

IN THE DISTRICT COURT OF APPEAL,
FIRST DISTRICT, STATE OF FLORIDA

FLORIDA BOARD OF
MEDICINE,
FLORIDA SOCIETY OF
ANESTHESIOLOGISTS and
FLORIDA HOSPITAL
ASSOCIATION, INC.,

NOT FINAL UNTIL TIME EXPIRES TO
FILE MOTION FOR REHEARING AND
DISPOSITION THEREOF IF FILED.

Appellants,

CASE NO. 1D00-3897

v.

FLORIDA ACADEMY OF COSMETIC
SURGERY, INC.; CHARLES GRAPER,
M.D., D.D.S., F.A.C.S.; R. GREGORY
SMITH, M.D., FLORIDA SOCIETY OF
PLASTIC SURGERY, INC. and FLORIDA
SOCIETY OF DERMATOLOGY, INC.,

Appellees.

FLORIDA BOARD OF MEDICINE,
et al.,

Appellants,

v.

CASE NO. 1D01-123

FLORIDA ACADEMY OF COSMETIC
SURGERY, INC., et al., FLORIDA
ASSOCIATION OF NURSE ANESTHETISTS
and FLORIDA NURSES ASSOCIATION,

Appellees.

Opinion filed January 23, 2002.

An appeal from Orders of the Division of Administrative Hearings.

Robert A. Butterworth, Attorney General; M. Catherine Lannon and Lee Ann Gustafson, Assistant Attorneys General, Tallahassee, for Appellant Board of Medicine; Jerome W. Hoffman of Holland & Knight, LLP, Tallahassee, for Appellant Florida Society of Anesthesiologists; Stephen A. Ecenia and J. Stephen Menton of Rutledge, Ecenia, Purnell & Hoffman, P.A., Tallahassee, for Appellant Florida Hospital Association, Inc.

Alfred W. Clark, Tallahassee, for Appellees Florida Academy of Cosmetic Surgery, Inc., Charles Graper, M.D., D.D.S., F.A.C.S., and R. Gregory Smith, M.D.; Christopher L. Nuland of Law Offices of Christopher L. Nuland, Jacksonville, for Appellees Florida Chapter, American College of Surgeons, Inc., Florida Society of Dermatology, Inc., and Florida Society of Plastic Surgeons, Inc.; James W. Linn of Lewis Longman & Walker, P.A., Tallahassee, and Cynthia Mikos, Brandon, for Appellees Florida Association of Nurse Anesthetists and Florida Nurses Association.

Alan L. Briggs and Scott T. Kragie of Squire, Sanders & Dempsey L.L.P., Washington, D.C., for Amicus Curiae American Society of Anesthesiologists; Gene A. Blumenreich of Nutter, McClennen & Fish, LLP, Boston, MA, for Amicus Curiae American Association of Nurse Anesthetists.

WEBSTER, J.

In these two consolidated administrative appeals, appellants seek review of final orders entered by an administrative law judge (ALJ) in rule challenge proceedings. Appellants contend that the ALJ committed reversible error when he held that (1) appellees Florida Nurses Association (FNA) and Florida Association of Nurse Anesthetists (FANA) had standing to challenge a portion of appellant Florida Board of Medicine's proposed rule 64B8-

9.009(6)(b)1.a. that required an anesthesiologist to be present for all level III office surgeries; (2) the Board of Medicine's rule 64B8-9.009(4)(b), requiring physicians without staff privileges who perform level II office surgeries to have a transfer agreement with a licensed hospital within reasonable proximity was an invalid exercise of delegated legislative authority; (3) the portion of proposed rule 64B8-9.009(6)(b)1.a. allowing physicians to perform level III office surgeries if they have staff privileges at a licensed hospital within reasonable proximity was an invalid exercise of delegated legislative authority; and (4) the portion of the Board of Medicine's proposed rule 64B8-9.009(6)(b)1.a. requiring an anesthesiologist to be present for all level III office surgeries was an invalid exercise of delegated legislative authority. We affirm the holding that FNA and FANA had standing to challenge the portion of proposed rule 64B8-9.009(6)(b)1.a. that required an anesthesiologist to be present for all level III office surgeries. However, we reverse the orders to the extent they hold that rule 64B8-9.009(4)(b) and the challenged portions of proposed rule 64B8-9.009(6)(b)1.a. constitute invalid exercises of delegated legislative authority.

I. BACKGROUND

Having become aware of a number of office surgery deaths and other adverse incidents, in October 1998, the Board of Medicine directed its Surgical Care Committee to evaluate, and to make recommendations for amendments to, Florida Rule of Administrative

Procedure 64B8-9.009, which governed the standards of care for office surgery. Following the receipt of recommendations from the Committee and meetings and hearings, the Board published proposed amendments to rule 64B8-9.009 in three separate notices of change. On July 8, 1999, appellants Florida Society of Anesthesiologists (FSA) and Florida Hospital Association (FHA) filed separate rule challenges to several of the proposed amendments. The parties to those pending rule challenges eventually agreed to permit those portions of the proposed amendments that were not being challenged to be submitted to the Department of State for codification. Those amendments were filed with the Department of State on January 28, 2000, and became effective on February 17, 2000. On February 18, 2000, the Board published a fourth notice of change, which proposed additional amendments to the rule.

On March 3, 2000, in Division of Administrative Hearings (DOAH) case number 00-1058RX, appellees Florida Academy of Cosmetic Surgery, Inc. (FACS), Dr. Charles Graper and Dr. R. Gregory Smith filed a challenge to the recently enacted rule 64B8-9.009(4)(b), which applied to level II office surgery (i.e., surgery requiring preoperative intravenous, intramuscular or rectal medication and sedation). That rule read:

(b) Transfer Agreement Required. The physician must have a transfer agreement with a licensed hospital within reasonable proximity if the physician does not have staff privileges to perform the same procedure as that being performed in the out-patient setting at a licensed hospital within reasonable proximity.

They also challenged rule 64B8-9.009(6)(b), which applied to level III office surgery (i.e., surgery requiring preoperative sedation by use of a general anesthesia or major conduction anesthesia). That rule read:

(b) Hospital Staff Privileges Required. The physician must have staff privileges to perform the same procedure as that being performed in the out-patient setting at a licensed hospital within reasonable proximity.

Leave to intervene was subsequently granted to appellants FHA and FSA, and to appellees Florida Society of Plastic Surgery, Inc. (FSPS), and Florida Society of Dermatology, Inc. (FSD).

FACS, Graper and Smith also filed a challenge to proposed rule 64B8-9.009(6)(b)1.a., which had been included in the fourth notice of change. That proposed rule, as amended, read:

(b) Standards for Level III Office Surgery. In addition to the standards for Level II Office Surgery, the surgeon must comply with the following:

1. Training Required.

a. The surgeon must have staff privileges at a licensed hospital to perform the same procedure in that hospital as that being performed in the office setting or must be able to document satisfactory completion of training such as Board certification or Board qualification by a Board approved by the American Board of Medical Specialties or any other

board approved by the Board of Medicine or must be able to demonstrate to the accrediting organization or to the Department comparable background, training, and experience. In addition, the surgeon must have knowledge of the principles of general anesthesia. If the anesthesia provider is not an anesthesiologist, there must be a licensed M.D., or D.O., anesthesiologist, other than the surgeon, to provide direct supervision of the administration and maintenance of the anesthesia.

This challenge was assigned DOAH case number 00-951RP. Leave to intervene was subsequently granted to appellants FHA and FSA and to appellees FSPS, FSD, FNA, FANA and the Florida Chapter of the American College of Surgeons. FSA argued unsuccessfully that FNA and FANA lacked standing to intervene. On April 17, 2000, FANA filed its own challenge to the portion of proposed rule 64B8-9.009(6)(b)1.a. which required an anesthesiologist to be present for all level III office surgeries. That challenge was assigned DOAH case number 00-1622RP. The Board argued unsuccessfully that FANA lacked standing to maintain such a challenge. DOAH case number 00-1622RP was eventually consolidated with DOAH case number 00-951RP.

Following a hearing in DOAH case number 00-1058RX, on September 7, 2000, the ALJ entered a final order holding that the transfer agreement provision of rule 64B8-9.009(4)(b) and the staff privileges provision of rule 64B8-9.009(6)(b) were invalid exercises of delegated legislative authority. Following a subsequent hearing in DOAH case numbers 00-951RP and 00-1622RP, on November 16, 2000, the ALJ

entered a final order holding that the portion of the first sentence of proposed rule 64B8-9.009(6)(b)1.a. relating to staff privileges and the last sentence of that rule (requiring anesthesiologist supervision of the administration of general anesthesia), were invalid exercises of delegated legislative authority. These appeals follow.

II. STANDING OF FNA AND FANA

Standing to challenge proposed or existing administrative rules is governed by statute in Florida. Section 120.56(1)(a), Florida Statutes (1999), provides that "[a]ny 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." To demonstrate that one is or will be "substantially affected by a rule or a proposed rule," one must establish both that application of the rule will result in "a real and sufficiently immediate injury in fact" and that "the alleged interest is arguably within the zone of interest to be protected or regulated." See, e.g., Lanoue v. Fla. Dep't of Law Enforcement, 751 So. 2d 94, 96 (Fla. 1st DCA 1999); Ward v. Bd. of Trs. of Internal Improvement Trust Fund, 651 So. 2d 1236, 1237 (Fla. 4th DCA 1995); All Risk Corp. of Fla. v. State Dep't of Labor & Employment Sec., 413 So. 2d 1200, 1202 (Fla. 1st DCA 1982); Fla. Dep't of Offender Rehab. v. Jerry, 353 So. 2d 1230 (Fla. 1st DCA 1978). Our supreme court

has held that trade or professional associations have standing in certain circumstances to challenge, pursuant to section 120.56(1), Florida Statutes, an agency rule on behalf of their members. Fla. Home Builders Ass'n v. Dep't of Labor & Employment Sec., 412 So. 2d 351 (Fla. 1982). To be permitted to do so, the trade or professional association

must demonstrate that [1] a substantial number of its members, although not necessarily a majority, are "substantially affected" by the challenged rule[;] . . . [2] the subject matter of the rule [is] within the association's general scope of interest and activity[;] and [3] the relief requested [is] of the type appropriate for a trade association to receive on behalf of its members.

Id. at 353-54.

The Board and FSA assert that the ALJ erred in concluding that FNA and FANA had standing to challenge that portion of proposed rule 64B8-9.009(6)(b)1.a. which requires supervision by an anesthesiologist of the administration of general anesthesia. Specifically, they contend that FNA and FANA failed to demonstrate that a substantial number of their members would be substantially affected by the proposal. Having carefully reviewed the extensive record, we are unable to agree. On the contrary, we conclude that competent substantial evidence supports the ALJ's findings regarding standing.

Both FNA and FANA presented evidence that their memberships included certified registered nurse anesthetists (CRNA's) who had office practices. The fact that the proposed rule would not directly regulate CRNA's is not fatal to a finding of standing. A challenger to a rule may be "substantially affected" by a rule, and thus have standing to challenge it, even where the rule or promulgating statute does not regulate the challenger's profession per se. Ward v. Bd. of Trs. of Internal Improvement Trust Fund, 651 So. 2d 1236, 1238 (Fla. 4th DCA 1995). For instance, we have held that a challenger can be substantially affected by a rule which has a collateral financial impact on the challenger's business. See Televisual Communications, Inc. v. State Dep't of Labor & Employment Sec., 667 So. 2d 372 (Fla. 1st DCA 1995) (a publisher of medical educational video programs had standing to challenge a proposed rule that would require an instructor to be present whenever audio-visual materials were used in educational programs required for health care professional certification because the rule had the collateral effect of regulating the publisher's industry by precluding the sale of its home study videos). Here, a number of physicians testified that they would not employ CRNA's in level III office surgeries if the presence of an anesthesiologist was required because it would be unnecessary and cost-prohibitive to pay two anesthesia providers to perform a single surgery. Although the Board and FSA argue that the proposed rule would not completely

eliminate the opportunity for CRNA's to participate in office surgeries because it does not apply to level I and level II office surgeries, this goes merely to the scope of the injury, and not to whether it is real and sufficiently immediate. Moreover, we note that FNA and FANA never asserted that their members had a protected interest in being free from competition. Rather, they claimed that their members had an interest in continuing to provide anesthesia services for level III office surgeries without having to be supervised by anesthesiologists, pointing out that the statute governing CRNA's requires only that they be supervised by a physician licensed pursuant to chapter 458, Florida Statutes, an osteopath licensed pursuant to chapter 459, or a dentist licensed pursuant to chapter 466. See § 464.012(3)&(4), Fla. Stat. (1999). Because the pertinent findings are supported by competent substantial evidence, we affirm the ALJ's holding that FNA and FANA had standing to challenge that portion of proposed rule 64B8-9.009(6)(b)1.a. which requires supervision by an anesthesiologist of the administration of general anesthesia.

III. RULE CHALLENGE ANALYSIS

The petitioner has the burden of going forward in a rule challenge proceeding. § 120.56(2)(a), Fla. Stat. (1999). However, once the petitioner has carried that burden, the agency must demonstrate by the greater weight of the evidence that the rule is not

"an invalid exercise of delegated legislative authority." Id. "Invalid exercise of delegated legislative authority" is defined as follows:

(8) "Invalid exercise of delegated legislative authority" means action which 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 any one of the following applies:

(a) The agency has materially failed to follow the applicable rulemaking procedures or requirements 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;

(f) The rule is not supported by competent substantial evidence; or

(g) The rule imposes regulatory costs on the regulated person, county, or city which could be reduced by the adoption of less costly alternatives that substantially accomplish the statutory objectives.

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 same statute.

§ 120.52(8), Fla. Stat. (1999). See Southwest Fla. Water Mgmt. Dist. v. Save the Manatee Club, Inc., 773 So. 2d 594 (Fla. 1st DCA 2000). The ALJ held that the transfer agreement provision of rule 64B8-9.009(4)(b) and the staff privileges and anesthesiologist provisions of proposed rule 64B8-9.009(6)(b)1.a. all constituted invalid exercises of delegated legislative authority. He concluded that the transfer agreement provision of rule 64B8-9.009(4)(b) was an invalid exercise of delegated legislative authority because it (1) exceeded the Board's grant of rulemaking authority, in violation of section 120.52(8)(b); (2) enlarged, modified, and contravened the specific provisions of law implemented, in violation of section 120.52(8)(c); (3) failed to establish adequate standards for agency decisions, in violation of section 120.52(8)(d); (4) was arbitrary and capricious, in violation of section 120.52(8)(e); (5) was not supported by competent substantial evidence, in violation of section 120.52(8)(f); and (6) restricted competition, in violation of section 455.517, Florida Statutes (1999). He concluded that the portion of proposed rule 64B8-9.009(6)(b)1.a.

that allows physicians to perform level III office surgeries if they have staff privileges at a licensed hospital within reasonable proximity was an invalid exercise of delegated legislative authority because it (1) exceeded the Board's grant of rulemaking authority, in violation of section 120.52(8)(b); (2) enlarged, modified, and contravened the specific provisions of law implemented, in violation of section 120.52(8)(c); (3) failed to establish adequate standards for agency decisions, in violation of section 120.52(8)(d); (4) was arbitrary and capricious, in violation of section 120.52(8)(e); (5) was not supported by competent substantial evidence, in violation of section 120.52(8)(f); and (6) restricted competition, in violation of section 455.517. Finally, he concluded that the portion of proposed rule 64B8-9.009(6)(b)1.a. that requires an anesthesiologist to be present for all level III office surgeries was an invalid exercise of delegated legislative authority because it (1) was arbitrary and capricious, in violation of section 120.52(8)(e); (2) was not supported by competent substantial evidence, in violation of section 120.52(8)(f); (3) imposed unnecessary regulatory costs, in violation of section 120.52(8)(g); and (4) restricted competition, in violation of section 455.517. Appellants dispute all pertinent findings.

A.

Section 120.52(8)(b)&(c)

Section 120.52(8)(b), Florida Statutes (1999), provides that "[a] proposed or

existing rule is an invalid exercise of delegated legislative authority if . . . [t]he agency has exceeded its grant of rulemaking authority, citation to which is required by s. 120.54(3)(a)1."; and section 120.52(8)(c) provides that "[a] proposed or existing rule is an invalid exercise of delegated legislative authority if . . . [t]he rule enlarges, modifies, or contravenes the specific provisions of law implemented, citation to which is required by s. 120.54(3)(a)1." The ALJ concluded that both the transfer agreement provision of rule 64B8-9.009(4)(b) and the portion of proposed rule 64B8-9.009(6)(b)1.a. that allows physicians to perform level III office surgeries if they have staff privileges at a licensed hospital within reasonable proximity were invalid pursuant to these two related provisions. The standard of review by which we determine whether an agency has exceeded its rulemaking authority or enlarged the specific provisions of law purportedly implemented is de novo. See, e.g., State Bd. of Trs. of Internal Improvement Trust Fund v. Day Cruise Ass'n, Inc., 794 So. 2d 696, 701 (Fla. 1st DCA 2001). "[T]he authority to adopt an administrative rule must be based on an explicit power or duty identified in the enabling statute. Otherwise, the rule is not a valid exercise of delegated legislative authority." Southwest Fla. Water Mgmt. Dist. v. Save the Manatee Club, Inc., 773 So. 2d 594, 599 (Fla. 1st DCA 2000). Moreover, "the authority for an administrative rule is not a matter of degree. The question is whether the statute contains a specific grant of legislative authority for the

rule, not whether the grant of authority is specific enough." Id. (emphasis in original).

Accordingly, we must examine the ALJ's conclusions pursuant to these directives.

1.

Rule 64B8-9.009(4)(b)

As authority for rule 64B8-9.009(4)(b), the Board relied on section 458.331(1)(v), Florida Statutes (1999), which authorizes the Board to

establish by rule standards of practice and standards of care for particular practice settings, including, but not limited to, education and training, equipment and supplies, medications including anesthetics, assistance of and delegation to other personnel, transfer agreements, sterilization, records, performance of complex or multiple procedures, informed consent, and policy and procedure manuals.

(Emphasis added.) The ALJ concluded that this language did not provide rulemaking authority for the transfer agreement provision in rule 64B8-9.009(4)(b) essentially because the grant of authority in section 458.331(1)(v) was not specific enough. Section 458.331(1)(v) clearly grants the Board authority to require by rule that physicians performing level II office surgeries who do not have staff privileges to perform the same procedure at a licensed hospital within reasonable proximity have, instead, a transfer agreement with a licensed hospital within reasonable proximity. As Save the Manatee makes clear, whether the grant of authority is specific enough is

beside the point. Accordingly, we conclude that the ALJ erred when he held that rule 64B8-9.009(4)(b) was invalid pursuant to section 120.52(8)(b) and (c).

2.

Proposed Rule 64B8-9.009(6)(b)1.a.
(Staff Privileges)

The Board also relied on section 458.331(1)(v) as authority for that portion of proposed rule 64B8-9.009(6)(b)1.a. which allows physicians to perform level III office surgeries if they have staff privileges at a licensed hospital within reasonable proximity. The ALJ concluded that section 458.331(1)(v) did not provide rulemaking authority for this provision for essentially the same reason that he concluded it did not provide authority for rule 64B8-9.009(4)(b)—because section 458.331(1)(v) is not specific enough. As previously indicated, the degree of specificity of the grant of authority is irrelevant. Here, it is apparent that this portion of proposed rule 64B8-9.009(6)(b)1.a. is intended to make having staff privileges one of several optional methods by which a physician might establish his or her credentials to perform level III office surgery. Section 458.331(1)(v) clearly gives broad, unqualified, rulemaking authority to the Board to establish "standards of practice and standards of care for particular practice settings." It does not specify what those standards should be, or how they should be established, leaving such matters to the discretion of the Board. It seems to us relatively clear that level III office surgery is a "practice setting," and that the staff

privilege provision constitutes a "standard[] of practice [or] standard[] of care." Accordingly, we conclude that the ALJ erred when he held that the portion of proposed rule 64B8-9.009(6)(b)1.a. that allows physicians to perform level III office surgeries if they have staff privileges at a licensed hospital within reasonable proximity was invalid pursuant to section 120.52(8)(b) and (c).

B.

Section 120.52(8)(d)&(e)

Section 120.52(8)(d), Florida Statutes (1999), provides that "[a] proposed or existing rule is an invalid exercise of delegated legislative authority if . . . [t]he rule is vague, fails to establish adequate standards for agency decisions, or vests unbridled discretion in the agency"; and section 120.52(8)(e) provides that "[a] proposed or existing rule is an invalid exercise of delegated legislative authority if . . . [t]he rule is arbitrary or capricious." The ALJ concluded that the transfer agreement provision of rule 64B8-9.009(4)(b) and the portion of proposed rule 64B8-9.009(6)(b)1.a. that allows physicians to perform level III office surgeries if they have staff privileges at a licensed hospital within reasonable proximity were invalid pursuant to both of these related provisions; and that the portion of proposed rule 64B8-9.009(6)(b)1.a. that requires an anesthesiologist to be present for all level III office surgeries was invalid pursuant to paragraph (8)(e). Those portions of the ALJ's conclusions that rest on

findings of fact are subject to a competent substantial evidence standard of review; however, those portions which are interpretations of law are subject to a de novo standard. See Southwest Fla. Water Mgmt. Dist. v. Save the Manatee Club, Inc., 773 So. 2d 594, 597 (Fla. 1st DCA 2000).

1.

Rule 64B8-9.009(4)(b)

The ALJ concluded that rule 64B8-9.009(4)(b) violated section 120.52(8)(d) because it failed to provide guidelines for a hospital's decision to enter into transfer agreements, and section 120.52(8)(e) because hospitals may enter into transfer agreements or not, according to their "sole discretion." We disagree. The rule cannot be vague for failing to provide guidelines for a hospital's decision to enter into transfer agreements because the Board does not possess the authority to dictate such guidelines. The Agency for Health Care Administration is responsible for promulgating rules regulating hospitals. See §§ 395.002(2), 395.1055, 395.10973, Fla. Stat. (1999). Moreover, a rule is "arbitrary" only if it is "not supported by facts or logic," and "capricious" only if it is irrational. Bd. of Clinical Lab. Pers. v. Fla. Ass'n of Blood Banks, 721 So. 2d 317, 318 (Fla. 1st DCA 1998). We fail to see how the fact that hospitals may have discretion to enter into transfer agreements makes this rule either "not supported by facts or logic" or irrational. Accordingly, we conclude that

the ALJ erred when he held that rule 64B8-9.009(4)(b) violated section 120.52(8)(d) and (e).

2.

Proposed Rule 64B8-9.009(6)(b)1.a.
(Staff Privileges)

The ALJ concluded that the portion of proposed rule 64B8-9.009(6)(b)1.a. that allows physicians to perform level III office surgeries if they have staff privileges at a licensed hospital within reasonable proximity "fail[ed] to establish adequate standards for agency decisions" in violation of section 120.52(8)(d) and was "arbitrary" in violation of section 120.52(8)(e) because the determination of who might have staff privileges was left to each hospital's own judgment, and a hospital might exercise its judgment in a manner not related to physician competency. We disagree. This conclusion was based upon the flawed legal premise that a hospital's long-recognized discretion in granting staff privileges permits a hospital to exercise that discretion arbitrarily and without any oversight. On the contrary, a hospital's discretion in setting standards for staff privileges is limited by rule, statute, and the state and federal constitutions. See, e.g., Fla. Admin. Code R. 59A-3.217(4) (setting general guidelines for the granting of hospital staff privileges, and providing that standards and procedures should not operate to deny staff privileges in an arbitrary, unreasonable,

or capricious manner); § 395.0191, Fla. Stat. (1999) (setting guidelines for the granting of hospital staff privileges); Hull v. Bd. of Comm'rs of Halifax Hosp. Med. Ctr., 453 So. 2d 519, 524 (Fla. 5th DCA 1984) (while Florida law accords hospitals considerable discretion in setting the standards for staff privileges, that discretion is limited "by the constitutional requirement 'that the standards for privileges be reasonably related to furthering the goal of providing high quality patient care, that the power of the hospital not be exercised in an unreasonably arbitrary and capricious manner and that the decisions of the hospital be subject to judicial review'" (citing Sarasota County Pub. Hosp. Bd. v. Shahawy, 408 So. 2d 644, 647 (Fla. 2d DCA 1981))). Accordingly, we conclude that the ALJ erred when he held that the portion of proposed rule 64B8-9.009(6)(b)1.a. that allows physicians to perform level III office surgeries if they have staff privileges at a licensed hospital within reasonable proximity violated section 120.52(8)(d) and (e).

3.

Proposed Rule 64B8-9.009(6)(b)1.a.
(Anesthesiologist Presence)

Initially, the Board claims that the ALJ abused his discretion by allowing FANA, over objection, to amend its petition during the hearing in DOAH case numbers 00-951RP and 00-1622RP to allege that the portion of proposed rule 64B8-9.009(6)(b)1.a. that requires an anesthesiologist to be present for all level III office

surgeries violated section 120.52(8)(e) because it conflicted with another section of the existing rule requiring patients to be informed of their right to a choice of anesthesia providers. A party is not precluded from amending its petition during the hearing if there is no showing of prejudice to the opposing party. See Key Biscayne Council v. State Dep't of Natural Res., 579 So. 2d 293 (Fla. 3d DCA 1991). The Board does not explain how it was prejudiced by allowing the amendment. Moreover, the ALJ correctly concluded that no prejudice could be shown because the internal consistency of the rule was a pure question of law which did not require discovery or extensive testimony, and the Board was afforded an adequate opportunity to respond because the hearing was continued. Accordingly, we conclude that the ALJ did not abuse his discretion by allowing the amendment.

The ALJ concluded that the portion of proposed rule 64B8-9.009(6)(b)1.a. that requires an anesthesiologist to be present for all level III office surgeries violated section 120.52(8)(e) because it conflicted with existing rule 64B8-9.009(2)(b), which requires a surgeon to maintain a record of a patient's written informed consent reflecting the patient's knowledge that "a choice of anesthesia provider exists, i.e., anesthesiologist, another appropriately trained physician as provided in this rule, a certified registered nurse anesthetist, or physician assistant qualified as set forth in Rule 64B8-30.012(2)(b)(6)." We disagree. Pursuant to the proposed rule, a patient

undergoing level III office surgery may choose either an M.D. anesthesiologist, a D.O. anesthesiologist, or a CRNA supervised by an anesthesiologist. On its face, the proposed rule does not eliminate the option of a CRNA. It merely requires that he or she be supervised by an anesthesiologist. The fact that it may not prove economically practicable to make such a choice does not, as a matter of law, create an internal inconsistency that renders the provision arbitrary or capricious. Accordingly, we conclude that the ALJ erred when he held that the portion of proposed rule 64B8-9.009(6)(b)1.a. that requires an anesthesiologist to be present for all level III office surgeries violated section 120.52(8)(e).

C.

Section 120.52(8)(f)

Section 120.52(8)(f), Florida Statutes (1999), provides that "[a] proposed or existing rule is an invalid exercise of delegated legislative authority if . . . [t]he rule is not supported by competent substantial evidence." After independently weighing and evaluating the evidence presented by the parties, the ALJ concluded that the transfer agreement provision of rule 64B8-9.009(4)(b) and the portions of proposed rule 64B8-9.009(6)(b)1.a. that allow physicians to perform level III office surgeries if they have staff privileges at a licensed hospital within reasonable proximity and require an anesthesiologist to be present for all level III office surgeries were all invalid pursuant

to section 120.52(8)(f) because they were not supported by competent substantial evidence.

The parties disagree as to the intended meaning of the term "competent substantial evidence," as used in section 120.52(8)(f). As our supreme court has observed, the term "competent substantial evidence" has two different meanings. Fla. Power & Light Co. v. City of Dania, 761 So. 2d 1089 (Fla. 2000). When applied by an agency at the fact-finding level, "competent substantial evidence" refers to a standard of proof. Id. at 1091-93 (citing Irvine v. Duval County Planning Comm'n, 495 So. 2d 167 (Fla. 1986)). However, at the appellate level, the term refers to a standard of review, and "is tantamount to legally sufficient evidence." Id. at 1092. In this latter sense, competent substantial evidence has been described as evidence that is "sufficiently relevant and material that a reasonable mind would accept it as adequate to support the conclusion reached." De Groot v. Sheffield, 95 So. 2d 912, 916 (Fla. 1957). Pursuant to this standard, the reviewing body may not reweigh the evidence, make determinations regarding credibility or substitute its judgment for that of the agency, even if the record contains some evidence supporting a contrary view. See, e.g., Dunham v. Highlands County Sch. Bd., 652 So. 2d 894, 896 (Fla. 2d DCA 1995); Panama City Hous. Auth. v. Sowby, 587 So. 2d 494, 497 (Fla. 1st DCA 1991). Appellants argue that "competent substantial evidence," as used in section

120.52(8)(f), is intended to have this latter meaning (i.e., that it refers to a standard of review), and that, therefore, the ALJ improperly reweighed the evidence and substituted his judgment for that of the Board. Appellees respond that, because a rule challenge is a de novo proceeding, the term is intended to refer to a standard of proof, rather than of review.

The parties have cited no case law or legislative history in support of their respective positions, and our independent research has failed to reveal any. However, upon reflection, we believe that appellants' position regarding the legislature's intent is the correct one. Although technically a de novo proceeding, a rule challenge before an ALJ is in many respects similar to certiorari review in circuit court of quasi-judicial action by local governmental agencies. In such cases, the circuit court must review the record to determine whether the agency action is supported by competent substantial (or "legally sufficient") evidence. See, e.g., Fla. Power & Light Co. v. City of Dania, 761 So. 2d 1089, 1092 (Fla. 2000). The circuit court may not reweigh the evidence or substitute its judgment for that of the agency. Id. at 1093. Moreover, we note that, were ALJ's permitted to reweigh the evidence regarding the need for rules, the rulemaking process would be turned on its head. The Division of Administrative Hearings would have the final say regarding the wisdom of agency rules, notwithstanding the special expertise possessed by agencies, and the lack thereof in

the Division. Regulation of trades and professions would be taken from the boards created precisely because they possessed special knowledge and expertise, and placed in the hands of ALJ's. We believe that the legislature intended by its use of the term "competent substantial evidence" to limit the scope of review by ALJ's in rule challenge proceedings to whether legally sufficient evidence exists supporting the agency's proposal. Accordingly, in these proceedings, the ALJ should not have independently reweighed the evidence, assessed the credibility thereof, or substituted his judgment regarding the wisdom of the rules for that of the Board.

Applying what we believe to be the correct standard, it is apparent that rule 64B8-9.009(4)(b) and the challenged portions of proposed rule 64B8-9.009(6)(b)1.a. were supported by competent substantial evidence. More particularly, although there was evidence suggesting the contrary, there was evidence supporting the need for, and efficacy of, transfer agreements. There was also evidence that staff privileges were a valid means of demonstrating physician competence. Finally, there was evidence supporting the requirement that an anesthesiologist be present to supervise all level III office surgeries. Accordingly, we conclude that the ALJ erred when he held that the challenged rules violated section 120.52(8)(f).

D.
Section 120.52(8)(g)

Section 120.52(8)(g), Florida Statutes (1999), provides that "[a] proposed or existing rule is an invalid exercise of delegated legislative authority if . . . [t]he rule imposes regulatory costs on the regulated person . . . which could be reduced by the adoption of less costly alternatives that substantially accomplish the statutory objectives." The ALJ concluded that the portion of proposed rule 64B8-9.009(6)(b)1.a. that requires an anesthesiologist to be present for all level III office surgeries imposed unnecessary regulatory costs in violation of this section because it created a "monopoly" for anesthesiologists for level III office surgeries which would "increase the total cost of a typical in-office plastic or cosmetic surgery procedure between 5 to 10 percent."

To invalidate a rule on the ground that it "imposes regulatory costs on the regulated person . . . which could be reduced by the adoption of less costly alternatives that substantially accomplish the statutory objectives," the challenger must comply with section 120.541(1)(a), Florida Statutes (1999). That provision requires a "substantially affected person" to submit to an agency within 21 days of publication of the notice of proposed action "a good faith written proposal for a lower cost regulatory alternative to a proposed rule which substantially accomplishes the objectives of the law being implemented." Appellants argue that, because nobody submitted such a proposal, section 120.541(1)(c), Florida Statutes (1999), prohibited

the ALJ from declaring the proposed rule an invalid exercise of delegated legislative authority pursuant to section 120.52(8)(g). Appellees present no argument to the contrary. We agree with appellants. Accordingly, we conclude that the ALJ erred when he held that the portion of proposed rule 64B8-9.009(6)(b)1.a. that requires an anesthesiologist to be present for all level III office surgeries violated section 120.52(8)(g).

E.

Section 455.517

Section 455.517, Florida Statutes (1999), which falls under part II of chapter 455, governing the Department of Health, provides in pertinent part:

(4)(a) Neither the department nor any board may create unreasonably restrictive and extraordinary standards that deter qualified persons from entering the various professions. Neither the department nor any board may take any action that tends to create or maintain an economic condition that unreasonably restricts competition, except as specifically provided by law.

(b) Neither the department nor any board may create a regulation that has an unreasonable effect on job creation or job retention in the state or that places unreasonable restrictions on the ability of individuals who seek to practice or who are practicing a profession or occupation to find employment.

See also §455.201, Fla. Stat. (1999) (identical statute applying to the Department of

Business and Professional Regulation under part I of chapter 455). The ALJ concluded that the transfer agreement provision of rule 64B8-9.009(4)(b) and the portions of proposed rule 64B8-9.009(6)(b)1.a. that allow physicians to perform level III office surgeries if they have staff privileges at a licensed hospital within reasonable proximity and require an anesthesiologist to be present for all level III office surgeries all violated section 455.517(4).

Initially, appellants argue that the ALJ's conclusions in this regard were erroneous because standing to challenge a proposed rule on the ground that it unreasonably restricts competition in violation of section 455.517(4) is granted exclusively to the Secretary of the Department of Health by section 455.544(1), Florida Statutes (1999), which provides:

(1) The secretary of the department shall have standing to challenge any rule or proposed rule of a board under its jurisdiction pursuant to s. 120.56. In addition to challenges for any invalid exercise of delegated legislative authority, the administrative law judge, upon such a challenge by the secretary, may declare all or part of a rule or proposed rule invalid if it:

(a) Does not protect the public from any significant and discernible harm or damages;

(b) Unreasonably restricts competition or the availability of professional services in the state or in a significant part of the state; or

(c) Unnecessarily increases the cost of professional services without a corresponding or equivalent benefit.

However, there shall not be created a presumption of the existence of any of the conditions cited in this subsection in the event that the rule or proposed rule is challenged.

See also § 455.211(1), Fla. Stat. (1999) (identical statute applying to the Department of Business and Professional Regulation under part I of chapter 455). However, nothing in section 455.544(1) explicitly provides that only the Secretary of the Department of Health has standing to challenge a rule on the ground that it unreasonably restricts competition in violation of section 455.517. The parties have cited no case law or legislative history directly bearing on this issue, and our independent research has failed to reveal any. But see Cole Vision Corp. v. Dep't of Bus. & Prof'l Regulation, 688 So. 2d 404 (Fla. 1st DCA 1997) (addressing the merits of a rule challenge brought pursuant to section 455.201(4) by a substantially affected person other than the Secretary of the Department of Business and Professional Regulation without discussing standing). Upon reflection, because we find nothing in section 455.544(1) suggesting an intent to restrict standing to only the Secretary of the Department of Health, and because section 455.517 itself contains nothing to suggest such a limitation, we conclude that the legislature intended that any "substantially affected" person (as that term is used in section 120.56, Florida Statutes) may challenge any rule of the Board which violates section 455.517(4) as exceeding the

Board's rulemaking authority and, therefore, an invalid exercise of delegated legislative authority pursuant to section 120.52(8)(b).

1.

Rule 64B8-9.009(4)(b)

The ALJ concluded that the transfer agreement provision of rule 64B8-9.009(4)(b) allowed a hospital and its medical staff to control the practice of physicians against whom the hospital or members of its staff compete. This control, he concluded, "tend[ed] to create . . . an economic condition that unreasonably restricts competition" and places "unreasonable restrictions on the ability of individuals who seek to practice . . . to find employment" in contravention of section 455.517(4)(a) and (b). We disagree. Even though the transfer agreement provision had been in existence since 1994, no testimony was presented that hospitals were, in fact, using transfer agreements to control the medical practice of office surgeons. A number of office surgeons testified that some hospitals had entered into transfer agreements with them, while others had not. None of them testified that their ability to perform level II office surgeries had been adversely affected in any way because of the provision. Accordingly, we conclude that the ALJ's holding that the provision violates section 455.517(4) is not supported by competent substantial evidence and that, therefore, he erred.

2.
Proposed Rule 64B8-9.009(6)(b)1.a.
(Staff Privileges)

The ALJ concluded that the portion of proposed rule 64B8-9.009(6)(b)1.a. that allows physicians to perform level III office surgeries if they have staff privileges at a licensed hospital within reasonable proximity allowed hospitals to determine unilaterally which physicians qualify for staff privileges, thereby allowing a hospital and its medical staff to control the medical practice of physicians against whom the hospital or members of its staff compete. This control, he concluded, "tend[ed] to create . . . an economic condition that unreasonably restricts competition" and places "unreasonable restrictions on the ability of individuals who seek to practice . . . to find employment" in contravention of section 455.517(4)(a) and (b). We disagree. Even though a hospital staff privilege requirement has been in existence since 1994, no testimony was presented that hospitals were, in fact, using staff privileges to control the medical practice of office surgeons. A number of office surgeons testified that they had received staff privileges from some hospitals and been denied them by others. None of them testified that their ability to perform level III office surgeries had been adversely affected in any way as a result of the requirement. Moreover, the ALJ failed to consider the fact that the proposed rule has dropped the "requirement" of staff privileges, instead making staff privileges merely one means of establishing a

physician's credentials to perform level III office surgery. If there is no longer any "requirement" that physicians have hospital staff privileges to perform level III office surgery, there is no basis on which to conclude that hospitals can control the practice of office surgeons by denying staff privileges. Accordingly, we conclude that the ALJ's holding that the portion of proposed rule 64B8-9.009(6)(b)1.a. that allows physicians to perform level III office surgeries if they have staff privileges at a licensed hospital within reasonable proximity violates section 455.517(4) is not supported by competent substantial evidence and that, therefore, he erred.

3.

Proposed Rule 64B8-9.009(6)(b)1.a.
(Anesthesiologist Presence)

The ALJ concluded that the portion of proposed rule 64B8-9.009(6)(b)1.a. that requires an anesthesiologist to be present to supervise all level III office surgeries unreasonably restricted competition in violation of section 455.517(4). Essentially, he concluded that, if a CRNA had to be supervised by an anesthesiologist during level III office surgery, physicians and patients would never select a CRNA because there is no need to pay for two anesthesia providers to perform the same procedure. This, according to the ALJ, would result in a "monopoly" for anesthesiologists, which would drive up the cost of level III office surgeries. We disagree.

Accepting the ALJ's factual findings as true, they do not establish that the

proposed rule violates section 455.517(4). The findings do not establish that the Board "create[d] unreasonably restrictive and extraordinary standards that deter qualified persons from" becoming CRNA's; "create[d] or maintain[ed] an economic condition that unreasonably restricts competition"; or "create[d] a regulation that has an unreasonable effect on job creation or job retention in the state or that places unreasonable restrictions on the ability of individuals who seek to practice or who are practicing a profession or occupation to find employment." Moreover, even if the proposed provision does have the effect of restricting competition in the provision of anesthesia services for level III office surgeries, such a restriction would not be unreasonable because, as previously discussed, there was competent substantial evidence to support the Board's determination that anesthesiologists should supervise CRNA's in level III office surgeries. Furthermore, the proposed provision has no effect whatsoever on the ability of CRNA's to administer anesthesia in hospitals, ambulatory surgical centers, and level I and II office surgeries. Uncontradicted testimony was presented that there is a high demand for the services of CRNA's in all of these practice settings. Accordingly, we conclude that the ALJ's holding that the portion of proposed rule 64B8-9.009(6)(b)1.a. that requires an anesthesiologist to be present for all level III office surgeries violates section 455.517(4) is not supported by competent substantial evidence and that, therefore, he erred.

IV. CONCLUSION

For the reasons discussed in this opinion, we hold that the ALJ correctly concluded that FNA and FANA had standing to challenge that portion of proposed rule 64B8-9.009(6)(b)1.a. that requires an anesthesiologist to be present to supervise all level III office surgeries, but that he incorrectly concluded that rule 64B8-9.009(4)(b) and the challenged provisions of proposed rule 64B8-9.009(6)(b)1.a. constituted invalid exercises of delegated legislative authority. Accordingly, we affirm that portion of the final order in DOAH case numbers 00-951RP and 00-1622RP denying the challenges to standing of FNA and FANA. However, we reverse the portions of that order, and of the order in DOAH case number 00-1058RX, that hold that rule 64B8-9.009(4)(b) and the challenged provisions of proposed rule 64B8-9.009(6)(b)1.a. constitute invalid exercises of delegated legislative authority.

AFFIRMED IN PART and REVERSED IN PART.

MINER and WOLF, JJ., CONCUR.