Comments Regarding Duke Raleigh Hospital CON Application for Fixed MRI Scanner
Project No. J-12524-24

Submitted by WakeMed Health & Hospitals
July 31, 2024

WakeMed appreciates the opportunity to provide the following comments opposing the certificate of need application filed by Duke University Health System to develop a fixed MRI scanner at Duke Raleigh Hospital (DRAH), in response to the need determination for Wake County in the 2024 State Medical Facilities Plan.

Overview

The proposed project should not be approved, as it does not conform with applicable certificate of need Review Criteria found in N.C.G.S. §131E-183, as described below. Duke submitted the only CON application in the review; however, the Agency is not obligated to approve Duke's proposal simply because it is the sole applicant.

Review Criterion 3

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

In response to Section C.1, Duke indicates that the new fixed MRI scanner will be located in a "new imaging suite" on the DRAH campus, although no further description is provided in the narrative. The site address provided in response to Section K.3 indicates the scanner will be developed at 3300 Executive Drive, Raleigh, NC 27609, which is not within the main hospital building. The application is not clear whether the new fixed MRI will serve outpatients only.

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

- Volume projections and their underlying assumptions are unreliable and unsupported;
- Justification for the proposed shift in cases is unreasonable and unsubstantiated;
- The proposed location does not materially improve access to MRI services in Wake County;
- The project may have a detrimental effect on existing services in the Duke Health System.

Volume Projections are Unreliable and Unsupported

Duke provides no explanation for the sharp decline in fixed MRI volume in Duke-owned scanners at DRAH from FY 2022 to FY 2023 (page 37), or for the projected recovery in FY 2024 (page 90). It is unclear whether one or more fixed scanners were out of service for all or part of the year.

On page 90 in Section Q, Duke projects MRI volumes at DRAH for FYs 2024-2029. The FY 2024 volumes are based on 8 months' data annualized. Projected utilization for FYs 2025-2029 assumes a shift in cases from DRAH to other Duke Imaging facilities in Wake and Durham Counties. The application states that projections – prior to the shift – "are calculated by applying anticipated population growth rates to FY24 DRAH annualized volumes at the zip code level. The applied population growth rates are based on Sg2 projections for the years 2024 through 2029. Compounded annual growth rates for zip codes…range from -1.8% to 3.2%." However, Duke provides no analysis of current-year and 5-year populations by ZIP Code for the 35 ZIPs identified on page 91.

More importantly, volume shifts at the ZIP Code-level from DRAH to other locations provide no detail regarding the *number* of projected cases to be shifted by ZIP as a result of the project. Because patient origin for MRI was not provided at the ZIP Code level, there is no way to determine the reasonableness of the projections. For example, on page 91, Duke projects that 10 percent of DRAH's MRI scans originating from ZIP Code 27502 (Apex) will shift to Duke-Holly Springs, as well as 5 percent of scans from DRAH to Duke-Arringdon. The application does not provide the *pre-shift* DRAH MRI volume from ZIP 27502 or any other ZIP Code in the table.

Moreover, some of the proposed shift percentages are seemingly illogical. For example, it is not explained why MRI patients originating from ZIPs 27591 (Wendell) and 27597 (Zebulon), who would be geographically more proximate to both DRAH, Duke-Heritage and Duke-Knightdale, would shift from DRAH to Duke-Arringdon, which is significantly further away. The ZIP Code-level "percent shift" table on page 91 lists 35 ZIPs. However, ZIP Codes 27607 and 27608 (Raleigh) are listed twice in the table; whether this apparent double counting is immaterial cannot be ascertained, as no detail is provided.

On page 92, Duke provides the "cumulative shift" of volume to other facilities as well as DRAH's post-shift fixed MRI volume. Duke mentions on page 90 that these shifts are intended "to account for the potential shift of volume to other DUHS imaging sites that are new and/or under development and therefore continuing to experience a ramp-up in volume" and goes on to describe Duke MRIs that opened in 2020 (Holly Springs in Wake County), as well as in 2021 and 2023 (Arringdon in Durham County). Because Project Year 1 for the fixed MRI scanner proposed in this application is FY 2027, it would appear that any shifts in volume would have occurred well *before* the proposed project becomes operational. The DRAH proposes to shift

even more cases to its outpatient imaging sites, while claiming to need additional MRI capacity at the hospital campus.

With the exception of the Duke-Holly Springs site, the DRAH application provides no projected utilization for other Duke Imaging locations with MRI scanners.

Unsupported Correlation Between Provider Network and MRI Utilization

On page 38, the DRAH application describes how growth in the Duke Health provider network, particularly Duke Primary Care, has influenced increases in patient volumes. Duke cites that more than 1,100 providers referred patients to DRAH for MRI procedures from July-December 2023. On page 39, the application asserts: "As the number of providers relying on this imaging modality increases, the high volumes on the hospital's existing scanners can create capacity constraints [that] can lead to delays in scheduling procedures, and can affect the ability to start treatment for patients." However, the application provides no documentation of delays, either for MRI scans or for other diagnostic or therapeutic procedures. There is no discussion or analysis presented regarding increases in wait times for MRI services. The reader is expected to believe that scheduling delays and wait times are increasing at face value, without any evidence provided to support this assertion.

In the same paragraph on page 39, the application states: "Increasing fixed capacity which can be operated longer hours than a mobile scanner under contract with a third party will increase scheduling flexibility and allow DRAH to better meet patient needs without undue delays." The new scanner will be located in a medical office building, which suggests it will be used by outpatients only. DRAH did not provide projected hours of operation, how MRI capacity will increase as a result of the project, or the effect of the project on reducing wait times. Because no details regarding inpatient/outpatient split were provided for historic or projected utilization, the effect of the new scanner on hospital operations is uncertain. The extent to which wait times differ for inpatient scans versus outpatient scans is not known.

The DRAH application does not adequately describe how developing additional *hospital-based* fixed MRI services will improve access by primary care patients, or how primary care referrals to medical specialists correlate to additional MRI procedures. According to Duke, approximately 95 percent of MRI referrals were for outpatient procedures. In an era where healthcare costs are under increasing scrutiny and payers are rewarding providers for enhancing value, additional hospital-based fixed MRI services, where growth in volume appears to be greater for lower cost, non-HOPD services, the DRAH project appears superfluous. Please see the discussion for Review Criterion 4.

Not Clear Whether Mobile MRI Services Will Be Discontinued

DRAH is currently served by two fixed MRI scanners and one mobile scanner provided via contract with Alliance Health. The application does not state how many days per week mobile MRI services are provided. Projections provided in Section Q appear to exclude mobile MRI

volume in Project Year 1-3, but this is not explicitly stated anywhere in the application. On page 38, the DRAH application states "[t]his project to add fixed capacity will allow DUHS to reduce and potentially eliminate the need for mobile services at this location", and on page 90, "[m]obile services will be reduced or eliminated to the extent that the fixed scanners can accommodate all anticipated volume." On page 92, Duke hedges further by stating: "…DUHS anticipates being able to contract for additional mobile services if the actual utilization is higher than these conservative projections." Missing from the application and exhibits is an attestation that Alliance Health's mobile MRI scanner will discontinue service at DRAH following project completion.

Ratio of MRI Procedures to Patients is Unclear

On pages 28-31, Duke provides FY 2023 patient origin for existing MRI services at DRAH. The total on page 31 does not match the MRI volume for FY 2023 provided on page 37. Duke indicates on page 31 that it is providing patient origin data for "discrete patients" who received an MRI scan, rather than for total procedures. Duke did not indicate whether the historic patient origin table includes patients who received an MRI at both the fixed and mobile MRIs located on the DRAH campus, or whether these are patients who received an MRI *only* on the Duke-owned MRIs at DRAH. All MRI projections provided in Section Q are based on MRI scans, not patients. Duke does not describe the metric for projecting MRI patients vs. MRI procedures, or if its MRI patient origin based on MRI procedures would be any different.

Review Criterion 4

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

In Section E, Duke outlined the alternatives it considered to the proposed project, including developing MRI capacity at another location and maintaining or increasing mobile MRI services, both of which were dismissed. Duke's desire to reduce its dependence on mobile MRI providers is understandable, both for cost and patient convenience. On pages 37-38, Duke provides historic MRI utilization for its owned and contracted scanners located at facilities in Wake County. Duke states that its MRI volume experienced "a growth of more than 40% over 5 years". However, this statement is misleading, since the referenced growth is largely the product of its outpatient-only fixed and mobile scanners in Cary, Heritage (Wake Forest) and Holly Springs. Of these, utilization at its Holly Springs IDTF nearly doubled from FY 2021 to FY 2023. One cannot correlate volume growth at these outpatient sites to that of DRAH.

Total MRI volume of all MRI scanners in operation at DRAH, including the mobile scanner provided through service agreement with Alliance Health, grew only 8.8 percent from FY 2019-2023, in contrast to the purported "high and growing MRI utilization on the Duke Raleigh Hospital campus" (page 38). Utilization of DRAH's 2 fixed MRIs declined by 16 percent. By

comparison, Duke MRI volume at non-DRAH sites in Wake County grew 257 percent over the same period.

Given the recent utilization growth in MRI volume at its non-hospital imaging sites, a more effective alternative would have been to develop a fixed MRI away from DRAH, particularly at a location that would provide non-hospital-based imaging services. Therefore, the DRAH application does not conform with Review Criterion 4.

Review Criterion 5

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

As described in Review Criteria 3 and 12, DRAH's MRI volume projections are not reasonable, reliable or adequately supported, and the project's capital cost is unreliable. Because projected revenues and expenses are based at least in part on projected volumes and capital cost, then projected revenues and expenses in the DRAH application are also unreasonable. Therefore, DRAH does not conform with Review Criterion 5.

Review Criterion 12

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

The proposed capital cost estimate for this project identical in Form F.1a, on page 97, and in correspondence from the project architect found in Exhibit F.1a. The architect's letter provided in Exhibit F.1a provides information and cost estimates for a "shared support space" totaling $2,258,000, which is not included in the total capital cost for either this application for fixed MRI or the concurrent application for 2 CT scanners (Project No. J-12525-24). The "shared support space" appears to be integral to the development of both projects, and it is unclear whether this cost should have been included in one application or prorated between the two projects. At any rate, this unexplained discrepancy calls into question the validity of project's capital cost.

The omission of such a substantial portion of the project and associated capital cost renders Forms F.1a, F.2b, and F.3b unreliable and unreasonable. For these reasons the application is nonconforming with Criterion 12.

Review Criterion 18a

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

In response to Question N.2, Duke discusses the project's impact on competition in the service area. Duke notes that increasing MRI capacity at DRAH "will increase scheduling flexibility and reduce delays in treatment", although this claim is not substantiated anywhere in the application. Although the project will add 1 fixed MRI at DRAH, the new scanner is proposed to be located in a medical office building – Duke does not describe its proposed hours of operation, how capacity will be increased over current inventory, or how the new scanner will affect operation of existing scanners.

Summary

The DRAH application is nonconforming with numerous CON Review Criteria. The assumptions used to develop projections are vague and not backed with demonstrable evidence. Duke did not fully explore other viable alternatives to the project. Because it is nonconforming with these criteria, WakeMed recommends that the Agency deny the application.