COURT OF APPEALS OF VIRGINIA

UNPUBLISHED

Present: Chief Judge Decker, Judges Malveaux and Athey
Argued by videoconference

CHESAPEAKE HOSPITAL AUTHORITY
d/b/a CHESAPEAKE REGIONAL MEDICAL CENTER

v. Record No. 0116-20-1

STATE HEALTH COMMISSIONER AND
SENTARA HOSPITALS

MEMORANDUM OPINION[*] BY
JUDGE CLIFFORD L. ATHEY, JR.
OCTOBER 27, 2020

FROM THE CIRCUIT COURT OF THE CITY OF CHESAPEAKE
Mary Jane Hall, Judge Designate

Peter M. Mellette (Elizabeth D. Coleman; H. Guy Collier; Mellette, P.C.; McDermott Will & Emery LLP, on briefs), for appellant.

Vanessa C. MacLeod, Assistant Attorney General (Mark R. Herring, Attorney General; Keonna C. Austin, Deputy Attorney General; Allyson K. Tysinger, Senior Assistant Attorney General, on brief), for appellee State Health Commissioner.

Jamie B. Martin (Jeremy A. Ball; Matthew M. Cobb; Jennifer L. Ligon; Williams Mullen, on brief), for appellee Sentara Hospitals.

Chesapeake Hospital Authority d/b/a Chesapeake Regional Medical Center ("CRMC") appeals from the Circuit Court for the City of Chesapeake's ("circuit court") final order which upheld the decision of the State Health Commissioner ("Commissioner") denying CRMC a Certificate of Public Need ("COPN") for the creation of a new open-heart surgery service and additional dedicated cardiac catherization equipment. On appeal, CRMC presents four assignments of error:

[*] Pursuant to Code § 17.1-413, this opinion is not designated for publication.

1. Whether the [circuit] court erred in finding that the Commissioner's incorrect interpretation and application of the State Medical Facilities Plan Need Provision in his Case Decision was harmless error.

2. Whether the [circuit] court erred in finding that the State Medical Facilities Plan cardiac cath volume requirements for a new open heart surgery service as written and as applied were ambiguous and warranted deference to the Commissioner's interpretation.

3. Whether the [circuit] court erred in finding that the Commissioner did not commit reversible errors of law in excluding the utilization of PD 20 services by North Carolina residents and by relying on an incomplete data set to assess utilization of open and closed heart surgery services.

4. Whether the [circuit] court erred in finding that the Commissioner's factual findings were supported by substantial evidence and that a reasonable mind would not necessarily reach a different conclusion.

For the reasons that follow, we affirm the circuit court.

I. BACKGROUND

A. Statutory and Regulatory Framework

"A comprehensive regulatory system governs nearly every aspect of medical care facilities in the Commonwealth." Reston Hosp. Ctr. v. Remley, 63 Va. App. 755, 760 (2014). "No person shall commence any project without first obtaining a certificate issued by the Commissioner." Code § 32.1-102.3(A). Any decision to issue a certificate must be consistent with the State Medical Facilities Plan ("SMFP"), unless the Commissioner, in his or her discretion, chooses to set aside the SMFP. Id. "No certificate may be issued unless the Commissioner has determined that a public need for the project has been demonstrated." Id.

To determine whether a public need has been demonstrated, the Commissioner must consider the statutory factors in Code § 32.1-102.3(B). In short, the Commissioner must consider whether the project meets the following criteria: 1) Increased access to health services

for residents of the area, 2) the public need for the project, 3) the project's consistency with the SMFP, 4) improving access to essential health services for the residents of the area, 5) relationship between the project and the utilization and efficiency of existing services, 6) financial feasibility of the project, and 7) the project provides improvement or innovation in the delivery of health services. See Code § 32.1-102.3(B).

In determining whether the project is consistent with the SMFP, the Commissioner looks to the regulations setting out the plan. Code § 32.1-102.1. Relevant here is 12 VAC 5-230-450(A), which establishes certain utilization metrics that must be met to establish a public need for new open heart services. Under 12 VAC 5-230-450(A):

> No new open heart services should be approved unless:
>
> 1. The service will be available in an inpatient hospital with an established cardiac catherization service that has performed an average of 1,200 DEPs for the relevant reporting period and has been in operation for at least 30 months;
>
> 2. Open heart surgery services located in the health planning district performed an average of 400 open heart and closed heart surgical procedures for the relevant reporting period; and
>
> 3. The proposed new service will perform at least 150 procedures per room in the first year of operation and 250 procedures per room in the second year of operation without significantly reducing the utilization of existing open heart surgery services in the health planning district.

B. CRMC's Application for a Certificate of Public Need[1]

CRMC submitted an application for a COPN in September 2017. CRMC sought to introduce open heart surgery services and add cardiac catherization equipment in the form of a cardiac surgery operating room.

[1] As the parties are fully conversant with the record in this case and because this memorandum opinion carries no precedential value, this opinion recites only those facts and incidents of the proceedings as are necessary to the parties' understanding of the disposition of this appeal.

CRMC's application was reviewed by the Virginia Health Department's Division of Certificate of Public Need ("DCOPN"). In November 2017, DCOPN recommended to the Commissioner that CRMC's project be conditionally approved contingent upon the acceptance of a charity care condition.

Multiple informal fact-finding hearings were subsequently conducted. At those hearings, CRMC presented testimony and other evidence that the proposed open heart surgery project would benefit the entirety of Health Planning District 20 ("PD 20"). The adjudication officer conducting the various hearings recommended denying CRMC's application in August 2018.

The Commissioner reviewed the record, adopted the findings of the adjudication officer, applied the relevant statutes and regulations, and ultimately denied CRMC's application. The Commissioner cited the following reasons for denying the issuance of a COPN to CRMC:

> 1. CRMC's proposed project is not consistent with the State Medical Facilities Plan;
>
> 2. The proposed project would likely decrease utilization at existing providers of open heart surgery – a type of surgery that consists of a highly-specialized, high-acuity, utilization-sensitive and narrow subset of cardiac surgery procedures;
>
> 3. The project is duplicative of existing and accessible open heart surgery services in PD 20;
>
> 4. The project would not significantly improve geographic or financial access for residents of PD 20 to open heart surgery services; and
>
> 5. Open heart surgery services are fully accessible and available in PD 20, in a timely manner and within applicable driving time standards.

CRMC appealed the Commissioner's decision to the circuit court, arguing that the Commissioner erred in his application of the relevant factors and further that the decision was arbitrary and capricious. The circuit court concluded that although the Commissioner had misinterpreted a single provision of the SMFP related to the establishment of new open heart

surgery services, this misinterpretation of a single provision was harmless error. The circuit court found no further error by the Commissioner related to CRMC's remaining assignments of error and affirmed the Commissioner's decision. CRMC appeals from the decision of the circuit court.

II. ANALYSIS

A. Harmless Error

CRMC alleges that the circuit court erred in finding that the Commissioner's incorrect interpretation and application of the SMFP was harmless error. We disagree.

"[U]nder the [Virginia Administrative Process Act], the circuit court's role in an appeal from an agency decision is equivalent to an appellate court's role in an appeal from a trial court." LifeCare Med. Transps., Inc. v. Va. Dep't of Med. Assistance Servs., 63 Va. App. 538, 548 (2014). While pure statutory construction requires *de novo* review, Reston Hosp., 63 Va. App. at 770, "courts give 'great deference to an agency's interpretation of its own regulations," Bd. of Supervisors v. State Bldg. Code Tech. Review Bd., 52 Va. App. 460, 466 (2008). A court cannot "substitute its own judgment for the agency's on matters committed by statute to the agency's discretion." Reston Hosp., 63 Va. App. at 770. The determination of what is "relevant to understanding public need lies within an area of [the Commissioner's] experience and specialized competence and therefore, is entitled to great deference." Doctors' Hosp. of Williamsburg, LLC v. Stroube, 52 Va. App. 599, 609-10 (2008). On appeal of an administrative agency's decision, "[t]he party complaining of an agency action has the burden of demonstrating an error of law subject to review." Hilliards v. Jackson, 28 Va. App. 475, 479 (1998).

Here, the circuit court determined that the Commissioner misinterpreted 12 VAC 5-230-450(A)(2) when he determined that the term "services" referred to per operating room. The circuit court then went on to determine that,

> because the Commissioner misinterpreted one subparagraph of one regulation that constitutes only one part of the SMFP regulations regarding the introduction of new open heart surgery services, and because compliance with the SMFP is but one of eight factors that Code § 32.1-102.3(B) requires the Commissioner to consider, the [circuit court] holds that the misinterpretation constituted harmless error.

In determining if this misinterpretation of the term "services" constitutes error which is reversible we apply familiar principles.

> Error will be presumed prejudicial unless it plainly appears that it could not have affected the result. A plaintiff in error must always show not only error . . . , but also error of a substantial nature. When once he has pointed out an error of a substantial character, he is entitled to have it corrected if it appears from the record that there is reasonable probability that it did him any harm.

State Health Comm'r v. Sentara Norfolk Gen. Hosp., 260 Va. 267, 277 (2000).

CRMC alleges that the misinterpretation was prejudicial because it interfered with its ability to demonstrate that the proposed new open heart surgery service was consistent with the SMFP. We disagree.

The misinterpreted portion of the single subsection is only one of three factors the Commissioner must review under 12 VAC 5-230-450(A) in determining whether an application for a new open heart surgery service is consistent with the SMFP. As noted in the Commissioner's decision, the project's consistency with the SMFP is but one of five reasons the Commissioner cited in denying CRMC's application. This error is not substantial in nature and as such, we find that the circuit court did not err in its determination that the Commissioner's misinterpretation of 12 VAC 2-230-450(A)(2) was harmless.

B. Deference

CRMC alleges that the Commissioner incorrectly applied the open heart surgery standard when he determined that CRMC had not met the requisite DEP[2] volume threshold. We disagree.

It is well settled that "[t]he construction which an administrative agency gives to its regulations, if reasonable, is entitled to great deference." Virginia Real Estate Bd. v. Clay, 9 Va. App. 152, 160 (1989). "This deference stems from Code § 2.2-4027, which requires that reviewing courts 'take due account' of the 'experience and specialized competence of the agency' promulgating the regulation." Bd. of Supervisors of Culpeper Cnty. v. State Bldg. Code Tech. Review Bd., 52 Va. App. 460, 466 (2008) (quoting Clay, 9 Va. App. at 160-61).

12 VAC 5-230-450(A)(1) requires that a "service . . . performed an average of 1,200 DEPs for the relevant reporting period." The Commissioner reviewed the DCOPN staff report, which found CRMC performed an average of 1,374 DEPs in 2015, but the Commissioner noted that the staff report failed to take into account that CRMC had two cardiac catherization labs. The Commissioner determined that CRMC performed an *average* of 687 DEPs per laboratory in 2015, well below the required 1,200. CRMC alleges that it has satisfied this portion of the application and that the Commissioner erred in determining that it must meet the standard *per lab*.

Unlike the portion of the regulations discussed above, the circuit court found that 12 VAC 5-230-450(A)(1) is ambiguous due to the words "on average." The Commissioner must therefore "average" the number of procedures completed. We agree with the circuit court that the term "on average," in the context of this regulation, is ambiguous because it does not state if the average to be met is on a per service basis or a per lab basis.

[2] "DEP" refers to a diagnostic equivalent procedure which is "a method for weighing the relative value of various cardiac catherization procedures." 12 VAC 5-230-10.

Since this competing interpretation of the meaning of the term "on average" in the context of the regulation results in a genuine ambiguity, this Court must defer to the agency's interpretation of the regulation if it is "reasonable, actually made by the agency, implicates substantive expertise, and reflects the agency's fair and considered judgment." Kisor v. Wilkie, 139 S. Ct. 2400, 2415-16 (2019). "An agency's interpretation of its governing statutes, as reflected in its regulations, is entitled to great weight." Manassas Auto Cars, Inc. v. Couch, 274 Va. 82, 87 (1988).

Because "[a]n agency's interpretation of its own regulations is controlling unless plainly erroneous or inconsistent with the regulations being interpreted," Mathews v. PHH Mortg. Corp., 283 Va. 723, 724 (2012), the circuit court did not err in deferring to the Commissioner in determining how to calculate the average number of procedures completed annually and whether that number complied with the SMFP. Since the Commissioner could have concluded that the term "on average" required an average of DEPs completed per laboratory, his decision that the required volume of DEPs performed, averaged by each laboratory, did not meet the threshold required by the SMFP was not plainly erroneous or inconsistent with the regulations being interpreted.

C. Relevant Data

CRMC's third assignment of error contends that the circuit court should have found error in the Commissioner's failure to consider certain evidence in denying the COPN. Specifically, CRMC alleges that the Commissioner should have considered the impact North Carolina residents would have in the utilization calculation of PD 20 services and that his failure to do so was arbitrary and capricious. CRMC additionally contends that the Commissioner relied upon an incomplete data set, specifically the Service Line Data set, in determining the utilization of open and closed heart surgery services. We disagree.

1. North Carolina Resident Utilization

Where an "issue concerns an agency decision based on the proper application of its expert discretion, the reviewing court will not substitute its own independent judgment for that of the agency but rather will reverse the agency only if that decision was arbitrary and capricious." Johnston-Willis, Ltd. v. Kenley, 6 Va. App. 231, 246 (1988). Courts must "consider the experience and specialized competence of the agency and the purposes of the basic law under which the agency acted." Id.

CRMC contends that the Commissioner did not consider the needs of North Carolina residents in making the determination of whether the proposed project warranted the issuance of a COPN. However, after reviewing the evidence submitted by CRMC on this subject, the Commissioner acknowledged CRMC's position before ultimately rejecting it. The circuit court found that this determination was within the Commissioner's expert discretion, and we cannot substitute our judgment for that of the Commissioner. Id.

Moreover, the purpose of the COPN application process is to determine whether a proposed project is needed by the citizens of the Commonwealth who live within a particular planning district. Although the Commissioner considered evidence presented by CRMC related to the utilization of their proposed facility by North Carolina residents, he was also presented evidence that no additional public need had been identified for open heart surgery services in the area of North Carolina that may have utilized CRMC's proposed project.

As such, a review of the record shows that the Commissioner's decision was not arbitrary and capricious, but rather accounted for the information CRMC provided but found it unpersuasive. We hold that the Commissioner's conclusion was within his proper discretion.

2. Reliable Data Sets

CRMC further contends that the Commissioner relied on incomplete data sets to determine the volume of open heart surgeries in PD 20. Specifically, CRMC alleges that the Commissioner erroneously relied on the Service Line Data, instead of the Annual Licensure Survey Data or Truven data, in determining utilization of open heart surgery services.

In making its ruling, the circuit court stated that "[t]he reliability of these data sets constitute the Commissioner's factual findings." The sole question on factual issues is "whether there was substantial evidence in the agency record to support the agency decision." Code § 2.2-4027. This Court will reject an agency's factual finding "only if, considering the record as a whole, a reasonable mind would necessarily come to a different conclusion." Doctor's Hosp., 52 Va. App. at 607. The reviewing court has no authority to reweigh the facts in the record. Reston Hosp., 63 Va. App. at 770.

Substantial evidence exists in the record that the Commissioner assessed conflicting evidence of the historical utilization data of open and closed heart surgery services. This factual determination is well within the experience and specialized competence of the Commissioner. CRMC asks us to substitute our judgment for that of the Commissioner; we decline to do so. We cannot say that a "reasonable mind would necessarily come to a different conclusion." Doctors' Hosp., 52 Va. App. at 707. This determination is supported in the record by substantial evidence and thus we must defer to the Commissioner's factual finding.

D. Factual Findings

Finally, CRMC contends that the circuit court erred by upholding the Commissioner's factual findings on a quality-volume connection, access to open heart surgery services, and the impact of beneficial competition. CRMC contends that these findings are arbitrary and capricious and unsupported by substantial evidence. We disagree.

It is the duty of the reviewing Court "to determine whether there was substantial evidence in the record to support the agency decision." Code § 2.2-4027. When issuing the case decision, the Commissioner is not required to provide detailed findings regarding every statutory factor in Code § 32.1-102.3(B). Rather, he "needs only to notify the parties briefly and generally in writing[] of the factual basis for an adverse decision." Va. Ret. Sys. v. Cirillo, 54 Va. App. 193, 199 (2009). Substantial evidence is "such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." State Health Comm'r v. Sentara Norfolk Gen. Hosp., 260 Va. 267, 275 (2000) (quoting Virginia Real Estate Comm'n v. Bias, 226 Va. 264, 268-69 (1983)). "An agency's factual findings should only be rejected if, 'considering the record as a whole, a reasonable mind would necessarily come to a different conclusion.'" Id.

1. Quality-Volume Determination

CRMC challenges the circuit court's ruling regarding the Commissioner's finding that there is a link between quality and volume in open heart surgery services and that CRMC's proposed project would have the potential to divert patients from already existing open heart projects.

CRMC presented evidence to the Commissioner that it claims quality is more tied to the experience of the surgical team and that an open heart surgery program is able to be successful regardless of volume.

The Commissioner directly addressed CRMC's concerns in the case decision, finding CRMC's contentions unpersuasive. The Commissioner stated in the case decision, "I do not believe that the possibility that quality would result from an approval of CRMC's project is sufficient to find a public need for it, looking at this point and the administrative record overall."

We cannot say that "a reasonable mind would necessarily come to a different conclusion." Id. As such, the circuit court did not err in relying on the Commissioner's factual

determination. The Commissioner's factual determination regarding the correlation between quality and volume is based on substantial evidence in the record and should not be disturbed.

2. Geographic Access to Services

CRMC contends that substantial evidence exists in the record that approval of its proposed open heart surgery service would improve patient access to services. CRMC supports this contention with alleged wait times for open heart surgeries within PD 20. Additionally, CRMC contends that the Commissioner erred in his conclusion that residents of PD 20 are currently well served by existing open heart surgery providers. We disagree.

CRMC conflates the standard of review that we must apply with its preferred review of the record. This Court must determine if the *Commissioner's* factual findings are supported by the record, not CRMC's proposed conclusions. See Code § 2.2-4027.

Substantial evidence exists in the record to support the Commissioner's decision. The Commissioner determined that "the CRMC project . . . would not meaningfully increase access, geographic or financial, to needed services for residents of the area."

In fact, the Commissioner considered the other three open heart services in PD 20 noting that all of the facilities are located within thirty minutes of CRMC. Of these three service providers, one is currently operating near capacity while the other two facilities are currently underutilized.

The SMFP requires that open heart surgery services be located within sixty minutes' driving time of 95% of the population in a planning district. See 12 VAC 5-230-440. Since that standard is currently being met, it was neither arbitrary nor capricious for the Commissioner to determine that the addition of CRMC's proposed project would not substantially improve the geographic access for residents of PD 20. As a result, substantial evidence exists in the record to support the Commissioner's conclusion.

3. Beneficial Competition

Finally, CRMC contends that the Commissioner's factual determination that the addition of CRMC's proposed open heart surgery service would not result in beneficial competition was in error. The circuit court held that the Commissioner reached this conclusion, after considering and weighing all the evidence in the record. The court therefore declined to substitute its judgment for that of the Commissioner because a reasonable mind would not necessarily come to a different conclusion. We agree with the circuit court.

The Commissioner found that 66% of Sentara's open heart surgery patients are Medicare-covered patients, thus, Sentara receives non-negotiable reimbursement rates. Based thereon, the Commissioner determined that the potential for competition was limited by the structure of the payments open heart surgery services in PD 20 receive.

The Commissioner also noted that "[f]ostering competition has not historically been a primary objective in regulating highly specialized services such as open heart surgery . . . ."

Since these factual determinations made by the Commissioner were supported in the record, they are entitled to great deference. The Commissioner provided a very thorough explanation of the evidence in support of his findings under each of the statutory factors in Code § 32.1-102.3(B). His findings addressed each of CRMC's arguments which he simply did not find sufficiently persuasive to grant their COPN application. This matter was thoroughly litigated, and substantial evidence exists in the record in support of the Commissioner's decision. Like the circuit court, which determined that a reasonable mind would not necessarily come to a different conclusion, this Court cannot "reweigh the facts in the record" and reach a different conclusion. As a result, we find that the circuit court did not err in deferring to the Commissioner's factual determinations supported by substantial evidence.

III. CONCLUSION

The decision of the circuit court is therefore affirmed.

Affirmed.