STATE OF FLORIDA
DIVISION OF ADMINISTRATIVE HEARINGS

SHANDS JACKSONVILLE MEDICAL
CENTER, INC., d/b/a UF HEALTH
JACKSONVILLE,

Petitioner,

vs. Case No. 17-3265

DEPARTMENT OF HEALTH,

Respondent,

and

MEMORIAL HEALTHCARE GROUP, INC.,
d/b/a MEMORIAL HOSPITAL
JACKSONVILLE,

Intervenor.
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RECOMMENDED ORDER

A final hearing was held in this matter before Robert S. Cohen, Administrative Law Judge ("ALJ") with the Division of Administrative Hearings ("DOAH"), on November 16, 17, and 20, 2017, in Tallahassee, Florida.

APPEARANCES

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STATEMENT OF THE ISSUES

Whether the application timely filed with the Department of Health ("Department") by Memorial Healthcare Group, Inc., d/b/a Memorial Hospital Jacksonville ("Memorial"), met the applicable standards for approval to operate as a provisional Level II trauma center; and whether the Department's approval of the application was based upon an unadopted rule.

PRELIMINARY STATEMENT

On May 1, 2017, the Department approved Memorial's timely submitted application ("Memorial's Application") for approval to operate as a provisional Level II trauma center. After review, the Department determined that Memorial's Application met the critical elements required by law for a trauma center, and Memorial's Application was approved.

On May 22, 2017, Shands Jacksonville Medical Center, Inc., d/b/a UF Health Jacksonville ("Shands") challenged the approval of Memorial's Application with the filing of a petition, pursuant

to section 120.57(1), Florida Statutes, seeking to reverse the Department's decision.

The final hearing in this matter was held on November 16, 17, and 20, 2017, in Tallahassee, Florida. At the hearing, Shands presented the testimony of Cynthia Gerdik, assistant vice president of nursing trauma at Shands; Chad McIntyre, manager of TraumaOne Flight Services; and Dean Cocchi, associate vice president of finance at Shands. In lieu of live testimony, the Department presented the depositions of Cindy Dick, assistant deputy secretary for the Department; and Leah Colston, chief of the Bureau of Emergency Medical Oversight at the Department. Memorial presented the testimony of Eleanor Lynch, senior vice president of operations at Memorial; Ernest Block, M.D., trauma surgeon at Memorial; Greg Miller, emergency medical services ("EMS") coordinator at Memorial; Marca Bonta, M.D., a department consultant; and Nurse Marla Vanore, a department consultant.

Shands' Exhibits 1, 2, 4, 9, 12 through 14, 19, and 20 were admitted into evidence. Memorial's Exhibits 16 through 20, 22, 24 through 27, 29, 30, 32 through 35, 38, 40, 41, 43, and 47 were admitted into evidence. Joint Exhibits 1 through 8 were admitted into evidence. The four-volume Transcript of the final hearing was filed with DOAH on December 15, 2017. After an initial deadline of January 12, 2018, for the filing of the proposed recommended orders was established, the parties requested, and

were granted, three extensions of time to file their proposals. All parties timely submitted Proposed Recommended Orders on February 14, 2018, which have been duly considered in the preparation of this Recommended Order.

References to statutes are to Florida Statutes (2017), unless otherwise noted.

FINDINGS OF FACT

1. The Department is an agency of the State of Florida created pursuant to section 20.43, Florida Statutes. The Department's mandate is to "promote, protect and improve the health of all people in the state," and it has a primary responsibility for evaluating provisional trauma center applications submitted by acute care hospitals. §§ 381.001 and 395.40(3), Fla. Stat.

2. Shands is an acute-care hospital located in Trauma Service Area ("TSA") 5, which lies in Baker, Nassau, Duval, Clay, and St. Johns counties. Shands has been designated by the Department as a Level I trauma center.

3. Memorial is an acute-care hospital also located in TSA 5.

4. Memorial operates a provisional Level II trauma center. The application that was submitted by Memorial and approved by the Department on May 1, 2017, is the subject of this proceeding.

5. Chapter 395, Part II (§§ 395.40 – 395.51), Florida Statutes ("Trauma Statute"), sets forth the statutory framework for the development of a statewide trauma system. The Department is charged with the planning and establishment of the statewide inclusive trauma system. See, § 395.40(3), Fla. Stat. The Legislature recognized the benefits of trauma care provided within an "inclusive trauma system," that is "designed to meet the needs of all injured trauma victims." § 395.40(2), Fla. Stat.

6. Section 395.401(2) directs the Department to "adopt, by rule, standards for verification of trauma centers based on national guidelines, including those established by the American College of Surgeons." The Trauma Center Standards are published in DH Pamphlet (DHP) 150-9, which is incorporated by reference in Florida Administrative Code Rule 64J-2.011 (the "Trauma Standards").

7. Section 395.4025 (the "Application Statute") describes the application process for hospitals seeking to become designated as a trauma center.

8. Section 395.4025(2)(c) requires the Department to conduct a "provisional review" of each trauma center application to determine if "the hospital's application is complete and that the hospital has the critical elements required for a trauma center." This "critical review" shall be based on "trauma center

standards" and shall include a review of whether the hospital has: (1) equipment and physical facilities necessary to provide trauma services; (2) personnel in sufficient numbers and with proper qualifications to provide trauma services; and (3) an effective quality assurance process. Id.

9. Notably, the provisional review described in section 395.4025(1)(c) looks only to the application to determine whether an application "has [met] the critical elements required for a trauma center." Id.

10. Section 395.4025(13) authorizes the Department to "adopt, by rule, the procedures and processes by which it will select trauma centers." Pursuant to this authorization, the Department issued rule 64J-2.012, which provides detailed regulations governing the application process.

11. Rule 64J-2.012(1)(d) includes a detailed list of elements that a provisional trauma center applicant must satisfy (the "critical elements") to receive provisional approval from the Department.

12. The Trauma Standards contain other elements that were not designated by the Department as "critical" (the "non-critical elements"). These standards pertain primarily to ensuring the programmatic integrity of a trauma center. Provisional trauma center applications must eventually establish compliance with the non-critical elements, but the non-critical elements are not

examined by the Department until after a provisional trauma center application is granted. See Fla. Admin. Code R. 64J-2.012(1)(h).

13. The process for obtaining designation as a provisional trauma center begins on October 1 each year. By that date, hospitals must submit to the Department a letter of intent to file a provisional trauma center application. See § 395.4025(2)(a), Fla. Stat.; Fla. Admin. Code R. 64J-2.012(1)(a). If a hospital timely submits a letter of intent, the Department must provide the hospital with a provisional trauma center application and instructions for submitting it to the Department. § 395.4025(2)(b), Fla. Stat.

14. April 1 of the following year is the deadline for the hospital to submit a provisional trauma center application. See Fla. Admin. Code R. 64J-2.012(1)(a). The Department conducts a review of the application to determine whether it is complete and has established compliance with the critical elements. See Fla. Admin. Code R. 64J-2.012(1)(d). The Department does not conduct a site visit until a provisional trauma center application is approved and the trauma center is operational. § 395.4025(2)(d) and (5), Fla. Stat.

15. By April 15, the Department must provide the applicant with written notice of any deficiencies in the critical elements and gives the hospital the opportunity to submit additional

clarifying or correcting information. See Fla. Admin. Code R. 64J-2.012(1)(e). Applicants then have five working days to address the identified deficiencies and submit additional information. See Fla. Admin. Code R. 64J-2.012(1)(f).

16. On or before May 1, the Department must send written notification to each applicant hospital advising whether its application was approved or denied. See Fla. Admin. Code R. 64J-2.012(1)(g)1.-2.

17. If a hospital is granted provisional approval, it is required to begin operation as a provisional trauma center on May 1 and becomes a full member of Florida's integrated trauma system on that day. § 395.4025(3), Fla. Stat.; Fla. Admin. Code R. 64J-2.012(1)(g)1. The Department also immediately notifies EMS providers of the newly operational provisional trauma center. Providers are required immediately to begin transporting "trauma alert" victims, as identified pursuant to field triage criteria, to the newly designated provisional trauma center for trauma care when it is the nearest trauma center to the location of the incident. See Fla. Admin. Code R. 64J-2.002(3)(g).

18. In the summer of 2016, Memorial received a letter from the Department notifying Memorial of the opportunity to submit a letter of intent to become a trauma center.

19. Memorial timely submitted a letter of intent to the Department in September 2016. This letter indicated that

Memorial would seek approval from the Department to operate as a Level II trauma center.

20. After Memorial submitted its letter of intent, the Department responded by sending Memorial a notice accepting its letter of intent and providing information on the application process. The notice directed Memorial to the Department's trauma center application and contained instructions for the completion and submission of the application.

21. Once Memorial received the Department's notice confirming acceptance of its letter of intent, it began making significant investments of resources and capital to develop its trauma program. It did so to ensure that its application would be compliant with the Trauma Standards.

22. In order to implement its trauma program and meet the required Trauma Standards, Memorial made investments in a number of areas, including the renovation of its emergency department ("ED") to accommodate two dedicated trauma resuscitation bays; the hiring and recruitment of new physicians and staff; conducting significant staff education; and beginning work towards the construction of a new helipad.

23. By May 1, 2017, Memorial had invested over $4 million to develop its trauma program. This capital investment included approximately $2.5 million in construction and equipment.

24. Memorial also invested $1.7 million in recruiting physicians and staff, as well as trauma-related training and education. Memorial was well positioned to develop its trauma program, since many of the needed surgical specialties were already offered at the hospital. The hospital recruited additional physicians to fill the more than 20 non-surgical specialties required by the Trauma Standards. In addition to new physicians, Memorial recruited many new specialized nurses needed to serve trauma patients.

25. Memorial ultimately provided over 6,000 hours of trauma training before May 1, 2017, and continues to train new nurses. The hospital ensured that over 200 nurses received training in Trauma Nurse Core Competencies, which ensures that nursing staff can provide high quality care for severely injured patients.

26. Memorial made all of the above investments prior to March 31, 2017, the date on which Memorial submitted its application to the Department.

27. Memorial's Application was prepared by a core team, headed by Eleanor Lynch, senior vice president of operations at Memorial. The key members of the team included Memorial's trauma medical director, trauma program director, as well as representatives from the intensive care unit ("ICU") and operating room. In order to ensure Memorial's Application met the Trauma Standards, the team preparing the application met at

least three times each week. Those meetings sometimes consisted of 30 different individuals from a variety of disciplines, including the trauma program director, trauma medical director, registration, respiratory, ICU, and the ED. The process was comprehensive and inclusive to ensure the hospital was fully prepared to address each Trauma Standard in its application. This team reviewed the application before it was submitted to the Department to ensure that it complied with the Trauma Standards.

28. Memorial also received assistance from K.C. Pidgeon, vice president of trauma for HCA South Atlantic Division--which includes Memorial. Mr. Pidgeon, who has significant experience in developing trauma programs in Florida, participated in each of the team meetings. He provided guidance into making sure the hospital and its application met the Trauma Standards, including updating policies and procedures, purchasing equipment, recruiting staff, and development of nurse leaders.

29. The final application submitted to the Department consisted of 32 separate binders encompassing thousands of pages of information.

30. In order to be ready to operate by May 1, 2017, Memorial set an internal deadline of February 27, 2017, for the hospital to meet each of the Trauma Standards. Memorial met this internal deadline and included a letter in its application from Memorial’s CEO confirming this milestone.

31. Memorial timely submitted its trauma center application to the Department on March 31, 2017.

32. In developing its trauma program and preparing its application, Memorial ensured that it met all of the Trauma Standards that are required for provisional approval.

33. After receiving Memorial's Application, the Department arranged for it to be reviewed by two outside experts, Dr. Marco Bonta and Nurse Marla Vanore. Both Dr. Bonta and Nurse Vanore have reviewed numerous trauma applications on behalf of the Department, and are very familiar with the Trauma Standards. Following their review, Dr. Bonta and Nurse Vanore sent the Department a checklist identifying alleged deficiencies in Memorial's Application. Both reviewers concluded that the quality of the application on initial review was excellent, and reflected a serious effort to meet the Trauma Standards before beginning operations.

34. On April 14, 2017, the Department sent Memorial a letter notifying it of the deficiencies that Dr. Bonta and Nurse Vanore had identified. The few deficiencies identified by the Department were mainly clerical in nature or required simple clarifications. For instance, one of the noted deficiencies included updating the curriculum vitae of Memorial's trauma program director.

35. Memorial timely responded to each deficiency identified by the Department on April 22, 2017.

36. Memorial's deficiency response was also reviewed by Dr. Bonta and Nurse Vanore. Following their review of Memorial's deficiency response, the expert reviewers concluded that Memorial properly addressed each deficiency identified during the Department's initial review.

37. On May 1, 2017, the Department informed Memorial that its application was in compliance with the applicable Trauma Standards and directed it to begin trauma operations on that same day.

38. As indicated by the parties' stipulation, Shands takes issue with only a few of the hundreds of requirements that comprise the Trauma Standards. The only aspects of Memorial's Application which Shands disputes are the standards related to trauma surgeon call coverage (Standards II.A.4-5, II.B.2, and III.A) and the helipad (Standard V.A.5). Shands does not dispute that the application meets the remaining Trauma Standards.

39. Standard III of the Trauma Standards details the surgical staffing requirements that each trauma center must meet. Standard III.A specifically addresses the requirements for general trauma surgeons. Standard III.A.1 requires that "[t]here shall be a minimum of five qualified trauma surgeons, assigned to the trauma service, with at least two trauma surgeons available

to provide primary and backup trauma coverage 24 hours a day at a trauma center when summoned." Standard III.A.2 requires each trauma surgeon to sign the General Surgeons Commitment Statement, which confirms that each surgeon on primary and backup call will comply with certain conditions, including arriving promptly when summoned. Standard III.A.3 lists the minimum qualifications for each trauma surgeon taking call, such as certifications and hospital privileges.

40. Memorial submitted substantial documentation which demonstrated its compliance with the requirements in Standard III.A. Although the Trauma Standards only require five trauma surgeons, Memorial secured nine trauma surgeons for its program. For each of these surgeons, Memorial provided proof of hospital privileges, board certification, state licensure, Advanced Trauma Life Support ("ATLS") certification, proof of participation in past trauma cases, completion of continuing medical education courses, attestation by the Chief of Neurosurgery, and the commitment statement, among other documentation. Memorial's documentation for this section totaled more than 500 pages.

41. Memorial also submitted primary and backup call schedules for February, March, April, and May 2017, indicating when each trauma surgeon was scheduled to take trauma call.

42. In addition, Memorial submitted a number of policies and procedures, including Memorial's credentialing criteria,

which is more stringent than what the Department requires. In order to be credentialed at Memorial, a trauma surgeon must agree to the following requirements for primary trauma call: be physically present in-house to meet all trauma patients in the trauma resuscitation areas at the time of the trauma patient's arrival; perform no elective surgery or procedures during the on-call period that would render the trauma surgeon unavailable to arrive promptly to a trauma alert patient; and refrain from taking general surgery emergency call at any other facility or trauma call at any other facilities while on trauma call at the primary facility. Similar requirements exist for trauma backup call.

43. Standard II of the Trauma Standards sets forth the trauma call coverage requirements that each trauma center must meet. Specifically, Standards II.A.4 and II.A.5 require "[a]t least one qualified trauma surgeon (as described in Standard III.A) to be on primary trauma call at all times to provide trauma service care" and "[a]t least one qualified trauma surgeon (as described in Standard III.A) to be on backup trauma call at all times to provide trauma service care." Simply put, there must be one trauma surgeon on primary call and one trauma surgeon on backup call at all times.

44. As part of its application, Memorial submitted detailed information about each of the nine trauma surgeons on its monthly

call schedules, including the call schedules themselves. The call schedules detail each of the trauma surgeons scheduled to take primary and backup trauma call for February through May 2017.

45. Memorial secured and submitted commitment statements (DH Form 2043E) from each of the trauma surgeons on its call schedule. These signed commitment letters indicate that each trauma surgeon agreed to commit to the call schedules submitted to the Department and be available as indicated. These letters also indicate that each surgeon pledged not to take trauma call at any other facility while on trauma call at Memorial.

46. Trauma Standard II also includes a requirement that the hospital ensure any new trauma surgeons are appropriately qualified and sign the commitment statement. Specifically, "[a]s surgeons change, the trauma medical director must ensure that the new surgeons have the qualifications delineated in Standard III.A.3 and that they sign the General Surgeons Commitment Statement. The trauma service shall keep a current and up-to-date commitment statement on file in the hospital's trauma center application at all times for Department of Health review." In response to this subpart, Memorial appropriately submitted the commitment statements for its initial nine trauma surgeons. Because this was Memorial's provisional application, none of the

new trauma surgeons who have subsequently joined its program after May 1, 2017, were included with this submission.

47. After completing their initial review of Memorial's Application, the Department's expert reviewers identified only one issue to be addressed in the above sections. For one of the trauma surgeons, Dr. Alton Parker, there was a question as to whether he had met all the required continuing medical education ("CME") requirements. As requested, Memorial submitted additional documentation with its Deficiency Response confirming that Dr. Parker had in fact completed the required CME courses. With this concern resolved, the expert reviewers ultimately concluded that Memorial's Application met every requirement.

48. At hearing, Shands alleged that because some of the trauma surgeons listed in Memorial's Application do not live in Jacksonville year round, the application did not meet the Trauma Standards detailed above. However, there is no requirement in the Trauma Standards that trauma surgeons must live full time in the same community as the hospital at which they take trauma call. Rather, the Trauma Standards require that trauma surgeons on primary and backup trauma call in Level II trauma centers be available within 30 minutes once summoned. In actuality, Shands' criticisms appear to be a matter of preference or imagining the ideal situation, rather than substantive questions about compliance with the legal requirements for trauma surgeon call.

49. Memorial has not had any gap in trauma call coverage or similar issues since it began operations on May 1, 2017; every shift has been covered and each trauma surgeon available as required. Memorial's trauma surgeons are committed members of the trauma team, including active participants in the quality improvement process, regardless of where their permanent residence may be.

50. As part of its mission to ensure high-quality care, Memorial requires its trauma surgeons on primary trauma call to be physically present at the hospital during the entire shift, which is beyond what the Trauma Standards require for Level II trauma centers. Memorial established this requirement in part to ensure that there would be no issues with response time for trauma surgeons. Any trauma surgeons on backup call that do not have permanent residences within 30 minutes response time of the hospital, typically stay at a hotel close to the hospital in order to comply with the Trauma Standards and Memorial's own requirements. For any trauma surgeons who do not live full time in the Jacksonville area, Memorial requires that they report well in advance of beginning the call coverage to ensure there are no issues, e.g., a trauma surgeon beginning call at 9:00 a.m. Monday morning must report to the hospital by 9:00 p.m. the night before.

51. Memorial's trauma surgeons have positive working relationships with other team members, like the ED physicians, and have collaborated well with local EMS. Memorial has worked to build a full-time trauma surgeon roster, with the hope that recruited physicians will ultimately decide to make the Jacksonville area their home. Memorial currently has three trauma surgeons, including the trauma medical director, Dr. Michael Samotowka, who live full time in Jacksonville and plans to continue recruiting until all six current spots are filled by full-time residents.

52. Both Dr. Bonta and Nurse Vanore determined that Memorial's trauma call coverage met the applicable Trauma Standards, including Standards II.A.4-5, II.B.2, and III.A. Both expert reviewers confirmed at hearing that the Trauma Standards only require trauma surgeons on primary and backup call to be readily available--they do not dictate where surgeons must reside full time. Nurse Vanore also testified that many trauma centers across the country utilize physicians who do not live in the immediate vicinity of the hospital. These physicians either stay at the hospital or make arrangements to stay nearby when on call. This reflects a common trend in trauma centers nationwide, which often use the rotation of trauma surgeon (both on- and off-call) shifts to enhance patient care. Most trauma centers do not use trauma surgeons to provide longitudinal care (one surgeon with

the patient throughout the care process). Instead, there is a comprehensive patient handoff to the next trauma surgeon. There was no indication in Memorial's Application that its trauma surgeons would not fulfill their call obligations.

53. The general trauma surgeon call schedules submitted by Memorial adequately demonstrated that Memorial would be able to fulfill its trauma call coverage requirements. Since beginning trauma operations, Memorial has not had any gaps in coverage or other issues related to trauma call. Therefore, Memorial satisfied Standards II.A.4-5, II.B.2, and III.A.

54. The helipad became a central issue at hearing. Standard V addresses the facility requirements relating to the ED, including the helipad. Standard V.A.5 requires that each hospital must have a "helicopter-landing site in close proximity to the resuscitation area." "Close proximity" is defined to mean that "the interval of time between the landing of the helicopter and the transfer of the patient into the resuscitation area will be such that no harmful effect on the patient's outcome results." In addition to this requirement, the helipad must be properly licensed by state and federal authorities, and have appropriate policies and procedures for helipad operations.

55. Memorial has used the helipad in its current location since 1993. Before it began operations as a trauma center, Memorial effectively used its helipad to transport trauma

patients out of its ED to Shands and other trauma centers without incident for the entirety of that time period.

56. The helipad is located approximately 1900 feet from Memorial's ED. To meet this Trauma Standard, Memorial hired Liberty Ambulance Service, a private ambulance service, to staff the helipad 24/7, so that at all times there is an advanced life support ambulance with two paramedics ready to transport patients from the helipad to the ED. In addition, the ambulance driver has received emergency vehicle operations course training. Memorial also provided training to the ambulance crew members to ensure they were proficient in helicopter safety. This training included in-depth interaction with air crew of TraumaOne, which is one of the region's air transport providers.

57. Memorial hires deputies from the Jacksonville Sheriff's Office to be present at all times for helicopter arrivals. These deputies can be used to block any pedestrian or vehicle access to the transport route or otherwise provide transport assistance, although this has not been needed.

58. Memorial conducted numerous time studies, almost daily since February 27, 2017, to ensure it could quickly move patients from the helipad to the ED without delaying treatment. The time trials entailed actually loading a stretcher onto an ambulance at the helipad, driving the ambulance to the ED, and unloading the stretcher at the ED. These time trials, which were conducted

beginning in December 2016 and continue today, showed an average transport time of two to three minutes. Each time trial was attended by Memorial's EMS Coordinator, Greg Miller, and signed off by each ambulance crew that participated. These time trials helped familiarize the ambulance crew with the short route from the helipad to the ED, as well as to identify an alternate route that can be used if needed. Admittedly, the trials were performed using hospital personnel posing as patients, rather than actual trauma patients, but the methodology, while presenting a best case scenario, was nonetheless reasonable.

59. In addition to the time trials, actual air transports of non-trauma patients confirm the close proximity of the helipad. It only took five minutes to transport a recent non-trauma patient from the helipad to the ED, as documented by the LifeFlight air crew which transported the patient.

60. Since beginning trauma operations, there have not been any issues with trauma patients arriving by helipad. At the time of hearing, Memorial had only had one trauma patient delivered by helicopter since May 1, 2017. Memorial has only had 24 total non-trauma patients delivered by helipad in 2017. In fact, very few patients are transported by air in TSA 5, generally.

61. As part of ongoing renovations, Memorial is currently constructing a new helipad, which will be situated one floor

directly above the ED. The new helipad is scheduled to be completed in July 2018.

62. Shands alleged at hearing that Memorial's helipad was not optimally located and voiced general concerns about its potential impact on patient care. While 1900 feet from the ED cannot be considered the "optimal location" for the helipad, the claims of adverse impact on patient care were not supported by evidence produced at hearing. None of Shands' witnesses suggested that the patient transport times reflected in Memorial's Application would adversely impact patient care, or that any adverse incidents had occurred on Memorial's helipad. Actually, none of Shands' witnesses had even reviewed any of the time trials or actual patient transport information included in Memorial's Application. The time it takes to transport patients from Memorial's helipad to the ED is not substantially different from other trauma centers in the region. Shands' own witnesses confirmed that Shands' helipad sits atop a six-story parking garage across the street from its ED, which requires patients to be transported down an elevator and wheeled on a stretcher across a road while security blocks traffic access. Despite their criticisms, none of Shands' witnesses knew how long it took to transport patients from Shands' helipad to the ED. Moreover, with the construction of its new helipad atop the ED, any concerns about the current transport times will be eliminated.

63. Both Dr. Bonta and Nurse Vanore determined that Memorial's helipad met the applicable Trauma Standard, namely Standard V.A.5. Based on the time studies provided by Memorial which showed the average transport time from the helipad to the ED was only two to three minutes, the expert reviewers determined that the helipad was in "close proximity" to the resuscitation area. Based on their experience, the expert reviewers concluded that two to three minutes was typical of other trauma centers, including hospitals with rooftop helipads. This duration of transport time is actually quite good and would not adversely affect patient care.

64. Memorial's helipad is in close proximity to the trauma resuscitation area, as the Department properly concluded based on the information provided in Memorial's Application. The two-to-three minute transport time for trauma patients is well within the acceptable range and demonstrates that Memorial met Standard V.A.5.

65. Memorial elicited testimony from a longtime expert in health care planning, Gene Nelson of Health Strategies, Inc. Mr. Nelson spoke at length in an effort to establish need for an additional trauma center in TSA 5 through a feasibility study employing well recognized health planning concepts. He focused primarily on access to trauma care for patients needing the comprehensive specialized care offered by trauma centers.

66. Mr. Nelson noted that many trauma patients were being treated in general acute care hospitals without trauma centers which fell short of the care provided in centers like Shands and the proposed Memorial trauma center. He concluded that a substantial need exists for another trauma center in TSA 5 and that Memorial would fulfill that need.

67. Shands objected to this discussion of need by Mr. Nelson on behalf of Memorial, and argues that the letter of intent and application filed by Memorial should not have been accepted in the first place, since there was not a documented need for another trauma center in TSA 5. As will be discussed in the Conclusions of Law below, the need for an additional trauma center is not a determination to be made at the time of a hospital's filing for authority to begin operating a provisional trauma center.

68. Shands testified that Memorial's operation of a trauma center in TSA 5 has already resulted in injury to its operations and profitability. This injury will only continue in the future as Memorial gains a stronger foothold in the TSA.

69. The negative impacts include fewer trauma patients at Shands resulting in a longer period for trauma nurses to acquire and maintain the specialized skills necessary for operating in a trauma center versus a general acute care hospital.

70. The opening of Memorial's provisional trauma center has caused the number of severely injured trauma patients at Shands to decrease. Shands predicts an annual loss of 324 trauma cases due to Memorial's opening, translating to a $2.25 to $2.7 million annual loss of revenues. If outpatient cases are included in this analysis, Shands projects an annual loss in revenues of $12,422 per case over the 324 lost cases, resulting in an annual total loss of approximately $4 million.

71. Memorial argues that sufficient trauma volume exists in TSA 5 for both facilities to operate their trauma centers. Memorial projects that it will treat 1,556 trauma patients per year, well above the American College of Surgeons' ("ACS") recommendation of at least 1,200 patients per year as a minimum volume level.

72. Mr. Nelson estimates that, annually, only between 300 and 500 trauma patients will be treated at Memorial that otherwise would have been treated at Shands. The rest likely would have received treatment at an acute care hospital, not a trauma center.

73. Mr. Nelson believes that Memorial's trauma program has had, at most, a minimal impact on Shands. An analysis produced by Shands demonstrates that Shands' own projections estimate a loss of only 154 trauma patient admissions, well below the numbers projected by Memorial.

74. Even with Memorial's trauma program being fully operational, Shands will continue to receive in excess of 2,000 trauma patients admitted annually. That volume is well above the ACS's recommended minimum patient volume of 1,200 for Level I trauma centers. Shands' own data shows that it will continue to see over 4,600 total trauma patients annually, including inpatient and outpatient cases.

75. Estimates prepared by Shands' associate vice president of finance, Dean Cocchi, demonstrate that even with a potential impact from Memorial, Shands will still have a contribution margin of well over $30 million. Mr. Cocchi also testified that Shands' projected financial impact from Memorial operations will not endanger the continued operation of its trauma program. While the presence of Memorial in the TSA 5 market will have a small negative financial impact on Shands, it is not projected to be substantially adverse.

76. The quality of care provided at Shands has not been impacted by the opening of Memorial's trauma center. Shands remains a high-quality provider of trauma care.

CONCLUSIONS OF LAW

77. The Division of Administrative Hearings has jurisdiction over the parties and subject matter of this cause of action pursuant to sections 120.569, 120.57(1), and 395.4025(7).

78. As the specifically named approved applicant, whose substantial interests are being determined in this proceeding, Memorial has standing to intervene in this case. Memorial bears the burden of proof to establish that its application met all of the substantive elements that are required in order to receive provisional approval. See Woodholly Assocs. v. Dep't of Nat. Res., 451 So. 2d 1002, 1004 (Fla. 1st DCA 1984). Shands bears the burden of proof regarding any factual issues relating to its claim that the Department acted pursuant to an unadopted rule. See Envtl. Trust v. State, Dep't of Envtl. Prot., 714 So. 2d 493, 497 (Fla. 1st DCA 1998) ("A party who asserts a disputed claim before an administrative agency generally has the burden of going forward with the evidence as well as the ultimate burden of establishing the basis for the claim.") (citing Young v. Dep't of Cmty. Aff., 625 So. 2d 831 (Fla. 1993); Balino v. Dep't of HRS, 348 So. 2d 349 (Fla. 1st DCA 1977)).

79. As this hearing is conducted pursuant to section 120.57, the standard of review is de novo. See § 120.57(1)(k), Fla. Stat. ("All proceedings conducted under this subsection shall be de novo."). The purpose of this de novo review is to formulate final agency action with respect to Memorial's Application. See, e.g., J.D. v. Fla. Dep't of Child. & Fams., 114 So. 3d 1127, 1132 (Fla. 1st DCA 2013) ("[T]he Legislature intended a 'typical' chapter 120.57 proceeding in which the

purpose is to 'formulate final agency action, not to review action taken earlier and preliminarily.'" (internal citation omitted)).

80. In this de novo hearing, the ALJ must recommend whether the Department's final agency action with respect to Memorial's Application should be to approve or deny the application. The answer to that question depends on whether Memorial's trauma program met the applicable standards. See § 395.4025(3), Fla. Stat.; Fla. Admin. Code R. 64J-2.012(1)(g); Galencare, Inc. v. Dep't of Health, Case No. 17-2754 (Fla. DOAH Dec. 20, 2017).

81. Under this standard of review, the ALJ stands in the shoes of the Department. The ALJ evaluates whether the Department's final agency action should be to accept or reject the Memorial Application.

82. In conducting this de novo review, the ALJ makes a determination as to whether the Memorial Application, as submitted to the Department, met applicable standards.

83. The ALJ, however, must follow the trauma statutes and the Department's trauma regulations. The ALJ must also defer to the Department's reasonable interpretation of those authorities. See, e.g., State Contracting & Eng'g Corp. v. Dep't of Transp., 709 So. 2d 607, 610 (Fla. 1st DCA 1998) ("this policy of deference to an agency's expertise in interpreting its rules applies not only to the courts but also to administrative law

judges."); Univ. Med. Ctr., Inc. v. Dep't of HRS, 483 So. 2d 712 (Fla. 1st DCA 1985) (batching cycle rules governing CON applications are binding on an ALJ). "[A]n agency's interpretation need not be the sole interpretation or even the most desirable one; it need only be within the range of permissible interpretations." Lakesmart Assocs., Ltd. v. Fla. Hous. Fin. Corp., Case No. 00-4287RU, RO at 44 (Fla. DOAH Feb. 7, 2001).

84. The ALJ owes heightened deference to the Department's interpretation of the standards the applicants must satisfy in order for the Department to grant provisional trauma center status. Such heightened deference is owed because determining whether a provisional trauma center applicant demonstrates readiness to provide high-quality trauma care on May 1, 2017, is an area within the Department's unique technical and medical expertise. See, e.g., Rizov v. State, Bd. of Prof'l Eng'rs, 979 So. 2d 979, 980-81 (Fla. 3d DCA 2008) ("Agencies generally have more expertise in a specific area they are charged with overseeing. Thus, in deferring to an agency's interpretation, courts benefit from the agency's technical and/or practical experience in its field."); Shands Teaching Hosp. & Clinics v. Dep't of Health, Case No. 14-1022RP, FO at 121 (Fla. DOAH June 20, 2014) (deferring to the Department's determinations with respect to the proposed trauma center allocation rule because it

"was the product of thoughtful consideration by the Department's experts").

85. In a hearing held pursuant to section 120.57(1), Memorial bears the ultimate burden of persuasion, by a preponderance of the evidence, of entitlement to operate as a provisional trauma center. See, e.g., Fla. Dep't of Transp. v. J.W.C. Co., 396 So. 2d 778, 787 (Fla. 1st DCA 1981) (it is "fundamental" that an applicant "carries the ultimate burden of persuasion of entitlement through all proceedings, of whatever nature, until such time as final action has been taken by the agency").

86. In order to prevail, Memorial must establish that its Application established compliance with the applicable standards within the prescribed time period, namely by May 1, 2017, the date established for the initiation of an approved provisional trauma program.

87. The Department, consistent with its mission to "promote, protect and improve the health of all people in the state" and to ensure the provision of optimal trauma care must be able to conclude from the face of the application that Memorial's proposed trauma center is compliant with those standards. See §§ 381.001, 395.40, and 395.4025(2)(c), Fla. Stat. The Department cannot approve a provisional trauma center application based on pledges to comply with certain standards, as doing so

would not be consistent with its mission to protect people in Florida.

88. The Legislature charged the Department with overseeing the State's "inclusive trauma system" that is "designed to meet the needs of all injured trauma victims who require care in an acute-care setting and into which every health care provider or facility with resources to care for the injured trauma victim is incorporated." § 395.40(2), Fla. Stat.

89. In section 395.4025, the Legislature established a detailed schedule governing the Department's review of trauma applications, which is supplemented by additional deadlines in the Department's regulations:

(a) The Department "shall" annually notify "each acute care general hospital" that "the Department is accepting letters of intent" to establish trauma centers. § 395.4025(2)(a), Fla. Stat.

(b) October 1: Letters of intent are due. § 395.4025(2)(a), Fla. Stat.

(c) October 15: The "department shall send to all hospitals that submitted a letter of intent an application package." § 395.4025(2)(b), Fla. Stat.

(d) April 1: Deadline for hospitals to submit trauma center applications to the Department. Upon receipt, the Department "shall conduct a provisional review of each

application for the purpose of determining that the hospital's application is complete and that the hospital has the critical elements required for a trauma center." § 395.4025(2)(c), Fla. Stat.

(e) April 15: The Department must notify a trauma center applicant of any deficiencies in its application. Fla. Admin. Code R. 64J-2.012(1)(e).

(f) Five working days from April 15: By this date, an applicant must submit whatever information is necessary to address the deficiencies identified by the Department. Fla. Admin. Code R. 64J-2.012(1)(f).

(g) April 30: After this date, "any hospital that submitted an application found acceptable by the department based on provisional review shall be eligible to operate as a provisional trauma center." § 395.4025(3), Fla. Stat. The Department's rules further specify that a provisionally approved trauma center must begin operations on May 1. Fla. Admin. Code R. 64J-2.012(1)(g)-(h).

(h) May 1 through October 1: The Department conducts an "in-depth" review of the application of each provisionally approved trauma center. § 395.4025(4), Fla. Stat.

(i) October 1 through June 1: The Department will send out-of-state reviewers to perform an assessment of each provisionally approved trauma center. § 395.4025(5), Fla. Stat.

(j) July 1: The Department will issue final verification to provisional trauma center applicants that have met all applicable criteria. § 395.4025(6), Fla. Stat.

90. Memorial established that its trauma center application met all the applicable Trauma Standards that are required for provisional approval, including those that remained at issue for Shands in this hearing. Memorial's Application was carefully reviewed by the out-of-state trauma experts hired by the Department. The Department and its experts properly concluded that Memorial's Application met each required Trauma Standard.

91. Shands agrees, pursuant to the Joint Prehearing Stipulation, that of the required 350 standards that a provisional trauma center applicant must satisfy, Memorial has satisfied all but a handful--those relating to trauma call coverage (Standards II.A.4-5, II.B.2, and III.A) and the helipad (Standard V.A.5). The evidence presented by Memorial at the hearing, however, demonstrates that Memorial satisfied all three of these standards and the Department properly approved Memorial's Application.

92. Memorial met Standards II.A.4-5, II.B.2, and III.A. These Trauma Standards relate to general trauma surgeon call coverage. They require an applicant to have at least five trauma surgeons assigned to its trauma program, with one trauma surgeon on primary call and one trauma surgeon on backup call at all

times. These surgeons must be appropriately qualified and must submit commitment statements to report promptly when summoned by the hospital. Memorial clearly demonstrated that each of its nine trauma surgeons met these requirements. Despite Shands' claims that it is optimal that trauma surgeons reside full time near the hospital, which might be preferable in a perfect world, there is no such residency requirement in the Trauma Standards. The evidence presented by Memorial demonstrated that its trauma surgeons would be available and, at the time of hearing, had been available for each of their trauma call coverage commitments. Memorial ensured that there would be no coverage problems by requiring that each trauma surgeon on primary call be stationed at the hospital during the entirety of their coverage shift. This is above and beyond what the Trauma Standards require of Level II trauma centers. Further, the evidence clearly showed that, since beginning trauma operations, Memorial has had no issues with trauma call coverage, nor could Shands identify any such issues. Therefore, Memorial satisfied Standards II.A.4-5, II.B.2, and III.A.

93. Similarly, Memorial proved that it met Standard V.A.5. This Trauma Standard requires that an applicant's helipad be located in "close proximity to the resuscitation area." "Close proximity" is defined to mean that the time it takes to transport the patient from the helipad to the resuscitation area will not

adversely impact the patient's outcome. Importantly, the Trauma Standard does not mandate an exact location for an applicant's helipad. Memorial demonstrated through dozens of realistic time trials that the transport time from its helipad to the ED is only two-to-three minutes. The Department's expert reviewers reasonably concluded that this length of transport time would not adversely affect patient care and is actually consistent with other trauma centers in the country, including those with rooftop helipads. Moreover, to make the helipad in even closer proximity to the ED, Memorial testified it was already in the process of building a new helipad atop the ED. While not completed at the time of hearing, this is further evidence of Memorial's commitment to making access to the ED for trauma patients even better. Memorial satisfied Standard V.A.5.

94. Despite the fact that Memorial satisfied the Trauma Standards, which would entitle it to provisional approval of its Level II trauma center, Shands argues that the Department violated its own rules and relied on unadopted and invalid rules in its approval of Memorial's Application. Particularly, Shands argues that the Department's rules prohibit the acceptance and review of trauma applications where there is no allocated need in a TSA, as is the case in TSA 5.

95. The gist of Shands' argument rests on an interpretation of section 395.4025, which requires the need allocation found in

rule 64J-2.010 to be considered at the provisional application stage; and a corresponding interpretation of rule 64J-2.012, which makes the receipt of a hospital's letter of intent conditional on an allocation of need in that hospital's TSA.

96. Section 395.4025(2) makes clear that need is not a consideration at the provisional stage. In Department of Health v. Bayfront HMA Medical Center, 236 So. 3d 466, 473 (Fla. 1st DCA 2018), the court confirmed this interpretation by holding that "[t]he provisions of subsection (2) do not confer discretion on the Department and require it to invite and accept a LOI and to accept, provisionally review, and provisionally grant an application without regard to need." "Notably," states the court, "section 395.4025(2)(d)1. authorizes the Department to grant an extension of time to an applicant if the number of applicants in the TSA is equal to or less than the service area allocation, not if the number of applicants is equal to or less than the number of open slots, which further evinces that the Legislature considers need irrelevant at the provisional review stage of the application process. Section 395.4025(3) provides that after April 30, any hospital whose application has been provisionally approved shall be eligible to operate as a provisional trauma center. Section 395.4025(4) governs the in-depth review of applications." Id.

97. In describing the steps that lead up to granting provisional approval, the statute repeatedly uses the term "shall" to mandate--without exception--the Department's actions in the provisional review process. These statutory provisions, however, say nothing about the consideration of an available "slot" during the stages that lead to provisional approval. Rather, the statute mentions "need" only in connection with final verification. Applying the principle of expressio unius est exclusio alterius, the discussion of need only in connection with final verification is decisive evidence that the Legislature did not authorize the Department to consider slot allocation in connection with the steps that lead to provisional approval. See, e.g., Moonlit Waters Apartments, Inc. v. Cauley, 666 So. 2d 898, 900 (Fla. 1996).

98. The Department and Memorial agree that section 395.4025 does not permit the Department to consider need in its determination of whether to provisionally approve a trauma center application. Since the Department is responsible for administering section 395.4025, the undersigned must defer to the Department's interpretation of it, so long as it is not clearly erroneous. See State Contracting & Eng'g Corp. v. Dep't of Transp., 709 So. 2d. 607, 610 (Fla. 1st DCA 1998) ("We have long recognized that the administrative construction of a statute by an agency or body responsible for the statute's administration is

entitled to great weight and should not be overturned unless clearly erroneous. . . . [T]his policy of deference to an agency's expertise in interpreting its rules applies not only to the courts but also to administrative law judges.") (internal citation omitted). Far from being erroneous, the Department's interpretation of section 395.4025 is the only interpretation that is consistent with the statute's plain meaning, as validated by the First DCA in Bayfront.

99. Shands also claims that rule 64J-2.012(1)(a) requires the Department to take the existence of a "slot" into account when deciding whether to provisionally approve Memorial's Application. The First DCA explained in Bayfront that this rule does not mandate the Department to consider need during its provisional review and is consistent with the statutory directives of the Trauma Statute. Bayfront, supra at 474.

100. Rule 64J-2.012(1)(a) states, that "[t]he letter of intent is non-binding, but preserves the hospital's right to complete its application by the required due date if an available position, as provided in Rule 64J-2.010, F.A.C., exists in the hospital's TSA."

101. Shands assumes that this provision requires the Department to consider whether there is a "slot" available at the provisional review stage, but that is not the case. As noted in Bayfront, this provision is not a prerequisite which prohibits a

hospital from submitting an application only if there is an open "slot." Bayfront, supra, at 474. Instead, the rule simply preserves the hospital's right to complete an application by filing a non-binding letter of intent. Id. There is no requirement or reference in rule 64J-2.012(1)(a) regarding the consideration of need at the provisional review.

102. Shands also assumes that there is currently only one "slot" in TSA 5. Rule 64J-2.010, which was promulgated by the Department in 2014, provided that there was one "slot" in TSA 5. This argument is based on a misunderstanding of rule 64J-2.010. This rule has two parts: (1) a list of the "scoring" criteria that the Department is to use in determining how many trauma centers should be permitted in each TSA; and (2) an allocation table that shows how many trauma center "slots" are in fact allocated to each TSA (results that are reached by applying some of the data set forth in the Department's review of the TSA Assessment to scoring criteria). Rule 64J-2.010 provides that the Department was to conduct a new assessment by August 30, 2015, and to revise the allocation table based on the results of the new assessment. Fla. Admin. Code R. 64J-2.010(2). Had the Department followed the plain language of the rule, it would have conducted a new assessment; conducted an analysis of the data from the new assessment; and promulgated a new rule that would have included a new allocation table. The Department conducted a

2015 TSA Assessment, reviewed the data, and proposed new allocations, which included increased allocations in TSA 5. Based on this 2015 assessment, the Department proposed two rules reflecting the allocation of at least one additional "slot" to TSA 5. Id. However, these proposed rules were not adopted, nor was the 2015 TSA Assessment incorporated into the current rule. Id. As the Department did not revise the allocation table by the August 30, 2015, deadline to reflect its updated assessment of the allocation of slots in the TSAs, the allocation table prepared in 2014 is no longer valid. Accordingly, there is no longer just one "slot" in TSA 5.

103. With the expiration of the 2014 rule, currently, the only limitation on trauma centers is the statewide statutory cap of 44 trauma centers. That cap does not preclude Memorial's trauma center being approved because there are fewer than 44 trauma centers statewide.

104. Even if Shands' interpretation of rule 64J-2.012(1)(a) were correct, which the Bayfront court has determined it is not, the Department would still have been required to provisionally approve Memorial's Application. Shands' interpretation of this rule would have put it in direct conflict with section 395.4025 of the Trauma Statute. "It is axiomatic that an administrative rule cannot enlarge, modify or contravene the provisions of a statute." Willette v. Air Prods., 700 So. 2d 397, 401 (Fla. 1st

DCA 1997) (citation omitted). Since the Department was statutorily required to provisionally approve Memorial's Application if it met the Trauma Standards, the Department's rule could not validly provide to the contrary. See id.

105. Since section 395.4025(2), as affirmed by the Bayfront court, makes clear that need is not a consideration at the provisional stage, no need for a rule reiterating the statutory language is required, or even permitted:

> [A]n agency interpretation of a statute which simply reiterates the legislature's statutory mandate and does not place upon the statute an interpretation that is not readily apparent from its literal reading, nor in and of itself purport to create certain rights, or require compliance, or to otherwise have the direct and consistent effect of the law, is not an unpromulgated rule, and actions based upon such an interpretation are permissible without requiring an agency to go through rulemaking.

St. Francis Hosp., Inc. v. Dep't of HRS, 553 So. 2d 1351, 1354 (Fla. 1st DCA 1989). When an agency simply follows the plain statutory text without issuing a rule that simply regurgitates that statutory text, the agency is not deemed to be acting pursuant to an unadopted rule. See, e.g., State Bd. of Admin. v. Huberty, 46 So. 3d 1144, 1147 (Fla. 1st DCA 2010).

106. The Department is not permitted to depart from its statutory mandate, by way of an unadopted rule or otherwise. "In cases of conflict, a statute takes precedence over an

administrative rule." One Beacon Ins. v. Ag. for Health Care Admin, 958 So. 2d. 1127, 1129 (Fla. 1st DCA 2007).

107. Since the question of need for Memorial's provisional trauma center cannot be an issue at the provisional stage of review and approval, no further discussion of the "need" for the center is necessary, despite the detailed testimony given by Mr. Nelson at hearing. That discussion may ripen at some point down the road, but not today. Since the First DCA has clearly spoken on the need issue as it related to provisional approval of trauma centers, the undersigned must, and will, abide by the decision in Bayfront, thus ending that discussion here.

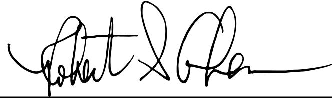
108. Based upon the foregoing Findings of Fact and Conclusions of Law, it is, therefore, concluded that: Memorial met its burden of establishing that its trauma center application met the applicable standards; and that Shands' argument that the Department acted pursuant to an unadopted rule when it provisionally approved Memorial's trauma center application even though there allegedly was no available "slot" in TSA 5 is contrary to section 395.4025 as interpreted by the First DCA in the Bayfront case.

RECOMMENDATION

Based on the foregoing Findings of Fact and Conclusions of Law, it is RECOMMENDED that the Department of Health enter a final order finding that Memorial met its burden of establishing

that its trauma center application met the applicable standards; awarding provisional Level II status to Memorial; and dismissing Shands' petition.

DONE AND ENTERED this 13th day of June, 2018, in Tallahassee, Leon County, Florida.



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NOTICE OF RIGHT TO SUBMIT EXCEPTIONS

All parties have the right to submit written exceptions within 15 days from the date of this Recommended Order. Any exceptions to this Recommended Order should be filed with the agency that will issue the Final Order in this case.