

PUBLIC COMMENTS ON 2024 DURHAM/CASWELL/WARREN FIXED MRI CON REVIEW SUBMITTED BY DUKE UNIVERSITY HEALTH SYSTEM, INC.

December 2, 2024

Two applicants submitted CON applications in response to the need identified in the 2024 SMFP for one additional fixed MRI scanner in Durham, Caswell, and Warren Counties, Duke University Health System ("DUHS") and UNC DCI, LLC (a subsidiary of UNC Health) ("UNC"). These comments are submitted by DUHS in accordance with N.C. Gen. Stat. § 131E-185(a1) to address the representations in the competing UNC application, including comparative factors and a discussion of the most significant issues regarding UNC's conformity with the statutory and regulatory review criteria ("the Criteria") in N.C. Gen. Stat. §131E-183(a) and (b). Other non-conformities in the competing application may exist and DUHS reserves the right to develop additional opinions, as appropriate upon further review and analysis.

Comparative Analysis

Only one of the applications can be approved as a result of the binding need determination in the SMFP. Even assuming UNC's application were conforming with all statutory and regulatory criteria, it is comparatively inferior to DUHS's application including in the following key aspects:

- DUHS projects a lower net revenue per procedure than UNC (dividing total net revenue from Form F.2(b) by total procedures from Form C).
- Payor mix is heavily dependent on the specific procedure mix at a given facility. Moreover, as set forth below, UNC's payor mix projections are unreliable. However, based on the data provided, DUHS projects a higher percentage of Medicare patients than UNC.
- UNC does not project opening its facility until at least November 2026, at which time MRIs will be deregulated in counties of Durham's size. UNC will be free to develop this facility after this time. DUHS proposes to develop its project more quickly, providing timelier access to patients in the service area.

As to geographic access, UNC itself designates the geographic area in which its facility would be located as the "South region" of the service area, and acknowledges that Duke Imaging Arringdon is located in this defined "South region." See UNC Application, p. 124. Therefore, the UNC facility does not increase geographic access in any way. At the same time, DUHS's facility is co-located with a variety of primary and specialty physician services and an ambulatory surgery facility, making access to care more efficient and convenient for patients at the DUHS facility than at UNC's proposal.

DUHS would also note that the Agency often finds the "new applicant" comparatively superior on the factor of access to a new provider/competition. For example, in the 2023 Wake County MRI review (p, 82), the Agency states, "Generally, the introduction of a new or alternate provider in the service area

would be a more effective alternative based on the assumption that increased patient choice would encourage all providers in the service area to improve quality and/or lower costs for services in order to compete for patients." This assumption is not warranted in this review. As discussed below, patients in most of the service area are and will be closer to UNC facilities in Orange County than to the proposed new facility, such that UNC is not truly a "new or alternate" provider for patients in the service area. Even if it were a "new" provider, furthermore, its project would not cause any other providers to improve quality or lower costs for services. The projected net revenue per procedure – reflecting the costs to patients and payors – is in fact lower in DUHS's application than in UNC's. Similarly, there is no basis for assuming that the addition of a single UNC freestanding imaging location would have any effect on DUHS's nationally recognized high quality services.

Moreover, in this review, DUHS's proposal provides greater efficiency and better access for patients than UNC's. While both applicants are proposing 3.0T MRI scanners, 3.0T scanners are not clinically appropriate or safe for many patients, including those with certain surgical implants, and UNC's proposal would not be able to serve such patients. At DUHS's facility, patients will be scanned on either a 1.5T scanner or a 3.0T scanner as may be more clinically appropriate.

Conformity with Statutory Criteria

UNC's application does not provide reasonable and supported assumptions to satisfy the applicable statutory and regulatory criteria. Key deficiencies are identified below.

Volume Assumptions

In order to demonstrate the need and utilization for its project, UNC assumes, without support, that it will attract a third of all new MRI volume generated by Durham County patients. This assumption is unreasonable and unsupported for the following reasons.

- UNC's claim that with just one of 17 fixed scanners in the service area, it will capture one-third
 of new MRI volume from Durham County patients is not logical. The other providers in Durham
 County are well-respected established providers with robust patient and provider referral bases.
 MRI services are accessed through provider referrals, not directly by patients. In contrast, UNC
 provides no documentation of significant physician referral sources for Durham County patients.
 UNC provides only one letter of support from a single family practice physician located in
 Durham. Its other 10 letters of support all come from physicians in Orange County, where UNC
 operates several existing and approved MRI imaging locations. Even if those 10 providers could
 generate referrals sufficient to utilize an MRI scanner, it is likely that the patients who seek care
 from these Chapel Hill providers would also obtain their imaging services from existing UNC
 locations adjacent to those providers' offices in Chapel Hill rather than traveling back to Durham
 for imaging.
- UNC apparently assumes that it will capture 1/3 of <u>all</u> new Durham County patient MRI scans, making no effort to analyze the percentage of MRI scans among this population that would be provided to inpatients or emergency room patients who could not be served at its proposed facility.

The volume projected for the single MRI at the new UNC facility is unreasonable compared to the Durham County volume that nearby UNC imaging locations currently serve. UNC Hospitals' Orange County locations are closer to many parts of Durham County than the proposed new facility location. The northern parts of Durham County are closer to UNC's Hillsborough campus Even in the "South region" in which the new facility will be located, Jordan High School (zip code 27707) and its surrounding neighborhoods are closer to UNC Imaging on Raleigh Road in Chapel Hill than to the proposed facility. According to the 2024 MRI patient origin reports maintained by DHSR, UNC Hospitals provided only 2731 procedures to Durham County patients – including inpatients, emergency department patients, and scheduled outpatients – on 9 machines across all locations in Orange County in 2023. UNC is not projecting any shift of these patients to the new facility, and instead projects that it will serve an <u>additional</u> 2067 Durham County patients at just one location in Durham. Simply adding one machine to UNC's system complement does not adequately support an assumption that its volume of Durham County outpatients patients will grow so significantly.

UNC's in-migration assumptions are similarly unreasonable. UNC provides no basis for assuming an additional 1378 patients would come to this facility in Durham County, when it is not located near any referring physicians or other clinical services. This would require these patients to drive past other UNC facilities in other counties, as well as other providers in Durham County, just to come to this facility. Without a referring physician base in Durham County that would attract patients from other counties, this is unreasonable.

Patient Origin

UNC also does not adequately document its patient origin assumptions in Section C. It claims that its inmigration assumptions are "based on" other providers in its defined South region, but does not explain how it arrived at the specific figures included. Moreover, its assumptions are internally contradictory: on page 124, UNC claims that the experiences of Emerge-Ortho and Duke Arringdon are inapposite for in-migration due to their locations closer to the other counties, while on page 39 it asserts it will have similar breakdown of in-migration origin as those facilities.

Duplication of Existing Services

In Section G on page 90, UNC claims that it will not unnecessarily duplicate existing services in part because "the facility's proximity to the approved but not yet developed UNC Hospitals-RTP community hospital enable UNC Durham County Imaging and its parent to offer access to a broader range of imaging services in both a hospital-based and freestanding setting." However, the projected third full project year for the instant MRI project is FY 2030, several years <u>before</u> the hospital is even projected to open in FY 2033 (see application filed in J-12509-24). Any assertion that the hospital to be opened several years in the future will have an effect on the need or utilization of UNC's proposed project beginning in 2026 is irrational at best. Furthermore, to the extent that UNC <u>also</u> plans to develop hospital-based MRI services in Durham, its assumptions about the percentage of Durham County patients it would capture at the proposed MRI facility would be even more reasonable.

Payor mix

UNC bases its payor mix on its existing UNC Durham County patient outpatient mix. However, this mix would apparently include emergency outpatient MRI procedures, as well as pediatric procedures. UNC's Durham County facility will not serve emergency department patients, and it is unlikely to serve significant pediatric patients, who typically are treated in hospital settings due to their specific needs. Both of these populations typically have a very different payor mix than scheduled adult outpatients, especially in terms of self-pay and Medicaid utilization. Therefore, this payor mix is unreliable.

This faulty assumption is highlighted by other choices UNC makes in its application. In Form F.2, UNC bases its revenue projections on the outpatient UNC Imaging location on Raleigh Road, an outpatient facility that is close to the "South" region in Durham. See Assumptions, page 132. This facility will have a much more similar patient/procedure mix as the proposed facility than UNC Hospitals' experience at its inpatient facilities. UNC does not explain why it would use that locations for revenue projections but not for payor mix projections.

Conclusion

For all the foregoing reasons, UNC's application is not conforming with applicable criteria, is not comparatively superior to the other application in this review, and should be disapproved.