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**SUPERIOR COURT OF NEW JERSEY  
APPELLATE DIVISION  
DOCKET NO. A-0258-21**

**TRINITAS REGIONAL  
MEDICAL CENTER,**

Petitioner-Appellant,

v.

**NEW JERSEY DEPARTMENT  
OF HEALTH,**

Respondent-Respondent,

and

**UNIVERSITY HOSPITAL,**

Intervenor-Respondent.

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Argued March 1, 2023 – Decided March 24, 2023

Before Judges Accurso, Vernoia and Natali.

On appeal from the New Jersey Department of Health,  
Docket No. FR 171101-20-01.

Craig A. Domalewski argued the cause for appellant  
(Dughi, Hewit & Domalewski, attorneys; Craig A.

Domalewski, of counsel and on the briefs; Ryan A. Notarangelo, on the briefs).

Mark D. McNally, Deputy Attorney General, argued the cause for respondent New Jersey Department of Health (Matthew J. Platkin, Attorney General, attorney; Melissa H. Raksa, Assistant Attorney General, of counsel; Mark D. McNally, on the brief).

James J. DiGiulio argued the cause for respondent University Hospital (O'Toole Scrivo, LLC, attorneys; James J. DiGiulio, of counsel and on the brief; Steven S. Fernandez, on the brief).

#### PER CURIAM

Trinitas Regional Medical Center (Trinitas) appeals from a final decision of the Deputy Commissioner of the New Jersey Department of Health (Department) that denied its certificate of need (CN) application for designation as a Level II trauma center. We affirm.

#### I.

On August 18, 2017, the Department issued a "Notice of Invitation for Certificate of Need Applications for Designation as a Level II Trauma Center in Union County." The Department explained it initiated the call "because an acute care hospital ha[d] presented documentation indicating that there may be a potential need for a Level II trauma center in Union County." The notice also stated, "[i]ssuance of this call does not constitute a finding of need by the

Department for the designation of an additional Level II trauma center in the affected area."

Trinitas, a full-service healthcare facility located in Elizabeth, was the acute care hospital suggesting the need for a new trauma center and was the only applicant to respond to the call. At the State Health Planning Board's (SHPB) public hearing to consider Trinitas's application, a staff member within the Department's Office of Emergency Medical Services (OEMS) noted Trinitas had also previously scheduled a consultation with the American College of Surgeons (ACS) and sought trauma center designation "three or four years ago."

The CN call required Trinitas to establish its designation as a Level II trauma center would satisfy the requirements of N.J.S.A. 26:2H-8, which provides:

No [CN] shall be issued unless the action proposed in the application for such certificate is [(1)] necessary to provide required health care in the area to be served, [(2)] can be economically accomplished and maintained, [(3)] will not have an adverse economic or financial impact on the delivery of health care services in the region or Statewide, and [(4)] will contribute to the orderly development of adequate and effective health care services.

[N.J.S.A. 26:2H-8.]

The statute also identifies the following criteria that shall be considered prior to issuing a CN:

(a) the availability of facilities or services which may serve as alternatives or substitutes, (b) the need for special equipment and services in the area, (c) the possible economies and improvement in services to be anticipated from the operation of joint central services, (d) the adequacy of financial resources and sources of present and future revenues, (e) the availability of sufficient manpower in the several professional disciplines, and (f) such other factors as may be established by regulation.

[N.J.S.A. 26:2H-8.]

Additionally, the Department required applicants to provide the following data for major trauma cases in 2015 and 2016:

1. Major traumas involving a Union County resident treated at a hospital in Union County or a contiguous county;
2. Major trauma cases occurring within Union County and treated at a hospital in Union County or a contiguous county;
3. Major trauma cases treated at a hospital in Union County or a contiguous county; and
4. Factors, including demographic and geographic, impacting trauma center access for major trauma cases that occur within Union County or a contiguous county.

The CN call also invited existing trauma centers to file written submissions addressing the impact any applicant's requested designation would have on its provision of trauma services. University Hospital (University), which is designated as a Level I trauma center and located in Newark, just eight travel miles from Trinitas, submitted an opposition to Trinitas's application. According to University, 20% of its trauma patients originate from Union County and 87% of its entire caseload originates from within a ten-mile radius surrounding Trinitas.

To supplement its application, the Department requested Trinitas answer completeness review questions. The Department identified University as a Level I trauma center less than thirty minutes from Trinitas, as well as Morristown Medical Center and Robert Wood Johnson University Hospital, each less than twenty-five travel miles and one hour from Trinitas. The Department requested Trinitas "explain and document any geographic barrier to existing trauma services in Union County," provide data on University's trauma capacity, and explain if University lacks the capacity "to accommodate those trauma cases [Trinitas] states it now captures."

In response, Trinitas referenced a 2008 report by the ACS, which the State commissioned to complete a statewide trauma system consultation. The ACS

found "[t]he geographic distribution of trauma centers appears to be appropriate and the reported volumes are adequate, supporting the contention that no reconfiguration or change in number of trauma centers is needed." It also observed, however, "the efficacy and efficiency of the current trauma center network cannot be accurately evaluated without performance and outcome data, which is not readily available."

The Legislature thereafter enacted N.J.S.A. 26:2KK-1 to -6 for the establishment of a statewide trauma system, requiring the Commissioner of Health to "establish a multidisciplinary State Trauma System Advisory Committee (STSAC) . . . ." N.J.S.A. 26:2KK-4(a). The STSAC is charged with "analyz[ing] data related to trauma care in the State." N.J.S.A. 26:2KK-4(d)(1).

Trinitas stated the data requested in the completeness questions was "precisely the type of comprehensive trauma systems information that was identified as lacking in the ACS report and in the legislation establishing the STSAC." According to Trinitas, the information requested with respect to other hospitals was unavailable, as "[t]he ACS report and minutes of STSAC Committees indicate[d] that such comprehensive data simply [did] not exist in an accessible format." Trinitas submitted Open Public Records Access (OPRA)

requests to seven divisions of the Department, each of which responded they were unable to provide the requested information.

Trinitas did not request any data from University, which is also subject to OPRA, nor from local, public third-parties, such as Emergency Medical Technicians (EMTs) or police departments. In response to Trinitas's OPRA requests to the Division of Long Term Care Health Facility Survey and Field Operations, the Division specifically recommended Trinitas contact the local departments of health for Union County and Essex County, the Office of Vital Statistics, and local police departments, but the record does not contain any such requests to these entities.

Despite its inability to obtain data requested in the CN call, Trinitas maintained that granting its application was necessary to provide effective trauma services to Union County residents because it already acted as a "de facto" trauma center and designating Trinitas as a Level II trauma center would align with the ACS's recommendations. Trinitas also claimed the Department's estimated proximity of Union County residents to existing trauma centers failed to adequately account for urban traffic delays.

It further asserted its designation was necessary to improve the State's preparedness "to respond to disasters and [m]ass [c]asualty [i]ncidents," noting

a recent bomb threat to the Elizabeth train station and its proximity to numerous "high risk locations," including Newark Liberty International Airport. Trinitas also included in its application a 2011 news article which reported the FBI and government officials have described the area surrounding Turnpike Exit 13A between Elizabeth and Newark as "'the most dangerous two miles in America' for terrorist attacks."

To establish its capacity to operate as a Level II trauma center, Trinitas engaged Dr. Jane O'Shaughnessy, M.D., who is board certified in emergency medicine, to audit its trauma cases from 2014 to 2017. Dr. O'Shaughnessy found Trinitas handled 419 trauma cases that met the State's definition of "major trauma" pursuant to N.J.A.C. 8:43G-12.13 in 2014, 391 such cases in 2015, 407 in 2016, and 376 in 2017. According to her report, for each of the years reviewed, Trinitas maintained the minimum volume of 350 major trauma cases necessary for Level II designation under N.J.A.C. 8:43G-12.14(b).

After review of Trinitas's application and completeness responses, Department staff recommended its application be denied. Specifically, Department staff concluded Trinitas failed to satisfactorily demonstrate: (1) "a need for Level II trauma center designation at Trinitas based upon the criteria found in the CN call"; (2) "existing providers would not be negatively impacted



by its designation as a Level II trauma center;" and (3) "Trinitas would meet and maintain the minimum volume standard of 350 major trauma cases per year in accordance with N.J.A.C. 8:43G-12.14(b)."

With respect to Trinitas's ability to maintain 350 major trauma cases per year, Department staff found insufficient information in its application to verify whether the cases identified by Dr. O'Shaughnessy met the major trauma criteria. For example, OEMS conducted a medical record audit of Dr. O'Shaughnessy's findings for 2017, reviewing 184 of the 373 cases identified, and determined sixteen of those cases definitively did not meet the major trauma criteria.

OEMS also questioned the validity of the major trauma designation for a significant percentage of the cases it reviewed. Specifically, it discovered EMS transported to Trinitas 101 of the patients whose cases were reviewed, which indicated EMS did not consider them to be major trauma cases, as existing EMS field triage guidelines require EMS to transport such cases directly to a trauma center. Of those 101 patients, 12 were transported directly to Trinitas instead of a trauma center because they died in the field and there was no chance of patient survival. OEMS also concluded many of the cases reviewed could have been

properly treated by any hospital's emergency room and did not require treatment at a trauma center.

Additionally, Department staff analyzed patient discharge data for cases Trinitas classified as major trauma for calendar years 2014, 2015, and 2016, and observed such data "call[ed] into question Trinitas'[s] classification of major trauma cases," as, "[i]n many cases, a trauma code was not in the first few diagnosis positions on the patients' discharge . . . record, meaning the trauma was not a primary reason for admission." Staff also found three to eight percent of the cases reviewed were readmissions, which also called into question their designation as major trauma cases.

Trinitas's application and the staff recommendations were submitted to the SHPB, an advisory panel tasked with making recommendations to the Department's Commissioner. N.J.A.C. 8:33-4.13(a). The SHPB held a public hearing in which several elected officials, Trinitas's CEO, and the head of its emergency department testified in favor of Trinitas's CN application, and several Department staff members explained its recommendation to deny the application. No representatives from University testified at the hearing. At the hearing's conclusion, the Board unanimously voted to recommend approval of Trinitas's CN.

The SHPB members acknowledged the lack of data to support Trinitas's application but determined Trinitas could not be held accountable for STSAC's failure to develop relevant data. In the absence of data, the SHPB members concluded Union County was an appropriate location for a designated trauma center due to its population density, the State's critical infrastructure located in the county, and the travel time from Union County to existing trauma centers, especially in light of traffic delays. The board also concluded Trinitas could satisfy the 350-case volume threshold and there was insufficient information to conclude Trinitas's designation would significantly impact University.

After conducting an independent review of the record, including the SHPB's recommendation, the Principal Deputy Commissioner denied Trinitas's application in a written decision. Applying the statutory criteria, the Principal Deputy Commissioner concluded Trinitas failed to establish existing healthcare providers "would not sustain a substantial negative impact by [its] designation as Level II trauma center," or that such designation would respond to an unmet need for healthcare services in the region. See N.J.S.A. 26:2H-8.

Specifically, the Principal Deputy Commissioner found Trinitas failed to establish its Level II designation would not have a substantial negative impact on University. On this point, she found Trinitas's designation as a Level II

trauma center had the potential to reduce University's trauma cases and, consequentially, its trauma funding, which it relies on to support other hospital functions integral to the region's delivery of health care services. She also reasoned "Trinitas failed to consider how a Level II trauma center designation would cause a reconfiguration of the existing [Emergency Medical Services (EMS)] system in the region."

With respect to the need requirement, the Principal Deputy Commissioner disagreed with the SHPB "that if the data does not exist to support an application, as is currently the case with trauma designation, th[en] alternate criteria should be used." The Principal Deputy Commissioner explained "[a] determination of need which ignores controlling statutory and regulatory criteria is arbitrary and capricious."

The Principal Deputy Commissioner also rejected Trinitas's contention that the current trauma care network failed to meet the State's trauma needs. She relied, in part, on the 2008 ACS consultation report, which described New Jersey's trauma centers as "well distributed" and "strategically placed" and found no need for additional trauma centers. In addition, in light of Union County's proximity to University, Morristown Medical, and Robert Wood Johnson, the Principal Deputy Commissioner found sufficient access to trauma

care existed for Union County residents. Further, according to the Principal Deputy Commissioner, "[University] is already addressing the need for trauma services in this region and adding another trauma center would not address a need, but rather cause a disruption of the current efficient system."

In addition, the Principal Deputy Commissioner agreed with Department staff "that Trinitas'[s] ability to meet the minimum volume requirement of 350 cases . . . is questionable based on the results of the 2017 medical record audit, the 2014-2016 discharge data analysis and the number of cases that could be excluded as major trauma." Finally, she acknowledged the STSAC's failure to release relevant trauma center data but concluded "the designation of a Level II trauma center at Trinitas is premature while the planning of a formal statewide trauma system is underway."

Trinitas appealed the denial of its CN application, and the matter was transferred to the Office of Administrative Law. The Administrative Law Judge (ALJ) granted University's motion to intervene and all parties filed motions for summary decision. After oral argument, the ALJ issued an initial decision denying Trinitas' motion for summary decision and granting the Department's cross-motion to deny Trinitas's application.

The Deputy Commissioner issued a final agency decision adopting the ALJ's initial decision and denying Trinitas's CN application. The Deputy Commissioner agreed with the ALJ that the Principal Deputy Commissioner's decision was reasonable, and concluded "the Principal Deputy Commissioner properly evaluated Trinitas's CN application against the applicable statutory and regulatory requirements for this matter." This appeal followed.

## II.

Trinitas contends it "adequately and appropriately established . . . there is an unmet need in Union County for a local Level II trauma center," and its designation as such "would not have an adverse effect on the [region's] trauma system under N.J.S.A. 26:2H-8 and N.J.A.C. 8:33-4.10." Trinitas also argues the Department "violated the doctrine of fundamental fairness by requiring [it] to produce data that it knew did not exist." It therefore asserts the Department's denial of its CN application was "arbitrary, unreasonable, and must be reversed."

With respect to need, Trinitas maintains "[t]he demographics of Union County and Elizabeth alone demand that the [Department] designate Trinitas as a Level II trauma center." According to Trinitas, the per capita income of Elizabeth residents is less than half of the State's average and a large percentage of its population consists of ethnic and racial minorities. It also relies on the

region's dense population, high traffic volume, and placement "next to much of New Jersey's critical infrastructure and industry." Additionally, Trinitas claims Dr. O'Shaughnessy's review of its major trauma cases established "there are a substantial number of trauma cases occurring in and around Elizabeth."

Further, Trinitas contends the Department's adverse impact findings were unreasonable and unsupported by the record. Specifically, Trinitas argues the Principal Deputy Commissioner accepted without independent investigation that granting Trinitas's application would lead to the following adverse consequences: (1) University would lose a substantial number of major trauma care patients; (2) any loss of major trauma care patients suffered by University would result in financial hardship and jeopardize its Level I and Level II status and proficiency in treating major trauma patients; (3) the region's EMS system would require reconfiguration; and (4) the region would suffer healthcare staffing shortages.

Similarly, Trinitas asserts the Department failed to adopt an objective standard to determine what constitutes an "adverse impact" or "substantial negative effect." Trinitas also notes the Department erroneously calculated that were University to lose 20% of its 1,250 yearly major trauma cases, it would lose 300 cases per year. As 20% of 1,250 equals 250, Trinitas contends

"mathematical errors permeate[d] the [Department]'s findings," making them unreasonable.

Having considered the parties' contentions in light of the record and applicable law, we are satisfied the record contains sufficient credible evidence to support the Department's conclusion Trinitas failed to demonstrate the action proposed in its CN application "is necessary to provide required health care in the area to be served." N.J.S.A. 26:2H-8. As such a showing is required under N.J.S.A. 26:2H-8 prior to the issuance of a CN, the Department properly denied Trinitas's application on that basis alone and we need not address whether its adverse impact findings were also supported by the record.

"Our review of an agency's decision is limited." In re Certificate of Need for the Mem. Hosp. of Salem Cnty., 464 N.J. Super. 236, 247 (App. Div. 2020).

"A reviewing court 'should not disturb an administrative agency's determinations or findings unless there is a clear showing that (1) the agency did not follow the law; (2) the decision was arbitrary, capricious, or unreasonable; or (3) the decision was not supported by substantial evidence.'" Ibid. (quoting In re Virtua-West Jersey Hosp. Voorhees for a Certificate of Need, 194 N.J. 413, 422 (2008)).



"In administrative law, the overarching informative principle guiding appellate review requires that courts defer to the specialized or technical expertise of the agency charged with administration of a regulatory system." Ibid. The burden of demonstrating arbitrary, capricious, or unreasonable agency action rests on the party opposing the agency's action. See E.S. v. Div. of Med. Assistance & Health Servs., 412 N.J. Super. 340, 349 (App. Div. 2010).

Here, the CN call required Trinitas to demonstrate its designation as a Level II trauma center satisfied the requirements of N.J.S.A. 26:2H-8. The Department concluded Trinitas failed to meet this burden, in part, because it failed to establish the trauma care it seeks to offer is not adequately provided by other hospitals.

The record supports the Department's finding "University is already addressing the need for trauma services in this region," as 20% of University's trauma cases originate from Union County and 87% of its entire caseload originates from within a ten-mile radius surrounding Trinitas. Additionally, the Department identified Morristown Medical and Robert Wood Johnson as alternative trauma centers within one hour of Trinitas. The Department's conclusion is also supported by the 2008 ACS report, which, although critical

of New Jersey's trauma care network as a whole, concluded the State contains a sufficient number of strategically placed trauma centers.

Furthermore, we reject Trinitas's contention that Dr. O'Shaughnessy's report demonstrated an unmet need for a designated trauma center in Union County. As noted, OEMS sampled the cases Dr. O'Shaughnessy identified as major trauma cases and found a substantial percentage of those cases did not require treatment at a designated trauma center. Similarly, the Department staff's discharge data analysis "call[ed] into question Trinitas'[s] classification of major trauma cases." The Department's reliance on the OEMS findings, as well as its staff's discharge data analysis, was not arbitrary, capricious, or unreasonable.

The Department was also not arbitrary, capricious, or unreasonable in determining Trinitas's application was premature in light of STSAC's ongoing data collection efforts. We defer to the agency's expertise that, absent a clear showing of need, the State's trauma care system is best served by delaying reconfiguration until such efforts can be adequately informed by the STSAC's findings. See Virtua-West, 194 N.J. at 422. The Department also correctly concluded that granting Trinitas's application absent the requisite finding of need would violate N.J.S.A. 26:2H-8.

We also reject Trinitas's contention the Department imposed an impossible burden by requiring Trinitas to produce data the STSAC had not yet published to demonstrate its designation as a Level II trauma center satisfied an unmet need in Union County. Relying on language from Hospital Center at Orange v. Guhl, 331 N.J. Super. 322, 334 (App. Div. 2000), and the holding of Oberhand v. Director, Division of Taxation, 193 N.J. 558, 579 (2008), Trinitas contends the Department's unreasonable reliance on its own failure to publish data as a reason to deny its CN application compels reversal under the fundamental fairness doctrine. Specifically, Trinitas asserts the Department requested data "the STSAC was charged with collecting in the statewide trauma registry in 2013, which otherwise would only be available directly from other hospitals."

"The doctrine of fundamental fairness 'serves to protect citizens generally against unjust and arbitrary governmental action, and specifically against governmental procedures that tend to operate arbitrarily.'" State v. Saavedra, 222 N.J. 39, 67-68 (2015) (emphasis omitted) (quoting Doe v. Poritz, 142 N.J. 1, 108 (1995)). Fundamental fairness is an essential part of the constitutional right to due process and is often inferred from other constitutional guarantees. State v. Melvin, 248 N.J. 321, 347 (2021).

The primary considerations for invoking the doctrine are fairness and the fulfillment of the parties' reasonable expectations. Saavedra, 222 N.J. at 67-68. The doctrine is to be applied sparingly, however, and only "in those rare cases where not to do so will subject the defendant to oppression, harassment, or egregious deprivation." State v. Yoskowitz, 116 N.J. 679, 712 (1989).

In Guhl the appellants brought an action against executive staff within the Division of Medical Assistance and Health Services due to the Division's failure to timely adjudicate their administrative appeals. 331 N.J. Super. at 326-27. We explained "our courts have held that undue delay in the administrative process may result in a denial of 'fundamental procedural fairness,'" Id. at 333 (quoting In re Arndt, 67 N.J. 432, 436 (1975)), and the Division's delay was "clearly unjustifiable," Id. at 334.

In Oberhand, the plaintiffs asserted the manifest injustice doctrine precluded retroactive application of an amendment to our State's tax laws to their decedents' estates. 193 N.J. at 562. To determine whether the doctrine of manifest injustice warranted relief, the Court balanced the respective interests of the parties, concluding the decedents' reasonable reliance on the previous law outweighed the State's interest in the law's retroactive application. Id. at 573.

It therefore held it would be "harsh and unfair" to apply the law retroactively. Id. at 574.

We are satisfied this is not the "rare" case where the doctrine of fundamental fairness warrants reversal, as the Department did not arbitrarily apply the CN application requirements to Trinitas or violate its reasonable expectations. See Saavedra, 222 N.J. at 67-68. The STSAC's failure to publish data did not relieve Trinitas of its independent burden to establish its designation as a Level II trauma center satisfied the requirements for granting its CN application under N.J.S.A. 26:2H-8. Trinitas does not contend it was reasonably unaware of its burden to demonstrate an unmet need in Union County as a requisite to Level II designation under the statute, such requirement changed while its application was under review, or that the requirement was disproportionately applied to its case.

Additionally, Trinitas could not have reasonably expected the Department would grant its application absent its satisfaction of the statutory criteria. As noted, Trinitas sought trauma center designation several years prior to its 2017 application and later requested the Department's CN call. Although Trinitas contends the Department requested data that did not exist, at no time, either in the years prior to the 2017 CN call, or in response to the Department's specific

requests that Trinitas provide data with respect to University's provision of trauma care, did Trinitas submit OPRA requests to University. Nor has Trinitas adequately explained its failure to submit such data requests or otherwise attempt to supplement its application with data from third-parties, such as local departments of health, police departments, or the Office of Vital Statistics, as the Division of Long Term Care Health Facility Survey and Field Operations suggested.

Finally, Trinitas's reliance on Guhl and Oberhand is misplaced. Trinitas does not contend the Department unreasonably delayed adjudicating its appeal, as in Guhl, or that the Department's actions deprived it of a protected property interest, as in Oberhand. Rather, Trinitas asserts its entitlement to Level II trauma center designation despite the Department's conclusion, which is supported by sufficient credible evidence in the record, that it failed to satisfy the statutory criteria for that designation. We therefore discern no "oppression, harassment, or egregious deprivation" resulting from the Department's denial of Trinitas's CN application. Yoskowitz, 116 N.J. at 712.

To the extent we have not specifically addressed any of the parties' arguments, it is because we have concluded they lack sufficient merit to warrant discussion in a written opinion. R. 2:11-3(e)(1)(E).

Affirmed.

I hereby certify that the foregoing  
is a true copy of the original on  
file in my office.



CLERK OF THE APPELLATE DIVISION