STATE OF FLORIDA
DIVISION OF ADMINISTRATIVE HEARINGS

GALENCARE, INC., d/b/a NORTHSIDE HOSPITAL,

Petitioner,

vs.

FLORIDA DEPARTMENT OF HEALTH,

Case No. 17-2754

Respondent,

and

BAYFRONT HMA MEDICAL CENTER, LLC, d/b/a BAYFRONT HEALTH-ST. PETERSBURG; AND ST. JOSEPH'S HOSPITAL, INC., d/b/a ST. JOSEPH'S HOSPITAL,

Intervenors.
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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 July 12 and 13, 2017, in Tallahassee, Florida.

APPEARANCES

For Galencare, Inc., d/b/a Northside Hospital:

Stephen A. Ecenia, Esquire
Rutledge Ecenia, P.A.
119 South Monroe Street, Suite 202
Post Office Box 551
Tallahassee, Florida 32302-0551

For Florida Department of Health:

Jay Patrick Reynolds, Esquire
Michael Jovane Williams, Esquire
Prosecution Services Unit
Department of Health
4052 Bald Cypress Way, Bin A02
Tallahassee, Florida 32399

For Bayfront HMA Medical Center, LLC, d/b/a Bayfront Health-St. Petersburg:

Timothy Bruce Elliott, Esquire
Smith & Associates
3301 Thomasville Road, Suite 201
Tallahassee, Florida 32308

For St. Joseph's Hospital, Inc., d/b/a St. Joseph's Hospital:

Karen Ann Putnal, Esquire
Moyle Law Firm, P.A.
118 North Gadsden Street
Tallahassee, Florida 32301

R. Kathleen Brown-Blake, Esquire
1520 Killearn Center Boulevard
Tallahassee, Florida 32309

STATEMENT OF THE ISSUE

The issue in this case is whether the application filed with the Department of Health ("Department") on March 31, 2017, by Galencare Inc., d/b/a Northside Hospital ("Northside"), to operate as a provisional Level II trauma center met the applicable criteria and standards under Part II, Chapter 395, Florida Statutes (2017),[1/] and Florida Administrative Code Chapter 64J-2.

PRELIMINARY STATEMENT

On May 1, 2017, the Department notified Petitioner, Northside, that its application to become a provisional Level II trauma center was denied. Northside challenged the denial by filing a petition pursuant to section 120.57(1), Florida Statutes. The Department's review determined that Northside's application failed to meet at least three of the Critical Elements required by law for a trauma center. On May 15, 2017, a Notice of Agency Referral was filed at DOAH, whereby the petition was assigned DOAH Case No. 17-2754. On May 18, 2017, Bayfront HMA Medical Center, LLC, d/b/a Bayfront Health-St. Petersburg ("Bayfront"), filed a Petition to Intervene asserting that, as an existing trauma center in the same Trauma Service Area ("TSA"), it had standing to intervene, including because its substantial interests would be impacted should Northside be approved. On May 25, 2017, St. Joseph's Hospital, Inc., d/b/a St. Joseph's Hospital ("SJH"), filed a Petition to Intervene with Full-party Status. In a June 9, 2017, Order, Bayfront's intervention was granted, but with some limitations on Bayfront's participation. In the same Order, SJH was granted leave to intervene, but with greater limitations than Bayfront. The final hearing in this matter was held on July 12 and 13, 2017, in Tallahassee, Florida. At the hearing, Northside presented the testimony of Peter Kennedy, Doreen Gilligan, Angela Chisolm, and Dr. Erik Barquist.

The Department presented the testimony of Cynthia Dick ("Chief Dick"), the Department's assistant deputy secretary of Health and also the interim director for the Division of Emergency Preparedness and Community Support, with oversight of several divisions, bureaus and programs, including the Department's "Trauma Program." Intervenor, Bayfront, presented the testimony of its corporate representative, Dr. Steven Epstein. Joint Exhibits 1 through 10 were admitted into evidence. Northside's Exhibits 1 through 6, 10 through 15, 20, 23, and 26 were admitted into evidence. In addition, the ALJ took official recognition of Northside's Exhibits 7 and 8. The Department's Exhibits 2 and 3 were admitted into evidence, and the ALJ took official recognition of Bayfront's Exhibits 11 through 13. Intervenor, SJH, monitored the hearing, but did not actively participate in the hearing and so did not offer any exhibits into evidence. After an initial deadline of 30 days from the filing of the transcript for filing proposed recommended orders was established, the parties requested, and were granted, three extensions of time to file their proposals. All parties have timely submitted proposed findings of fact and conclusions of law on or before October 2, 2017, which have been duly considered in the preparation of this Recommended Order.

FINDINGS OF FACT

I. Parties

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. Northside is a 288-bed acute-care hospital located in TSA 9, Pinellas County, Florida. Northside provides a wide range of services, including inpatient cardiovascular and neuroscience services.

3. Northside has developed a trauma program and submitted an application to operate as a provisional Level II trauma center in March 2017. The Department's preliminary determination to deny Northside's application on May 1, 2017, is the subject of this proceeding.

4. Bayfront is an acute-care hospital located in TSA 9, Pinellas County, Florida. Bayfront has been designated by the Department as a Level II trauma center.

II. Northside's Trauma Center Application

A. Northside Submitted a Timely Letter of Intent

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

6. Northside timely submitted a letter of intent with the Department in September 2016. This letter indicated that Northside would seek approval from the Department to operate as a Level II trauma center. Northside was well-situated for a trauma center because of the resources and services already in place at the hospital. Moreover, Northside was prepared to open a trauma program because it already had extensive experience treating critically ill patients.

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

B. Northside Established a Full Trauma Program after the Department Accepted its Letter of Intent

8. Once Northside 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 forthcoming application was compliant with the requirements set forth in DOH Pamphlet (DHP) 150-9 (the "Trauma Standards" or "DHP"), which is incorporated by reference in rule 64J-2.011.

9. As part of the development of its trauma program, Northside hired Doreen Gilligan in October 2016 to serve as director of Trauma Services. The hospital also worked with Angie Chisolm to draw on resources from other approved trauma centers, such as trauma-related policies and procedures and best practices for trauma center operations.

10. Northside's expertise in advanced, life-saving care, including cardiovascular and neuroscience programs and its intensive care unit ("ICU"), made it a well-qualified candidate to open a new trauma center.

11. Between October 1, 2016, and April 1, 2017, Northside invested over $4 million to develop its trauma program.

12. Northside invested $2.5 million in physical plant improvements and equipment. These improvements included:

- A helipad, which is properly licensed by the Department of Transportation and FAA. The helipad is operational and Northside is already receiving patients from helicopters on a daily basis in its capacity as an acute-care hospital.
- Two state-of-the-art trauma resuscitation bays in the emergency department ("ED") that are in immediate proximity to the helipad. These new trauma bays can accommodate up to four trauma patients at the same time.

- The expansion of the ICU to include 12 beds that are specifically designated for trauma patients.
- The expansion of one of the operating rooms because trauma patients often require care from multiple doctors simultaneously.
- The purchase of new equipment, including new ICU monitors, operating room equipment, and equipment to support physician subspecialists.
- The purchase of a blood track machine for the emergency department. This machine dramatically reduces the amount of time it takes for patients to receive blood transfusions.
- The purchase of a platelet function testing machine and a thromboelastography machine. These machines help identify where a trauma patient is bleeding. These machines also play a critical role in quickly stopping bleeding – one of the key functions that every trauma center must perform.
- The purchase of a second computed tomography ("CT") machine dedicated solely to the provision of radiology services needed by trauma patients.

13. Northside invested approximately $1.7 million in physician and staff employment and recruitment. This investment has enabled Northside to do the following:

- Provide continuous, around-the-clock trauma surgeon coverage, 7 days a week (beginning February 16, 2017).
- Provide continuous, around-the-clock anesthesiology coverage.
- Provide hospital coverage for the required 19 physician sub-specialty groups. These physicians are able to arrive at the hospital within 30 minutes or less.
- Hire more than 30 additional full-time nurses to meet the staffing requirements in the Trauma Standards. These hires have allowed Northside to provide a continuous,

in-house presence of operating room nurses and technicians.

- Hire specialized administrative staff for the trauma program, including Doreen Gilligan (Director of Trauma Services), a trauma registrar, and a performance improvement coordinator dedicated solely to ensuring Northside's trauma patients receive high quality care. Once Northside's trauma program becomes operational, Northside plans to hire a second trauma performance improvement coordinator.

14. Between January and March 2017, Northside provided over 5,000 hours of trauma training to its staff, including the CEO and CFO of the hospital. The major focus of this training was the Trauma Nursing Core Course ("TNCC") for nursing staff, which is the foundation of emergency nursing education and ensures that the nursing staff can provide high-quality care for the most severely injured patients. The hospital implemented nursing education requirements which exceeded the Trauma Standards. Some of this training included actual operational practice using simulations and mock trauma drills.

15. Northside implemented over 200 new facility policies related to trauma during this period. Northside subsequently trained its staff on these new programs.

16. Northside made all of these investments prior to March 31, 2017, the date on which Northside submitted its application to the Department.

C. Northside Timely Assembled and Submitted Its Trauma Center Application and Deficiency Response to the Department

17. Northside's application was prepared by a core team whose mission was to ensure that the application fully complied with the Trauma Standards. The key members of that team were Peter Kennedy, chief operating officer; Doreen Gilligan, director of Trauma Services; Dr. Erik Barquist, interim trauma medical director; and Angie Chisolm, assistant vice president of Trauma Services for HCA East and West Florida Divisions. The final application submitted to the Department encompassed over 10,000 pages of information. Because the application was too voluminous for any one person to prepare alone, each of the team members played an important role in ensuring the application addressed each Trauma Standard. Preparation of the application involved thousands of staff hours and required close cooperation with the physicians, staff, and community members.

18. Northside timely submitted its trauma center application ("Northside Application") to the Department on March 31, 2017.

19. After receiving the Northside Application, the Department arranged for it to be reviewed by two outside experts, Dr. Lawrence Reed and Nurse Susan Cox. Both Dr. Reed and Nurse Cox have reviewed trauma applications on behalf of the Department in the past.

20. On April 14, 2017, the Department sent Northside a letter notifying it of the deficiencies that Dr. Reed and Nurse Cox had identified (the "Deficiency Notice"). The Department provided a checklist (Department of Health Initial Provisional Review Checklist for Northside, April 5, 2017, hereafter referred to as the "Initial Checklist") based on the Trauma Standards with boxes marked "Yes" or "No" to indicate whether the reviewers found evidence to demonstrate that each particular Trauma Standard and subpart was met. The checklist also contained written comments from the reviewers for subparts which were checked "No." Of the more than 350 subparts that make up the Trauma Standards, the reviewers only identified 35 about which they had concerns or additional questions. Most of the comments from the reviewers consisted of simple requests for clarification. In some cases, the reviewers asked for information that Northside had already submitted with the initial application on March 31, 2017.

21. Northside timely responded to each deficiency identified by the Department on April 21, 2017 (the "Deficiency Response"), five business days after receipt of the Deficiency Notice. The Deficiency Response was prepared by the same team that prepared the initial application. Much like the initial application, the team's role was to ensure that each concern was addressed and that the application demonstrated that the hospital

met the Trauma Standards. The Deficiency Response included 78 supporting exhibits consisting of hundreds of pages.

22. The Deficiency Response was divided in two sections: (1) a narrative table; and (2) supporting exhibits to the narrative table. In the narrative table, Northside addressed each Trauma Standard subpart identified in the Initial Checklist as an area not met or an area of concern. The table was organized into three columns: the first reciting the subpart language; the second copying the reviewer concern from the Initial Checklist; and the third detailing Northside's narrative response or explanation to each comment.

23. The Deficiency Response was also reviewed by Dr. Reed and Nurse Cox. These reviewers determined that Northside addressed and corrected the vast majority of deficiencies identified in the initial review. Only three Trauma Standard subparts were identified as remaining areas of concern: Standard V(B)(3)(a)(1), Standard V(B)(3)(d), and Standard XVIII(G). Each of these issues was identified by Dr. Reed. Neither Dr. Reed nor Nurse Cox recommended to the Department that Northside's application be denied.

24. On May 1, 2017, the Department informed Northside that its application was not in compliance with the applicable Trauma Standards and would be denied ("Denial Letter"). The Denial Letter did not identify which (if any) of the Standards that the

Department believed that Northside had not met. Instead, the Denial Letter attached a checklist indicating concerns with only three subparts. The Department now takes the position that Northside's application is deficient because it did not satisfy Standard V(B)(3)(a)(1), Standard V(B)(3)(d), and Standard XVIII(G), although the Department has not stated whether each one of these Standards, standing alone, would have (in its view) warranted denial of the application.

25. The Denial Letter did not afford Northside any opportunity to address the potential issues identified with respect to the three Standards. Instead, it informed Northside that its only options were to seek an administrative hearing challenging the Department's denial or to submit a trauma center application the following year. Northside therefore did not submit any additional documentation to the Department.

D. Northside's Evidence Establishes That It Satisfied Each of the Three Standards the Department Claimed Were Deficient

i. Standard V(B)(3)(a)(1)

26. Standard V addresses the facility requirements relating to the emergency department. It includes requirements for a trauma resuscitation area, helipad, emergency physicians, support staff, and trauma flow sheet, among other criteria. This Standard also details the required qualifications for emergency room physicians who may provide care to trauma patients.

Emergency room physicians must be board certified in emergency medicine or meet stringent alternate criteria demonstrating their qualifications.

27. There are two ways to meet the alternate criteria. The first includes attestation from the trauma medical director that there is a critical need for the physician, completion of an accredited residency training program, documentation that the physician participated in the Advanced Trauma Life Support ("ATLS") program, 48 hours of trauma-related continuing medical education in the past three years, evidence that the physician attends at least 50 percent of the trauma performance improvement meetings, evidence of membership or attendance at regional or national trauma meetings during the past three years, and attestation by the trauma medical director and emergency department director that the physician compares favorably with other physicians on the trauma call schedule. The second way for a physician to meet the alternate criteria is by providing evidence of board certification in a primary care specialty and attestation by the emergency department director that the physician has worked as a full-time emergency physician for three of the last five years.

28. As part of its initial application, Northside provided the Department with staffing schedules for March, April, and May 2017, which documented the physicians on staff in the

emergency room during those months and the shift times they would cover. Northside also submitted substantial evidence regarding the qualifications of each of these emergency room physicians. One of these emergency room physicians was Dr. Abraham Wilks. At the time it submitted its initial application, Northside believed Dr. Wilks met both paths of the alternate criteria. In preparation for the initial application, Dr. Wilks, working with Northside, went to extraordinary lengths to secure the seven required components under the first alternate criteria path. Northside also provided evidence that Dr. Wilks qualified under the second alternate criteria path since he was board eligible for family medicine and had been working as an emergency physician for the past five years. The staffing schedules submitted with Northside's application on March 31, 2017, showed that Dr. Wilks was scheduled to be the sole physician provider for short periods of time on a limited number of days.

29. During his review of the initial application, Dr. Reed concluded that Dr. Wilks did not meet either of the alternative criteria because he did not complete an emergency medicine residency and was no longer board-certified in family medicine. Because Dr. Wilks did not meet these qualification requirements in Standard V(B)(3) as an emergency department physician, he could not be the sole physician provider in the emergency department.

30. After receiving the Deficiency Notice and Initial Checklist, Northside immediately took steps to address Dr. Reed's comments. Northside's leadership worked with the director of the emergency department to ensure that Dr. Wilks would not be the sole physician provider in the emergency room. After April 18, 2017, Dr. Wilks never served as the sole physician provider in the emergency room. The emergency department physician staffing schedule for April and May 2017, was updated to reflect these changes ("Updated Staffing Schedule"). The other physicians listed on the staffing schedule were appropriately qualified, and the staffing schedule provided for appropriate physician coverage.

31. In its Deficiency Response, Northside noted these operational changes regarding Dr. Wilks and specifically addressed Dr. Reed's concerns. Northside informed the Department that "Dr. Wilks has been removed from the ED Trauma assignment and will never be the single provider in the ED, effective immediately." Dr. Reed agreed at his deposition that if Dr. Wilks were removed from the staffing schedule, Northside would be in compliance with Standard V(B)(3)(a)(1).

32. The Deficiency Response also referenced a related exhibit, which Northside intended to be the amended staffing schedule. However, due to a clerical error, Northside's Deficiency Response included the old staffing schedule from the

initial application, which incorrectly showed Dr. Wilks as the sole provider for limited periods. The old staffing schedule contradicted the narrative explanation of Northside's operational changes included in the Deficiency Response and was clearly submitted in error. Dr. Reed himself noted this contradiction: The response document also states that "Dr. Wilks has been removed from the ED Trauma assignment and will never be the single provider in the ED, effective immediately. However, it appears that Dr. Wilks is the only ED physician on site from 6a-8a on May 4, May 7, May 20, and May 21. Please clarify this contradiction."

33. The Department did not follow Dr. Reed's recommendation. It never contacted Northside to ask why the staffing schedule listed Dr. Wilks as the sole provider for limited periods of time when Northside's submission expressly stated that Dr. Wilks would no longer be the sole provider. Had the Department contacted Northside, it would have learned that the "old" staffing schedule had been submitted rather than the current and correct staffing schedule, i.e., the one that did not include Dr. Wilks as the sole provider.

34. Thus, there can be no dispute that, as of April 18, 2017, (1) Northside's operative emergency department staffing schedule was updated to reflect that Dr. Wilks would never be the sole provider; and (2) at all times, Northside's emergency

department was fully staffed by properly qualified emergency department physicians. Under these circumstances, the Department erred in taking the position that Northside did not satisfy Standard V(B)(3)(a)(1) simply because it mistakenly submitted an outdated staffing schedule to the Department in conjunction with its clear narrative explanation.

ii. Standard V(B)(3)(d)

35. The physician qualifications included in Standard V also require that each physician maintain a current ATLS provider certification. The ATLS certification is required only of emergency department physicians and trauma surgeons because these are the physicians who treat trauma patients when they first arrive at the trauma center. One of the emergency department physicians included in Northside's application is Dr. Joseph Nelson. Dr. Nelson also serves as the emergency department's pre-hospital trauma care expert for the Committee of Emergency Preparedness and Readiness, meaning that he is the state's expert on issues relating to the emergency care provided on-site before patients are brought to the hospital. Northside's application included an extensive set of documents that established Dr. Nelson's credentials, including the following: a compilation of Dr. Nelson's certifications, proof of his osteopathic board certification, his Florida Department of Health medical license, his physician profile with the American Medical Association,

proof of his continuing medical education hours, his letter of privileges at Northside, and his most recent ATLS certificate. Dr. Nelson's ATLS certificate included a letter from ATLS that recognized Dr. Nelson for high scores on his written and practical tests and recommended that he apply to be an ATLS course instructor, an honor that is accorded only to doctors who attain the best performances at the training course.

36. At the time Northside submitted its initial application, Dr. Nelson's ATLS certification had recently expired and he was planning to take a course to renew his certification. Dr. Nelson was aware of the expiration before the submission and made a concerted effort to complete the course in advance by registering for a course in February 2017. However, the course Dr. Nelson was originally scheduled to take in February 2017 was cancelled due to a snowstorm. Because ATLS courses are in high demand and often full, Dr. Nelson was not able to immediately reschedule for a course in his region. After working with Northside and Angie Chisolm, he registered for another course to be held in Tallahassee on April 23, 2017. Northside included proof of his course registration with its initial application.

37. In the Deficiency Notice and Initial Checklist provided by the Department, Dr. Reed noted that Dr. Nelson's ATLS certificate had expired and acknowledged that he was scheduled to take his ATLS course on April 23, 2017. Dr. Reed asked the

hospital to "provide evidence of successful completion of the ATLS course he is scheduled to take on 4/23/2017." Dr. Reed did not ask the hospital to submit any further documentation before the certificate arrived.

38. On multiple occasions, Northside sought clarification from the Department regarding how it should establish that Dr. Nelson was in compliance with Standard V(B)(3)(d). Before Northside submitted its initial application to the Department, it informed the Department that Dr. Nelson was registered for and planned to take the ATLS course on April 23, 2017, and asked for guidance regarding how it should establish that Dr. Nelson was in compliance with Standard V(B)(3)(d). The Department advised Northside to provide proof of registration with its initial application, and Northside did just that. Northside returned to the Department for guidance after receiving the Deficiency Notice and reminded the Department that Dr. Nelson planned to complete the ATLS course on April 23, 2017. Once again, the Department directed Northside to submit documentation of course registration and to later submit Dr. Nelson's updated ATLS certificate when available.

39. In its Deficiency Response, Northside reiterated that Dr. Nelson was registered for and scheduled to complete the ATLS certification course on April 23, 2017, just two days later. Based on the Department's guidance, Northside also included

Dr. Nelson's ATLS course registration, which demonstrated that he was scheduled to take the course in Tallahassee on April 23, 2017, as well as email communication from the course host confirming that Dr. Nelson paid for and secured a seat at that course. Northside further indicated that it would provide evidence to the Department of Dr. Nelson's ATLS recertification following successful completion of the course. Northside also informed the Department that if Dr. Nelson did not attend and pass the course on April 23, 2017, he would be removed from the call schedule effective May 1, 2017.

40. Dr. Nelson successfully completed the course on April 23, 2017, and thus satisfied his ATLS requirement that day. Northside immediately confirmed with the ATLS coordinator that Dr. Nelson had passed the course and concluded that he was in compliance with Standard V(B)(3)(d).

41. Dr. Reed's review of Northside's Deficiency Response stated: "Upon receipt of a copy of Dr. Nelson's updated ATLS certification, compliance with this standard will have been met." Northside subsequently received Dr. Nelson's updated ATLS certification. It did not arrive at Northside until after May 1, 2017, due to normal delays in processing by the American College of Surgeons. At hearing, Northside presented Dr. Nelson's updated ATLS certification reflecting his successful completion on April 23, 2017.

42. In sum, Dr. Nelson was ATLS-certified as of April 23, 2017, which is before the Department's May 1, 2017, deadline. Northside also provided a litany of information to the Department with its initial application and Deficiency Response detailing Dr. Nelson's efforts to secure his ATLS certification. Northside therefore satisfied Standard V(B)(3)(d).

iii. Standard XVIII(G)

43. Standard XVIII addresses quality management, which is one of the core requirements of a trauma program. Since the time that Northside began building its trauma program, it has prioritized quality management. Northside began developing its trauma quality management program in early December 2016. As part of this effort, Northside developed a trauma quality management plan, which is essential for any quality management program. Following the beginning of limited trauma-related operations on February 16, 2017, Northside held its first peer review meeting on February 22, 2017, to discuss patient treatment issues. Dr. Barquist attended these meetings and minutes were kept. Northside also began to hold nursing and ancillary staff meetings, known as trauma quality management ("TQM") meetings, during this time. The directors of each department at the hospital attended these meetings, as well as the chief operating officer and chief financial officer. The objective of these meetings was to operationalize the more than 200 trauma-specific

policies and procedures put in place during the trauma program development. Any issues identified in these meetings were addressed immediately with the whole trauma staff to ensure program-wide compliance.

44. To demonstrate compliance with this Standard, Northside submitted nearly 400 pages of documents with its initial application. These included Northside's Trauma Performance Improvement and Patient Safety Plan, policies and procedures, and peer review minutes.

45. As part of its application, Northside submitted the minutes of its peer review meetings at which quality management issues were discussed. Even though Northside was not receiving trauma alert patients from local emergency medical services (something it could not do prior to becoming a provisionally approved trauma center), it routinely conducted quality management activities with regard to patients in the hospital with trauma injuries. With this patient population, Northside employed its trauma improvement processes to identify areas in which there was room for improvement in care, and to determine how education, training, and equipment could be enhanced to improve care for similar patients in the future.

46. In his review of Standard XVIII(F), Dr. Reed affirmed that Northside held quality management meetings at which the following issues were discussed:

- The subject matter discussed, including an analysis of all issues related to each case referred by the trauma service medical director to the trauma program manager, cases involving morbidity or mortality determining whether they were disease related or provider related and the preventability, and cases with other quality of care concerns.
- A summary of cases with variations not referred to the committee.
- A description of committee discussion of cases not requiring action, with an explanation or each decision.
- Any action taken to resolve problems or improve patient care and outcomes.
- Evidence that the committee evaluated the effectiveness of any action taken to resolve programs or improve patient care and outcomes.

47. Northside also submitted documents addressing Standard XVIII(G). This subpart addresses a quarterly report prepared by the trauma quality management committee which must be submitted to the Department by approved trauma centers 15 days after the end of each quarter. If approved as a provisional trauma center, Northside would have submitted its first quality report to the Department on August 15, 2017. The report, which is only submitted by provisionally approved and verified trauma centers, must include information related to patient case reviews, select clinical indicators, and patient complications. The report is only made available by the Department to approved trauma centers; it is not provided to applicants. The report form is not referenced in any Department rule, the Trauma Standards, or the

Department's website. However, to establish that Northside was prepared to provide the required report once it received provisional approval, Northside obtained a copy of the template from an affiliated operating trauma center and included that template in its application.

48. Because it was not an approved trauma center, Northside ultimately submitted a detailed template of the quality report to be submitted following approval as required. The detailed template included blank fields with the quality indicators selected by the Department and the hospital, benchmarking data points, patient complications, and case review information. The fields in the report regarding patient complications and case review information can be taken directly from the peer review minutes, which Northside submitted with its initial application and were located directly in front of its detailed template.

49. In his review of Northside's initial application, Dr. Reed concluded that Northside provided much of the required evidence, demonstrating "an active and effective trauma quality improvement program" and met the vast majority of subparts in this Standard. However, regarding Standard XVIII(G), Dr. Reed identified deficiencies on the basis that "[a] template of a report was submitted, but there were no cases recorded." Dr. Reed confirmed that he reviewed the peer review minutes Northside submitted with its application.

50. In response to Dr. Reed's comment, Northside submitted updated templates with additional information. The quality indicator and benchmarking templates were populated with data from its trauma registry regarding the patients with traumatic injuries that the hospital had treated since February 16, 2017. In addition to these documents, which specifically addressed Standard XVIII(G), Northside also submitted more peer review minutes from subsequent meetings since the initial application, which were included directly in front of Exhibit 75.

51. Dr. Reed ultimately concluded that Northside had not demonstrated compliance with Standard XVIII(G)(1)-(3). That conclusion, however, is unsupportable by the evidence at hearing. Dr. Reed acknowledged that Northside's Deficiency Response provided the "quarterly data regarding the state required indicators and the additional institution-specific indicators." The only reason he believed that Northside's application remained deficient was that it did not "address the individual case quality review issues required in Standard XVIII.G.1-3." This conclusion is undermined by Dr. Reed's recognition--as reflected in his review of Standard XVIII(F)--that Northside was conducting case quality reviews. In his deposition, Dr. Reed agreed that Northside's Deficiency Response "did include information regarding the number of cases and indicators and that sort of thing." Indeed, Dr. Reed's true concern appears to have been

that Northside's "numbers," i.e., the number of patient cases reviewed by Northside, were "still kind of thin." But Dr. Reed himself recognized that prior to the time that a trauma center application is provisionally approved and the trauma program begins treating trauma alert patients, a trauma program is unlikely to have a large number of patient cases to review.

52. The Department's view that Northside did not satisfy Standard XVIII(G) is not supported by the evidence. The section of the quality report addressing individual case reviews is simply a summary of the information contained in the hospital's peer review minutes--and Northside conducted the required peer review meetings. Northside demonstrated at hearing that it was capable of preparing a table summarizing its peer review cases and the corrective action taken for each case. All the information contained in the completed table was taken verbatim from the peer review minutes that Northside submitted with its initial application and Deficiency Response. If approved, Northside was prepared to submit the quarterly report as required on August 15, 2017. Thus, at worst, Northside did not copy and paste information from one place to another. To the extent possible, Northside complied with this Standard.

53. The Department's review of an earlier trauma center application confirms that the Department should not have determined that Northside did not satisfy Standard XVIII(G). In

April 2016, the Department approved an application to operate as a provisional Level II trauma center submitted by Jackson South Community Hospital. As part of its approval, the Department--based on a review by Dr. Reed--determined that Jackson South met each of the requirements in Standard XVIII(G). However, Jackson South only submitted hospital policies, promising to prepare and submit the required quality report if approved. Jackson South did not submit any quality report or even a template of such a report. Despite submitting far less evidence demonstrating compliance, Dr. Reed did not note any deficiencies for this Standard with regard to Jackson South's application. The Department ultimately approved the application. Dr. Reed confirmed that Northside's quality management program was significantly more developed than the one for Jackson South Community Hospital that Dr. Reed himself had recommended be approved only two years earlier. At hearing, Chief Dick could not explain the inconsistency.

54. In sum, the Department erred in concluding that Northside had not satisfied Standard XVIII(G) because Northside had an active and effective quality management program that involved thorough case reviews and Northside demonstrated that it was capable of submitting the required forms once its program was approved and its fully operational.

E. Contemporaneous Emails Demonstrate That the Department Denied Northside's Application for Reasons Having Nothing to Do with the Merits of Northside's Program

55. The Department's decision to deny Northside's application was not made in a vacuum. On April 28, 2017--only two days before the Department sent Northside the Denial Letter--a circuit judge in Leon County entered an order ("Injunction Order") temporarily enjoining Northside from operating as a trauma center and enjoining the Department from permitting Northside to operate as a provisional trauma center. This injunction was based exclusively on issues of administrative law and did not in any manner address the merits of Northside's application. In fact, the Department strongly opposed the injunction.

56. The injunction did not prevent the Department from approving Northside's application. The Department's internal correspondence demonstrates that the injunction led the Department to deny Northside's application, presumably because it was concerned about the ramifications of provisionally approving Northside's application while the injunction was pending and Northside could not begin trauma center operations. On April 28, 2017, just hours before the Injunction Order was issued, Kate Kocevar, head of the Department's Trauma Section, emailed Dr. Reed's final conclusions to Chief Dick and informed her that in her opinion "Northside Hospital appears to have passed the

reviewers [sic] survey and will be granted Provisional status." Chief Dick confirmed at hearing that her initial impression based on Ms. Kocevar's email was that Northside passed the survey. Later that day, Chief Dick received the injunction order and immediately emailed other Department personnel, "[l]ooks like the letter to Northside will not be going out on Monday as originally written." Three days later, on May 1, 2017, the Department sent Northside the Denial Letter, notifying the hospital that its application had not met the Trauma Standards and would be denied.

57. Given the looming injunction order, the Department's internal correspondence, and the fact that the three alleged deficiencies are minor, at the very most, the Department's decision to deny the application was apparently motivated by an administrative decision that it should not approve an application while the injunction was in place--not by any genuine concerns regarding the merits of Northside's program.

F. Northside Has Expended, and Continues to Expend, Millions of Dollars to Maintain an Operational Trauma Program

58. Northside has continued to maintain its trauma service capability, including retaining physicians and staff, while proceeding with its challenge of the Department's preliminary denial. As part of its readiness efforts, Northside's quality management program remains in place, meaning that Northside is still holding peer review and quality improvement meetings.

Maintaining a continued state of readiness to initiate operations as a provisional Level II trauma center will cost Northside approximately $13 million this year.

CONCLUSIONS OF LAW

59. 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).

60. Northside has standing to participate in this administrative hearing as a party substantially affected by the Department's denial of the Northside Application, pursuant to section 395.4025(7) and rule 64J-2.1012(2).

61. Bayfront petitioned to intervene as a party whose substantial interests would be affected by the hearing pursuant to sections 120.569, 120.57(1), and 395.4025(7), and Florida Administrative Code Chapters 28-106 and 64J-2.

62. SJH petitioned to intervene with full-party status pursuant to sections 120.569, 120.57(1), and 395.4025(7), and chapters 28-106 and 64J-2.

63. On June 9, 2017, the ALJ granted Bayfront's petition to intervene with limitations regarding interjection of issues, and granted SJH's petition with significant restrictions. See Order Denying Bayfront's Motion to Consolidate, Granting Bayfront's Motion for Leave to Intervene with Restrictions, and Granting

St. Joseph's Petition to Intervene with Limited Status (June 9, 2017).

64. Northside seeks a determination that the Department erred when it denied Northside's provisional Level II trauma center application.

65. The standard of review in this proceeding is de novo. See § 120.57(1)(k), Fla. Stat. The purpose of this de novo review is to formulate final agency action with respect to the Northside 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.'") (emphasis added).

66. 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 Northside Application.

67. In conducting this de novo review, the ALJ makes his or her own determination as to whether the Northside Application, as submitted to the Department, met applicable standards.

68. 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 23 (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. 00-4408RU, FO at 44 (Fla. DOAH Feb. 7, 2001).

69. 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").

70. In a hearing held pursuant to section 120.57(1), Northside 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").

71. In order to prevail, Northside must establish that the Northside 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.

72. 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

Northside'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.

73. In this de novo hearing, Northside can attempt to meet its burden by making arguments as to why the evidence that it provided to the Department, properly understood, requires approval of the Northside Application.

74. Bayfront and the Department argue that Northside impermissibly seeks to expand the scope of the ALJ's review to include: (1) evidence which was not submitted to the Department within the prescribed time period; and (2) explanations of evidence allegedly submitted in error. These categories of evidence cannot be relied upon, they say, to establish that the Northside Application met applicable standards within the prescribed time period.

75. Northside, they argue, cannot rely on evidence which was not submitted to the Department within the prescribed time period. In their eyes, the "prescribed time period" is either April 21 (Bayfront) or April 22 (the Department) 2017, the date of the Department's finding that the application was deficient. They submit that the Department's decision about whether to grant

or reject an application must be based solely on the applicant's submission to the Department. See Fla. Admin. Code R. 64J-2.012(e)-(f) ("[E]ach hospital whose application the department finds to be unacceptable or deficient . . . will be notified in writing of deficiencies. . . . Failure to provide the requested information, or failure to successfully address the deficiencies identified by the department, shall result in the denial of the hospital's application."). They conclude that the Department's rules and practice neither call for, nor authorize, the Department to consider evidence submitted by a trauma center applicant after the applicable deadlines.

76. However, since the principal requirement of approval as a provisional trauma center is that the applicant demonstrates it meets the criteria for approval by May 1 of the year in which it applies, the ALJ should be entitled to consider any evidence of compliance that existed, in this case, on May 1, 2017. To hold otherwise transforms this case from a de novo proceeding to an appellate or quasi-appellate proceeding where the ALJ is restricted to reviewing and deferring to the Department's evaluation of the decision of whether to approve the application at a point in time fixed at the Department's discretion, here April 22, 2017.

77. The Department has not offered a reasonable explanation for its position that this ALJ should ignore evidence that

Northside was compliant on May 1, 2017, merely because the evidence was not reflected on the application or response to deficiencies submitted to the Department. The ALJ's review should not be constrained to a paper review of the application completed by Northside, as well as its response to deficiencies found by the Department. While the undersigned does not concur with Judge Van Laningham's Order in the Jackson South case that the compliance period should be extended to the date of the hearing and that any amendments, updates, or supplements to the application may be provided even at hearing, that issue need not be addressed here. Northside was compliant with the three deficiencies that remained on April 21 or 22, 2017, by May 1, 2017. In this case, the deficiencies were relatively minor, and Northside addressed each fully to the satisfaction of this ALJ.

78. The issue with Dr. Wilks not being properly certified to be the sole physician provider in the emergency room was remedied by Northside amending its staffing schedules to have Dr. Wilks "removed from the ED trauma assignment and [he] will never be the single provider in the ED, effective immediately [as of April 18, 2017]." Dr. Reed testified that this action put Northside in compliance with Standard V(B)(3)(a)1. The issue of the purported amended staffing schedule removing Dr. Wilks from being the sole physician provider in the emergency department is a non-issue. Northside's key individuals involved with

establishing the trauma center testified, under oath, that the old staffing schedule was inadvertently provided a second time to the Department rather than the updated one. The credible evidence at hearing was that Dr. Wilks had been removed from the staffing schedule by April 18, 2017, well before the May 1, 2017, deadline. This clerical error is absolved as de minimus and should not be a reason for denying Northside's application, in light of the proven fact that Dr. Wilks had been removed. Additionally, when the Department saw that Dr. Wilks remained on the schedule, it had the opportunity to question the applicant as to its intention and the discrepancy between the narrative in the application and the schedule submitted in error, yet chose not to do so. The testimony was unequivocal that Northside would have corrected the schedule had it been pointed out by the Department.

79. Similarly, Northside demonstrated that it met Standard V(B)(3)(d) which requires that each physician in the trauma center maintain a current ATLS provider certification. The explanation given for Dr. Nelson's failure to have a certificate issued by May 1, 2017, even though he had completed the recertification course, is acceptable. The fact that credible proof was given to the Department that Dr. Nelson had successfully completed the course before that date is sufficient. No evidence was presented to refute the claim that he had successfully completed the course. In fact, the testimony

offered was along the lines of, "for something as important as a provisional approval of a trauma center, we would have made sure Dr. Nelson did not wait until the last minute to take the certification course." This does not amount to proof he had not completed the course; only that, in the eyes of a Department witness, the more prudent course of action would have been to take the course on an earlier date. The explanation of the course he intended to attend in February being canceled due to a snowstorm and the fact that he successfully completed the course in April 2017, are sufficient to show compliance with this standard.

80. Finally, Northside proved that it has been committed to quality management, one of the core requirements of a trauma program, since it began the process of initiating a trauma center program. Chief Dick's testimony showed that the Department determined that Jackson South, in a similar circumstance to this, had satisfied Standard XVIII(G), while Northside purportedly did not, notwithstanding that Northside had a far more developed quality management program and submitted more detailed information regarding the periodic reports that it would begin filing once it received provisional approval. The purported requirement that quality reports, or a mock-up of such reports, be given prior to the initiation of service as a provisional trauma center, makes little sense. Dr. Reed confirmed that

Northside's quality assurance program was more advanced than Jackson South's at this stage of review and the Department should consistently apply this standard to applicants for provisional status. No credible evidence was provided by the Department or Bayfront that Northside would not, as it testified, provide the first of the required quarterly quality assurance reports by August 15, 2017, after the initiation of the service on May 1, 2017.

81. The Trauma statutes and the Department's rules require that a provisional trauma center application must establish full compliance with each and every one of the Critical Elements. The Trauma statutes state that an applicant must "meet all requirements" mandated for the "critical review." The Department's regulations similarly require "compliance" without qualification, "with the revised standards" for provisional status. They also explicitly state that "completed applications for provisional trauma center status that do not demonstrate full compliance with these standards shall be denied." (emphasis added). Fla. Admin. Code R. 64J-2.011(1).

82. Northside's application and the reasonable explanations given at hearing, demonstrated full compliance with the Department's rules requiring Northside to demonstrate that it had met the Critical Elements required for operation as a trauma

center as of May 1, 2017. Full compliance with the Critical Elements is required for provisional approval.

83. The Department's position that Petitioner cannot excuse compliance with one or more of the Critical Elements on the basis of a "substantial compliance" theory is a reasonable interpretation of the Trauma statutes and the Department's rules. The Department's position is rooted in its unique technical and medical expertise regarding the standards that a trauma center must satisfy in order to provide appropriate care to all trauma patients. The ALJ, therefore, owes deference to the Department's position that a provisional trauma center application can be approved only if it establishes compliance with all of the Critical Elements.

84. For the reasons detailed above, Northside established compliance with all of the Critical Elements as defined by the Department's statute and rules. To summarize, Northside proved that Dr. Nelson had received his re-certification as an ATLS provider prior to the May 1, 2017, deadline; Dr. Wilks had been removed from the emergency department trauma assignment and would no longer be the single provider in the emergency department prior to the May 1, 2017, deadline; and Northside proved that it has been dedicated to and has been providing quality management since it initiated the building of its trauma program. This case came down to two "flaws" in the Northside Application, both of

which were explained away by credible evidence at hearing. The "old" schedule that was inadvertently put into the application was purely a clerical error, not a failure to meet the standard. The "requirement" that quality management meetings were already being held (see supra ¶ 46-47), was clearly established by the evidence. A template for quality assurance reports, although not specifically required, was provided in the application. Since Northside was not yet a provisional trauma center at the time of the application and its responses to deficiencies, it could not have submitted actual quality assurance reports. Requiring a hospital, prior to receiving provisional status as a trauma center, to submit actual quality assurance reports is a fiction not within the Department's purview as the trauma application reviewing agency. Dr. Reed, the Department's own expert reviewer, as noted previously, noted that Northside provided much of the evidence demonstrating "an active and effective trauma quality assurance program," finding only that not actual cases were recorded in the template provided. Northside adequately demonstrated full compliance with this standard as of the May 1, 2017, deadline for an applicant that had not yet been granted provisional status.

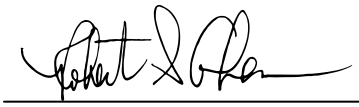
85. Finally, should the Department prevail in this matter, Northside would, once again, have to undergo the entire review process, submitting the same application, including the three

areas which were deemed deficient by the Department, but which were fully explained as having been met by the May 1, 2017, deadline. This would result in additional expenditures, in the millions of dollars, by Northside and a significant delay to the opening of its trauma program which it proved it is ready and able to provide to the residents of TSA 9. Such a harsh result does not represent prudent health care planning or allocation of resources when the applicant, Northside, demonstrated that it had fully complied with all of the Critical Elements that entitle it to be provisionally approved as a Level II trauma center. For all the reasons set forth above, the Department should provisionally approve Northside's application to operate a trauma center.

RECOMMENDATION

Based on the foregoing Findings of Fact and Conclusions of Law, it is RECOMMENDED that the Department enter a final order finding that Northside met its burden of establishing that its trauma center application met the applicable standards, and awarding provisional Level II status to the applicant.

DONE AND ENTERED this 20th day of December, 2017, in Tallahassee, Leon County, Florida.



ROBERT S. COHEN
Administrative Law Judge
Division of Administrative Hearings
The DeSoto Building
1230 Apalachee Parkway
Tallahassee, Florida 32399-3060
(850) 488-9675
Fax Filing (850) 921-6847
www.doah.state.fl.us

Filed with the Clerk of the
Division of Administrative Hearings
this 20th day of December, 2017.

ENDNOTE

[1/] References to statutes are to Florida Statutes (2017), unless otherwise noted.

COPIES FURNISHED:

Stephen A. Ecenia, Esquire
Rutledge Ecenia, P.A.
119 South Monroe Street, Suite 202
Post Office Box 551
Tallahassee, Florida 32302-0551
(eServed)

Michael Jovane Williams, Esquire
Prosecution Services Unit
Department of Health
4052 Bald Cypress Way, Bin A02
Tallahassee, Florida 32399
(eServed)

R. Kathleen Brown-Blake, Esquire
1520 Killearn Center Boulevard
Tallahassee, Florida 32309

Timothy Bruce Elliott, Esquire
Smith & Associates
3301 Thomasville Road, Suite 201
Tallahassee, Florida 32308
(eServed)

Karen Ann Putnal, Esquire
Moyle Law Firm, P.A.
118 North Gadsden Street
Tallahassee, Florida 32301
(eServed)

Gabriel F.V. Warren, Esquire
J. Stephen Menton, Esquire
Rutledge Ecenia, P.A.
119 South Monroe Street, Suite 202
Post Office Box 551
Tallahassee, Florida 32302-0551
(eServed)

Geoffrey D. Smith, Esquire
Corinne T. Porcher, Esquire
Smith & Associates
3301 Thomasville Road, Suite 201
Tallahassee, Florida 32308
(eServed)

Jon C. Moyle, Esquire
Moyle Law Firm, P.A.
118 North Gadsden Street
Tallahassee, Florida 32301
(eServed)

Shannon Revels, Agency Clerk
Department of Health
4052 Bald Cypress Way, Bin A02
Tallahassee, Florida 32399-1703
(eServed)

Nichole C. Geary, General Counsel
Department of Health
4052 Bald Cypress Way, Bin A02
Tallahassee, Florida 32399-1701
(eServed)

Celeste M. Philip, M.D., M.P.H.
State Surgeon General
Department of Health
4052 Bald Cypress Way, Bin A00
Tallahassee, Florida 32399-1701
(eServed)

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.