Present: Carrico, C.J., Lacy, Hassell, Keenan, Koontz, and Kinser, JJ., and Compton, Senior Justice

STATE HEALTH COMMISSIONER

v. Record No. 992018 OPINION BY JUSTICE ELIZABETH B. LACY
September 15, 2000

SENTARA NORFOLK GENERAL HOSPITAL

FROM THE COURT OF APPEALS OF VIRGINIA

In this appeal, we consider whether the Court of Appeals erred in concluding the State Health Commissioner (Commissioner) exceeded his statutory authority and committed reversible error by relying on evidence outside the record and on a mistake of fact when he denied a Certificate of Public Need (COPN) for creation of an additional liver transplant program in Virginia.

On July 31, 1996, Sentara Norfolk General Hospital (Sentara) submitted an application for a COPN pursuant to Code § 32.1-102.3 to establish a liver transplant facility in Norfolk. In accordance with the procedures governing consideration of an application for a COPN, § 32.1-102.6, a public hearing was held in Norfolk on September 16, 1996. Following the hearing, the staff of the Eastern Virginia Health Systems Agency Board recommended that the application be denied. The Board disagreed with the staff recommendation and voted to recommend approval of the application.

The application was then forwarded to the Virginia Department of Health (VDH), Division of Certificate of Public Need, for review. The staff of VDH recommended denial of the application. An informal non-adversarial fact finding conference was convened pursuant to § 9-6.14:11, and a VDH adjudication officer recommended that the application be approved.

The adjudication officer's recommendation along with the entire record of the proceeding was submitted to the Commissioner for decision. The Commissioner reviewed the agency record, rejected the adjudication officer's recommendation, and, by letter dated November 3, 1997, denied Sentara's application for a COPN, finding that there was currently no public need for the project. In his letter, the Commissioner stated three reasons for this decision. First, the Commissioner determined that the provisions of the State Medical Facilities Plan (SMFP) relating to liver transplants are "inaccurate, outdated, inadequate or otherwise inapplicable" and that "[b]ecause they fail to reflect current standards, they should not be applied here." The Commissioner based this finding on the fact that although the SMFP only requires that facilities perform a minimum of 12 liver transplant procedures annually, 12 VAC 5-280-70, "[t]he average number of liver transplants performed per transplant

center nationally in 1994 was 36. In 1996 the average number of liver transplants performed per transplant center in Virginia was 52."

Second, the Commissioner concluded that the establishment of an additional liver transplant facility at Sentara "may erode the quality of other transplant centers by reducing the volume of liver transplants at the other centers." The Commissioner made this statement based on his finding that "[i]ndications in the healthcare system are that the numbers of available organs may be reaching a plateau; consequently, the actual numbers of transplantations performed appear to be stabilizing."

Finally, the Commissioner stated that "an additional liver transplant center at [Sentara] may seriously impact the established liver transplant fellowship training program at MCVH [Medical College of Virginia Hospital]" because MCVH is required by the American College of Surgeons "to perform 45 liver transplants annually."

In conclusion, the Commissioner found that Sentara's application for a COPN was premature because "the system presently (i) reflects no need for additional liver transplantation sites in light of organ supply; (ii) appears to have no excess of transplantation procedures requiring accommodation whereas approval of another site could result in

an excess of facilities lacking volume to meet the national average or to assure essential technical experience; and (iii) should maintain and sustain necessary training programs in the Commonwealth."

Sentara filed a petition for appeal in the Circuit Court for the City of Norfolk, arguing that the Commissioner's decision should be reversed because the Commissioner exceeded the scope of his authority, relied on evidence not contained in the record, and relied on a mistake of fact regarding the impact of the proposed transplant program on accreditation of the liver transplant fellowship program at MCVH. During the circuit court proceedings, the Commissioner conceded that his recitation of the accreditation requirement was incorrect.

The circuit court affirmed the Commissioner's decision and dismissed Sentara's petition, holding that the Commissioner did not abuse his discretion in denying the COPN and that, considering the record as a whole, "a reasonable mind could not necessarily conclude that Sentara's COPN should be approved." Additionally, the circuit court held that the Commissioner's reliance on the mistake of fact regarding accreditation requirements was harmless error.

Sentara appealed to the Court of Appeals, raising the same three issues. The Court of Appeals resolved each issue adversely to the Commissioner, holding that: (1) the

Commissioner exceeded his authority in denying the petition because § 32.1-102.3(A) does not allow the Commissioner to deny an application for a COPN based on his determination that the SMFP standards are outdated, inaccurate, inadequate, or otherwise inapplicable; (2) the Commissioner's finding that the number of livers available for transplantation "may be reaching a plateau" was based on evidence outside the record, reliance on this finding prejudiced Sentara and, therefore, it was reversible error; and (3) the Commissioner's reliance on a mistake of fact regarding the number of transplant procedures necessary for a facility to maintain teaching accreditation constituted reversible error and was not harmless. Sentara Norfolk Gen. Hosp. v. State Health Comm'r, 30 Va. App. 267, 283, 516 S.E.2d 690, 698 (1999). The Commissioner appealed, assigning error to the holding of the Court of Appeals on each issue. We consider these assignments of error in order.

I. Commissioner's Statutory Authority

In his letter denying the COPN, the Commissioner stated that the SMFP standard of 12 liver transplants per year was "inaccurate and outdated" and "should not be applied" in this case. The Commissioner directed that procedures for amending the SMFP standard be initiated. Sentara claims that, in making this determination, the Commissioner "set aside the SMFP in order to impose a higher volume standard, rather than

a less strict standard as permitted by the statute." In doing so, Sentara asserts, the Commissioner exceeded his statutory authority because § 32.1-102.3(A) allows the Commissioner to set aside the SMFP if it is outdated and inaccurate only to grant a COPN application, not to deny an application.

Agreeing with Sentara, the Court of Appeals held that "[t]he plain language of the statute provides that the Commissioner 'may *issue* or *approve*' a petition that does not comply with an outdated or inaccurate SMFP" but it does not provide "that he may deny or disapprove a petition on this basis." Sentara, 30 Va. App. at 277, 516 S.E.2d at 695.

Section 32.1-102.3(A) provides in relevant part:

> No person shall commence any project without first obtaining a certificate issued by the Commissioner. No certificate may be issued unless the Commissioner has determined that a public need for the project has been demonstrated . . . . Any decision to issue or approve the issuance of a certificate shall be consistent with the most recent applicable provisions of the State Medical Facilities Plan; however, if the Commissioner finds, upon presentation of appropriate evidence, that the provisions of such plan are not relevant to a rural locality's needs, inaccurate, outdated, inadequate or otherwise inapplicable, the Commissioner, consistent with such finding, may issue or approve the issuance of a certificate and shall initiate procedures to make appropriate amendments to such plan.

This section clearly authorizes the Commissioner to conclude that provisions of the SMFP are outdated and directs the Commissioner to initiate the process for changing the

provisions found to be outdated. Thus, in this case, the Commissioner acted within his statutory authority when he determined that the existing SMFP requiring a minimum of 12 liver transplants was outdated and directed that procedures be instituted to adopt appropriate amendments.

We agree with the Court of Appeals, however, that the section specifically authorizes the Commissioner to grant a COPN even if he finds provisions of the SMFP "outdated" or "otherwise inapplicable," but does not contain similar specific authorization to deny a COPN under such circumstances. Denial of the COPN under such circumstances would allow the Commissioner to unilaterally impose new, and presumably higher, standards. The statute contemplates that new standards would be imposed as a result of amendment procedures initiated, not pursuant to unilateral adoption and application of new standards by the Commissioner in the course of the COPN process.

Section 32.1-102.3(A) does not, however, require the Commissioner to grant a COPN simply because a COPN application complies with the provisions of the existing SMFP. The Commissioner correctly points out that compliance with the SMFP is only one factor in the decision. The statute provides that to grant a COPN, the Commissioner must conclude that "a public need for the project has been demonstrated."

Subsection B of § 32.1-102.3 lists 20 factors which the Commissioner must consider in addition to compliance with the SMFP in determining whether a public need has been demonstrated. In this case, therefore, the Commissioner exceeded his authority under § 32.1-102.3(A) if the Commissioner denied Sentara's application solely on the basis that the SMFP regarding the average number of transplants was outdated and inapplicable. While the Court of Appeals opinion states that the Commissioner exceeded his authority "to the extent" he denied the COPN on the ground the SMFP was outdated, there is no discussion of the extent to which the denial was based on that ground.

Sentara argues that the Commissioner exceeded his authority because, in setting aside the existing SMFP, he applied "some higher, impromptu, unspecified standard" as a basis for denying the COPN. The record, however, contains no evidence that the Commissioner required Sentara to satisfy some higher standard in order to secure the COPN. The Commissioner's only references to higher standards were those regarding the national average for annual liver transplantations. First, the Commissioner observed that it was "reasonable to assume" that over time there would be an increase in the number of liver transplants performed by Sentara and that this would reduce the number of procedures at

other existing transplant centers. This redistribution of patients, the Commissioner wrote, "would place the Commonwealth's programs below the national average of 36 transplants per center." A second reference is contained within one of the three considerations cited in his conclusion: "[a]pproval of another site could result in an excess of facilities lacking volume to meet the national average or to assure essential technical experience."

These references to the national average were made in regard to future events, not requirements which the Commissioner imposed on Sentara as a prerequisite to securing a COPN in this proceeding. They are a reflection of the record evidence that the quality of transplant medical expertise is directly related to the number of procedures performed, and that the clinical outcome for liver transplants improves as the number of procedures performed in a facility increases. Thus, they cannot be the "higher, impromptu, unspecified standard" that Sentara argues the Commissioner applied as a basis for denying the COPN.

Furthermore, although the Commissioner stated that the SMFP standard was outdated and would not be applied, he nevertheless relied on the provisions of the existing SMFP in support of his decision that no public need existed for Sentara's proposed project. Citing the portion of the SMFP

that states that transplantation programs are expected "to perform substantially larger numbers of transplants annually" and that meeting the minimum volume "does not necessarily indicate a need for additional transplantation capacity or programs," the Commissioner concluded that the existing SMFP was "not binding as to minimum acceptable volumes." The Commissioner also stated that even the existing SMFP "does not support" the grant of a COPN to Sentara at this time.

In his letter denying Sentara's application, specifically in the section relating to the existing SMFP standards, the Commissioner made no statements which support the proposition that the COPN was denied solely on the basis of a determination that the existing SMFP was outdated and inapplicable. Rather, the statements as set out above indicate that the Commissioner found that even though Sentara complied with the existing SMFP, it had not demonstrated a public need for the project. This conclusion was within the discretion and authority of the Commissioner under both § 32.1-102.3 and the provisions of the SMFP.

For these reasons, we hold that the Commissioner did not exceed his statutory authority in denying the COPN in this case.

II. Evidence Outside the Record

The Commissioner's determination that a liver transplant facility at Sentara might reduce the quality of transplants at other facilities because a new facility would reduce the number of such procedures at those facilities was based on his conclusion that "the numbers of available organs may be reaching a plateau." The Court of Appeals concluded that the evidence on trends in organ donation rates was, at best, inconclusive and that the proposition was faulty because the number of liver transplants performed in Virginia increased in 1995 and 1996. Based on this rationale, the Court of Appeals held, "as a matter of law that the evidence contained in the record is insufficient to support the Commissioner's finding that organ donation rates have reached a plateau," 30 Va. App. at 279, 516 S.E.2d at 696, and, therefore, that the Commissioner must have relied upon evidence outside the record in making his decision. Because such evidence outside the record constituted neither "institutional knowledge" nor "a public statistic," the Commissioner's reliance on it was improper. Id. at 280, 516 S.E.2d at 696. Reliance on this improper evidence was reversible error, according to the Court of Appeals, because the record did not otherwise support the concerns of the Commissioner and, therefore, Sentara was prejudiced by the Commissioner's consideration of evidence outside the record regarding organ donation rates. Id. at

282, 516 S.E.2d at 697. We disagree with the Court of Appeals' analysis and conclusion.

In considering whether the record evidence is sufficient to support a factual finding made by an agency, we apply the substantial evidence standard of review. Virginia Real Estate Comm'n v. Bias, 226 Va. 264, 268-69, 308 S.E.2d 123, 125 (1983). Under that standard, substantial evidence is " 'such relevant evidence as a reasonable mind *might* accept as adequate to support a conclusion.' " Id. at 269, 308 S.E.2d at 125 (citations omitted). 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.

As the Court of Appeals and trial court acknowledged, the record in this case contains testimonial and documentary evidence suppporting the proposition that the number of livers available for transplantation has reached a plateau. Examples of this evidence include a chart prepared by MCVH showing a decline in liver donations in Virginia, testimony that MCVH must import livers from out of state for its transplant program, and various letters from members of the medical community involved in liver transplantation programs. These letters state that "there remains throughout the world, a scarcity of donor solid organs for transplantation"; that

"[t]here has been an increase in the numbers of liver transplants in the state with addition of programs at UVA (1988) and Fairfax (1992); however, over the past three years . . . this number has reached a state-steady plateau, indicating the driving force is now only the numbers of available donor organs"; that "the number of livers donated in our procurement region is inadequate to support the existing capacity of the region to perform liver transplantations"; that "[a]t the present time, the availability of liver transplants is limited primarily by the availability of transplantable livers. A second transplant program . . . will do nothing to change the one limiting factor. In addition, it may diminish the overall quality and effectiveness of this procedure in our area"; and "[t]he most dramatic improvements in access to liver transplantation for the residents of Virginia can be accomplished through initiatives directed at improving the rate of organ donations." (Emphasis omitted.)

Applying the substantial evidence standard of review, we conclude that the character of this evidence would not require a reasonable person to reject it as untrustworthy or incredible and that a "reasonable mind might accept" it to support the conclusion that the availability of livers "may have reached a plateau." And, in light of this evidence, we

cannot say that a reasonable person would necessarily come to a different conclusion.

For these reasons, we hold that the Court of Appeals erred in finding that the Commissioner relied on evidence outside the record in making a factual finding regarding organ donation rates. Because the Commissioner did not improperly base his finding on evidence outside the record, questions of prejudice to Sentara do not arise.

III. Mistake of Fact

The third reason cited by the Commissioner for denying Sentara's application for a COPN was that the new transplant center "may seriously impact the established liver transplant fellowship training program at MCVH." This conclusion was based on the Commissioner's factual finding that "the American College of Surgeons requires the training institution to perform 45 liver transplants annually." This factual finding was wrong. The accreditation requirement, which had been changed by the American College of Surgeons during the course of the application process, no longer required a specific number of procedures annually by the institution but rather required 45 procedures by the fellow as primary surgeon in the course of the fellowship, usually two years.

The Court of Appeals determined that "[i]n the absence of substantial credible evidence supporting the Commissioner's

decision to deny the COPN, we must assume that Sentara was also prejudiced by this mistake of fact." Sentara at 282, 516 S.E.2d at 698. We disagree with the Court of Appeals.

In determining whether an error 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.

Breeding v. Johnson, 208 Va. 652, 659, 159 S.E.2d 836, 842 (1968). The Commissioner argues that the factual mistake was not substantial and that there is no reasonable probability that it did Sentara any harm. We agree with the Commissioner.

In determining whether there was a public need for Sentara's transplant program, the Commissioner was required to consider the program's impact on "the clinical needs of health professional training programs in the area in which the project is proposed." § 32.1-102.3(B)(12). The gravamen of the Commissioner's expressed concern was whether the volume of liver transplant procedures would be sufficient to sustain MCVH's liver transplant training accreditation if Sentara established a transplant program. According to the record,

MCVH performed 66 liver transplants in 1996. That year, Sentara referred 28 patients for liver transplants and the majority of these patients went to MCVH for the procedure. Based on these figures, the Commissioner stated that, if the COPN were granted, over time Sentara would perform those transplant procedures and the volume of liver transplants at MCVH would be reduced by 40-50%. That degree of reduction in transplant procedures at MCVH would impact the accreditation of MCVH's liver transplant fellowship training program under either the current accreditation standard or the erroneous standard considered by the Commissioner.

Furthermore, the number of procedures which must be performed at MCVH each year to retain its accreditation under the current standard may be as many as 45 because, under the new standard, the requisite number of procedures must be performed by the fellow as primary surgeon. Presumably, a fellow will have to assist on some number of procedures before assuming the role of primary surgeon. As noted by the trial court, "[a]ssuming there is one new fellow each year, as well as an expert surgeon directing the program and performing the majority of procedures during the first year of each fellow's training, the training facility will exceed forty-five transplants per year."

Therefore, we conclude that the Commissioner's use of an accreditation requirement of 45 transplants per institution per year, rather than 45 transplants per fellow as primary surgeon, in considering the impact of Sentara's proposed transplant program on MCVH's liver fellowship training program, was not "error of a substantial nature."

Finally, as we have already noted, the Commissioner's decision to deny the COPN was based on multiple grounds. In addition to concern about the continued accreditation of MCVH's training program, the Commissioner's denial was based on the need to maintain the quality of the technical experience and the need for additional transplant centers in light of the availability of donated livers. These other reasons for denying the COPN are not affected by the mistake of fact. Thus, we cannot conclude that a different result would have occurred in the absence of the factual error.

In summary, we hold (1) that the Commissioner did not exceed his authority when he did not apply certain standards in the SMFP because he found that they were outdated, inaccurate, inadequate, and otherwise inapplicable; (2) that he did not rely on evidence outside the record when finding that "the numbers of available organs may be reaching a plateau"; and (3) that his reliance on a mistake of fact was harmless error.

For the foregoing reasons, the judgment of the Court of Appeals will be reversed and the judgment of the trial court dismissing Sentara's petition for appeal will be reinstated.

Reversed and final judgment.