The applicant proposes to develop two procedure rooms as part of the proposed project for a total of four approved and proposed procedure rooms but is not

applying to increase the number of ORs at UNC Hospitals-RTP. However, the applicant updated its projected OR utilization based on its updated projections for acute care days and the shift in the first three full fiscal years, and relies on the updated surgical cases to project procedure room utilization. Thus, the applicant's updated OR utilization is included in the discussion of projected utilization for procedure rooms. (pages 20-21)

- Consistent with Project ID #J-12065-21, the applicant used the FFY 2019 experience at UNC Hillsborough and assumed a ratio of 1.5 outpatient surgical cases to inpatient surgical cases and a ratio of 0.29 procedure room procedures to OR surgical cases. (pages 21-22)

- The applicant used the 2022 SMFP Group 4 inpatient and outpatient case times to project surgical hours through the third full fiscal year following project completion. (pages 22-23)

- The applicant assumed it would operate both approved ORs at 90% of capacity, or 1,800 hours per OR per year, that all inpatient surgical cases would be performed in one of the two approved ORs, and that any outpatient surgical cases that could not be performed in one of the ORs operating at 90% of capacity would be performed in a procedure room (which would be built to OR standards). (pages 23-26)

The applicant's OR and procedure room utilization assumptions are summarized below.

UNC Hospitals-RTP Projected Utilization – Surgical Services			
	SFY 2030	**SFY 2031**	**SFY 2032**
Inpatient Surgical Cases	867	1,238	1,459
Inpatient Surgical Hours (113.7 minutes)	1,643	2,347	2,765
Outpatient Surgical Cases (Inpatient * 1.5)	1,317	1,881	2,217
Outpatient Surgical Hours (72.7 minutes)	1,596	2,279	2,686
Total Surgical Cases (Inpatient & Outpatient)	**2,184**	**3,120**	**3,676**
Total Surgical Hours	**3,239**	**4,626**	**5,451**
ORs Needed (Group 4, 1,500 hours)	2.2	3.1	3.6
Available Surgical Hours (at 90% capacity)	3,600	3,600	3,600
Inpatient Surgical Hours	1,643	2,347	2,765
Remaining Surgical Hours for Outpatient Cases	1,957	1,253	835
Outpatient Surgical Cases in ORs (72.7 minutes)	1,317	1,034	689
Remaining Outpatient Surgical Cases in Procedure Rooms	0	847	1,528
Total Surgical Cases (Inpatient & Outpatient)	2,184	3,120	3,676
Procedure Room Procedures (0.29 ratio)	623	890	1,048
Total Outpatient Surgical Cases/Procedures in Procedure Rooms	623	1,737	2,576

The applicant states that it needs four procedure rooms due to the projected utilization of the ORs (and resulting need to perform outpatient cases in procedure rooms) and

because of the efficiencies involved in turning around procedure rooms typically used for shorter cases with faster turnaround times. (pages 26-27)

LDR and C-Section Rooms

The applicant is proposing to develop two unlicensed LDR beds in addition to the four unlicensed LDR beds approved in Project ID #J-12065-21 for a total of six unlicensed LDR beds. The applicant does not propose to develop any additional dedicated C-Section ORs and will have a total of two dedicated C-Section ORs (approved in Project ID #J-12065-21).

Consistent with its projections in Project ID #J-12065-21, the applicant used the same assumptions, based on IBM Watson Health data, that 90% of Durham County resident obstetrics acute care discharges in CY2019 resulted in a delivery and that 23.7% of those deliveries were via C-Section. The applicant's updated projections for obstetrics discharges, deliveries, and C-Sections are shown below. (page 27)

UNC Hospitals-RTP Projected Obstetrics Discharges, Deliveries, & C-Sections			
	SFY 2030	SFY 2031	SFY 2032
Obstetric Discharges	539	712	776
Deliveries	485	641	698
C-Sections	115	152	165

The applicant states it proposes to add two additional unlicensed LDR beds for a total of six unlicensed LDR beds to support the number of deliveries and discharges during SFY 2032.

Emergency Department

The applicant is proposing to add eight additional ED bays in addition to the 12 ED bays approved in Project ID #J-12065-21 for a total of 20 ED bays. Consistent with its projections in Project ID #J-12065-21, the applicant used the same assumptions, based on IBM Watson Health data, that 61.4% of Durham County resident acute care discharges in CY2019 were admitted through the ED and therefore 61.4% of UNC Hospitals-RTP's projected discharges would be admitted through the ED, and that 14% of ED visits for Durham County residents at all hospitals resulted in an admission and therefore 14% of UNC Hospitals-RTP's ED visits would result in an admission. (pages 12-14)

The applicant's projected ED visits and admissions are summarized in the table below.

UNC Hospitals-RTP Projected ED Utilization			
	FY 1 (SFY 2030)	FY 2 (SFY 2031)	FY 3 (SFY 2032)
Total Discharges	2,451	3,384	3,858
% Admitted from ED	61.4%	61.4%	61.4%
ED Admissions	1,505	2,078	2,369
ED Admissions as % of Visits	14.0%	14.0%	14.0%
ED Visits	10,743	14,832	16,908
Visits per ED Bay (20)	537	742	845

The applicant states its average visits per ED bay is slightly higher in the current application than in Project ID #J-12065-21, which it believes supports the need for the additional ED bays, and also states that the American College of Emergency Physicians guidelines state that a facility with 20,000 annual visits should have between 14-16 ED bays. The applicant states that having 20 ED bays will allow for continued growth before operational issues would require expansion.

The applicant further states that even assuming a slightly negative growth rate in ED visits, it would have a market share of approximately 13.9% of Durham County resident ED visits by its third full fiscal year, and that UNC facilities already served 9.5% of Durham County resident ED visits in CY 2019, without having any facilities in Durham County.

Imaging and Ancillary Services

- The applicant proposes to add one fixed CT scanner and one ultrasound unit in addition to the fixed CT scanner, two ultrasound units, and other imaging equipment approved in Project ID #J-12065-21.

- Consistent with its projections in Project ID #J-12065-21, the applicant assumed the ratio of procedures to acute care days at UNC Hillsborough during FFY 2019 would be the most appropriate assumption to project future imaging and ancillary procedures. Projected ratios and utilization of imaging and ancillary services is shown in the table below. (pages 15-18)

UNC Hospitals-RTP Projected Utilization – Imaging and Ancillary Services				
	Ratio to Days	FY 1 (SFY 2030)	FY 2 (SFY 2031)	FY 3 (SFY 2032)
Projected Acute Care Days		11,847	16,455	18,869
CT Scans	0.60	7,646	10,620	12,177
Ultrasound Procedures	0.30	4,138	5,747	6,590
X-ray Procedures	1.00	11,903	16,532	18,957
Nuclear Procedures	0.03	360	500	574
Mammography Procedures	0.30	3,006	4,175	4,787
Physical Therapy Units	1.50	18,271	25,377	29,099
Occupational Therapy Units	1.10	13,130	18,236	20,910
Speech Therapy Units	0.10	1,641	2,279	2,613
Lab Tests	12.80	151,142	209,925	240,713

- The applicant provides the calculations for CT HECT units using UNC Hillsborough's FFY 2019 ratio of HECT units to CT scans (1.66), as shown below. (page 18)

UNC Hospitals-RTP Projected CT Utilization			
	FY 1 (SFY 2030)	FY 2 (SFY 2031)	FY 3 (SFY 2032)
CT Scans	7,646	10,620	12,177
HECT Units per Scan	1.66	1.66	1.66
HECT Units	12,708	17,651	20,240
CT Scanners	2	2	2
HECT Units per CT Scanner	6,354	8,826	10,120

Observation Beds

The applicant proposes to add 10 unlicensed observation beds in addition to the 10 unlicensed observation beds approved in Project ID #J-12065-21 for a total of 20 unlicensed observation beds.

Consistent with its projections in Project ID #J-12065-21, the applicant assumed the ratio of observation days to acute care days at UNC Hillsborough during FFY 2019 (0.10) would be the most appropriate assumption to project future observation days. The applicant projects observation patient days of 1,230, 1,709, and 1,959 for SFY 2030, SFY 2031, and SFY 2032, respectively. (pages 19-20)

The applicant states that observation beds are also used for patients who need extra recovery time after procedures, for ED patients who need additional observation before determining if an inpatient admission is needed, or for ED patients waiting for test results during times of higher ED utilization. The applicant further states that developing the number of proposed observation beds will allow for future growth beyond the first three full fiscal years before utilization would require expansion.

Projected utilization is reasonable and adequately supported based on the following:

- The applicant bases its projections for all services on historical IBM Watson Health data, historical experience at UNC Hillsborough, a satellite campus of UNC Hospitals in Orange County with 83 acute care beds, or the historical experience of Durham County residents at UNC facilities.

- The applicant provides examples of data from other similarly situated facilities around the state to support the reasonableness of its assumptions.

- The applicant limits the projected utilization to inpatients needing the services and having the appropriate acuity level based on the services it proposes to offer.

- The applicant relies on either a historical 2-year CAGR or CY 2019 data as a base point in projections, which is consistent with Project ID #J-12065-21. The Agency

found Project ID #J-12065-21 and its projected utilization reasonable and adequately supported and there is nothing in the application as submitted or in other public materials that suggests the same type of projections in this specific application would not be reasonable or adequately supported.

- The applicant explains in detail why it chose to rely on CY 2019 data and not more recent data in making its utilization projections.

- The applicant provides analysis to show that projected growth in Durham County acute care bed utilization would exceed its own projected utilization.

Access to Medically Underserved Groups – In Section C, page 70, the applicant states:

> *"Access by medically underserved groups will not be different from what was projected in the previously approved application in terms of the percentage of care provided to underserved groups. UNC Hospitals provides and will continue to provide services to all persons in need of medical care, regardless of race, color, religion, national origin, sex, age, disability, or source of payment. The same will be true for the UNC Hospitals-RTP upon completion of the proposed change of scope project."*

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 based on the following:

- The applicant provides its policy on Assuring Access at UNC Health Care in Exhibit B.20-5, which states it does not exclude or otherwise discriminate against medically underserved groups.

- The applicant provides copies of its financial policies in Exhibit B.20-6.

- Project ID #J-12065-21 was conforming with this criterion and the applicant proposes no changes in the application as submitted which would affect that determination.

Conclusion – The Agency reviewed the:

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

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

(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.

NA – Both Applications

Neither of the applicants propose to reduce a service, eliminate a service, or relocate a facility or service. Therefore, Criterion (3a) is not applicable to this review.

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

NC – Duke University Hospital
C – UNC Hospitals-RTP

Project ID #J-12211-22/Duke University Hospital/Add 68 acute care beds

The applicant proposes to add 68 new acute care beds to DUH, a hospital with 1,062 existing and approved acute care beds, for a total of 1,130 acute care beds upon completion of this project and Project ID #J-11717-19 (add 34 beds).

In Section E, pages 52-53, 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 inpatient utilization increases combined with the current occupancy rate at DUH demonstrate that maintaining the status quo is not an effective option and it would face ongoing pressures to meet demand due to severe capacity constraints; therefore, maintaining the status quo was not an effective alternative.

- Develop Beds at a New Campus or Facility: the applicant states developing a new inpatient hospital would require extensive work, including site identification and preparation, utility and infrastructure construction, and numerous other challenges that would be costly and require lots of time. Additionally, the applicant states the services that are needed are the tertiary and quaternary care services that can't be

provided at another facility; therefore, developing beds at a new campus was not an effective alternative.

- Develop Beds at DRH: the applicant states there is more capacity at DRH than at DUH right now, so the more pressing need to develop new capacity is at DUH. The applicant also states DRH could not necessarily accommodate demand for DUH's tertiary and quaternary care; therefore, developing beds at DRH was not an effective alternative.

However, the applicant does not adequately demonstrate that the alternative proposed in this application is the most effective alternative to meet the need based on the following:

- The applicant did not adequately demonstrate the need it has for the proposed project or that projected utilization is based on reasonable and adequately supported assumptions. The discussion regarding analysis of need including projected utilization found in Criterion (3) is incorporated herein by reference. A proposal that is not needed by the population proposed to be served cannot be the most effective alternative.

- The applicant did not demonstrate in the application as submitted that it was conforming with the Criteria and Standards for Acute Care Beds promulgated in 10A NCAC 14C .3803(a). The discussion regarding analysis of need including projected utilization found in Criterion (3) is incorporated herein by reference. A proposal that cannot meet required performance standards cannot be the most effective alternative.

- Because the applicant did not demonstrate the need to develop the proposed project, the applicant cannot demonstrate that it needs to develop 68 new acute care beds in addition to the existing and approved acute care beds in the Durham/Caswell multicounty service area. The discussion regarding unnecessary duplication found in Criterion (6) is incorporated herein by reference. A project that is unnecessarily duplicative cannot be the most effective alternative.

- Because the applicant did not demonstrate the need to develop 68 new acute care beds, it cannot demonstrate that any enhanced competition in the service area includes a positive impact on the cost-effectiveness of the proposed services. An applicant that did not demonstrate the need for a proposed project cannot demonstrate the cost-effectiveness of the proposed project. The discussion regarding demonstrating 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, found in Criterion (18a) is incorporated herein by reference. A project that cannot show a positive impact on the cost-effectiveness of the proposed services as the result of any enhanced competition cannot be the most effective alternative.

- The application is not conforming to all statutory and regulatory review criteria. An application that cannot be approved cannot be the most effective alternative.

Conclusion – The Agency reviewed the:

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

Based on that review, the Agency concludes that the application is not conforming to this criterion for all the reasons stated above.

Project ID #J-12214-22/UNC Hospitals-RTP/Add 34 acute care beds

The applicant proposes a change of scope to Project ID #J-12065-21, which approved the development of UNC Hospitals-RTP with 40 acute care beds (currently under appeal; no CON has been issued). The applicant proposes to add 34 acute care beds and additional hospital-based services for a total of 74 acute care beds upon approval of this project and Project ID #J-12065-21.

In Section E, pages 78-79, 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 maintaining the status quo would not address any part of the need for 68 additional acute care beds and would prevent UNC from having sufficient capacity to expand access for the growing population particularly in the southern part of Durham County. The applicant also states that adding more beds to the facility while it is under development is more patient-focused and financially prudent than doing the same thing after the facility has opened, and that the types of services driving the need for additional acute care beds are lower acuity services which it can provide at an appropriately-sized community hospital. Therefore, this was not an effective alternative.

- Develop the Hospital at a Different Location: the applicant states development of the hospital at a different location may end up being a better alternative than the selected site, but at this time the most effective location is the approved site in southern Durham County; therefore, this was not an effective alternative.

- Develop a Different Number of Beds: the applicant states that developing fewer acute care beds would be less effective at meeting the needs of physicians and patients, and developing more acute care beds, while likely feasible, would prevent the development of additional acute care bed capacity at tertiary and quaternary hospitals in the service area; therefore, this was not an effective alternative.

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 other statutory and regulatory review criteria.

Conclusion – 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 application is conforming to this criterion for all the reasons stated above.

(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.

NC – Duke University Hospital
C – UNC Hospitals-RTP

Project ID #J-12211-22/Duke University Hospital/Add 68 acute care beds

The applicant proposes to add 68 new acute care beds to DUH, a hospital with 1,062 existing and approved acute care beds, for a total of 1,130 acute care beds upon completion of this project and Project ID #J-11717-19 (add 34 beds).

Capital and Working Capital Costs – On Form F.1a in Section Q, the applicant projects a total capital cost of $4,828,000, consisting entirely of medical equipment.

The applicant provides its assumptions and methodology for projecting capital cost immediately following Form F.1a in Section Q. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based on the following:

- The applicant explains why construction and other typical costs are unnecessary.
- The applicant explains how it determined the cost to equip each individual room.

In Section F, page 56, the applicant states there will be no working capital costs because DUH is an existing and operational facility that currently offers the services proposed in this application. This information is reasonable and adequately supported because DUH is an existing hospital and will continue to operate during and after development of the proposed project.

Availability of Funds – In Section F, pages 54-55, the applicant states the entire projected capital expenditure of $4,828,000 will be funded by Duke's accumulated reserves.

In Exhibit F.2(a), the applicant provides a letter dated April 7, 2022, from the Senior Vice President, Chief Financial Officer & Treasurer for Duke, stating that Duke has sufficient accumulated reserves to fund all projected capital costs and committing to providing that funding to develop the proposed project.

Exhibit F.2(b) contains a copy of the audited Consolidated Financial Statements and Supplemental Information for Duke University Health System, Inc. and Affiliates for the years ending June 30, 2021, and 2020. According to the audited Consolidated Financial Statements, as of June 30, 2021, Duke had adequate cash and assets to fund all the capital needs of the proposed project.

The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project based on the following:

- The applicant provides a letter from the appropriate Duke official confirming the availability of the funding proposed for the capital needs of the project and the commitment to use those funds to develop the proposed project.

- The applicant provides adequate documentation of the accumulated reserves it proposes to use to fund the capital needs of the project.

Financial Feasibility – The applicant provided pro forma financial statements for the first three full fiscal years of operation following project completion. On Form F.2b in Section Q, the applicant projects operating expenses will exceed revenues in each of the first three full fiscal years following project completion, as shown in the table below.

DUH Revenues and Operating Expenses – Adult Inpatient Beds			
	1st Full FY SFY 2024	2nd Full FY SFY 2025	3rd Full FY SFY 2026
Number of Discharges	37,222	37,780	38,347
Total Gross Revenues (Charges)	$3,501,033,221.11	$3,553,517,680.23	$3,606,848,662.88
Total Net Revenue	$1,139,164,151.04	$1,167,737,968.06	$1,197,065,445.03
Total Net Revenue per Discharge	$30,604.59	$30,908.90	$31,216.66
Total Operating Expenses (Costs)	$1,379,150,007.25	$1,432,676,730.65	$1,488,469,720.18
Total Operating Expense per Discharge	$37,052.01	$37,921.57	$38,815.81
Net Income/(Losses)	**($239,985,856.20)**	**($264,938,762.59)**	**($291,404,275.15)**

The applicant also provides pro formas for the entire Duke system for the first three full fiscal years of operation following project completion. The applicant projects revenues for the entire Duke system will exceed operating expenses in each of the first three full fiscal years following project completion, as shown in the table below.

Duke System Revenues and Operating Expenses (in thousands)			
	1st Full FY SFY 2024	2nd Full FY SFY 2025	3rd Full FY SFY 2026
Total Gross Revenues (Charges)	$15,357,606	$16,077,027	$16,829,388
Total Net Revenue	$4,750,949	$4,953,979	$5,173,504
Total Operating Expenses (Costs)	$4,656,472	$4,780,806	$4,914,982
Net Income/(Losses)	**$94,447**	**$173,173**	**$258,522**

The assumptions used by the applicant in preparation of the pro forma financial statements are provided immediately following Forms F.2b and F.3b for both DUH and the entire Duke system in Section Q.

However, the assumptions used by the applicant in preparation of the pro forma financial statements are not reasonable and adequately supported because projected utilization is questionable. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference. Therefore, since projected revenues and expenses are based at least in part on projected utilization, projected revenues and expenses are also questionable.

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 not conforming to this criterion because the applicant does not adequately demonstrate that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

Project ID #J-12214-22/UNC Hospitals-RTP/Add 34 acute care beds

The applicant proposes a change of scope to Project ID #J-12065-21, which approved the development of UNC Hospitals-RTP with 40 acute care beds (currently under appeal; no CON has been issued). The applicant proposes to add 34 acute care beds and additional hospital-based services for a total of 74 acute care beds upon approval of this project and Project ID #J-12065-21.

Capital and Working Capital Costs – On Form F.1b in Section Q, the applicant provides the original approved capital expenditure for Project ID #J-12065-21, the proposed capital expenditure for the current proposal, and the combined total capital expenditure, as shown in the table below.

UNC Hospitals-RTP Previously Approved & Newly Projected Capital Expenditures			
	Previously Approved (J-12065-21)	Newly Proposed (J-12214-22)	Total
Purchase Price of Land	$35,000,000	$0	$35,000,000
Closing Costs	$184,000	$0	$184,000
Site Preparation	$26,868,714	$7,395,138	$34,263,852
Construction Contracts	$126,448,482	$197,034,266	$323,482,748
Landscaping	$398,401	$302,690	$701,091
Architect/Engineering Fees	$14,846,480	$18,607,294	$33,453,774
Medical Equipment	$22,833,519	$26,882,730	$49,716,249
Non-Medical Equipment	$8,924,842	$10,507,540	$19,432,382
Furniture	$3,880,484	$4,568,635	$8,449,119
Consultant Fees*	$2,203,391	$309,801	$2,513,192
Other**	$10,320,216	$13,698,075	$24,018,291
Total	**$251,908,529**	**$279,306,169**	**$531,214,698**

*Third-party inspections, commissioning authority fees
**Contingency, permits/fees inspection

The applicant provides its assumptions and methodology for projecting capital cost immediately following Form F.1b in Section Q. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based on the following:

- The applicant provides assumptions about costs included in the calculation of each line item in the projected capital cost.
- The applicant states much of the projections are based on UNC's history or the project architect's history in developing similar projects.

In Section F, page 91, the applicant states that working capital costs are projected to increase and provides the following information:

UNC Hospitals-RTP Previously Approved & Newly Projected Working Capital Costs	
New total estimated start-up costs	$5,831,936
New total estimated initial operating costs	$8,747,905
New total working capital	$14,579,841
Previously approved total working capital (J-12065-21)	$6,143,566
Difference	$8,436,275

In Section F, page 91, the applicant provides the assumptions used to project the increase in working capital costs. The information is reasonable and adequately supported based on the following:

- The applicant states the updated utilization projections are part of the increase in working capital costs.

- The applicant states the additional capital cost with the change of scope is also part of the increase in working capital costs.

Availability of Funds – In Section F, pages 89-91, the applicant states the entire projected capital expenditure of $279,306,169 and the entire working capital cost of $14,579,841 will be funded with UNC's accumulated reserves.

In Exhibit F.5-2, the applicant provides a letter dated April 15, 2022, from the Chief Financial Officer for UNC Hospitals, stating that UNC Hospitals has sufficient accumulated reserves to fund the projected capital and working capital costs and committing to providing that funding to develop the proposed project.

Exhibit F.5-3 contains a copy of UNC's Financial Statement Audit Report for the year ending June 30, 2021, completed by the State Auditor. According to the Financial Statement Audit Report, as of June 30, 2021, UNC had adequate cash and assets to fund all the capital and working capital needs of the proposed project.

The applicant adequately demonstrates the availability of sufficient funds for the capital and working capital needs of the project based on the following:

- The applicant provides a letter from the appropriate UNC official confirming the availability of the funding proposed for the capital and working capital needs of the project and the commitment to use those funds to develop the proposed project.

- The applicant provides adequate documentation of the accumulated reserves it proposes to use to fund the capital and working capital needs of the project.

Financial Feasibility – The applicant provided pro forma financial statements for the first three full fiscal years of operation following project completion. In Form F.2b, the applicant projects operating expenses will exceed revenues in the first full fiscal year following project completion, but revenues will exceed operating expenses in the

second and third full fiscal year following project completion, as shown in the table below.

Revenues and Operating Expenses – UNC Hospitals-RTP			
	1st Full FY SFY 2030	2nd Full FY SFY 2031	3rd Full FY SFY 2032
Total Discharges	8,038	8,161	8,277
Total Gross Revenues (Charges)	$251,449,915	$361,378,755	$429,396,602
Total Net Revenue	$88,830,807	$127,740,417	$151,898,157
Total Net Revenue per Discharge	$11,051	$15,653	$18,352
Total Operating Expenses (Costs)	$95,022,529	$122,954,094	$141,129,372
Total Operating Expenses per Discharge	$11,822	$15,066	$17,051
Net Income/(Losses)	**($6,191,722)**	**$4,786,323**	**$10,768,785**

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in forms immediately prior to Forms F.2b and F.3b in Section Q. The applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

- The applicant clearly details the sources of data used to project revenues and expenses.

- The applicant bases its projections on its own historical experience at UNC Hillsborough, a satellite campus of UNC Hospitals in Orange County with 83 acute care beds.

- 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 for all the reasons described above.

- The applicant adequately demonstrates availability of sufficient funds for the capital and working capital needs of the proposal for all the reasons described above.

- 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 revenues and operating expenses for all the reasons described above.

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

NC – Duke University Hospital
C – UNC Hospitals-RTP

The 2022 SMFP includes a need determination for 68 acute care beds in the Durham/Caswell multicounty service area.

On page 33, the 2022 SMFP defines the service area for acute care beds as *"... the single and multicounty groupings shown in Figure 5.1."* Figure 5.1, on page 38, shows Durham and Caswell counties in a multicounty grouping. Thus, the service area for these facilities is the Durham/Caswell multicounty service area. Facilities may also serve residents of counties not included in their service area.

As of the date of this decision, there are 1,442 existing and approved acute care beds, allocated between four existing and approved hospitals owned by three providers in the Durham/Caswell multicounty service area, as illustrated in the following table.

Durham/Caswell Multicounty Service Area Acute Care Hospital Campuses	
Facility	**Existing/(Approved) Beds**
Duke University Hospital*	1,048 (+14)
Duke Regional Hospital	316
Duke Total	**1,364 (+14)**
North Carolina Specialty Hospital	18 (+6)
UNC Hospitals-RTP**	0 (+40)
Durham/Caswell Multicounty Service Area Total	**1,382 (+60)**

Source: Table 5A, 2022 SMFP; applications under review; 2022 LRAs; Agency records.
Note: Numbers in parentheses reflect approved changes in bed inventory which have not yet been developed.
*Includes 14 Policy AC-3 NICU beds that are not included in Table 5A or the planning inventory for DUH.
**As of the date of this decision, the 40 acute care beds have been awarded to UNC Hospitals-RTP; however, the decision is under appeal and no CON has been issued at this time.

Project ID #J-12211-22/Duke University Hospital/Add 68 acute care beds

The applicant proposes to add 68 new acute care beds to DUH, a hospital with 1,062 existing and approved acute care beds, for a total of 1,130 acute care beds upon completion of this project and Project ID #J-11717-19 (add 34 beds).

In Section G, pages 62-63, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved acute care beds in the Durham/Caswell multicounty service area. The applicant states that North Carolina Specialty Hospital offers primarily surgical services in a limited number of specialties and serves a much different patient population than DUH. The applicant states DRH's capacity is restricted by facility limitations, and it does not offer the same tertiary or quaternary care services as DUH, but despite that its utilization is growing. The applicant states the beds awarded to UNC Hospitals-RTP are under appeal but that regardless they have already been subtracted from the Durham/Caswell multicounty service area's need determination and so would not be duplicative. On page 62, the applicant states:

> *"…the need for additional inpatient capacity was driven by the demand for DUH's highly specialized services. The proposed 68 additional acute care beds are specifically needed at DUH to expand access to the hospital's well-utilized inpatient acute care services which do not duplicate the services provided by any other facility. …, DUH patients come from across the state, and it is their need that drives the demand for additional capacity."*

However, the applicant does not adequately demonstrate that the proposal would not result in an unnecessary duplication of existing or approved services in the service area based on the following analysis:

- The applicant did not adequately demonstrate the need it has for the proposed project or that its projected utilization is based on reasonable and adequately supported assumptions. The discussion regarding analysis of need including projected utilization found in Criterion (3) is incorporated herein by reference.

- The applicant did not demonstrate in the application as submitted that it was conforming with the Criteria and Standards for Acute Care Beds promulgated in 10A NCAC 14C .3803(a). The discussion regarding analysis of need including projected utilization found in Criterion (3) is incorporated herein by reference.

- Because the applicant did not demonstrate the need to develop 68 new acute care beds, it cannot demonstrate that the 68 new acute care beds are needed in addition to the existing and approved acute care beds in the Durham/Caswell multicounty service area.

<u>Conclusion</u> – The Agency reviewed the:

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

Based on that review, the Agency concludes that the application is not conforming to this criterion for all the reasons described above.

Project ID #J-12214-22/UNC Hospitals-RTP/Add 34 acute care beds

The applicant proposes a change of scope to Project ID #J-12065-21, which approved the development of UNC Hospitals-RTP with 40 acute care beds (currently under appeal; no CON has been issued). The applicant proposes to add 34 acute care beds and additional hospital-based services for a total of 74 acute care beds upon approval of this project and Project ID #J-12065-21.

In Section G, page 94, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved acute care bed services in the Durham/Caswell multicounty service area. On page 94, the applicant states:

> *"All service components involved in the proposed change of scope project were included in the previously approved Project ID #J-12065-21. Further, the 2022 SMFP includes a need for 68 additional acute care beds in the Durham/Caswell service area, of which this project proposes to develop only 34. …, the proposed project will better optimize UNC Hospitals-RTP by enhancing capacity and ensuring sufficient resources to provide all the services required to support the provision of high-quality care.*
>
> *In addition, all of the services to be offered at UNC Hospitals-RTP, which include not only acute care inpatient services, but also emergency services, surgical services, imaging services, as well as ancillary and support services, are part of both the previously approved application and the proposed change of scope and are essential to the development and operation of the previously approved facility as a full service hospital. Other existing outpatient services in the market, such as imaging or surgical services, do not offer services to inpatients as proposed at UNC Hospitals-RTP."*

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

- There is a need determination in the 2022 SMFP for the proposed acute care beds.

- The applicant provides information to explain why it believes the proposed project will not unnecessarily duplicate existing or approved acute care beds in the Durham/Caswell multicounty service area.

- The applicant adequately demonstrates that the proposed acute care beds are needed in addition to the existing and approved acute care beds. The discussion regarding demonstration of need found in Criterion (3) is incorporated herein by reference.

Conclusion – 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 application is conforming to this criterion for all the reasons described above.

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

C – Both Applications

Project ID #J-12211-22/Duke University Hospital/Add 68 acute care beds

The applicant proposes to add 68 new acute care beds to DUH, a hospital with 1,062 existing and approved acute care beds, for a total of 1,130 acute care beds upon completion of this project and Project ID #J-11717-19 (add 34 beds).

On Form H in Section Q, the applicant provides current and projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

DUH Current & Projected Staffing				
Position	Current	Projected		
	SFY 2022	FY 1 SFY 2024	FY 2 SFY 2025	FY 3 SFY 2026
Nurse Practitioners	5.0	5.2	5.4	5.7
Registered Nurses	1,869.9	1,926.4	2,014.4	2,138.0
Licensed Practical Nurses	4.6	4.7	4.9	5.2
Certified Nurse Aides/ Nursing Assistants	457.3	471.1	492.6	522.9
Surgical Technicians	2.7	2.8	2.9	3.1
Clerical	5.7	5.9	6.2	6.5
Nurse Manager	26.0	26.0	26.0	26.0
Physician	2.3	2.4	2.5	2.7
Total Staffing	**2,373.5**	**2,444.5**	**2,554.9**	**2,710.1**

The assumptions and methodology used to project staffing are provided on Form H Assumptions immediately following Form H in Section Q. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.3b, which is found in Section Q. In Section H, pages 65-66, the applicant describes the methods to be used to recruit or fill new positions and its proposed training and continuing education programs. The applicant provides supporting documentation in Exhibit H-3.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services based on the following:

- The applicant adequately demonstrates it has experience in acquiring sufficient personnel to provide services and provides documentation about the ways it has done so in the past that will be used for the proposed project.

- The applicant adequately documents the number of FTEs it projects will be needed to offer the proposed services.

- The applicant accounts for projected salaries and other costs of employment in its projected operating expenses found on Form F.3b in Section Q.

- The applicant provides adequate documentation of its policy for continuing education programs, leave, and financial assistance associated with continuing education for nurses.

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 described above.

Project ID #J-12214-22/UNC Hospitals-RTP/Add 34 acute care beds

The applicant proposes a change of scope to Project ID #J-12065-21, which approved the development of UNC Hospitals-RTP with 40 acute care beds (currently under appeal; no CON has been issued). The applicant proposes to add 34 acute care beds and additional hospital-based services for a total of 74 acute care beds upon approval of this project and Project ID #J-12065-21.

On Form H in Section Q, the applicant provides projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

UNC Hospitals-RTP Projected Staffing			
Position	**FY 1 (SFY 2030)**	**FY 2 (SFY 2031)**	**FY 3 (SFY 2032)**
Registered Nurses	89.6	128.8	153.0
Director of Nursing	1.0	1.0	1.0
Surgical Technicians	19.9	28.6	34.0
Lab Technicians	7.1	10.3	12.2
Radiology Technologists	12.6	18.1	21.5
Pharmacists	3.0	4.4	5.2
Pharmacy Technicians	4.0	5.7	6.8
Physical Therapists	1.9	2.7	3.2
Speech Therapists	1.2	1.2	1.2
Occupational Therapists	1.3	1.9	2.2
Respiratory Therapists	6.4	9.3	11.0
Dieticians	1.9	1.9	1.9
Cooks	5.9	8.4	10.0
Dietary Aides	3.3	4.7	5.6
Social Workers	2.0	2.0	2.0
Housekeeping	17.5	25.1	29.8
Bio-medical Engineering	2.0	2.0	2.0
Maintenance/ Engineering	14.0	14.0	14.0
Chief Operating Officer	1.0	1.0	1.0
Clerical	13.9	19.9	23.7
Other*	72.4	101.8	118.0
Total	**284.9**	**392.6**	**459.3**

*The applicant lists the positions and FTEs in the “Other” category on Form H in Section Q.

The assumptions and methodology used to project staffing are provided on Form H Assumptions immediately following Form H in Section Q. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.3b, which is found in Section Q.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services based on the following:

- The applicant adequately documents the number of FTEs it projects will be needed to offer the proposed services.

- The applicant's projections for FTEs are based on its own historical experience at other UNC facilities.

- The applicant accounts for projected salaries and other costs of employment in its projected operating expenses found on Form F.3b in Section Q.

- The methods to be used by the applicant to recruit or fill new positions and its proposed training and continuing education programs were found conforming with this criterion in Project ID #J-12065-21 and the applicant proposes no changes in the application as submitted that would affect that determination.

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 described 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 – Both Applications

Project ID #J-12211-22/Duke University Hospital/Add 68 acute care beds

The applicant proposes to add 68 new acute care beds to DUH, a hospital with 1,062 existing and approved acute care beds, for a total of 1,130 acute care beds upon completion of this project and Project ID #J-11717-19 (add 34 beds).

Ancillary and Support Services – In Section I, page 67, the applicant identifies the necessary ancillary and support services for the proposed services. In Section I, page 67, the applicant explains how each ancillary and support service will be made available. The applicant adequately demonstrates that the necessary ancillary and support services will be made available because it currently provides those services for its existing acute care beds and will continue to do so for its proposed acute care beds.

Coordination – In Section I, pages 67-68, the applicant describes Duke's existing and proposed relationships with other local health care and social service providers. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the following:

- The applicant is part of a large and existing healthcare system in the Durham/Caswell multicounty service area.

- On page 68, Duke provides a link to its 2021 Report on Community Benefit which describes its community investment.

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.

Project ID #J-12214-22/UNC Hospitals-RTP/Add 34 acute care beds

The applicant proposes a change of scope to Project ID #J-12065-21, which approved the development of UNC Hospitals-RTP with 40 acute care beds (currently under appeal; no CON has been issued). The applicant proposes to add 34 acute care beds and additional hospital-based services for a total of 74 acute care beds upon approval of this project and Project ID #J-12065-21.

Ancillary and Support Services – In Section I, page 98, the applicant states that the proposed change of scope project will not change its commitment to the provision of necessary ancillary and support services. The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on the following:

- In Exhibit I.3-1, the applicant provides a letter from the President of UNC Hospitals, committing to provide the necessary ancillary and support services for the proposed project.

- Project ID #J-12065-21 was found conforming with this criterion and the applicant proposes no changes in the application as submitted which would affect that determination.

Coordination – In Section I, page 99, the applicant states the proposed change of scope project will not result in changes to coordination with the existing health system described in the application for Project ID #J-12065-21. The applicant adequately

demonstrates that the proposed services will be coordinated with the existing health care system based on the following:

- The applicant provides letters of support from local physicians and healthcare providers documenting their support for UNC Hospitals-RTP in Exhibit I.3-2.

- Project ID #J-12065-21 was found conforming with this criterion and the applicant proposes no changes in the application as submitted which would affect that determination.

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 – Both Applications

Neither of the applicants 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, neither of the applicants 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 – Both Applications

Neither of the applicants are HMOs. Therefore, Criterion (10) is not applicable to this review.

(11) Repealed effective July 1, 1987.

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

NA – Duke University Hospital
C – UNC Hospitals-RTP

Project ID #J-12211-22/Duke University Hospital/Add 68 acute care beds

The applicant proposes to add 68 new acute care beds to DUH, a hospital with 1,062 existing and approved acute care beds, for a total of 1,130 acute care beds upon completion of this project and Project ID #J-11717-19 (add 34 beds).

The applicant does not propose to construct any new space or make more than minor renovations to existing space. Therefore, Criterion (12) is not applicable to this review.

Project ID #J-12214-22/UNC Hospitals-RTP/Add 34 acute care beds

The applicant proposes a change of scope to Project ID #J-12065-21, which approved the development of UNC Hospitals-RTP with 40 acute care beds (currently under appeal; no CON has been issued). The applicant proposes to add 34 acute care beds and additional hospital-based services for a total of 74 acute care beds upon approval of this project and Project ID #J-12065-21.

In Section K, page 104, the applicant states that the project involves constructing an additional 251,580 square feet of space in addition to the previously approved 189,838 square feet of space for a combined total construction of 441,418 square feet of space. Line drawings are provided in Exhibit C.8-1.

In Section K, pages 104-105, the applicant adequately explains how the cost, design, and means of construction represent the most reasonable alternative for the proposal based on the following:

- The applicant states the overall layout of the hospital is designed to provide the most efficient circulation and throughput for patients and caregivers.
- The applicant states adding the 34 acute care beds to the proposed facility while it is still under development is more financially prudent and better for patients because it will reduce later costs associated with demolition and renovation and reduce patient disruptions.
- The applicant details proposals to use sustainable strategies in developing the facility.

On page 105, 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 following:

- The applicant states that additional acute care capacity is needed in the proposed location of the proposed project.
- The applicant states conservative fiscal management has allowed UNC to set aside past excess revenues to pay for the proposed project without necessitating an increase in costs or charges.

In Section B, page 32, 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 – Duke University Hospital
NA – UNC Hospitals-RTP

Project ID #J-12211-22/Duke University Hospital/Add 68 acute care beds

In Section L, page 74, the applicant provides the historical payor mix during SFY 2021 for the proposed services, as shown in the table below.

DUH Historical Payor Mix – SFY 2021	
Payor Category	**% of Total Patients Served**
Self-Pay	2.2%
Charity Care	2.6%
Medicare*	37.8%
Medicaid*	10.9%
Insurance*	43.3%
Workers Compensation	0.2%
TRICARE	1.4%
Other	1.5%
Total	**100.0%**

*Including any managed care plans.

In Section L, page 75, the applicant provides the following comparison.

DUH	Percentage of Total Patients Served During SFY 2021	Percentage of the Population of Durham County
Female	58.7%	52.3%
Male	41.3%	47.7%
Unknown	0.0%	0.0%
64 and Younger	65.3%	84.4%
65 and Older	34.7%	13.6%
American Indian	0.5%	0.9%
Asian	3.3%	5.5%
Black or African-American	26.4%	36.9%
Native Hawaiian or Pacific Islander	0.1%	0.1%
White or Caucasian	61.5%	54.0%
Other Race	3.9%	0.0%
Declined / Unavailable	4.1%	0.0%

Source: US Census Bureau

<u>Conclusion</u> – 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 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.

Project ID #J-12214-22/UNC Hospitals-RTP/Add 34 acute care beds

UNC Hospitals-RTP is not an existing facility. Therefore, Criterion (13a) is not applicable to this review.

(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 – Duke University Hospital
NA – UNC Hospitals-RTP

Project ID #J-12211-22/Duke University Hospital/Add 68 acute care beds

Regarding any obligation to provide uncompensated care, community service, or access by minorities and persons with disabilities, in Section L, page 76, the applicant states it satisfied the requirements of providing uncompensated care in exchange for Hill Burton funds previously received, and has no other such obligation.

In Section L, page 77, the applicant states that during the 18 months immediately preceding the application deadline, no patient civil rights access complaints have been filed against the facility.

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.

Project ID #J-12214-22/UNC Hospitals-RTP/Add 34 acute care beds

UNC Hospitals-RTP is not an existing facility. Therefore, Criterion (13b) is not applicable to this review.

(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 – Both Applications

Project ID #J-12211-22/Duke University Hospital/Add 68 acute care beds

In Section L, page 78, the applicant projects the following payor mix during the third full fiscal year of operation following completion of the project, as illustrated in the following table.

DUH Projected Payor Mix – FY 3 (SFY 2026)		
Payor Category	**Entire Facility**	**Adult Acute Care Services**
Self-Pay	1.9%	2.5%
Charity Care	2.4%	3.0%
Medicare*	38.2%	46.2%
Medicaid*	12.3%	14.1%
Insurance*	41.8%	29.9%
Workers Compensation	0.2%	0.3%
TRICARE	1.4%	1.3%
Other	1.7%	2.7%
Total	**100.0%**	**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 1.9% of total services and 2.5% of adult acute care services will be provided to self-pay patients, 2.4% of total services and 3.0% of adult acute care services to charity care patients, 38.2% of total services and 46.2% of adult acute care services to Medicare patients, and 12.3% of total services and 14.1% of adult acute care services to Medicaid patients.

On pages 78-79, the applicant provides the assumptions and methodology used to project payor mix during the third full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported based on the following:

- The projected payor mix is based on the historical payor mix from the first six months of SFY 2022.

- The applicant explains a one-time shift of managed care patients to Medicare during SFY 2023 to reflect the aging of DUH population projections.

- The applicant clearly explains how it calculated the charity care 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.

Project ID #J-12214-22/UNC Hospitals-RTP/Add 34 acute care beds

In Section L, pages 112-113, the applicant states:

> *"Projected access by medically underserved groups will not change from the previously approved Project ID J-12065-21 in terms of the percentage of care provided to underserved groups. As previously stated, UNC Hospitals provides and will continue to provide services to all persons in need of medical care, regardless of race, color, religion, national origin, sex, age, disability, or source of payment. The same will be true for the UNC Hospitals-RTP upon completion of the proposed change of scope project. ..., UNC Hospitals' charity care program ensures that all eligible individuals receive medically necessary care at UNC Hospitals regardless of their ability to pay. No citizen of North Carolina is refused non-elective treatment at UNC Hospitals because of his/her inability to pay. .... As noted in the previously approved project, although a separately licensed hospital, the previously approved UNC Hospitals-RTP will be developed under the provider number for UNC Hospitals and will use UNC Hospitals' policies. However, the proposed project will increase access to the medically underserved by expanding the capacity of the previously approved project to all patients, including the medically underserved groups."*

Project ID #J-12065-21 was found conforming with this criterion and the applicant proposes no changes in the application as submitted which would affect that determination.

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.

(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 – Both Applications

Project ID #J-12211-22/Duke University Hospital/Add 68 acute care beds

In Section L, page 80, 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
- Written comments
- Responses to comments

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

Project ID #J-12214-22/UNC Hospitals-RTP/Add 34 acute care beds

Project ID #J-12065-21 was conforming with this criterion and the applicant proposes no changes in the application as submitted which would affect that determination. Therefore, the application is conforming to this criterion.

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

C – Both Applications

Project ID #J-12211-22/Duke University Hospital/Add 68 acute care beds

The applicant proposes to add 68 new acute care beds to DUH, a hospital with 1,062 existing and approved acute care beds, for a total of 1,130 acute care beds upon completion of this project and Project ID #J-11717-19 (add 34 beds).

In Section M, pages 81-82, 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 will have access to the facility for training purposes because it is an academic medical center teaching hospital.

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.

Project ID #J-12214-22/UNC Hospitals-RTP/Add 34 acute care beds

The applicant proposes a change of scope to Project ID #J-12065-21, which approved the development of UNC Hospitals-RTP with 40 acute care beds (currently under appeal; no CON has been issued). The applicant proposes to add 34 acute care beds and additional hospital-based services for a total of 74 acute care beds upon approval of this project and Project ID #J-12065-21.

In Section M, page 114, the applicant states the proposed project does not involve any changes to the information provided in the application for Project ID #J-12065-21.

Project ID #J-12065-21 was conforming with this criterion and the applicant proposes no changes in the application as submitted which would affect that determination. Therefore, the application is conforming to this criterion.

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.

(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.

NC – Duke University Hospital
C – UNC Hospitals-RTP

The 2022 SMFP includes a need determination for 68 acute care beds in the Durham/Caswell multicounty service area.

On page 33, the 2022 SMFP defines the service area for acute care beds as *"... the single and multicounty groupings shown in Figure 5.1."* Figure 5.1, on page 38, shows Durham and Caswell counties in a multicounty grouping. Thus, the service area for these facilities is the Durham/Caswell multicounty service area. Facilities may also serve residents of counties not included in their service area.

As of the date of this decision, there are 1,442 existing and approved acute care beds, allocated between four existing and approved hospitals owned by three providers in the the Durham/Caswell multicounty service area, as illustrated in the following table.

Durham/Caswell Multicounty Service Area Acute Care Hospital Campuses	
Facility	**Existing/(Approved) Beds**
Duke University Hospital*	1,048 (+14)
Duke Regional Hospital	316
Duke Total	**1,364 (+14)**
North Carolina Specialty Hospital	18 (+6)
UNC Hospitals-RTP**	0 (+40)
Durham/Caswell Multicounty Service Area Total	**1,382 (+60)**

Source: Table 5A, 2022 SMFP; applications under review; 2022 LRAs; Agency records.
Note: Numbers in parentheses reflect approved changes in bed inventory which have not yet been developed.
*Includes 14 Policy AC-3 NICU beds that are not included in Table 5A or the planning inventory for DUH.
**As of the date of this decision, the 40 acute care beds have been awarded to UNC Hospitals-RTP; however, the decision is under appeal and no CON has been issued at this time.

Project ID #J-12211-22/Duke University Hospital/Add 68 acute care beds

The applicant proposes to add 68 new acute care beds to DUH, a hospital with 1,062 existing and approved acute care beds, for a total of 1,130 acute care beds upon completion of this project and Project ID #J-11717-19 (add 34 beds).

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 83, the applicant states:

> *"…, DUH is a crucial provider of tertiary and quaternary care to patients from not only the Triangle and surrounding counties, but across the state and nation. By ensuring sufficient capacity to meet demand for DUH's specialized inpatient services, this project will increase patient choice for patients throughout this region.*
>
> *DUH currently operates on divert status a significant percentage of the time, which affects its ability to accept transfers and potentially limits access for patients."*

Regarding the impact of the proposal on cost effectiveness, in Section N, page 83, the applicant states:

> *"This project will not affect the cost to patients or payors for the services provided by DUH 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. Also, DUHS will continue to participate in initiatives aimed at promoting cost effectiveness and optimizing quality healthcare."*

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

Regarding the impact of the proposal on quality, in Section N, pages 83-84, the applicant states:

> *"The US News and World Report ranks Duke University Hospital as the best hospital in the state. DUH has existing 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. ...*
>
> *All clinical and technical staff will be required to maintain appropriate and current licensure and continuing education. Expanding capacity to improve access also benefits quality of care for patients, who might otherwise face delays or inability to receive DUH's highly specialized care."*

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

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 84, the applicant states:

> *"By expanding inpatient capacity, DUH strives to reduce the time that it must operate on divert status and therefore to increase access to all patients needing its services.*
>
> *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."*

See also Sections B, C, and L of the application and any exhibits.

However, the applicant does not adequately demonstrate how any enhanced competition in the service area will have a positive impact on the cost-effectiveness of the proposed services. The applicant did not adequately demonstrate the need to develop 68 new acute care beds or that the project is the least costly or most effective alternative. The discussions regarding analysis of need, including projected utilization, and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference. A project that cannot demonstrate the need for the services proposed and a project that cannot demonstrate it is the least costly or most effective alternative cannot demonstrate how any enhanced competition will have a positive impact on the cost-effectiveness of the proposal.

Conclusion – 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 application is not conforming to this criterion based on all the reasons stated above.

Project ID #J-12214-22/UNC Hospitals-RTP/Add 34 acute care beds

The applicant proposes a change of scope to Project ID #J-12065-21, which approved the development of UNC Hospitals-RTP with 40 acute care beds (currently under appeal; no CON has been issued). The applicant proposes to add 34 acute care beds and additional hospital-based services for a total of 74 acute care beds upon approval of this project and Project ID #J-12065-21.

Regarding the expected effects of the proposal on competition, cost-effectiveness, quality, and access by medically underserved groups in the service area, in Section N, page 116, the applicant states:

> *"The proposed project will continue to stimulate competition and will appropriately balance access, quality, and cost-effectiveness of health services for Durham and Caswell County patients and will not result in changes to the expected effects of the proposal on competition in the proposed service area from what was stated in the previously approved application. ..., UNC Hospitals believes that, at this time, a 74-bed hospital is well suited to deliver the much-needed lower acuity hospital services to Durham and Caswell County patients. Further, UNC Hospitals believes that the additional 34 acute care beds and the proposed augmentation of multiple other ancillary and support services to support the acute care beds, including additional observation beds, labor and delivery recovery beds, procedure rooms, emergency department bays, and imaging equipment, will improve access to the lower acuity community hospital services to be provided at UNC Hospitals-RTP upon completion of the proposed project while also allowing UNC Hospitals to remain good stewards of the resources available to serve the residents of Durham County and the surrounding area."*

See also Sections B, C, F, K, L, O, and Q of the application and any exhibits.

Project ID #J-12065-21 was found conforming with this criterion and the applicant proposes no changes in the application as submitted which would affect that determination.

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 demonstrated in this application and in Project ID #J-12065-21: 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 in this application and in Project ID #J-12065-21 about how it will ensure the quality of the proposed services and the applicant'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 in this application and in Project ID #J-12065-21 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
- Information which was publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion based on all 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 – Both Applications

Project ID #J-12211-22/Duke University Hospital/Add 68 acute care beds

The applicant proposes to add 68 new acute care beds to DUH, a hospital with 1,062 existing and approved acute care beds, for a total of 1,130 acute care beds upon completion of this project and Project ID #J-11717-19 (add 34 beds).

On Form O in Section Q, the applicant identifies hospitals located in North Carolina owned, operated, or managed by the applicant or a related entity. The applicant identified three other existing and approved hospitals in North Carolina. The applicant is also part of a joint venture, Duke LifePoint Healthcare, which owns, operates, or manages nine additional existing hospitals in North Carolina.

In Section O, page 87, the applicant states that during the 18 months immediately preceding the submittal of the application, there were no incidents related to quality of care resulting in a finding of immediate jeopardy at any of the hospitals. 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 incidents related to quality of care in four of the hospitals. Two of the hospitals, Duke University Hospital and Duke Raleigh Hospital, are back in compliance at this time. Two of the hospitals, DLP Frye Regional Medical Center and DLP Wilson Medical Center, are not in compliance with all Medicare Conditions of Participation as of the date of these findings. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at all 11 existing hospitals, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

Project ID #J-12214-22/UNC Hospitals-RTP/Add 34 acute care beds

The applicant proposes a change of scope to Project ID #J-12065-21, which approved the development of UNC Hospitals-RTP with 40 acute care beds (currently under appeal; no CON has been issued). The applicant proposes to add 34 acute care beds and additional hospital-based services for a total of 74 acute care beds upon approval of this project and Project ID #J-12065-21.

On Form O in Section Q, the applicant identifies the hospitals located in North Carolina owned, operated, or managed by the applicant or a related entity. The applicant identified a total of 13 hospitals in North Carolina.

In Section O, page 118, the applicant states that during the 18 months immediately preceding the submittal of the application, there were two incidents resulting in an Immediate Jeopardy finding – one incident each at Onslow Memorial Hospital and UNC Health Blue Ridge. The applicant states both facilities are back in compliance and provides supporting documentation in Exhibit O.4. The applicant states that no other facilities had immediate jeopardy findings during the 18 months immediately preceding the submittal of the application. 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 incidents related to quality of care that occurred in nine of the 13 hospitals. All nine hospitals are back in compliance as of the date of these findings. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at all 13 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.

NC – Duke University Hospital
C – UNC Hospitals-RTP

SECTION .3800 – CRITERIA AND STANDARDS FOR ACUTE CARE BEDS are applicable to both projects. The specific criteria are discussed below.

10A NCAC 14C .3803 PERFORMANCE STANDARDS

(a) An applicant proposing to develop new acute care beds shall demonstrate that the projected average daily census (ADC) of the total number of licensed acute care beds proposed to be licensed within the service area, under common ownership with the applicant, divided by the total number of those licensed acute care beds is reasonably projected to be at least 66.7 percent when the projected ADC is less than 100 patients, 71.4 percent when the projected ADC is 100 to 200 patients, and 75.2 percent when the projected ADC is greater than 200 patients, in the third operating year following completion of the proposed project or in the year for which the need determination is identified in the State Medical Facilities Plan, whichever is later.

-NC- **Duke University Hospital.** The applicant proposes to develop 68 acute care beds at DUH. The projected ADC of the total number of acute care beds proposed to be licensed at Duke is greater than 200. The applicant projects a utilization rate of 83% by the end of the third operating year following completion of the proposed project.

However, the applicant does not adequately demonstrate that the projected utilization of the total number of acute care beds proposed to be licensed within the service area and which are owned by Duke is reasonably projected to be at least 75.2% by the end of the third operating year following completion of the proposed project. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference. Therefore, the application is not conforming with this Rule.

-C- **UNC Hospitals-RTP.** The applicant proposes to develop 34 additional acute care beds at UNC Hospitals-RTP. The projected ADC of the total number of acute care beds proposed to be licensed within the service area and owned by UNC is less than 100. The applicant projects a utilization rate of 69.9% by the end of the third operating year following completion of the proposed project.

The applicant adequately demonstrates that the projected utilization of the total number of acute care beds proposed to be licensed within the service area and which are owned by UNC is reasonably projected to be at least 66.7% by the end of the third operating year following completion of the proposed project. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

(b) An applicant proposing to develop new acute care beds shall provide all assumptions and data used to develop the projections required in this rule and demonstrate that they support the projected inpatient utilization and average daily census.

-NC- **Duke University Hospital.** See Section C, pages 32-38, for the applicant's discussion of need, and Section Q, for the applicant's data, assumptions, and methodology used to project utilization. The applicant does not adequately demonstrate that the assumptions and data used to develop the projections required in this rule are reasonable and adequately support the projected inpatient utilization and average daily census. The discussions regarding analysis of need and projected utilization found in Criterion (3) are incorporated herein by reference. Therefore, the application is not conforming with this Rule.

-C- **UNC Hospitals-RTP.** See Section C, pages 52-65, for the applicant's discussion of need, and Section Q for the applicant's data, assumptions, and methodology used to project utilization. The discussions regarding analysis of need and projected utilization found in Criterion (3) are incorporated herein by reference.

COMPARATIVE ANALYSIS FOR ACUTE CARE BEDS

Pursuant to G.S. 131E-183(a)(1) and the 2022 State Medical Facilities Plan, no more than 68 acute care beds may be approved for the Durham/Caswell multicounty service area in this review. Because the applications in this review collectively propose to develop 102 additional acute care beds in the Durham/Caswell multicounty service area, all applications cannot be approved for the total number of beds proposed. Therefore, after considering all the information in each application and reviewing each application individually against all applicable review criteria, the Project Analyst conducted a comparative analysis of the proposals to decide which proposal should be approved.

Below is a brief description of each project included in the Acute Care Bed Comparative Analysis.

- Project ID #J-12211-22 / **Duke University Hospital** / Develop 68 additional acute care beds pursuant to the 2022 SMFP need determination
- Project ID #J-12214-22 / **UNC Hospitals-RTP** / Develop 34 additional acute care beds pursuant to the 2022 SMFP Need Determination

The table below summarizes information about each application.

	Duke University Hospital	**UNC Hospitals-RTP**
Hospital Level of Care	Quaternary Academic Medical Center	Community
Number of Existing Beds*	1,062	40
Beds Proposed to be Added	68	34
Total Number of Proposed Beds**	1,130	74
Third Full Fiscal Year	SFY 2026	SFY 2032
Projected Acute Care Days – FY 3	343,639	18,869
Projected Discharges – FY 3	45,591	3,858
% of Beds Compared to Quaternary Hospital***	NA	6.5%

*Includes beds previously approved but not yet developed and excludes beds approved to be relocated away from the facility
**Proposed Beds = Number of existing beds + Number of beds requested in the application
***Assuming all beds requested by each applicant are approved

Because of the significant differences in types of facilities, numbers of total acute care beds, numbers of projected acute care days and discharges, levels of patient acuity which can be served, total revenues and expenses, and the differences in presentation of pro forma financial statements, some comparatives may be of less value and result in less than definitive outcomes than if both applications were for like facilities of like size proposing like services and reporting in like formats.

The inequity in a comparison of the two hospitals is highlighted by the applicants themselves. Both applications call attention to the dissimilarity of the two hospitals.

Duke University Hospital. In Section E, page 52, the applicant states:

> *"Additional capacity is currently needed in the service area for the tertiary and quaternary care services provided by DUH and which are not readily duplicated at another facility."*

And in Section G, page 63, the applicant states:

> *"UNC's approved Durham County hospital project under appeal is for a small community hospital that would not offer the scope of services provided by DUH."*

UNC Hospitals-RTP. In Section C, page 47, the applicant states:

> *"…, UNC Hospitals-RTP is expected to focus on a broad range of community hospital services in contrast to the academic medical center, tertiary, and specialty acute care hospitals that already exist in Durham County."*

Further, the analysis of comparative factors and what conclusions the Agency reaches (if any) with regard to specific comparative analysis factors is determined in part by whether or not the applications included in the review provide data that can be compared and whether or not such a comparison would be of value in evaluating the competitive applications.

Conformity with Review Criteria

An application that is not conforming or conforming as conditioned with all applicable statutory and regulatory review criteria cannot be approved.

Table 5B on page 47 of the 2022 SMFP identifies a need for 68 additional acute care beds in the Durham/Caswell multicounty service area. As shown in Table 5A, page 40, the Duke health system shows a projected deficit of 141 acute care beds for 2024, which in combination with the need determinations from the 2021 and 2022 SMFPs results in the Durham/Caswell multicounty service area need determination for 68 acute care beds. However, the application process is not limited to the provider (or providers) that show a deficit and create the need for additional acute care beds. Any qualifying provider can apply to develop the 68 acute care beds in the Durham/Caswell multicounty service area. Furthermore, it is not necessary that an existing provider have a projected deficit of acute care beds to apply for more acute care beds. However, it is necessary that an applicant adequately demonstrate the need to develop its project, as proposed.

Duke University Hospital's application, **Project ID #J-12211-22**, is not conforming to all applicable statutory and regulatory review criteria. **UNC Hospitals-RTP's** application, **Project ID #J-12214-22**, is conforming to all applicable statutory and regulatory review criteria. Therefore, with regard to conformity with review criteria, the application submitted by **UNC Hospitals-RTP** is a more effective alternative than the application submitted by **Duke University Hospital**.

Scope of Services

Generally, the application proposing to provide the greatest scope of services is the more effective alternative with regard to this comparative factor.

One application involves an existing acute care hospital which provides numerous types of medical services. Another application involves an approved acute care hospital proposing to offer numerous types of medical services. However, **Duke University Hospital** is a Level I trauma center, a quaternary care center, and an academic medical center. **UNC Hospitals-RTP** will be a smaller community hospital that does not propose to offer all of the same types of services and will not offer services for high acuity patients.

Therefore, **Duke University Hospital** is the more effective alternative with respect to this comparative factor and **UNC Hospitals-RTP** is a less effective alternative.

Geographic Accessibility

As of the date of this decision, there are 1,402 existing and approved acute care beds, allocated between three existing hospitals owned by two providers in the the Durham/Caswell multicounty service area, as illustrated in the following table.

Durham/Caswell Multicounty Service Area Acute Care Hospital Campuses	
Facility	**Existing/(Approved) Beds**
Duke University Hospital*	1,048 (+14)
Duke Regional Hospital	316
Duke Total	**1,364 (+14)**
North Carolina Specialty Hospital	18 (+6)
Durham/Caswell Multicounty Service Area Total	**1,382 (+60)**

Source: Table 5A, 2022 SMFP; applications under review; 2022 LRAs; Agency records.
Note: Numbers in parentheses reflect approved changes in bed inventory which have not yet been developed.
*Includes 14 Policy AC-3 NICU beds that are not included in Table 5A or the planning inventory for DUH.

In Project ID #J-12065-21, **UNC Hospitals-RTP** was approved by the Agency to develop 40 acute care beds at a new hospital in southern Durham County. However, as of the date of these findings, that decision is under appeal and no CON has been issued. Since no CON has been issued and it is unclear where the beds will ultimately be located, they are not considered for purposes of this comparative analysis factor.

The following table illustrates where the existing and approved (CON issued) acute care beds are located within Durham County.

Facility	Total AC Beds	Address	Location
Duke University Hospital	1,062	2301 Erwin Rd, Durham 27710	Central Durham County
Duke Regional Hospital	316	3643 N. Roxboro Rd, Durham 27704	Central Durham County
North Carolina Specialty Hospital	24	3916 Ben Franklin Blvd, Durham 27704	Central Durham County

As shown in the table above, the three existing hospitals are all located in the central part of Durham County, within approximately five miles of one another.

Duke University Hospital proposes to add 68 acute care beds at its existing facility in the central part of Durham County. **UNC Hospitals-RTP** proposes to develop acute care beds in the southern part of Durham County where there are currently no existing acute care beds. Therefore, **UNC Hospitals-RTP** is a more effective alternative with regard to geographic accessibility and **Duke University Hospital** is a less effective alternative.

Historical Utilization

The table below shows acute care bed utilization for existing facilities based on acute care days as reported in Table 5A of the 2022 SMFP. Generally, the applicant with the higher historical utilization is the more effective alternative with regard to this comparative analysis factor.

Historical Utilization – Hospitals in the Durham/Caswell Multicounty Service Area					
Facility	**FFY 2021 Days**	**ADC**	**Total Beds***	**Utilization**	**Projected (Surplus)/Deficit**
Duke University Hospital	303,671	832	946	87.9%	141
Duke Regional Hospital	69,486	190	316	60.1%	(33)
NC Specialty Hospital	2,905	8	18	44.4%	(11)

Sources: Table 5A, 2022 SMFP; Agency records
*Existing acute care beds during FFY2021 only. While Duke University Hospital brought 88 beds online in June 2021, they were not available for use during most of the reporting period.

As shown in the table above, **Duke University Hospital** has a higher historical utilization than the other two acute care facilities in Durham County. However, **Duke University Hospital** is the only existing facility applying to add acute care beds in Durham County. **UNC Hospitals-RTP** is not an existing facility and thus has no historical utilization.

Therefore, a comparison of historical utilization cannot be effectively evaluated.

Competition (Patient Access to a New or Alternate Provider)

Generally, the introduction of a new provider in the service area would be the most effective alternative based on the assumption that increased patient choice would encourage all providers in the service area to improve quality or lower costs in order to compete for patients. However, the expansion of an existing provider that currently controls fewer acute care beds than another provider would also presumably encourage all providers in the service area to improve quality or lower costs in order to compete for patients.

As of the date of this decision, there are 1,442 existing and approved acute care beds in the Durham/Caswell multicounty service area. **Duke University Hospital** and Duke Regional Hospital are affiliated with Duke, which currently controls 1,378 of the 1,442 acute care beds in the Durham/Caswell multicounty service area, or 95.6%. **Duke University Hospital** alone controls 73.6% of the existing and approved acute care beds in the Durham/Caswell multicounty service area.

If **Duke University Hospital's** application to add 68 beds is approved, **Duke University Hospital** would control 1,130 of the 1,510 existing and approved acute care beds in the Durham/Caswell multicounty service area, or 74.8%, with the Duke health system controlling 95.8% of all the Durham/Caswell multicounty service area acute care beds. If **UNC Hospitals-RTP's** application is approved, **UNC Hospitals-RTP** would control 74 of the 1,510 existing and approved acute care beds in the Durham/Caswell multicounty service area, or 4.9% of the Durham/Caswell multicounty service area acute care beds.

Therefore, with regard to patient access to a new or alternate provider, the application submitted by **UNC Hospitals-RTP** is the more effective alternative, and the application submitted by **Duke University Hospital** is the less effective alternative.

<u>Access by Service Area Residents</u>

On page 31, the 2021 SMFP defines the service area for acute care beds as *"... the single or multicounty grouping shown in Figure 5.1."* Figure 5.1, on page 36, shows Durham and Caswell counties in a multicounty grouping. Thus, the service area for this facility is the Durham/Caswell multicounty service area. Facilities may also serve residents of counties not included in their service area. Generally, regarding this comparative factor, the application projecting to serve the largest number of service area residents is the more effective alternative based on the assumption that residents of a service area should be able to derive a benefit from a need determination for additional acute care beds in the service area where they live.

The following table illustrates access by service area residents during the third full fiscal year following project completion.

Projected Service to Durham/Caswell Multicounty Service Area Residents (FY3)		
Applicant	**# Durham/Caswell Residents**	**% Durham/Caswell Residents**
Duke University Hospital	10,939	28.5%
UNC Hospitals-RTP	3,291	85.3%

Sources: Project ID #J-12211-22 p.30, Project ID #J-12214-22 p.67

As shown in the table above, **Duke University Hospital** projects to serve the highest number of Durham/Caswell multicounty service area residents and **UNC Hospitals-RTP** projects to serve the highest percentage of Durham/Caswell multicounty service area residents.

However, the acute care bed need determination methodology is based on utilization of all patients that utilize acute care beds in the Durham/Caswell multicounty service area and is not only based on patients originating from the Durham/Caswell multicounty service area. Durham County is also a relatively large urban county currently served by the Duke health system and its two hospitals. Further, **Duke University Hospital** is a Level I trauma quaternary care academic medical center which, because of its numerous advanced specialties and extremely specialized level of care, pulls in many patients from significant distances who are seeking the specialized level of health care offered by **Duke University Hospital**. **UNC Hospitals-RTP** will be a small community hospital. Obviously the two hospitals are different types of facilities and offer a different scope of services.

Considering the discussion above, the Agency believes that in this specific instance attempting to compare the applicants based on the projected acute care bed access of residents of the Durham/Caswell multicounty service area would be ineffective. Therefore, the result of this analysis is inconclusive.

Access by Underserved Groups

"Underserved groups" is defined in G.S. 131E-183(a)(13) as follows:

> *"Medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority."*

For access by underserved groups, the applications in this review are compared with respect to three underserved groups: charity care patients (i.e., medically indigent or low-income persons), Medicare patients, and Medicaid patients. Access by each group is treated as a separate factor.

Projected Charity Care

The following table shows projected charity care during the third full fiscal year following project completion for each facility. Generally, the application projecting to provide the most charity care is the more effective alternative with regard to this comparative factor.

Projected Charity Care Inpatient Services – 3rd Full FY			
Applicant	**Total Charity Care**	**Average Charity Care per Discharge**	**% of Gross Revenue**
Duke University Hospital	$106,030,462	$2,765	2.9%
UNC Hospitals-RTP	$20,692,825	$5,364	8.8%

Sources: Forms C and F.2 for each applicant

In Section L, page 79, **Duke University Hospital** defines charity care as free or discounted care provided to persons in medical need who are unable to financially afford to pay for their care, and who do not qualify for public or private assistance.

In its Form F.2 Assumptions, **UNC Hospitals-RTP** states that projected charity care is the difference between projected gross revenue and projected net revenue for self-pay patients.

Based on the differences in how each applicant categorizes charity care and the differences in presentation of pro forma financial statements, the Agency determined it could not make a valid comparison of the charity care provided by each applicant for purposes of evaluating which application was more effective with regard to this comparative factor. **Duke University Hospital**, an existing large quaternary care academic medical center proposing to add adult inpatient beds, has pro forma financial statements that are structured differently than **UNC Hospitals-RTP**, which is proposing to add acute care beds to an approved but not yet

developed relatively small community hospital.

However, even if the applicants had provided pro forma financial statements in a manner that would allow the Agency to compare reasonably similar kinds of data, differences in the acuity level of patients at each facility and the level of care (community hospital, quaternary care academic medical center) at each facility would make any comparison of little value. Therefore, the result of this analysis is inconclusive.

Projected Medicare

The following table shows projected Medicare revenue during the third full fiscal year following project completion for each facility. Generally, the application projecting the highest Medicare revenue is the more effective alternative with regard to this comparative factor to the extent the Medicare revenue represents the number of Medicare patients served.

Projected Medicare Revenue – 3rd Full FY			
Applicant	**Total Medicare Rev.**	**Av. Medicare Rev./Discharge**	**% of Gross Rev.**
Duke University Hospital	$1,780,560,702	$46,533	49.4%
UNC Hospitals-RTP	$120,659,542	$31,275	51.2%

Sources: Forms C and F.2 for each applicant

Based on the differences in presentation of pro forma financial statements, the number of patients, and the level of care at each facility, the Agency determined it could not make a valid comparison for purposes of evaluating which application was more effective with regard to this comparative factor. **Duke University Hospital**, an existing large quaternary care academic medical center proposing to add adult inpatient beds, has pro forma financial statements that are structured differently than **UNC Hospitals-RTP**, which is proposing to add acute care beds to an approved but not yet developed relatively small community hospital.

Further, even if the applicants had provided pro forma financial statements in a manner that would allow the Agency to compare reasonably similar kinds of data, differences in the acuity level of patients at each facility and the level of care (community hospital, quaternary care academic medical center) at each facility would make any comparison of little value. Therefore, the result of this analysis is inconclusive.

Projected Medicaid

The following table shows projected Medicaid revenue during the third full fiscal year following project completion for each facility. Generally, the application projecting the highest Medicaid revenue is the more effective alternative with regard to this comparative factor to the extent the Medicaid revenue represents the number of Medicaid patients served.

Projected Medicaid Revenue – 3rd Full FY			
Applicant	**Total Medicaid Rev.**	**Av. Medicaid Rev./Discharge**	**% of Gross Rev.**
Duke University Hospital	$426,696,656	$11,127	11.8%
UNC Hospitals-RTP	$36,194,498	$9,382	15.4%

Sources: Forms C and F.2 for each applicant

Based on the differences in presentation of pro forma financial statements, the number of patients, and the level of care at each facility, the Agency determined it could not make a valid comparison for purposes of evaluating which application was more effective with regard to this comparative factor. **Duke University Hospital**, an existing large quaternary care academic medical center proposing to add adult inpatient beds, has pro forma financial statements that are structured differently than **UNC Hospitals-RTP**, which is proposing to add acute care beds to an approved but not yet developed relatively small community hospital.

Further, even if the applicants had provided pro forma financial statements in a manner that would allow the Agency to compare reasonably similar kinds of data, differences in the acuity level of patients at each facility and the level of care (community hospital, quaternary care academic medical center) at each facility would make any comparison of little value. Therefore, the result of this analysis is inconclusive.

Projected Average Net Revenue per Patient

The following table shows the projected average net revenue per patient in the third full fiscal year following project completion for each facility. Generally, the application projecting the lowest average net revenue per patient is the more effective alternative with regard to this comparative factor since a lower average may indicate a lower cost to the patient or third-party payor.

Projected Average Net Revenue per Discharge – 3rd Full FY			
Applicant	**Total # of Discharges**	**Net Revenue**	**Average Net Revenue / Discharge**
Duke University Hospital	38,347	$1,197,065,445	$31,217
UNC Hospitals-RTP	3,858	$92,650,396	$24,015

Sources: Forms C and F.2 for each applicant

Based on the differences in presentation of pro forma financial statements, the number of patients, and the level of care at each facility, the Agency determined it could not make a valid comparison for purposes of evaluating which application was more effective with regard to this comparative factor. **Duke University Hospital**, an existing large quaternary care academic medical center proposing to add adult inpatient beds, has pro forma financial statements that are structured differently than **UNC Hospitals-RTP**, which is proposing to add acute care beds to an approved but not yet developed relatively small community hospital.

Further, even if the applicants had provided pro forma financial statements in a manner that would allow the Agency to compare reasonably similar kinds of data, differences in the acuity level of patients at each facility and the level of care (community hospital, quaternary care

academic medical center) at each facility would make any comparison of little value. Therefore, the result of this analysis is inconclusive.

Projected Average Operating Expense per Patient

The following table shows the projected average operating expense per patient in the third full fiscal year following project completion for each facility. Generally, the application projecting the lowest average operating expense per patient is the more effective alternative since a lower average may indicate a lower cost to the patient or third-party payor or a more cost-effective service.

Projected Operating Expense per Discharge – 3rd Full FY			
Applicant	**Total # of Discharges**	**Operating Expense**	**Average Operating Expense / Discharge**
Duke University Hospital	38,347	$1,488,469,720	$38,816
UNC Hospitals-RTP	3,858	$79,776,658	$20,678

Sources: Forms C and F.2 for each applicant

Based on the differences in presentation of pro forma financial statements, the number of patients, and the level of care at each facility, the Agency determined it could not make a valid comparison for purposes of evaluating which application was more effective with regard to this comparative factor. **Duke University Hospital**, an existing large quaternary care academic medical center proposing to add adult inpatient beds, has pro forma financial statements that are structured differently than **UNC Hospitals-RTP**, which is proposing to add acute care beds to an approved but not yet developed relatively small community hospital.

Further, even if the applicants had provided pro forma financial statements in a manner that would allow the Agency to compare reasonably similar kinds of data, differences in the acuity level of patients at each facility and the level of care (community hospital, quaternary care academic medical center) at each facility would make any comparison of little value. Therefore, the result of this analysis is inconclusive.

SUMMARY

Due to significant differences in the size of hospitals, levels of acuity each hospital proposes to serve, total revenues and expenses, and the differences in presentation of pro forma financial statements, some of the comparatives may be of less value and result in less than definitive outcomes than if all applications were for like facilities of like size and reporting in like formats.

The following table lists the comparative factors and states which application is the more effective alternative with regard to that particular comparative factor. The comparative factors are listed in the same order they are discussed in the Comparative Analysis which should not be construed to indicate an order of importance.

Comparative Factor	Duke University Hospital	UNC Hospitals-RTP
Conformity with Review Criteria	Less Effective	**More Effective**
Scope of Services	**More Effective**	Less Effective
Geographic Accessibility	Less Effective	**More Effective**
Historical Utilization	Inconclusive	Inconclusive
Competition/Access to New/Alternate Provider	Less Effective	**More Effective**
Access by Service Area Residents	Inconclusive	Inconclusive
Access by Underserved Groups		
Projected Charity Care	Inconclusive	Inconclusive
Projected Medicare	Inconclusive	Inconclusive
Projected Medicaid	Inconclusive	Inconclusive
Projected Average Net Revenue per Case	Inconclusive	Inconclusive
Projected Average Operating Expense per Case	Inconclusive	Inconclusive

- With respect to Conformity with Review Criteria, **UNC Hospitals-RTP** offers the more effective alternative. See Comparative Analysis for discussion.

- With respect to Scope of Services, **Duke University Hospital** offers the more effective alternative. See Comparative Analysis for discussion.

- With respect to Geographic Accessibility, **UNC Hospitals-RTP** offers the more effective alternative. See Comparative Analysis for discussion.

- With respect to Competition/Access to New Provider, **UNC Hospitals-RTP** offers the more effective alternative. See Comparative Analysis for discussion.

CONCLUSION

G.S. 131E-183(a)(1) states that the need determination in the SMFP is the determinative limit on the number of acute care beds that can be approved by the Healthcare Planning and Certificate of Need Section. Approval of all applications submitted during this review would result in acute care beds in excess of the need determination for the Durham/Caswell multicounty service area.

However, the application submitted by **Duke University Hospital** is not approvable and therefore cannot be considered an effective alternative. Consequently, the application submitted by **Duke University Hospital, Project ID #J-12211-22**, is denied.

The application submitted by **UNC Hospitals-RTP** is conforming to all applicable statutory and regulatory review criteria and is approvable. Further, based on the applications as submitted and the Comparative Analysis, the application submitted by **UNC Hospitals-RTP** is comparatively superior to the application submitted by **Duke University Hospital**, even if **Duke University Hospital's** application could be approved. The application submitted by **UNC Hospitals-RTP** is a more effective alternative for three comparative analysis factors, while the application submitted by **Duke University Hospital** is a more effective alternative for only one comparative analysis factor.

The application submitted by **UNC Hospitals-RTP**, **Project ID #J-12214-22**, is comparatively superior and is approved as submitted, subject to the following conditions.

1. University of North Carolina Hospitals at Chapel Hill and University of North Carolina Health Care System (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.

2. The certificate holder shall develop no more than 34 acute care beds at UNC Hospitals-RTP pursuant to the need determination in the 2022 SMFP.

3. The certificate holder shall also develop no more than two additional unlicensed procedure rooms, 10 additional unlicensed observation beds, two additional unlicensed labor and delivery room beds, eight additional emergency department bays, one additional fixed CT scanner, and one additional ultrasound unit at UNC Hospitals-RTP.

4. Upon completion of this project and Project ID #J-12065-21, UNC Hospitals-RTP shall be licensed for no more than 74 acute care beds.

5. 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. The first progress report shall be due on July 1, 2023.

6. 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.

7. The certificate holder shall develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes.

8. 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.

9. 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.

Exhibit C

REQUIRED STATE AGENCY FINDINGS

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

Decision Date: September 27, 2023
Findings Date: October 4, 2023

Project Analyst: Julie M. Faenza
Co-signer: Micheala Mitchell

COMPETITIVE REVIEW

Project ID #: J-12371-23
Facility: UNC Rex Hospital
FID #: 953429
County: Wake
Applicant: Rex Hospital, Inc.
Project: Acquire one linear accelerator pursuant to the 2023 SMFP need determination

Project ID #: J-12376-23
Facility: WakeMed Raleigh Medical Park
FID #: 090441
County: Wake
Applicant: WakeMed
Project: Acquire one linear accelerator pursuant to the 2023 SMFP need determination

Project ID #: J-12379-23
Facility: Duke Radiation Oncology Garner
FID #: 230343
County: Wake
Applicant: Duke University Health System, Inc.
Project: Acquire one linear accelerator pursuant to the 2023 SMFP need determination

Each application was reviewed independently against the applicable statutory review criteria found in G.S. 131E-183(a) and the regulatory review criteria found in 10A NCAC 14C. After completing an independent analysis of each application, the Healthcare Planning and Certificate of Need Section (Agency) also conducted a comparative analysis of all the applications. The Decision, which can be found at the end of the Required State Agency Findings (Findings), is based on the independent analysis and the comparative analysis.

Given the complexity of this review and the multiple entities involved in projections, the Project Analyst created the table below listing acronyms or abbreviations used in the findings.

Acronyms/Abbreviations Used	
Acronym/Abbreviations Used	**Full Term**
ESTV	Equivalent Simple Treatment Visits
LINAC	Linear Accelerator
SBRT	Stereotactic Body Radiation Therapy
SRS	Stereotactic Radiosurgery
CAGR	Compound Annual Growth Rate
FFY	Federal Fiscal Year (October 1 – September 30)
FY	Fiscal Year
NC OSBM	North Carolina Office of State Budget and Management
SFY	State Fiscal Year (July 1 – June 30)
SHCC	State Health Coordinating Council
SMFP	State Medical Facilities Plan
DUHS	Duke University Health System, Inc.
Duke Cary	Duke Cancer Center Cary Radiation Oncology
Duke Garner	Duke Radiation Oncology Garner
Duke Green Level	Duke Cancer Center Green Level Radiation Oncology
Duke Women's Cancer	Duke Women's Cancer Care Raleigh
UNC-CH	University of North Carolina Hospitals at Chapel Hill
UNC Panther Creek	UNC Health Cancer Care of Panther Creek
UNC Rex East Raleigh	UNC Health Rex Cancer Care of East Raleigh
UNC Rex Wakefield	UNC Health Rex Cancer Care of Wakefield
UNC System	University of North Carolina Health Care System
WakeMed RMP	WakeMed Raleigh Medical Park

REVIEW CRITERIA

G.S. 131E-183(a): The Department 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.

NC – UNC Rex Hospital, Duke Radiation Oncology Garner
C – WakeMed Raleigh Medical Park

Need Determination – Chapter 17 of the 2023 State Medical Facilities Plan (SMFP) includes a methodology for determining the need for additional LINAC equipment in North Carolina by service area. Application of the need methodology in the 2023 SMFP did not result in a need determination for any LINACs in any service area in North Carolina. However, pursuant to a petition filed with the State Health Coordinating Council (SHCC), the SHCC approved an adjusted need determination for one LINAC in Service Area 20. Service Area 20 is comprised of Franklin and Wake counties.

Policies – There are two policies in the 2023 SMFP which are applicable to this review.

Policy GEN-3: Basic Principles, on page 30 of the 2023 SMFP, states:

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

Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities, on page 30 of the 2023 SMFP, states:

> *"Any person proposing a capital expenditure greater than $4 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."*

Both policies apply to all applications.

Project ID #J-12371-23/UNC Rex Hospital/Acquire one LINAC
Rex Hospital, Inc. (hereinafter referred to as "Rex," "UNC Health," or "the applicant") proposes to add a second fixed linear accelerator (LINAC) at UNC Health Rex Cancer Care of Wakefield (UNC Rex Wakefield), a campus of UNC Health Rex Hospital (UNC Rex Hospital).

Rex Hospital, Inc. is a North Carolina nonprofit corporation whose sole member is Rex Healthcare, Inc. Rex Healthcare, Inc. is a North Carolina nonprofit corporation whose sole member is the University of North Carolina Health Care System (UNC System). On its 2023 Hospital License Renewal Application, Rex identifies itself as being part of the UNC System.

Need Determination. The applicant does not propose to acquire more LINACs than are determined to be needed in Service Area 20 and proposes to develop the LINAC in Wake County. Therefore, the application is consistent with the need determination.

Policy GEN-3. In Section B, pages 26-32, the applicant explains why it believes its proposal is consistent with Policy GEN-3.

However, the applicant does not adequately demonstrate how its projected volumes incorporate the concept of maximizing healthcare value for resources expended. The applicant does not adequately demonstrate the need to acquire a new LINAC and does not adequately demonstrate that acquiring a new LINAC would not be an unnecessary duplication of existing and approved services. The discussions regarding need (and projected utilization) and unnecessary duplication found in Criterion (3) and Criterion (6), respectively, are incorporated herein by reference. An applicant that does not demonstrate the need for the proposed project, does not demonstrate that projected utilization is reasonable and adequately supported, and does not demonstrate that the proposed project is not an unnecessary duplication of existing and approved health care services in the service area cannot demonstrate that it will maximize healthcare value for resources expended in meeting the need identified in the 2023 SMFP. Thus, the application is not consistent with Policy GEN-3.

Policy GEN-4. The capital expenditure of the project is greater than $5 million. In Section B, page 33, the applicant describes its plan to assure improved energy efficiency and water conservation.

Conclusion – The Agency reviewed the:

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

Based on that review, the Agency concludes that the application is not conforming to this criterion based on the following:

- The applicant does not adequately demonstrate the need to acquire a new LINAC or that acquiring a new LINAC would not be an unnecessary duplication of existing and approved health care services.

- Therefore, the applicant does not adequately demonstrate how its projected volumes incorporate the concept of maximum healthcare value for resources expended as required in Policy GEN-3.

Project ID #J-12376-23/WakeMed Raleigh Medical Park/Acquire one LINAC
WakeMed (hereinafter referred to as "WakeMed" or "the applicant") proposes to acquire a fixed LINAC and a CT simulator to be located at WakeMed Raleigh Medical Park (WakeMed RMP), a medical office building that will be located adjacent to WakeMed's main campus (WakeMed Raleigh Campus).

Need Determination. The applicant does not propose to acquire more LINACs than are determined to be needed in Service Area 20 and proposes to develop the LINAC in Wake County. Therefore, the application is consistent with the need determination.

Policy GEN-3. In Section B, pages 29-35, the applicant explains why it believes its proposal is consistent with Policy GEN-3.

Policy GEN-4. The capital expenditure of the project is greater than $5 million. In Section B, pages 36-38, the applicant describes its plan to assure improved energy efficiency and water conservation.

Conclusion – The Agency reviewed the:

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

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

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

- The applicant does not propose to develop more LINACs than are determined to be needed in the service area.

- The applicant adequately demonstrates that the proposal is consistent with Policy GEN-3 based on the following:

  - The applicant adequately documents how the project will promote safety and quality in the delivery of LINAC services in Service Area 20.

  - The applicant adequately documents how the project will promote equitable access to LINAC services in Service Area 20.

  - The applicant adequately documents how the project will maximize healthcare value for the resources expended.

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

Project ID #J-12379-23/Duke Radiation Oncology Garner/Acquire one LINAC
Duke University Hospital System, Inc. (hereinafter referred to as "Duke," "DUHS," or "the applicant") proposes to acquire a LINAC and CT simulator and develop a new radiation oncology facility, Duke Radiation Oncology Garner (Duke Garner). The facility will be licensed under Duke Raleigh Hospital.

Need Determination. The applicant does not propose to acquire more LINACs than are determined to be needed in Service Area 20 and proposes to develop the LINAC in Wake County. Therefore, the application is consistent with the need determination.

Policy GEN-3. In Section B, page 28, the applicant explains why it believes its proposal is consistent with Policy GEN-3. The applicant cites to Sections M, N, and O on pages 83-88 where it discusses how the proposed project will promote safety, quality, and ensure equitable access to care as well as maximize healthcare value for the resources expended.

However, the applicant does not adequately demonstrate how its projected volumes incorporate the concept of maximizing healthcare value for resources expended. The applicant does not adequately demonstrate the need to acquire a new LINAC and does not adequately demonstrate that acquiring a new LINAC would not be an unnecessary duplication of existing and approved services. The discussions regarding need (and projected utilization) and unnecessary duplication found in Criterion (3) and Criterion (6), respectively, are incorporated herein by reference. An applicant that does not demonstrate the need for the proposed project,

does not demonstrate that projected utilization is reasonable and adequately supported, and does not demonstrate that the proposed project is not an unnecessary duplication of existing and approved health care services in the service area cannot demonstrate that it will maximize healthcare value for resources expended in meeting the need identified in the 2023 SMFP. Thus, the application is not consistent with Policy GEN-3.

Policy GEN-4. The capital expenditure of the project is greater than $5 million. In Section B, pages 28-29, the applicant describes its plan to assure improved energy efficiency and water conservation.

Conclusion – The Agency reviewed the:

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

Based on that review, the Agency concludes that the application is not conforming to this criterion based on the following:

- The applicant does not adequately demonstrate the need to acquire a new LINAC or that acquiring a new LINAC would not be an unnecessary duplication of existing and approved health care services.

- Therefore, the applicant does not adequately demonstrate how its projected volumes incorporate the concept of maximum healthcare value for resources expended as required in Policy GEN-3.

(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.

NC – UNC Rex Hospital, Duke Radiation Oncology Garner
C – WakeMed Raleigh Medical Park

Project ID #J-12371-23/UNC Rex Hospital/Acquire one LINAC
The applicant proposes to acquire and add an additional LINAC at UNC Health Rex Cancer Care of Wakefield (UNC Rex Wakefield)

Patient Origin – In Chapter 17, page 311, the 2023 SMFP defines a LINAC's service area as "*…one of the 28 multicounty groupings described in the Assumptions of the Methodology.*" Table 17C-4 on page 320 shows Service Area 20 is comprised of Franklin and Wake counties.

Thus, the service area for this project consists of those two counties. Facilities may also serve residents of counties not included in their service area.

The following table illustrates current and projected patient origin.

Current & Projected Patient Origin – UNC Rex Wakefield – Radiation Therapy								
	Current – SFY* 2022		FY 1 – SFY* 2026		FY 2 – SFY* 2027		FY 3 – SFY* 2028	
	# Patients	% Patients	# Patients	% Patients	# Patients	% Patients	# Patients	% Patients
Wake	471	70.9%	528	71.4%	537	71.5%	548	71.5%
Franklin	151	22.7%	169	22.9%	172	22.9%	176	22.9%
Vance	11	1.7%	11	1.5%	11	1.5%	11	1.5%
Other**	31	4.7%	31	4.2%	31	4.2%	31	4.2%
Total	**664**	**100.0%**	**740**	**100.0%**	**752**	**100.0%**	**766**	**100.0%**

Source: Section C, pages 39-40
Note: Table may not foot due to rounding.
*SFY – State Fiscal Year (July 1 – June 30)
**Other: Other counties in North Carolina as well as other states

In Section C, page 40, the applicant provides the assumptions and methodology used to project its patient origin. The applicant's assumptions and methodology used to project patient origin are reasonable and adequately supported based on the following:

- The applicant projects patient origin based on historical patient origin.
- The applicant adjusts the projected patient origin based on projected changes in utilization that impact the patient origin.

Analysis of Need – In Section C, pages 42-63, the applicant explains the reasons why it believes the population projected to utilize the proposed services needs the proposed services, which are summarized below.

- There is an adjusted need determination for one LINAC in Service Area 20. The applicant states that, at the time of the petition requesting the adjusted need determination, the applicant was opposed to the petition; however, the applicant states its situation has changed between when the petition was filed and the submission of the application. The applicant states its annualized LINAC utilization has increased by 9.3% over State Fiscal Year (SFY) 2022 and increased by 4.2% over its SFY 2019 volume. (pages 42-44)
- Developing a second LINAC at the UNC Rex Wakefield campus will allow the applicant to provide stereotactic radiosurgery (SRS) and stereotactic body radiation therapy (SBRT) services at that location, which are not currently offered there. (pages 44-45)
- The applicant states that, according to the NC Office of State Budget and Management (NC OSBM), the Wake County total population grew by 22.3% between 2013 and 2023, and over the last 10 years Wake County added more residents than the combined 2023 total population of 88 of North Carolina's 100 counties. The applicant states the Franklin County total population increased by even more – 22.8% – during the same time period. The

applicant states that NC OSBM data shows the population in Service Area 20 grew at twice the rate of the overall statewide population growth. The applicant also states NC OSBM projects Service Area 20 will grow at a compound annual growth rate (CAGR) of 2.1% between 2023 and 2028, while the total statewide population growth rate is projected to be 1.1% between 2023 and 2028. (pages 45-46)

- The applicant states the population in Service Area 20 is aging at a more rapid rate than the state as a whole. The applicant states that, according to NC OSBM, the Service Area 20 population age 65 and older grew at a CAGR of 5.5% between 2013 and 2023, compared with 3.3% for the total statewide population age 65 and older. The applicant states NC OSBM projects Service Area 20's population age 65 and older will grow at a 5% CAGR between 2023 and 2028, compared with the total statewide population age 65 and older, which is projected to grow at a 2.8% CAGR between 2023 and 2028. The applicant states people aged 65 and older are eleven times more likely to develop cancer than younger patients. (pages 46-47)

- The applicant states Franklin County has been without a LINAC since 2019 and that there are health, socioeconomic, and other disparities that necessitate putting the LINAC at UNC Rex Wakefield. (pages 47-52)

- The applicant's LINACs in Service Area 20 were the highest utilized out of all LINACs in Service Area 20 in the three most recent historical periods for which data is available. (pages 52-57)

- The LINAC at UNC Rex Wakefield is the highest utilized LINAC in all of Service Area 20. Because of additional services available on the campus, and because of the need to provide SRT and SBRT services to Franklin County residents, the LINAC is needed specifically at UNC Rex Wakefield. (pages 57-63)

However, the information is not reasonable and adequately supported based on the following reasons:

- The applicant is part of the UNC System. The UNC System is also the parent company of University of North Carolina Hospitals at Chapel Hill (UNC-CH), which holds a certificate of need to develop a LINAC in Service Area 20 that is more than seven years old, and which does not appear to be under development.

  UNC-CH applied to acquire a new LINAC, to be located at its hospital campus in Holly Springs, as part of the 2014 Service Area 20 LINAC review. A decision was issued in that competitive review on January 28, 2015 and was appealed. As the result of a settlement agreement, a certificate of need was issued to UNC-CH on April 29, 2016. Progress reports submitted by UNC-CH subsequent to the issuance of the certificate of need through the end of 2019 stated that the LINAC was to be located on the UNC Rex Holly Springs hospital campus under development and therefore could not be fully developed until the hospital campus itself was fully developed.

On September 8, 2020, UNC-CH submitted a material compliance request to relocate the approved but not yet developed LINAC to the UNC Panther Creek campus in Morrisville, roughly 16 miles north of the location approved in the certificate of need. The Agency issued a determination that the proposed relocation was materially compliant with the certificate of need on September 16, 2020.

The subsequent progress reports submitted by UNC-CH to the Agency on February 1, 2021, July 1, 2021, and November 1, 2021 stated that because of the impact of the COVID-19 pandemic on healthcare, there was a delay in developing the campus. The progress report submitted on November 1, 2021 stated that development was anticipated to begin again in early 2022.

In a progress report submitted to the Agency on March 1, 2022, UNC-CH stated that the proposed project was now part of a system-wide review process and anticipated development would begin upon completion of that review process. UNC-CH did not provide any timetable upon which the development would begin again and has not submitted another progress report to the Agency in the 18 months since.

- On May 30, 2023 – after the beginning of this review – UNC-CH submitted a material compliance requesting a transfer for good cause. UNC-CH proposed to transfer ownership to the applicant and noted that it was an intraorganizational transfer due to the shared parent company. The letter also stated that the material compliance request submitted on September 8, 2020 would be withdrawn and the applicant would develop the LINAC at the location originally approved in the certificate of need. The Agency approved the transfer for good cause on June 6, 2023. No timetable for development was provided in the letter requesting the transfer for good cause.

- In Section C, page 43, the applicant states that its comments in opposition to WakeMed's petition for an adjusted need determination *"…were also reflective of volume trends at the time of submission, which indicated flat to negative growth in LINAC utilization at UNC Rex Health facilities."* The applicant was able to provide care to its existing LINAC patients during the last seven and a half years without taking further steps to develop the approved LINAC. The applicant does not explain how its utilization increase over the last eight months shows a need for an additional LINAC when it has not yet developed the LINAC it was approved to develop nearly seven and a half years ago.

<u>Projected Utilization</u> – On Forms C.2a and C.2b in Section Q, the applicant provides historical and projected utilization, as illustrated in the following table.

UNC Rex Wakefield LINAC – Historical and Projected Utilization				
	Historical SFY 2022	**FY 1 SFY 2026**	**FY 2 SFY 2027**	**FY 3 SFY 2028**
# of Units	1	2	2	2
# of ESTV Treatments*	6,768	7,538	7,662	7,804
# of Patients	664	740	752	766

*ESTV = Equivalent Simple Treatment Visits

In the Form C Utilization – Methodology and Assumptions subsection of Section Q, the applicant provides the assumptions and methodology used to project utilization, which are summarized below.

- The applicant's LINAC utilization at UNC Rex Wakefield increased at a CAGR of 0.1% between SFY 2019 and SFY 2023 annualized. The applicant states the lack of growth is due to the high capacity of patients treated at UNC Rex Wakefield.

- The applicant begins projections with SFY 2023 annualized utilization and assumes that utilization will increase at an annual rate of 0.1% through the end of the third full fiscal year following project completion.

- The applicant projects growth in the patient population receiving SRT and SBRT services at UNC Rex Hospital and that live in northern Wake County and Franklin County will grow at an annual rate of 16.4%, consistent with the SFY 2019 through SFY 2023 CAGR for those patients. The applicant then assumes 90% of those patients will shift care to UNC Rex Wakefield once the second LINAC is operational.

The applicant's assumptions and methodology are summarized in the table below.

UNC Rex Wakefield LINAC – Historical and Projected Utilization						
	Interim			Projected		
	SFY 2023	SFY 2024	SFY 2025	FY 1 SFY 2026	FY 2 SFY 2027	FY 3 SFY 2028
# of Units	1	1	1	2	2	2
# of Patients (0.1% growth)	668	668	669	669	670	671
# of SRT/SBRT Patients (16.4% growth)	50	58	67	78	91	106
# of SRT/SBRT Patients Shifting (90%)	--	--	--	70	82	95
Total # of Patients	668	668	669	740	752	766
Average # of Patients per LINAC	668	668	669	370	376	383

UNC Health System – Service Area 20 – Pursuant to 10A NCAC 14C .1903(e), an applicant proposing to add a LINAC must project that all LINACs in the service area owned or operated by the applicant or a related entity will perform at least 6,750 ESTVs per LINAC or serve at least 250 patients per LINAC in the third full fiscal year following project completion.

In the Form C Utilization – Assumptions and Methodology subsection of Section Q, the applicant provides the assumptions and methodology used to project utilization for all UNC LINACs in Service Area 20, which are summarized below.

- The applicant has a total of six existing and approved LINACs. There are three existing LINACs at UNC Rex Hospital. There is one existing LINAC at UNC Rex Wakefield and one existing LINAC at UNC Rex East Raleigh. There is an approved but not yet developed LINAC that will be located at UNC Panther Creek in Cary.

- The applicant analyzed the number of patients it had served each year at UNC Rex Hospital and at UNC Rex East Raleigh between SFY 2019 and SFY 2023 annualized. The applicant

determined patient utilization had increased at a CAGR of 3.3% between SFY 2019 and SFY 2023 annualized at UNC Rex Hospital and patient utilization had decreased at a CAGR of -5.9% between SFY 2019 and SFY 2023 annualized at UNC Rex East Raleigh.

- The applicant begins its utilization projections with SFY 2023 annualized utilization at each facility.

- The applicant projected growth in patient utilization at UNC Rex Hospital through the third full fiscal year following project completion at an annual rate of 3.3%, consistent with its historical CAGR between SFY 2019 and SFY 2023 annualized.

- The applicant projected patients from northern Wake County and Franklin County that had historically received SRT and SBRT at UNC Rex Hospital would grow at an annual rate of 16.4% through the third full fiscal year following project completion, consistent with the applicant's SFY 2019 through SFY 2023 annualized CAGR for those patients. The applicant projected 90% of the SRT and SBRT patients who live in northern Wake County and Franklin County will shift to UNC Rex Wakefield once the second LINAC is operational.

- The applicant projected patients from southwest Wake County that had historically utilized the LINACs at UNC Rex Hospital would grow at an annual rate of 6.1% through the third full fiscal year following project completion, consistent with the applicant's SFY 2019 through SFY 2023 annualized CAGR for those patients. The applicant projected 50% of the patients who live in southwest Wake County will shift to UNC Panther Creek once the approved LINAC is developed.

- The applicant states patient utilization at UNC Rex East Raleigh was relatively steady between SFY 2019 and SFY 2022 before a decline in SYF 2023 annualized. The applicant states it has taken steps to stabilize scheduling and expects utilization to increase as there are capacity constraints elsewhere. The applicant states that it projects no growth in the utilization rate at UNC Rex East Raleigh through the third full fiscal year following project completion.

The applicant's assumptions and methodology are summarized in the table below.

UNC Rex Health System LINAC Utilization – Service Area 20								
Facility	**Patients**						**# LINACs**	**Patients/LINAC**
	SFY 2023*	**SFY 2024**	**SFY 2025**	**SFY 2026**	**SFY 2027**	**SFY 2028**		
UNC Rex Hospital (3.3%)	1,748	1,806	1,866	1,929	1,993	2,060		
Patient Shift to UNC Rex Wakefield	--	--	--	-70	-82	-95		
Patient Shift to UNC Panther Creek	--	--	--	-380	-404	-429		
UNC Rex Hospital Patients	1,748	1,806	1,866	1,478	1,508	1,536	3	512
UNC Rex Wakefield (0.1%, w/shifts)	668	668	669	740	752	766	2	383
UNC Rex East Raleigh (0.0%)	386	386	386	386	386	386	1	386
UNC Panther Creek (all shifts)	--	--	--	380	404	429	1	429
Total	**2,802**	**2,860**	**2,921**	**2,984**	**3,050**	**3,117**	**7**	**445**

*Annualized

As shown in the table above, each individual LINAC as well as the average utilization across all LINACs owned and operated by UNC Rex in Service Area 20 are projected to exceed 250 patients per LINAC during the third full fiscal year following project completion. This meets the performance standard required by 10A NCAC 14C .1903(e).

However, projected utilization is not reasonable and adequately supported based on the following reasons:

- The UNC System and its subsidiaries have not yet developed the LINAC approved to develop nearly seven and a half years ago and has not provided any update to the Agency about when the LINAC will be developed. Please see the discussion above Analysis of Need. The history with regard to development of the approved LINAC calls into question the utilization projections from the applicant.

- The applicant does not adequately explain why it relied on historical utilization data that has an outlier year which significantly changes utilization projections.

  The applicant projects growth in utilization of potential SRS and SBRT patients from northern Wake County and Franklin County based on its SFY 2023 annualized data and using the CAGR for utilization between SFY 2019 and 2023 annualized. However, historical utilization for SRS and SBRT patients from northern Wake County and Franklin County was flat between SFY 2019 and SFY 2022 before doubling between SFY 2022 and 2023 annualized. The inclusion of this outlier year skews the CAGR significantly higher than historical utilization trends reflect. Further, the applicant applied the skewed CAGR to the outlier year with double the historical utilization to project future utilization.

  In its responses to comments, the applicant states that the utilization trend between SFY 2019 and 2023 annualized is consistent with overall growth in utilization after a decline due to the impact of the COVID-19 pandemic. However, that is not consistent with the information provided by the applicant about historical utilization.

  The table below shows all historical utilization data sets provided by the applicant in Section Q.

Historical Utilization Data Sets in Section Q					
	SFY 2019	SFY 2020	SFY 2021	SFY 2022	SFY 2023*
UNC Rex Hospital Patients (p.1)	1,532	1,670	1,458	1,424	1,748
UNC Rex Wakefield Patients (p.1)	665	708	682	664	668
UNC Rex East Raleigh Patients (p.1)	491	497	475	474	386
Average Patients per LINAC (p.1)	538	575	523	512	560
Potential Patients from Holly Springs/Panther Creek (p.3)	501	653	563	490	636
Potential SRS/SBRT Patients from N Wake/Franklin (p.3)	27	24	24	25	50

*Annualized

In all other sets of historical utilization provided by the applicant, utilization increased between SFY 2019 and 2020, then declined (presumably due to the impact of COVID-19) between SFY 2020 and 2022, before increasing again in SFY 2023 annualized. In some

cases, utilization in SFY 2023 annualized was higher than it had been in SFY 2020; in other cases, utilization in SFY 2023 annualized increased noticeably over SFY 2022 but did not eclipse utilization in SFY 2020. However, in no other data set did utilization decline or remain flat between SFY 2019 and SFY 2020, and in no other data set did utilization remain flat between SFY 2020 and 2022 before doubling between SFY 2022 and SFY 2023 annualized.

Further, the data set for UNC Rex East Raleigh is also an outlier. Instead of following the historical utilization trends for the other data sets listed above, utilization for UNC Rex East Raleigh noticeably declined between SFY 2022 and SFY 2023 annualized. However, the applicant treated this outlier differently. The applicant did not rely on what would be a negative SFY 2019 through 2023 annualized CAGR to project utilization at UNC Rex East Raleigh; instead, it projected no growth in utilization.

The applicant provides no information in the application as submitted to explain why it is reasonable to include an outlier year which results in a significantly higher CAGR and increased utilization over historical trends while not including an outlier year which would result in a negative CAGR and decreased utilization over historical trends.

- On May 30, 2023 – after the beginning of this review – UNC-CH submitted a material compliance requesting a transfer for good cause. UNC-CH proposed to transfer ownership to the applicant and noted that it was an intraorganizational transfer due to the shared parent company (UNC System). The letter also stated that the material compliance request submitted on September 8, 2020 would be withdrawn and the applicant would develop the LINAC at the location originally approved in the certificate of need. The Agency approved the transfer for good cause on June 6, 2023. No timetable for development was provided in the letter requesting the transfer for good cause.

  Utilization projections in this application assume the approved LINAC will be developed at the UNC Panther Creek campus. The location where the LINAC will be developed is approximately 16 miles further south into Wake County. Because the LINAC will not be developed where the utilization projections assume the LINAC will be developed, that further calls into question the reasonableness of the utilization projections made by the applicant.

<u>Access to Medically Underserved Groups</u> – In Section C, page 70, the applicant states:

> *"…, UNC Health Rex prohibits the exclusion of services to any patient on the basis of age, race, sex, creed, religion, disability, or the patient's ability to pay. …. In particular, as stated in UNC Health Rex's Patient Rights and Responsibilities Policy, patients have the right to receive "care that is free of discrimination" and "medically necessary treatment regardless of [their] ability to pay."*

The applicant provides the estimated percentage for each medically underserved group, as shown in the following table.

Medically Underserved Groups	Percentage of Total Patients
Racial and ethnic minorities	26.3%
Women	60.2%
Persons 65 and older	57.0%
Medicare beneficiaries	59.3%
Medicaid recipients	1.3%

Source: Section C, page 74

On page 75, the applicant states it does not maintain data on the number of low-income or disabled people it serves but that neither low-income nor disabled people are denied access to services.

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 based on the following:

- The applicant provides a statement saying it will provide service to all residents of the service area, including underserved groups, without regard for anything other than the need for LINAC services.

- The applicant provides documentation of its existing policies regarding non-discrimination in Exhibit B.20-3 and its financial policies in Exhibit B.20-4.

Conclusion – The Agency reviewed the:

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

Based on that review, the Agency concludes that the application is not conforming to this criterion based on all the reasons described above.

Project ID #J-12376-23/WakeMed Raleigh Medical Park/Acquire one LINAC
The applicant proposes to acquire a fixed LINAC and a CT simulator to be located at WakeMed Raleigh Medical Park (WakeMed RMP), a medical office building that will be located adjacent to WakeMed Raleigh Campus.

Patient Origin – In Chapter 17, page 311, the 2023 SMFP defines a LINAC's service area as "*…one of the 28 multicounty groupings described in the Assumptions of the Methodology.*" Table 17C-4 on page 320 shows Service Area 20 is comprised of Franklin and Wake counties. Thus, the service area for this project consists of those two counties. Facilities may also serve residents of counties not included in their service area.

WakeMed RMP is not an existing facility and thus does not have historical patient origin. The table below shows projected patient origin.

Projected Patient Origin – WakeMed RMP – LINAC/Simulator						
	FY 1 – FFY* 2025		FY 2 – FFY* 2026		FY 3 – FFY* 2027	
	# Patients	% Patients	# Patients	% Patients	# Patients	% Patients
Wake	189	74.0%	253	74.0%	327	74.0%
Franklin	10	3.9%	13	3.9%	17	3.9%
Harnett	19	7.6%	26	7.6%	34	7.6%
Johnston	11	4.2%	15	4.2%	19	4.2%
Other NC Counties	24	9.3%	32	9.3%	41	9.3%
Other States	3	1.0%	3	1.0%	4	1.0%
Total	**255**	**100.0%**	**342**	**100.0%**	**442**	**100.0%**

Source: Section C, page 51
*FFY = Federal Fiscal Year (October 1 – September 30)

In Section C, page 50, the applicant provides the assumptions and methodology used to project its patient origin. The applicant's assumptions and methodology used to project patient origin are reasonable and adequately supported based on the following:

- The applicant considered the distribution of other LINACs in Wake and Durham counties in projecting utilization.
- The applicant relied on its Tumor Registry in projecting patient origin.

Analysis of Need – In Section C, pages 54-66, the applicant explains the reasons why it believes the population projected to utilize the proposed services needs the proposed services, which are summarized below.

- The applicant has offered oncology services for many years but had to refer patients needing radiation therapy to other providers in the area because it lacks a LINAC. The applicant states analysis of data from its Tumor Registry and other acquired data shows its patients wait longer than the average for insured patients in Wake County from diagnosis to radiation therapy. The applicant states that it serves a significant number of medically underserved and indigent patients, and that while the WakeMed Raleigh campus may be accessible for those patients, other providers don't necessarily have the same kind of access available for those medically underserved and indigent patients. (pages 54-56)
- Radiation therapy has become a standard modality in cancer care and treatment. The applicant needs a LINAC to be able to provide the standard modality in its cancer care program. (page 56)
- The applicant states that, in both 2021 and 2022, it referred out more patients for radiation therapy than it would need to meet the applicable performance standard for LINACs. (page 57)
- The applicant states its patients originate primarily from Franklin, Harnett, Johnston, and Wake counties. The applicant states that construction projects designed to connect highways and ease traffic will make the WakeMed Raleigh Campus more accessible for residents in Harnett and Johnston counties. Additionally, data from NC OSBM projects

population growth in Service Area 20 at an annual rate of 2.1% between 2023 and 2028 and population growth in the four counties that patients primarily originate from will increase by 2.0% between 2023 and 2028. Further, the population aged 45 and older, which account for 9 out of 10 cancer diagnoses, is projected to grow faster than the overall population projected growth in the four counties where patients primarily originate from. (pages 57-61)

- The applicant states the North Carolina Center for Health Statistics, Central Cancer Registry projected there would be 8,776 new cancer cases during 2022 in the four counties that patients primarily originate from. The applicant states that new cancer case rates increased in each of the four counties patients primarily originate from. (pages 61-62)

- The applicant states its Tumor Registry data shows that WakeMed radiation therapy patients between 2018 and 2022 waited an average of nearly 99 days for radiation therapy services, compared with the average of 27 days for Wake County commercially insured patients. The applicant states its own internal data shows patients with commercial insurance had the shortest wait times from referral to appointment, and patients with managed care, uninsured patients, and low-income underinsured patients had the longest waits. The applicant states that, as a Disproportionate Share Hospital (a designation from the Centers for Medicare and Medicaid Services for safety-net hospitals), it serves a significant amount of patients from minority and historically underserved groups and needs access to a LINAC. (pages 62-64)

- The applicant states that care fragmentation – when a patient has to visit different systems to receive services – increases the time from diagnosis to treatment and cites studies showing care fragmentation results in increased time to treatment, increased costs, and reduction in survival compared with care delivered by a single system. The applicant states that the difficulties can be compounded for patients who have difficulties with transportation access. (pages 64-65)

- The applicant states there are 11 existing and approved LINACs in the 2023 SMFP inventory for Service Area 20, but that only 9 of them are operational and two are not in service. The applicant states there is a third LINAC that was approved to be developed in Harnett County (Service Area 21) which was approved in 2015 but there is no indication of when it will be operational. The applicant states all other LINACs are each serving more than 250 patients per LINAC, and that projected growth in patient population will result in greater demand than the three approved but not yet developed LINACs will be able to handle. (pages 65-66)

The information is reasonable and adequately supported based on the following reasons:

- As a Disproportionate Share Hospital, WakeMed serves more medically underserved patients than hospitals without that designation.

- WakeMed's data shows that patients it refers elsewhere for treatment must wait longer than average for access to radiation therapy services.

- WakeMed is already referring more than 250 patients per year to other systems for LINAC services.

- The adjusted need determination for the additional LINAC in Service Area 20 was approved by the SHCC because the SHCC believes radiation therapy is now the standard of care for cancer programs.

Projected Utilization – On Form C.2b in Section Q, the applicant provides projected utilization, as illustrated in the following table.

WakeMed RMP – Projected Utilization – LINAC/Simulator			
	FY 1 FY 2026	FY 2 FY 2027	FY 3 FY 2028
# of Units	1	1	1
# of ESTV Treatments*	4,070	5,459	7,054
# of Patients	255	342	442

*ESTV = Equivalent Simple Treatment Visits

In the WakeMed Need and Utilization Methodology for Section C subsection of Section Q, the applicant provides the assumptions and methodology used to project utilization, which are summarized below.

- The applicant assumes that its area of patient origin will encompass Franklin, Harnett, Johnston, and Wake counties, because nearly 86% of WakeMed's medical oncology patients originated from those four counties between August 2022 and March 2023. The applicant states approximately 2.9% of patients originated from Durham County, but because Durham County will soon have two LINACs developed close to its border in western Wake County, the applicant assumes the area of patient origin will not include Durham County and adjusted the project patient origin to account for the removal of Durham County patients. The applicant assumes that patient origin will be constant during the first three full fiscal years of operation.

- The applicant assumes that medical oncology patient patterns provide a reasonable baseline for projecting the need for radiation therapy patients. The applicant states the WakeMed Tumor Registry has a lag in data entry so not all FY 2022 patients are represented in the Tumor Registry (as of the submission of this application).

- The applicant projected population growth in the four counties using data from NC OSBM. The applicant states projections from NC OSBM are in calendar years, not fiscal years, but assumes any difference will not meaningfully impact projections.

- The applicant reviewed historical rates of new cancer cases per 1,000 population by county and by year using data from the North Carolina State Center for Health Statistics. The applicant then plotted the historical rates for each county and used Microsoft Excel's graph trend function to calculate linear trends for the historical rates of new cancer cases that could be used in projecting future rates of new cancer cases. The applicant states that because each county has unique demographic and population trends, it is more accurate to

calculate rates individually by county rather than an aggregated rate. The applicant also notes that the historical rates of new cancer cases are based on reported diagnoses, and the historical data includes years where COVID kept many people from doing routine cancer screenings (and so the actual rates may be higher than the projected rates).

- The applicant projected the number of new cancer cases by county through the third full fiscal year of operation by applying the projected rates of new cancer cases (described above) to the projected population of each county.

- The applicant states data shows up to 60% of cancer patients will receive radiation therapy treatment and assumes, based on data from a different source, that 52.3% of new cancer patients will need radiation oncology. The applicant applied that assumption to the projected number of new cancer patients to estimate how many would need radiation therapy. The applicant also assumed there would be a recurrence rate requiring retreatment of approximately 23% and calculated the number of patients requiring more than one course of radiation therapy. The applicant then combined the number of patients needing radiation therapy and the patients requiring a second course of radiation therapy.

- The applicant assumed patients who had been treated by other providers would continue to be treated by other providers, and projected growth in the number of patients treated by other providers at the same growth rate NC OSBM projects for each county.

- The applicant subtracted the projected number of patients to be served by existing providers from the total projected number of new cancer cases that would need radiation therapy to obtain the number of unserved radiation therapy patients. The applicant assumed it would serve an increasing percentage of unserved radiation therapy patients originating from Franklin, Harnett, Johnston, and Wake counties during the first, second, and third full fiscal years of operation (21%, 23%, and 25%, respectively).

- The applicant assumed that approximately 10.32% of its patients would originate from outside of the four-county area of patient origin. The applicant multiplied the projected number of unserved patients it would serve by 10.32% to obtain the number of patients that would originate from outside of the four-county area of patient origin.

- The applicant states it referred 385 patients for treatment outside of WakeMed in FY 2022. The applicant states it will retain an increasing percentage of patients it historically referred elsewhere for treatment in the first, second, and third full fiscal years of operation (33%, 44%, and 55%, respectively) and adds those patients to the total.

The applicant's assumptions and methodology are summarized in the tables below.

WakeMed RMP Projected Utilization – Wake County						
	Interim			Projected		
	FFY 2023	FFY 2024	FFY 2025	FY 1 FFY 2026	FY 2 FFY 2027	FY 3 FFY 2028
Population (2.082% CAGR)	1,204,356	1,230,400	1,256,524	1,282,697	1,308,878	1,335,058
New Cancer Cases (based on county linear trend)	6,521	6,811	7,108	7,411	7,721	8,037
New Radiation Oncology Cases (52.3%)	3,410	3,562	3,717	3,876	4,038	4,203
Retreated Cases (23% of New Cases above)	784	819	855	891	929	967
Total Cases	4,195	4,381	4,572	4,768	4,967	5,170
Radiation Oncology Cases at Other Providers (2.082%)	4,146	4,233	4,321	4,411	4,503	4,596
Unserved Radiation Oncology Cases	48	149	252	357	464	574

WakeMed RMP Projected Utilization – Franklin County						
	Interim			Projected		
	FFY 2023	FFY 2024	FFY 2025	FY 1 FFY 2026	FY 2 FFY 2027	FY 3 FFY 2028
Population (2.148% CAGR)	73,668	75,332	76,971	78,625	80,278	81,928
New Cancer Cases (based on county linear trend)	493	509	524	540	556	572
New Radiation Oncology Cases (52.3%)	258	266	274	282	291	299
Retreated Cases (23% of New Cases above)	59	61	63	65	67	69
Total Cases	317	327	337	347	358	368
Radiation Oncology Cases at Other Providers (2.148%)	278	284	290	296	302	309
Unserved Radiation Oncology Cases	40	44	48	52	56	59

WakeMed RMP Projected Utilization – Harnett County						
	Interim			Projected		
	FFY 2023	FFY 2024	FFY 2025	FY 1 FFY 2026	FY 2 FFY 2027	FY 3 FFY 2028
Population (1.584% CAGR)	137,811	139,774	142,008	144,340	146,736	149,076
New Cancer Cases (based on county linear trend)	748	769	793	818	843	868
New Radiation Oncology Cases (52.3%)	391	402	415	428	441	454
Retreated Cases (23% of New Cases above)	90	93	95	98	101	104
Total Cases	481	495	510	526	542	558
Radiation Oncology Cases at Other Providers (1.584%)	415	421	428	435	442	449
Unserved Radiation Oncology Cases	66	74	82	91	100	110

WakeMed RMP Projected Utilization – Johnston County						
	Interim			Projected		
	FFY 2023	FFY 2024	FFY 2025	FY 1 FFY 2026	FY 2 FFY 2027	FY 3 FFY 2028
Population (2.087% CAGR)	235,925	241,433	246,695	251,779	256,733	261,592
New Cancer Cases (based on county linear trend)	1,345	1,402	1,458	1,515	1,572	1,629
New Radiation Oncology Cases (52.3%)	703	733	763	792	822	852
Retreated Cases (23% of New Cases above)	162	169	175	182	189	196
Total Cases	865	902	938	974	1,011	1,048
Radiation Oncology Cases at Other Providers (2.087%)	870	888	907	926	945	965
Unserved Radiation Oncology Cases	--	13	31	49	66	83

WakeMed RMP Projected Utilization – Total Unserved Cases in Area of Patient Origin						
	Interim			Projected		
	FFY 2023	FFY 2024	FFY 2025	FY 1 FFY 2026	FY 2 FFY 2027	FY 3 FFY 2028
Wake County	48	149	252	357	464	574
Franklin County	40	44	48	52	56	59
Harnett County	66	74	82	91	100	110
Johnston County	--	13	31	49	66	83
Total	**154**	**279**	**412**	**548**	**686**	**826**

WakeMed RMP Projected Utilization		
Unserved Patients Projected to be Served		
FY 1 (FFY 2026) – 21%	**FY 2 (FFY 2027) – 23%**	**FY 3 (FFY 2028) – 25%**
115	158	206
Projected Inmigration of Patients		
FY 1 (FFY 2026) – 10.32%	**FY 2 (FFY 2027) – 10.32%**	**FY 3 (FFY 2028) – 10.32%**
13	18	24
Projected Retained WakeMed Patients Currently Referred Elsewhere		
FY 1 (FFY 2026) – 33%	**FY 2 (FFY 2027) – 44%**	**FY 3 (FFY 2028) – 55%**
127	166	212
Total Projected Patients		
FY 1 (FFY 2026)	**FY 2 (FFY 2027)**	**FY 3 (FFY 2028)**
255	**342**	**442**
Total ESTVs (15.96078 ESTVs per Patient)		
FY 1 (FFY 2026)	**FY 2 (FFY 2027)**	**FY 3 (FFY 2028)**
4,070	5,459	7,055

Pursuant to 10A NCAC 14C .1903(e), an applicant proposing to add a LINAC must project that all LINACs in the service area owned or operated by the applicant or a related entity will perform at least 6,750 ESTVs per LINAC or serve at least 250 patients per LINAC in the third full fiscal year following project completion.

WakeMed does not currently have any existing or approved LINACs owned by the applicant or a related entity in Service Area 20. As shown in the table above, WakeMed RMP projects

to serve at least 250 patients per LINAC in the third full fiscal year following project completion. This meets the performance standard required by 10A NCAC 14C .1903(e).

Discussion

- Comments received during the public comment period state that counting "retreatment" patients as more than one patient are unreasonable and that without those patients, WakeMed RMP would not meet the appropriate performance standard. However, on the 2023 License Renewal Application for Hospitals, the section asking for data on LINAC utilization states the following:

  > *"Patients shall be counted once if they receive one course of treatment and more if they receive additional courses of treatment. For example, one patient who receives one course of treatment counts as one, and one patient who receives three courses of treatment counts as three."*

  WakeMed RMP's utilization projections for "retreatment" patients are consistent with information collected by the Agency on LRAs for license renewals and for data used in need methodologies in the SMFP.

- Comments received during the public comment period suggested that it is unreasonable to use a 52.3% rate as the estimate for the percentage of all cancer patients that require radiation therapy treatment because the citation for that rate came from an article based on Australian patients which was published 18 years ago.

  The Project Analyst researched the percentage of cancer patients that will require radiation therapy treatment using sources from 2019 through the present. While most current information discusses radiation therapy utilization based on the specific type of cancer, the World Health Organization, the American Cancer Society, and the Mayo Clinic all state that more than half of all cancer patients will receive radiation therapy. Please see the Working Papers for documentation. Additionally, another application in this review cites the American Cancer Society as saying that approximately two-thirds of cancer patients will need radiation therapy. See page 55 of Project ID #J-12371-23.

Projected utilization is reasonable and adequately supported based on the following reasons:

- The applicant's assumptions are consistent with publicly available information.

- The applicant relies on data from publicly available and reliable sources such as NC OSBM.

- The applicant referred more patients out for radiation therapy in a single year than it would need to meet the relevant performance standard.

<u>Access to Medically Underserved Groups</u> – In Section C, page 73, the applicant states:

> *"WakeMed ensures access to health care services for all patients, regardless of income, payer status, gender, race, ethnicity, or* [disability]. *At WakeMed, the goal is to provide outstanding and thoughtful care to all who seek services."*

The applicant provides the estimated percentage for each medically underserved group, as shown in the following table.

Medically Underserved Groups	Percentage of Total Patients
Low-income persons	1.7%
Racial and ethnic minorities	30.9%
Women	70.5%
Persons 65 and older	46.7%
Medicare beneficiaries	50.8%
Medicaid recipients	4.7%

Source: Section C, page 82

The applicant does not include projections for the percentage of patients with disabilities it anticipates serving in the third full fiscal year following project completion. In Section C, pages 71-82, the applicant discusses its commitment to medically underserved groups, including specific discussions about care for persons with disabilities.

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 based on the following:

- The applicant provides a statement saying it will provide service to all residents of the service area, including underserved groups.

- The applicant provides its Americans with Disability Policy and its Financial Assistance Policy in Exhibit C.6.

Conclusion – The Agency reviewed the:

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

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

Project ID #J-12379-23/Duke Radiation Oncology Garner/Acquire one LINAC
The applicant proposes to acquire a LINAC and CT simulator to develop Duke Garner, a new radiation oncology facility licensed under Duke Raleigh Hospital.

Patient Origin – In Chapter 17, page 311, the 2023 SMFP defines a LINAC's service area as "*…one of the 28 multicounty groupings described in the Assumptions of the Methodology.*" Table 17C-4 on page 320 shows Service Area 20 is comprised of Franklin and Wake counties. Thus, the service area for this project consists of those two counties. Facilities may also serve residents of counties not included in their service area.

Duke Garner is not an existing facility. The following table illustrates projected patient origin.

Projected Patient Origin – Duke Garner						
ZIP Code	**FY 1 – SFY* 2027**		**FY 2 – SFY* 2028**		**FY 3 – SFY* 2029**	
	# Patients	**% Patients**	**# Patients**	**% Patients**	**# Patients**	**% Patients**
27520	9	8%	17	9%	21	8%
27529	13	11%	24	13%	31	11%
27545	8	7%	15	8%	21	8%
27592	6	5%	10	5%	13	5%
27601	6	5%	9	5%	13	5%
27604	10	9%	14	7%	22	8%
27605	5	4%	8	4%	11	4%
27608	6	5%	9	5%	13	5%
27610	13	11%	22	11%	33	12%
27539	9	7%	15	8%	22	8%
27603	12	10%	19	10%	29	11%
27606	8	6%	13	7%	19	7%
Inmigration	11	9%	18	9%	25	9%
Total	**116**	**100%**	**193**	**100%**	**273**	**100%**

Source: Section C, page 33
Note: Table may not foot due to rounding.
*SFY – State Fiscal Year (July 1 – June 30)

In Section Q, the applicant provides the assumptions and methodology used to project its patient origin. The applicant's assumptions and methodology used to project patient origin are not reasonable and adequately supported because the applicant's utilization projections are not reasonable and adequately supported. See the discussion below regarding projected utilization for additional information.

Analysis of Need – In Section C, pages 36-41, the applicant explains the reasons why it believes the population projected to utilize the proposed services needs the proposed services, which are summarized below.

- The applicant states its existing LINACs have experienced significant growth. The applicant states that there was a disruption in care during the COVID-19 pandemic, reducing utilization, and there has been a return to historical growth patterns. (page 37)

- The applicant states that, according to NC OSBM, the projected rate of population growth in Wake County between July 1, 2020 and July 1, 2030 will be nearly double that of the state as a whole. The applicant further states that, according to NC OSBM, the Wake County population aged 65 and older will grow at more than double the rate of the Wake County population as a whole. (pages 38-39)

- The applicant states that, according to Sg2, ZIP codes within a 20-minute drive of the proposed Duke Garner will increase their population by an average of 6.4% between 2023 and 2028. The applicant states there is only one existing LINAC within that area which does not appear to have capacity and which forces patients in that area to travel further distances to reach other LINACs. (page 39)

- The applicant states developing Duke Garner will not only allow coordination between other medical services, such as physician services, imaging, and ambulatory surgery services, but will also allow for a local access point to coordinated care provided by the Duke Cancer Institute. (pages 39-41)

- The applicant states that there is *"…a broad, proven MRI referral base which supports vital patient care throughout the Triangle and beyond, including oncology screening and treatment."* (page 41)

However, the information provided by the applicant is not reasonable and adequately supported based on the following reasons:

- The applicant states that its strong provider support is evidence of the need for LINAC services at Duke Garner. The applicant discusses the referral base for MRI patients and how primary care providers refer patients for MRI screening and specialists that rely on MRI screening. The applicant states that there will be a primary care practice in the same location where the LINAC will be developed.

  However, the applicant provides no information in the application as supported to explain why the location of a primary care clinic in the same place at the proposed LINAC demonstrates the need for a LINAC in that location. The applicant also provides no information as to what correlation, if any, exists between a broad MRI referral base and the need for additional LINAC services.

- The adjusted need determination for the LINAC is the result of a petition to the SHCC from WakeMed. Duke submitted comments in response to that petition. Duke's comments stated, in part:

  > *"Duke supports the application of the existing methodology and resulting determination that no need exists for additional equipment in the service area.*
  >
  > …
  >
  > *One of the linear accelerators…has been approved for acquisition and relocation into Wake County by Duke. The other is under development by UNC. In light of the fact that the two identified 'underutilized' linear accelerators are in fact both projects that are under development and projected to be available to increase access for patients in the near future and are not simply chronically underutilized, it is premature to determine that there is insufficient inventory to meet the future needs of the service area."*

Duke does not provide any information in the application as submitted as to what changed in the eight months between the deadline for comments in response to Summer 2022 petitions (August 10, 2022) and the application deadline for this review cycle (April 17, 2023) that now causes them to believe that there is an additional need for LINAC services in Service Area 20. Further, Duke's comments are premised in part on the fact that two LINACs in Service Area 20 are under development and therefore any determination of insufficiency is premature; however, the two LINACs are still under development as of the date of these findings, and Duke does not provide any information in the application as submitted to explain the discrepancy in its position in August 2022 and its application in April 2023.

Projected Utilization – On Form C.2b in Section Q and in the Assumptions – Form C subsection of Section Q, the applicant provides projected utilization, as illustrated in the following table.

Duke Garner LINAC –Projected Utilization			
	FY 1 SFY 2027	FY 2 SFY 2028	FY 3 SFY 2029
# of Units	1	1	1
# of ESTV Treatments*	1,972	3,281	4,641
# of Patients	116	193	273

*ESTV = Equivalent Simple Treatment Visits

In the Assumptions – Form C subsection of Section Q, the applicant provides the assumptions and methodology used to project utilization, which are summarized below.

- The applicant used ZIP codes to delineate geographical boundaries and isolated "catchment areas" for its approved but not yet developed Duke Green Level LINAC and the proposed Duke Garner LINAC. The applicant defined its catchment areas as ZIP codes within 20 minutes driving time of a facility. Three of the ZIP codes are in both the Duke Green Level and the Duke Garner catchment areas.

- The applicant identified the SFY 2022 radiation procedures at all Duke sites (including sites in Durham County) by ZIP code and projected procedures would increase at a 1.3% annual rate through SFY 2029.

- The applicant projects the percentage of procedures that will shift from existing Duke locations to the Duke Green Level and Duke Garner facilities. The applicant projects procedures from the ZIP codes closest to the new facilities will be more likely to shift than ZIP codes further away. The applicant states it reduced the projections for the three ZIP codes that were in both the Duke Green Level and Duke Garner catchment areas because patients will have multiple options to choose from.

- The applicant divided the number of procedures by 17, the ratio of patients to ESTVs that was reported for Duke Raleigh Hospital's LINACs in the 2023 SMFP, to determine the number of patients that would shift.

- The applicant projected a statewide use rate using its ratio of 17 ESTVs/patient applied to the combined total ESTVs reported statewide in the 2023 SMFP. The applicant calculated a use rate of 3.5 patients per 1,000.

- The applicant applied the use rate to the 2021 populations of both catchment areas and calculated the estimated total number of LINAC patients in each catchment area. The applicant then subtracted the number of its actual existing patients in each catchment area in 2021 to determine the percentage of market share it currently has. The applicant determined it has a 20% market share in its Duke Garner catchment area and 36% in its Duke Green Level catchment area.

- The applicant projected a 6.5% increase in market share for the Duke Garner catchment area. The applicant states this will happen due to the proximity of LINAC services, access to Duke Cancer Institute services, and coordination with other types of care at the Duke Garner site. The applicant projects a ramp-up period in the gain in market share during each of the first three full fiscal years following project completion.

- The applicant projected a 3% increase in market share for the Duke Green Level catchment area. The applicant states the projected gain in market share will be lower because there are more options for LINAC services in that catchment area and market share increase will potentially be lower as a result.

- The applicant states that 23% of LINAC patients at Duke Raleigh Hospital originate from outside of Service Area 20. The applicant then projects an in-migration rate of 10% for both Duke Green Level and Duke Garner.

The applicant's assumptions and methodology are summarized in the table below.

Duke Garner – Projected Utilization							
	Interim				Projected		
	SFY 2023	SFY 2024	SFY 2025	SFY 2026	FY 1 SFY 2027	FY 2 SFY 2028	FY 3 SFY 2029
# of Radiation Oncology Procedures (1.3%)	23,606	23,914	24,225	24,540	24,860	25,183	25,511
Duke Garner							
# Procedures Shifting to Duke Garner					866	1,585	2,369
# of Patients Shifting to Duke Garner*					51	93	139
Market Share Increase Duke Garner (6.5%)					55	82	109
In-migration – Duke Garner (10%)					11	18	25
Total Patients – Duke Garner					116	193	273
Green Level							
# Procedures Shifting to Duke Green Level					1,760	2,836	3,938
# of Patients Shifting to Duke Green Level*					103	166	231
Market Share Increase Duke Green Level (3%)					43	65	87
In-migration – Duke Green Level (10%)					15	23	32
Total Patients – Duke Green Level					161	255	350

*Based on a ratio of 17 procedures per patient.

Duke Health System – Service Area 20 – Pursuant to 10A NCAC 14C .1903(e), an applicant proposing to add a LINAC must project that all LINACs in the service area owned or operated by the applicant or a related entity will perform at least 6,750 ESTVs per LINAC or serve at least 250 patients per LINAC in the third full fiscal year following project completion.

In the Form C Utilization – Assumptions and Methodology subsection of Section Q, the applicant provides the assumptions and methodology used to project utilization for all Duke LINACs in Service Area 20, which are summarized below.

- The applicant projected utilization for the approved but not yet operational Duke Green Level LINAC with the same projections as Duke Garner.

- The applicant projected utilization at all of its Duke Raleigh Hospital LINACs by applying different projected growth rates to the historical patients based on where those historical patients originated from:

  - ZIP codes in Duke Garner catchment area: 1.3%
  - ZIP codes in Duke Green Level catchment area: 1.3%
  - Other ZIP codes in Wake County: 1.4%
  - Durham County: 1.0%
  - Other NC Areas: 1.1%

- The applicant then subtracted the Duke Green Level and Duke Garner patients projected to shift from existing LINACs operated by Duke in Wake County.

The applicant's calculations result in the following utilization projections.

Duke Health System LINAC Utilization – Service Area 20									
	Patients							# LINACs	Patients/ LINAC
	SFY 2023	SFY 2024	SFY 2025	SFY 2026	SFY 2027	SFY 2028	SFY 2029		
Duke Cary	364	369	374	365	348	330	311	1	311
Duke Raleigh Hospital	574	582	589	578	567	546	522	2	261
Women's Cancer Care	306	310	314	308	302	290	277	1	277
Duke Green Level				68	161	255	350	1	350
Duke Garner				43	116	193	273	1	273
Total	**1,244**	**1,261**	**1,277**	**1,362**	**1,494**	**1,614**	**1,733**	**6**	**289**

As shown in the table above, each individual LINAC as well as the average utilization across all LINACs owned and operated by Duke in Service Area 20 are projected to exceed 250 patients per LINAC during the third full fiscal year following project completion. This meets the performance standard required by 10A NCAC 14C .1903(e).

However, projected utilization is not reasonable and adequately supported based on the following reasons:

- In Section Q, the applicant states the following:

> *"…, the highest anticipated shift is 50% for the closest zip* [sic] *codes to the new LINAC locations, with lower anticipated shifts for other zip* [sic] *codes. DUHS also anticipates that for those zip* [sic] *codes that may be within a 20-minute drive of either Garner or Green Level will have a lower shift rate to each facility since patients will have both options."*

However, the applicant does not project a shift of 50% for any of the ZIP codes with patients projected to shift to Duke Green Level. The applicant projects no more than 20% of the patients in a given ZIP code in the Duke Green Level catchment area will shift to Duke Green Level. In contrast, the applicant projects that no less than 30% of patients in ZIP codes in the Duke Garner catchment area will shift to Duke Garner. In responses to public comments, the applicant states the application as submitted explains that some ZIP codes will have lower shifts due to having access to multiple options for treatment sites; however, that is not consistent with the representations in the application as submitted. The applicant makes that statement about the three ZIP codes that are in both the Duke Garner and Duke Green Level catchment area, not about other ZIP codes.

- The applicant projects patient shifts that are not consistent with the assumptions it provides in the application as submitted.

  The applicant states that the ZIP codes closest to Duke Green Level and Duke Garner will have the highest patient shifts, with ZIP codes being further away having lower patient shifts and ZIP codes with multiple options for treatment centers having lower shifts. However, the applicant projects higher patient shifts from certain ZIP codes that have multiple treatment options located closer than Duke Garner while projecting lower patient shifts from ZIP codes closer to Duke Garner.

  For example, ZIP code 27608 is located near the center of Raleigh. The applicant projects that 45% of patients in ZIP code 27608 will shift to Duke Garner. However, the LINACs at Duke Raleigh Hospital and Duke Cary are significantly closer to all of ZIP code 27608 than to Duke Green Level or to Duke Garner. The applicant does not explain in the application as submitted why the shift for this ZIP code is so high, while the shift for ZIP codes 27605 and 27601 – both ZIP codes closer to Duke Garner than ZIP code 27608 is to Duke Garner – is projected to be only 30%.

<u>Access to Medically Underserved Groups</u> – In Section C, page 46, the applicant states:

> *"The services of Duke University Health System facilities, including the proposed radiation oncology services, are open to all area and non-area residents. Policies to provide access to services by low income, medically indigent, uninsured, or underinsured patients are described and provided elsewhere in this application. The facility will meet all ADA requirements for physical accessibility."*

The applicant provides the estimated percentage for each medically underserved group, as shown in the following table.

Medically Underserved Groups	Percentage of Total Patients
Low income persons	8.0%
Racial and ethnic minorities	24.2%
Women	50.5%
Persons 65 and older	45.0%
Medicare beneficiaries	47.9%
Medicaid recipients	6.1%

Source: Section C, page 46

On page 46, the applicant states data on the number of persons with disabilities is unavailable.

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 based on the following:

- The applicant provides a statement saying it will provide service to all patients regardless of location.

- The applicant provides documentation of its existing policies regarding non-discrimination and patients' rights in Exhibit C.6.

Conclusion – The Agency reviewed the:

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

Based on that review, the Agency concludes that the application is not conforming to this criterion for all the reasons described above.

(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.

NA – All Applications

None of the applicants propose to reduce a service, eliminate a service, or relocate a facility or service. Therefore, Criterion (3a) is not applicable to this review.

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

NC – UNC Rex Hospital, Duke Radiation Oncology Garner
C – WakeMed Raleigh Medical Park

Project ID #J-12371-23/UNC Rex Hospital/Acquire one LINAC
The applicant proposes to acquire and add an additional LINAC at UNC Health Rex Cancer Care of Wakefield (UNC Rex Wakefield).

In Section E, pages 84-85, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- Maintain the Status Quo – The applicant states that maintaining the status quo would not reduce utilization demands at UNC Rex Wakefield, which has the most heavily utilized LINAC in Service Area 20. The applicant further states additional capacity is needed because of the population growth in Service Area 20; therefore, this was not an effective alternative.

- Develop the LINAC at a Different Facility in Wake County – The applicant states developing the LINAC at a different facility would not meet the needs of the service area as effectively, especially for Franklin County residents, and would not introduce a new service at UNC Rex Wakefield that is currently unavailable at that location; therefore, this was not an effective alternative.

- Develop the LINAC in Franklin County – The applicant states this alternative would require additional construction costs, would replicate existing services, and the population of Franklin County along with travel patterns in Wake County would not support the placement of a LINAC in Franklin County; therefore, this was not an effective alternative.

However, the applicant does not adequately demonstrate that the alternative proposed in this application is the most effective alternative to meet the need based on the following:

- The applicant did not adequately demonstrate the need it has for the proposed project and did not demonstrate that projected utilization is based on reasonable and adequately supported assumptions. The discussions regarding analysis of need and projected utilization found in Criterion (3) are incorporated herein by reference. A proposal that is not needed by the population proposed to be served cannot be an effective alternative to meet the need.

- The applicant does not demonstrate sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of revenues and operating expenses. The discussion regarding financial feasibility found in Criterion (5) is incorporated herein by reference. A proposal that cannot demonstrate it will be financially feasible cannot be an effective alternative to meet the need.

- The applicant does not demonstrate that the proposed project is not an unnecessary duplication of existing and approved services in Service Area 20. The discussion regarding unnecessary duplication found in Criterion (6) is incorporated herein by reference. A

proposal that cannot demonstrate it is not an unnecessary duplication of existing and approved services in the service area cannot be an effective alternative to meet the need.

- The applicant does not demonstrate that any enhanced competition from the proposed project will have a positive impact on cost-effectiveness. The discussion regarding enhanced competition and the impact on cost-effectiveness found in Criterion (18a) is incorporated herein by reference. A proposal that cannot demonstrate how any enhanced competition will have a positive impact on cost-effectiveness cannot be an effective alternative to meet the need.

- The application is not conforming to all other statutory and regulatory review criteria. An application that cannot be approved cannot be an effective alternative to meet the need.

Conclusion – The Agency reviewed the:

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

Based on that review, the Agency concludes that the application is not conforming to this criterion for the reasons stated above.

Project ID #J-12376-23/WakeMed Raleigh Medical Park/Acquire one LINAC
The applicant proposes to acquire a fixed LINAC and a CT simulator to be located at WakeMed Raleigh Medical Park (WakeMed RMP), a medical office building that will be located adjacent to WakeMed Raleigh Campus.

In Section E, pages 89-92, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- Maintain the Status Quo – The applicant states that maintaining the status quo would result in the patients who seek WakeMed for cancer care would not be able to receive radiation therapy at WakeMed and must go to one of the other two health systems in Wake County. The applicant states that waits are already disproportionately long; therefore, this was not an effective alternative.

- Work with a Different Health System – The applicant states it had a joint venture with Duke Health in the late 2010s, Cancer Care Plus+, but that program dissolved by mutual agreement. The applicant states its cancer patients wait longer to receive radiation therapy than the average Wake County patient and delays caused by care fragmentation are made worse for people who are medically underserved; therefore, this was not an effective alternative.

- Wait for a Need Determination in a Future SMFP – The applicant states the existing LINACs in Wake County are not operating at the level that would trigger a need determination and that both Duke and UNC have approved LINACs that are not operational; therefore, this was not an effective alternative.

- Acquire Different Equipment – The applicant states new equipment represents a better investment for the planned purposes of the community cancer program and choosing equipment with more advanced features and functions would be more difficult to maintain and only serve a fraction of WakeMed patients; therefore, this was not an effective alternative.

- Develop a Freestanding Radiation Oncology Center – The applicant states the logistics necessary to seek accreditation, licensure, and coordination with WakeMed would delay the process significantly, and that it would potentially result in more bills sent to patients; therefore, this was not an effective alternative.

- Locate the LINAC Elsewhere in Service Area 20 – The applicant states the resources are already in place at WakeMed that would facilitate this specialty service. The applicant states Franklin County is not yet populous enough to support stand-alone specialty services and that Duke is relocating the LINAC from Franklin County to Wake County for that reason; therefore, this was not an effective alternative.

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 reasonable information to explain why it believes the proposed project is the most effective alternative.

- The application is conforming to all other statutory and regulatory review criteria. Therefore, the application can be approved.

Conclusion – The Agency reviewed the:

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

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

Project ID #J-12379-23/Duke Radiation Oncology Garner/Acquire one LINAC
The applicant proposes to acquire a LINAC and CT simulator to develop Duke Garner, a new radiation oncology facility licensed under Duke Raleigh Hospital.

In Section E, page 55, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- Maintain the Status Quo – The applicant states maintaining the status quo would not expand geographic access to patients in the Garner area or meet the need identified in the 2023 SMFP; therefore, this was not an effective alternative.

- Develop the LINAC in a Different Location – The applicant states Garner is a fast-growing part of the service area and does not have radiation oncology services; therefore, this was not an effective alternative.

- Develop the LINAC in an Existing Medical Office Building – The applicant states it does not have any space in any buildings under development for the equipment and support space required; therefore, this was not an effective alternative.

- Develop Other Affiliations – The applicant states it is willing to consider other affiliations to offer the proposed services but has not identified one that would meet the need; therefore, this was not an effective alternative.

However, the applicant does not adequately demonstrate that the alternative proposed in this application is the most effective alternative to meet the need based on the following:

- The applicant did not adequately demonstrate the need it has for the proposed project and did not demonstrate that projected utilization is based on reasonable and adequately supported assumptions. The discussions regarding analysis of need and projected utilization found in Criterion (3) are incorporated herein by reference. A proposal that is not needed by the population proposed to be served cannot be an effective alternative to meet the need.

- The applicant does not demonstrate sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of revenues and operating expenses. The discussion regarding financial feasibility found in Criterion (5) is incorporated herein by reference. A proposal that cannot demonstrate it will be financially feasible cannot be an effective alternative to meet the need.

- The applicant does not demonstrate that the proposed project is not an unnecessary duplication of existing and approved services in Service Area 20. The discussion regarding unnecessary duplication found in Criterion (6) is incorporated herein by reference. A proposal that cannot demonstrate it is not an unnecessary duplication of existing and approved services in the service area cannot be an effective alternative to meet the need.

- The applicant does not demonstrate that any enhanced competition from the proposed project will have a positive impact on cost-effectiveness. The discussion regarding enhanced competition and the impact on cost-effectiveness found in Criterion (18a) is incorporated herein by reference. A proposal that cannot demonstrate how any enhanced

competition will have a positive impact on cost-effectiveness cannot be an effective alternative to meet the need.

- The application is not conforming to all other statutory and regulatory review criteria. An application that cannot be approved cannot be an effective alternative to meet the need.

Conclusion – The Agency reviewed the:

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

Based on that review, the Agency concludes that the application is not conforming to this criterion for the reasons stated above.

(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.

NC – UNC Rex Hospital, Duke Radiation Oncology Garner
C – WakeMed Raleigh Medical Park

Project ID #J-12371-23/UNC Rex Hospital/Acquire one LINAC
The applicant proposes to acquire and add an additional LINAC at UNC Health Rex Cancer Care of Wakefield (UNC Rex Wakefield).

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.

Construction/Renovation Contracts	$4,833,374
Architect/Engineering/Consultant Fees	$824,006
Medical Equipment	$3,399,998
Non-Medical Equipment/Furniture	$188,483
Other (Contingency, DHSR Fees)	$1,329,693
Total	**$10,575,554**

The applicant provides its assumptions and methodology for projecting capital cost immediately following Form F.1a in Section Q. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based on the following:

- The applicant provides assumptions about costs included in the calculation of each line item in the projected capital cost.

- The applicant states much of the projections are based on the applicant's history or the project architect's history in developing similar projects.

- In Exhibit F.1, the applicant provides a registered architect's certification dated March 3, 2023, stating the construction costs listed (which match those listed in Form F.1a) are accurate.

- The applicant provides a quote for the proposed LINAC in Exhibit C.1-2.

In Section F, page 89, the applicant states that there are no projected start-up expenses or initial operating expenses because the project does not involve a new service. This information is reasonable and adequately supported because UNC Rex Wakefield is an existing facility currently offering LINAC services and will continue to offer LINAC services during and after development of the proposed project.

Availability of Funds – In Section F, pages 87-88, the applicant states the entire projected capital expenditure of $10,575,554 will be funded with Rex's accumulated reserves.

In Exhibit F.2-1, the applicant provides a letter dated April 17, 2023 from the Chief Financial Officer for Rex Hospital, Inc., stating that Rex Hospital, Inc. has sufficient accumulated reserves to fund the projected capital cost and committing to providing that funding to develop the proposed project.

Exhibit F.2-2 contains a copy of Rex Healthcare, Inc. and Subsidiaries Combined Financial Statements for the years ending June 30, 2022 and 2021. According to the Combined Financial Statements, as of June 30, 2022, Rex Hospital, Inc. had adequate cash and assets to fund all the capital needs of the proposed project.

The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project based on the following:

- The applicant provides a letter from the appropriate Rex Hospital, Inc. official confirming the availability of the funding proposed for the capital needs of the project and the commitment to use those funds to develop the proposed project.

- The applicant provides adequate documentation of the accumulated reserves it proposes to use to fund the capital needs of the project.

Financial Feasibility – The applicant provided pro forma financial statements for the first three full fiscal years of operation following project completion. On Form F.2b in Section Q, the applicant projects revenues will exceed operating expenses in each of the first three full fiscal years following project completion, as shown in the table below.

Revenues and Operating Expenses – UNC Rex Wakefield Radiation Oncology			
	FY 1 (SFY 2026)	**FY 2 (SFY 2027)**	**FY 3 (SFY 2028)**
Total Patients	740	752	766
Total Gross Revenues (Charges)	$13,889,862	$14,512,636	$15,196,700
Total Net Revenue	$5,954,859	$6,221,854	$6,515,126
Total Net Revenue per Patient	$8,047	$8,274	$8,505
Total Operating Expenses (Costs)	$3,902,566	$4,299,179	$4,403,599
Total Operating Expenses per Patient	$5,274	$5,717	$5,749
Net Profit/(Loss)	**$2,052,293**	**$1,922,675**	**$2,111,528**

The assumptions used by the applicant in preparation of the pro forma financial statements are provided immediately following Form F.3b in Section Q. However, the applicant does not adequately demonstrate that the financial feasibility of the proposal is reasonable and adequately supported because projected utilization is not based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference. Therefore, projected revenues and operating expenses, which are based in part on projected utilization, are also questionable.

Conclusion – The Agency reviewed the:

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

Based on that review, the Agency concludes that the application is not conforming to this criterion because the applicant does not adequately demonstrate sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of revenues and operating expenses for all the reasons described above.

Project ID #J-12376-23/WakeMed Raleigh Medical Park/Acquire one LINAC
The applicant proposes to acquire a fixed LINAC and a CT simulator to be located at WakeMed Raleigh Medical Park (WakeMed RMP), a medical office building that will be located adjacent to WakeMed Raleigh Campus.

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.

Construction/Renovation Contracts	$3,095,580
Architect/Engineering/Consultant Fees	$436,947
Medical Equipment	$5,175,776
Non-Medical Equipment/Furniture	$375,000
Other*	$518,580
Total	**$9,601,883**

*"Other" includes project testing, permits, fees, IAQ, communications, security, artwork & signage, and contingency.

The applicant provides its assumptions and methodology for projecting capital cost immediately following Form F.1a in Section Q. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based on the following:

- In Exhibit C.1, the applicant includes price quotes for the LINAC and CT simulator.

- In Exhibit K.1, the applicant provides a letter from a licensed architect, stating that the projected capital costs are *"a reasonable estimate of the costs to be expected on a project of the scope and complexity defined."*

- In Exhibit K.1, the applicant provides a detailed breakdown of capital costs, including information about costs per gross square foot.

In Section F, page 96, the applicant provides assumptions for initial operating costs and start-up costs as an illustration. The applicant states it is an existing acute care hospital with an established cash flow. This information is reasonable and adequately supported because WakeMed RMP will be licensed under WakeMed, an existing facility with a cancer care program.

Availability of Funds – In Section F, page 94, the applicant states the projected capital cost of $9,601,883 will be funded by WakeMed's accumulated reserves.

In Exhibit F.2, the applicant provides a letter dated April 12, 2023 from the Senior Vice President, Finance & Interim Chief Financial Officer at WakeMed Health & Hospitals, committing to funding the capital cost of $9,601,883 with accumulated reserves.

Exhibit F.2 also contains a copy of the WakeMed Combined Financial Report with Supplementary Information for the year ending September 30, 2022. According to the Combined Financial Report, as of September 30, 2022, the applicant had $867,151,000 in unrestricted reserves, which is adequate to fund both the projected capital cost and the illustrative working capital costs.

The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project based on the following:

- The applicant provides a letter from the appropriate WakeMed official confirming the availability of the funding proposed for the capital needs of the project and the commitment to use those funds to develop the proposed project.

- The applicant provides adequate documentation of the accumulated reserves it proposes to use to fund the capital needs of the project.

Financial Feasibility – The applicant provided pro forma financial statements for the first three full fiscal years of operation following project completion. On Form F.2b in Section Q, the applicant projects revenues will exceed operating expenses in each of the first three full fiscal years following project completion, as shown in the table below.

Revenues and Operating Expenses – WakeMed RMP			
	FY 1 (FY 2026)	**FY 2 (FY 2027)**	**FY 3 (FY 2028)**
Total Patients	255	342	442
Total Gross Revenues (Charges)	$11,240,068	$15,547,259	$20,672,890
Total Net Revenue	$3,703,739	$5,081,011	$6,698,020
Total Net Revenue per Patient	$14,524	$14,857	$15,154
Total Operating Expenses (Costs)	$2,880,340	$4,583,630	$5,398,833
Total Operating Expenses per Patient	$11,295	$13,402	$12,213
Net Profit/(Loss)	**$823,399**	**$497,381**	**$1,299,187**

The assumptions used by the applicant in preparation of the pro forma financial statements are provided immediately following Form F.3b in Section Q. The applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

- The applicant clearly details the sources of data used to project revenues and expenses.
- The applicant bases projections on its own historical experience.
- The applicant accounts for the potential future impact of Medicaid expansion in North Carolina.
- 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 costs are based on reasonable and adequately supported assumptions for all the reasons described above.
- The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal for all the reasons described above.
- 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 revenues and operating expenses for all the reasons described above.

Project ID #J-12379-23/Duke Radiation Oncology Garner/Acquire one LINAC
The applicant proposes to acquire a LINAC and CT simulator to develop Duke Garner, a new radiation oncology facility licensed under 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/Landscaping	$1,300,000
Construction/Renovation Contracts	$16,173,950
Architect/Engineering Fees	$2,007,500
Medical Equipment	$4,700,000
Non-Medical Equipment/Furniture	$3,750,000
Other (Contingency, Filing)	$5,586,550
Total	**$33,518,000**

The applicant provides its assumptions and methodology for projecting capital cost immediately following Form F.1a in Section Q. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based on the following:

- The applicant states much of the projections are based on the applicant's history in developing similar projects.
- In Exhibit F.1(a), the applicant provides quotes for the proposed LINAC and CT simulator.
- In Exhibit F.1(b), the applicant provides a registered architect's certification dated April 3, 2023, stating the construction costs listed (which match those listed in Form F.1a) are accurate and reasonable.

In Section F, pages 57-58, the applicant projects start-up costs of $316,002 and projects a 3.5-year initial operating period and $3,385,218 in initial operating costs for a projected total of $3,701,220 in working capital costs. The applicant provides its assumptions and methodology for projecting working capital cost on pages 58-59. The applicant adequately demonstrates that the projected working capital cost is based on reasonable and adequately supported assumptions based on the following:

- The applicant identifies the different components of the start-up expenses projected.
- The applicant provides the calculations to show that there will be negative net revenue through the end of the third full fiscal year following project completion.

Availability of Funds – In Section F, pages 56 and 59, the applicant states the entire projected capital expenditure of $33,518,000 and the entire working capital expenditure of $3,701,220 will be funded with Duke's accumulated reserves.

In Exhibit F.2(a), the applicant provides a letter dated April 12, 2023 from the Vice President, Finance – Corporate Controller and Treasurer of DUHS, stating Duke has sufficient

accumulated reserves to fund the projected capital and working capital costs and committing to providing that funding to develop the proposed project. The letter also states:

> *"We would note that FY 2024 reflects a significant operating loss due in part to an investment in acquiring and integrating the Duke faculty physician practice into the health system. We anticipate a return to profitability by FY 2029. In the interim, DUHS is committed to funding continued operations and capital investments from accumulated reserves, and has sufficient reserves to ensure the financial feasibility of this project and its operations overall."*

Form F.2b in Section Q shows that the Duke system (including the proposed project) will incur approximately $1,082,502,000 in operating losses between now and the end of the third full fiscal year following project completion.

Exhibit F.2(b) contains a copy of Duke University Health System, Inc. and Affiliates Consolidated Financial Statements and Supplementary Schedules for the years ending June 30, 2022 and 2021. According to the Consolidated Financial Statements, as of June 30, 2022, Duke had $1,376,395,000 in current assets (excluding assets limited as to use), which is sufficient to fund the proposed capital expenditure, proposed working capital expenditure, and any system losses through the third full fiscal year following project completion.

The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project based on the following:

- The applicant provides a letter from the appropriate Duke official confirming the availability of the funding proposed for the capital needs of the project and the commitment to use those funds to develop the proposed project.

- The applicant provides adequate documentation of the accumulated reserves it proposes to use to fund the capital needs of the project.

Financial Feasibility – The applicant provided pro forma financial statements for the first three full fiscal years of operation following project completion. On Form F.2b in Section Q, the applicant projects operating expenses will exceed revenue in each of the first three full fiscal years following project completion, as shown in the table below.

Revenues and Operating Expenses – Duke Garner			
	FY 1 (SFY 2027)	**FY 2 (SFY 2028)**	**FY 3 (SFY 2029)**
Total Patients	116	193	273
Total Gross Revenues (Charges)	$6,278,249	$10,449,674	$14,780,679
Total Net Revenue	$1,501,602	$2,544,842	$3,664,796
Total Net Revenue per Patient	$12,945	$13,186	$13,424
Total Operating Expenses (Costs)	$5,437,291	$5,791,128	$5,971,791
Total Operating Expenses per Patient	$46,872	$30,006	$21,875
Net Profit/(Loss)	**($3,935,689)**	**($3,246,286)**	**($2,306,994)**

The applicant also provided pro forma financial statements for the Duke system for the first three full fiscal years of operating following project completion. The applicant projects revenue will exceed operating expenses by the third full fiscal year of operation following project completion, as shown in the table below.

Revenues and Operating Expenses – DUHS			
	FY 1 (SFY 2027)	**FY 2 (SFY 2028)**	**FY 3 (SFY 2029)**
Total Gross Revenues (Charges)	$22,748,151,000	$23,682,833,000	$24,655,396,000
Total Net Revenue	$6,916,399,000	$7,188,183,000	$7,474,213,000
Total Operating Expenses (Costs)	$7,040,310,000	$7,245,457,000	$7,459,321,000
Net Profit/(Loss)	**($123,911,000)**	**($57,274,000)**	**$14,891,000**

The assumptions used by the applicant in preparation of the pro forma financial statements are provided immediately following Form F.3b in Section Q. However, the applicant does not adequately demonstrate that the financial feasibility of the proposal is reasonable and adequately supported because projected utilization is not based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference. Therefore, projected revenues and operating expenses, which are based in part on projected utilization, are also questionable.

Conclusion – The Agency reviewed the:

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

Based on that review, the Agency concludes that the application is not conforming to this criterion because the applicant does not adequately demonstrate sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of revenues and operating expenses for all the reasons described above.

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

NC – UNC Rex Hospital, Duke Radiation Oncology Garner
C – WakeMed Raleigh Medical Park

The 2023 SMFP includes an adjusted need determination for one LINAC in Service Area 20.

In Chapter 17, page 311, the 2023 SMFP defines a LINAC's service area as "*…one of the 28 multicounty groupings described in the Assumptions of the Methodology.*" Table 17C-4 on page 320 shows Service Area 20 is comprised of Franklin and Wake counties. Thus, the service area for this project consists of those two counties. Facilities may also serve residents of counties not included in their service area.

There are a total of 11 existing and approved LINACs associated with five different facilities in Service Area 20. Information about each of the facilities and utilization of the LINACs in Service Area 20 during FFY 2021 is provided in the table below.

Service Area 20 LINACs				
Facility	**County**	**# of LINACs**	**# of Procedures /ESTVs**	**Average # of Procedures /ESTVs per LINAC**
Franklin County Cancer Center*	Franklin	1	0	0
Duke Raleigh Hospital	Wake	4	21,075	5,269
UNC Hospital Radiation Oncology – Holly Springs**	Wake	1	0	0
UNC Rex Cancer Care of East Raleigh	Wake	1	5,148	5,148
UNC Rex Hospital	Wake	4	21,639	5,410
Total		**11**	**47,862**	**4,351**

Source: Table 17C-1, 2023 SMFP
*Project ID #J-12000-20 authorized the replacement and relocation of this LINAC to Cary, in Wake County. The project is still under development.
**Approved but not yet developed.

Project ID #J-12371-23/UNC Rex Hospital/Acquire one LINAC
The applicant proposes to acquire and add an additional LINAC at UNC Health Rex Cancer Care of Wakefield (UNC Rex Wakefield).

In Section G, page 97, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing linear accelerator services in Service Area 20. The applicant states:

> *"The proposed project will allow UNC Health Rex to ensure capacity for future growth and expand the availability of radiosurgery treatments to the Cancer Care of Wakefield facility. This will improve accessibility for residents of northern Wake and Franklin counties. The proposed LINAC at Cancer Care of Wakefield is needed to accomplish UNC Health Rex's strategy for creating a geographically diverse complement of cancer care resources that maximize accessibility and high quality care for the entire population of Service Area 20. The proposed LINAC is necessary, given the growing population within the service area, the increasing number of residents age 65 and older, the health disparities for communities in Franklin County, the operational efficiencies of having a second LINAC at the Cancer Care of Wakefield facility, and the resulting enhancements for the patient experience. Moreover, the proposed LINAC will bring, for the first time, SRS and SBRT capabilities to northern Wake and Franklin counties, expanding access to this life-saving technology. The proposed LINAC at Cancer Care of Wakefield will not result in the unnecessary duplication of existing services."*

However, the applicant does not adequately demonstrate that the proposal would not result in an unnecessary duplication of existing or approved services in the service area based on the following reasons:

- The applicant does not demonstrate the need the population proposed to be served has for the proposed services or that projected utilization is based on reasonable and adequately

supported assumptions. The discussions regarding need and projected utilization found in Criterion (3) are incorporated herein by reference. An application that cannot demonstrate that the population proposed to be served needs the proposed services cannot demonstrate that the project will not be an unnecessary duplication of existing or approved services.

- The UNC System has an existing certificate of need for a LINAC, issued nearly seven and a half years ago, that has not been developed. The applicant does not demonstrate that the proposed LINAC is not an unnecessary duplication when it has not developed the LINAC approved nearly seven and a half years ago.

Conclusion – The Agency reviewed the:

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

Based on that review, the Agency concludes that the application is not conforming to this criterion for all the reasons described above.

Project ID #J-12376-23/WakeMed Raleigh Medical Park/Acquire one LINAC
The applicant proposes to acquire a fixed LINAC and a CT simulator to be located at WakeMed Raleigh Medical Park (WakeMed RMP), a medical office building that will be located adjacent to WakeMed Raleigh Campus.

In Section G, pages 106-107, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing linear accelerator services in Service Area 20. The applicant states:

> *"…neither Service Area 20 nor Harnett and Johnston Counties* [sic] *have excess linear accelerator capacity today in operational equipment. WakeMed's experience with patient waits shows this is affecting patient care. Close review of individual facilities affirms low capacity.*
>
> *…*
> *…, UNC Rex East Raleigh linear accelerator operated above the Performance Standard in 10A NCAC 14C.1903(5) for patients served in FY 2021. This linear accelerator served the highest ratio of patients per unit in the service area. Its proximity to WakeMed Raleigh Campus, combined with WakeMed patients' high wait times for radiation therapy, lends credence to the notion that demand for LINAC services is high and that service area need will continue to grow."*

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

- There is a need determination in the 2023 SMFP for the proposed linear accelerator in Service Area 20.

- The applicant adequately demonstrates that the proposed linear accelerator is needed in addition to the existing or approved linear accelerators in Service Area 20.

Conclusion – The Agency reviewed the:

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

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

Project ID #J-12379-23/Duke Radiation Oncology Garner/Acquire one LINAC
The applicant proposes to acquire a LINAC and CT simulator to develop Duke Garner, a new radiation oncology facility licensed under Duke Raleigh Hospital.

In Section G, pages 65-66, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing linear accelerator services in Service Area 20. The applicant states:

> *"The State Medical Facilities Plan includes a need determination for an additional linear accelerator in Service Area 20. DUHS evaluated and developed this specific proposal in response to the state identified need determination to provide radiation oncology services in a new service location that will not create any unnecessary duplication of existing or approved health service facilities.*
>
> …
>
> *There are no services currently locally available in Garner, a fast-growing part of Wake County. This project will meet the need for additional capacity identified in the SMFP in a new location and therefore will not unnecessarily duplicate existing or approved capacity that may exist or be in development elsewhere in the service area."*

However, the applicant does not adequately demonstrate that the proposal would not result in an unnecessary duplication of existing or approved services in the service area because the applicant does not demonstrate the need the population proposed to be served has for the proposed services or that projected utilization is based on reasonable and adequately supported assumptions. The discussions regarding need and projected utilization found in Criterion (3) are incorporated herein by reference. An application that cannot demonstrate that the population proposed to be served needs the proposed services cannot demonstrate that the project will not be an unnecessary duplication of existing or approved services.

Conclusion – The Agency reviewed the:

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

Based on that review, the Agency concludes that the application is not conforming to this criterion for all the reasons described above.

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

C – All Applications

Project ID #J-12371-23/UNC Rex Hospital/Acquire one LINAC
The applicant proposes to acquire and add an additional LINAC at UNC Health Rex Cancer Care of Wakefield (UNC Rex Wakefield).

On Form H in Section Q, the applicant provides current and projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

UNC Rex Wakefield LINAC – Current & Projected FTEs			
	Current (6/30/2022)	**FY 1 (SFY 2026)**	**FYs 2-3 (SFYs 2027-2028)**
Administrative Support	1.0	1.0	1.0
Clinical Support – CMA	0.0	0.0	1.0
Nurse	1.0	1.0	1.0
Radiation Therapist	2.0	5.0	5.0
Radiation Coordination Supervisor	1.0	1.0	1.0
Dosimetrist	0.5	1.5	2.0
Physicist	1.0	1.5	2.0
Manager	0.5	0.5	0.5
Total	**7.0**	**11.5**	**13.5**

The assumptions and methodology used to project staffing are provided in Section Q. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in Form F.3b. In Section H, pages 99-100, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs and provides supporting documentation in Exhibit B.20-2.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services based on the following:

- The applicant adequately documents the number of FTEs it projects will be needed to offer the proposed services.

- The applicant accounts for projected salaries and other costs of employment for FTEs in its projected operating expenses found on Form F.3b in Section Q.

- In Exhibit B.20-2, the applicant provides policies and guidelines provided to staff at UNC Rex Wakefield.

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.

Project ID #J-12376-23/WakeMed Raleigh Medical Park/Acquire one LINAC
The applicant proposes to acquire a fixed LINAC and a CT simulator to be located at WakeMed Raleigh Medical Park (WakeMed RMP), a medical office building that will be located adjacent to WakeMed Raleigh Campus.

On Form H in Section Q, the applicant provides projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

WakeMed RMP Projected FTEs			
	FY 1 (FY 2026)	**FY 2 (FY 2027)**	**FY 3 (FY 2028)**
Registered Nurses	2.00	2.00	2.00
Radiation Oncologist	1.00	1.25	1.75
Lead Radiation Therapist	1.00	1.00	1.00
Radiation Therapist	2.00	3.00	4.10
PAR (reception)	2.00	2.00	2.00
Total	**8.00**	**9.25**	**10.85**

The assumptions and methodology used to project staffing are provided in Section Q on Form F.3b and Form H. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in Form F.3b. In Section H, pages 109-117, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services based on the following:

- The applicant adequately documents the number of FTEs it projects will be needed to offer the proposed services.

- The applicant accounts for projected salaries and other costs of employment for FTEs in its projected operating expenses found on Form F.3b in Section Q.

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.

Project ID #J-12379-23/Duke Radiation Oncology Garner/Acquire one LINAC
The applicant proposes to acquire a LINAC and CT simulator to develop Duke Garner, a new radiation oncology facility licensed under Duke Raleigh Hospital.

On Form H in Section Q, the applicant provides projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

Duke Garner LINAC – Projected FTEs	
	FYs 1-3 (SFYs 2027-2029)
Registered Nurses	2.24
Information Technology	0.06
Administrator/CEO	0.06
Radiation Therapist	4.76
Dosimetrist	2.28
Chief Dosimetrist	0.28
Chief Radiation Therapist	1.12
Regional Director	0.28
Financial Care Counselor	1.12
Patient Service Associate	1.12
Total	**13.31**

The assumptions and methodology used to project staffing are provided in Section Q. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in Form F.3b. In Section H, pages 67-68, the applicant describes the methods used to recruit or fill new positions and its proposed training and continuing education programs. Supporting documentation is provided in Exhibit H.3.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services based on the following:

- The applicant adequately documents the number of FTEs it projects will be needed to offer the proposed services and the modeling it used to project FTEs.

- The applicant accounts for projected salaries and other costs of employment for FTEs in its projected operating expenses found on Form F.3b in Section Q.

- In Exhibit H.3, the applicant provides the Duke system policy on continuing education.

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.

(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 – All Applications

Project ID #J-12371-23/UNC Rex Hospital/Acquire one LINAC
The applicant proposes to acquire and add an additional LINAC at UNC Health Rex Cancer Care of Wakefield (UNC Rex Wakefield).

Ancillary and Support Services – In Section I, page 102, the applicant identifies the necessary ancillary and support services for the proposed services. In Section I, pages 102-103, the applicant explains how each ancillary and support service is made available and provides supporting documentation in Exhibit I.1. The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on the following:

- The applicant is currently providing the necessary ancillary and support services at the same facility where it proposes to develop the additional LINAC.

- In Exhibit I.1, the applicant provides a letter from the president of Rex Hospital, Inc., attesting to the existence of the necessary ancillary and support services and committing to continue to provide the necessary ancillary and support services for the proposed project.

Coordination – In Section I, page 103, the applicant describes UNC Rex Wakefield's existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit 1.2. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the following:

- UNC Rex Wakefield is an existing facility and thus has established many relationships with area healthcare providers.

- In Exhibit I.2, the applicant provides letters of support from local physicians and healthcare providers documenting their support for UNC Rex Wakefield and the proposed 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 application is conforming to this criterion for all the reasons described above.

Project ID #J-12376-23/WakeMed Raleigh Medical Park/Acquire one LINAC
The applicant proposes to acquire a fixed LINAC and a CT simulator to be located at WakeMed Raleigh Medical Park (WakeMed RMP), a medical office building that will be located adjacent to WakeMed Raleigh Campus.

Ancillary and Support Services – In Section I, page 118, the applicant identifies the necessary ancillary and support services for the proposed services. In Section I, pages 119-120, the applicant explains how each ancillary and support service is made available and provides supporting documentation in Exhibits C.1, H.2, and I.1. The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on the following:

- The applicant is currently providing many of the necessary ancillary and support services at the adjacent hospital campus and the proposed facility will be licensed as part of the hospital.

- In Exhibit I.1, the applicant provides a letter dated March 24, 2023 from the Senior Vice President & Administrator at WakeMed Raleigh Campus, attesting to the existence of the necessary ancillary and support services at WakeMed and committing to provide the necessary ancillary and support services at WakeMed RMP.

Coordination – In Section I, pages 120-122, the applicant describes WakeMed RMP's existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit 1.2. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the following:

- WakeMed RMP will be part of the WakeMed Raleigh Campus, which is an existing hospital with many established relationships with area healthcare providers.

- In Exhibit I.2, the applicant provides letters of support from local physicians and healthcare providers documenting their support for WakeMed RMP and the proposed 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 application is conforming to this criterion for all the reasons described above.

Project ID #J-12379-23/Duke Radiation Oncology Garner/Acquire one LINAC
The applicant proposes to acquire a LINAC and CT simulator to develop Duke Garner, a new radiation oncology facility licensed under Duke Raleigh Hospital.

Ancillary and Support Services – In Section I, page 69, the applicant identifies the necessary ancillary and support services for the proposed services. In Section I, pages 69-70, the applicant explains how each ancillary and support service is made available. The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on the following:

- The applicant states the services will be provided by existing Duke departments that already provide the necessary ancillary and support services at Duke's existing radiation oncology sites.

- The applicant explains that professional services will bill payors separately for services.

Coordination – In Section I, page 70, the applicant describes Duke Garner's proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit C.4. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the following:

- Duke and Duke Cancer Institute are existing facilities with many established relationships with area healthcare providers.

- In Exhibit C.4, the applicant provides letters of support from local physicians and healthcare providers documenting their support for Duke Garner and the proposed 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 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 – All Applications

None of the applicants 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, none of the applicants 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 – All Applications

None of the applicants are HMOs. 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 – All Applications

Project ID #J-12371-23/UNC Rex Hospital/Acquire one LINAC
The applicant proposes to acquire and add an additional LINAC at UNC Health Rex Cancer Care of Wakefield (UNC Rex Wakefield).

In Section K, page 106, the applicant states that the project involves constructing 2,507 square feet of new space and renovating 1,917 square feet of existing space. Line drawings are provided in Exhibit C.1-1.

In Section K, page 107, the applicant adequately explains how the cost, design, and means of construction represent the most reasonable alternative for the proposal based on the following:

- The applicant states that while the construction involves specialized materials and techniques, the proposed construction and renovation is much more cost-effective than an entirely new building.

- The applicant plans to develop the LINAC adjacent to the existing LINAC at the same location, which the applicant states will minimize impacts of construction and help streamline patient flow.

In Section K, pages 107-108, 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 following:

- The applicant describes its "conservative fiscal management" that has allowed it to pay for projects such as the project proposed in this application.

- The applicant states the proposal is designed to minimize cost by utilizing existing resources.

- The applicant states that efficiencies of scale that result from being part of UNC Health provide significant cost savings.

In Section B, page 33, 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.

Project ID #J-12376-23/WakeMed Raleigh Medical Park/Acquire one LINAC
The applicant proposes to acquire a fixed LINAC and a CT simulator to be located at WakeMed Raleigh Medical Park (WakeMed RMP), a medical office building that will be located adjacent to WakeMed Raleigh Campus.

In Section K, page 125, the applicant states that the project involves renovating 10,823 square feet of existing space in a medical office building under development. Line drawings are provided in Exhibit K.1.

In Section K, pages 129-130, the applicant identifies the proposed site and provides information about the current owner, zoning and special use permits for the site, and the availability of water, sewer and waste disposal, and power at the site. Supporting documentation is provided in Exhibit K.4. The site appears to be suitable for the proposed radiation therapy center based on the applicant's representations and supporting documentation.

In Section K, page 126, the applicant adequately explains how the cost, design, and means of construction represent the most reasonable alternative for the proposal based on the following:

- The applicant states developing the proposed project in a medical office building will cost nearly two-thirds less per square foot than developing the proposed project in a hospital.

- The applicant states multiple building designs were considered before deciding on the proposed design, in order to provide the most effective layout for patients, caregivers, and vehicles.

- The applicant states that it is familiar with local zoning ordinances and state and federal requirements for developing health service facilities and will be able to work with architectural and engineering firms that are also familiar with the requirements.

In Section K, pages 126-127, 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 following:

- The applicant states the proposed project will save costs and benefit from economies of scale.

- The applicant states its established referral network and existing services will mean it reaches a breakeven point in a short amount of time.

- The applicant states it will offset any potential cost increases with its charity care program.

- The applicant states that its status as a Disproportionate Share Hospital means it will continue to serve many at-risk patients that might otherwise go without care.

In Section K, pages 127-128, 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.

Project ID #J-12379-23/Duke Radiation Oncology Garner/Acquire one LINAC
The applicant proposes to acquire a LINAC and CT simulator to develop Duke Garner, a new radiation oncology facility licensed under Duke Raleigh Hospital.

In Section K, page 73, the applicant states that the project involves constructing 14,870 square feet of new space. Line drawings are provided in Exhibit K.1.

In Section K, pages 75-76, the applicant identifies the proposed site and provides information about the current owner, zoning and special use permits for the site, and the availability of water, sewer and waste disposal, and power at the site. The site appears to be suitable for the proposed radiation oncology center based on the applicant's representations.

In Section K, page 73, the applicant adequately explains how the cost, design, and means of construction represent the most reasonable alternative for the proposal based on the following:

- The applicant states that the architect developed the projected design based on a review of actual costs for similar projects, publicly available data, and the experience of the architect.

- The applicant states that it plans to develop additional space for future services to avoid increased future expenses that would be required to develop the additional space at a future date.

In Section K, page 74, 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 following:

- The applicant states that it gave careful consideration into factors related to project development so that it would not unduly increase costs to deliver services or require higher charges to consumers.

- The applicant states the proposed project will not increase the actual day-to-day operating costs of the proposed project.

In Section K, page 74, 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 – UNC Rex Hospital
NA – All Other Applications

Project ID #J-12371-23/UNC Rex Hospital/Acquire one LINAC
In Section L, page 111, the applicant provides the historical payor mix during the last full fiscal year for all services at UNC Rex Wakefield, as shown in the table below.

UNC Rex Wakefield Historical Payor Mix – SFY 2022	
Payor Category	**% of Total Patients Served**
Self-Pay	1.2%
Medicare*	59.3%
Medicaid*	1.3%
Insurance*	37.0%
Other**	1.2%
Total	**100.0%**

*Including any managed care plans.
**Includes TRICARE.
Note: The applicant states charity care is provided to patients in any payor category and that its internal data does not include charity care as a payor source.

In Section L, page 112, the applicant provides the following comparison.

UNC Rex Wakefield	% of Total Patients Served During SFY 2022	% of Population of Service Area
Female	60.2%	51.1%
Male	39.8%	48.9%
Unknown	0.0%	0.0%
64 and Younger	43.0%	87.4%
65 and Older	57.0%	12.6%
American Indian	0.2%	0.8%
Asian	1.2%	8.3%
Black or African-American	21.4%	21.0%
Native Hawaiian or Pacific Islander	0.0%	0.1%
White or Caucasian	72.0%	67.1%
Other Race	3.6%	2.7%
Declined / Unavailable	1.6%	0.0%

Conclusion – 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.

Project ID #J-12376-23/WakeMed Raleigh Medical Park/Acquire one LINAC
WakeMed RMP is not an existing facility. Therefore, Criterion (13a) is not applicable to this review.

Project ID #J-12379-23/Duke Radiation Oncology Garner/Acquire one LINAC
Duke Garner is not an existing facility. Therefore, Criterion (13a) is not applicable to this review.

(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 – UNC Rex Hospital
NA – All Other Applications

Project ID #J-12371-23/UNC Rex Hospital/Acquire one LINAC
Regarding any obligation to provide uncompensated care, community service, or access by minorities and persons with disabilities, in Section L, page 113, the applicant states it has no such obligation.

In Section L, page 114, the applicant states that one patient civil rights access complaint was filed against UNC Rex Hospital on February 21, 2022. The applicant states:

> *"…. Due to the nature of the allegations which included age discrimination, the complaint was referred to the Federal Mediation and Conciliation Service (FMCS). UNC Health Rex has been in contact with OCR and engaged in multiple communications with the complainant to address and resolve any and all issues. UNC Health Rex believes the matter to be closed as mediation was not required and there has been no further contact from the OCR related to this complaint."*

The applicant states that there were no other civil rights equal access complaints filed against UNC Rex Wakefield or other affiliated entity during the 18 months immediately prior to submission of the application.

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.

Project ID #J-12376-23/WakeMed Raleigh Medical Park/Acquire one LINAC
WakeMed RMP is not an existing facility. Therefore, Criterion (13b) is not applicable to this review.

Project ID #J-12379-23/Duke Radiation Oncology Garner/Acquire one LINAC
Duke Garner is not an existing facility. Therefore, Criterion (13b) is not applicable to this review.

(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 – All Applications

Project ID #J-12371-23/UNC Rex Hospital/Acquire one LINAC

In Section L, page 115, the applicant projects the following payor mix during the third full fiscal year of operation following completion of the project, as illustrated in the following table.

UNC Rex Wakefield Projected Payor Mix – SFY 2028		
Payor Category	**% of Total Patients Served**	**% of LINAC Patients Served**
Self-Pay	1.2%	1.4%
Medicare*	59.3%	59.2%
Medicaid*	1.3%	0.6%
Insurance*	37.0%	37.6%
Other**	1.2%	1.2%
Total	**100.0%**	**100.0%**

*Including any managed care plans.
**Includes TRICARE.
Note: The applicant states charity care is provided to patients in any payor category and that its internal data does not include charity care as a payor source.

As shown in the table above, during the third full fiscal year of operation following completion of the project, the applicant projects that 1.2% of all services and 1.4% of LINAC services will be provided to self-pay patients, 59.3% of all services and 59.2% of LINAC services to Medicare patients, and 1.3% of all services and 0.6% of LINAC services to Medicaid patients.

On page 114, the applicant provides the assumptions and methodology used to project payor mix during the third full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported based on the following:

- The projected payor mix is based on the historical payor mix.

- The applicant provides reasonable explanations for why it projects no change from the historical 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.

Project ID #J-12376-23/WakeMed Raleigh Medical Park/Acquire one LINAC
In Section L, page 136, the applicant projects the following payor mix during the third full fiscal year of operation following completion of the project, as illustrated in the following table.

WakeMed Raleigh Campus Projected Payor Mix – FY 2028		
Payor Category	**% of Total Patients Served**	**% of LINAC Patients Served**
Self-Pay*	7.01%	1.70%
Medicare**	40.48%	50.80%
Medicaid**	18.58%	4.70%
Insurance**	28.73%	42.80%
Other***	5.20%	0.00%
Total	**100.00%**	**100.00%**

*On page 132, the applicant states charity care is included in the self-pay category.
**Including any managed care plans.
***Includes TRICARE and Workers Compensation.

As shown in the table above, during the third full fiscal year of operation following completion of the project, the applicant projects that 7.01% of all services and 1.70% of LINAC services will be provided to self-pay patients (including patients receiving charity care), 40.48% of all services and 50.80% of LINAC services to Medicare patients, and 18.58% of all services and 4.70% of LINAC services to Medicaid patients.

The applicant provides the assumptions and methodology used to project payor mix during the third full fiscal year of operation following completion of the project in Section L, page 136, and immediately following Form F.2b in Section Q. The projected payor mix is reasonable and adequately supported based on the following:

- The projected payor mix is based on the historical payor mix.
- The applicant explains why the Medicaid percentage is lower for radiation therapy services than for other services at WakeMed Raleigh Campus.
- The applicant considered the impact of the upcoming Medicaid expansion in North Carolina in making its payor mix projections.

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.

Project ID #J-12379-23/Duke Radiation Oncology Garner/Acquire one LINAC

In Section L, page 80, the applicant projects the following payor mix during the third full fiscal year of operation following completion of the project, as illustrated in the following table.

Duke Garner Projected Payor Mix – SFY 2029	
Payor Category	**% of Total Patients Served**
Self-Pay	0.3%
Charity Care	1.8%
Medicare*	47.9%
Medicaid*	6.1%
Insurance*	40.9%
TRICARE	1.1%
Other	1.8%
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 0.3% of services will be provided to self-pay patients, 1.8% of services to charity care patients, 47.9% of services to Medicare patients, and 6.1% of services to Medicaid patients.

On pages 80-81, the applicant provides the assumptions and methodology used to project payor mix during the third full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported based on the following:

- The projected payor mix is based on the historical payor mix of patients from the proposed catchment area.
- The applicant explains the reasons adjustments were made from the actual historical payor mix to 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.

(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 – All Applications

Project ID #J-12371-23/UNC Rex Hospital/Acquire one LINAC
In Section L, page 116, 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
- Written comments
- Responses to comments

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

Project ID #J-12376-23/WakeMed Raleigh Medical Park/Acquire one LINAC
In Section L, pages 138-141, 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
- Written comments
- Responses to comments

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

Project ID #J-12379-23/Duke Radiation Oncology Garner/Acquire one LINAC
In Section L, page 82, 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
- Written comments
- Responses to comments

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 – All Applications

Project ID #J-12371-23/UNC Rex Hospital/Acquire one LINAC
The applicant proposes to acquire and add an additional LINAC at UNC Health Rex Cancer Care of Wakefield (UNC Rex Wakefield).

In Section M, pages 118-119, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M.1. The applicant adequately demonstrates that health professional training programs in the area will have access to the facility for training purposes based on the following:

- In Exhibit M.1, the applicant provides documentation of existing health professional training programs in the area which already have access to UNC Rex Wakefield.

- In Exhibit M.1, the applicant provides a copy of the clinical instruction agreement between UNC School of Nursing and Rex Healthcare, Inc.

- The applicant's parent company is an academic medical center.

<u>**Conclusion**</u> – 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.

Project ID #J-12376-23/WakeMed Raleigh Medical Park/Acquire one LINAC
The applicant proposes to acquire a fixed LINAC and a CT simulator to be located at WakeMed Raleigh Medical Park (WakeMed RMP), a medical office building that will be located adjacent to WakeMed Raleigh Campus.

In Section M, pages 143-145, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M.1. The applicant adequately demonstrates that health professional training programs in the area will have access to the facility for training purposes based on the following:

- In Exhibit M.1, the applicant provides a list of existing health professional training programs in the area which already have access to WakeMed Raleigh Campus.

- In Exhibit M.1, the applicant provides a copy of the clinical instruction agreement between WakeMed and Pitt Community College.

- The applicant states that the existing health professional training programs in the area that have access to WakeMed Raleigh Campus will also have access to WakeMed RMP as appropriate.

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.

Project ID #J-12379-23/Duke Radiation Oncology Garner/Acquire one LINAC
The applicant proposes to acquire a LINAC and CT simulator to develop Duke Garner, a new radiation oncology facility licensed under Duke Raleigh Hospital.

In Section M, page 83, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes. The applicant adequately demonstrates that health professional training programs in the area will have access to the facility for training purposes because the applicant is an existing academic medical center with established health professional training programs.

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.

(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.

NC – UNC Rex Hospital, Duke Radiation Oncology Garner
C – WakeMed Raleigh Medical Park

The 2023 SMFP includes an adjusted need determination for one LINAC in Service Area 20.

In Chapter 17, page 311, the 2023 SMFP defines a LINAC's service area as "*…one of the 28 multicounty groupings described in the Assumptions of the Methodology.*" Table 17C-4 on page 320 shows Service Area 20 is comprised of Franklin and Wake counties. Thus, the service area for this project consists of those two counties. Facilities may also serve residents of counties not included in their service area.

There are a total of 11 existing and approved LINACs associated with five different facilities in Service Area 20. Information about each of the facilities and utilization of the LINACs in Service Area 20 during FFY 2021 is provided in the table below.

Service Area 20 LINACs				
Facility	**County**	**# of LINACs**	**# of Procedures /ESTVs**	**Average # of Procedures /ESTVs per LINAC**
Franklin County Cancer Center*	Franklin	1	0	0
Duke Raleigh Hospital	Wake	4	21,075	5,269
UNC Hospital Radiation Oncology – Holly Springs**	Wake	1	0	0
UNC Rex Cancer Care of East Raleigh	Wake	1	5,148	5,148
UNC Rex Hospital	Wake	4	21,639	5,410
Total		**11**	**47,862**	**4,351**

Source: Table 17C-1, 2023 SMFP
*Project ID #J-12000-20 authorized the replacement and relocation of this LINAC to Cary, in Wake County. The project is still under development.
**Approved but not yet developed.

Project ID #J-12371-23/UNC Rex Hospital/Acquire one LINAC
The applicant proposes to acquire and add an additional LINAC at UNC Health Rex Cancer Care of Wakefield (UNC Rex Wakefield).

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 120, the applicant states:

> *"The proposed project is expected to enhance competition in Service Area 20 by promoting cost effectiveness, quality, and access to radiation oncology services."*

Regarding the impact of the proposal on cost effectiveness, in Section N, page 120, the applicant discusses its *"…commitment to maximizing the healthcare value for resources expended in the delivery of healthcare services, including acute care services, and the positive impact that the proposed project will have on the cost effectiveness of the proposed service."*

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 120, the applicant discusses its *"…commitment to promoting safety and quality in the delivery of healthcare services,*

including acute care services, and the positive impact that its proposed project will have on the quality of the proposed service."

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, pages 120-121, the applicant states:

> *"UNC Health Rex Cancer Care of Wakefield will continue to provide access to medically underserved groups in a manner consistent with UNC Health Rex Hospital's historical experience. For members of these groups who reside in northern Wake County and Franklin County communities, access to quality cancer care will be increased and the need for a lengthy commute to UNC Health Rex Hospital's Raleigh campus will be eliminated. The proposed project will greatly reduce the burden of coordinating transportation and caregiver resources for patients who must regularly travel to a radiation oncology facility. All UNC Health Rex facilities, including Cancer Care of Wakefield, provide care for all patients without regard to race, color, religion, creed, national origin, sex, sexual preference, disability, age, or ability to pay. Additionally, Cancer Care of Wakefield will continue to participate in both the Medicaid and Medicare programs."*

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

However, the applicant does not adequately demonstrate the proposal would have a positive impact on cost-effectiveness because the applicant did not adequately demonstrate: a) the need the population to be served has for the proposal or that projected utilization is based on reasonable and adequately supported assumptions; b) that projected revenues and operating costs are reasonable; and c) that the proposal would not result in an unnecessary duplication of existing and approved health services. The discussions regarding demonstration of need and projected utilization, projected revenues and operating costs, and unnecessary duplication found in Criterion (3), Criterion (5), and Criterion (6), respectively, are incorporated herein by reference. A proposal that cannot demonstrate need, cannot demonstrate that projected revenues and operating costs are based on reasonable and adequately supported assumptions, and cannot demonstrate that the proposed project is not an unnecessary duplication cannot have a positive impact on cost-effectiveness.

Conclusion – The Agency reviewed the:

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

Based on that review, the Agency concludes that the application is not conforming to this criterion based on all the reasons described above.

Project ID #J-12376-23/WakeMed Raleigh Medical Park/Acquire one LINAC
The applicant proposes to acquire a fixed LINAC and a CT simulator to be located at WakeMed Raleigh Medical Park (WakeMed RMP), a medical office building that will be located adjacent to WakeMed Raleigh Campus.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 147, the applicant states:

> *"Two health systems, Duke Health, and UNC Health, own all linear accelerators in Service Area 20 (Wake and Franklin Counties). WakeMed will be a new provider of linear accelerator services in Service Area 20 and a new competitive option for radiation therapy for residents of Johnston, Harnett, and surrounding counties, as well. WakeMed is the only North Carolina hospital system of its size and complexity that does not offer radiation oncology services or is not part of a health system offering radiation oncology services within its system. Even as a hospital-based provider, WakeMed will offer pricing that is competitive with radiation oncology services at other area hospitals. WakeMed will significantly improve competitive options for access by medically underserved persons, and it has contracts with most insurance companies that have beneficiaries in the service area."*

Regarding the impact of the proposal on cost effectiveness, in Section N, pages 147-150, the applicant states:

> *"WakeMed's proposal will be cost effective with regard to equipment, construction approach, funding, patient care protocols, service organization and payment value.*
>
> *…*
>
> *…. WakeMed proposes to acquire IMRT and IGRT software and hardware and precision IDENTIFY and HyperArc modifications that provide submillimeter precision that will spare normal tissue. These advances will save the cost of the radiation therapy protocol and more importantly, save long term costs of care for WakeMed Cancer Care patients. …*
>
> *…*
>
> *The Applicant proposes to fund the project with its own accumulated reserves, thus eliminating the cost of borrowing, and limiting project costs.*
>
> *…*
>
> *…, WakeMed is a private, not-for-profit tertiary community health care system. It is true to its tax-exempt status and gives back to the community in the dozens of ways described in this application, at rates unmatched by many other health systems.*
>
> *…*

> *Recognizing the breadth of need in Service Area 20 and the proposed project service area, WakeMed proposes equipment and staffing that can accommodate most cancers. WakeMed will be both a new provider and one that can accommodate the wide variety of needs in this complex community."*

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

Regarding the impact of the proposal on quality, in Section N, pages 150-151, the applicant states:

> *"The proposed project will operate as part of WakeMed Raleigh Campus. This automatically subjects it to Joint Commission quality standards.*
>
> *WakeMed has an excellent quality rating. …. The program will immediately participate in an existing Tumor Registry and Tumor Boards and WakeMed proposes to pursue American College of Surgeons Designation as a Community Cancer Program. All equipment will be new and radiation equipment will be subject to American College of Radiology accreditation.*
>
> *…*
>
> *All Radiation Oncologists will be board certified. Other staff members, including those provided by third party vendors, will be held to the highest levels of certification for their respective jobs. …*
> *…*
>
> *WakeMed strives to provide high-quality services to all. Because the linear accelerator, simulator and radiation oncology program will be part of WakeMed Raleigh, the program will follow and maintain the same quality and performance improvement policies and programs already established at WakeMed."*

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, pages 152-153, the applicant states:

> *"…, WakeMed plans to serve a high proportion of Medicaid, Medicare, and Charity Care patients. As noted in Figure 5, WakeMed Tumor Registry history demonstrates access to medically underserved patients; 19 percent had no insurance, or prescription coverage only.*
>
> *WakeMed has contract arrangements with three of the five North Carolina Medicaid managed care plans; and it is working on arrangements with the other two. Proformas assume that legislation related to North Carolina Medicaid Expansion and activities related to HASP will be in place by the first project year. This will increase Medicaid eligibles. …*

> …
>
> *…, WakeMed facilities do not discriminate against any patient based on income, age, gender, ethnicity, physical* [disability]*, ability to pay, or insurance coverage. …*
>
> …
>
> *WakeMed has a long history of working with Advance Community Health Center locations throughout Wake, Franklin, and Harnett County to meet the specialty care needs of people who rely on Advance for their primary care. Advance is a Federally Qualified Health Center whose mission is to address the health needs of medically underserved communities. Through its partnership with Advance and with other county institutions like Urban Ministries, WakeMed* [stays] *directly connected with geographic and informally organized hot spots where residents may be at risk of chronic disease. WakeMed's Population Health Program proactively works with these partnerships, to improve the health status of the medically underserved and all residents."*

See also Sections 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 demonstrated: 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.

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.

<u>Conclusion</u> – The Agency reviewed the:

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

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

Project ID #J-12379-23/Duke Radiation Oncology Garner/Acquire one LINAC
The applicant proposes to acquire a LINAC and CT simulator to develop Duke Garner, a new radiation oncology facility licensed under Duke Raleigh Hospital.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 84, the applicant states:

> *"This project creates a new radiation oncology facility in an underserved part of the county, significantly increasing patient choice and competition, particularly for patients in Garner and the southeastern part of Wake County."*

Regarding the impact of the proposal on cost effectiveness, in Section N, page 84, the applicant states:

> *"The proposed facility will have lower average reimbursement for Medicare patients than on-campus hospital facilities. Creating a new site of service also reduces transportation barriers and increases patients for convenience, decreasing the time they may need to take away from work for treatment."*

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 84, the applicant states:

> *"Patients will have access to high-quality state-of-the-art services for which Duke is renowned in a new location. This will also improve coordination of care for patients seeking other services within the Duke Health system, including other services within the Duke Cancer Institute.*
>
> *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."*

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 85, the applicant states:

> *"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. Duke's financial assistance policy will apply to these services. This facility will also bring critical oncology services to a new geographic area, which will lower transportation and other barriers to care."*

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

However, the applicant does not adequately demonstrate the proposal would have a positive impact on cost-effectiveness because the applicant did not adequately demonstrate: a) the need the population to be served has for the proposal or that projected utilization is based on reasonable and adequately supported assumptions; b) that projected revenues and operating costs are reasonable; and c) that the proposal would not result in an unnecessary duplication of existing and approved health services. The discussions regarding demonstration of need and projected utilization, projected revenues and operating costs, and unnecessary duplication found in Criterion (3), Criterion (5), and Criterion (6), respectively, are incorporated herein by reference. A proposal that cannot demonstrate need, cannot demonstrate that projected revenues and operating costs are based on reasonable and adequately supported assumptions, and cannot demonstrate that the proposed project is not an unnecessary duplication cannot have a positive impact on cost-effectiveness.

Conclusion – The Agency reviewed the:

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

Based on that review, the Agency concludes that the application is not conforming to this criterion based on all the reasons described 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 – All Applications

Project ID #J-12371-23/UNC Rex Hospital/Acquire one LINAC
The applicant proposes to acquire and add an additional LINAC at UNC Health Rex Cancer Care of Wakefield (UNC Rex Wakefield).

On Form O in Section Q, the applicant identifies the facilities with LINACs located in North Carolina owned, operated, or managed by the applicant or a related entity. The applicant identifies a total of 10 hospitals with LINACs and three freestanding facilities with existing and operational LINACs located in North Carolina.

In Section O, pages 123-125, the applicant states that during the 18 months immediately preceding the submittal of the application there were two incidents each at two separate hospitals resulting in findings of immediate jeopardy out of the 10 hospitals identified in Form O. The applicant states all incidents of immediate jeopardy were adequately responded to and all termination notices withdrawn. The applicant provides supporting documentation in Exhibits O.4-2 and O.4-3. The applicant further describes an incident related to quality of care that did not result in a finding of immediate jeopardy at an additional hospital. The applicant

states that the incident was appropriately resolved and provides supporting documentation in Exhibit O.4-1. After reviewing and considering information provided by the applicant and considering the quality of care provided at all 10 hospitals and three freestanding facilities with LINACs, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

Project ID #J-12376-23/WakeMed Raleigh Medical Park/Acquire one LINAC
The applicant proposes to acquire a fixed LINAC and a CT simulator to be located at WakeMed Raleigh Medical Park (WakeMed RMP), a medical office building that will be located adjacent to WakeMed Raleigh Campus.

On Form O in Section Q, the applicant identifies the facilities with LINACs located in North Carolina owned, operated, or managed by the applicant or a related entity. There are no facilities owned, operated, or managed by WakeMed or a related entity that have a LINAC and are located in North Carolina.

In Section O, page 163, the applicant states that during the 18 months immediately preceding the submittal of the application, there were no incidents resulting in a finding of immediate jeopardy that occurred at WakeMed. After reviewing and considering information provided by the applicant and considering the quality of care provided at WakeMed, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

Project ID #J-12379-23/Duke Radiation Oncology Garner/Acquire one LINAC
The applicant proposes to acquire a LINAC and CT simulator to develop Duke Garner, a new radiation oncology facility licensed under Duke Raleigh Hospital.

On Form O in Section Q, the applicant identifies the facilities with LINACs located in North Carolina owned, operated, or managed by the applicant or a related entity. The applicant identifies a total of 3 hospitals with LINACs and one freestanding facility with an approved but not yet developed LINAC located in North Carolina. Additionally, Duke LifePoint, a joint venture that the applicant is involved with, has four additional hospitals with LINACs in North Carolina.

In Section O, pages 87-88, the applicant states that during the 18 months immediately preceding the submittal of the application there were two separate incidents at the same facility resulting in findings of immediate jeopardy. The applicant states that the facility was back in compliance after the first incident. The second incident happened approximately one month prior to the submission of this application. The applicant states the facility has submitted an action plan, had a follow up survey, and is now awaiting a formal response. After reviewing and considering information provided by the applicant and considering the quality of care provided at all seven hospitals with existing LINACs, 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.

NC – UNC Rex Hospital, Duke Radiation Oncology Garner
C – WakeMed Raleigh Medical Park

SECTION .1900 - CRITERIA AND STANDARDS FOR RADIATION THERAPY EQUIPMENT are applicable to all projects. The specific criteria are discussed below.

10A NCAC 14C .1903 PERFORMANCE STANDARDS

An applicant proposing to acquire a LINAC pursuant to a need determination in the annual State Medical Facilities Plan in effect as of the first day of the review period shall:

(1) identify the existing LINACs owned or operated by the applicant or a related entity and located in the proposed LINAC service area;

-C- **UNC Rex Wakefield.** On Forms C.2a and C.2b in Section Q, the applicant identifies the existing LINACs owned or operated by the applicant or a related entity and located in Service Area 20.

-NA- **WakeMed RMP.** There are no existing LINACs owned or operated by the applicant or a related entity and located in Service Area 20. Therefore, this Rule is not applicable to this review.

-C- **Duke Garner.** In Section Q, the applicant identifies the existing LINACs owned or operated by the applicant or a related entity and located in Service Area 20.

(2) identify the approved LINACs owned or operated by the applicant or a related entity and located in the proposed LINAC service area;

-C- **UNC Rex Wakefield.** On Forms C.2a and C.2b in Section Q, the applicant identifies the approved LINACs owned or operated by the applicant or a related entity and located in Service Area 20.

-NA- **WakeMed RMP.** There are no approved LINACs owned or operated by the applicant or a related entity and located in Service Area 20. Therefore, this Rule is not applicable to this review.

-C- **Duke Garner.** In Section Q, the applicant identifies the approved LINACs owned or operated by the applicant or a related entity and located in Service Area 20.

(3) *provide projected utilization of the LINACs identified in Items (1) and (2) of this Rule and the proposed LINAC during each of the first three full fiscal years of operation following completion of the project;*

-C- **UNC Rex Wakefield.** On Forms C.2a and C.2b in Section Q, the applicant provides projected utilization of all existing and approved LINACs owned or operated by the applicant or a related entity located in Service Area 20 and the proposed LINAC during each of the first three full fiscal years of operation following completion of this project. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

-NA- **WakeMed RMP.** There are no existing or approved LINACs owned or operated by the applicant or a related entity and located in Service Area 20. Therefore, this Rule is not applicable to this review.

-C- **Duke Garner.** In Section Q, the applicant provides projected utilization of all existing and approved LINACs owned or operated by the applicant or a related entity located in Service Area 20 and the proposed LINAC during each of the first three full fiscal years of operation following completion of this project. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

(4) *provide the assumptions and methodology used for the projected utilization required by Item (3) of this Rule;*

-C- **UNC Rex Wakefield.** In the Form C Utilization – Assumptions and Methodology subsection of Section Q, the applicant provides the assumptions and methodology used to project utilization for all existing and approved LINACs owned or operated by the applicant or a related entity located in Service Area 20 and the proposed LINAC during each of the first three full fiscal years of operation following completion of this project. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

-C- **WakeMed RMP.** In the Form C Utilization – Assumptions and Methodology subsection of Section Q, the applicant provides the assumptions and methodology used to project utilization for all existing and approved LINACs owned or operated by the applicant or a related entity located in Service Area 20 and the proposed LINAC during each of the first three full fiscal years of operation following completion of this project. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

-C- **Duke Garner.** In the Assumptions – Form C subsection of Section Q, the applicant provides the assumptions and methodology used to project utilization for all existing and approved LINACs owned or operated by the applicant or a related entity located in Service Area 20 and the proposed LINAC during each of the first three full fiscal years of operation following completion of this project. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

(5) *project that the LINACs identified in Items (1) and (2) of this Rule and the proposed LINAC shall perform during the third full fiscal year of operation following completion of the project either:*

(a) 6,750 or more ESTVs per LINAC; or

(b) serve 250 or more patients per LINAC.

-NC- **UNC Rex Wakefield.** On Form C.2b in Section Q, the applicant projected that all existing and approved LINACs owned or operated by the applicant or a related entity located in Service Area 20 and the proposed LINAC will serve 250 or more patients per LINAC. However, projected utilization is not reasonable and adequately supported. The discussion regarding need, including projected utilization, found in Criterion (3) is incorporated herein by reference. Therefore, the application is not conforming to this Rule.

-C- **WakeMed RMP.** On Form C.2b in Section Q, the applicant projected that all existing and approved LINACs owned or operated by the applicant or a related entity located in Service Area 20 and the proposed LINAC will serve 250 or more patients per LINAC. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

-NC- **Duke Garner.** In Section Q, the applicant projected that all existing and approved LINACs owned or operated by the applicant or a related entity located in Service Area 20 and the proposed LINAC will serve 250 or more patients per LINAC. However, projected utilization is not reasonable and adequately supported. The discussion regarding need, including projected utilization, found in Criterion (3) is incorporated herein by reference. Therefore, the application is not conforming to this Rule.

COMPARATIVE ANALYSIS FOR ACUTE CARE BEDS

Pursuant to G.S. 131E-183(a)(1) and the 2023 State Medical Facilities Plan, no more than one LINAC may be approved for Service Area 20 in this review. Because the applications in this review collectively propose to develop three LINACs in Service Area 20, all applications cannot be approved for the total number of beds proposed. Therefore, after considering all the information in each application and reviewing each application individually against all applicable review criteria, the Project Analyst conducted a comparative analysis of the proposals to decide which proposal should be approved.

Below is a brief description of each project included in the LINAC Comparative Analysis.

- Project ID #J-12371-23 / **UNC Rex Hospital** / Acquire a new LINAC pursuant to the 2023 SMFP adjusted need determination
- Project ID #J-12376-23 / **WakeMed Raleigh Medical Park** / Acquire a new LINAC pursuant to the 2023 SMFP adjusted need determination
- Project ID #J-12379-23 / **Duke Radiation Oncology Garner** / Acquire a new LINAC pursuant to the 2023 SMFP adjusted need determination

The analysis of comparative factors and what conclusions the Agency reaches (if any) regarding specific comparative analysis factors is determined in part by whether the applications included in the review provide data that can be compared and whether or not such a comparison would be of value in evaluating the competitive applications.

Conformity with Review Criteria

An application that is not conforming or conforming as conditioned with all applicable statutory and regulatory review criteria cannot be approved.

UNC Rex Hospital's application, **Project ID #J-12371-23**, and **Duke Radiation Oncology Garner's** application, **Project ID #J-12379-23**, are not conforming to all applicable statutory and regulatory review criteria. The application submitted by **WakeMed Raleigh Medical Park**, **Project ID #J-12376-23** is conforming to all applicable statutory and regulatory review criteria. Therefore, with regard to conformity with review criteria, the application submitted by **WakeMed Raleigh Medical Park** is a more effective alternative than the applications submitted by **UNC Rex Hospital** and **Duke Radiation Oncology Garner**.

Scope of Services

Generally, the application proposing to provide the greatest scope of services is the more effective alternative with regard to this comparative factor.

Each application proposes to provide radiation therapy services and CT simulation services. Therefore, regarding scope of services, all three applications are equally effective.

Geographic Accessibility

As of the date of this decision, there are 11 existing and approved LINACs in Service Area 20, as illustrated in the following table.

Location of Service Area 20 Existing/Approved LINACs	
Facility	**Existing/Approved LINACs**
Duke Green Level*	1
Duke Raleigh Hospital	2
Duke Women's Cancer	1
UNC Rex Hospital	3
UNC Rex Wakefield	1
UNC Rex East Raleigh	1
UNC Panther Creek*	1
Service Area 20 Total	**11**

Sources: Table 17C-1, 2023 SMFP; applications under review; Agency records.
*LINAC approved for development or approved for relocation and not currently operational.

The following table illustrates where the existing and proposed LINACs are located or are proposed to be located within Service Area 20.

Facility	Total LINACs*	Address	Location
Duke Green Level	1	3208 Green Level W Road, Cary	Central Wake County
Duke Raleigh Hospital	2	3400 Wake Forest Road, Raleigh	Central Wake County
Duke Women's Cancer	1	4101 Macon Pond Road, Raleigh	Central Wake County
Duke Radiation Oncology Garner	1	130 Timber Drive East, Garner	Southeast Wake County
UNC Rex Hospital	2	4420 Lake Boone Trail, Raleigh	Central Wake County
UNC Rex Wakefield	1	11200 Governor Manly Way, Raleigh	Northern Wake County
UNC Rex East Raleigh	1	117 Sunnybrook Road, Raleigh	Central Wake County
UNC Panther Creek**	1**	6715 McCrimmon Parkway, Cary	Eastern Wake County
UNC Rex Holly Springs**	1**	850 South Main Street, Holly Springs	Southern Wake County
WakeMed Raleigh Medical Park	1	25 Sunnybrook Road, Raleigh	Central Wake County

*If all requested LINACs could be approved
**After the beginning of the review for these applications, based on a material compliance approval, the new location for the LINAC that was previously going to be located at UNC Panther Creek is UNC Rex Holly Springs Hospital, 850 South Main Street in Holly Springs, which is located in southwest Wake County.

There are currently five facilities with existing and operational LINACs in Service Area 20.

UNC Rex Hospital proposes to add a second LINAC to UNC Rex Wakefield in northeast Raleigh/Wake County, where there is currently an existing and operational LINAC. **WakeMed Raleigh Medical Park** proposes to develop a LINAC adjacent to its campus in southeast Raleigh/southeast Wake County, where there is not currently an existing or approved LINAC. However, the proposed location is approximately half a mile away on the same road as an existing LINAC (UNC Rex East Raleigh). **Duke Radiation Oncology Garner** proposes to develop a LINAC in Garner, in southern Wake County, where there is not currently an existing or approved LINAC. Therefore, **Duke Radiation Oncology Garner** is the more effective alternative with regard to

geographic accessibility and **UNC Rex Hospital** and **WakeMed Raleigh Medical Park** are less effective alternatives.

Historical Utilization

The table below shows LINAC utilization for existing facilities as reported in Table 17C-1 of the 2023 SMFP. Generally, the applicant with the higher historical utilization is the more effective alternative with regard to this comparative analysis factor.

Service Area 20 Historical Utilization - LINACs					
Facility	County	LINACs	# of Procedures /ESTVs	Average # of Procedures /ESTVs per LINAC	(Surplus) /Deficit
Duke Raleigh Hospital	Wake	4	21,075	5,269	(0.88)
UNC Rex Cancer Care of East Raleigh	Wake	1	5,148	5,148	(0.24)
UNC Rex Hospital (includes UNC Rex Wakefield)	Wake	4	21,639	5,410	(0.79)
Total		**11**	**47,862**	**4,351**	**(3.91)**

Sources: Table 17C-1, Table 17C-5 – 2023 SMFP

As shown in the table above, **UNC Rex Hospital** is the only existing facility applying to acquire a LINAC in Service Area 20. **Duke Radiation Oncology Garner** is not an existing facility and thus has no historical utilization, but its parent company has existing LINACs in Service Area 20. **WakeMed Raleigh Medical Park** is not an existing facility and thus has no historical utilization and does not have a parent company operating existing LINACs in Service Area 20.

Therefore, a comparison of historical utilization cannot be effectively evaluated.

Competition (Patient Access to a New or Alternate Provider)

Generally, the introduction of a new provider in the service area would be the most effective alternative based on the assumption that increased patient choice would encourage all providers in the service area to improve quality or lower costs in order to compete for patients. However, the expansion of an existing provider that currently controls fewer acute care beds than another provider would also presumably encourage all providers in the service area to improve quality or lower costs in order to compete for patients.

As of the date of this decision, there are 11 existing and approved LINACs in Service Area 20. **UNC Rex Hospital** (via its parent company) currently controls 54.5% of the LINACs and **Duke Radiation Oncology Garner** (via its parent company) controls 45.5% of the LINACs in Service Area 20. **WakeMed Raleigh Medical Park** (via its parent company) does not have existing or approved LINACs in Service Area 20.

If **UNC Rex Hospital's** application is approved, **UNC Rex Hospital** (via its parent company) would control 7 of the 12 existing and approved LINACs in Service Area 20, or 58.3% of the 12 existing and approved LINACs. If **Duke Radiation Oncology Garner's** application is approved, **Duke Radiation Oncology Garner** (via its parent company) would control 5 of the 12 existing and approved LINACs in Service Area 20, or 41.7% of the 12 existing and approved LINACs. If **WakeMed Raleigh Medical Park's** application is approved, **WakeMed Raleigh Medical Park** (via its parent company) would

control 1 of the 12 existing and approved LINACs in Service Area 20, or 8.3% of the 12 existing and approved LINACs.

Therefore, with regard to patient access to a new or alternate provider, the application submitted by **WakeMed Raleigh Medical Park** is the more effective alternative, and the applications submitted by **UNC Rex Hospital** and **Duke Radiation Oncology Garner** are less effective alternatives.

Access by Service Area Residents

In Chapter 17, page 311, the 2023 SMFP defines a LINAC's service area as "*…one of the 28 multicounty groupings described in the Assumptions of the Methodology."* Table 17C-4 on page 320 shows Service Area 20 is comprised of Franklin and Wake counties. Thus, the service area for this project consists of those two counties. Facilities may also serve residents of counties not included in their service area. Generally, regarding this comparative factor, the application projecting to serve the largest number of service area residents is the more effective alternative based on the assumption that residents of a service area should be able to derive a benefit from a need determination for additional acute care beds in the service area where they live.

The following table illustrates access by service area residents during the third full fiscal year following project completion.

Projected Service to Service Area 20 Residents (FY3)		
Applicant	**# Service Area 20 Residents**	**% Service Area 20 Residents**
UNC Rex Hospital	724	94.5%
WakeMed Raleigh Medical Park	344	77.8%
Duke Radiation Oncology Garner	151*	55.3%*

Sources: Project ID #J-12371-23 p.40, Project ID #J-12376-23 p.51, Project ID #J-12379-23 p.33
*Incomplete information; see discussion below

As shown in the table above, **UNC Rex Hospital** projects to serve both the highest number of Service Area 20 residents and the highest percentage of Service Area 20 residents.

However, **Duke Radiation Oncology Garner** projects utilization based on ZIP codes. At least four of the ZIP codes it uses in projecting patient origin extend beyond the Wake County line into other counties (27520, 27529, 27592, and 27603). There is not a way to identify which of the patients from those ZIP codes actually reside in Service Area 20 and which ones do not.

Considering the discussion above, the Agency believes that in this specific instance attempting to compare the applicants based on access to LINAC services for residents of Service Area 20 would be ineffective. Therefore, the result of this analysis is inconclusive.

Access by Underserved Groups

"Underserved groups" is defined in G.S. 131E-183(a)(13) as follows:

> *"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 access by underserved groups, the applications in this review are compared with respect to two underserved groups: Medicare patients and Medicaid patients. Access by each group is treated as a separate factor.

Projected Medicare

The following table compares projected access by Medicare patients in the third full fiscal year following project completion for each facility using the following metrics: Total Medicare Revenue, Average Medicare Revenue per Patient, and Percentage of Gross Revenue.

Projected Medicare Revenue – 3rd Full FY			
Applicant	Total Medicare Rev.	Av. Medicare Rev./Patient	% Of Gross Rev.
UNC Rex Hospital	$8,994,433	$11,742	59.2%
WakeMed Raleigh Medical Park	$10,464,283	$23,675	50.6%
Duke Radiation Oncology Garner	$7,074,886	$25,915	47.9%

Sources: Forms C and F.2b for each applicant

As shown in the table above, **WakeMed Raleigh Medical Park** projects the highest total Medicare revenue, **Duke Radiation Oncology Garner** projects the highest average Medicare revenue per patient, and **UNC Rex Hospital** projects the highest Medicare revenue as a percentage of gross revenue. Generally, the application projecting to serve a larger number of Medicare patients is the more effective alternative for this comparative factor. Therefore, regarding projected access for Medicare patients, all three applications are equally effective alternatives.

Projected Medicaid

The following table compares projected access by Medicaid patients in the third full fiscal year following project completion for each facility using the following metrics: Total Medicaid Revenue, Average Medicaid Revenue per Patient, and Percentage of Gross Revenue.

Projected Medicaid Revenue – 3rd Full FY			
Applicant	Total Medicaid Rev.	Av. Medicaid Rev./Patient	% of Gross Rev.
UNC Rex Hospital	$91,546	$120	0.6%
WakeMed Raleigh Medical Park	$968,152	$2,190	4.7%
Duke Radiation Oncology Garner	$981,086	$3,594	6.6%

Sources: Forms C and F.2b for each applicant

As shown in the table above, **Duke Radiation Oncology Garner** projects the highest total Medicaid revenue, the highest average Medicaid revenue per patient, and the highest Medicaid revenue as a percentage of gross revenue. Generally, the application projecting to serve a larger number of Medicaid patients is the more effective alternative for this comparative factor. Therefore, regarding projected access for Medicaid patients, the application submitted by **Duke Radiation Oncology Garner** is a

more effective alternative and the applications submitted by **UNC Rex Hospital** and **WakeMed Raleigh Medical Park** are less effective alternatives.

Projected Average Net Revenue per Patient

The following table shows the projected average net revenue per patient in the third full fiscal year following project completion for each facility. Generally, the application projecting the lowest average net revenue per patient is the more effective alternative with regard to this comparative factor since a lower average may indicate a lower cost to the patient or third-party payor.

Projected Average Net Revenue per Patient – 3rd Full FY			
Applicant	**Total # of Patients**	**Net Revenue**	**Av. Net Revenue/Patient**
UNC Rex Hospital	766	$6,515,126	$8,505
WakeMed Raleigh Medical Park	442	$6,698,020	$15,154
Duke Radiation Oncology Garner	273	$3,664,796	$13,424

Sources: Forms C and F.2b for each applicant

As shown in the table above, **UNC Rex Hospital** projects the lowest average net revenue per patient in the third full fiscal year following project completion. Therefore, regarding this comparative factor, the application submitted by **UNC Rex Hospital** is a more effective alternative and the applications submitted by **WakeMed Raleigh Medical Park** and **Duke Radiation Oncology Garner** are less effective alternatives.

Projected Average Operating Expense per Patient

The following table shows the projected average operating expense per patient in the third full fiscal year following project completion for each facility. Generally, the application projecting the lowest average operating expense per patient is the more effective alternative since a lower average may indicate a lower cost to the patient or third-party payor or a more cost-effective service.

Projected Average Operating Expense per Patient – 3rd Full FY			
Applicant	**Total # of Patients**	**Operating Expenses**	**Av. Operating Expense/Patient**
UNC Rex Hospital	766	$4,403,599	$5,749
WakeMed Raleigh Medical Park	442	$5,398,833	$12,215
Duke Radiation Oncology Garner	273	$5,971,791	$21,875

Sources: Forms C and F.2b for each applicant

As shown in the table above, **UNC Rex Hospital** projects the lowest average operating expense per patient in the third full fiscal year following project completion. Therefore, regarding this comparative factor, the application submitted by **UNC Rex Hospital** is a more effective alternative and the applications submitted by **WakeMed Raleigh Medical Park** and **Duke Radiation Oncology Garner** are less effective alternatives.

SUMMARY

The following table lists the comparative factors and states which application is the more effective alternative with regard to that particular comparative factor. The comparative factors are listed in the same order they are discussed in the Comparative Analysis which should not be construed to indicate an order of importance.

Comparative Factor	UNC Rex Hospital	WakeMed Raleigh Medical Park	Duke Radiation Oncology Garner
Conformity with Review Criteria	Less Effective	**More Effective**	Less Effective
Scope of Services	Equally Effective	Equally Effective	Equally Effective
Geographic Accessibility	Less Effective	Less Effective	**More Effective**
Historical Utilization	Inconclusive	Inconclusive	Inconclusive
Competition/Access to New/Alternate Provider	Less Effective	**More Effective**	Less Effective
Access by Service Area Residents	Inconclusive	Inconclusive	Inconclusive
Access by Underserved Groups			
Projected Medicare	Equally Effective	Equally Effective	Equally Effective
Projected Medicaid	Less Effective	Less Effective	**More Effective**
Projected Average Net Revenue per Patient	**More Effective**	Less Effective	Less Effective
Projected Average Operating Expense per Patient	**More Effective**	Less Effective	Less Effective

- With respect to Conformity with Review Criteria, **WakeMed Raleigh Medical Park** offers the more effective alternative. See Comparative Analysis for discussion.

- With respect to Geographic Accessibility, **Duke Radiation Oncology Garner** offers the more effective alternative. See Comparative Analysis for discussion.

- With respect to Competition/Access to New Provider, **WakeMed Raleigh Medical Park** offers the more effective alternative. See Comparative Analysis for discussion.

- With respect to Projected Medicaid Access, **Duke Radiation Oncology Garner** offers the more effective alternative. See Comparative Analysis for discussion.

- With respect to Projected Average Net Revenue per Patient, **UNC Rex Hospital** offers the more effective alternative. See Comparative Analysis for discussion.

- With respect to Projected Average Operating Expense per Patient, **UNC Rex Hospital** offers the more effective alternative. See Comparative Analysis for discussion.

CONCLUSION

G.S. 131E-183(a)(1) states that the need determination in the SMFP is the determinative limit on the number of acute care beds that can be approved by the Healthcare Planning and Certificate of Need Section. Approval of all applications submitted during this review would result in LINACs in excess of the need determination for Service Area 20.

However, the applications submitted by **UNC Rex Hospital** and **Duke Radiation Oncology Garner** are not approvable and therefore cannot be considered an effective alternative. Consequently, the following applications are denied:

Project ID #J-12371-23 / **UNC Rex Hospital** / Acquire one linear accelerator pursuant to the 2023 SMFP need determination

Project ID #J-12379-23 / **Duke Radiation Oncology Garner** / Acquire one linear accelerator pursuant to the 2023 SMFP need determination

Based upon the independent review of each application and the Comparative Analysis, the following application is approved:

Project ID #J-12376-23 / **WakeMed Raleigh Medical Park** / Acquire one linear accelerator pursuant to the 2023 SMFP need determination

Project ID #J-12376-23, **WakeMed Raleigh Medical Park**, is approved subject to the following conditions.

1. **WakeMed (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**

2. **The certificate holder shall acquire no more than one linear accelerator pursuant to the need determination in the 2023 SMFP.**

3. **The certificate holder shall acquire no more than one CT simulator.**

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. **The first progress report shall be due on March 1, 2024.**

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. **The certificate holder shall develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes.**

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.**