

STATE OF FLORIDA
DEPARTMENT OF HEALTH

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IN RE:

Emergency Petition for Temporary
Variance from Florida Rule of
Administrative Procedure 64J-2.011(3)

Rendition No. DOH-21-1070-FOI-HSEM
DOH Case No. 2021-0237

Filed by:
Tallahassee Memorial Healthcare, Inc.,
Petitioner.

ORDER GRANTING TEMPORARY VARIANCE

On September 23, 2021, pursuant to section 120.542, Florida Statutes (2021), Tallahassee Memorial Healthcare, Inc. (Petitioner), filed with the Department of Health (Department) an "Emergency Petition for Temporary Variance from Florida Rule of Administrative Procedure 64J-2.011(3)" (Petition). The Department published notice of the Petition in the *Florida Administrative Register* on September 28, 2021. No comments were received.

Petitioner requests a temporary variance from the surgical staffing requirements of Rule 64J-2.011(3) of the *Florida Administrative Code* (Rule). Upon consideration of the Petition and supporting materials, the Department makes the following findings of fact and conclusions of law.

FINDINGS OF FACT

1. Petitioner is Tallahassee Memorial Healthcare, Inc., a not-for-profit corporation organized under Florida law. (See Pet., at ¶ 1.) Petitioner operates Tallahassee Memorial Hospital, an acute care hospital (Hospital), in Leon County, Florida. (Id.) The Department has designated the Hospital as a Level II Trauma Center (TMH Trauma Center).
2. The Department designates trauma centers in accordance with the provisions of sections 395.4001(6), (7), 395.402, 395.4025(14), Florida Statutes (2021), and Rule 64J-2.011 of the *Florida Administrative Code*, in the trauma service areas (TSAs) established by section

395.402(1)(a), Florida Statutes. The Department apportions trauma centers across TSAs as provided by section 395.402(1)(c), Florida Statutes, to provide trauma treatment and care that is consistent with national standards, 24 hours per day, every day. See § 395.401(2), Fla. Stat. (2021).

3. Leon County is in TSA 3, which consists of Calhoun, Franklin, Gadsden, Jackson, Jefferson, Leon, Liberty, Madison, Taylor, and Wakulla Counties. See § 395.402(1)(a)3., Fla. Stat. As subparagraph (1)(a)3. only permits the Department to designate one trauma center to operate within TSA 3, the TMH Trauma Center is the only trauma center serving the ten counties in TSA 3.

4. The TMH Trauma Center is required to maintain surgical staffing to include at least one plastic surgeon who is either board certified or actively seeking board certification and who has hospital privileges to care for adult and pediatric patients (“board-certified plastic surgeons”).¹ This requirement is at page 3.10 of the Department of Health Pamphlet 150-9, January 2010 edition, “Trauma Center Standards” (Standards), which is incorporated by reference in Rule 64J-2.011(1) of the *Florida Administrative Code*.

5. Any board-certified plastic surgeon staffing the TMH Trauma Center must be available to “arrive promptly” at the trauma center when called. Department of Health Pamphlet 150-9, at 3.10. The Standards define “arrive promptly” to mean “arriving within 30 minutes, 90 percent of the time, from inside or outside the hospital to a specified area within the trauma center when summoned . . . The interval between the delivery of the patient at the trauma center and the arrival of the respondent should not have a measurably harmful effect on the course of patient management or outcome”. See Department of Health Pamphlet 150-9, at 1.1.

6. The TMH Trauma Center currently staffs with board-certified plastic surgeons from the only two Tallahassee professional associations of plastic surgeons, which between

¹ “Hospital privileges” are granted by a hospital to allow a physician to treat patients on the premises. See §§ 395.002(5), 456.039(1)(a), Fla. Stat. (2021).

them employ the total of six board-certified plastic surgeons practicing in the area. (See Pet., at ¶¶ 6, 8.)

7. Beginning on November 1, 2021, both professional associations will cease providing board-certified plastic surgeons to staff the TMH Trauma Center 24 hours per day, 7 days per week, regardless of the amount of compensation Petitioner offers. (See Pet., at ¶ 7.) One professional association will only provide call coverage one of every two days, while the other will only provide call coverage one of every three days. (Id.) Consequently, Petitioner will be unable to staff the TMH Trauma Center with board-certified plastic surgeons two out of seven days per week.

8. Petitioner requests a temporary variance from the requirement that plastic surgeons staffing the TMH Trauma Center be board certified or actively pursuing board certification. (See Pet., at ¶ 4.) Petitioner requests the variance through October 31, 2022, during which time Petitioner will “recruit additional plastic surgeons to the community.” (See Pet., at 13.)

9. Complex lacerations, primarily facial lacerations, are the types of trauma presentations treated by on-call board-certified plastic surgeons. (See Pet., at ¶ 9.) Petitioner proposes staffing with other “qualified surgeons – including board-certified general surgeons, otolaryngologic surgeons, and oral/maxillofacial surgeons – who have been trained to stabilize patients with complex lacerations” on the days that board-certified plastic surgeons are not available to staff the TMH Trauma Center. (Id.)

10. Plastic surgeons who have completed residency and are eligible to pursue board certification may also be qualified to stabilize patients with complex lacerations even if those plastic surgeons are not actively pursuing board certification. See Hamidian Jahromi A., Arnautovic A., Konofaos, P., *Impact of the COVID-19 Pandemic on the Education of Plastic Surgery Trainees in the United States* JMIR Med Educ 2020;6(2):e22045, <https://mededu.jmir.org/2020/2/e22045>, DOI: 10.2196/22045. Because the postponement of

elective surgeries due to the pandemic led to an extended interruption in the plastic surgery fellowship and training programs that are necessary for board certification, the Accreditation Council for Graduate Medical Education permitted training program directors to assess the competence of residents and fellows to determine whether that individual met the minimum competency to graduate and practice plastic surgery unsupervised. (Id.) Plastic surgeons who are not board certified or actively pursuing board certification may therefore be qualified to staff the TMH Trauma Center when board-certified plastic surgeons are unavailable.

11. The Standards make the TMH Trauma Center Medical Director “responsible for credentialing and attesting to the medical ability of all personnel who provide trauma services” and for appointing and removing personnel from the trauma service. Department of Health Pamphlet 150-9, at 2.3. The TMH Trauma Center Medical Director may approve as qualified by education and training board-certified general surgeons, otolaryngologic surgeons, and oral/maxillofacial surgeons who are trained in the stabilization of patients with complex lacerations, and plastic surgeons who are not board certified or actively pursuing board certification, to take call for the TMH Trauma Center on the two days per week when board-certified plastic surgeons are unavailable.

12. Petitioner will suffer a substantial hardship if the Rule is strictly applied to Petitioner after October 31, 2021. (See Pet., at ¶¶ 5, 10, 12.) This is because the failure to maintain compliance with the requirement to staff the TMH Trauma Center 24 hours per day, every day, with board-certified plastic surgeons would put Petitioner at risk of losing its Level II trauma center designation.

13. The TMH Trauma Center can achieve the purpose of the statutes implemented by the Rule by staffing with board-certified plastic surgeons for five days per week, and staffing for two days per week with a combination of board-certified general surgeons, otolaryngologic surgeons, and oral/maxillofacial surgeons who are trained in the stabilization of patients with

complex lacerations, and plastic surgeons who have completed residency but are not actively pursuing board certification. (See Pet., at ¶¶ 4, 8, 9.)

CONCLUSIONS OF LAW

14. Section 120.542, Florida Statutes, authorizes state agencies to waive a rule or vary rule requirements when a party subject to the rule demonstrates that the purpose of the statutes underlying the rule will be or has been met by means other than strict compliance with the rule and that the application of the rule would create a substantial hardship or violate principles of fairness.

15. The Department adopted Rule 64J-2.011 of the *Florida Administrative Code*, and the Standards to implement and enforce sections 395.1031, 395.401, 395.4015, 395.402, 395.4025, 395.404, 395.4045, and 395.405, Florida Statutes. The primary purpose of these provisions is to ensure that the needs of trauma victims are met in an inclusive trauma system. The Rule requires Petitioner to staff the TMH Trauma Center 24 hours per day, every day, with board-certified plastic surgeons or plastic surgeons who are actively seeking board certification and who have hospital privileges to treat adult and pediatric patients. See Department of Health Pamphlet 150-9, at 1.1, 3.1, 3.10.

16. Petitioner has demonstrated that requiring compliance with the Rule creates a substantial hardship to Petitioner sufficient to warrant a temporary, provisional variance from the Rule. The only board-certified plastic surgeons who practice in the area have refused, no matter the amount of compensation, to provide staffing services for more than five of seven days per week beginning on November 1, 2021. Strictly applying the Rule to Petitioner after October 31, 2021, will put Petitioner's designation as a Level II trauma center at risk. Loss of the Level II trauma center designation would create a substantial hardship to Petitioner.

17. Petitioner has demonstrated that the purpose of the underlying statute can be met by temporarily permitting Petitioner to staff the TMH Trauma Center with board-certified plastic surgeons and, on the two days per week when board-certified plastic surgeons will not

provide services, a combination of board-certified general surgeons, otolaryngologic surgeons, and oral/maxillofacial surgeons trained in the stabilization of patients with complex lacerations, and with plastic surgeons who have completed residency but are not actively pursuing board certification.

WHEREFORE, based on the foregoing findings of fact and conclusions of law, Tallahassee Memorial Healthcare, Inc., is GRANTED a temporary variance from the requirement in Rule 64J-2.011(3) of the *Florida Administrative Code*, Department of Health Pamphlet 150-9, at 3.10, to staff the TMH Trauma Center 24 hours per day, every day, with board-certified plastic surgeons or plastic surgeons who are actively pursuing board certification and who have hospital privileges to care for adult and pediatric patients.

Petitioner may staff the TMH Trauma Center on two of every seven days with board-certified general surgeons, otolaryngologic surgeons, or oral/maxillofacial surgeons who are trained in the stabilization of patients with complex lacerations and with plastic surgeons who are not board certified or actively seeking board certification but have completed residency and are eligible to begin pursuing board certification. Any surgeons staffing the TMH Trauma Center in lieu of board-certified plastic surgeons or plastic surgeons who are actively pursuing board certification must have hospital privileges to treat adult and pediatric patients and be approved by the TMH Trauma Center Medical Director as qualified by education and training to stabilize patients presenting with complex lacerations. This variance is granted from November 1, 2021 through July 31, 2022, during which time Petitioner will recruit to the area board-certified plastic surgeons and/or plastic surgeons who are actively pursuing board certification who will take trauma call.

DONE and ORDERED this 25 day of October, 2021 in Tallahassee, Leon County, Florida.

Joseph A. Ladapo, MD, PhD
State Surgeon General

By: Michele Tallent
Michele Tallent
Deputy Secretary for Operations

FILED ON THIS DATE PURSUANT TO § 120.52, FLORIDA STATUTES, WITH THE DESIGNATED DEPARTMENT CLERK, RECEIPT OF WHICH IS HEREBY ACKNOWLEDGED.

Randa Large
CLERK

10/25/2021
DATE

NOTICE OF RIGHTS

This order is agency action for purposes of sections 120.569 and 120.57, Florida Statutes. A person whose substantial interests are adversely affected by this action may file with the Agency Clerk a written petition for an administrative hearing. The petition must comply with Rule 28-106.201 or 28-106.301 of the *Florida Administrative Code*, as applicable, and must be received by the Agency Clerk within 21 days of your receipt of this order.

The petition may be mailed to: Agency Clerk, Department of Health, 4052 Bald Cypress Way, Bin A-02, Tallahassee, Florida 32399-1703; hand delivered to: Agency Clerk, Department of Health, 2585 Merchants Row Boulevard, Prather Building, Suite 110, Tallahassee, Florida 32311-3645; or transmitted by facsimile to: (850) 413-8743.

Mediation is not available.

Failure to file a petition within 21 days from receipt of this order is a waiver of the right to an administrative hearing and this order becomes final agency action subject to judicial review as provided by section 120.68, Florida Statutes.

Judicial review proceedings are governed by the *Florida Rules of Appellate Procedure*. Review proceedings are commenced by filing, within 30 days of rendition of this order, a Notice of Appeal with the Agency Clerk and a copy of the Notice of Appeal accompanied by the filing fee with the District Court of Appeal in the appellate district where the party resides or the First District Court of Appeal.

Copies furnished to:

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CERTIFICATE OF SERVICE

I CERTIFY that a copy hereof has been furnished by First-Class Mail Service, interoffice mail, facsimile, or hand delivery, with courtesy copies by electronic mail to the above this 23rd day of October, 2021.



Wanda Range, Agency Clerk
Department of Health
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