

STATE OF FLORIDA
DIVISION OF ADMINISTRATIVE HEARINGS

THE PUBLIC HEALTH TRUST OF
MIAMI-DADE COUNTY, FLORIDA,

Petitioner,

vs.

Case No. 15-6204RP

DEPARTMENT OF HEALTH,

Respondent,

and

KENDALL HEALTHCARE GROUP, LTD,
d/b/a KENDALL REGIONAL MEDICAL
CENTER; AND ORANGE PARK MEDICAL
CENTER, INC., d/b/a ORANGE PARK
MEDICAL CENTER,

Intervenors.

_____ /

FINAL ORDER

Administrative Law Judge John D. C. Newton, II, of the
Division of Administrative Hearings (DOAH) conducted the final
hearing on February 22, 2016, in Tallahassee, Florida.

APPEARANCES

For Petitioner: Thomas Francis Panza, Esquire
Paul Buckley, Esquire
Panza, Maurer & Maynard, P.A.
Bank of America Building, Third Floor
3600 North Federal Highway
Fort Lauderdale, Florida 33308

For Respondent: Daniel Ryan Russell, Esquire
Jones, Walker, Waechter, Poitevent,
Carrere and Denegre, LLP
Post Office Box 351
Tallahassee, Florida 32302-0351

Nichole Chere Geary, General Counsel
Department of Health
Bin A-02
4052 Bald Cypress Way
Tallahassee, Florida 32399

For Intervenors: Stephen A. Ecenia, Esquire
J. Stephen Menton, Esquire
Gabriel F.V. Warren, Esquire
Rutledge, Ecenia and Purnell, P.A.
119 South Monroe Street, Suite 202
Post Office Box 551
Tallahassee, Florida 32302-0551

STATEMENT OF THE ISSUES

- A. Does Petitioner, The Public Health Trust of Miami-Dade County, Florida (Health Trust), have standing to challenge Department of Health (Department) proposed rules 64J-2.007, 64J-2.008, and 64J-2.009?
- B. Is proposed rule 64J-2.007 an invalid exercise of delegated legislative authority?
- C. Is proposed rule 64J-2.008 an invalid exercise of delegated legislative authority?
- D. Is proposed rule 64J-2.009 an invalid exercise of delegated legislative authority?

PRELIMINARY STATEMENT

This is a challenge, brought under the authority of section 120.56, Florida Statutes (2015),^{1/} to the validity of three proposed rules of the Department. Health Trust filed a Petition for Determination of Invalidity of Proposed Rules. The petition challenges the validity of proposed rules 64J-2.007, 64J-2.008, 64J-2.009, and 64J-2.010. Three of those rules regulate approval of trauma agencies. Kendall Healthcare Group, Ltd., d/b/a Kendall Regional Medical Center (Kendall Regional), and Orange Park Medical Center, Inc., d/b/a Orange Park Medical Center (Orange Park), were granted leave to intervene.

After the parties conducted discovery, the Department withdrew proposed rule 64J-2.010. The validity of that proposed rule is no longer an issue in this proceeding. The parties twice sought and obtained a continuance of the final hearing scheduled, thereby waiving the time periods established by section 120.56(1)(c). By Order Granting Second Continuance and Scheduling Pre-Hearing Conference, the undersigned scheduled the final hearing for February 22, 2016. The final hearing convened as scheduled.

Health Trust presented testimony from Leah Colston and offered Exhibits 1 through 11 into evidence. The exhibits were admitted. The Health Trust also offered as Exhibit 12 excerpts of the deposition of Laura Hunter. Those excerpts along with

other excerpts, designated by the other parties for completeness, were accepted. The excerpts of the deposition admitted are:

page 5, line 5, through page 7, line 23
page 11, line 15, through page 13, line 2
page 12, line 6, through page 13, line 2
page 17, Line 2, through page 18, line 4
page 52, line 2, through page 55, line 12
page 59, line 15, through page 61, line 16
page 61, line 17, through page 62, line 18
page 65, line 7, through page 68, line 1
page 66, line 9 through page 66, line 23
page 67, line 24, through page 68,^{2/} line 1
page 97, lines 4 through 18

The Department, Kendall Regional, and Orange Park did not otherwise offer evidence. The parties timely filed proposed orders, which have been considered in the preparation of this Final Order.

FINDINGS OF FACT

The Parties

1. Health Trust is an entity of Miami-Dade County. Health Trust oversees the Jackson Health System, a health care provider functioning as a three-hospital system. One hospital is Jackson Memorial Hospital, a licensed acute care general hospital located in Trauma Service Area (TSA) 19. It operates a verified Level I trauma center, which is a part of the Miami-Dade County trauma system. Health Trust also operates Jackson South Community Hospital (Jackson South), a licensed acute care general hospital in TSA 19.

2. There is no trauma agency in TSA 19. Health Trust is not a trauma agency. It is not attempting to form or to be a part of a coalition to form a trauma agency for Miami-Dade County.

3. Jackson South is committed to obtaining authority to operate a Level II trauma center. In April 2015, it applied to operate a Level II trauma center. The Department denied the application. Jackson South challenged the denial and requested a formal administrative hearing. The Department referred the challenge to DOAH, where it was assigned Case No. 15-3171. Since the hearing in this case, Administrative Law Judge John Van Laningham issued an order recommending approval of Jackson South's application.^{3/} As of the date of this Order, the Department has not issued a final order.

4. In September 2015, Jackson South submitted a trauma center letter of intent to the Department expressing its intent to become a Level II trauma center in TSA 19. This was a cautionary filing in the event the Department denies Jackson South's first application now pending in DOAH Case No. 15-3171.

5. Kendall Healthcare is located in Miami, Florida. It is a licensed acute care general hospital located in TSA 19. Kendall Healthcare is a verified Level II trauma center.

6. Orange Park is located in Orange Park, Florida. Orange Park is a licensed acute care general hospital located in TSA 5.

There is no trauma agency in TSA 5. Orange Park submitted a Trauma Center letter of intent to the Department in September 2015, expressing its intent to file an application to become a Level II trauma center.

7. The Department is the state agency authorized to verify and regulate trauma centers and approve the establishment of trauma agencies in the state of Florida. It published the proposed trauma agency rules challenged in this proceeding.

The Florida Trauma System

8. Chapter 395, Part II, Florida Statutes, creates a plan to establish an inclusive trauma system to meet the needs of trauma victims. § 395.40(2), Fla. Stat. The Legislature defined "inclusive trauma system" to mean "a system 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." Id. The Legislature placed primary responsibility for the planning and establishment of this statewide inclusive trauma system with the Department.

§ 395.40(3), Fla. Stat.

9. Section 395.402 establishes trauma service areas. One component of the trauma system is the option for certain local or regional organizations to form and operate trauma agencies to

plan, implement, and evaluate trauma services systems in their trauma system area. § 395.401(1)(a), Fla. Stat.

10. Section 395.4001(11) defines a "trauma agency" as "a department-approved agency established and operated by one or more counties, or a department-approved entity with which one or more counties contract, for the purpose of administering an inclusive regional trauma system." According to Leah Colston, Bureau Chief for the Department's Bureau of Emergency Medical Oversight, a trauma agency "is the coordinating body for all of the emergency health care systems in a regional area that is designed to evaluate the system and perform its improvement opportunities to better outputs for patients." (Tr. 34, lines 22-25.)

11. Section 395.401 governs establishment of trauma agencies. It provides that the Department "may approve or not approve trauma agency plans based on the conformance of the plan with [sections 395.401,] 395.4015, 395.404, and 395.4045 and the rules and definitions adopted by the department." § 395.401(1)(c), Fla. Stat.

12. There are four trauma agencies in Florida. One agency covers 13 rural counties. The other three are for single counties. The counties are Palm Beach, Broward, and Hillsborough. There are no trauma agencies in TSA 19, which covers Miami-Dade and Monroe Counties.

13. The last time the Department received an application to establish a new trauma agency was in 1991. There is no dedicated funding source for trauma agencies. They must find their own funding. Absent a consistent funding source, how and where and when future trauma agencies may develop is unclear.

Rulemaking Process

14. Over the past five years, there has been a considerable amount of litigation about the Department's rules governing the allocation of the trauma centers around the state and applications for new trauma centers.

15. In September 2011, Administrative Law Judge David Watkins issued a Final Order invalidating Department rules governing the allocation of trauma centers throughout the state. The First District Court of Appeal affirmed the Final Order.^{4/}

16. The Department proposed a new trauma allocation rule in February 2014. Health Trust and other providers challenged that rule. The rule was determined valid.^{5/} Afterwards, several providers applied for designation as a trauma center in TSA 19, including Jackson South.

17. After adoption of the new rule, the Department undertook review of its trauma center rules, including the rules pertaining to trauma agencies. This was part of the Department's compliance with its rule reduction mandate. In an effort to reduce the number of Department rules and to align the rules with

the statutory requirements, the Department promulgated the proposed rules challenged in this proceeding. As Ms. Colston explained, the Department intended for the proposed rules to align the rule requirements with the statutory provisions governing the formation of a trauma agency and to delete unnecessary or redundant information.

18. During the rulemaking process, the Department conducted several workshops. They were well-attended by representatives of health care providers, including representatives of trauma centers and emergency medical services providers. Health Trust's representatives and legal counsel participated in the workshops.

19. The Department heard testimony and accepted written comments from the public. The Department thoroughly reviewed the public comments and considered them in finalizing the proposed rules.

CONCLUSIONS OF LAW

20. The Division of Administrative Hearings has jurisdiction over the subject matter of this proceeding.

§§ 120.56(1)(a), 120.569 and 120.57(1), Fla. Stat.

Section 120.56(1)(a) provides:

Any person substantially affected by a rule or a proposed rule may seek an administrative determination of the invalidity of the rule on the ground that the rule is an invalid exercise of delegated legislative authority.

21. Jurisdiction attaches when a person who is substantially affected by a proposed rule claims that it is an invalid exercise of delegated legislative authority. The party challenging the proposed rule bears the burden of going forward. The agency then must prove by a preponderance of the evidence that the proposed rule is not an invalid exercise of delegated legislative authority. § 120.56(2), Fla. Stat.

22. The Department, Kendall Regional, and Orange Park maintain that Health Trust does not have standing to challenge the proposed rules. Health Trust relies on its status as an applicant for certification as a trauma center for its standing. Health Trust must demonstrate that the proposed rules will substantially affect it in order to prove standing. § 120.56(1)(a); Agrico Chemical Co. v. Dep't of Env'tl. Reg., 406 So. 2d 478 (Fla. 2d DCA 1981).

23. "[T]he law of standing is often hard to define and subject to dispute." NAACP, Inc. v. Fla. Bd. of Regents, 822 So. 2d 1, 14 (Fla. 1st DCA 2002) (dissenting opinion, Judge Browning), reversed, 863 So. 2d 294 (Fla. 2003). But standing has its limits. Fla. Soc. of Ophthalmology v. State Bd. of Optometry, 532 So. 2d 1279, 1284 (Fla. 1st DCA 1988). A party's substantial interests are determined if: (1) the party will suffer injury in fact which is of sufficient immediacy to entitle it to a section 120.57 hearing, and (2) the party's substantial injury is of a

type or nature which the proceeding is designed to protect. Agrico, 406 So. 2d at 482. The first prong of this test deals with the degree of injury or "injury in fact." The second deals with the nature of the injury. The Department, Kendal Regional, and Orange Park argue that Health Trust does not have standing under this test because the injury asserted is not real and immediate. It is instead hypothetical, conjectural and speculative, and based on future events that may never happen.

24. Determination of Health Trust's standing requires analysis of a trauma agency's role in the regulation of trauma centers. Health Trust rests its claim for standing on specific statutory provisions on the subject.

25. Section 395.4025(1), Florida Statutes, is one. That statute charges the Department with responsibility for developing a system of trauma centers. It says that the Department "shall establish the approximate number of trauma centers needed" in each TSA "based on the state trauma system plan, the local or regional trauma services system plan, and recommendations of the local or regional trauma agency." The Department must develop this allocation by rule. The validity of the Department's rule for developing the allocation is no longer at issue in this proceeding. However, Health Trust has challenged the newly-proposed allocation rule in Public Health Trust of Miami-Dade

26. In order to be considered by the Department, a would-be trauma center "that operates within the geographic area of a local or regional trauma agency must certify that its intent to operate as a trauma center is consistent with the trauma services plan of the local or regional trauma agency." § 395.4025(2)(a), Fla. Stat.

27. The critical elements for a trauma center application include "review of whether the applicant has" the necessary equipment and physical facilities, sufficient qualified personnel, an effective quality assurance process, and written confirmation by the local or regional trauma agency that the applicant is consistent with the trauma agency's plan, "as approved by the department, if such agency exists." § 395.4025(1)(c), Fla. Stat.

28. Ultimately, during the Department's review of competing trauma center applications, the trauma agency's recommendation, in a Department-approved plan, may serve as a "tie-breaker."

Florida Administrative Code Rule 64J-2.016(11) currently says:

If the number of Provisional trauma centers found eligible for selection by the department in a given TSA exceeds the number permitted, as provided in subsection 64J-2.010(3),^[7/] F.A.C., the following criteria shall be applied independently and consecutively to all Provisional trauma centers in the TSA until application of the

criteria results in the number of trauma centers authorized in subsection 64J-2.010(3), F.A.C., for that TSA. When that occurs, the remaining criteria shall not be considered. The criteria to be applied are as follows:

(a) A hospital recommended to be a trauma center in the department-approved local or regional trauma agency plan pursuant to subparagraph 64J-2.007(2)(d)3., F.A.C., shall be given approval preference over any hospital which was not recommended.

29. The question is: Is the secondary role of trauma agencies in the Department's review of trauma center applications explicated above sufficient to create an injury in fact of sufficient immediacy to support standing for Health Trust to challenge the rules governing the establishment of the agencies? It is not.

30. In every instance, it is the Department, not the agency, that makes the decisions which may substantially affect a trauma center applicant like Health Trust. The trauma agencies are secondary and removed from any concrete decision. In addition, all along the process, the decisions that Health Trust claims may affect it, such as approval of trauma system plans or trauma agency recommendations, are decisions separately subject to challenge under section 120.569 as decisions affecting substantial interests. Finally the ineluctable fact is that the likelihood of a trauma agency being established in TSA 19 in the

foreseeable future is remote. Health Trust's theory for standing rests on speculation and conjecture.

31. The cases Health Trust relies upon do not involve facts where the effect is as remote as presented here. None involve challenges to a process for selecting a group permitted to make comments or recommendations to a decision maker. A discussion of representative cases follows.

32. Professional Firefighters of Florida v. Department of Health & Rehabilitative Services, 396 So. 2d 1194 (Fla. 1st DCA 1981), involved changes in rules for certification as a paramedic. The petitioning association represented firefighters who performed paramedic functions in their employment as firefighters. The rule changes required state certification as a paramedic and would have made it illegal for the firefighters to continue performing paramedic functions in their jobs. The First District Court of Appeal easily found that people who would be prohibited from continuing to perform their job duties by a rule change had standing to challenge the rule change.

33. Judge Booth's opinion noted the difference between the case and Department of Health & Rehabilitation Services v. Alice P., 367 So. 2d 1045, 1052 (Fla. 1st DCA 1979), and Florida Department of Offender Rehabilitation v. Jerry, 353 So. 2d 1230 (Fla. 1st DCA 1978), cert. denied, 359 So. 2d 1215 (Fla. 1978), in words appropriate here: "In both Jerry and Alice P., supra,

the challengers were not subject to the rule or immediately affected by it at the time suit was filed and were unlikely to be affected in the future.” Prof’l Firefighters of Fla. V. Dep’t of Health & Rehabilitative Servs., 396 So. 2d 1194, 1196 (Fla. 1st DCA 1981).

34. Health Trust’s reliance upon the opinion of Coalition of Mental Health Professions, 546 So. 2d 27 (Fla. 1st DCA 1989), is also misplaced. That opinion, like the opinions in Professional Firefighters and Reiff v. Northeast Florida State Hospital, 710 So. 2d 1030 (Fla. 1st DCA 1998), holds that parties whose behavior a rule directly regulates or whose rights a rule limits have standing to challenge the rule. The challenged rules in Coalition of Mental Health Professions “define[d] the practices of clinical social workers, marriage and family therapists and mental health counselors, respectively.” Coal. of Mental Health Professions, 546 So. 2d at 28 (Fla. 1st DCA 1989). That substantially affected members of those mental health professions.

35. The Department’s proposed rules do not directly regulate the behavior of Health Trust or limit its rights in the way that the behavior and rights of the petitioners were affected in Professional Firefighters and Reiff. The opinion in Professional Firefighters has been discussed.

36. Dr. Reiff was a licensed psychologist and Director of Psychological Services at Northeast Florida State Hospital. He challenged bylaws of the hospital's Professional Staff Organization because they had not been formally adopted. He also challenged the bylaws because they excluded psychologists from obtaining clinical privileges to perform services that they were authorized by the licensing laws to perform. The court reversed a final order holding Dr. Reiff did not have standing. Reiff v. Ne. Fla. State Hosp., 710 So. 2d 1030 (Fla. 1st DCA 1998). It held that the bylaws directly limited Dr. Reiff's rights. The proposed rules here do not directly, or even indirectly, limit Health Trust's rights.

37. Health Trust, citing Shands Jacksonville Medical Center, Inc. v. State, 123 So. 3d 86 (Fla. 1st DCA 2013), tries to piggyback on the unchallenged, but inapplicable, proposition that a determination of the number of trauma centers permitted in a TSA would affect would-be trauma centers in that TSA. That is not this case.

38. Parties do not have to prove immediate and actual harm to establish standing, NAACP, Inc. v. Fla. Bd. of Regents, 863 So. 2d 294, 300 (Fla. 2003). But they have to show something. This case involves rules that just do not have a real and sufficiently immediate effect upon Health Trust. The record demonstrates no effect that the proposed rules might have on

Health Trust. Its arguments about how it may be affected are speculation.

39. Health Trust's speculation is much like the speculation of the Jai-Alai Players Association in International Jai-Alai Players Association v. Florida Pari-Mutuel Community, 561 So. 2d 1224 (Fla. 3d DCA 1990). The Association tried to contest an application by jai-alai fronton owners to change opening and closing dates, operation dates and make-up performance dates. The Association claimed that the date changes would help fronton owners in a labor dispute with the players. The court held that the alleged injury was "far too remote and speculative in nature to qualify under the first prong of the Agrico standing test." Int'l Jai-Alai Players Ass'n v. Fla. Pari-Mutuel Com., 561 So. 2d at 1226. The same applies to Health Trust's amorphous claims.

40. Florida Society of Ophthalmology v. State Board of Optometry, 532 So. 2d 1279 (Fla. 1st DCA 1988), is another instructive case. The Florida Society of Ophthalmology tried to challenge Board of Optometry rules for certifying optometrists to administer and prescribe some topical drugs. The theory was that optometrists prescribing the drugs to patients would take business, and therefore revenue, from ophthalmologists who would otherwise have prescribed them. The court recognized that ophthalmologists might suffer some economic injury because of competition from optometrists performing services that

ophthalmologists "alone were previously permitted to perform."
Id. at 1285. But the potential injury did not satisfy the
"immediacy" requirement.

41. Health Trust's possible injury, whatever it may be, is not immediate enough. Notably Health Trust has not identified what injury might follow from the rules for creating trauma agencies. How would one process as opposed to another result in an agency more or less favorable to a Health Trust application? Who could say? Health Trust does not. It just speculates that there may be some injury.

42. Standing under Florida's Administrative Procedure Act is broad. It is not and should not be limitless, as the opinion in Florida Society of Ophthalmology, 532 So. 2d at 1284, observes:

We initially observe that not everyone having an interest in the outcome of a particular dispute over an agency's interpretation of the law submitted to its charge, or the agency's application of that law in determining the rights and interests of members of government or the public, is entitled to participate as a party in an administrative proceeding to resolve that dispute. Were that not so, each interested citizen could, merely by expressing an interest, participate in the agency's efforts to govern, a result that would unquestionably impede the ability of the agency to function efficiently and inevitably cause an increase in the number of litigated disputes well above the number that administrative and appellate judges are capable of handling.

43. Health Trust does not have standing to challenge the Department's proposed rules. There is no need to address the arguments about the validity of the rules.

ORDER

Based on the foregoing Findings of Fact and Conclusions of Law, it is ORDERED that the Petition for Determination of Invalidity of Proposed Rules is DISMISSED.

Jurisdiction to determine entitlement to attorney's fees and costs and, if any, their amounts is reserved.

DONE AND ORDERED this 8th day of April, 2016, in Tallahassee, Leon County, Florida.



JOHN D. C. NEWTON, II
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 8th day of April, 2016.

ENDNOTES

^{1/} All citations to Florida Statutes are to the 2015 compilation unless otherwise noted.

^{2/} The Order on Hunter Deposition Excerpts inadvertently and incorrectly referred to page 67, line 24, through page 28, line 1.

^{3/} Section 90.202, Florida Statutes, permits official recognition of the status of the proceeding.

^{4/} Bayfront Med. Ctr., Inc. v. Dep't of Health, Case No. 11-2602RX (Fla. DOAH Sept. 23, 2011), aff'd, Dep't of Health v. Bayfront Med. Ctr., Inc., 134 So. 3d 1017 (Fla. 1st DCA 2012).

^{5/} Shands Teaching Hosp. and Clinics, Inc. v. Dep't of Health, Case No. 14-1022RP (Fla. DOAH June 20, 2014).

^{6/} Section 90.202, Florida Statutes, permits official recognition of the status of the proceeding.

^{7/} Rule 64J-2.010 governs allocation of trauma centers among the TSAs.

COPIES FURNISHED:

Thomas Francis Panza, Esquire
Panza, Maurer & Maynard, P.A.
Bank of America Building, Third Floor
3600 North Federal Highway
Fort Lauderdale, Florida 33308
(eServed)

Nichole Chere Geary, General Counsel
Department of Health
Bin A-02
4052 Bald Cypress Way
Tallahassee, Florida 32399
(eServed)

Abigail Price-Williams, Esquire
Miami-Dade County Attorney's Office
West Wing, Suite 108
1611 Northwest 12th Avenue
Miami, Florida 33136

Daniel Ryan Russell, Esquire
Jones, Walker, Waechter, Poitevent,
Carrere and Denegre, LLP
Post Office Box 351
Tallahassee, Florida 32302-0351
(eServed)

Marc W. Dunbar, Esquire
Jones, Walker, Waechter, Poitevent,
Carrere and Denegre, LLP
Post Office Box 351
Tallahassee, Florida 32302
(eServed)

J. Stephen Menton, Esquire
Rutledge Ecenia, P.A.
Post Office Box 551 (32302)
119 South Monroe Street, Suite 202
Tallahassee, Florida 32301
(eServed)

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

Gabriel F.V. Warren, Esquire
Rutledge Ecenia, P.A.
Post Office Box 551
Tallahassee, Florida 32301
(eServed)

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

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

Ernest Reddick, Chief
Alexandra Nam
Department of State
R. A. Gray Building
500 South Bronough Street
Tallahassee, Florida 32399-0250
(eServed)

Ken Plante, Coordinator
Joint Administrative Procedures Committee
Room 680, Pepper Building
111 West Madison Street
Tallahassee, Florida 32399-1400
(eServed)

NOTICE OF RIGHT TO JUDICIAL REVIEW

A party who is adversely affected by this Final Order is entitled to judicial review pursuant to section 120.68, Florida Statutes. Review proceedings are governed by the Florida Rules of Appellate Procedure. Such proceedings are commenced by filing the original notice of administrative appeal with the agency clerk of the Division of Administrative Hearings within 30 days of rendition of the order to be reviewed, and a copy of the notice, accompanied by any filing fees prescribed by law, with the clerk of the District Court of Appeal in the appellate district where the agency maintains its headquarters or where a party resides or as otherwise provided by law.