

IN THE COURT OF APPEALS OF NORTH CAROLINA

No. COA14-1076

Filed: 18 August 2015

Office of Administrative Hearings, Nos. 13 DHR 18127, 18223

TOTAL RENAL CARE OF NORTH CAROLINA, LLC, Petitioner,

v.

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

and

BIO-MEDICAL APPLICATIONS OF NORTH CAROLINA, INC., Respondent-
Intervenor.

Appeal by petitioner from final decision entered 23 June 2014 by
Administrative Law Judge Craig Croom in the Office of Administrative Hearings.

Heard in the Court of Appeals 3 March 2015.

*Wyrick Robbins Yates & Ponton LLP, by K. Edward Greene, Lee M. Whitman,
and Tobias S. Hampson, for petitioner-appellant.*

*Attorney General Roy Cooper, by Special Deputy Attorney General June S.
Ferrell, for respondent-appellee.*

*Smith Moore Leatherwood LLP, by Marcus C. Hewitt and Elizabeth Sims
Hedrick, for respondent-intervenor-appellee.*

DIETZ, Judge.

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This appeal challenges the process by which the Department of Health and Human Services determines whether two certificate-of-need applications are “competitive,” meaning they must be reviewed together.

The certificate of need law directs DHHS to “establish schedules for submission and review of completed applications” and further directs that “[t]he schedules shall provide that applications for similar proposals in the same service area will be reviewed together.” N.C. Gen. Stat. § 131E-182(a) (2013). The agency also promulgated its own regulation stating that applications must be reviewed together if “the approval of one or more of the applications may result in the denial of another application reviewed in the same review period.” 10A N.C. Admin. Code 14C.0202(f) (2013).

As part of the 2013 State Medical Facilities Plan, DHHS determined that Franklin County needed 10 additional dialysis stations. Petitioner Total Renal Care of North Carolina, LLC (TRC) and Respondent-Intervenor Bio-Medical Applications of North Carolina, Inc. (BMA) both applied to fill this need.

This case arose because the two companies did *not* file their applications in the same “review period.” BMA proposed moving ten existing dialysis stations from Wake County to Franklin County and, under the schedules established by the agency, was required to file its application on 15 March 2013. TRC proposed moving two dialysis stations from Wake County and another eight stations from a different site

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within Franklin County. Because TRC's application involved moving stations both from another county and from within the same county, TRC *could* have filed its application on 15 March 2013, but it also could wait and file it in a separate review period beginning 15 April 2013. TRC chose the latter. As a result, the agency's schedules did not treat the two applications as "similar proposals for the same service area," and thus the agency did not review them together. On appeal, TRC argues that DHHS's failure to review the applications together violates the certificate-of-need statute, the agency's own regulations, and TRC's due process rights.

As explained below, we reject these arguments. Our precedent requires us to defer to the agency's reasonable interpretation of an ambiguous statute and to an agency's interpretation of its own rules and regulations. In the context of medical services, the statutory term "similar proposals" is ambiguous. Medical services that appear "similar" to a layperson (or an appellate judge) might be entirely dissimilar to experts in the field. That is precisely why the General Assembly tasked DHHS, the state agency with expertise in this area, with determining what is, and is not, a similar proposal. Because we conclude that the agency's interpretations of the statute and its regulations are reasonable, we must defer to those interpretations. Accordingly, we affirm the final decision of the Office of Administrative Hearings.

Facts and Procedural Background

In January 2013, the Department of Health and Human Services published its Semiannual Dialysis Report, identifying a need for ten additional dialysis stations in Franklin County. DHHS publishes this report in January and July of each year as part of its State Medical Facilities Plan, cataloguing surpluses and deficits of stations by county and forecasting the number of stations that will be needed to serve dialysis patients in the future.

Private providers seeking to fill a deficit of medical facilities in our State must apply for and obtain “certificate of need” approval. N.C. Gen. Stat. § 131E-178(a); *see also id.* § 131E-176(16). The Certificate of Need Section of DHHS reviews all certificate of need applications for conformity with the statutory review criteria set forth in the applicable statute. *Id.* § 131E-183(a). To facilitate this process, the statute authorizes DHHS to adopt rules governing the orderly administration of certificate of need applications. *See, e.g., id.* §§ 131E-177(1); 131E-182.

The statute requires the agency to establish review schedules under which “similar proposals in the same service area will be reviewed together.” *Id.* § 131E-182(a). Additionally, the agency’s review is limited to a period of 90 days,¹ starting

¹ The statute provides that the Agency “may extend the review period for a period not to exceed 60 days and provide notice of such extension to all applicants.” N.C. Gen. Stat. § 131E-185(c); *see also* 10A N.C. Admin. Code 14C.0205(b) (“Except in the case of an expedited review, the period for review may be extended for up to 60 days by the agency if it determines that . . . it cannot complete the review within 90 days.”).

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“on the day established by rule as the day on which applications for the particular service in the service area shall begin review.” *Id.* § 131E-185(a1).

As the statute instructs, the agency has adopted schedules setting forth deadlines for the filing and review of various categories of medical services. *See* 10 N.C. Admin. Code 14C.0202(e). These categories and filing dates are contained in the State Medical Facilities Plan each year, and applicants must comply with the filing deadlines to ensure consideration in any particular period of review. *Id.*; *see also id.* § 14C.0203(a)-(b) (mandating that the agency “shall not . . . review[]” applications unless they are “filed in accordance with this Rule”).

The categories relevant to this appeal are Category D and Category I. Category D includes applications proposing the “relocation of existing certified dialysis stations *to another county* pursuant to Policy ESRD-2.” N.C. Dep’t of Health & Human Servs., Div. of Health Serv. Regulation, Med. Facilities Planning Branch, *North Carolina 2013 State Medical Facilities Plan*, N.C. Dep’t of Health & Human Servs., 18 (January 1, 2013), <http://www.ncdhhs.gov/dhsr/ncsmfp/2013/2013smfp.pdf>. (emphasis added). Policy ESRD-2, which governs dialysis services, permits an applicant to relocate dialysis stations into a contiguous county only if there is a surplus in the “giving” county and a deficit in the “receiving” county. *Id.* at 36. Category I, on the other hand, covers applications seeking to relocate existing certified dialysis stations *within the same county*. *Id.* at 20.

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On 15 March 2013, BMA submitted its application to develop a ten-station dialysis facility in Louisburg, Franklin County. BMA's application proposed moving ten dialysis stations from two of its existing facilities in Wake County, which is contiguous to Franklin County. As a result, BMA's application fell within Category D. *See id.* at 18. BMA timely submitted its proposal by the deadline for Category D applications, as set forth in the State Medical Facilities Plan, to be reviewed in the period beginning 1 April 2013. *Id.* at 21-22.

One month later, on 15 April 2013, TRC submitted its application to develop a ten-station dialysis facility in Youngsville, Franklin County. Unlike BMA, which did not have an existing facility in the county, TRC proposed moving eight stations from its existing facility within Franklin County. TRC also proposed moving two additional stations from one of its facilities in Wake County, for a total of ten stations. Because TRC's application involved moving stations both from another county and from within Franklin County, TRC's application met the criteria of both a Category D and a Category I application. TRC missed the deadline for Category D applications but timely submitted its proposal by the deadline for Category I applications, to be reviewed in the period beginning on 1 May 2013.² *Id.*

² DHHS envisioned there would be times when applications fell into more than one category. The State Medical Facilities Plan requires that "[f]or proposals which include more than one category, an applicant must contact the Certificate of Need Section prior to submittal of the application for a determination regarding the appropriate review category or categories and the applicable review period in which the proposal must be submitted." *Id.* at 18. TRC conceded at oral argument that it

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Nearly a month after filing its application, on 13 May 2013, TRC submitted a letter to the agency requesting that it conduct a competitive review of the BMA and TRC applications. In a competitive review, the agency undergoes a two-step process: first, it reviews each application standing alone for conformity with the applicable review criteria, standards, and plans; and second, it compares the applications against each other to determine which is comparatively superior and therefore will be approved. *See Britthaven, Inc. v. N.C. Dep't of Human Res.*, 118 N.C. App. 379, 384, 455 S.E.2d 455, 460 (1995). The agency designates applications as competitive “if they, in whole or in part, are for the same or similar services and the agency determines that the approval of one or more of the applications may result in the denial of another application *reviewed in the same review period.*” 10A N.C. Admin. Code 14C.0202(f) (emphasis added).

The agency determined that BMA and TRC submitted applications in different review periods and therefore declined to review the applications competitively. On 27 August 2013, the agency issued a decision approving BMA’s application, thereby eliminating the ten-station deficit identified in the State Medical Facilities Plan. The following month, on 25 September 2013, the agency issued its decision denying TRC’s application. The agency determined that TRC’s application could not be granted because the ten-station deficit had been eliminated by the approval of BMA’s earlier

did *not* contact the agency regarding the appropriate review category for its application and that it missed the deadline for filing a Category D application.

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application and, therefore, TRC's proposal to relocate two stations from Wake County to Franklin County would result in a surplus of two stations in Franklin County in violation of the State Medical Facilities Plan.

TRC then initiated a contested case before the Office of Administrative Hearings. The administrative law judge (ALJ) granted BMA's motion to intervene. On 23 June 2014, the ALJ entered partial summary judgment concluding that the agency did not err in declining to review the two applications competitively. That same day, the ALJ entered a final decision concluding that BMA's application conformed to the applicable review criteria. The ALJ therefore upheld the agency's decision. TRC timely appealed to this Court.

Analysis

On appeal, TRC argues that the ALJ erred in affirming the agency's decision because (1) the agency failed to conduct a competitive review of the TRC and BMA applications, substantially prejudicing TRC's rights, and (2) the agency erroneously approved BMA's application. For the reasons set forth below, we reject TRC's arguments and affirm the ALJ's final decision.

I. Requirement of Competitive Review

a. Compliance with the Statute

TRC first argues that the agency violated Section 131E-182(a) of the General Statutes when it reviewed BMA's application in an earlier, separate review period from TRC's application.

Section 131E-182(a) directs the Department of Health and Human Services to "establish schedules for submission and review of completed applications" and further directs that "[t]he schedules shall provide that applications for similar proposals in the same service area will be reviewed together." TRC argues that the statutory term "similar proposals in the same service area" is unambiguous, and under its plain meaning the two companies' applications were similar proposals in the same service area. Thus, because the schedules established by the agency caused those two applications to be reviewed at different times, TRC contends the agency violated the statute. For the reasons discussed below, we reject this argument and hold that the agency's schedules comply with the statute.

The interpretation of a statute is a question of law and thus is reviewed *de novo* in an administrative appeal. N.C. Gen. Stat. § 150B-51 (2013). But because this statute instructs a state agency to promulgate regulations to administer it, there is an additional layer of review. If the statutory language is unambiguous and the statutory intent clear, this Court must give effect to that unambiguous language

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regardless of the agency's interpretation. *AH N.C. Owner LLC v. N.C. Dep't of Health & Human Servs.*, ___ N.C. App. ___, 771 S.E.2d 537, 549 (2015). But if the statute is silent or ambiguous on an issue, this Court must defer to the agency's interpretation "as long as the agency's interpretation is reasonable and based on a permissible construction of the statute." *Id.* at ___, 771 S.E.2d at 543.

Here, the statute does not define "similar proposals for the same service area" and we do not believe that term is so plainly unambiguous that the agency has no role in determining what is and is not a "similar proposal." For example, one hospital's request to purchase an MRI scanner and another's request to purchase a CT scanner or PET scanner could be viewed as "similar proposals" in the sense that both providers are requesting medical imaging technologies used to diagnose medical conditions. But those applications also could be viewed as entirely dissimilar proposals because they concern different types of medical scanning technology used for different diagnostic purposes. Indeed, medical services that appear entirely "similar" to a layperson may be quite dissimilar to a medical expert. Because the term "similar proposals" with regard to healthcare services is open to multiple interpretations, we hold that the Department of Health and Human Services is entitled to deference in interpreting its meaning. *AH N.C. Owner LLC*, ___ N.C. App. at ___, 771 S.E.2d at 543. As a result, our role is to determine if the agency's interpretation is reasonable and a permissible construction of the statute. *Id.*

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To ensure that its schedules “provide that applications for similar proposals in the same service area will be reviewed together,” the agency created “categories” of medical services and corresponding review periods that are listed in the applicable State Medical Facilities Plan. *See* 10A N.C. Admin. Code 14C.0202(e). Relevant here, the agency created a category, Category D, that includes all proposals to move dialysis stations from one county to another, contiguous county. A separate category, Category I, covers proposals to move dialysis stations to a new location within the same county. *See* 2013 SMFP at 18-20.

An agency official testified about why the agency created these two distinct categories. The official explained that the State Medical Facilities Plan examines needs based on counties. Proposals to transfer dialysis stations across county lines, which fall under Category D, affect need assessments for both the county losing the facilities and the county gaining them. As a result, there are more regulatory hurdles to overcome before dialysis stations may be moved from one county to another. *See id.* at 36.

By contrast, proposals to relocate dialysis stations within the same county, which fall under Category I, have no impact on overall county need assessments because the number of certified stations in that county will remain the same. As a result, proposals to move stations within the same county have fewer implications

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under the State Medical Facilities Plan and thus fewer regulatory hurdles to overcome.

In light of these distinctions, the agency concluded that Category D and Category I proposals are not “similar proposals in the same service area” and need not be reviewed together. The 2013 review schedule established by the agency in the State Medical Facilities Plan reflects this determination. For the health service area that includes the counties at issue in this case, Category D applications are not reviewed in the same review period as Category I applications.

Under the deferential standard of review applicable here, we must conclude that the agency’s schedules and review categories satisfy the statutory requirement that “similar proposals in the same service area” be reviewed together. The agency provided an explanation of why proposals seeking to move dialysis stations across county lines are not “similar” to proposals merely relocating stations within a county under the medical plan established by state regulators. Because the agency’s interpretation of “similar proposals within the same service area” is reasonable, and a permissible construction of the statute, we are required to defer to that interpretation. *See AH N.C. Owner LLC*, ___ N.C. App. at ___, 771 S.E.2d at 543. Accordingly, we reject TRC’s statutory argument.

b. Compliance with the Applicable Regulations

TRC next contends that the agency's schedules with respect to dialysis services violate its own regulations, which require that applications must be reviewed together if the agency determines "that the approval of one or more of the applications may result in the denial of another application *reviewed in the same review period.*" 10A N.C. Admin. Code 14C.0202(f) (emphasis added). It is undisputed here that approving one of the parties' applications may have resulted in denial of the other application. TRC argues that the two applications were "reviewed in the same review period" because the time frame in which Category D and Category I applications were reviewed overlapped. Thus, TRC argues that the agency's own regulations required it to review the two applications simultaneously. For the reasons discussed below, we reject this argument and hold that the agency properly interpreted its own regulations.

An administrative agency's interpretation of its own regulations is entitled to deference unless it is plainly erroneous or inconsistent with the regulation's plain text. *York Oil Co. v. N.C. Dep't of Env't*, 164 N.C. App. 550, 554-55, 596 S.E.2d 270, 273 (2004). Here, the agency interprets the term "review period" to mean the specific time frame in which a particular category of applications are reviewed. Because reviews for each category last several months, there is overlap between these review periods—here for example, while the agency was still reviewing its Category D

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applications, it began receiving Category I applications, the filing deadline for which was one month later. But the agency does not consider those Category I applications to be filed in the same “review period” as the Category D applications. In the agency’s view, *overlapping* review periods are not the *same* review period, they are simply overlapping review periods.

As with TRC’s statutory argument, we are constrained to reject TRC’s regulatory argument under the deferential standard of review. The agency’s interpretation “is neither plainly erroneous nor inconsistent with the regulation.” *Id.* When one speaks of a “review period,” it is certainly permissible to interpret that phrase as a distinct period of time, with a beginning and an end, as the agency does here, and to treat proposals as being in different “review periods” if they have some overlap in time frame but are not reviewed entirely at the same time from beginning to end. This is particularly true with respect to this regulatory regime, where the agency has established categories for different types of proposals, with different filing deadlines for each category. Accordingly, we reject TRC’s regulatory argument.

c. Constitutionality of Review Categories and Schedules

Finally, TRC argues that failing to review its application with BMA’s application violates its due process rights, citing the U.S. Supreme Court’s decision in *Ashbacker Radio Corporation v. Federal Communications Commission*, 326 U.S. 327, 333 (1945). In *Ashbacker*, which involved federal statutes and regulations, the

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U.S. Supreme Court held that “where two *bona fide* applications are mutually exclusive the grant of one without a hearing to both deprives the loser of the opportunity which Congress chose to give him.” *Id.* Although *Ashbacker* did not directly reference constitutional principles, some courts have suggested the opinion is grounded in due process principles. *See, e.g., Frontier Airlines, Inc. v. Civil Aeronautics Bd.*, 349 F.2d 587, 590 (10th Cir. 1965).

Even if we assume *Ashbacker* imposes a constitutional requirement that certain administrative applications submitted to state agencies be reviewed simultaneously by that agency, TRC’s argument fails because this Court previously has held that the statutory review process established by the General Assembly satisfies the requirements of *Ashbacker*. *See Britthaven*, 118 N.C. App. at 384-85, 455 S.E.2d at 460. Because, as explained above, the agency’s review categories do not violate the statute, and ensure that “similar proposals” are reviewed together, those categories also satisfy whatever due process requirements are encapsulated in *Ashbacker*. Accordingly, we reject TRC’s argument.

II. Agency’s Final Decision

TRC next argues that a series of findings by the administrative law judge are not supported by the record.

We review a challenge to the ALJ’s findings to determine whether the findings are supported by substantial evidence. N.C. Gen. Stat. § 150B-51(b), (c). “Substantial

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evidence is such relevant evidence as a reasonable mind might accept as adequate to support a conclusion.” *Surgical Care Affiliates v. N.C. Dep’t of Health & Human Servs.*, ___ N.C. App. ___, ___, 762 S.E.2d 468, 470 (2014) (internal quotation marks omitted). Even if the record contains evidence that could also support a contrary finding, we may not substitute our judgment for that of the ALJ and must affirm if there is substantial evidence supporting the ALJ’s findings. *Id.*

a. Criterion 5

TRC first argues that the ALJ erred in concluding that BMA’s application satisfied N.C. Gen. Stat. § 131E-183(a)(5) (Criterion 5). Criterion 5 requires, in relevant part, that an applicant demonstrate the long-term financial feasibility of its proposed project based upon reasonable projections of costs and charges for services. *See id.* TRC maintains that BMA’s projected payor mix for home hemodialysis services was unreasonable, and therefore its proposal is inconsistent with Criterion 5. We reject this argument because the ALJ’s findings are supported by substantial evidence.

An applicant’s anticipated “payor mix” refers to the breakdown in the percentage of total projected dialysis treatments for which the applicant expects to be reimbursed by each payor category, including, for example, Medicare, Medicaid, and commercial insurance. In its application, BMA projected to serve 34 in-center patients, four home hemodialysis patients, and four home peritoneal dialysis patients

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by the end of the second operating year. With respect to the four home hemodialysis patients, BMA projected that commercial insurance would reimburse 87% of treatments. TRC contends that BMA grossly overestimated this percentage, and “[t]he high levels of projected commercial reimbursement served to inflate BMA’s revenue projections.” Thus, TRC argues, BMA’s application was nonconforming with Criterion 5.

Substantial evidence in the record supports the ALJ’s conclusion that BMA’s proposed payor mix was reasonable and satisfied Criterion 5. There is detailed evidence and testimony in the administrative record regarding the reasonableness of BMA’s projected reimbursements for services. At the hearing, BMA identified trends suggesting higher use of home hemodialysis by commercially insured patients, and witnesses for all parties agreed that working people tend to prefer home hemodialysis and also are more likely to have commercial insurance coverage. This evidence is sufficient for a reasonable mind to accept BMA’s projected payor mix and therefore constitutes substantial evidence. *Surgical Care Affiliates*, ___ N.C. App. at ___, 762 S.E.2d at 470.

b. Criterion 4

TRC next challenges the ALJ’s finding that BMA satisfied N.C. Gen. Stat. § 131E-183(a)(4) (Criterion 4) “[b]ecause the BMA Application did not demonstrate conformity with Criterion 5.” This argument turns entirely on TRC’s success in its

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challenge to Criterion 5. Because we reject that argument, we likewise reject this argument.

c. Criterion 13c

Finally, TRC argues that BMA's application does not satisfy N.C. Gen. Stat. § 131E-183(a)(13)c (Criterion 13(c)). Criterion 13(c) requires an applicant to demonstrate that "the elderly and the medically underserved groups . . . will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services." *Id.* TRC contends that the ALJ should have adopted the view of its expert witness, who testified that "Medicaid patients would [not] have adequate access to home hemodialysis and peritoneal dialysis, because BMA projected lower utilization for these services by medically underserved patients, as compared to its projections of utilization for in-center services by these patients."

The ALJ's decision on this issue is supported by substantial evidence. BMA provided data and projections showing an expected 91% of its in-center patients would be drawn from underserved populations. BMA also showed that it would provide services to all patients without regard to income, race or ethnicity, gender, ability to pay, or any other factor that would classify a patient as underserved. Relying on this record evidence, the ALJ made detailed findings about BMA's compliance with Criterion 13(c). Because this evidence is sufficient for a reasonable

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mind to accept BMA's projections, the ALJ's findings are supported by substantial evidence and we must reject TRC's argument.

Conclusion

We affirm the final decision of the Office of Administrative Hearings.

AFFIRMED.

Judges McCULLOUGH and INMAN concur.