

IN THE COURT OF APPEALS OF NORTH CAROLINA

2021-NCCOA-302

No. COA20-605

Filed 6 July 2021

Office of Administrative Hearings, No. 19 DHR 03066

MOBILE IMAGING PARTNERS OF NORTH CAROLINA, LLC, Petitioner,

v.

NORTH CAROLINA DEPARTMENT OF HEALTH AND HUMAN SERVICES,
DIVISION OF HEALTH SERVICE REGULATION, HEALTHCARE PLANNING
AND CERTIFICATE OF NEED SECTION, Respondent,

and

INSIGHT HEALTH CORP., Respondent-Intervenor.

Appeal by petitioner from final decision entered 20 February 2020 by
Administrative Law Judge William T. Culpepper, III in the Office of Administrative
Hearings. Heard in the Court of Appeals 9 June 2021.

*Wyrick Robbins Yates & Ponton LLP, by Lee M. Whitman and J. Blakely Kiefer,
for petitioner-appellant.*

*Attorney General Joshua H. Stein, by Assistant Attorney General Derek L.
Hunter, for respondent-appellee.*

*Fox Rothschild LLP, by Marcus C. Hewitt and Elizabeth Sims Hedrick, for
respondent-intervenor.*

TYSON, Judge.

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Decision by an Administrative Law Judge (“ALJ”) affirming the decision of the North Carolina Department of Health and Human Services, Division of Health Service Regulation, Healthcare Planning and Certificate of Need Section’s (“DHHS”) decision to approve InSight Health Corps’ (“InSight”) (together, “Respondents”) application for a certificate of need (“CON”) for a mobile PET/CT (“PET”) scanner. This machine combines a positron emission tomography scan and a computerized tomography scan.

¶ 2 Petitioner appealed DHHS’ decision to the Office of Administrative Hearings. In February 2020, the ALJ affirmed and entered a Final Decision for Respondents. Petitioner appeals. We affirm.

I. Background

¶ 3 Petitioner is a joint venture between Alliance HealthCare Services Inc. (“Alliance”) and University of North Carolina Rockingham Health Care, Inc. (“UNC-Rockingham”), a UNC-owned affiliate of the UNC Health Care System. Alliance operates two mobile PET scanners in North Carolina. InSight is a national provider of imaging services and offers mobile PET services in other states. Providers who desire to offer PET services within North Carolina must obtain a CON from DHHS. See N.C. Gen. Stat. §§ 131E-175 and -176(16)(f1)(8)(2019).

¶ 4 The 2018 State Medical Facilities Plan (“SMFP”) identified a statewide need for one additional mobile PET scanner to operate within North Carolina. InSight, Petitioner, and two other organizations each submitted CON applications to be issued

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the certificate for the additional mobile PET scanner pursuant to the SMFP.

¶ 5 Petitioner proposed to serve nine host sites across five of the six health service areas (“HSAs”) established across North Carolina. InSight proposed to initially serve two host sites located in only one of the six HSAs. The last date to submit applications to DHHS was 1 December 2018. DHHS reviewed timely submitted applications.

¶ 6 Both Petitioner’s and InSight’s applications included a letter of support from the Caldwell Memorial Hospital (“Caldwell”) signed by President/CEO Laura Easton. After applicants timely submitting their applications, Petitioner submitted written comments to DHHS within the form of another letter signed by Easton on 28 December 2018. This subsequent letter purportedly rescinded Caldwell’s previous letter of support for InSight and advised DHHS that Caldwell was now fully supporting Petitioner’s application. Without Easton’s letter of support for Caldwell to host, InSight had only one remaining host site, Harris Regional Hospital, in Jackson County.

¶ 7 DHHS issued its decision approving InSight’s application and disapproving the remaining applications in April 2019. DHHS found and concluded InSight, Petitioner and Novant each conformed with all applicable statutory review criteria and performance standards, but it awarded the CON to InSight based upon the comparative review.

II. Jurisdiction

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¶ 8 Petitioner's appeal is proper pursuant to N.C. Gen. Stat. §§ 131E-188(b) and 7A-29(a) (2019).

III. Issues

¶ 9 Petitioner challenges whether InSight's application conformed with statutory criteria for the issuance of a CON. Petitioner argues InSight failed to meet Criterion 1 and did not satisfy the statewide need determination. Petitioner also argues the ALJ erred in concluding InSight's application conformed with Criterion 3 and 5 and concluding Petitioner's rights were not substantially prejudiced.

IV. Standard of Review

¶ 10 This Court reviews a decision by the ALJ, and may reverse or modify the decision if:

[T]he 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 the statutory authority or jurisdiction of the agency or administrative law judge;
- (3) Made upon unlawful procedure;
- (4) Affected by other error of law;
- (5) Unsupported by substantial evidence admissible under G.S. 150B-29(a), 150B-30, or 150B-31 in view of the entire record as submitted; or
- (6) Arbitrary, capricious, or an abuse of discretion.

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N.C. Gen. Stat. § 150B-51(b) (2019).

¶ 11 Alleged errors in the ALJ’s decision in categories one through four are reviewed by this Court *de novo*. N.C. Gen. Stat. §150B-51(c) (2019). Under *de novo* review, this Court “considers the matter anew and freely substitutes its own judgment for that of the lower tribunal.” *Cumberland Cnty. Hosp. Sys., Inc. v. N.C. Dep’t Health & Hum. Servs.*, 237 N.C. App. 113, 117, 764 S.E.2d 491, 494 (2014) (citations and internal quotations omitted). Categories five and six of N.C. Gen. Stat. § 150B-51(b) are reviewed under the “whole record” test. N.C. Gen. Stat. § 150B-51(c). Petitioner argues the issues before this Court are errors of law and subject to *de novo* review.

V. Conforming with Criterion 1 and Statewide Need Determination

A. Criterion 1

¶ 12 DHHS’ review criteria are statutory and the first is referred to as “Criterion 1” throughout the record. Criterion 1 requires:

The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service, health service facility, health service facility beds, dialysis stations, operating rooms, or home health offices that may be approved.

N.C. Gen. Stat. § 131E-183(a)(1) (2019).

¶ 13 “The Department shall review all applications utilizing the criteria outlined in this subsection and shall determine that an application is either consistent with or

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not in conflict with these criteria before a certificate of need for the proposed project shall be issued.” N.C. Gen. Stat. § 131E-183(a).

¶ 14 The 2018 SMFP included a need determination for one additional mobile PET scanner statewide. We combine the analysis of Petitioner’s first two issues in this section, because the answer to one will also necessarily answer the other.

¶ 15 Criterion 1 requires an applicant to demonstrate its application is “consistent with applicable policies and need determinations in the [SMFP].” N.C. Gen. Stat. §131E-183(a)(1). “Mobile PET Scanner” is defined as “a PET scanner and transporting equipment that is moved, at least weekly, *to provide services at two or more host facilities.*” 10A N.C. Admin. Code 14C.3701.(5) (2019) (emphasis supplied).

¶ 16 All CON applications, including InSight’s application, must demonstrate conformity with all statutory and regulatory review criteria. *See Presbyterian-Orthopaedic Hosp. v. N.C. Dep’t Hum. Res.*, 122 N.C. App. 529, 534, 470 S.E.2d 831,834 (1996) (holding “an application must comply with *all* review criteria” and the failure to comply with one review criterion supports entry of summary judgment against the applicant) (emphasis in original).

¶ 17 “It is well settled that when a court reviews an agency’s interpretation of a statute it administers, the court should defer to the agency’s interpretation of the statute . . . as long as the agency’s interpretation is reasonable and based on a permissible construction of the statute.” *AH N.C. Owner LLC v. N.C. Dep’t of Health*

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& Human Servs., 240 N.C. App. 92, 102, 771 S.E.2d 537, 543 (2015) (citation omitted).

“It is proper to presume that an administrative agency has properly performed its official duties.” *In re Broad & Gales Creek Cmty. Ass’n*, 300 N.C. 267, 280, 266 S.E.2d 645, 654 (1980).

¶ 18 “[The ALJ] is properly limited to consideration of evidence which was before the CON Section when making its initial decision.” *Robinson v. N.C. Dep’t of Health & Human Servs.*, 215 N.C. App. 372, 376, 715 S.E.2d 569, 571 (2011).

¶ 19 InSight pointed to Petitioner’s effective monopoly on mobile PET services outside of Novant’s services and facilities. InSight also described Petitioner’s history of opposing opportunities to allow additional providers to introduce services to North Carolina’s health care market. InSight predicted new providers would find it difficult to obtain public support for their applications, based upon feedback it had received from potential host sites, who were wary of taking action to put their current service with Petitioner at risk.

¶ 20 InSight proposed a statewide mobile PET route with the scanner moving weekly between six potential host sites in eastern, central, and western North Carolina. At least three potential host sites told InSight they would not provide documentation to support its CON application due to their concerns about Petitioner’s reaction.

¶ 21 Petitioner undertook efforts to encourage InSight’s two host sites to rescind

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their support for InSight's CON application. Petitioner prepared draft rescission letters for both of InSight's host sites: Caldwell and Harris Regional. Caldwell's president signed the letter. Harris' did not.

¶ 22 Respondents set forth ample evidence before the DHHS and the ALJ showing any rescission of support was the result of Petitioner's anti-competitive behavior to ensure it was awarded the CON.

¶ 23 Additional evidence led both DHHS and the ALJ to conclude that InSight's application met the two-host-site requirements notwithstanding Caldwell's rescission letter. DHHS evaluated the rescission letter, wrote two pages in its findings addressing the rescission drafted by the Petitioner and explained why it did not affect InSight's conformity with Criterion 1. DHHS recognized Caldwell's rescission letter did not indicate that Caldwell was no longer interested in a contract with InSight to the extent InSight was awarded the CON. The letter merely expressed a preference that Petitioner be awarded the CON. The ALJ was limited to the record evidence before the agency's hearing. *Robinson*, 215 N.C. App. at 375-76, 715 S.E.2d at 571 (citation omitted). Caldwell's president testified that if InSight had contacted her, she would have confirmed she would still consider contracting with InSight if it received the CON.

¶ 24 It cannot be said the ALJ's review and interpretation of DHHS' findings and conclusion that InSight met Criterion 1 is either unsupported or unreasonable.

Substantial evidence supports the conclusion that InSight’s application complied with the host site requirement. Petitioner’s argument is overruled.

B. Statewide

¶ 25 Petitioner contends the term “statewide” in the SMFP means “throughout the State,” while Respondents argue the term “statewide” means “anywhere in the State.”

1. Standard of Review

¶ 26 Petitioner asserts the determination of whether an agency erred in its interpretation of a *statutory* term is entitled to *de novo* review. *Cashwell v. Dep’t State Treasurer*, 196 N.C. App. 81, 89, 675 S.E.2d 73, 78 (2009); N.C. Gen. Stat. § 150B-51(b)(3). “When the issue on appeal is whether a state agency erred in interpreting a statutory term, an appellate court may freely substitute its judgment for that of the agency and employ *de novo* review.” *Britthaven, Inc. v. N.C. Dept. of Human Resources*, 118 N.C. App. 379, 384, 455 S.E.2d 455, 460 (1995) (citation omitted). The SMFP created by DHHS uses the word “statewide” in the need determination, but the word “statewide” is not included in the statute, Respondent’s administrative rules, or statutorily defined. N.C. Gen. Stat. § 150B-2(8a)(k) (2019).

2. Interpretation

¶ 27 Petitioner argues the ALJ failed to conduct any analysis of the evidence demonstrating Respondent’s interpretation of “statewide” was contrary to: (1) the plain language of the need determination; (2) the rationale for the North Carolina

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State Health Coordinating Council’s inclusion of the need determination in the SMFP; (3) the CON statute; and (4) the policies in the CON Act.

¶ 28 The 2018 SMFP expressly concludes there is a “need for one additional mobile dedicated PET scanner statewide” and “the service areas listed in the table below need additional mobile dedicated PET scanners.”

¶ 29 DHHS prepared the need determination pursuant to its discretionary authority granted by the General Assembly as part of the CON Act. *See* N.C. Gen. Stat. § 131E-177(4) (2019). Petitioner’s argument, asserting the ALJ and DHHS misinterpreted its own meaning of “statewide,” would require us to conclude DHHS abused its own discretion by determining InSight’s application met DHHS’ own meaning of “statewide.” We conclude the ALJ properly upheld and concluded DHHS’ interpretation of the term “statewide” was supported by substantial evidence. N.C. Gen. Stat. § 150B-51(b).

C. Letter as Amendment

¶ 30 DHHS asserts Caldwell’s purported rescission letter was properly disregarded because it was an improper attempt by Petitioner to amend InSight’s submitted application. “An applicant may not amend an application.” 10A N.C. Admin. Code 14C.0204 (2019). Caldwell was not an applicant in this CON review. Rule .0204 does not apply as a matter of law because, here, a CON applicant was not seeking to amend its own application. *See In re Application of Wake Kidney Clinic*, 85 N.C. App. 639,

643, 355 S.E.2d 788, 790–91 (1987) (“The rules adopted by the Department of Human Resources to govern contested certificates of need hearings prevent a party from amending his application once it is deemed completed”). It stands to reason that if pursuant to Rule .0204 an applicant cannot “amend an application,” then another applicant cannot amend a competitor’s application. 10A N.C. Admin. Code 14C.0204; *see In re Application of Wake Kidney Clinic*, 85 N.C. at 643, 355 S.E.2d at 791. Petitioner’s argument is without merit.

VI. Criterion 3 and 5

A. Criterion 3

¶ 31 Petitioner argues InSight’s utilization and revenue projections were not reasonable nor adequately supported. “[F]indings of fact made by the agency are conclusive on appeal if they are supported by substantial evidence in the record reviewed as a whole.” *Id.* at 644, 355 S.E.2d at 791. The ALJ reviewed DHHS’ decision to determine if, based upon the information available to it, it was supported by evidence in the record and was reasonable. *Britthaven*, 118 N.C. App. at 382, 455 S.E. 2d at 459.

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.

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N.C. Gen. Stat. § 131E-183(a)(3).

¶ 32 The president of Strategic Healthcare Consultants, who was charged with “prepar[ing] certificate of need applications, provid[ing] healthcare consulting, and strategic planning services,” testified the projections made in the application must be “reasonable and adequately supported” to conform with Criterion 3. To receive the CON in question, this Criterion required InSight to meet the performance standard, pursuant to 10A N.C. Admin. Code 14C.3703(a)(3), “of projecting of at least 2,080 PET” scans in the third operating “year following completion of the project.”

¶ 33 “To fulfill its obligation of determining whether applications are consistent with statutory review criteria, [DHHS] must perform a meaningful analysis.” *AH N.C. Owner*, 240 N.C. App. at 108, 771 S.E.2d at 547. DHHS performs a meaningful analysis by determining “whether an applicant conforms to [the criterion], [DHHS] must analyze and give due regard to the information available to it that is reasonably related to an applicant’s history of providing quality care.” *Id.* at 109, 771 S.E.2d at 547.

¶ 34 The ALJ made twenty-one findings of fact regarding Criterion 3 in the Final Decision. These findings of fact include:

56. . . . [P]hysicians are using PET for an increasing number of indications, [InSight] assumed that the demand for PET services will continue to increase in the future.

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....

62. [InSight] projected that annual utilization of the proposed mobile PET scanner would exceed 2,080 procedures within the first three years of operation based on assumptions described in its application.

63. [InSight's] projections relied on a "need-based" or "use rate" methodology to project demand based on application of the use rate to the population to be served. A need-based methodology is just one of many accepted methodologies used by healthcare planners. [DHHS] deemed [InSight's] use of a use rate/need-based methodology to be reasonable.

64. . . . [InSight] began by using data from the North Carolina Office of State Budget and Management to project the population in the counties to be served . . .

65. . . . [InSight's] calculation was based on historical use of both mobile and fixed PET scanners . . .

....

67. . . . [InSight] projected its anticipated market shares in the various counties that it proposed to serve. . . .

InSight incorporated these presumptions into its methodology to project the number of scans it would provide in the first three operating years, by applying the projected market share to the projected demand in each county. Petitioner's arguments were raised, responded to by InSight, and considered by DHHS. DHHS addressed these presumptions and found them to be reasonable and adequately supported.

¶ 35 DHHS and the ALJ's Final Decision addressed the bases for InSight's projections in detail and both determined that its demonstration of need and

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projected utilization were reasonable and adequately supported. Substantial evidence supports the reasonableness and adequacy of InSight's projections. Petitioner's argument is overruled.

B. Criterion 5

¶ 36 Petitioner argues the ALJ's findings on Criterion 5 are unreasonable and not adequately supported.

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).

¶ 37 During the hearing, Martha Frisone, chief of the Health Care Planning and CON Section of DHHS, offered testimony. Her duties include directing and managing a team of twenty individuals in the implementation of North Carolina CON law. When asked about the requirements for Criterion 5, Frisone responded:

There are several components. First, the financial and operational projections have to 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 cost of and charges for providing health services by the person proposing the service.

¶ 38 When asked why InSight's application was found to conform with Criterion 5, Frisone replied, "they provided what the capital cost was. We were satisfied that it

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was based on reasonable assumptions which were provided.” The exchange between Frisone and counsel continued:

[Frisone]: We were satisfied that they had adequately documented the availability of those funds, and we were satisfied that the projected utilization and projected cost and charges were reasonable and adequately supported.

[Counsel]: Okay. And as you sit here today, do you have any reason to disagree with the [DHHS] determination that InSight was conforming with Criterion (5)?

[Frisone]: I do not.

¶ 39 Petitioner further argues Caldwell’s President Easton, demonstrated InSight’s projections were unreasonable. Petitioner relies upon Easton’s testimony she “[did not] think” Caldwell needed twelve times its current service, she had “no reason to believe” that Caldwell could support 1,046 scans on a mobile PET per year, and Caldwell had not achieved a 95 percent market share in another service.

¶ 40 Easton did not share any concerns about InSight’s projections with DHHS in the rescission letter or otherwise during testimony. Easton acknowledged Caldwell was losing volume to other health care providers because its access to mobile PET scanners is limited. She also conceded it was reasonable to expect Caldwell’s volume to increase if it provided more services. Easton was unaware that InSight proposed to charge Caldwell a fee per scan and Caldwell would only have to pay the amounts InSight projected if it achieved the projected volumes to support it.

¶ 41 Evidence proffered at the ALJ hearing showed InSight anticipated helping

Caldwell increase its market share. Through increased access and resources, InSight would help Caldwell leverage existing and new referral relationships.

¶ 42 The ALJ stated DHHS’ analysis relied upon four factors. “Of those four factors, Petitioner was found most effective on one factor and least effective on two factors. Novant was found most effective on one factor and least effective on one factor.” Petitioner was found lacking in two areas, and InSight was found lacking only in one.

¶ 43 Substantial evidence supports the ALJ’s conclusion DHHS acted reasonably and did not commit reversible error regarding review of InSight’s projections. The ALJ’s findings and conclusion that DHHS correctly determined InSight met the requirements of Criterion 5 is affirmed.

VII. Petitioner’s Substantial Rights

¶ 44 “[A] petitioner in a CON case must show (1) either that the agency (a) has deprived the petitioner of property, (b) ordered the petitioner to pay a fine or civil penalty, or (c) substantially prejudiced the petitioner’s rights, *and* (2) that the agency erred.” *Surgical Care Affiliates, LLC v. N.C. Dep’t of Health & Human Servs.*, 235 N.C. App. 620, 624, 762 S.E.2d 468, 471 (2014) (emphasis in original).

¶ 45 Petitioner contends both DHHS and the ALJ erred by concluding Petitioner’s rights were not substantially prejudiced. Without error in the underlying decisions, we need not reach this analysis. For the reasons described previously herein, we affirm the ALJ’s Final Decision and decline to address Petitioner’s argument on

prejudice.

VIII. Conclusion

¶ 46 The ALJ reviewed DHHS' evidence and findings and heard arguments from DHHS and Petitioner. Substantial evidence supported DHHS' finding InSight complied with Criterion 1 and met the meaning of statewide in the ALJ's Final Decision to grant them the CON for the additional mobile PET scanner.

¶ 47 The ALJ also affirmed DHHS' finding InSight had complied with both Criterion 3 and 5 based upon DHHS' analysis of the evidence and requirements in InSight's application.

¶ 48 The ALJ Final Decision to affirm DHHS' CON designation as properly complying with the statutory CON requirements is affirmed. *It is so ordered.*

AFFIRMED.

Judges INMAN and ARROWOOD concur.