Comments of Alliance HealthCare Services, Inc. on the Petition of Raleigh Radiology, LLC for an Adjusted Need Determination for an MRI Scanner

I. Alliance Supports the Standard Need Methodology

Alliance HealthCare Services, Inc. ("Alliance") supports the Standard Methodology which shows the nearly twenty-five (25) fixed equivalent MRI scanners already in Wake County are performing over four thousand (4,000+) procedures *below* what is necessary to trigger need determination for a new fixed MRI scanner in the 2020 Plan. Despite its sweeping claims (and numerous inaccuracies), the Raleigh Radiology, LLC ("Raleigh Radiology") Petition never questions the correctness and completeness of the data which, in accordance with proper application of the Standard Methodology, shows no need for a fixed MRI scanner for Wake County. The Raleigh Radiology Petition fails to show any basis for departing from the Standard Methodology.

The crux of the Raleigh Radiology Petition for an adjusted need is its claim that Raleigh Radiology wants to replace Alliance's contracted service to reduce Raleigh Radiology's cost of providing MRI services. The State Plan recognizes that, *in response to a need determination*, a CON applicant can argue it wants to replace a contracted service to reduce cost; however, that argument is only properly advanced in response to an existing need determination.

The lone argument that a provider wants to replace a contracted service has **NEVER** sufficed for approval of an adjusted need determination for an MRI. When Person Memorial Hospital requested an adjusted need for an MRI in the 2014 Plan, its Petition focused on the fact that 75% of patients were traveling out of county for scans due to limited scanner availability. When Dosher Memorial requested an adjusted need for an MRI in the 2016 Plan, its Petition centered on classification of the Dosher scanner, distance to treatment, and cost to transport hospitalized patients. When Raleigh Radiology sought an adjusted need for an MRI in the 2016 Plan, its Petition illustrated that total Wake County scans would exceed the threshold for a need

determination. A "special" need determination is only appropriate in response to a "special" circumstance. Not only has Raleigh Radiology failed to articulate such a circumstance in its Petition, its Petition actually documents that it is one of many providers utilizing a vendor contract for MRI services – the <u>opposite</u> of a special circumstance.

The Instructions in the State Plan require a showing that "adverse effects on the population" of the affected area" are likely to ensue absent the adjustment. Raleigh Radiology's Petition is self-defeating because it admits Raleigh Radiology already offers "extended hour schedules" and the "lowest comprehensive prices" in Wake County. Raleigh Radiology Petition, p. 5. Raleigh Radiology repeatedly admits that, even without an adjusted need, the population of the affected area has good financial and geographic access to MRI services. When the population of the affected area is already well-served, a Petition focused solely on bettering Raleigh Radiology's bottom-line does NOT present a bona fide basis for an adjusted need.

A. Adjusted Need is Not Properly Based on Scanners Per Capita

A need determination is not properly based on the number of scanners per capita in a service area. Raleigh Radiology Petition, pp. 2-3. Recognizing need on this basis would ignore the most salient fact: the number of procedures performed per scanner in the service area. Even assuming Wake County has fewer scanners per capita as compared to other service areas (such as Mecklenburg and Durham Counties), that comparison alone is not a logical basis for finding need. Not all service area populations require MRI scans at the same rates. Raleigh Radiology's comparison of number of MRI scanners per person offers no reason to identify a special need determination when procedures per scanner in Wake County do not show need.

B. Adjusted Need is Not Properly Tied to the Number of Alliance Scanners

Many years ago, Alliance became the first national provider of shared imaging services to receive accreditation from The Joint Commission. Alliance is now one of the nation's largest and most successful healthcare services organizations and a leader in providing essential services and exceptional care in radiology services. Although Alliance proudly offers access to quality

diagnostic imaging services in North Carolina (and many other States), the extent to which various areas are served by Alliance-owned scanners is irrelevant.¹ On the one hand, Raleigh Radiology argues about the extent to which Alliance has multiple scanners in operation in North Carolina while, on the other hand, it argues there are too few scanners in Wake County such that the State needs to recognize the need for one more. The Raleigh Radiology Petition arguments are either illogical or simply irrelevant to the appropriate analysis of need for a new scanner in Wake County.

II. Raleigh Radiology's Petition does Not Demonstrate a Proper Basis for its Proposed Adjustment

A. An Adjusted Need Cannot be Based on an Unsubstantiated Notion that Raleigh Radiology will be Forced to Raise its Patient Charges in the Future

Raleigh Radiology claims to offer patients in the affected area the "lowest comprehensive MRI prices." It obviously does so while paying Alliance for equipment and staff, including, when necessary, overtime charges for after-hours staff. Raleigh Radiology Petition, p. 5. And, by its own admission, Raleigh Radiology's contract with Alliance includes only modest CPI-based annual increases.² While Raleigh Radiology states its contract with Alliance ends in 2020, Raleigh Radiology has already willingly extended its agreement with Alliance through November of 2022.³ As such, nothing supports the notion that, absent an adjusted need, Raleigh Radiology would be forced in the future to dramatically inflate charges for MRI services for the population of the

¹ Alliance has 24, not 26, grandfathered MRI scanners that can be used as fixed or mobile units in North Carolina; Alliance has 4 MRI scanners that are CON-approved as mobile units which must move weekly to serve at least two sites. Two of Alliance's fixed MRI units are jointly-held installed units. Alliance also leases MRI scanners to facilities that hold CON approvals. The Proposed 2020 SMFP shows that Raleigh Radiology uses MRI scanners provided not only by Alliance but also by Foundation Health Mobile Imaging and Pinnacle Health Services. Alliance scanners operate in accordance with North Carolina CON Law, not per a "loophole."

² In fact, Alliance did not impose any CPI increase in 2016 or 2017. The price paid by Raleigh Radiology to Alliance for use of the scanner at the Blue Ridge location went <u>down</u> between 2014 and 2016. Raleigh Radiology's Cary location also had a similar price reduction.

³ When Raleigh Radiology renewed its contract with Alliance in 2016, Alliance <u>reduced</u> monthly fees at both Raleigh Radiology locations, while adding provisions to accommodate the potential that Raleigh Radiology might obtain its own fixed MRI CON. Instead of opposing Raleigh Radiology when it proposed to obtain a CON, Alliance offered to joint venture. No one at Alliance recalls any offer by Raleigh Radiology to buy an Alliance MRI scanner.

affected area. Raleigh Radiology has never claimed to be experiencing any loss on its MRI service, or that it will need to increase charges to remain viable.

B. An Adjusted Need is Not Properly Grounded on Vague and/or Disputed Complaints about the Equipment and Staff furnished by Alliance

The Raleigh Radiology Petition is filled with loose references and comments regarding Alliance's "11-year old . . . equipment" and "inflexible" staff schedules. These attempts to paint a negative picture of the cost and the quality of the Alliance service are belied by the facts. For instance, in Cary, Raleigh Radiology has routinely given Alliance customer satisfaction scores of 100% since at least the fourth quarter of 2017. Alliance works with Raleigh Radiology and its other clients on quality management, staffing and cost containment. Alliance made a reduction in overtime rates to allow Raleigh Radiology to more affordably increase hours at its locations. By agreement, Alliance has spent hundreds of thousands of dollars on multiple equipment upgrades. Between 2012 and 2015, Alliance spent \$297,000 on equipment upgrades, but Raleigh Radiology saw no price increase as a result of these expenditures. And, Alliance increased staffing for Raleigh Radiology, moving from a technologist and patient care coordinator to two technologists, without a price increase. Raleigh Radiology has consistently – and happily – worked with an Alliance technologist for the last twelve-and-a-half years and recently honored her with a baby shower.

Raleigh Radiology cannot claim the population of the affected area will be adversely affected without a need determination that allows Raleigh Radiology to buy a new MRI scanner. An 11-year old MRI scanner can be expected to have several more years of strong useful life. GE Healthcare reports that only about half of installed MRI scanners will be replaced within 11 years of installation. An MRI scanner can be replaced in three years or operate for over twenty-two years. According to GE, about 20% of scanners are older than 10 years. Raleigh Radiology

⁴ Alliance absorbed the approximately \$125,000 per year in extra payroll costs to transition to this model without passing any of those costs along to Raleigh Radiology.

provides no statistics on the age of the scanners in use across North Carolina and offers nothing to support the notion that a scanner should automatically be retired at age 11. Raleigh Radiology specifically chose the Espree unit and, at Raleigh Radiology's request, this is the unit Alliance provides. The unit at Raleigh Radiology is American College of Radiology (ACR) accredited and Alliance is Joint Commission accredited at the Raleigh Radiology sites. In fact, due to Alliance's experience and expertise, Raleigh Radiology implemented certain Alliance quality policies after indicating Raleigh Radiology did not have the same level of sophistication as Alliance.

That a scanner at Raleigh Radiology had a recent repair need is hardly a basis to jump to the conclusion that the scanner must be scrapped in favor of new equipment to properly serve the population of the affected area. When the Alliance unit experienced an issue, Alliance had another unit in place within 24 hours. The unit Alliance brought in was a one-year-old wide-bore high-end unit. Alliance received positive feedback on the unit from the Raleigh Radiology radiologists. Alliance is left to speculate over what the Raleigh Radiology Petition means when it represents that this temporary replacement unit had its "own problems;" Raleigh Radiology fails to articulate any basis for this statement. Even before the recent equipment issue, Alliance offered to discuss the timing of a future equipment replacement; Alliance works with Raleigh Radiology to consistently manage quality. Yet, instead of fairly describing Alliance's prompt response to an equipment issue and Alliance's dependable client-service efforts, the Raleigh Radiology Petition uses sensationalized descriptions contrary to the facts.

III. The Raleigh Radiology Petition Does Not Meet Petition Requirements

The Raleigh Radiology Petition fails to properly address the requirements for a conforming Petition for a Need Determination Adjustment:

A. Failure to Properly Address Alternatives

The Raleigh Radiology Petition speaks to the "risk" associated with filing a potentially competitive 2019 CON application in response to the identified need determination for a new MRI for Wake County but conspicuously fails to state whether it will in fact apply. Raleigh Radiology

Petition, p. 8. As a result, the Raleigh Radiology Petition for a 2020 Adjusted Need Determination appears to be a hedge against the potential that Raleigh Radiology will yet again be incapable of presenting a conforming and comparatively superior CON Application for an MRI scanner in 2019 when vying against other applicants on a level playing field. The Raleigh Radiology Petition seeks to change the rules by placing limits on the potential applicant pool for a CON for a new MRI scanner in 2020.⁵ Instead of committing to pursue the already-announced 2019 CON Application filing opportunity for a new Wake County MRI, Raleigh Radiology appears to be using the Petition process to attempt to better its odds in a future review in which it will seek the very same equipment it could pursue in 2019. Its Petition fails to properly address the 2019 CON alternative.

The Raleigh Radiology Petition is likewise vague as to the status of its 2016 CON Application. On May 7, 2019, the Court of Appeals affirmed the 2016 decision of the Agency to award the MRI CON to Duke University Health System instead of to Raleigh Radiology. Raleigh Radiology LLC v. N.C. Dep't of Health & Human Servs., 827 S.E.2d 337, 341 (N.C. App. 2019). On August 6, 2019, after the Raleigh Radiology Petition was filed, the Court of Appeals issued a superseding opinion, Raleigh Radiology LLC v. N.C. Dep't of Health & Human Servs., No. COA18-785.2 (N.C. App. 2019) (attached as Exhibit A), which reconsidered the appeal at Raleigh Radiology's request but reached the same result. Raleigh Radiology presumably considers the case "unresolved" based on its ability to pursue discretionary review or other relief at the North Carolina Supreme Court. To that end, it is still possible Raleigh Radiology could be awarded a CON if the Supreme Court reversed the Court of Appeals' decision. If the case over the 2016 MRI CON remains, as the Raleigh Radiology Petition describes it, "unresolved," its Petition also fails to meaningfully address this alternative.

⁵ Raleigh Radiology cherry-picks the facts that suit it best when describing its purported disadvantage in a competitive review. For instance, on page 4 of its petition, it states that it declined to apply pursuant to the MRI need in 2005 because it "did not have the history to compete for it." Then, in its oral remarks offered in support of its petition, Raleigh Radiology laments that the CON review process will favor "a new vendor with no history."

B. Failure to Address "Unnecessary Duplication" of Services

The Raleigh Radiology Petition is required to provide evidence that the scanner purchase contemplated by the proposed adjustment will not result in unnecessary duplication. If Raleigh Radiology receives CON approval to acquire a new scanner and discontinues its use of the unit provided by Alliance, the Alliance scanner could nonetheless remain in use at another location in Wake County. In fact, Raleigh Radiology's Petition does not actually commit to giving up any of the MRI scanners that Raleigh Radiology uses through contracts with Alliance, Foundation Health and Pinnacle Health. The Raleigh Radiology Petition fails to address the potential for unnecessary duplication inherent in its request for a proposed adjustment.

C. Failure to Address the SMFP Basic Principles

Raleigh Radiology's Petition fails to conform with the State Plan's Basic Principles. For instance, Raleigh Radiology's lone statement as to Safety and Quality is a remark about bringing in an option for an ACR accredited provider. As noted above, Alliance's unit at Raleigh Radiology is ACR accredited and Alliance is Joint Commission accredited. Raleigh Radiology does not demonstrate that, if approved, its proposal for a new MRI scanner would reduce any economic, time or distance barriers or promote access. Indeed, Raleigh Radiology projects serving the same population it currently serves, in the same location it currently serves them – a far cry from increasing access. Raleigh Radiology has a contract with Alliance through late 2022 and no basis to forecast any future shifts in patient charges. It will not suddenly begin serving higher proportions of Medicare, Medicaid, and private pay patients. The failure to tie the pursued special need adjustment to the State Plan's Basic Principles should render Raleigh Radiology's effort fatal.

Conclusion

Raleigh Radiology already secures comprehensive levels of MRI access from Alliance and has reported 100% satisfaction with those services over multiple years. The Raleigh Radiology Petition is riddled with mischaracterizations, inaccuracies and claims that simply do not support

an adjusted need determination that runs contrary to an appropriate application of the Standard Methodology. And, there is a need determination for a fixed MRI in the 2019 Plan that Raleigh Radiology could elect to pursue. For these reasons, Alliance opposes the Raleigh Radiology Petition for an adjusted need determination for an additional fixed MRI in the 2020 Plan.

IN THE COURT OF APPEALS OF NORTH CAROLINA

No. COA18-785-2

Filed: 6 August 2019

Office of Administrative Hearings, No. 17 DHR 04088

RALEIGH RADIOLOGY LLC d/b/a RALEIGH RADIOLOGY CARY, Petitioner,

V.

N.C. DEPARTMENT OF HEALTH AND HUMAN SERVICES, DIVISION OF HEALTH SERVICE REGULATION, HEALTH CARE PLANNING & CERTIFICATE OF NEED, Respondent,

and

DUKE UNIVERSITY HEALTH SYSTEM, Respondent-Intervenor.

Appeal by Respondents and cross-appeal by Petitioner from an amended final decision entered 16 March 2018 by Judge J. Randolph Ward in the Office of Administrative Hearings. Heard originally in the Court of Appeals 13 March 2019. This matter was reconsidered in the Court pursuant to an order allowing Petitioner's Petition for Rehearing. This opinion supersedes the opinion *Raleigh Radiology v. NC DHHS*, No. 18-785, ____ N.C. App. ____, 827 S.E.2d 337 (2019), previously filed on 7 May 2019.

Brooks, Pierce, McLendon Humphrey & Leonard, L.L.P., by James C. Adams, II, for Petitioner Raleigh Radiology LLC.

Attorney General Joshua H. Stein, by Assistant Attorney General Bethany A. Burgon, for Respondent N.C. Department of Health and Human Services, Division of Health Service Regulation, Health Care Planning & Certificate of Need.



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Poyner Spruill LLP, by Kenneth L. Burgess, William R. Shenton, and Matthew A. Fisher, for Respondent-Intervenor Duke University Health System.

DILLON, Judge.

Petitioner Raleigh Radiology LLC ("Raleigh") and Respondents N.C. Department of Health and Human Services, Division of Health Care Regulation, Healthcare Planning and Certificate of Need (the "Agency"), and Duke University Health System ("Duke") all appeal a final decision of the Office of Administrative Hearings ("OAH") regarding the award of a Certificate of Need ("CON") for an MRI machine in Wake County.

I. Background

In early 2016, the Agency determined a need for a fixed MRI machine in Wake County and began fielding competitive requests. In April 2016, Duke and Raleigh each filed an application for a CON with the Agency.

Section 131E-183 of our General Statutes sets forth the procedure the Agency should use when reviewing applications for a CON. N.C. Gen. Stat. § 131E-183 (2016). The Agency uses a two stage process: First, the Agency reviews each application independently to make sure that it complies with certain statutory criteria. See Britthaven, Inc. v. N.C. Dep't of Human Res., 118 N.C. App. 379, 385, 455 S.E.2d 455, 460 (1995) (citing N.C. Gen. Stat. § 131E-183(a)). Typically, if only one application is found to have complied with the statutory criteria, that applicant

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is awarded the CON. But if more than one application complies, the Agency moves to a second step, whereby the Agency conducts a comparative analysis of the compliant applications. *Britthaven*, 118 N.C. App. at 385, 455 S.E.2d at 461.

In the present case, the Agency approved Duke for the CON, denying Raleigh's application, on two alternate grounds. First, the Agency determined that Duke's application alone was compliant. Alternatively, the Agency conducted a comparative analysis, assuming *both* applications were compliant, and determined that Duke's application was superior.

In October 2016, Raleigh filed a Petition for Contested Case Hearing. After a hearing on the matter, the administrative law judge (the "ALJ") issued a Final Decision, determining that both applications were compliant *but that*, based on its own comparative analysis, Raleigh's application was superior. Accordingly, the ALJ reversed the decision of the Agency and awarded the CON to Raleigh.

Duke and the Agency timely appealed. Raleigh also timely cross-appealed.

II. Standard of Review

We review a final decision from an ALJ for whether "substantial rights of the petitioners may have been prejudiced[.]" N.C. Gen. Stat. § 150B-51(b) (2018). We use a *de novo* standard if the petitioner appeals the final decision on grounds that it violates the constitution, exceeds statutory authority, was made upon unlawful procedure, or was affected by another error of law. N.C. Gen. Stat. § 150B-51(b)(1)-

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(4), (c) (2018). And we use the whole record test if the petitioner alleges that the final decision is unsupported by the evidence or is "[a]rbitrary, capricious, or an abuse of discretion." N.C. Gen. Stat. § 150B-51(b)(5)(6), (c) (2018).

III. Analysis

On appeal, Duke and the Agency argue that the ALJ erred in reversing the Agency's decision. Though successful in its appeal before the ALJ, Raleigh cross-appeals certain aspects of the ALJ's decision and with the process in general. We address the issues raised in the appeal and cross-appeal below.

A. ALJ's Finding that Duke's Application Conformed

We first address Raleigh's cross-appeal challenge to the ALJ's finding that Duke's application complied with the Agency criteria. That is, though the ALJ awarded Raleigh the CON based on a determination that Raleigh's compliant application was superior to Duke's compliant application, Raleigh contends that the ALJ should have determined that Duke's application was not compliant to begin with. Specifically, Raleigh contends that Duke did *not* conform with Criteria 3, 5, 12, and 13(c) found in Section 131E-183(a). For the following reasons, we disagree.

We review this argument under the whole record test, N.C. Gen. Stat. § 150B-51(b)(5)(6), (c), and properly "take[] into account the administrative agency's expertise" in evaluating applications for a CON. *Britthaven*, 118 N.C. App. at 386, 455 S.E.2d at 461.

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A review of the whole record reveals that the evidence presented by Duke in its CON application, the Agency hearings, and the Office of Administrative Hearings amounts to substantial evidence of Duke's compliance with the review criteria.

In conformity with Criteria 3, Duke "identif[ied] the population to be served by the proposed project, and . . . demonstrate[d] the need that this population has for the services proposed, and the extent to which all residents of the area . . . are likely to have access to the services proposed." N.C. Gen. Stat. § 131E-183(a)(3). More specifically, in its application, Duke illustrated the current levels of accessibility to MRI scanners in Wake County and identified the location of its proposed MRI, the Holly Springs/Southwest Wake County area, as one in need of increased access to scanners, particularly due to its rapidly growing population. Duke also laid out the current travel burdens faced by Wake County residents in the Duke Health System who require access to an MRI scanner and how the addition of a new MRI scanner in its proposed location could have a favorable impact on those geographic burdens. Duke coupled those factors with the historically consistent utilization rate for MRIs in Wake County to demonstrate the need in the area for the MRI scanner.

In conformity with Criteria 5, Duke provided financial and operational projections that demonstrated "the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal[.]" N.C. Gen. Stat. § 131E-183(a)(5). For example, Duke set forth the anticipated source

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of financing for the project, with all the funding projected to be drawn from its accumulated reserves. Duke also provided five-year projections for its financial position and income statements, as well as three-year projections for the revenues to be produced by the new MRI scanner. The Chief Financial Officer of Duke also certified the existence and availability of funding for the project and referenced Duke's most recent audited financial statement to demonstrate the availability of such funds.

Duke also conformed with Criteria 12 by delineating that the construction "cost, design, and means" were reasonable by comparing its proposed project with potential alternatives. N.C. Gen. Stat. § 131E-183(a)(12). Essentially, Duke compared its proposal to potential alternatives, including maintaining the status quo, developing the proposed MRI scanner in a different location, developing a mobile MRI service in Holly Springs, and pursuing the current project.

Lastly, Duke conformed with Criteria 13(c) by "demonstrat[ing] the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups . . . [and] show[ing] [t]hat the elderly and the medically underserved groups identified in this subdivision will be served by [its] proposed services and the extent to which each of these groups is expected to utilize the proposed services[.]" N.C. Gen. Stat. § 131E-183(a)(13)(c). Duke demonstrated that it expects almost one-third (1/3) of its patients to be

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Medicare or Medicaid recipients and that it has the support of community programs, which help in providing healthcare access to low-income, uninsured residents of Wake County. In addition, Duke provided statistics regarding its interactions with female and elderly patients, along with its policy of non-discrimination against handicapped persons. Using this data, Duke asserted that these kinds of patients will receive the same access to the new MRI scanner at the Holly Springs location.

In accordance with our previous holdings in CON cases, this Court "cannot substitute our own judgment for that of the Agency if substantial evidence exists." *Total Renal Care of N.C., LLC v. N.C. Dep't of Health & Human Servs.*, 171 N.C. App. 734, 739, 615 S.E.2d 81, 84 (2005). Indeed, Duke met this threshold by putting forth the aforementioned evidence; and the Agency is entitled to deference, as Duke put forth substantial evidence of its conformity with these criteria. Thus, we affirm the ALJ's finding of fact number 24 that Duke's application was compliant.

B. Comparative Analysis Review

Duke and the Agency argue that the ALJ erred in conducting its own comparative analysis review of the two CON applications. That is, they argue that the ALJ should have given deference to the Agency' determination that Duke's application was superior. We review this question of law *de novo*. *Cumberland Cty*. *Hosp. Sys. v. N.C. Dep't of Health & Human Servs.*, 242 N.C. App. 524, 527, 776 S.E.2d 329, 332 (2015).

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Our Court has held that where the Agency compares two or more applications which otherwise comply with the statutory criteria, "[t]here is no statute or rule which requires the Agency to utilize certain comparative factors." Craven Reg'l Med. Auth. v. N.C. Dep't of Health & Human Servs., 176 N.C. App. 46, 58, 625 S.E.2d 837, 845 (2006) (emphasis added). But, rather, the Agency has discretion to determine factors by which it will compare competing applications. Id.

However, the ALJ on appeal of an Agency decision does not have this same discretion to conduct a comparative analysis. That is, where an unsuccessful applicant appeals an Agency decision in a CON case, the ALJ does not engage in a de novo review of the Agency decision, but simply reviews for correctness of the Agency decision, pursuant to N.C. Gen. Stat. § 150B-23(a). E. Carolina Internal Med., P.A. v. N.C. Dep't of Health & Human Servs., 211 N.C. App. 397, 405, 710 S.E.2d 245, 252 (2011). Indeed, "there is a presumption that 'an administrative agency has properly performed its official duties.' " Id. at 411, 710 S.E.2d at 255 (quoting In re Cmty. Ass'n, 300 N.C. 267, 280, 266 S.E.2d 645, 654 (1980)).

In the present case, the Agency reviewed Duke's application and Raleigh's application for the CON independently. *Britthaven*, 118 N.C. App. at 385, 455 S.E.2d at 460 (citing N.C. Gen. Stat. § 131E-183(a)). This review revealed that Duke's application conformed with all criteria and that Raleigh failed to conform with respect to certain criteria. At that point, assuming that Raleigh's application indeed failed

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to conform to certain criteria, it would have been appropriate for the Agency to proceed with issuing the CON to Duke. Nevertheless, the Agency, as stated in its seventy-four (74) pages of findings, additionally "conducted a comparative analysis of [Duke's and Raleigh's applications] to decide which [one] should be approved," assuming that Raleigh's application did satisfy all of the criteria. *See id.* at 385, 455 S.E.2d at 461.

The Agency, in its discretion, used seven comparative factors in reviewing the CON applications: (1) geographic distribution, (2) demonstration of need, (3) access by underserved groups, (4) ownership of fixed MRI scanners in Wake County, (5) projected average gross revenue per procedure, (6) projected average net revenue per procedure, and (7) projected average operating expense per procedure. This comparative analysis led the Agency to approve and award the CON to Duke.

However, on appeal to the OAH, the ALJ deviated from the above factors by considering two additional factors: (1) the types of scanners proposed by each applicant, and (2) the timeline of each proposed project. Admittedly, there was evidence that Raleigh's proposed MRI machine was superior to the machine which Duke would use. It is this deviation and the reliance on additional comparative factors by the ALJ which we must conclude was error.

Indeed, adding two additional comparative factors is not affording deference to the Agency, but rather constitutes an impermissible *de novo* review of this part of the

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Agency's decision. Such a substitute of judgment by the ALJ is not allowed. E. Carolina Internal Med., 211 N.C. App. at 405, 710 S.E.2d at 252.

Evidence was provided that the factors utilized by the Agency have been used in two previous MRI CON decisions and that the additional factors used by the ALJ have not been a part of the Agency's policies and procedures for many years. We note that information pertaining to Raleigh's allegedly superior MRI machine was not included in Raleigh's application, though it was otherwise presented at the Agency public hearing, but without an expert testifying as to the machine's medical efficacy. Even so, the Agency has the discretion to pick which factors it evaluates in conducting its own comparative analysis. Craven Reg'l Med. Auth., 176 N.C. App. at 58, 625 S.E.2d at 845. Further, regarding the timeline factor used by the ALJ, there was testimony that the Agency puts little, if any, weight to this factor as the factor disadvantages new providers. The ALJ did not determine that the Agency acted arbitrarily and capriciously, but rather simply substituted his own judgment in weighing the factors. We cannot say, though, that the Agency abused its discretion to rely on the factors that it did. Therefore, we conclude that the ALJ exceeded its authority conducting a *de novo* comparative analysis of the competing applications.

Separately, Raleigh argues that the Agency erred by concluding that its application was not conforming. But even assuming that the Agency incorrectly made a determination that Raleigh's application did not conform to certain statutory

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criteria, such error was harmless: the Agency proceeded with a comparative analysis of both applications as if Raleigh's application did comply and, in its discretion, determined that Duke's application was superior.

Therefore, we reverse the Final Decision and reinstate the decision of the Agency.¹

C. Motion in Limine – Spoliation of Evidence

In its cross-appeal, Raleigh argues that the ALJ erred in denying its motion in limine to apply adverse inference based on Duke's alleged spoliation of certain evidence. We disagree.

"[W]hen the evidence indicates that a party is aware of circumstances that are likely to give rise to future litigation and yet destroys potentially relevant records without particularized inquiry, a factfinder may reasonably infer that the party probably did so because the records would harm its case." *McLain v. Taco Bell Corp.*, 137 N.C. App. 179, 187-88, 527 S.E.2d 712, 718, *disc. rev. denied*, 352 N.C. 357, 544 S.E.2d 563 (2000). This inference is a permissible adverse inference. *Id.* "To qualify for [an] adverse inference, the party requesting it must ordinarily show that the spoliator was on notice of the claim or potential claim at the time of the destruction."

¹ We note that additional arguments were made on appeal. For instance, Duke and the Agency contend that Raleigh did not establish substantial prejudice and that the Final Decision was incomplete and untimely by thirty-seven (37) minutes. However, in light of the ALJ's comparative analysis error and our subsequent reversal of the Final Decision, we need not address these arguments.

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McLain, 137 N.C. App. at 187, 527 S.E.2d at 718 (internal citations omitted). However, "[i]f there is a fair, frank and satisfactory explanation" for the absence of the documents, an adverse inference will not be applied. Yarborough v. Hughes, 139 N.C. 199, 211, 51 S.E. 904, 908 (1905).

In the present case, Duke contracted with a third-party consultant, ("Keystone"), to perform and draft its CON application. Keystone's practice is to discard all useless documentation and application references so as to keep only relevant, accurate applications and data. This practice is consistent with most consultants in this field, it is not disputed, and amounts to "a fair, frank and satisfactory explanation[.]" *Id*.

Moreover, as Duke and the Agency correctly point out, these documents would not be the subject of review or an appeal. Rather, the ALJ's review of the Agency's decision is limited to its seventy-four pages of findings and conclusions. We conclude that the ALJ did not err in not applying an adverse inference based on the absence of certain documents.

IV. Conclusion

The ALJ erred in not deferring to the comparative analysis performed by the Agency and conducting its own comparative analysis. However, the ALJ did not err in finding and concluding that Duke conformed with the applicable review criteria nor in not applying an adverse inference against Duke regarding certain information.

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Thus, we reverse the Final Decision and reinstate and affirm the decision of the Agency awarding the CON to Duke.²

REVERSED.

Judges BRYANT and ARROWOOD concur.

² We acknowledge Raleigh's motion for leave to file a supplemental brief regarding the ALJ's authority to remand a contested case to the Agency. We deny this motion as our resolution has rendered such an issue moot.