



State of New Jersey
DEPARTMENT OF HEALTH

PO BOX 360
TRENTON, N.J. 08625-0360

www.nj.gov/health

PHILIP D. MURPHY
Governor

SHEILA Y. OLIVER
Lt. Governor

SHEREEF M. ELNAHAL, MD, MBA
Commissioner

May 17, 2019

VIA ELECTRONIC & FIRST-CLASS MAIL

Gary S. Horan, FACHE
President and CEO
Trinitas Regional Medical Center
225 Williamson Street
Elizabeth, New Jersey 07202

Re: Application for Level II Trauma Center
Designation
CN# FR 171101-20-01

Dear Mr. Horan:

For the reasons that follow, I am denying the certificate of need (CN) application submitted for Level II trauma center designation by Trinitas Regional Medical Center (Trinitas). In reaching this decision, I have considered the CN application, responses to completeness questions, written comments, Department staff recommendations, public testimony and the State Health Planning Board (SHPB) recommendations. The referenced materials are incorporated herein and made a part of this final decision.

The Department of Health (Department) issued a CN call for applications for designation as a Level II trauma center in Union County and contiguous counties on August 17, 2017, 49 N.J.R. 2553 (a). The CN call cautioned that “[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. Acceptance of applications pursuant to this notice does not constitute a finding of need by the Department for the services proposed in the application(s). The Department reserves the right to disapprove all applications submitted in response to the call if the Department determines that applicants have not satisfactorily demonstrated need or compliance with the requirements of N.J.S.A. 26:2H-8, N.J.A.C. 8:33 and 8:43G.” The CN call also contained provisions for existing trauma centers as well as non-applicants to address the impact that an applicant’s requested designation would have on the trauma services provided by the existing trauma center. The Department issued the CN call because an acute care hospital had presented documentation indicating that there may be a potential need for a Level II trauma center in Union County.

Department staff review of Trinitas' application, which was the only application submitted in response to the CN call, included a medical record audit conducted by the Department's Office of Emergency Medical Services (OEMS.) Department staff recommended to the SHPB denial of Trinitas' application on the basis that Trinitas failed to demonstrate a need for a new Level II trauma center in Union and contiguous counties based upon the criteria found in the CN call, N.J.S.A. 26:2H-8, N.J.A.C. 8:33 and N.J.A.C. 8:43G-12. Department staff found that Trinitas was unable to: demonstrate a need in Union County; satisfactorily demonstrate that existing providers would not be negatively impacted by its designation as a Level II trauma center and satisfactorily demonstrate that Trinitas would meet and maintain the minimum volume standard of 350 major trauma cases per year, which is the minimum volume requirement to have an efficient/effective trauma center and not a number that indicates a need for more trauma centers.

Public input into the review process was achieved by permitting public comment on the Level II trauma center application to the Department prior to completeness declaration and also at the SHPB meeting. State Health Planning Board members were provided with the complete CN application, affected party written material, Department staff recommendations and review materials in advance of their deliberations on this application.

State Health Planning Board Meeting:

The SHPB reviewed the application at their January 17, 2019 public meeting and unanimously voted to approve Trinitas' application for Level II trauma center designation, contrary to the Department staff's recommendation for denial. Several issues were raised by SHPB members which led to their recommendation, the most notable concern being Trinitas' inability to obtain critical data to determine need for the service. The legislatively mandated State Trauma System Advisory Committee (STSAC) is currently collecting and evaluating a trauma data collection tool, the results of which are not published. SHPB members were critical that the STSAC has been operating for four years but has yet to release any data. A SHPB member stated the applicant cannot be held accountable if the data does not exist and that "common sense" should be used to consider looking at other factors.

The SHPB members further stated that despite the Department's desire for a comprehensive statewide trauma program to be developed, the need to have a trauma center in Union County takes priority due to the area's vulnerability to threats with its critical energy, economic and transportation infrastructure. The SHPB members also discussed travel times to University Hospital, including what is the ideal treatment time for trauma patients. Department OEMS staff advised that the goal for trauma treatment is one hour. The SHPB members stated that Trinitas seems to be in the best location for such a designation based on geography and travel time.

The SHBP considered the effect on other providers to address statutory requirements and stated they did not have enough information to say that Trinitas' application would seriously jeopardize University Hospital's Level I trauma center. The

SHPB members stated they did not find the Department staff's reasons for denial to be strong enough to be able to support the recommendation of denial. The SHPB further stated it considered its statutory requirement to look at how an application contributes to the orderly development of the healthcare system of the area. The SHPB members also stated they are comfortable that Trinitas could meet and maintain the 350-case volume threshold.

Analysis:

N.J.S.A. 26:2H-8, as well as N.J.A.C. 8:33-4.9(a), provide for the issuance of a CN only where the action proposed in the application for such certificate is necessary to provide required health care in the areas to be served, can be economically accomplished and maintained, will not have an adverse economic or financial impact on the delivery of health services in the region or statewide and will contribute to the orderly development of adequate and effective health care services. In making such determinations, I must take into consideration: (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.

I am therefore required by statute to review the Trinitas CN application in accordance with the CN call notice, the statutory criteria contained in the Health Care Facilities Planning Act (N.J.S.A. 26:2H-1.1 et seq.), as amended, the CN administrative process rules as set forth at N.J.A.C. 8:33, and the trauma center licensing rules as set forth at N.J.A.C. 8:43G-12.

As to the specifics of this application, N.J.S.A. 26:2H-8 requires that I determine that the approval of a CN will not have an adverse economic or financial impact on the delivery of health care services in the region. Further, N.J.S.A. 26:2H-6.1(h) requires that for reasons of maintaining the quality of certain health care services, a limitation of the proliferation of services may be essential to protect the viability of the services as well as the providers now rendering them. It is important to protect the role of institutions, particularly urban hospitals, whose importance to the Statewide health care system is indisputable, and to guard against the closing of important facilities and the transfer of services from facilities in a manner which is harmful to the public interest.

With respect to the above statutory criteria, I concur with the Department staff findings that Trinitas did not satisfactorily demonstrate that existing providers, specifically University Hospital, would not sustain a substantial negative impact by Trinitas' designation as a Level II trauma center. As the total number of trauma cases in the greater Northern New Jersey region is largely static, any disruption in the trauma network will necessarily trigger a dramatic decline in cases at University Hospital and result in a breakdown of the delivery of trauma services in the Northern region. On average, University Hospital states it treats and bills approximately 1,250 trauma patients per year, of which 20 percent originate from Union County. Should these cases migrate to Trinitas, University Hospital's trauma billings would reduce by three hundred per year. Based on the data presented by

University Hospital, 87 percent of University Hospital's entire caseload originates within a ten-mile radius surrounding Trinitas. The collateral consequences, however, do not end there in that University Hospital relies on trauma funding to support other operations, including its Emergency Medical Services, which provides statewide Air Medical Dispatch Services and also serves as the Department's designated operator of the Regional Emergency Medical Communication System.

I also take into consideration the fact that University Hospital serves as the Northern anchor agency for the New Jersey Emergency Medical Services Task Force and provides statewide notification, dispatch, and coordination for their resources. University Hospital also hosts the Northeast Medical Coordination Center (MCC) on behalf of the Department and is responsible for emergency planning and response at Newark Liberty International Airport and at the Port of New York and New Jersey. The responsibilities noted above confirm University Hospital's critical role in the established, coordinated system of emergency response in the Northern region. A reduction in trauma revenue, by means of reduced caseload, would have the potential to disrupt existing services provided to the State and the current predictability of the entire first response system in the Northern region would be compromised.

I am required by Supreme Court ruling in re: Virtua-West Jersey Hosp. Voorhees for a CN 194 N.J. 413. 945 A.2d 692, 2008 N.J. Lexis 410 ((N.J. 2008) to examine whether a CN's approval will have a substantial negative effect on an urban hospital. Based on the information provided by University Hospital, an urban hospital, I agree with Department staff and find that Trinitas' application would have a substantial negative impact on University Hospital, and the existing trauma system in the region. I disagree with the SHPB findings that they did not have enough information to say that Trinitas' application would seriously jeopardize University Hospital and that the impact on University Hospital would not be significant. I find that the SHPB looked solely at potential patient volume generated by Trinitas but failed to consider the crucial interconnected trauma system in the Northern region.

Trinitas notes that N.J.S.A. 26:2H-8 provides that, when considering a CN application by a recognized religious domination or body, the needs of the members of such denomination for care and treatment in accordance with their religious or ethical convictions may be considered a public need. It is asserted that designating Trinitas as a Level II trauma center would satisfy an increasing public need because five formerly Catholic hospitals have either closed or are no longer Catholic. Notably, none of these hospitals were Level II trauma centers and Trinitas has failed to demonstrate how the need for trauma services among Catholics has been affected. Furthermore, the provisions of N.J.S.A. 26:2H-8 do not provide for a blanket exemption for religious institutions from the CN requirements imposed by law, but rather that the element of religious need may be considered as an exercise of administrative discretion. Atty. Gen F.O. No. 2 (1974)

N.J.S.A. 26:2H-8(a) requires that I consider the availability of facilities or services which may serve as alternatives or substitutes. I find that there are sufficient alternatives for trauma services in that University Hospital, which is a Level I trauma center, is located eight miles away, Robert Wood Johnson University Hospital, a Level I trauma center, is located

21 miles away and Morristown Memorial Hospital, a Level II trauma center, is located 23 miles away. I also consider that University Hospital is within one-hour travel time from Trinitas, the recognized ideal treatment time for trauma care. I am satisfied that there is access to available trauma care for Union County.

N.J.S.A. 26:2H-8(b) requires that I consider the need for special equipment and services in the area. Trinitas states it already has the infrastructure in place to implement a Level II trauma center designation and that there is no record of any Union County trauma patient required to be transferred from Trinitas because of a lack of appropriate equipment or services. This ignores that fact that Emergency Medical Services (EMS) trauma triage guidelines require the transport of trauma cases to the nearest trauma center. In the event Trinitas were to become a designated trauma center, EMS providers would then be required to transport to Trinitas those cases from Trinitas' service area that were historically transported to University Hospital. Trinitas failed to consider how a Level II trauma center designation would cause a reconfiguration of the existing EMS system in the region. University Hospital 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.

With respect to N.J.S.A. 26:2H-8(c), regarding the possible economies and improvement in services to be anticipated, Trinitas states that economies have already been obtained due to Trinitas sharing with University Hospital some of the same physicians that provide emergency room call coverage by means of contracts with Rutgers employed physicians. I find that contracting for emergency room physician coverage is not unique to Trinitas and that this arrangement does not necessarily improve economies between Trinitas and University Hospital with respect to Trinitas' application for Level II trauma center designation.

N.J.S.A. 26:2H-8(d) requires consideration of the adequacy of financial resources and sources of present and future revenues. Trinitas states that it is financially stable and that it continues to underwrite its trauma care itself as an expression of patient commitment and community concern. Trinitas stated that the project requires no capital expenditures or other costs as the care is currently being provided. I note that Trinitas underwent an emergency room renovation project separate from this application. While the Department staff analysis focused on demonstration of need and impact on other providers, I find that adequacy of financial resources would not prohibit Trinitas from implementing a CN application.

With respect to N.J.S.A. 26:2H-8(e), regarding the availability of sufficient manpower in the several professional disciplines, Trinitas states it is well staffed in all disciplines related to trauma and other care. I am concerned that without a thoughtful statewide approach to manpower needs in this specialized field, staffing shortages in the specialized trauma professions may occur if an additional program is approved.

N.J.S.A. 26:2H-8(f) requires consideration of such other factors as may be established by administrative rule. Therefore, I have taken into consideration the applicable

administrative rules governing the services subject to full review (N.J.A.C. 8:33-1.1 et seq.) and trauma services (N.J.A.C. 8:43G-12 and N.J.A.C. 8:41 et seq.).

I find that Trinitas has provided an appropriate project description, information as to the financial impact of the project, including operating costs and revenues, services affected, equipment involved, source of funds, utilization statistics, and justification for the proposed project (N.J.A.C. 8:33-4.10(b)), assurance that all residents of the area, particularly the medically underserved, will have access to services (N.J.A.C. 8:33 Certificate of Need: Application and Review Process-4.10(a)), and assurance that it will meet appropriate licensing and construction standards (N.J.A.C. 8:43G -1.1 et seq. and N.J.A.C. 8:33-4.10(d)).

I considered the potential impact that the EMS trauma triage guidelines would have on the transport of trauma patients in the region as New Jersey EMS are required by Department regulation (N.J.A.C. 8:41, Appendix E and F) to transport trauma patients to an appropriate level trauma center. Due to the triage protocol, EMS currently bypasses Trinitas when transporting trauma patients and those patients that Trinitas claims are trauma cases may arrive by means other than EMS transport (walk-in, private transport.) Also, the 2017 medical record audit found 101 of 184 cases arrived by EMS, which calls into question Trinitas' classification of these cases as major trauma. Due to the EMS bypass, I agree with Department staff findings that Trinitas does not distinguish itself from any other non-trauma hospital in the cases it currently treats and claims as major trauma. I further agree with Department staff that Trinitas' ability to meet the minimum volume requirement of 350 cases, in accordance with N.J.A.C. 8:43G-12, 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, I must also take into consideration the recommendations made to me by the SHPB and the public testimony, applicant and facility presentations and deliberations that took place at the SHPB's January 17, 2019 meeting. The recommendations, testimonies, presentations and deliberations must be considered in the context of prevailing statutory and regulatory criteria and standards. I do not agree with the SHPB findings that if the data does not exist to support an application, as is currently the case with trauma designation, that alternate criteria should be used. A determination of need which ignores controlling statutory and regulatory criteria is arbitrary and capricious. I also do not agree with the SHPB's findings that they did not have enough information regarding the impact Trinitas' application would have on University Hospital and the existing trauma system.

Additionally, I find that there is no support for the proposition that New Jersey's trauma needs are not satisfied under the current system of care. The American College of Surgeons ("ACS"), the national trauma verification organization, concludes in its official report on New Jersey's Trauma System commissioned by the Department that the current Level I and Level II trauma centers are "well distributed." The ACS further stated, "[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.”¹

I also refer to legislation, P.L. 2013 Ch. 223, which among other tasks, establishes a State Trauma Advisory Committee (STSAC) charged with the development of a formal statewide trauma plan that defines the roles of all health care facilities in the state. Trinitas' attempt to secure data to demonstrate need was unsuccessful due to the STSAC's continuing effort of data collection. Therefore, I agree with Department staff that absent such data, the designation of a Level II trauma center at Trinitas is premature while the planning of a formal statewide trauma system is underway. I find that the STSAC needs to complete its work and the Department will not make a determination on trauma system changes until their findings are complete.

Denial:

For the reasons set forth in this letter, I am denying the Trinitas application for the Level II trauma center designation. Pursuant to N.J.S.A. 26:2H-9, Trinitas is entitled to a hearing at the Office of Administrative Law to contest this denial of its application. A request for such a hearing should be made in writing and should be forwarded to the Department's Office of Legal and Regulatory Compliance, P.O. Box 360, Room 805, Trenton, New Jersey 08625, within 30 days of receipt of this notice. Failure to do so will negate the opportunity for such a hearing.

If you have any questions concerning this CN approval, please do not hesitate to contact Marcela Ospina Maziarz, Deputy Commissioner, at 609-292-7874.

Sincerely,

A handwritten signature in black ink, appearing to be 'Jackie Cornell', written over a horizontal line.

Jackie Cornell, MPAP
Principal Deputy Commissioner

C: Marcela Ospina Maziarz, DOH (Electronic Mail)
Jean M. DeVitto, DOH (Electronic Mail)
Michael Kennedy, DOH (Electronic Mail)
Susan Brocco, DOH (Electronic Mail)

¹ American College of Surgeons, Trauma System Evaluation and Planning Committee, *Trauma System Consultation State of New Jersey*, August 4-7, 2008, at 55.