

Comments on Alamance Health Company, LLC, Duke University Health System, Inc., and Novant Health, Inc.'s Acute Care Bed Certificate of Need Application, Project ID # G-012641-25

June 2, 2025

Competitive Comments on Alamance County Acute Care Bed Applications

submitted by

Alamance Regional Medical Center, Inc.

In accordance with N.C. GEN. STAT. § 131E-185(a1)(1), Alamance Regional Medical Center, Inc. (Cone Health) hereby submits the following comments related to the application filed by Alamance Health Company, LLC, Duke University Health System, Inc. and Novant Health, Inc. (collectively referred to herein as Duke Novant unless otherwise specified) to develop a new 46-bed acute care hospital called Duke Novant Mebane Hospital (Duke Novant Mebane) in response to the need identified in the *2025 State Medical Facilities Plan (SMFP)* for 46 additional acute care beds in Alamance County. Cone Health'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). In order to facilitate the Agency's ease in reviewing these comments, Cone Health has organized its discussion by issue, specifically noting the general Certificate of Need (CON) statutory review criteria and regulations creating the non-conformity of each issue, as they relate to the Duke Novant Mebane application, Project ID # G-012641-25. Cone Health's comments include issue-specific comments on the Duke Novant Mebane application as well as a comparative analysis related to its application:

• Cone Health Mebane Hospital (Cone Health Mebane), develop 46 acute care beds and related services on its existing Mebane hospital campus, Project ID # G-012638-25

As detailed above, given the number of additional acute care beds, both applications cannot be approved as proposed. The comments below include substantial issues that Cone Health believes render Duke Novant's application non-conforming with applicable statutory criteria and regulatory review criteria. However, as presented at the end of these comments, even if the Duke Novant Mebane application was conforming, the Cone Health Mebane Hospital application filed by Cone Health is comparatively superior to the application filed by Duke Novant and represents the most effective alternative for expanding access to acute care services in Alamance County.

GENERAL COMMENTS

As detailed in the issue-specific comments in the following section, the Duke Novant Mebane application does not conform to all of the Certificate of Need (CON) statutory review criteria and regulations. The application contains fundamental inconsistencies regarding the identity of the applicant entity and fails to provide necessary clarity on operational structure. The application includes multiple references to different legal entities as "Applicant 1," making it impossible to determine which entity is actually seeking CON approval and which entity will own and operate the proposed hospital.

Furthermore, the Duke Novant application lacks substantive details regarding how the proposed new joint venture hospital would be operationalized and managed. This approach stands in stark contrast to the comprehensive, thoughtfully planned full-service hospital proposal submitted by Cone Health.

Beyond these basic identification issues, Duke Novant projects unreasonable and unsupported market share capture for Alamance County patients; inappropriately relies on Duke Raleigh Hospital and Duke Regional Hospital as benchmark facilities for volume projections despite significant differences in size, service scope, and market characteristics; and includes significant mathematical errors in its financial projections.

The application fails to demonstrate financial feasibility as the facility is projected to operate at a significant net loss in the third project year with no documentation of how these losses will be addressed or overcome in the long term. Additionally, Duke Novant's application lacks clarity on how critical ancillary and support services will be provided, with vague references to services being provided by "one or both of DUHS and/or Novant Health" or "one of the LLC members and/or third party vendors."

Even if Duke Novant's application were approvable, the Cone Health Mebane Hospital application is the more effective alternative for the 46 acute care beds needed in Alamance County as demonstrated in the comparative analysis section.

ISSUE-SPECIFIC COMMENTS

1. <u>The Duke Novant Hospital Mebane application fails to consistently identify the applicant entity and</u> lacks clarity on operational structure, making it impossible to determine who will own, operate, and manage the proposed facility.

The Duke Novant Mebane application contains fundamental inconsistencies regarding the identity of the applicant entity (Applicant 1) that would own and operate the proposed hospital. These inconsistencies appear across multiple sections of the application and create significant uncertainty about the actual legal entities seeking Certificate of Need approval.

On the cover page, fee sheet, and certification page, the first applicant is identified as "Alamance Health Company, LLC." In Section C.1, "Alamance Health Company, LLC" is described as "the entity that will own and operate Duke Novant Mebane Hospital." However, Section F.2a and F.3f reference "Duke Novant Mebane Hospital, LLC" as Applicant 1, which is the first time this entity is introduced in the document. Form F.1a also lists this different entity. This inconsistency creates uncertainty about which legal entity is actually seeking approval and which entity will own and operate the proposed hospital.

For example, see the following excerpts from the Duke Novant Hospital Mebane application with different legal entities listed for Applicant 1.

Applicant 1			
Business ID # (Internal Use Only)			
Legal Name (do NOT include a d/b/a)	Alamance Health Company, LLC		
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Source: Duke Novant Mebane application, p. 16, Section A.1

 Applicant 1
 Duke Novant Mebane Hospital, LLC

 Source: Duke Novant Mebane application, p. 78, Section F.2a

Further complicating this issue, Section K.4.b states that "DUHS owns the site where the Duke Novant Mebane Hospital will be developed and will enter into a ground lease with Alamance Health LLC for the site." Here, the entity is referred to as "Alamance Health LLC," omitting the word "Company" that appears elsewhere, potentially introducing a third variant of the first applicant's name.

Beyond these inconsistencies, the application critically fails to provide any discussion of the intended management or operations of the proposed hospital. The North Carolina Certificate of Need statute and regulations require clear identification of the applicant entity to ensure proper accountability, evaluate financial capability, and assess qualifications to provide the proposed services. The application fails to provide operating agreements, articles of organization, or other legal documents that would confirm the actual structure, membership, or existence of the applicant entity in the absence of clear information in the narrative. Without this basic information, it is impossible to properly evaluate the application against key statutory requirements and criteria.

Furthermore, little information is provided about the new Duke and Novant Health joint venture – merely general concepts without substantive understanding of how the facility will be implemented or managed. The Duke Novant application uses vague and general language regarding plans to operationalize the proposed facility. For example, parts of Section C.4 indicate the proposed facility will be developed by "Duke University Health System" – not even referring to the new partnership entity.

Duke Novant Mebane Hospital will play a critical role in strengthening the continuum of care for residents in Mebane and throughout Alamance County. As part of a broader effort to expand access, Duke University Health System is developing the Duke Health Mebane campus to offer a comprehensive range of healthcare services—bringing hospital-based care closer to the communities that need it most.

Source: Duke Novant Mebane application, p. 16, Section A.1

In the discussion of critical ancillary and support services on p. 94, the Duke Novant Mebane application does not clearly identify service providers, instead listing services to be provided by "one or both of DUHS and/or Novant Health" or "one of the LLC members and/or third party vendors" across numerous categories of services.

"Additional administrative and operational support services including patient accounting, marketing, and information technology will be provided by contract with one or both of DUHS and/or Novant Health."

"Janitorial, laundry, linen, and security services will be provided by third-party vendors. Lab services will be provided by hospital site on staff with available specialized services available <u>via</u> contracts with one of the LLC members and/or third party vendors."

Source: Duke Novant Mebane application, p. 94

This suggests a lack of sufficient planning and clear understanding of how the hospital will be operationalized, as these are all critical administrative, support, and ancillary services of any acute care hospital. This renders the application non-conforming with Criterion 8, as the applicants have not demonstrated that the provider of the proposed services will make available or arrange for the provision of necessary ancillary and support services.

The ambiguity continues in Section Q. In the assumptions outlined for other expenses related to even more key ancillary and support services, the Duke Novant Application included the following:

Corporate Allocations calculated based on the Corporate template based on the FY2024 Corporate Services Allocation budget. Allocated expenses include (but are not limited to) items like IT, Scheduling, nurse education, medical director, human resources, finance, marketing and radiation safety. Expenses are based on the FY2024 budgeted allocated expense as a % of total system gross charges. Note that services could be provided by either partner and/or an external contract.

Source: Duke Novant Mebane application, p. 157

This ambiguity also raises questions regarding the accuracy of the operating costs. Operating costs could vary significantly depending on whether Duke, Novant Health, or a third-party contractor manages the facility or provides one or more of these services under contract, yet the application provides no clarity on this fundamental aspect.

Based on these inconsistencies and omissions, the application fails to demonstrate who will own, operate, and manage the proposed facility. Without clarity on the legal entity that would provide those services and how it would function operationally, it is impossible for the Agency to evaluate whether the applicant is qualified to develop the proposed project. Furthermore, without clarity on the applicant entity, it is impossible to evaluate if the application properly identifies who will serve the population and how, rendering the application non-conforming with Criterion 3.

In summary, the application contains fundamental inconsistencies regarding the identity of the applicant entity seeking Certificate of Need approval and fails to provide necessary clarity on operational structure. The Agency cannot approve an application when it cannot determine the entities who are applying. Key questions regarding how the facility will be operationalized remain unanswered, in contrast with Cone Health's comprehensive application.

In summary, based on the issues detailed above, the Duke Novant Hospital Mebane application is nonconforming with the review criteria established under N.C. Gen. Stat. § 131E-183, specifically Criteria 1, 3, 5, 7, and 8, and the application should not be approved. 2. <u>The Duke Novant Hospital Mebane application fails to demonstrate the reasonableness of its</u> <u>projected market share capture in Alamance County.</u>

The Duke Novant Mebane application contains inadequate support for its utilization projections, relying on overstated and unsubstantiated market share assumptions for Alamance County. On page 126 of the application, Duke Novant projects to capture 10.0 percent of Alamance County patients for the proposed hospital without providing any quantitative evidence, historical comparative data, or specific precedent cases to validate this market share projection. Instead, the application offers only general qualitative assertions lacking substantive supporting documentation.

This absence of rigorous analytical support is especially problematic given the documented history of Novant Health's market share projection methodologies being rejected in recent Certificate of Need reviews. Consider these relevant precedents:

- The Agency found Novant Health's application for Novant Health Asheville Medical Center (Project ID # B-012230-22) non-conforming with Criterion 3 in the 2022 Buncombe/Graham/Madison/Yancey Acute Care Bed Review. The Findings specifically noted that "Novant's assumptions about what percentage of acute care patients treated in Buncombe County will shift to NH Asheville are not reasonable and adequately supported." The Duke Novant Mebane application employs a similarly unsupported methodology, projecting a 10 percent market share capture without providing the quantitative evidence or historical data that the Agency has consistently required in prior reviews.
- In the more recent 2024 Wake County Acute Care Bed and OR Review, Novant Health's application for Novant Health Knightdale Medical Center (Project ID # J-012534-24) was determined nonconforming with Criterion 3. The Agency Findings explicitly stated that the "Projected market share of discharges is not reasonable." Of particular relevance, that application projected market share captures of 20 percent for primary service area ZIP codes and 10 percent for secondary service area ZIP codes. The current application applies similarly aggressive market share assumptions to the entirety of Alamance County, rendering the Duke Novant Mebane Hospital projections even more unreasonable in comparison to these previously rejected methodologies.

In summary, based on the issues detailed above, the Duke Novant Hospital Mebane application is nonconforming with the review criteria established under N.C. Gen. Stat. § 131E-183, specifically Criteria 1, 3, 4, 5, 6, and 18a as well as the performance standards specified in 10A NCAC 14C .3803 and the application should not be approved.

3. <u>The Duke Novant Health application inappropriately relies on Duke Raleigh Hospital and Duke</u> <u>Regional Hospital as comparable facilities for volume projections</u>. As a result, its volume projections <u>are unreasonable</u>.

The Duke Novant Mebane Hospital application relies heavily on Duke Raleigh Hospital and Duke Regional Hospital as "reasonable proxies" for projecting utilization patterns at the proposed facility. Specifically, the application uses these facilities to calculate ratios for ICU utilization (p. 130), observation bed utilization (pp. 133-134), outpatient surgical cases (p. 136), emergency department utilization (pp. 136-138), imaging services (pp. 138-139), and ancillary services (p. 140). The applicant claims these facilities were selected "due to their respective status as community hospitals within the respective health systems" and because they are "similarly aligned in scope of services and operational experience" (p. 130).

However, the use of Duke Raleigh Hospital and Duke Regional Hospital as comparable facilities for projecting utilization at Duke Novant Mebane Hospital is fundamentally flawed for several critical reasons.

The population characteristics of Wake and Durham counties bear little resemblance to Alamance County. According to the NC Office of State Budget and Management, the projected 2025 population of Alamance County is 185,255, compared to 344,427 for Durham County, and 1,238,879 for Wake County. Wake County's population is nearly seven times larger than Alamance County, while Durham's is nearly twice as large. These dramatic differences in population fails to acknowledge or account for these substantial demographic differences when applying utilization ratios from facilities serving much larger population centers to a rural/suburban county with vastly different characteristics. Population density, income level, age distributions, and health status indicators in Alamance County differ significantly from the urban centers where Duke Raleigh Hospital and Duke Regional Hospital operate, rendering direct comparisons methodologically unsound.

Beyond population differences, the dynamics of the Wake and Durham healthcare markets bear no resemblance to Alamance County's healthcare landscape. The following table highlights the stark contrast in healthcare resources across these counties:

	Alamance Durham		Wake
Hospitals (Approved)	1	3 (+1)	6 (+2)
Beds Licensed (Approved)	170	1,297 (+152)	1,464 (+159)
FFY 2023 Patient Days of Care	44,878	382,770	435,963
Operating Rooms (Approved)	12	93 (+5)	111 (+12)
Ambulatory Surgery Centers (Approved)	N/A	4 (+1)	14 (+7)

Comparison of Alamance, Durham, and Wake Counties

Source: 2025 SMFP

Remarkably, the applicant explicitly acknowledges these dramatic differences in competitive dynamics on page 137 of its application, stating: "In contrast to Duke Raleigh Hospital, which operates in the highly competitive Wake County service area—where multiple hospitals and FSERs offer emergency services— Duke Novant Mebane Hospital will serve a county with limited emergency care infrastructure and no FSERs." Despite this clear understanding of the fundamental dissimilarity between the markets, the applicant still inexplicably proceeds to use Duke Raleigh Hospital's utilization ratios for projecting emergency department volumes at the proposed facility. This logical inconsistency further undermines the credibility of the utilization projections throughout the application.

Adding to these discrepancies, the application projects that 90 percent of Duke Novant Mebane Hospital patients will originate from Alamance County (p. 43), indicating a highly localized service area. This projection further highlights the major differences between the proposed facility and the "reasonable proxies" used for utilization projections. Duke Raleigh Hospital and Duke Regional Hospital draw patients from a much broader geographic area, with only 62.93 percent of Duke Raleigh Hospital patients and 53.61 percent of Duke Regional Hospital patients originating from their respective home counties according to the 2024 NC DHSR Acute Care Hospital Admissions: Patient Origin by Facility report. These facilities attract significant numbers of patients from surrounding counties due to their size, scope of

services, and established referral networks within large metropolitan areas. These divergent patient origin patterns reflect the fundamental differences in facility characteristics, service area dynamics, and regional healthcare infrastructure. The application fails to address how these substantial disparities in service area characteristics might affect utilization patterns when applying ratios from Duke Raleigh Hospital and Duke Regional Hospital to the proposed hospital.

Finally, there is clear regulatory precedent for finding applications non-conforming when they rely on inappropriate facility comparisons for utilization projections. In the 2022 Buncombe/ Graham/ Madison/ Yancey Acute Care Bed Review, Novant's application (Project ID # B-012230-22) was found non-conforming for similar methodological flaws. In that case, Novant inappropriately used NH Mint Hill located in urban Mecklenburg County as a benchmark for projecting utilization in the rural Buncombe County market. The Agency specifically criticized Novant's application for using "data from NH Mint Hill, with 36 acute care beds, 3 ORs, and in a large urban county with multiple healthcare systems, to project utilization at NH Asheville, with almost twice the number of acute care beds, one-third the number of ORs, and in a multicounty service area with less than one-third the population of Mecklenburg County." The parallels to the current application are striking, as Duke Novant Mebane Hospital similarly relies on facilities from large urban counties with different competitive dynamics, populations, and healthcare infrastructure to project utilization in a county that is partially rural.

In addition to the population, competitive dynamics, and patient origin dynamics described above, Duke Novant fails to demonstrate the reasonableness of selecting Duke Raleigh Hospital and Duke Regional Hospital in terms of size and scope of services. In the 2024 Wake County Acute Care Bed and OR Review, Novant Health Knightdale Medical Center's application was found non-conforming specifically because its methodology relied on benchmarks from inappropriate comparative hospitals, including Duke Raleigh Hospital. The Agency concluded that "Duke Raleigh Hospital, WakeMed Cary, Nash UNC Health Care and UNC Health Johnston are not reasonable comparative hospitals to use in projecting an ALOS for Novant Knightdale" (p. 39).

If the Agency deemed Duke Raleigh Hospital an unreasonable benchmark for the Novant Knightdale proposal, it is unreasonable as a benchmark for the similar Duke Novant Mebane Hospital, which also proposes a small community hospital model. While Duke Novant claims that Duke Regional Hospital is a community hospital, the care it provides includes many tertiary services such as open heart surgery and neonatology. Additionally, Duke Regional Hospital provides many of the services the Duke Novant Hospital Mebane application specifically says it will not provide as a new community hospital including cardiac catheterization, inpatient rehabilitation, behavioral health, and neonatal intensive care. According to Duke Regional Hospital's 2025 LRA, it had 1,196 cardiac catheterizations, 9,304 inpatient rehabilitation days of care, 12,372 psychiatry days of care, and 5,041 neonatal days of care in FFY 2024. Similar to the Agency's previous conclusion on Duke Raleigh Hospital, the Duke Regional Hospital is unreasonable to use as a benchmark for a small community hospital that will not provide a similar scope of services.

In its application, Duke Novant attempts to explain the use of Duke Raleigh Hospital and Duke Regional Hospital as benchmarks by using misleading statements regarding patient shifts. On page 130, the application states: "Additionally, a portion of the respective facilities' existing share of discharges will shift to Duke Novant Mebane Hospital as part of the shift described." According to the 2024 NC DHSR patient origin reports, the following patients from Alamance County were treated at Duke facilities in FY 2023:

	Patients	% of Duke Total
Duke University Hospital	1,408	76.2%
Duke Regional Hospital	401	21.7%
Duke Raleigh Hospital	39	2.1%
Total	1,848	100.0%

Source: 2024 NC DHSR Patient Origin Report

As shown in the table above, only 23.8 percent of Alamance patients treated at a Duke facility were treated at either Duke Raleigh Hospital or Duke Regional Hospital. Taken a step further, based on Duke Novant's methodology, that means only 202 out of the 2,628 projected Project Year 3 discharges at Duke Novant Hospital Mebane will originate from these two facilities.¹ This is less than 7.6 percent of discharges and does not justify the need to use these two large hospitals as benchmarks for Duke Novant Hospital Mebane.

In contrast, Cone Health Mebane Hospital's use of Alamance Regional Medical Center (ARMC) as a benchmark is entirely reasonable and appropriate. First, both ARMC and Cone Health Mebane Hospital are located within Alamance County, ensuring that the facilities serve the same patient population with similar demographic and health needs. Second, 84.0 percent of patient days at Cone Health Mebane Hospital are projected to shift from ARMC, creating a direct and substantial relationship between the existing facility and the proposed hospital. Additionally, the facilities will be on the same license and the medical staff will be the same for both campuses, ensuring that practice patterns will be similar across both facilities. This significant patient volume transfer and consistency in clinical practices establishes ARMC as a valid and logical benchmark for projections, unlike Duke Novant's reliance on facilities with minimal patient transfers from the service area.

Based on these fundamental methodological flaws, the Duke Novant application is non-conforming with Criteria 1, 3, 4, 5, 6, and 18a as well as the performance standards specified in 10A NCAC 14C .3803. The Duke Novant Mebane Hospital application should not be approved.

4. <u>The Duke Novant financial projections include significant mathematical errors and fail to demonstrate</u> <u>financial feasibility</u>

The Duke Novant Mebane Hospital application fails to demonstrate financial feasibility as required by Criterion 5. The financial projections contain multiple significant mathematical errors that render the applicants' financial projections unreliable and contradictory.

First, the Duke Novant Mebane application includes five Form F.2bs on pages 142-146. Form F.2b for three of the service components (IP & IP ED, IP & OP Surgery, and Outpatient ED & Radiology) contain mathematical errors. For each of these service components, the total gross revenue does not equal the total patient services gross revenue. With no other revenue reported, these two figures should be identical, but they differ significantly. This discrepancy renders these forms materially incorrect as the calculation of total net revenue is based on total gross revenue which is unsupported (total gross revenue less total adjustments to revenue equals total net revenue).

¹

Duke Market Share of 11.43% x Duke Regional Hospital and Duke Raleigh Hospital's share of 23.8% = 2.72% x PY 3 50% shift = 1.36% x 2032 projected discharges of 14,854 = 202 discharges

Second, the facility-level Form F.2b on page 142 contains substantial inconsistencies when compared to the service component Forms F.2b on pages 143-146. The total facility gross revenue reported on page 142 significantly exceeds the sum of all service component gross revenues. No explanation is provided for this material inconsistency.

Third, basic arithmetic errors exist in the calculation of adjustments to revenue on the facility-level Form F.2b. The reported total adjustments to revenue does not equal the sum of the individual adjustment line items (charity care, bad debt, and contractual adjustments). Similarly, the total adjustments to revenue for the facility differ substantially from the sum of the total adjustments to revenue reported for the individual service components.

These are not minor rounding discrepancies or typographical errors but substantial flaws that materially affect the projected financial performance. Without accurate, consistent, and reliable financial data, it is impossible to properly evaluate the financial feasibility of this project.

Given these fundamental inconsistencies in the financial projections, the application fails to demonstrate financial feasibility as required by Criterion 5 and should not be approved.

5. <u>The Duke Novant financial projections significantly understate the corporate allocation expenses and</u> <u>fail to demonstrate reasonable projections of health service costs and charges.</u>

Duke Novant's application fails to adequately demonstrate financial feasibility due to significantly understated corporate allocation expenses and vague descriptions of which entity will provide these services. These deficiencies raise substantial concerns about the accuracy and reliability of the financial projections presented in the application.

In Form F.3b of the application, Duke Novant Mebane Hospital projects "Other Expenses" of \$1,528,485 in Project Year 3 for corporate allocations. The application vaguely states that these allocated services "could be provided by either partner and/or an external contract." As discussed previously, this ambiguity makes it impossible to determine which entity will be responsible for providing these essential administrative services or that the costs accurately reflect the eventual contract with an unknown entity, undermining the credibility of the financial projections.

More concerning is the fact that the projected corporate allocation expenses are dramatically lower than those reported in similar recent applications by the same applicants for hospitals of comparable size:

Novant Health Cabarrus Medical Center's application (Project ID # F-012588-25, filed February 13, 2025) for a 50-bed hospital projected \$9,610,078 in corporate overhead allocation for Project Year 3 – more than six times the amount projected by Duke Novant Mebane Hospital for its 46-bed facility.

	1st Full FY	2nd Full FY	3rd Full FY
Form F.3a Projected Operating Costs	F: 01/01/2030	F:01/01/2031	F: 01/01/2032
NH Cabarrus Facility	T: 12/31/2030	T: 12/31/2031	T: 12/31/2032
Salaries (from Form H Staffing)	\$22,051,510	\$26,190,918	\$31,950,260
Taxes and Benefits	\$5,301,616	\$6,296,811	\$7,681,470
Independent Contractors (1)	\$1,533,530	\$2,536,655	\$4,243,742
Medical Supplies	\$2,046,060	\$3,382,831	\$5,660,437
Other Supplies	\$1,845,419	\$3,052,284	\$5,106,541
Dietary (2)	\$0	\$0	\$0
Housekeeping/Laundry (2)	\$0	\$0	\$0
Equipment Maintenance	\$1,104,623	\$1,126,715	\$1,149,249
Building & Grounds Maintenance (2)	\$402,372	\$410,420	\$418,628
Utilities	\$0	\$0	\$0
Insurance	\$214,262	\$218,547	\$222,918
Professional Fees	\$0	\$0	\$0
Interest Expense	\$0	\$0	\$0
Rental Expense	\$118,646	\$121,019	\$123,439
Depreciation - Buildings	\$8,801,058	\$8,801,058	\$8,801,058
Depreciation - Equipment	\$6,566,836	\$6,566,836	\$6,566,836
Other Expenses (Corporate Overhead Allocation)	\$9,236,907	\$9,421,645	\$9,610,078
Other Expenses (On-Call and Med Dir Payments, IP Hospitalists Allocation)	\$3,395,016	\$3,462,916	\$3,532,174
Total Expenses	\$62,617,855	\$71,588,654	\$85,066,831

 Duke Cary Hospital's expansion application (Project ID # J-012548-24, filed August 15, 2024) to increase from 40 to 57 acute care beds projected a combined \$10,369,269 in central office overhead and allocated services in Project Year 3 – nearly seven times the amount projected by Duke Novant Mebane Hospital.

Form F.3b Projected Operating	1st Full FY	2nd Full FY	3rd Full FY
Costs Upon Project Completion	F: 07/01/2029	F:07/01/2030	F:07/01/2031
Duke Health Cary - Total Facility	T: 06/30/2030	T:06/30/2031	T:06/30/2032
Salaries (from Form H Staffing)	\$47,640,646	\$57,703,088	\$68,778,391
Taxes and Benefits	\$11,260,932	\$13,615,170	\$16,211,045
Travel Reimbursement (2)	\$10,724	\$12,369	\$14,047
Training (2)	\$42,896	\$49,477	\$56,190
Medical Supplies	\$10,822,220	\$15,478,460	\$19,495,377
Other Supplies	\$209,815	\$191,965	\$237,913
Pharmacy (2)	\$6,890,550	\$9,416,434	\$11,984,726
Dietary (2)	\$545,111	\$700,127	\$865,588
Housekeeping / Laundry (2)	\$582,742	\$725,240	\$896,431
Equipment Maintenance (2)	\$453,920	\$582,968	\$720,657
Building & Grounds Maintenance (2)	\$1,511,294	\$1,536,677	\$1,567,455
Central Office Overhead	\$2,326,138	\$5,000,100	\$5,737,468
Professional Fees	\$1,316,484	\$1,775,352	\$2,285,747
Contract Work - Other	\$2,990,119	\$3,840,283	\$4,747,504
Other Fees (Allocated Services)	\$2,661,199	\$3,543,075	\$4,631,801
Utilities	\$2,506,709	\$2,556,843	\$2,607,980
Insurance	\$290,491	\$296,301	\$302,227
Machinery & Equipment	\$1,451,869	\$720,290	\$736,043
Depreciation - Buildings	\$10,210,000	\$10,210,000	\$10,210,000
Depreciation - Equipment	\$20,620,825	\$20,620,825	\$20,620,825
Other Expenses (specify)	\$500,997	\$49,734	\$37,373
Total Expenses	\$124,845,680	\$148,624,779	\$172,744,790

This stark discrepancy cannot be explained by the minimal bed difference between the Duke Novant Mebane Hospital (46 beds), the NH Cabarrus Medical Center (50 beds), and the Duke Cary Hospital (57

beds). Furthermore, it is particularly troubling that both Duke University Health System and Novant Health – the joint applicants for this project – have separately projected substantially higher corporate allocation costs for their own recent projects of similar size.

Whether these services are ultimately provided by Duke, Novant, or an external contractor, the projected costs should reasonably align with the applicants' own recent projections for comparable facilities. The current projection of \$1,528,485 represents a significant and unjustifiable deviation from established cost patterns.

The unreasonably low corporate allocation expense projection artificially improves the financial feasibility of the project by understating operating costs by at least \$8 million annually based on the applicants' own recent, comparable projects. When these costs are properly accounted for, the application would show significantly higher operating expenses and worse financial performance than currently projected.

Therefore, based on these issues, the Duke Novant Mebane Hospital application is non-conforming with Criterion 5 and should not be approved.

6. <u>The Duke Novant financial projections do not demonstrate financial feasibility as the facility operates</u> <u>at a net loss in Project Year 3.</u>

The Duke Novant Mebane Hospital application fails to demonstrate financial feasibility as required by Criterion 5. The applicants' financial projections clearly indicate that the proposed facility will operate at a loss through the third project year without providing adequate documentation to demonstrate long-term financial feasibility.

According to Form F.2b on page 142, Duke Novant Mebane Hospital is projected to operate with a loss of \$8,279,011 in Project Year 3, the third full fiscal year of operation. This is before any adjustment for the understated corporate allocation expense discussed above. This operating loss directly contradicts the requirement in Criterion 5 to demonstrate "the immediate and long-term financial feasibility of the proposal."

Section F.4.b of the application requires that a hospital project revenues and operating costs for the entire facility if necessary to demonstrate the financial feasibility of the proposal. While the applicants vaguely state on page 80 that they are "committed to the financial feasibility of the facility to meet the identified needs of the patients to be served," they provide no future projections to validate this claim.

In previous Certificate of Need applications, Duke has routinely included system-level financial projections to demonstrate financial support for projects that show operating losses. For example, in the Duke Raleigh Beds application (Project ID # J-012546-24), Duke included financial projections for Duke University Health System to demonstrate financial feasibility. In this application, neither Duke nor Novant has provided system-level financial projections to demonstrate how they will sustain a facility operating at a loss. The application's reliance on audited financial statements provides only a point-in-time snapshot of financial capacity, without demonstrating how the projected operating losses will be addressed in subsequent years or establishing any pathway to long-term financial viability.

Without sufficient documentation demonstrating the long-term financial feasibility of a facility projected to operate at a loss, the application fails to conform with Criterion 5 and should not be approved.

7. <u>The Duke Novant Mebane Hospital's application fails to demonstrate the reasonableness of its initial</u> <u>operating cost projections as required by Criterion 5.</u>

The Duke Novant Mebane Hospital application calculates \$10,800,000 in working capital on page 80, which includes \$3,800,000 in initial operating costs. This calculation is based on the estimated operating losses (excluding depreciation) for Project Years 1 and 2. However, Duke Novant's own financial statements contradict this minimal approach to working capital.

On page 81, the applicants state "the applicants would note that they have documented the availability of funds to cover all operating costs (less depreciation) in the first two project years, which would also ensure financial feasibility during any lag in the initiation of collection of reimbursement for services." This statement suggests that a more accurate calculation of initial operating costs could be as high as \$77,645,849, the sum of operating costs (excluding depreciation) from Forms F.3b for the first two project years.

This inconsistency exposes a fundamental issue in Duke Novant's financial planning. The application presents a working capital calculation that assumes immediate reimbursement for services while simultaneously acknowledging that reimbursement could be delayed by up to two years.

A review of Section P reveals that Duke Novant did not provide a Medicare and/or Medicaid Certification date in its timeline, further complicating the evaluation of the project's initial operating costs. Without an estimated certification date, it is impossible to validate the accuracy of the working capital calculation and it is unclear if initial operating costs are \$3,800,000 or \$77,654,849.

While Duke Novant will likely argue that their funding letters provide a buffer for additional working capital needs, it is important to note that Criterion 5 requires financial projections to be "based upon reasonable projections of the costs of and charges for providing health services." Given the uncertainty and unlikely nature of the working capital calculation presented in the application, Duke Novant fails to meet this requirement.

Duke Novant calculates \$250,000,000 in capital costs and \$10,800,000 in working capital, for a total project cost of \$260,800,000. However, the funding letters in Exhibit F.2 total \$400,000,000 (\$200,000,000 from each applicant). Wildly overstating the available funding does not reduce the applicant's burden to provide reasonable projections of the actual costs associated with the project. The significant discrepancy between the calculated project costs and the funding commitments suggests either poor financial planning or an attempt to compensate for the unreliable working capital projections without addressing the underlying calculation flaws.

In summary, based on the issues detailed above, the Duke Novant Mebane Hospital application is nonconforming with Criterion 5 and should not be approved.

8. <u>The Duke Novant Mebane Hospital's position to develop a new hospital with only procedure rooms is</u> <u>contradictory to the position that Novant Health has taken in previous comments.</u>

Duke Novant's application to develop a new hospital with only procedure rooms and a dedicated C-section OR contradicts positions previously advocated by Novant Health, undermining the credibility of the current application.

The Duke Novant Mebane Hospital application states on page 40 that "Surgical services can be provided in properly configured procedure rooms as well as a dedicated C-Section operating room." The application further states that Duke Novant Mebane Hospital will develop "two procedure rooms for the provision of the proposed surgical services" and "one dedicated operating room (OR) exclusively for C-Section procedures." The application indicates that all procedure rooms "will be constructed to be consistent with the standard of care of the scope of procedures to be provided and designed and equipped to satisfy recognized standards for the surgeries to be performed at this facility."

In its opposition of AdventHealth Asheville's application (Project ID # B-012233-22) in the 2022 Buncombe/ Graham/ Madison/ Yancey Acute Care Bed Review, Novant Health took the explicit position that operating rooms are essential for being a qualified applicant and for hospital licensure:

"As the 2022 SMFP does not include a need determination for any operating rooms within the Buncombe/Madison/Yancey OR Service Area, AdventHealth Asheville cannot propose the development of an operating room and, as a result, cannot be a qualified applicant."

"As the following four tables highlight, an operating room is essential to being a licensed ambulatory surgical facility, excluding gastrointestinal endoscopy rooms as defined in General Statute 131E-176(1b), or licensed acute care hospital in North Carolina."

In those same comments, Novant Health conducted extensive analysis showing that "there are no licensed acute care hospitals in North Carolina that operate without at least one operating room" and concluded that AdventHealth's application was "non-conforming with Criterion (3) and cannot be approved." This position directly contradicts arguments Duke Novant is now making in its current application.

Furthermore, although the Agency conditionally approved AdventHealth's CON application (Project ID # B-12233-22) proposing a new hospital with only a dedicated C-section OR and procedure rooms, the case remains under review by the North Carolina Court of Appeals and a CON has not been issued. Therefore, to date, no CON exists for a hospital with only a C-section OR and procedure rooms in North Carolina.

Novant Health cannot argue that operating rooms are "essential" for being a qualified applicant and hospital licensure when opposing a competitor's application, then take the opposite position when submitting its own application as part of Duke Novant. This contradictory stance undermines the credibility of Duke Novant's current application as to whether Duke Novant Mebane Hospital meets the regulatory requirements that Novant Health has previously defined as essential for hospital licensure.

Thus, Duke Novant's application is non-conforming with Criteria 3, 6, and 18a, as its inconsistent positioning on the necessity of operating rooms undermines the reliability of its projected utilization and operational assumptions.

COMPARATIVE ANALYSIS

The Cone Health Mebane Hospital application (Project ID # G-012638-25) and the Duke Novant Mebane Hospital application (Project ID # G-012641-25) both propose to develop acute care beds in response to the *2025 SMFP* need determination for Alamance County. Given that both applicants propose to meet all of the need for the 46 additional acute care beds in Alamance County, both cannot be approved as proposed. To determine the comparative factors that are applicable in this review, Cone Health examined recent Agency findings for competitive acute care bed reviews. Based on that examination and the facts and circumstances of the competing applications in this review, Cone Health considered the following comparative factors:

- Conformity with Review Criteria
- Scope of Services
- Geographic Accessibility
- Historical Utilization
- Competition
- Access by Service Area Residents
- Projected Medicare
- Projected Medicaid
- Average Net Revenue per Discharge
- Average Operating Expense per Discharge

Cone Health believes that the factors presented above and discussed in turn below should be used by the Agency in reviewing the competing applications.

Conformity with Applicable Statutory and Regulatory Review Criteria

Cone Health's application adequately demonstrates that its acute care bed proposal conforms to all applicable statutory and regulatory review criteria. In contrast, the Duke Novant application does not adequately demonstrate that its proposal is conforming to all applicable statutory review criteria, as discussed previously. Specifically, the Duke Novant application is non-conforming with Criteria 1, 3, 4, 5, 6, 7, 8, and 18a and fails to meet the performance standards specified in 10A NCAC 14C .3803. An application that is not conforming to all applicable statutory and regulatory review criteria cannot be approved. Therefore, with regard to conformity, Cone Health's application is more effective than the Duke Novant application.

Scope of Services

Both Cone Health and Duke Novant propose to develop 46-bed community hospitals in Mebane. However, differences exist in their scope of services. Cone Health Mebane Hospital includes the development of three licensed operating rooms, while the Duke Novant Health Hospital includes no licensed operating rooms beyond a dedicated C-section operating room, an issue which, as previously noted, Novant Health has argued makes an applicant unqualified to develop a new hospital or obtain a license. The Cone Health facility also includes one fixed CT scanner with cardiac capabilities, whereas the Duke Novant proposal includes a CT scanner without specified cardiac functionality. The Duke Novant application emphasizes future plans for an ambulatory surgical facility on the hospital campus rather than inpatient surgical needs, an atypical approach for a community hospital proposal. On page 136, the application states, "DUHS is planning a regional ambulatory care campus co-located with the proposed Duke Novant Mebane Hospital. Duke Health Mebane will include a freestanding ambulatory surgery facility to deliver high quality surgical care to outpatient populations." Further, page 126 notes, "The applicants intend to develop a QASF [qualified urban ambulatory surgical facilities] after the November 21, 2025 effective date."

Thus, the Duke Novant application allocates significant attention to future outpatient surgical services while providing more limited discussion of inpatient surgical services within the hospital itself. Furthermore, these plans indicate that Duke Novant intends to shift outpatient surgical cases to its future ASC facility, whereas these same cases would likely be the most suitable candidates for procedure rooms in typical community hospitals. With procedure rooms in the proposed Duke Novant Mebane Hospital but no licensed operating rooms, questions remain about the scope of surgical services that will be available to inpatients and potential distinctions in the types of surgeries typically performed. Such distinctions are typically determined by the facility's governing body and clinical authority. As identified in issue-specific comment #1, the Duke Novant application lacks clarity regarding the governance and management of the proposed facility, which further complicates this issue. This raises questions about whether this approach has been fully developed, as it is difficult to state with confidence that a complete complement of surgical services could be provided when governance and management remain undefined.

The absence of defined governance structure and clinical authority is particularly concerning given the scope of acute care services proposed. Clear governance frameworks and established clinical decision-making processes are essential for managing complex patient care decisions, including appropriate patient transfers and coordination of services across the joint venture partners. As identified in issue-specific comment #1, the Duke Novant application lacks clarity regarding the governance and management of the proposed facility, which further complicates understanding how clinical services will be coordinated and delivered. This fundamental uncertainty raises questions about the applicant's preparedness to provide the proposed scope of services.

For these reasons discussed above, Cone Health's application is the most effective for the scope of services factor.

Geographic Accessibility

Both applications submitted in response to the need identified in the 2025 SMFP for 46 additional acute care beds in Alamance County propose to locate the beds within the city of Mebane in eastern Alamance County. The applicant sites are less than 3.0 miles (6-minute drive time) apart. Given the close proximity, neither applicant offers meaningful improvement in geographic accessibility compared to the other. Both would serve the same population center with similar accessibility. The applications are therefore comparable with regard to geographic accessibility, with no distinct advantage between them in terms of location.

Historical Utilization

The table below shows acute care bed utilization for existing Alamance County facilities based on acute care days as reported in Table 5A of the *2025 SMFP*. As reported in the *2025 SMFP*, Alamance Regional Medical Center demonstrates a deficit of 46 acute care beds.

	FFY23 Inpatient Days of Care	FFY27 Projected Days of Care	Proj. (Surplus) / Deficit 2027
Alamance Regional Medical Center	44,878	56,337	46

Alamance County Historical Acute Care Bed Utilization

Source: 2025 SMFP

As shown above, Alamance Regional Medical Center has demonstrated strong historical utilization and created the need for 46 additional acute care beds in Alamance County. In contrast, Duke Novant has no existing acute care beds in Alamance County and thus no historical utilization to demonstrate.

It should be noted that Novant Health has a history of recommending this comparative factor, including competitive applications when its competitor does not currently operate in the service area. In the 2023 New Hanover Cardiac Catheterization review, Novant stated "WASC does not currently operate any cardiac cath machines and is not affiliated with any cardiac cath labs in New Hanover County. Therefore, NH Scotts Hill is the more effective alternative regarding this factor."

Competition

In evaluating competitive impact, proposals that increase competition in the service area are typically considered more effective. While Duke Novant's proposed hospital would introduce a second acute care hospital provider to Alamance County, competition must be evaluated within the geography of the proposed facilities. Both applicants propose hospitals in the far eastern portion of the county in Mebane, an area currently lacking any full-service acute care community hospitals.

Competition in this area, specifically ZIP code 27302 (where the proposed hospitals will be located), is highly fragmented with many providers serving this population. As shown in the table below, when combining affiliated hospitals into health systems, UNC Hospitals served more than 40 percent of patient days from this ZIP code. Cone Health facilities (including ARMC) collectively served 27.3 percent of the market in 2023 (28.8 percent for 2024 YTD). Duke Health system accounted for 27.1 percent of patient days in 2023 (26.9 percent in 2024 YTD). This distribution clearly demonstrates that patients from this area already have multiple options and that adequate competition exists among health systems serving this population. Further, both Duke and Cone Health have three hospitals that serve patients from this market today.

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Hospital	2023	Market Share	2024 YTD Jan-July	Market Share	
UNC Hospitals	12.8	32.9%	13.5	29.7%	
Cone Health ARMC	9.5	24.5%	10.9	23.9%	
Duke University Hospital	8.2	21.0%	10.4	22.9%	
UNC Health Hillsborough Campus	4.0	10.1%	5.1	11.1%	
Duke Regional Hospital	2.3	5.8%	1.7	3.8%	
Cone Health Moses H. Cone Memorial	0.9	2.4%	2.0	4.4%	
Cone Health Wesley Long Hospital	0.2	0.4%	0.2	0.4%	
Duke Raleigh Hospital	0.1	0.4%	0.1	0.2%	
Other	1.0	2.5%	1.6	3.6%	
Total	39.0	100.0%	45.6	100.0%	

ZIP Code 27302 ADC by Hospital

Source: NC HIDI Data, excludes normal newborns, neonatal, and behavioral health

Given the current distribution of market share across multiple health systems, with patients traveling to various facilities outside their immediate area for care, both applications would introduce new acute care capacity to an area without existing hospital services. Each would enhance the healthcare landscape by bringing needed services closer to the communities they would serve, particularly benefiting residents in ZIP code 27302 who currently disperse to multiple distant facilities for care. With Duke Health and Cone Health having materially similar market shares in the ZIP code proposed for both applications, the development of either would enhance competition, assuming Duke Novant could be approved.

However, as detailed in the issue-specific comments, the Duke Novant application is non-conforming with multiple review criteria and should not be approved. Therefore, with regard to competition, the Cone Health Mebane Hospital application is superior and represents the most effective alternative.

Access by Service Area Residents

Both applicants respond to the acute care bed need determination in Alamance County set forth in the 2025 SMFP. The applicable service area for this review is Alamance County.

Comparison of projected patient origin reveals significant differences in methodology between the applicants. Duke Novant projects that 90 percent of its patients will originate from Alamance County in each of the first three years of operation, while Cone Health projects a much narrower geographic focus, stating that 86.8 percent of patients will come from just four specific zip codes within Alamance County, with an additional 10 percent coming from "other zip codes in Alamance County and surrounding counties" (emphasis added) (p. 44).

Given that a significant portion of the 10 percent that Cone Health allocates to "**other zip codes in Alamance County** and surrounding counties" will naturally come from within Alamance County, Cone Health's total projected service to Alamance County residents is comparable to or exceeds the 90 percent projected by Duke Novant. Thus, with regard to access by service area residents, the applications are equally effective, if not more effective for Cone Health.

Projected Medicare

The table below shows each applicant's projected Medicare as a percentage of total acute care charges, as reported in Form F.2b and Section L.3 of the respective applications.

	Medicare Gross Revenue	Total Gross Revenue	% of Medicare Gross Revenue	% of Medicare Section L.3
Cone Health Mebane	\$71,371,984	\$113,385,062	62.9%	62.9%
Duke Novant Mebane	\$27,630,666	\$55,600,135	49.7%	49.7%

Projected Medicare as a Percentage of Charges

Source: Form F.2b, Section L.3.

As shown in the table above, Cone Health projects to serve a higher percentage of Medicare patients, making it the more effective alternative for projected Medicare.

In the 2024 Buncombe-Graham-Madison-Yancey Acute Care Bed Competitive Review, the Agency determined it could not make a valid comparison of all three applications for purposes of evaluating which application was more effective due to the differences in the level of care and types of services between Mission Hospital and two small community hospitals. However, the Agency determined a valid comparison could be made between the two applications for small community hospitals submitted by NH Asheville and AdventHealth Asheville (p. 101). Based on this decision and given that Cone Health and Duke Novant both propose 46 acute care bed community hospitals, a comparison can be made in this instance.

Projected Medicaid

The table below shows each applicant's projected Medicaid as a percentage of total acute care charges, as reported in Form F.2b and Section L.3 of the respective applications.

	Medicaid Gross Revenue	Total Gross Revenue	% of Medicaid Gross Revenue	% of Medicaid Section L.3
Cone Health Mebane	\$19,676,728	\$113,385,062	17.4%	17.4%
Duke Novant Mebane	\$5,544,173	\$55,600,135	10.0%	10.0%

Projected Medicaid as a Percentage of Charges

Source: Form F.2b, Section L.3.

As shown in the table above, Cone Health projects to serve a higher percentage of Medicaid patients, making it the more effective alternative for projected Medicaid.

In the 2024 Buncombe-Graham-Madison-Yancey Acute Care Bed Competitive Review, the Agency determined it could not make a valid comparison of all three applications for purposes of evaluating which application was more effective due to the differences in the level of care and types of services between Mission Hospital and two small community hospitals. However, the Agency determined a valid comparison could be made between the two applications for small community hospitals submitted by NH Asheville and AdventHealth Asheville (page 101). Based on this decision and given that Cone Health and Duke Novant both propose 46 acute care bed community hospitals, a comparison can be made in this instance.

Average Net Revenue per Discharge

The following table shows average net revenue per patient day and per patient in the third full fiscal year of operation.

	Net Revenue	# of Discharges	Net Revenue per Discharge
Cone Health Mebane	\$37,850,437	3,039	\$12,455
Duke Novant Mebane	\$21,021,462	2,628	\$7,999

Projected Net Revenue per Discharge

Source: Form F.2.

As shown above, Duke Novant has a lower net revenue per discharge than Cone Health. However, it is clear that the two applicants used different methods for allocating inpatient revenue and expenses. According to Cone Health Mebane Hospital's Form F.2 assumptions, "inpatient services include all services provided to patients during their inpatient stay, including emergency, surgery, imaging, pharmacy, laboratory, therapy, and other ancillary support services" (p. 170). Conversely, Duke Novant includes inpatient surgical revenue and expenses in its surgery service component and obstetrics in another separate service component. As a result, Duke Novant's IP & IP ED service component only includes some of the inpatient cost of a patient.

Given that one application includes all revenue and expenses of an inpatient visit while another application does not, a meaningful comparison cannot be made for this comparative factor.

Average Operating Expense per Discharge

The following table shows average operating expense per discharge in the third full fiscal year of operation.

	Operating Expenses	# of Discharges	Operating Expense per Discharge
Cone Health Mebane	\$41,253,215	3,039	\$13,575
Duke Novant Mebane	\$22,674,509	2,628	\$8,628

Projected Operating Expenses per Discharge

Source: Form F.2.

As noted in issue-specific comment #5, Duke Novant's operating expenses appear to be significantly understated due to unreasonably low corporate allocation projections, which would materially impact this per-discharge calculation.

As shown above, Duke Novant has a lower operating expense per discharge than Cone Health. However, it is clear that the two applicants used different methods for allocating inpatient revenue and expenses. According to Cone Health's Form F.2 assumptions, "inpatient services include all services provided to patients during their inpatient stay, including emergency, surgery, imaging, pharmacy, laboratory, therapy, and other ancillary support services" (page 170). Conversely, Duke Novant includes IP surgical

revenue and expenses in its surgery service component and obstetrics in another separate service component. As a result, Duke Novant's IP & IP ED service component only includes some of the inpatient cost of a patient.

Given that one application includes all revenue and expenses of an inpatient visit while another application does not, a meaningful comparison cannot be made for this comparative factor.

SUMMARY

The Duke Novant Mebane application fails to meet the most fundamental Certificate of Need requirements, as evidenced by the critical inconsistencies and deficiencies detailed in the issue-specific comments above. The application lacks thoughtful planning, with inconsistent applicant identification and minimal substantive details about how the joint venture hospital would be operationalized and managed. It projects unreasonable market share capture, relies on inappropriate benchmark facilities, and presents significant financial feasibility issues including mathematical errors, understated corporate allocations, and projected operating losses. These foundational flaws make the application non-conforming with multiple statutory review criteria and regulatory standards, rendering it unsuitable for approval.

In contrast, the Cone Health Mebane Hospital application represents a well-conceived proposal from an established healthcare provider with deep roots and demonstrated commitment to serving Alamance County residents. Even if the Duke Novant Mebane application were approvable, Cone Health believes that the Cone Health Mebane Hospital application is the more effective alternative for the 46 acute care beds needed in Alamance County. In summary, the Cone Health Mebane Hospital application is fully conforming to all applicable statutory and regulatory review criteria and comparatively superior on the relevant factors in this review. As such, the Cone Health Mebane Hospital application submitted by Cone Health should be approved.

Please note that in no way does Cone Health intend for these comments to change or amend its application filed on April 15, 2025. If the Agency considers any statements to be amending Cone Health's application, those comments should not be considered.