STATE OF FLORIDA
DIVISION OF ADMINISTRATIVE HEARINGS

SHANDS TEACHING HOSPITAL AND CLINICS, INC., d/b/a UF HEALTH SHANDS HOSPITAL,

Petitioner,

vs. Case No. 14-1022RP

DEPARTMENT OF HEALTH,

Respondent,

and

OSCEOLA REGIONAL HOSPITAL, INC., d/b/a OSCEOLA REGIONAL MEDICAL CENTER,

Intervenor.
_____/

THE PUBLIC HEALTH TRUST OF MIAMI-DADE COUNTY,

Petitioner,

vs. Case No. 14-1027RP

DEPARTMENT OF HEALTH,

Respondent,

and

OSCEOLA REGIONAL HOSPITAL, INC., d/b/a OSCEOLA REGIONAL MEDICAL CENTER,

Intervenor.
_____/

ST. JOSEPH'S HOSPITAL, INC.,
d/b/a ST. JOSEPH'S HOSPITAL,

Petitioner,

vs. Case No. 14-1028RP

DEPARTMENT OF HEALTH,

Respondent,

and

OSCEOLA REGIONAL HOSPITAL, INC.,
d/b/a OSCEOLA REGIONAL MEDICAL
CENTER,

Intervenor.
_____/
FLORIDA HEALTH SCIENCES CENTER,
INC., d/b/a TAMPA GENERAL
HOSPITAL,

Petitioner,

vs. Case No. 14-1034RP

DEPARTMENT OF HEALTH,

Respondent,

and

OSCEOLA REGIONAL HOSPITAL, INC.,
d/b/a OSCEOLA REGIONAL MEDICAL
CENTER,

Intervenor.
_____/

BAYFRONT HMA MEDICAL CENTER, LLC, d/b/a BAYFRONT MEDICAL CENTER,

Petitioner,

vs. Case No. 14-1035RP

DEPARTMENT OF HEALTH,

Respondent,

and

OSCEOLA REGIONAL HOSPITAL, INC., d/b/a OSCEOLA REGIONAL MEDICAL CENTER,

Intervenor.
_____/

FINAL ORDER

Pursuant to notice, a formal hearing was held in this case before R. Bruce McKibben, Administrative Law Judge of the Division of Administrative Hearings, on April 28-30 and May 2, 5-7 and 22, 2014, in Tallahassee, Florida.

APPEARANCES

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STATEMENT OF THE ISSUE

Whether the Proposed Rule 64J-2.010 enlarges, modifies or contravenes the specific provisions of law implemented, or is arbitrary or capricious, and thus constitutes an invalid exercise of delegated legislative authority.

PRELIMINARY STATEMENT

On March 6, 2014, Shands Teaching Hospitals and Clinics, Inc., d/b/a UF Health Shands Hospital ("Shands") filed its Petition to Determine Invalidity of Proposed Rule 64J-2.010 originated by the Florida Department of Health (the "Department" or "DOH"). The Shands petition was assigned DOAH Case No. 14-1022RP.

On March 7, 2014, The Public Health Trust of Miami-Dade County (which governs the Jackson Health System and will be referred to herein as "Jackson Memorial"), filed its Petition for Determination of Invalidity of Proposed Rule. The Jackson Memorial petition was assigned DOAH Case No. 14-1027RP.

St. Joseph's Hospital, Inc., d/b/a St. Joseph's Hospital ("St. Joseph") filed its Petition to Determine Invalidity of Proposed Rule on March 7, 2014. St. Joseph's petition was assigned DOAH Case No. 14-1028RP.

Also filed on March 7, 2014, was the Petition for Determination of Invalidity of DOH's Proposed Trauma Center Need Rule. That petition, filed by Florida Health Sciences Center,

Inc., d/b/a Tampa General Hospital ("Tampa General") was assigned DOAH Case No. 14-1034RP.

The Petition for Determination of Invalidity of DOH's Proposed Trauma Center Need Rule filed by Bayfront HMA Medical Center, LLC, d/b/a Bayfront Medical Center ("Bayfront") was filed on March 7, 2014, and assigned DOAH Case No. 14-1035RP.

A Petition to Intervene was filed by Osceola Regional Hospital, Inc., d/b/a Osceola Regional Medical Center ("Osceola") on March 11, 2014, in each of the aforementioned cases. Intervention was granted by Order of the undersigned dated March 12, 2014. That Order also consolidated all of the cases noted above.

This matter was set for hearing on March 31 – April 4, 10, and 11, 2014 by agreement of all parties. On March 21, 2014, a motion hearing was held during which the parties asked to amend the proposed final hearing dates. Upon agreement of the parties, the final hearing was rescheduled for April 10-11, 14, 17, 21-22, and 25. An amended Notice of Hearing was issued that day. A status conference was held via telephone on March 31, 2014. At that time, the parties agreed to amend the final hearing schedule once again. On April 1, 2014, an Amended Notice of Hearing was entered setting the final hearing for April 28-30 and May 2, 5, and 6.

The final hearing was ultimately held on April 28-30 and May 2, 5-7, and 22, 2014, in Tallahassee, Florida.

At final hearing, Shands called five witnesses: Steve McCoy, Program Administrator for the Department's Health Analysis Bureau; Jennifer Tschetter, Esquire, general counsel for the Department; Dr. David Ciesla, accepted as an expert in trauma systems design and performance; Dr. Fred Moore, accepted as an expert in acute care surgery and trauma systems development; and Dr. Joseph Tepas, accepted as an expert in pediatric surgery, pediatric trauma surgery, and trauma systems planning. Shands' Exhibits 13, 22-25, 27, 31-35, 52-53, and 64-65 were admitted into evidence.

Jackson Memorial called one witness: Dr. Nicholas Namias, accepted as an expert in trauma surgery and trauma systems. Jackson Memorial's Exhibits 30-32, 34-35, and 46 were admitted into evidence.

St. Joseph called no witnesses. St. Joseph's Exhibits 1 and 2 were admitted into evidence.

Tampa General and Bayfront, collectively, called one witness: Mark Richardson, accepted as an expert in health care planning. Tampa General and Bayfront's Joint Exhibits 2-5, 8-10, 12, 23, 35-38, 42-44, 46-47, 57-58, as well as pages 175-200 and Exhibits 8-10 and 12-15 of Exhibit 59, were admitted into evidence.

The Department called two witnesses: Steve McCoy and Jennifer Tschetter. DOH's Exhibits 1-10, 12-28, 30-31, and 34 were admitted into evidence.

Osceola called six witnesses: Gene Nelson, expert in health planning, health policy, and trauma center feasibility analysis; Dr. James Hurst, expert in trauma surgery, trauma systems development, trauma surgery training and education, and surgical critical care; Michael Heil, expert in trauma system planning and development, trauma center planning and operation, hospital administration, and pre-hospital transport; Dr. Eriq Barquist, expert in trauma surgery and trauma planning; Anna Burrus; and Dr. Darwin Ang, expert in epidemiology, trauma surgery and trauma planning. Osceola's Exhibits 1-2, 15, 22-32, 38-40, 131, 146, 148, 152, 158, 184, 186-189, 258, 263, 265, 293, 295, 345, and 346 were admitted into evidence.

A transcript of the proceeding was ordered by the parties. Proposed final orders were to be filed no later than ten days after the filing of the hearing transcript at DOAH. The transcript was filed on May 30, 2014. Each party timely filed a Proposed Final Order, all of which have been carefully considered in the preparation of this Final Order.

All citations are to Florida Statutes (2013), unless otherwise indicated.

FINDINGS OF FACT

The Parties

1. Shands operates an 852-bed hospital and Level I trauma center in Gainesville, Alachua County, Florida. Its business address is 1600 Southwest Archer Road, Gainesville, Florida. Shands treats about 2,500 trauma patients each year. Shands is located within trauma service area (TSA) 4, which is comprised of Alachua, Bradford, Columbia, Dixie, Gilchrist, Hamilton, Lafayette, Levy, Putnam, Suwannee, and Union counties.

2. St. Joseph's is a regional tertiary hospital and has served the Tampa area for 75 years and has approximately 800 licensed acute care beds. St. Joseph offers a broad array of acute care services including tertiary health care, serves as a comprehensive regional stroke center, and has been repeatedly recognized as a Consumers Choice hospital. St. Joseph operates a Level II trauma center and a Level I pediatric trauma center. St. Joseph is located in TSA 10, consisting of a single county, Hillsborough.

3. Tampa General is a major tertiary hospital that is designated by the state as a Level I trauma center. Tampa General also serves as a teaching hospital for the University of South Florida, College of Medicine ("USF"). Tampa General is located in Tampa, Hillsborough County, Florida, TSA 10.

4. Bayfront is a 480-bed tertiary hospital located in Pinellas County, Florida. In addition to serving as a teaching hospital, Bayfront is designated as a Level II trauma center pursuant to chapter 395, Part II, Florida Statutes. It is located in TSA 9, composed of Pinellas and Pasco counties.

5. The Public Health Trust of Miami-Dade County, is an entity which governs and operates the Jackson Health System, including the Ryder Trauma Center at Jackson Memorial Hospital. It is in TSA 19, consisting of Dade and Monroe counties.

6. The Florida Department of Health is the state agency authorized to verify and regulate trauma centers in the state of Florida pursuant to chapter 395, Part II, Florida Statutes, and Florida Administrative Code Rule 64J-2.001 et seq. The Division of Emergency Medical Operations, Office of Trauma, oversees the Department's responsibilities with respect to the statewide trauma system.

7. Osceola is a licensed acute care general hospital, located at 700 West Oak Street, Kissimmee, Florida. Osceola provides a wide array of high quality health services to the residents and visitors within its service area. It is located in TSA 8, consisting of Lake, Orange, Osceola, Seminole, and Sumter counties.

The Florida Trauma System

8. For purposes of organizing a statewide network of trauma services, the Florida Legislature directed the Department to undertake the implementation of a statewide inclusive trauma system as funding is available. § 395.40(3), Fla. Stat.

9. The need for a trauma system is premised on the basic principle that a trauma victim who is timely transported and triaged to receive specialized trauma care will have a better clinical outcome. § 395.40(2), Fla. Stat. A trauma victim's injuries are evaluated and assigned an Injury Severity Score ("ISS"). § 395.4001(5), Fla. Stat. Patients with ISS scores of nine or greater are considered trauma patients. § 395.402(1), Fla. Stat.

10. Trauma experts speak in terms of "a Golden Hour," a clinical rule of thumb that postulates no more than 60 minutes should elapse from the occurrence of an injury to the beginning of definitive treatment. There is, however, no current consensus on what constitutes the "Golden Hour" for transport times. A 1990 Department study recommended travel time of 25-35 minutes as the outside range for optimal outcomes. A 1999 Department study favored a goal of 30 minutes transport time by ground, and a 50-mile radius by helicopter. By contrast, a 2005 study conducted for the Department used 85 minutes "total evacuation time" as "acceptable."

11. A trauma center is a hospital that has a collection of resources and personnel who are charged with taking care of trauma patients. They are recognized by the community as a resource for care of severely injured patients. The International Classification Injury Severity Score ("ICISS") methodology, considered with discharged patient data from the Agency for Health Care Administration database, was used by DOH to determine severely injured patients. An ICISS score is the product of the survival risk ratios (i.e., the probabilities of survival) calculated for each traumatic injury a single patient suffers.

12. Level I trauma centers are generally larger and busier and treat more patients than Level II centers. Level I trauma centers are required to engage in education and research.

13. Trauma centers are required to have several types of physician specialists at the ready at all times. For instance, with respect to surgical services, a Level I trauma center must have a minimum of five qualified trauma surgeons, assigned to the trauma service, with at least two trauma surgeons available to provide primary (in-hospital) and backup trauma coverage 24 hours a day at the trauma center when summoned.

14. Further, in addition to having at least one neurosurgeon to provide in-hospital trauma coverage 24 hours a day at the trauma center, a Level I provider must also have

surgeons available to arrive promptly at the trauma center in 11 other specialties, including (but not limited to) hand surgery, oral/maxillofacial surgery, cardiac surgery, orthopedic surgery, otorhinolaryngologic surgery and plastic surgery. Level II trauma centers must comply with similar physician specialist standards. Little if any credible evidence was presented in the present case to suggest that the ability to hire qualified clinical staff, technicians, specialty physicians and other personnel would be severely impacted if the Proposed Rule is implemented. Rather, the existing trauma centers lamented the possibility of reduced case loads which could make it more difficult to retain proficiency.

Invalidation of Former Rule 64J-2.010

15. In 1992, the Department of Health and Rehabilitative Services (HRS), the Department of Health's predecessor, promulgated Florida Administrative Code Rule 64J-2.010, titled "Apportionment of Trauma Centers within a Trauma Service Area," (hereinafter referred to as the "Former Rule"). The Department of Health assumed administration of the Former Rule in 1996, when the Legislature split HRS into two new agencies, the Department of Health and the Department of Children and Families.

16. The Former Rule regulated the number of trauma centers that could be established in Florida. The Former Rule divided

the state into TSAs as set forth in section 395.402(4), and for each TSA, announced the number of trauma center "positions" available.

17. In 2004, the Florida Legislature amended section 395.402 to require the Department to complete an assessment of Florida's trauma system, and to provide a report to the Governor and Legislature no later than February 1, 2005 (the 2005 Assessment). The scope of the assessment was defined in paragraphs (2)(a) through (g) and subsection (3) of section 395.402.

18. One objective of the assessment was to consider aligning trauma service areas within the trauma region boundaries as established in section 395.4015(1). It required the Department to establish trauma regions that cover all geographic areas of the state and have boundaries that are coterminous with the boundaries of the Regional Domestic Security Task Forces ("RDSTF") established under section 943.0312.

19. In a related 2004 amendment, the Legislature added a provision that gave the Department the option to use something other than the trauma service areas codified in section 395.402(4) upon completion of the 2005 Assessment. See § 395.402(2), Fla. Stat. ("Trauma service areas as defined in this section are to be utilized until the Department of Health

completes" the 2005 Assessment.) § 395.402(4), Fla. Stat. ("Until the department completes the February 2005 assessment, the assignment of counties shall remain as established in this section.").

20. As part of the 2004 amendments to the trauma statute, the Legislature also required the Department to conduct "subsequent annual reviews" of Florida's trauma system. In conducting such annual assessments, the Legislature required the Department to consider a non-exhaustive list of criteria set forth in section 395.402(3)(a)-(k). Further, the Legislature required the Department to annually thereafter review the assignment of Florida's 67 counties to trauma service areas.

21. The Department timely submitted its 2005 Assessment to the Legislature on February 1, 2005.

22. With respect to its review of the trauma service areas, the 2005 Assessment recommended against the continued use of the 19 trauma service areas. The 2005 Assessment instead suggested that it may be feasible for the existing trauma service areas to be modified to fit the seven RDSTF regions to facilitate regional planning.

23. Following receipt of the 2005 Assessment, the Department took no action to amend the Former Rule and adopt the recommendations of the 2005 Assessment. As a result, in June 2011, several existing trauma centers challenged the

validity of the Former Rule pursuant to sections 120.56(1) and (3). See Bayfront Med. Ctr., Inc. et al. v. Dep't of Health, DOAH Case Nos. 11-2602RX, 11-2603RX, 11-2746RX, 11-2796RX (Fla. Div. Admin. Hear., Sept. 23, 2011).

24. On September 23, 2011, an administrative law judge of the Division of Administrative Hearings entered a final order holding that the Former Rule was an invalid exercise of delegated legislative authority. The administrative law judge concluded that the Former Rule was invalid because it contravened the laws it purportedly implemented, including section 395.402. The judge found:

> The authority granted by section 395.402 for the use of the [nineteen] identified TSAs existed only until February 2005. After that time, the Department was required to consider the findings of the 2005 Assessment, as well as the recommendations made as part of the regional trauma system plan. Thus, section 395.402 can no longer service as a valid basis for the Rule.

25. However, as set forth below, the authority to utilize the 19 TSAs was not rescinded; rather, the mandated requirement to use only the TSAs was rescinded.

26. The Department was required to review the assignment of Florida's 67 counties to trauma service areas, taking into consideration the factors set forth in paragraphs (2)(b)-(g) and subsection (3) of section 395.402. Having done so, it was incumbent on the Department to amend its [Former] Rule to

allocate the number of trauma centers determined to be needed within each designated area through systematic evaluation and application of statutory criteria.

27. On November 30, 2012, the First District Court of Appeal affirmed the administrative law judge's determination that the Former Rule was an invalid exercise of delegated legislative authority. See Dep't of Health v. Bayfront Med. Ctr., Inc., 134 So. 3d 1017 (Fla. 1st DCA 2012).

28. After noting that the Former Rule claimed to implement sections 395.401, 395.4015, and 395.402, the appellate court held that the Former Rule was invalid because it failed to reflect the substantial amendments to those laws that were enacted in 2004. The appellate court held:

> Both the pre-and post-2004 versions of the statute require the Department to establish trauma regions that "cover all geographic areas of the state." However, the 2004 amendment requires that the trauma regions both "cover all geographical areas of the state and have boundaries that are coterminous with the boundaries of the regional domestic security task forces established under s. 943.0312." § 395.4015(1), Fla. Stat. (2004).
>
> Similarly, the rule fails to implement the 2004 amendments to section 395.402. The version of the statute in effect at the time the rule was promulgated set forth the nineteen trauma service areas reflected in the rule. [T]he 2004 version of the statute required the Department to complete an assessment of Florida's trauma system no later than February 1, 2005. It further

> provides that the original nineteen trauma service areas shall remain in effect until the completion of the 2005 Assessment.

Bayfront, 134 So. 3d at 1019–20 (Emphasis added).

29. It should be noted that the 2004 version of the statute does not specify at what point in time the 19 TSAs could no longer be utilized, only that they would have to be used at least until completion of the 2005 Assessment.

Rule Development

30. The Department thereafter initiated rule development workshops to commence construction of a new rule. The first workshop concerning this rule was in Tallahassee, Florida, on December 21, 2012. In January and February 2013, workshops were then held in Pensacola, Tampa, Ocala, Jacksonville, and Miami, as DOH continued working on a new rule. Each of the sessions involved input from interested persons both live and by telephone. Written comments and oral presentations by these persons were considered by the Department. After these first six workshops, held in various regions of the State to make them more accessible to more citizens, DOH then scheduled three more workshops in March 2013, to be held in areas where there were no existing trauma centers, specifically Ft. Walton Beach, Naples, and Sebring.

31. DOH also considered the recommendations of a report issued by the American College of Surgeons ("ACS"), the lead

professional group for trauma systems and trauma care in the United States. The ACS sent a consultation team to Tallahassee, Florida, to conduct a three-day site visit and hold public workshops in February 2013. The ACS ultimately issued a report entitled "Trauma System Consultation Report: State of Florida," in May 2013. The report included as one of its recommendations the use of RDSTF regions as the TSA areas to be used in determining need for additional trauma centers.

32. In November 2013, DOH released a draft proposed rule and a draft of its first TSA Assessment (the January TSA Assessment). The Department then conducted three additional workshops in Pensacola, Orlando, and Miami. Again, DOH solicited comments from interested persons and entered into a dialogue as to what the proposed rule should look like upon publication.

33. On January 23, 2014, DOH conducted a Negotiated Rulemaking Committee meeting at the Department's headquarters in Tallahassee, Florida. The committee consisted of seven persons: Karen Putnal, Esquire and Dr. Fred Moore--representing existing trauma centers; Steve Ecenia, Esquire and Dr. Darwin Ang--representing new trauma centers currently under challenge; Dr. Patricia Byers--representative of the EMS Advisory Council; Jennifer Tschetter, Esquire and Dr. Ernest Block--representing

DOH. The public was invited to attend the session but was not afforded an opportunity to speak.

34. The Department considered all the input from each of the workshops, the ACS Report, and the negotiated session, as well as all the applicable items enumerated in section 395.402(3)(a)-(k).

The Proposed Rule

35. On February 3, 2014, the Department published Notice of Development of Proposed Rule 64J-2.010 (the "Proposed Rule") in Florida Administrative Register, Volume 40, Number 22.

36. The Department's Notice cited section 395.405, as rulemaking authority for the Proposed Rule. The Notice also cited sections 395.401, 395.4015, 395.402, and 395.405 as the laws intended to be implemented by the Proposed Rule.

37. The following day, February 4, 2014, the Department published a Notice of Correction in Florida Administrative Register, Volume 40, No. 23, to correct the history notes of the Proposed Rule. In the corrected Notice, the Department cited section 395.402 as its rulemaking authority in addition to section 395.405. The correction also removed reference to sections 395.401, 395.4015, and 395.405, as laws implemented by the Proposed Rule. Following the Department's correction, the Proposed Rule was intended only to implement section 395.402.

38. The Proposed Rule established 19 TSAs and determined the number of trauma centers to be allocated within each TSA, based upon a scoring system established in the Proposed Rule.

39. Under the scoring system, TSAs were awarded positive or negative points based on data in an annual Trauma Service Area Assessment relating to the following six criteria: (1) population; (2) median transport times; (3) community support; (4) severely injured patients not treated in trauma centers; (5) Level 1 trauma centers; and (6) number of severely injured patients (in each TSA).

40. Ms. Tschetter added the last two criteria (Level I Trauma Centers and Number of Severely Injured Patients) in response to comments received at the negotiated rulemaking session.

41. Subsequent to a final public hearing held on February 25, 2014, DOH revised its January TSA Assessment and the earlier version of the Proposed Rule. The revised TSA assessment (the "March TSA Assessment") reflected more conservative calculations (as gleaned from input and discussions with stakeholders) and documents the statutory patient volumes for the existing Level I and Level II trauma centers in each TSA. The March TSA Assessment further recalculated the Median Transport times, including all transports from 0-10 minutes (as opposed to only those transports greater than 10 minutes) and

only transports to trauma centers (as opposed to transports to all hospitals).

42. On March 25, 2014, a Notice of Change was published in the Florida Administrative Register. The Proposed Rule, as published on that date, is as follows:

Notice of Change/Withdrawal

DEPARTMENT OF HEALTH

Division of Emergency Medical Operations

RULE NO.: RULE TITLE:

64J-2.010 Apportionment of Trauma Centers within a Trauma Service Area (TSA)

NOTICE OF CHANGE

Notice is hereby given that the following changes have been made to the proposed rule in accordance with subparagraph 120.54(3)(d)1., F.S., published in Vol. 40, No. 22, February 3, 2014 issue of the Florida Administrative Register.

64J-2.010 Allocation of Trauma Centers A~~a~~mong the Trauma Service Areas (TSAs).

(1) Level I and Level II trauma centers shall be allocated among the trauma service areas (TSAs) based upon the following:

(a) The following criteria shall be used to determine a total score for each TSA. Points shall be determined based upon data in the Trauma Service Area Assessment.

1. Population

a. A total population of less than ~~0 to~~ 600,000 receives 2 points.

b. A total population of 600,001 to 1,200,000 receives 4 points.

c. A total population of 1,200,001 to 1,800,000 ~~1,700,000~~ receives 6 points.

d. A total population of 1,800,000 ~~1,700,001~~ to 2,400,000 ~~2,300,000~~ receives 8 points.

e. A total population greater than 2,400,000 ~~2,300,000~~ receives 10 points.

2. Median Transport Times

a. Median transport time of less than ~~0 to~~ 10 minutes receives 0 points.

b. Median transport time of 10~~1~~ to 20 minutes receives 1 point.

c. Median transport time of 21 to 30 minutes receives 2 points.

d. Median transport time of 31 to 40 minutes receives 3 points.

e. Median transport time of greater than 41 minutes receives 4 points.

3. Community Support

a. Letters of support for an additional trauma center from 25~~0~~ to 50 percent of the city and county commissions located within the TSA receive 1 point. Letters of support must be received by the Department on or before April 1 annually.

b. Letters of support for an additional trauma center from more than 50 percent of the city or county commissions located within the TSA receive 2 points. Letters of support must be received by the Department on or before April 1 annually.

4. Severely I~~i~~njured Patients Discharged from Acute Care Hospitals ~~Not Treated In Trauma Centers~~

a. Discharge of 0 to 200 patients with an International Classification Injury Severity Score ("ICISS") score of less than 0.85 ("severely injured patients") from hospitals other than trauma centers receives 0 points.

b. Discharge of 201 to 400 severely injured patients from hospitals other than trauma centers receives 1 point.

c. Discharge of 401 to 600 severely injured patients from hospitals other than trauma centers receives 2 points.

d. Discharge of 601 to 800 severely injured patients from hospitals other than trauma centers receives 3 points.

e. Discharge of more than 800 severely injured patients from hospitals other than trauma centers receives 4 points.

5. Level I Trauma Centers

a. The existence of a verified Level I trauma center receives one negative point.

b. The existence of two verified Level I trauma centers receives two negative points.

c. The existence of three verified Level I trauma centers receives three negative points.

6. Number of Severely Injured Patients

a. If the annual number of severely injured patients exceeds the statutory trauma center patient volumes identified in Section 395.402(1), F.S., by more than 500 patients, the TSA receives 2 points.

b. If the annual number of severely injured patients exceeds the statutory trauma center patient volumes identified in Section 395.402(1), F.S., by 0 to 500 patients, the TSA receives 1 point.

c. If the annual number of severely injured patients is less than the statutory trauma center patient volumes identified in Section 395.402(1), F.S., by 0 to 500 patients, the TSA receives one negative point.

d. If the annual number of severely injured patients is less than the statutory trauma center patient volumes identified in Section 395.402(1), F.S., by more than 500 patients, the TSA receives two negative points.

(b) The following scoring system shall be used to allocate trauma centers within the TSAs:

1. TSAs with a score of 5 points or less shall be allocated 1 trauma center.

2. TSAs with a score of 6 to 10 points shall be allocated 2 trauma centers.

3. TSAs with a score of 11 to 15 points shall be allocated 3 trauma centers.

4. TSAs with a score of more than 15 points shall be allocated 4 trauma centers.

(2) An assessment and scoring shall be conducted by the Department annually on or before August 30th, beginning August 30, 2015.

(3) The number of trauma centers allocated for each TSA based upon the Amended Trauma Service Area Assessment, dated March 24, 2014 ~~January 31, 2014~~, which can be found at www.FLHealth.gov/licensing-and-regulation/trauma-system/ documents/trauma-area-service-assessment.pdf, is as follows:

TSA	Counties	Trauma Centers
1	Escambia, Okaloosa, Santa Rosa, Walton	1
2	Bay, Gulf, Holmes, Washington	1
3	Calhoun, Franklin, Gadsden, Jackson, Jefferson, Leon, Liberty, Madison, Taylor, Wakulla	1
4	Alachua, Bradford, Columbia, Dixie, Gilchrist, Hamilton, Lafayette, Levy, Putnam, Suwannee, Union	1
5	Baker, Clay, Duval, Nassau, St. Johns	1~~2~~
6	Citrus, Hernando, Marion	2
7	Flagler, Volusia	1
8	Lake, Orange, Osceola, Seminole, Sumter	3
9	Pasco, Pinellas	2~~3~~
10	Hillsborough	1
11	Hardee, Highlands, Polk	1
12	Brevard, Indian River	1
13	DeSoto, Manatee, Sarasota	2
14	Martin, Okeechobee, St. Lucie	1
15	Charlotte, Glades, Hendry, Lee	1~~2~~
16	Palm Beach	1
17	Collier	1
18	Broward	2
19	Dade, Monroe	3

Rulemaking Authority 395.402, 395.405 FS. Law Implemented 395.402 FS. History-New 12-10-92, Formerly 10D-66.1075, Amended 6-9-05, 12-18-06,Formerly 64E-2.022, Amended_____.

43. DOH did not incorporate the March TSA Assessment by reference in the rule. After exchanges of communications with

the Joint Administrative Procedures Committee ("JAPC"), wherein DOH sought guidance concerning this matter, there was no directive by JAPC that such adoption by reference would be required.

44. DOH revised the population criterion in the Proposed Rule to have even breaks in intervals of 600,000 people. The February proposed rule awarded 6 points in TSAs with a population of 1,200,001 to 1,700,000 people (i.e., a 500,000 person interval), where all other measures were based upon a 600,000 person interval. This discrepancy is corrected in the newly Proposed Rule.

45. DOH revised the community support criterion in the Proposed Rule to no longer award a point to TSAs where 0-50% of the city and county commissions send letters of support, because this could have reflected the need for a trauma center (by awarding points to the TSA) when no letters of support were received. The Proposed Rule now awards a point to TSAs where 25-50% of the county commissions send letters of support. DOH chose twenty-five percent as the minimum necessary community support because the smallest number of city and county commissions in all of the TSAs is four, which ensures everyone has a voice.

46. DOH revised the title of the fourth criterion from "severely injured patients not treated in trauma centers" to

"severely injured patients discharged from acute care hospitals," which more accurately depicts the function of the criterion.

47. DOH revised the sixth criterion to include citations to the statutory minimum volumes for Level I and Level II trauma centers in response to a request by the staff attorney for the Joint Administrative Procedures Committee.

48. DOH also revised the rule to reference the March TSA Assessment in place of the January TSA Assessment.

49. Finally, DOH revised the Proposed Rule's allocation table based on the revisions to the rule and assessment. The Proposed Rule as amended allocates a total of 27 trauma centers throughout Florida's 19 TSAs. Each TSA is still allocated at least one trauma center.

50. The Proposed Rule allocates only Level I and Level II trauma centers, not pediatric trauma centers. The rulemaking directive in section 395.402(4) is interpreted by DOH to be limited to the allocation of Level I and Level II trauma centers. In addition, the allocation of stand-alone pediatric centers would not be feasible because pediatric trauma patients make up such a small percentage of the population and all of the Level I and II trauma centers have the ability to become pediatric trauma centers. Currently, all of the existing Level

I trauma centers provide pediatric care and there are only two stand-alone pediatric centers in Florida.

51. The Proposed Rule's allocation of 27 trauma centers is conservative. There are currently 27 verified trauma centers in the state, including two verified trauma centers under administrative challenge.

52. There are several elements of the Proposed Rule which Petitioners have raised as evidence of the Department's failure to comply with its rulemaking authority. Petitioners maintain that DOH failed to consider all of the items enumerated in section 395.402(3)(a)-(k). Each of those criteria is addressed below.

53. (a) T*he recommendations made as part of the regional trauma system plans submitted by regional trauma agencies*-- There is only one regional trauma agency in Florida. DOH reviewed the regional agency's plan, but it was devoid of any recommendations related to trauma center allocation within the TSAs. The regional agency did not amend its plan or submit any separate recommendations throughout the year-long, public rulemaking process.

54. (b) S*takeholder recommendations*--Petitioners complain that DOH did not do enough to solicit input from everyone who would be affected by the Proposed Rule. The Department, however, obtained stakeholder testimony from 171 individuals and

written comments from 166 stakeholders through the course of the 12 rule development workshops conducted around the state. The workshops were held in several cities to allow for geographic access by more residents. Over 400 people attended the workshops. The January TSA Assessment was also modified prior to its publication as a result of the stakeholder discussions at the workshops and the negotiated rulemaking session. The March TSA Assessment was further amended after its publication as a result of testimony at the public hearing for the Proposed Rule.

55. (c) T*he geographical composition of an area to ensure rapid access to trauma care by patients*--While Florida contains no mountains, its geography is unique to other states in that it contains several inlets, bays, jetties, and swamplands. As such, the DOH data unit examined the coastal areas versus non-coastal areas. The unit also analyzed urban versus rural areas. The unit also looked at the communities surrounding Lake Okeechobee. Ultimately, the analysis was not meaningful because the effect geography has on access to trauma centers is captured by Florida's transport time records for emergency vehicles and helicopters. Thus, by reviewing the Emergency Medical Services Tracking and Reporting System ("EMSTARS") database, DOH could know the actual effects of Florida's geography on access to trauma centers.

56. (d) H*istorical patterns of patient referral and transfer*--This item was considered, but the January TSA Assessment does not address it because it was neither measurable nor meaningful. The data was not measurable because of limitations of data quality in the Trauma Registry. Even if the data were measureable it would not have been meaningful because it would have only illustrated the catchment areas--i.e., the geographic distribution of patients served by existing trauma centers. As recommended by the ACS, DOH's primary focus is on the trauma system as a whole, not individual trauma centers. Moreover, transfer and referral history is not meaningful to an assessment designed to inform an allocation rule because, again, DOH does not have the authority to define where new trauma centers are developed within a TSA. See § 402.395(4)(b), Fla. Stat. (charging DOH with allocating by rule the number of trauma centers in each TSA, not trauma center location within a trauma service area).

57. (e) I*nventories of available trauma care resources, including professional medical staff*--Petitioners suggest that DOH should have made a determination of existing professional medical staff, but suggest no viable means of doing so. The January TSA Assessment catalogues several trauma care resources within TSAs, including financing, trauma centers, acute care hospitals, and EMS response capabilities. The January TSA

Assessment does not catalogue available professional medical staff. DOH is unaware of any database that compiles this information. DOH sent a survey to the existing trauma centers requesting information as to their resources and professional staff, however it was not useful due to the limited responses and potential for bias. The data unit also reviewed the DOH Division of Medical Quality Assurance health professional licensure database (COMPASS), however, it was not helpful because physician specialty reporting is voluntary. Similarly, the data unit reviewed AHCA's inventory of licensed acute care hospitals and the DOH annual physician workforce survey results, but neither data source provided trauma-specific information. As such, the information was not complete and so was not included in the January TSA Assessment.

58. (f) P*opulation growth characteristics*--In response to this criterion, the DOH data unit analyzed the potential for growth in all of the TSAs, but the January TSA Assessment did not include this analysis because it was not meaningful given DOH's requirement to conduct the assessment annually. The January TSA Assessment does however document the population in each TSA. DOH decided that in light of the continuing change of population in Florida, the best it could do would be to make a finding as to the population in each TSA and use it--year by year--to look at the potential need for additional (or

presumably fewer) trauma centers in an area. Obviously the population of an area is not directly commensurate with the number of severely injured patients that might be found. Not all areas have equal percentages of severely injured patients; urban areas would have higher percentages than rural areas, in general. Areas through which a major interstate highway runs would expect a higher percentage. There are a number of factors that could potentially affect an area's expectation of trauma services. Inasmuch as they could not all possibly be included in an analysis, DOH defaulted to a more general view, i.e., the total population. The total population figure became the first measurement in the Proposed Rule.

59. (g) T*ransportation capabilities;* and (h) M*edically appropriate ground and air travel times*--DOH considered these two factors together and determined to cover them by way of a determination of median transport time, which was to become the second measurement in the Proposed Rule. The data unit gathered transport capability data by reviewing the COMPASS licensure database and archived paper applications to discern the number of licensed emergency medical stations, helicopters, and vehicles in each TSA. The data unit further calculated the number of ground vehicles per the population in each TSA and every 100 square miles. The January TSA Assessment included this information because it was meaningful and gathered from a

reliable database. DOH considered the testimony from a number of trauma surgeons during the 12 workshops regarding transport times and learned that the medically appropriate transport time depends on the nature of injuries and individual patients, which are not always discernable at the scene of an accident. Because of this, the sooner a patient can be transported to a trauma center, the better it is for patient outcomes. In light of the patient-specific realities of establishing a medically appropriate transport time, the data team used EMSTARS to calculate the median emergency transport times in each TSA for the assessment. Granted the EMSTARS is a fairly new system under development, and it reports all 911 calls voluntarily reported (not just trauma patients), so it is not a completely accurate measure. But it is a reasonable approach based upon what is available. Also, the transport times do not reflect whether pre-hospital resources are sufficient for the patient or how far away the closest trauma center may be. It is not an absolutely perfect measurement, but it is reasonable and based on logic.

60. (i) R*ecommendations of the Regional Domestic Security Task Force*--Like Florida's lone regional trauma agency, the RDSTF did not offer any input throughout the year-long, public rulemaking process. However, DOH considered the testimony of numerous emergency management and law enforcement officials

during the rule development process. For example, Chief Loren Mock, the Clay County fire chief and also a member of the Domestic Security Oversight Council, testified at the Jacksonville workshop. There is no evidence DOH directly contacted a RDSTF representative to solicit input.

61. (j) T*he actual number of trauma victims currently being served by each trauma center*--The March TSA Assessment included the annual trauma patient volume reported to the Trauma Registry by the existing trauma centers. When comparing the average patient volume reported to trauma registry from 2010-2012 to the data unit's calculation of the average number of severely injured patients treated in trauma centers during this same time span, the volumes reported by the trauma centers were approximately 333% greater. This large disparity prompted DOH to follow the example of many other states and use population as a proxy for the number of potential trauma patients in each TSA in its Proposed Rule. DOH found that: greater population means a greater need for health care; population is a good indicator of need for medical services; population is a reasonable proxy for patient volume; and, more people in a given area results in more trauma cases in a given area.

62. (k) O*ther appropriate criteria*: It was well documented in literature presented to DOH during the rulemaking process that there were a large percentage of severely injured

patients in Florida not being seen by trauma centers. The data unit confirmed this by evaluating the AHCA administrative database, which identifies the injuries suffered by patients as well as the type of hospitals discharging those patients, i.e., comparing the total number of severely injured patients with the number of severely injured patients discharged from acute care hospitals in each TSA. This disparity was worrisome to DOH and therefore included in the March TSA Assessment. As pointed out by Petitioners, the Department's figures include patients who may have received treatment outside the TSA in which the injury occurred. The figures may not have contained patients who needed trauma care but could not access it for other reasons. The Proposed Rule, however, makes as complete an evaluation of the potential patient base for trauma centers as is possible.

63. Notwithstanding complaints about how the Department addressed some of the criteria set forth in the statute, it is clear that all criteria were considered and implemented into the Proposed Rule to the extent feasible and possible. The most credible testimony at final hearing supports the Department's process. Criticisms of the various elements within the Proposed Rule expressed by Petitioners at final hearing seemed to be based on the concept that the Proposed Rule may allow competition to existing trauma centers rather than real complaints about the elements themselves. All agree, for

example, that population, transportation times, number of patients, and the existence of nearby trauma centers are important factors that should be considered. Petitioners just seemed to want those factors expressed in different (though unspecified) terms.

64. Petitioners did enunciate certain shortcomings they felt made the Proposed Rule less than complete. St. Joseph lamented the absence of all the Department's analysis and background for each of the proposed measurements contained in the Proposed Rule. Jackson Memorial pointed out that pediatric trauma centers were not specifically included in the Proposed Rule. Shands showed that odd or unusual results could arise from implementation of the Proposed Rule. For example, the March TSA Assessment showed a total of 216 severely injured patients in TSA 6, comprised of Marion, Citrus, and Hernando counties. The Proposed Rule called for two trauma centers in that TSA. Although the number of patients necessary to maintain a trauma center's proficiency was disputed by various experts in the field, it is clear that 108 patients per center would be extremely low. However, the figure appearing in the March Assessment is not absolute or necessarily completely definitive of need. There are other factors concerning population and patients that may affect that figure.

The Six Measurement Criteria in the Proposed Rule

65. Petitioners also took exception to the measurement criteria in the Proposed Rule. Each of those six criterion is discussed below.

Population

66. The Proposed Rule awards from two to ten points to a TSA, depending on the TSA total population. Two points are awarded for a population of less than 600,000 and ten points are awarded for a popu1ation greater than 2.4 million.

67. The Department used total population as a "proxy" for the actual number of trauma patients in the state rather than using the actual number of trauma victims in the state. The Proposed Rule does not define “population” or “Total Population,” nor are those terms defined in the trauma statute, but those words are subject to their normal definition.

68. The Proposed Rule does not re-state the source of the summary Total Population data; it is already contained in the TSA Assessment. Neither the Proposed Rule nor the March TSA Assessment contains any data or analysis reflecting population by age cohort, population density, or incidence of trauma injury in relation to these factors, and the Department did not specifically conduct any analysis of the significance of any aspect of population data as it relates to the need for new trauma centers, other than determining the total population

growth rate in the TSAs. Rather, DOH decided upon total population as the most reliable measure available.

69. Traumatic injury rates and the severity of traumatic injury vary widely based on a number of factors, including whether the area is urban or rural, the population age cohort, and the infrastructure and physical characteristics or features of the geographic area. Thus, the most reasonable way to measure possible need was to look at the total population of an area and extrapolate from that basis.

70. The Department presented no specific data or analysis to support the incremental cutoff points for the Total Population scale contained in the Proposed Rule. Rather, the Department took population as a whole because it was the most readily available, annually updateable, and understandable factor it could access.

71. The use of population as a proxy is not without problems, however. In TSA 19, for instance, the population has increased by about thirty-eight percent in recent decades, but the number of trauma victims has declined by approximately twelve percent. As stated, the Proposed Rule as written is not inerrant.

Median Transport Times

72. The Proposed Rule awards from zero to four points to a TSA, depending on the Median Transport Time within a TSA.

73. "Median Transport Time" is not defined in the Proposed Rule, nor is the methodology for determining the summary "Median Transport Time" statistics set forth in the TSA Assessment and relied on in the Proposed Rule. Information concerning transport times is, however, contained within the TSA Assessment.

74. The Median Transport Time used in the Proposed Rule represents the average transport time for all 911 transports voluntarily reported to the state EMSTARS database. EMSTARS is a database that is under development and that collects information voluntarily provided by emergency medical transport providers throughout the state. Although not all EMS providers currently report to EMSTARS (most notably, Miami-Dade County EMS does not participate), the database is useful for research and quality improvement initiatives.

75. The Median Transport Time set forth in the March TSA Assessment and used in the Proposed Rule includes transport time for all patients, regardless of the nature of the emergency, whether the call involved trauma, other types of injury, or illness, and regardless of whether the transport was conducted with the regular flow of traffic or required "lights and siren."

76. The Median Transport Time used in the Proposed Rule includes all EMS transports of up to two hours in duration. The Median Transport Time excludes transports of patients to trauma

centers operating pursuant to the initial stage of trauma center licensure known as “provisional approval.”

77. The Department addressed “medically appropriate air or ground transport times,” as required by section 395.402(3)(h), by its generally accepted conclusion that "faster is better."

78. Not all injured patients, however, benefit from receiving care at a trauma center. Thus, while an existing trauma center is an appropriate destination for all patients with any level of injury who live in the area of a trauma center, the trauma center’s value beyond its immediate area is as a resource for the most severely injured patients whose problems exceed the capabilities of their nearest hospital.

79. The Department did not undertake any analysis to balance its "faster is better" approach to trauma planning against the reality that the resources necessary to provide high quality trauma care are limited, as is the number of severely injured patients.

80. There is a general (but not universal) consensus among trauma experts that access to a trauma center within 30-50 minutes is an appropriate benchmark for access to trauma care. Other than "faster is better," the Department did not determine a medically appropriate travel time for any type of trauma or any geographic area, but recognizes the general consensus as appropriate.

81. The Proposed Rule awards from one to four points that weigh in favor of approval of a new trauma center within a TSA if the Median Transport Time of patients transported in response to any 911 call is between 10 and 42 minutes, i.e., within but faster than the generally accepted consensus.

Community Support

82. The Proposed Rule awards from one to two points to each TSA depending on the number of letters of support written by elected city or county commissioners.

83. The Proposed Rule allows for consideration of stakeholder recommendations by way of allowing letters of support from local governments. "Stakeholders" in the state trauma system include existing trauma centers, as well as all acute care hospitals, and pre- and post-hospital care providers, including emergency transport services, air ambulances, and emergency management planning agencies.

84. The Department could find no better way to acknowledge support from those stakeholders, and citizens in general, than to have their elected representatives listen to their constituents and then reflect those people's desires and comments.

Severely Injured Patients Discharged from Acute Care Hospitals

85. The Proposed Rule awards from zero to four points to a TSA, depending on the number of severely injured patients discharged from acute care hospitals (non-trauma centers).

86. The Proposed Rule addresses the number of severely injured patients, i.e., those with an ICISS score of < 0.85, discharged from hospitals other than trauma centers. The Proposed Rule does not specifically define "severely injured patient," but it is obvious from the context in which that term is used.

87. The summary data in the TSA Assessment labeled "number of severely injured patients" within each TSA is intended to reflect the number of severely injured patients who "didn't get to trauma care." The Department's numbers may include patients who received treatment at a trauma center outside of the TSA in which the injury occurred. The Department did not conduct any analysis of the "number of severely injured patients not treated at a trauma center" to determine whether the patients not treated at a trauma center received timely and appropriate care at a non-trauma center hospital with the capability to treat the patient's injuries. The number of "severely injured patients who did not get to trauma care" as reported by the Department is unlikely to reflect the actual number of patients who required care at a trauma center but did not have access, and suggests

that this number is far higher than it actually is. The Department, for example (and in response to discussion with stakeholders), excluded from its analysis all patients with isolated hip fractures as well as all patients who were released from the hospital within 24 hours, which resulted in fewer severely injured patients.

88. Neither the Proposed Rule nor the TSA Assessment considers demographics or outcomes for "severely injured patients" treated at general acute care hospitals or outcome data for these patients.

89. The Proposed Rule does not include any method for projecting the actual demand for trauma services in the future; it is used to determine need at a single point in time (and will be done so annually). The Proposed Rule does not include any criteria or method for evaluating whether there are any capacity problems at existing trauma centers, or other barriers that impede access to trauma care.

90. The Department intended this criterion to show a highly conservative estimate of patients who definitely need trauma care.

Level I Trauma Centers

91. With respect to “Level I Trauma Centers,” the Proposed Rule awards from negative one to negative three points to a TSA,

depending on whether the TSA already has one, two, or three verified Level I trauma center(s), respectively.

92. The Proposed Rule creates the opportunity for establishment of both additional Level I and also additional Level II trauma centers, pursuant to the allocation of need, but the Proposed Rule does not assign or subtract points for the existence of Level II trauma centers.

93. This criterion reflects the recommendations of stakeholders at the rule workshops. It was the consensus of many stakeholders that Level I trauma centers should be protected in order to safeguard the research and teaching missions of those centers. The earlier proposal of a "halo" around existing centers, i.e., not approving a new trauma center within a certain radius of existing centers, was not incorporated into the Proposed Rule. This criterion, however, offers some protection for existing centers.

Number of Severely Injured Patients

94. The Proposed Rule awards negative two to two points based on the "number of severely injured patients" in a TSA. The criterion awards points based on the number of Severely Injured Patients which exceed the target trauma center patient volumes as provided in section 395.402(1). If the annual number of Severely Injured Patients exceeds the statutory volumes by more than 500 patients, the TSA will receive two points; if it

exceeds it by less than 500 the TSA receives one point; if the number of Severely Injured Patients is less than the statutory volumes by zero to 500 patients, the TSA receives one negative point; if it is less than the volumes by more than 500 patients, the TSA receives two negative points.

95. The Proposed Rule does not include any criterion addressing the actual number of trauma victims currently being served by each trauma center. Instead, Section 6 of the Proposed Rule substitutes the "minimum statutory capacity" of existing trauma centers for the actual capacity of existing trauma centers.

96. The Department could not find "a meaningful" way to measure actual capacity of existing trauma centers. The most accurate way to measure capacity was a contentious topic at rule workshops, and the Department spent a good deal of time working with stakeholders on how to measure capacity in such a way that it could be included as a factor in the Proposed Rule. One suggestion as to how to measure trauma center capacity is by how often existing trauma centers actually divert trauma patients to other facilities. However, trauma centers rarely admit that they are not able to take any more patients, and this is not a realistic method to evaluate capacity.

97. The capacity of an existing trauma center may be measured by various means, including the number of beds at the

trauma center, the number of ICU beds, the number of trauma bays, number of operating rooms, as well as the frequency of and reasons for diversion. The trauma center's clinical staff, including medical and surgical specialists, and supporting clinical personnel, are also indicators of capacity. The Department already routinely collects data reflecting trauma center capacity as part of the quarterly and annual reports that all existing trauma centers are required to submit, and by way of on-site licensure surveys. None of those means, however, provided DOH with sufficiently reliable information and data.

98. The Proposed Rule comports with the DOH Mission to protect, promote, and improve the health of all Floridians through integrated state, county, and community efforts. While by no means perfect, the Proposed Rule is based upon logic and reason derived from an extensive analysis of all relevant factors.

History of the Rule

99. The rationale for DOH's inclusion of those particular six criteria in the Proposed Rule can be better understood by considering some more history of the trauma rule.

100. As stated earlier herein, in 2004 the Legislature made substantial revisions to the trauma statute and ordered the Department to complete an assessment of Florida's trauma system. The scope of this assessment was defined in paragraphs (2)(a)

through (g) and subsection (3) of section 395.402. An appropriation of $300,000 was authorized for the Department to contract with a state university to perform the actions required under the amended statute. Ch. 2004-259, § 10, Laws of Florida.

101. One proposal of the 2005 Assessment was to "[c]onsider aligning trauma service areas within [sic] the trauma region boundaries as established in" section 395.4015(1). § 395.402(2)(a), Fla. Stat. In a related 2004 amendment, the Legislature ended the statutory mandate to use the service areas created in 1990.

102. The obvious conclusion from the above statutory change is that the section 395.402(4) service areas could be replaced by the service areas DOH established or adopted once it had the results of the 2005 Assessment. Unlike the prior statute, there is no mandate for specific new service areas, only the option not to use the prior service areas.

103. The 2005 Assessment included five "Recommendations":

> 1. Trauma centers should be placed in Tallahassee and in Bay County, which do not currently have a trauma center . . . .
>
> 2. It is reasonable to set, as a system goal, that 65 percent of trauma center patients will be treated at a trauma center. . . .
>
> 3. Designation of additional trauma centers should be based on the need as determined by trauma region. Deployment of additional trauma centers should take place based, not

> only on the number of patients served per trauma center, but according to the concept of "trauma center capacity" which should be determined by the staffing levels of medical specialists and other healthcare professionals. . . .
>
> 4. The data support the feasibility of transforming the Florida Trauma Services Areas so that these would coincide with the Domestic Security Task Force Regions. . . .
>
> 5. It is reasonable to fund trauma centers with public funds, based on the unrecoverable financial burden incurred by trauma centers.

104. The only legislative response to the 2005 Assessment was an increase in funding to trauma centers. The Legislature did not repeal the statute establishing the current 19 TSAs. Likewise, the Department has not amended the Rule to implement the recommendations contained in the 2005 Assessment until the present Proposed Rule.

105. The Department, instead, reviewed existing statutes, interpreted section 395.4015 to mandate the establishment of a trauma system plan (which plan would include trauma regions that have boundaries coterminous with those of the regional domestic security task force boundaries). The development of the trauma system plan is distinct from the determination of need for new trauma systems addressed by the Proposed Rule.

CONCLUSIONS OF LAW

106. The Division of Administrative Hearings has jurisdiction over the parties and subject matter of this cause pursuant to section 120.56, Florida Statutes.

107. Section 395.402, is the statutory authority for the Proposed Rule and the law implemented. It states, in its entirety:

> **395.402 Trauma service areas; number and location of trauma centers.**—
> (1) The Legislature recognizes the need for a statewide, cohesive, uniform, and integrated trauma system. Within the trauma service areas, Level I and Level II trauma centers shall each be capable of annually treating a minimum of 1,000 and 500 patients, respectively, with an injury severity score (ISS) of 9 or greater. Level II trauma centers in counties with a population of more than 500,000 shall have the capacity to care for 1,000 patients per year.
>
> (2) Trauma service areas as defined in this section are to be utilized until the Department of Health completes an assessment of the trauma system and reports its finding to the Governor, the President of the Senate, the Speaker of the House of Representatives, and the substantive legislative committees. The report shall be submitted by February 1, 2005. The department shall review the existing trauma system and determine whether it is effective in providing trauma care uniformly throughout the state. The assessment shall:
>
> (a) Consider aligning trauma service areas within the trauma region boundaries as established in July 2004.

(b) Review the number and level of trauma centers needed for each trauma service area to provide a statewide integrated trauma system.

(c) Establish criteria for determining the number and level of trauma centers needed to serve the population in a defined trauma service area or region.

(d) Consider including criteria within trauma center approval standards based upon the number of trauma victims served within a service area.

(e) Review the Regional Domestic Security Task Force structure and determine whether integrating the trauma system planning with interagency regional emergency and disaster planning efforts is feasible and identify any duplication of efforts between the two entities.

(f) Make recommendations regarding a continued revenue source which shall include a local participation requirement.

(g) Make recommendations regarding a formula for the distribution of funds identified for trauma centers which shall address incentives for new centers where needed and the need to maintain effective trauma care in areas served by existing centers, with consideration for the volume of trauma patients served, and the amount of charity care provided.

(3) In conducting such assessment and subsequent annual reviews, the department shall consider:

(a) The recommendations made as part of the regional trauma system plans submitted by regional trauma agencies.

(b) Stakeholder recommendations.

(c) The geographical composition of an area to ensure rapid access to trauma care by patients.

(d) Historical patterns of patient referral and transfer in an area.

(e) Inventories of available trauma care resources, including professional medical staff.

(f) Population growth characteristics.

(g) Transportation capabilities, including ground and air transport.

(h) Medically appropriate ground and air travel times.

(i) Recommendations of the Regional Domestic Security Task Force.

(j) The actual number of trauma victims currently being served by each trauma center.

(k) Other appropriate criteria.

(4) Annually thereafter, the department shall review the assignment of the 67 counties to trauma service areas, in addition to the requirements of paragraphs (2)(b)-(g) and subsection (3). County assignments are made for the purpose of developing a system of trauma centers. Revisions made by the department shall take into consideration the recommendations made as part of the regional trauma system plans approved by the department and the recommendations made as part of the state trauma system plan. In cases where a trauma service area is located within the boundaries of more than one trauma region, the trauma service area's needs, response capability, and system requirements shall be considered by each trauma region served by that trauma service area in its regional

system plan. Until the department completes the February 2005 assessment, the assignment of counties shall remain as established in this section.

(a) The following trauma service areas are hereby established:

1. Trauma service area 1 shall consist of Escambia, Okaloosa, Santa Rosa, and Walton Counties.

2. Trauma service area 2 shall consist of Bay, Gulf, Holmes, and Washington Counties.

3. Trauma service area 3 shall consist of Calhoun, Franklin, Gadsden, Jackson, Jefferson, Leon, Liberty, Madison, Taylor, and Wakulla Counties.

4. Trauma service area 4 shall consist of Alachua, Bradford, Columbia, Dixie, Gilchrist, Hamilton, Lafayette, Levy, Putnam, Suwannee, and Union Counties.

5. Trauma service area 5 shall consist of Baker, Clay, Duval, Nassau, and St. Johns Counties.

6. Trauma service area 6 shall consist of Citrus, Hernando, and Marion Counties.

7. Trauma service area 7 shall consist of Flagler and Volusia Counties.

8. Trauma service area 8 shall consist of Lake, Orange, Osceola, Seminole, and Sumter Counties.

9. Trauma service area 9 shall consist of Pasco and Pinellas Counties.

10. Trauma service area 10 shall consist of Hillsborough County.

11. Trauma service area 11 shall consist of Hardee, Highlands, and Polk Counties.

12. Trauma service area 12 shall consist of Brevard and Indian River Counties.

13. Trauma service area 13 shall consist of DeSoto, Manatee, and Sarasota Counties.

14. Trauma service area 14 shall consist of Martin, Okeechobee, and St. Lucie Counties.

15. Trauma service area 15 shall consist of Charlotte, Glades, Hendry, and Lee Counties.

16. Trauma service area 16 shall consist of Palm Beach County.

17. Trauma service area 17 shall consist of Collier County.

18. Trauma service area 18 shall consist of Broward County.

19. Trauma service area 19 shall consist of Miami-Dade and Monroe Counties.

(b) Each trauma service area should have at least one Level I or Level II trauma center. The department shall allocate, by rule, the number of trauma centers needed for each trauma service area.

(c) There shall be no more than a total of 44 trauma centers in the state.

History.—ss. 5, 15, ch. 90-284; ss. 37, 98, ch. 92-289; s. 195, ch. 99-397; s. 26, ch. 2000-242; s. 6, ch. 2004-259; s. 100, ch. 2008-4.

Note.—Former s. 395.033.

108. Section 120.56(1)(a), provides that any person substantially affected by "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."

Standing

109. As stipulated by the parties, all Petitioners and Intervenor have standing under section 120.56(1), to participate in this administrative hearing as persons substantially affected by the Proposed Rule.

Burden of Proof

110. Petitioners seek a determination that the Proposed Rule constitutes an invalid exercise of delegated legislative authority and is arbitrary and capricious, in violation of section 120.52(8). Under section 120.56(2)(a), the petitioner has a burden of going forward and only thereafter is the agency required to demonstrate by a preponderance of evidence that the proposed rule is not an invalid exercise of legislative authority. Petitioners met their burden in this proceeding.

111. An invalid exercise of delegated legislative authority means action that goes beyond the powers, functions, and duties delegated by the Legislature. A proposed or existing rule is an invalid exercise of delegated legislative authority if:

> (a) The agency has materially failed to follow the applicable rulemaking procedures or requirement set forth in this chapter;

(b) The agency has exceeded its grant of rulemaking authority, citation to which is required by s. 120.54(3)(a)1.;

(c) The rule enlarges, modifies, or contravenes the specific provisions of law implemented, citation to which is required by s. 120.54(3)(a)1.;

(d) The rule is vague, fails to establish adequate standards for agency decisions, or vests unbridled discretion in the agency;

(e) The rule is arbitrary or capricious. A rule is arbitrary if it is not supported by logic or the necessary facts; a rule is capricious if it is adopted without thought or reason or is irrational;

(f) A grant of rulemaking authority is necessary but not sufficient to allow an agency to adopt a rule; a specific law to be implemented is also required. An agency may adopt only rules that implement or interpret the specific powers and duties granted by the enabling statute. No agency shall have authority to adopt a rule only because it is reasonably related to the purpose of the enabling legislation and is not arbitrary and capricious or is within the agency's class of powers and duties, nor shall an agency have the authority to implement statutory provisions setting forth general legislative intent or policy. Statutory language granting rulemaking authority or generally describing the powers and functions of an agency shall be construed to extend no further than implementing or interpreting the specific powers and duties conferred by the enabling statute.

§ 120.52(8), Fla. Stat.

Standard of Review

112. A proposed rule may be challenged pursuant to section 120.56, only on the ground that it is an invalid exercise of delegated legislative authority. An Administrative Law Judge is without authority to declare a proposed rule invalid on any other ground. To do so would be an impermissible extension of the judge's authority beyond the boundaries established by the legislature.

113. "An arbitrary decision is one not supported by facts or logic, or despotic." Bd. of Trs. of Int. Imp. Trust Fund v. Levy, 656 So. 2d 1359, 1362 (Fla. 1st DCA 1995) (quoting Agrico Chem. Co. v. Dep't of Envtl. Reg., 365 So. 2d 759, 763 (Fla. 1st DCA 1978)). "A capricious action is one which is taken without thought or reason or irrationally." Id. A determination is not arbitrary or capricious if it is justifiable "under any analysis that a reasonable person would use to reach a decision of similar importance." Dravo Basic Materials Co., Inc. v. State of Fla., Dep't of Transp., 602 So. 2d 632 (Fla. 2nd DCA 1992).

114. An administrative agency's interpretation of the statute it is charged with implementing is entitled to great deference. See Level 3 Commc'ns, LLC v. Jacobs, 841 So. 2d 447, 450 (Fla. 2003); PW Ventures, Inc. v. Nichols, 533 So. 2d 281, 283 (Fla. 1988); Fla. Hosp. (Adventist Health) v. Agency for Health Care Admin., 823 So. 2d 844, 847 (Fla. 1st DCA 2002).

The deference to agency interpretation of a statute it is charged with enforcing applies even if other interpretations or alternative rules exist. Atlantic Shores Resort v. 507 S. St. Corp., 937 So. 2d 1239, 1245 (Fla. 3d DCA 2006); Miles v. FAMU, 813 So. 2d 242, 245 (Fla. 1st DCA 2002); Bd. of Trs., 656 So. 2d at 1363. Similarly, "[a]gencies are accorded wide deference in the exercise of lawful rulemaking authority which is clearly conferred or fairly implied and consistent with the agency's general statutory duties. Charity v. FSU, 680 So. 2d 463, 466 (Fla. 1st DCA 1996).

115. The challenger's burden to demonstrate an invalid exercise of delegated legislative authority "is a stringent one indeed." Agrico, 365 So. 2d at 763.

116. The Department drafted the proposed rule pursuant to section 395.402(4). It developed a scoring system to assess need based upon six criteria and allocated between one and three trauma centers per TSA. The Proposed Rule allocated a maximum total of 27 positions for trauma centers, precisely the number currently existing or approved and fewer than the 44 allowed by statute.

117. Petitioners claim that the Proposed Rule is invalid because it does not incorporate all of the criteria set forth in section 395.402(3). These criteria, however, are part of a separate and distinct statutory requirement that the Department

conduct an annual assessment as to whether the existing trauma system is effective in providing trauma care throughout the state. The statutory requirement for rulemaking (section 395.402(b)-(c)) does not specify the criteria the Department was required to use in allocating trauma centers.

118. Nonetheless, during the rulemaking process, the Department did consider each of the criteria listed in section 395.402(3). If particular criteria were not reflected in the Proposed Rule it was because, after careful consideration, the data could not be confidently used.

119. The Proposed Rule was issued after a rule development process over the course of more than one year. The Department afforded every impacted constituency the opportunity to express their views and conducted an extensive review of literature and data related to trauma care. During this process, the Department carefully considered the views of Stakeholders, including Petitioners (or their representatives) and, where appropriate, modified the Proposed Rule to take into account their input.

120. The Legislature did not specify the criteria that the Department was required to use in allocating TSAs but instead delegated the Department a mandate to allocate "by rule" the number of trauma centers in each TSA. The Legislature recognized that the Department, as a specialized administrative

body with expertise in public health, was in the best position to make that determination. The allocation of trauma centers is a complex process and there is no universally accepted methodology. As the ACS has explained:

> The optimal balance between these choices and trade-offs will not yield a single universal solution, but will depend upon uniquely local factors, including geography, resource availability, and regional social elements. In the end, the decision is inherently political rather than purely scientific. For that reason, it is a decision that few regions have been able to execute successfully.

Bayfront Exhibit 12.

121. The Department's Proposed Rule was the product of thoughtful consideration by the Department's experts during an extensive rulemaking development process. Under these circumstances, the Department's determinations are accorded deference. See, e.g., Island Harbor Beach Club, Ltd. v. Dep't of Nat. Res., 495 So. 2d 209, 223 (Fla. 1st DCA 1986) ("The complexity of the scientific and technical issues in this case and the consequent deference necessarily given to [the Department of Natural Resource's] expertise vividly illustrate the limited role an appellate court can play in resolving disputes arising out of an administrative agency's exercise of delegated discretion in respect to technical matters . . . ."); Rizov v. State, Bd. of Prof. 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."); see also Avatar Dev. Corp. v. State, 723 So. 2d 199, 207 (Fla. 1998) ("Under the complexities of our modern system of government, the Legislature has recognized that [the Department of Environmental Protection], as a specialized administrative body, is in the best position to establish appropriate standards and conditions . . . .")

122. The rulemaking process also refutes any claim that the Proposed Rule was arbitrary or capricious. There was ample testimony as to the facts and logic supporting each of the criteria in the Proposed Rule--negating any claim of arbitrariness. The fact that the Department developed the Proposed Rule after a year of careful analysis as to the factors that should be used to assess trauma center need negates any claim that the Proposed Rule is "capricious" because it was one allegedly "taken without thought or reason or irrationally."

123. The Department's determination that the TSAs should not be abolished and that their borders should not be realigned should be accorded deference because there was no statutory mandate to abolish or realign the TSAs. It is difficult to reconcile the continued existence of section 395.402 after the

recommendations in the 2005 Assessment, unless the Legislature meant for DOH to have an option to use the 19 TSAs until they found a more effective and manageable way to allocate trauma centers within the State. In this case, DOH adequately described its analysis resulting in the decision to continue (for the present) to use the 19 TSAs in lieu of the RDSTF regions or any other system.

124. The Legislature has mandated that the Department address two separate functions: trauma planning (for example, in response to mass-casualty events) and the allocation of trauma centers to TSAs.

125. Section 395.4015, is focused exclusively on trauma planning--not trauma center allocation--as indicated by its title: "State regional trauma planning; trauma regions." As part of the Legislature's 2004 amendments to the Trauma Statute, the Legislature mandated that "the department shall establish trauma regions that cover all geographical areas of the state and have boundaries that are coterminous with the boundaries of the regional domestic security task forces," which "may serve as the basis for the development of department-approved local or regional trauma plans." § 395.4015(1), Fla. Stat. While this section mandated that the Department establish trauma regions that were coterminous with the RDSTFs, it said nothing about

TSAs, the allocation of trauma centers, or the provision of trauma care.

126. Section 395.402, the section implemented by the Proposed Rule, explicitly recognizes the continued existence of TSAs. Subsection (2)(a) states that in conducting its annual assessment, the Department was required to "[c]onsider aligning trauma service areas within the trauma region boundaries as established in July 2004." The meaning of the term "consider" as a matter of plain English is permissive, not mandatory. See, e.g., Merriam-Webster dictionary (defining "consider" as "to think about (something or someone) carefully especially in order to make a choice or decision"). In other words, the Department was supposed to consider whether the boundaries of the TSAs should be redrawn to fit neatly within the trauma regions; this provision did not contemplate abolishing TSAs altogether. Subsection (4) similarly required the Department to conduct an annual review [of] the assignment of the 67 counties to trauma service areas and stated that "[i]n cases where a trauma service area is located within the boundaries of more than one trauma region, the trauma service area's needs, response capability, and system requirements shall be considered by each trauma region served by that trauma service area in its regional system plan." This subsection contemplated the ongoing existence for TSAs--creating the need for annual reviews--and a clear

distinction between TSAs on the one hand and trauma regions or RDSTFs on the other, including the fact that they are different entities and could have overlapping geographical boundaries. It is noteworthy that the above-cited provisions were also added as a result of the 2004 statutory amendments. Unlike the amendments to section 395.4015, which included a mandate to establish trauma regions that were coterminous with the RDSTFs, the Legislature did not include any similar mandates with respect to TSAs.

127. As set forth above, the Department extensively considered whether the boundaries of TSAs should be realigned within the RDSTFs and reasonably concluded that the interests of Florida's public health was best served by maintaining the status quo until such time as an appropriate regional trauma planning structure was developed or the Department was given clear authority to allocate trauma centers within RDSTFs.

128. Due to the size of the trauma planning regions, which mirror the RDSTF boundaries, regional trauma agencies are necessary to aid in trauma center allocation and ensure trauma centers are appropriately located throughout the regions. At this time, there is only one regional trauma planning agency in Florida.

129. In Citizens of Florida v. Mayo, 357 So. 2d 731, 733 (Fla. 1970), the Florida Supreme Court held that no court can

require an agency to adopt a specific rule, noting that "the agency rulemaking function involves the exercise of agency discretion and this Court will not substitute its judgment for that of the agency on an issue of discretion." The Court's analysis recognized that it is the statutory language which controls the adoption of a rule, not the Court's opinion as to what a rule should include. In Bayonet Point Hospital, Inc. v. Department of Health & Rehabilitative Services, 490 So. 2d 1318, 1320 (Fla. 1st DCA 1986), the First District adopted the analysis in Mayo, supra, and confirmed that a court has no authority to compel agency adoption of a rule which represents a policy choice in the area of the agency's statutory concern. Id. (citing FEA/United v. PERC, 346 So. 2d 551 (Fla. 1st DCA 1977)). Prior decisions related to the 1992 Rule (Bayfront Med. Ctr, Inc. et al. v. Dep't of Health, Case Nos. 11-2602RX, et al. (Fla. DOAH, Sept. 23, 2013); and Dep't of Health v. Bayfront Med. Ctr., Inc., 134 So. 3d 1017 (Fla. 1st DCA 2012)), could not dictate the results of the Department's consideration over the course of the rule development process for this Proposed Rule about whether the TSAs should be aligned with the trauma regions/RDSTFs, or mandate that the TSAs be abolished.

130. Contrary to the claim made by Petitioners, the Proposed Rule is valid even though the Proposed Rule, on its face, does not define the sources of data that would be used to

measure population, median transport time or hospital discharge data.

131. In February 2014, the JAPC sent the Department a letter stating that the Trauma Service Area Assessment, which identifies the source data for criteria used in the Proposed Rule, was not specifically incorporated by reference into the text of the Proposed Rule. The Department responded that the assessment was prepared pursuant to a different statutory requirement and that it did not have the force of law. The JAPC has not objected to the Proposed Rule. The March TSA Assessment does not constitute a rule as defined by section 120.52(16). It is an informational reference only and therefore is not required to be incorporated by reference. See "Looking Glass Law: Legislation by Reference in the States," F. Scott Boyd, Louisiana L. Rev., Vol. 68, Number 4, Summer 2008.

132. Rules are valid even if they afford discretion to the administrative agency in carrying them out. In Florida East Coast Industries, Inc. v. State Department of Community Affairs, 677 So. 2d 357 (Fla. 1st DCA 1996), petitioners claimed that proposed rules related to urban sprawl vested the agency with unbridled discretion. The court agreed with the ALJ's finding that the rule in question did not vest the agency with unbridled discretion, relying upon testimony that determining what constituted urban sprawl was so complex that it made a more

specific rule impossible. Id. at 361. The court concluded that "executive agencies may exercise some discretion without breaching their authority." Id.

133. Similarly, in Southwest Florida Water Management District v. Charlotte County, 774 So. 2d 903, 911 (Fla. 2d DCA 2001), the court upheld the ALJ's finding that a rule that used subjective terminology like "adverse impact" did not improperly vest the agency with "unbridled discretion." It agreed with the ALJ's conclusion that "[i]t is appropriate and acceptable for the rules to allow for the exercise of professional judgment." Id. It stated that if determining what constitutes an adverse impact to the environment requires professional judgment, then determining what measures could be taken to prevent or lessen the adverse impact also allow for the use of professional judgment. Id.

134. The Proposed Rule affords the Department far less discretion than the rules in the cases described above. It is certainly well within the Department's professional judgment to identify appropriate sources of data to measure population, median transport time and hospital discharge data. This is particularly true since these criteria reflect data gathered by the Department or other government entities. Further, the Department is working to improve and expand data sources available, and the absence of defined data sources gives the

Department flexibility to use improved data sources in the future.

135. The reasonableness of the Department's use of criteria without specific definitions as a means for allocating points is confirmed by other rules with similar characteristics. See, e.g., Fla. Admin. Code R. 5F-14.003(6)(b)1. (awarding points if a "[p]roject results in significant bioenergy production from Florida grown biomass resources"--without definitions for measurement of "bioenergy production" or "biomass resources"); Fla. Admin. Code R. 14-79.006(8)(a)2. (awarding points for bidding/estimates based on the criteria of: "[d]emonstrates an understanding of all requisite steps in the preparation of Department bids" and "demonstrates competence in estimating project cost accurately"--without defining either criteria); Fla. Admin. Code R. 1T-1.038(4) (awarding points for "artistic excellence," "tradition and authenticity," and "community impact and engagement"--without defining those terms).

136. The crux of Petitioners' objection is that the Proposed Rule is invalid because it will result in increased competition, which will allegedly cause harm to Petitioners' trauma centers. As discussed above, the Legislature delegated to the Department the responsibility to allocate trauma centers--which meant the Department was required to balance a myriad of

interests including those of Petitioners' trauma centers, the Intervenor, newly established trauma centers that have not yet received final approval, EMS providers, elected representatives and patient advocates. It would be impossible to develop a rule that could simultaneously satisfy all of these interests--although, as discussed above, the Department incorporated the Petitioners' concerns into the Proposed Rule as the Department believed appropriate. The Department's determination of the appropriate balance of conflicting interests is owed deference--even if the result was a Proposed Rule with which Petitioners do not agree.

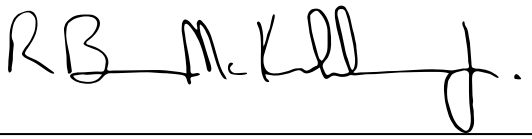
137. In Board of Trustees, petitioner challenged the decision of the Trustees (an administrative agency) to deny his application to extend his existing 500-foot dock to 600 feet, based upon a rule that mandated that the maximum dock length as 500 feet. 656 So. 2d at 1361. The ALJ found that the decision was not capricious because it reflected "the thoughtful balancing of varying factors," but found that the rule was arbitrary because there was no evidence that the 500 foot limit protected environmental interests. Id. at 1362. The appellate court agreed with the ALJ's finding with respect to capriciousness but reversed with respect to arbitrariness. Id. at 1363. The court found that in promulgating a predecessor rule, the Trustees "attempted to balance competing interests

such as environmental, aesthetic, recreational, and private commercial." Id. It concluded by stating: "The issue before the hearing officer . . . was not whether Trustees made the best choice . . . or whether their choice is one that the appellee finds desirable for his particular location. The issue is whether the Trustees made a choice based upon facts, logic and reason. It is clear they did." Id. at 1364. Here too, the Department developed the allocation rule based upon facts, logic and reason. The fact that the Proposed Rule may cause Petitioners economic harm is not a basis to invalidate it.

ORDER

Based on the foregoing Findings of Fact and Conclusions of Law, it is ORDERED that rule 64J-2.010 does not constitute an invalid exercise of delegated legislative authority.

DONE AND ORDERED this 20th day of June, 2014, in Tallahassee, Leon County, Florida.



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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.