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IN THE COURT OF APPEALS OF NORTH CAROLINA

No. COA22-1008

Filed 05 September 2023

N.C. Office of Administrative Hearings, No. 22 DHR 415

WR IMAGING, LLC, and
WAKE RADIOLOGY DIAGNOSTIC IMAGING, INC., Petitioners,

v.

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

and

RALEIGH RADIOLOGY, LLC, Respondent-Intervenor.

Appeal by petitioners from decision entered 8 August 2022 by Administrative
Law Judge Michael Byrne in the N.C. Office of Administrative Hearings. Heard in
the Court of Appeals 23 May 2023.

Charles George, Frank S. Kirschbaum, and J. Blakely Kiefer, for Appellants.

*James C. Adams, II, Forrest W. Campbell, Jr., and Katrina K. Wong, Brooks,
Pierce, McLendon, Humphrey & Leonard, L.L.P. for Respondent-Intervenor.*

*Attorney General Joshua Stein by Special Deputy Attorney General Derek L.
Hunter, for Appellee.*

DILLON, Judge.

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WR Imaging, LLC, and Wake Radiology Diagnostic Imaging, Inc., (collectively the “Appellants”) appeal the decision of the N.C. Office of Administrative Hearings (“OAH”) denying their application to fix an MRI scanner in Wake County.

I. Background

In 2019, the State Medical Facilities Plan (“SMFP”) determined that a service area in Wake County needed a fixed MRI scanner. Six applicants, including WR Imaging, Wake Radiology, and Raleigh Radiology, LLC, applied for a Certificate of Need (“CON”).

The following year, in April 2020, our Department of Health and Human Services (the “Agency”) denied Appellants’ application and approved Raleigh Radiology’s application based on its finding that Raleigh Radiology’s application conformed with the applicable criteria and performance standards. The Agency found that Wake Radiology’s application was non-approvable because it did not comply with Criteria (3), (4), and (5) of N.C. Gen. Stat. § 131E-183 and performance standards in 10A NCAC 14C.2703. Appellants challenged the Agency’s decision by filing a Petition for a Contested Case Hearing in the OAH.

On 8 August 2022, after a hearing on the matter, Administrative Law Judge Michael Byrne (“ALJ Byrne”). upheld the Agency’s decision awarding the CON to Raleigh Radiology.

ALJ Byrne also affirmed the Agency’s decision that Wake Radiology’s application did not conform with N.C. Gen. Stat. §§ 131E-183(a)(3), (4), and (5)

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because Appellants used data from March through August 2019 in determining their utilization projections. The Agency found it unreasonable for Appellants to retroactively apply data from March 2019 through August 2019 to January and February 2019 because it created a “manipulated representation of its own history” as it “did not use data reflecting the number of scans performed by the fixed scanner at its Cary location in January, February, or September of 2019.” ALJ Byrne also concluded that Appellants “calculated a growth rate from a pre-joint-venture number of scans in 2016 to a post-joint-venture number of scans in 2019 to calculate its compound annual growth rate of four (4) percent for the fixed scanner at Cary.”

Finally, the Agency and ALJ Byrne found Wake Radiology’s application nonconforming with the Agency’s performance standards for MRIs. Wake Radiology was required to show that the existing MRI scanners “performed an average of 3,328 weighted MRI procedures in the most recent 12-month period for which the applicant has data” 10 NCAC 14C.2703(b)(1). The Agency and ALJ Byrne concluded the Rule applied to Wake Radiology’s application and found it nonconforming because it failed to demonstrate it did not have access to data for the most recent 12-month period. ALJ Byrne explained that the Agency was entitled to deference because “[its] interpretation of the Rule is reasonable.” WR Imaging and Wake Radiology appeal.

II. Standard of Review

Our General Statutes provide that:

The court reviewing a final decision may affirm the

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decision or remand the case for further proceedings. It may also reverse or modify the decision if the substantial rights of the petitioners may have been prejudiced because the findings, inferences, conclusions, or decisions are:

- (1) In violation of constitutional provisions;
- (2) In excess of statutory authority or jurisdiction of the agency or administrative law judge;
- (3) Made upon unlawful procedure;
- (4) Affected by other error or law;
- (5) Unsupported by substantial evidence . . . in view of the entire record as submitted; or
- (6) Arbitrary, capricious, or an abuse of discretion.

N.C. Gen. Stat. § 150B-51(b) (2021). Appealed errors under subsection (1) through (4) are assessed *de novo*, and errors under subsections (5) and (6) are assessed using *the whole record test* standard of review. N.C. Gen. Stat. § 150B-51(c) (2021) (emphasis added). Under this whole record test standard, this Court assesses evidence in the whole record to determine whether the Agency's decision is supported by "substantial evidence" which is "such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." *Parkway Urology v. N.C. Dep't of Health and Hum. Servs.*, 205 N.C. App. 529, 534–35, 696 S.E.2d 187, 192 (2010).

In making its determination, the Agency considers fifteen review criteria and assesses whether "an application is either consistent with or not in conflict with these criteria before issuing a certificate of need." N.C. Gen. Stat. § 131E-183(a) (2021). The Agency may adopt "rules for the review of particular types of applications that

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will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed.” N.C. Gen. Stat. § 131E-183(b) (2021).

III. Analysis

Appellants make four arguments on appeal, which we address in turn.

A. Raleigh Radiology’s Conformity with Criterion 20

Appellants first claim the ALJ erred by affirming the Agency’s Decision that Raleigh Radiology’s application conformed with Criterion 20. We disagree.

Criterion 20 provides that “[a]n applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.” N.C. Gen. Stat. § 131E-183(a)(20) (2021). We have held that “[b]ecause the General Assembly has not articulated with specificity how the Agency should determine an applicant’s conformity with Criterion 20, the Agency [is] authorized to establish its own standards in assessing whether an applicant that was already involved in providing health care services had provided quality care in the past.” *AH N.C. Owner v. NC DHHS.*, 240 N.C. App. 92, 100–01, 771 S.E.2d 537, 542–43 (2015).

The Agency considers information on a case-by-case basis of quality care provided by the applicant from the 18 months preceding the submission of the application. This information, provided mainly by expert witnesses, extends beyond the services the applicant is seeking to provide and includes evidence of quality care in addition to incidents which demonstrate a lack thereof. The applicant bears the

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burden to disclose such evidence. N.C. Gen. Stat. § 131E-183(a).

In this case, Raleigh Radiology provided documentation about the accreditation of its facilities, quality oversight and review programs, and good-standing with Medicare, Medicaid, and the N.C. Medical Board in the 18-month lookback period. However, it omitted any reference to the loss of its accreditation for mammography at its Blue Ridge facility, which it lost due to insufficient image quality and the loss of its patients' images because of a malfunction within its image storage system. As a result, the ALJ found the Agency erred in its analysis of Criterion 20. However, the ALJ held that this error alone was not enough to reverse the Agency's decision because failing to disclose information of a potential quality care issue does not itself result in an applicant's failure to conform with Criterion 20.

Furthermore, the evidence tended to show that Raleigh Radiology's loss of mammography accreditation was a result of flawed positioning during a single picture and did not tarnish quality of care. The Agency was aware of Raleigh Radiology's loss of accreditation and reaccreditation, prior to its decision, and its reaccreditation demonstrated that this issue had been addressed. As a result of this and other substantial evidence tending to show that Raleigh Radiology provided quality care in the past, the Agency reasonably concluded it satisfied Criterion 20.

Accordingly, we hold that substantial evidence supported the Agency's decision that Raleigh Radiology conformed with Criterion 20.

B. Wake Radiology's Non-Conformity with Criterion 3, 4, and 5

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Appellants contend that the findings that Wake Radiology did not conform with Criteria 3, 4, and 5 were erroneous because it was not obligated to include data not representative of the expected future utilization of the MRI. We disagree. Alternatively, Appellees argue that Appellants' exclusion of data from January, February, and September 2019 produced a grossly overinflated number of scans.

We assess this assignment of error using the whole record test. *See* N.C. Gen. Stat. § 150B-51(b)(5)-(6).

1. Criterion 3

According to our General Statutes:

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.

N.C. Gen. Stat. § 131E-183(a)(3) (2021).

Here, the Agency concluded that Wake Radiology's application was non-conforming with Criterion 3 because its projected annualizations were unreasonably calculated, specifically that allowing an applicant to exclude its lower performing months to report an overinflated growth rate is inconsistent with the statutory purpose of diminishing waste. *See* N.C. Gen. Stat. § 131E-183(a) (2021). Appellants argue that including data from January and February 2019 would unfairly represent the benefits of the joint venture. However, the evidence tended to show that

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Appellants' three-year compound annual growth rate was overinflated due to the omission of data from January, February, and September 2019.

Although an expert in health planning testified that excluding data from January and February 2019 was reasonable, the Agency was concerned that Wake Radiology used more advantageous numbers from March through August 2019 to inflate the numbers because its highest performing months in 2018 occurred March through August. While Wake Radiology determined that the MRI at the Cary location had performed an average of 315 scans per month and would continue to perform an average of 315 scans per month in 2019, testimony uncovered that the fixed scanner never performed a monthly average of 315 scans from September 2018 through February 2019, with the exception of October 2018. Thus, these calculations were skewed.

Accordingly, we hold that substantial evidence supported the Agency's conclusion that Wake Radiology's application did not conform with Criterion 3.

2. Criterion 4

"Where alternative methods of meeting the needs for the proposed project exists, the applicant shall demonstrate that the least costly or most effective alternative has been proposed." N.C. Gen. Stat. § 131E-183(a)(4) (2021).

Here, the Agency concluded that because Wake Radiology's application was non-conforming with Criterion 3, it could not reasonably be considered the "least costly or most effective alternative" as required by § 131E-183(a)(4). It was

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reasonable to conclude that an application based on overinflated projections cannot be considered the “least costly or most effective alternative.” Wake Radiology contends it considered other alternatives such as maintaining the status quo and developing the MRI at another location, but concluded that maintaining the status quo did not allow it to secure adequate fixed MRI capacity to meet the demands of the joint venture. It also would not develop the MRI at another location because Wake Radiology could not guarantee permanent access at its Cary location since the scanner was owned by another company. As a result, the Agency found it was non-conforming with Criterion 4.

Accordingly, we hold that the Agency’s conclusion that Appellants’ application was non-conforming with Criterion 4 was supported by substantial evidence.

3. Criterion 5

“Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.” N.C. Gen. Stat. § 131E-183(a)(5) (2021).

The Agency considers several factors under Criterion 5, such as capital and working capital costs, availability of funds, and financial feasibility of the project.

Here, the Agency concluded that assumptions used by Wake Radiology in preparation of its financial statements were not reasonable nor adequately supported

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because its projected utilization was questionable. The projected revenues and expenses were based, in part, on the projected utilization, which the Agency had already concluded was overinflated. Appellants' only argument to the contrary is that its projections under Criterion 3 were reasonable and adequately supported.

Accordingly, we hold that the Agency's conclusion that Wake Radiology's application did not conform with Criterion 5 was supported by substantial evidence.

C. Wake Radiology's Non-Conformity with Performance Standards

Appellants next contend that the ALJ and the Agency erred by finding that Wake Radiology's application did not conform with the Agency's performance standards. We disagree.

This assignment of error is also reviewed under the "whole record" test. See N.C. Gen. Stat. § 150B-51(c); *E. Carolina Internal Med v. N.C. Dep't of Health and Hum. Servs.*, 211 N.C. App. 397, 418, 710 S.E.2d 245, 259 (2011). Wake Radiology was required to: "(1) demonstrate that the existing fixed MRI scanners which the applicant or a related entity owns a controlling interest in and locates in the proposed MRI service area performed an average of 3,328 weighted MRI procedures in the most recent 12-month period for which the applicant has data[.]" 10 NCAC 14C.2703(b).

Wake Radiology argued that the performance standards did not apply because the two fixed MRI scanners were transferred to WR Imaging in February 2019 when the joint venture began and that, therefore, WR Imaging did not own the scanners

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for a 12-month period. Under the Agency's interpretation, the rule regarding performance standards applies if the applicant is proposing to acquire a fixed MRI scanner and owns a fixed MRI scanner in the service area. If it applies, the Applicant must demonstrate that the MRI scanners it owns in the service area performed an average of 3,328 weighted MRI procedures in the most recent 12-month period for which the applicant has data.

In the instant case, the Agency concluded that the performance standards applied to Wake Radiology and that Wake Radiology's application did not conform with these standards. It further found that Wake Radiology possessed data for the most recent 12-month period relating to the fixed scanners.

The applicant bears the burden to demonstrate it does not have access to data for the most recent 12-month period. Here, Wake Radiology failed to do so. N.C. Gen. Stat. § 131E-183(a). Additionally, the MRIs did not change location; and Wake Radiology continued to operate and manage the MRIs, employ the employees, collect the data, and collect the money. The Agency's interpretation and application is consistent with the statutory purpose of preventing waste. *See* N.C. Gen. Stat. § 131E-183(a) (2021). Thus, the Agency's requirement of performance metrics is entitled to deference. *See Craven Reg'l*, 176 N.C. App. At 58, 625 S.E.2d at 844.

Accordingly, we hold that the Agency did not err by finding that Wake Radiology's application did not conform with its performance standards.

D. Findings that Wake Radiology's Application was Non-Approvable

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Finally, appellants argue that “[a]s a result of the Agency’s decision to approve the unapprovable Raleigh Radiology Application and the failure to approve the Wake Radiology Application that complied with all statutory Criterion and regulations applicable to it, Wake Radiology demonstrated both substantial prejudice as a matter of law and Agency error as required under N.C. Gen. Stat. § 150B-23(a) and N.C. Gen. Stat. § 150B-51(b).” It concludes that because Wake Radiology and Raleigh Radiology are the only parties to this appeal, “Wake Radiology is entitled to be awarded the certificate of need for the MRI scanner for Wake County provided for in the 2019 SMFP.” We disagree for the following reasons.

This assignment of error is reviewed *de novo*. *Parkway Urology*, 205 N.C. App. at 535, 696 S.E.2d at 192 (quoting *NCDR v. Bill Davis Racing*, 205 N.C. App. 35, 42, 684 S.E.2d 914, 920 (2009)).

Despite our conclusion that the Agency did not err by finding Raleigh Radiology’s application conformed with Criterion 20 and in finding Wake Radiology’s application did not conform with statutory standards, assuming, *arguendo*, that the Agency and ALJ erred, Appellants have failed to demonstrate substantial prejudice.

To establish substantial prejudice, a petitioner must provide “specific evidence of harm resulting from the award.” *Parkway Urology, P.A.*, 205 N.C. App. at 539, 696 S.E.2d at 195. Showing that an application was rejected or showing status as an “affected person” under § 131E-188(a) is not enough. *CaroMont Health, Inc. v. NC DHHS*, 231 N.C. App. 1, 5, 751 S.E.2d 244, 248 (2013). Appellants must “provide

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specific evidence of harm resulting from the award of the CON to [a competitor] that went beyond any harm that necessarily resulted from additional . . . competition.” *Parkway*, 205 N.C. App. at 539, 696 S.E.2d at 195.

Here, Appellants argue they were substantially prejudiced by Raleigh Radiology’s receipt of the CON because they “would have had an opportunity to reapply for an MRI sooner if Raleigh Radiology’s erroneous approval was not upheld and the MRI was returned to the SMFP.” As a result, they argue that they have made the requisite showing of substantial prejudice. However, substantial prejudice cannot solely be based on the Agency’s proposed error nor additional competition for the certificate of need. *See CaroMont Health, Inc.*, 231 N.C. App. at 5, 751 S.E.2d at 248. Therefore, Appellants have not demonstrated substantial prejudice. *See Parkway Urology, P.A.*, 205 N.C. App. at 539, 696 S.E.2d at 195.

II. Conclusion

For the reasons set forth above, we affirm the OAH’s decision.

AFFIRMED.

Judges TYSON and CARPENTER concur.

Report per Rule 30(e).