STATE OF FLORIDA
DIVISION OF ADMINISTRATIVE HEARINGS

FLORIDA ACADEMY OF COSMETIC SURGERY, INC.,	)	
Petitioner,	)	
vs.	)	Case No. 05-0402RX
DEPARTMENT OF HEALTH, BOARD OF MEDICINE,	)	
Respondent.	)	

FINAL ORDER

A formal hearing was conducted in this case on April 26, 2005, in Tallahassee, Florida, before Suzanne F. Hood, Administrative Law Judge with the Division of Administrative Hearings.

APPEARANCES

For Petitioner: Alfred W. Clark, Esquire
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For Respondent: Edward A. Tellochea, Esquire
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Department of Legal Affairs
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STATEMENT OF THE ISSUE

The issue is whether Florida Administrative Code Rules 64B-9.0092(2)(f), 64B8-9.0092(4)(a), and 64B8-9.0092(4)(c) constitute invalid exercises of delegated legislative authority as defined by Section 120.52(8), Florida Statutes (2004).

PRELIMINARY STATEMENT

On July 12, 2004, Petitioner Florida Academy of Cosmetic Surgery (FLACS) filed an application for approval as an office surgery accrediting organization pursuant to Section 458.309, Florida Statutes (2004) and Florida Administrative Code Rule 64B8-9.0092. On August 20, 2004, Respondent Department of Health (DOH), Board of Medicine (Board), issued a Notice of Intent to Deny the application.

On or about September 2, 2004, FLACS filed a Petition for Formal Administrative Proceedings pursuant to Sections 120.569 and 120.57(1), Florida Statutes (2004). On September 17, 2004, the Board referred the petition to the Division of Administrative Hearings (DOAH). DOAH assigned the case DOAH Case No. 04-3249.

On September 28, 2004, the undersigned issued a Notice of Hearing, scheduling DOAH Case No. 04-3249 for hearing on December 13, 2004. Pursuant to the Board's unopposed Motion for Continuance dated December 1, 2004, the undersigned rescheduled DOAH Case No. 04-3249 for hearing on February 23 and 24, 2005.

On February 4, 2005, FLACS filed a Petition for an Administrative Determination of the Invalidity of Florida Administrative Code Rule 64B8-9.0092. DOAH assigned the rule challenge DOAH Case No. 05-0402RX.

On February 4, 2005, FLACS filed an unopposed Motion to Consolidate DOAH Case Nos. 04-3240 and 05-0402RX. An Order of Consolidation dated February 15, 2005, granted the motion.

On February 14, 2005, the Board filed an unopposed Motion for Continuance. An Order Granting Continuance and Re-scheduling Hearing was entered on February 17, 2005, rescheduling the hearing for April 25 and 26, 2005.

By letter dated April 18, 2005, the parties advised the undersigned that they required only one day for hearing and requested that the hearing commence on April 26, 2005. The undersigned granted the parties' request via telephonic communication.

During the hearing, the parties offered one joint exhibit, which was accepted as evidence. FLACS presented the testimony of two witnesses and offered four exhibits that were accepted as evidence. The Board presented the testimony of two witnesses and offered five exhibits that were accepted as evidence. At the conclusion of the hearing, the parties agreed to file late-filed depositions and exhibits in lieu of testimony during the hearing.

During the final hearing, the parties also agreed to file separate proposed orders for DOAH Case Nos. 04-3249 and 05-0404RX. Accordingly, the cases are hereby deconsolidated.[1]

On May 13, 2005, the court reporter filed the Transcript of the proceedings.

On May 17, 2005, the Board filed the deposition of Charles E. Grapper, M.D., D.D.S.

On May 19, 2005, the undersigned issued an Order Granting Agreed Motion for Extension of Time to file proposed orders.

On May 27, 2005, FLACS filed the deposition of R. Gregory Smith, M.D.

The Board filed the deposition of Jerry A. Cohen, M.D. and Rina A. Palladino on May 31, 2005, and June 1, 2005, respectively.

On June 13, 2005, the Board filed an unopposed Motion for Extension of Time to file proposed Orders.

FLACS filed its Proposed Final Order on June 21, 2005. The Board filed its Proposed Final Order on June 22, 2005.

All citations hereinafter shall refer to Florida Statutes (2004) unless otherwise indicated.

FINDINGS OF FACT

1. In Florida, physicians who perform certain surgical procedures in their offices are required to register the office with DOH. Additionally, DOH must inspect such offices unless a

nationally recognized accrediting agency or an accrediting organization approved by the Board inspects and accredits the offices every three years. See § 458.309(3), Fla. Stat. and Fla. Admin. Code R. 64B8-0.0091.

2. Florida Administrative Code Rule 64B8-9.0092, entitled "Approval of Physician Office Accrediting Organizations," establishes requirements that FLACS must meet in order to achieve the Board's approval to operate as an accrediting organization. FLACS is the only organization that the Board has ever approved as an accrediting organization.

3. FLACS is a not-for-profit corporation, organized for the following purposes: (a) to promote office safety through its accreditation activities; (b) to promote cosmetic surgery; and (c) to provide continuing education courses related to office surgery. FLACS was formed in 1999 and, since that time, has participated actively in office surgery issues considered by the Board.

4. FLACS began operating as an approved office surgery accrediting organization early in 2001. In January 2003 FLACS filed a complete renewal application, seeking the Board's approval to continue operating as an office surgery accrediting organization. The Board denied the application and, after a formal administrative hearing, entered a Final Order denying FLACS's application. See Florida Academy of Cosmetic Surgery,

Inc. v. Board of Medicine, Case No. DOH-04-0661-FOF-MQA (Final Order, June 18, 2004)(adopting Recommended Order in DOAH Case No. 03-3349, April 15, 2004.)

5. FLACS filed a new application for approval as an office surgery accrediting organization on July 12, 2004. The Board never advised FLACS whether its application was complete or incomplete. There is evidence that a member of the Board's staff, Melinda Grey, reviewed the application, finding it incomplete in many respects.

6. On August 5, 2004, Ms. Grey prepared a spreadsheet entitled "Board of Medicine Staff Issues Regarding FLACS Application." The spreadsheet compared the application with the requirements of the applicable provisions of the Florida Administrative Code, including Florida Administrative Code Rule 64B8-9.0092.

7. Larry McPherson, the Board's Executive Director, was aware that Ms. Grey was reviewing FLACS's application. She did not tell Mr. McPherson that the application was incomplete. Instead, she informed the Board's legal counsel that FLACS had filed the application. Subsequently, Ms. Grey placed the application on the Board's next scheduled meeting agenda.

8. On August 7, 2004, the Board voted to deny the new application. On August 23, 2004, the Board entered an Notice of Intent to Deny FLACS's new application on the following grounds:

1. When participating in accrediting activities in the past, the applicant violated Section 458.331(1)(nn), Florida Statutes, by failing to comply with rules of the Board in the following manner:

a. The applicant failed to provide copies of accreditation reports and corrective action plans to the Board office within 30 days of completion of accrediting activities in violation of Rule 64B8-9.0092(4)(e), Florida Administrative Code.

b. The applicant failed to immediately report to the Department conditions in physicians' offices that posed a potential immediate threat to patients in violation of Rule 64B8-9.0092(4)(f), Florida Administrative Code.

c. When inspecting and accrediting facilities the applicant ignored its written accreditation standards and failed to provide the Board office with accreditation standards under which it was actually operating. Such facts reveal that the applicant operated in violation of Rule 64B8-9.0092(4)(g), Florida Administrative Code.

d. When inspecting the facilities, the applicant operated with inadequate or applied inconsistently its quality assurance program in violation of Rule 64B8-9.0092(4)(a), Florida Administrative Code.

2. The applicant failed to provide evidence of an adequate quality assurance program as required by Rule 64B8-9.0092(4)(a), Florida Administrative Code.

3. The applicant failed to provide evidence of an adequate ongoing anesthesia related accreditation and quality assurance processes as required by Rule 64B8-9.0092(4)(c), Florida Administrative Code.

4. The applicant failed to submit copies of all incident reports filed with the state that originated at FLACS accredited facilities as required by Rule 64B8-9.0092(4)(f), Florida Administrative Code.

Rule 64B8-9.0092(2)(f)--Incident Reports

9. Florida Administrative Code Rule 64B8-9.0092(2)(f) requires an application for approval as an office surgery accreditation organization to include copies of all incident reports filed with the state. The incident reports are defined by Section 458.351(4), Florida Statutes, which reads as follows:

> (4) For purposes of notification to the department pursuant to this section, the term "adverse incident" means an event over which the physician or licensee could exercise control and which is associated in whole or in part with a medical intervention, rather than the condition for which such intervention occurred, and which results in the following patient injuries:
>
> (a) The death of a patient.
>
> (b) Brain or spinal damage to a patient.
>
> (c) The performance of a surgical procedure on the wrong patient.
>
> (d) 1. The performance of a wrong-site surgical procedure;
>
> 2. The performance of a wrong surgical procedure; or
>
> 3. The surgical repair of damage to a patient resulting from a planned surgical procedure where the damage is not a recognized specific risk as disclosed to the patient and documented through the informed-consent process if it results in: death; brain or spinal damage; permanent disfigurement not to include the incision scar; fracture or dislocation of bones or joints; a limitation of neurological, physical or sensory function; or any condition that required transfer of the patient.
>
> (e) A procedure to remove unplanned foreign objects remaining from a surgical procedure.

(f) Any condition that required transfer of a patient to a hospital licensed under Chapter 395, Florida Statutes, from any facility or any office maintained by a physician for the practice of medicine which is not licensed under Chapter 395, Florida Statutes.

10. The incident reports are further defined by Florida Administrative Code Rule 64B8-9.001(1)(a), which states as follows in relevant part:

> . . . an event over which the physician or other licensee could exercise control and which is associated in whole or in part with a medical intervention, rather than the condition for which such intervention occurred, and which results in the following patient injuries:
>
> 1. The death of a patient.
> 2. Brain or spinal damage to a patient.
> 3. The performance of a surgical procedure on the wrong patient.
> 4. The performance of a wrong-site surgical procedure, the performance of a wrong surgical procedure; or the surgical repair of damage to a patient resulting from a planned surgical procedure where the damage is not a recognized specific risk as disclosed to the patient and documented through the informed-consent process and if one of the listed procedures in the paragraph results in: death; brain or spinal damage; permanent disfigurement not to include the incision scar; fracture or dislocation of bones or joints; a limitation of neurological, physical or sensory function; or any condition that required transfer of the patient.
> 5. A procedure to remove unplanned foreign objects remaining from a surgical procedure.
> 6. Any condition that required transfer of a patient to a hospital licensed

under Chapter 395, Florida Statutes, from any facility or any office maintained by a physician for the practice of medicine which is not licensed under Chapter 395, Florida Statutes.

11. FLACS understood that the "incident reports" referenced in Florida Administrative Code Rule 64B8-9.0092(2)(f) are the same as the "reports on adverse incident" defined by Section 458.351, Florida Statutes. FLACS's application specifically references adverse incident reports as defined by Section 458.351, Florida Statutes. FLACS filed two such adverse incident reports with its new application.

12. FLACS has several methods to use in collecting incident reports. First, FLACS requires its accredited physicians and office surgery facilities to attest and acknowledge that they are required to provide FLACS with any and all adverse incident reports related to or following surgery in the accredited offices. Second, FLACS requires the staff of accredited offices to perform self-evaluation surveys after the first and second year of accreditation, said surveys to include such incident reports. Third, FLACS watches for information about adverse incidents as reported by news media or complaints from the public.

13. Most important, FLACS can make quarterly public record searches even though the state system of record keeping for adverse incident reports is not computerized. There is no

persuasive evidence that FLACS ever made an oral or written public records request for copies of incident reports related to its accredited practices.

14. There is no statutory or rule requirement for physicians to file copies of incident reports with their accrediting organization. However, at least two of the nationally recognized accrediting agencies, Joint Commission on Accreditation of Healthcare Organizations (JACHO) and American Association for Accreditation of Ambulatory Surgical Facilities (AAAASF), have provisions in their accreditation manuals related to adverse incidents.

15. JACHO's "Accreditation Manual for Office-Based Surgery Practices," Second Edition (2005), defines a "sentinel event" as follows:

> A sentinel event is an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof. Serious injury specifically includes loss of limb or function. The phrase "or risk thereof" includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome.
>
> Such events are called "sentinel" because they signal the need for immediate investigation and response.
>
> The terms "sentinel event" and "medical error" are not synonymous; not all sentinel events occur because of an error, and not all errors result in sentinel events.

16. JACHO requires each accredited practice to define "sentinel event" for its own purposes in establishing mechanisms to identify, report, and manage these events. JACHO encourages, but does not require, its clients to report "sentinel events" to the accrediting agency within 45 days of the event or of becoming aware of the event. The report should include a root cause analysis and an action plan. If JACHO becomes aware of an unreported "sentinel event," JACHO will advise the accredited practice to prepare and submit the report within a certain time frame. If the accredited practice fails to file an appropriate report within that time frame, JACHO will not revoke accreditation, but will place the accredited practice on an "Accreditation Watch" list.

17. AAAASF's "Standards and Checklist for Accreditaion of Ambulatory Surgery Facilities" contains forms for accredited surgery facilities to use in reporting "unanticipated sequela." The forms refer one to AAAASF's "Quality Assurance and Peer Review Manual" for questions relative to their completion. The record indicates that "unanticipated sequela" are the equivalent of adverse incident reports, including but not limited to, events that result in unplanned hospital admissions.

18. In Florida, physicians are required to file adverse incident reports with DOH's Consumer Services Unit (CSU), which is part of DOH's Medical Quality Assurance Program. On at least

a quarterly basis, the Board's staff requests CSU to provide it with copies of adverse incident reports filed during a certain time frame.

19. The staff of the CSU has access to medical consultants who review the incident reports to determine whether there might have been a violation of law or a violation of a standard of care. If so, the matter is referred for further investigation, determination of probable cause, and possible disciplinary prosecution by the Board.

20. The Board's staff places the incident reports in physician registration files and in office surgery inspection/accreditation files. The Board's staff also places copies of incident reports involving physicians or facilities in the respective file of their accrediting agency or accrediting organization.

21. The Board's staff provides copies of adverse incident reports to DOH's state inspectors before they make office inspections of non-accredited facilities or facilities formerly accredited by a national agency or FLACS. The state inspector/risk manager uses the incident reports during inspections to recommend improvements so that such incidents can be avoided in the future.

22. The Board's Surgical Care Committee, uses the incident reports for statistical purposes. The Surgical Care Committee

reviews the reports to determine whether changes need to be made in administrative rules, including but not limited to, rules related to standard of care or physician registration.

23. It is important for FLACS to be aware of adverse incident reports filed by its accredited physicians and office-surgery facilities. Such reports are an essential part of any accreditation program. Without such knowledge, FLACS cannot be assured that its accredited physicians and offices are taking steps to prevent such incidents from occurring in the future. Moreover, if FLACS is not aware of the adverse incidents occurring in the offices it inspects, FLACS cannot implement changes in its policies to improve the accreditation process.

24. The Board has no policy or practice for routinely sharing incident reports with accrediting organizations. Nevertheless, requiring FLACS to file copies of incident reports with the Board could alert the Board to incidents that were known to FLACS but never reported to the state and vice versa. As stated above, FLACS could make routine public records requests for copies of reports filed with the Board but not reported directly to FLACS.

Rule 64B8-9.0092(4)(a)--Quality Assurance Program

25. Florida Administrative Code Rule 64B8-9.0092(4)(a) requires an accrediting organization to "have a mandatory quality assurance program approved by the Board of Medicine."

Though it is not apparent on the face of the rule, this provision relates to an "internal" quality assurance program used by the accrediting organization, not a quality assurance program implemented at a physician's office.

26. The rule does not define a quality assurance program or describe the required contents of a quality assurance program necessary to achieve the Board's approval. There are no forms or instructions to provide guidance in designing an such a program.

27. Mr. McPherson testified that FLACS could have used the quality assurance programs of national accrediting agencies as a reference when designing its own program. The greater weight of the evidence indicates that the "internal" quality assurance programs of national agencies are proprietary and not available to the public.

28. Public information from JACHO and AAAASF relates to the ways that they monitor the quality assurance programs of the offices they inspect. For example, JACHO's manual discusses quality management issues for accredited practices, including standards, elements of participation, and the rationale that supports each. There is no evidence to show what internal steps the national agencies take to assure the quality of their programs apart from monitoring the programs of the accredited practices. Therefore, the Board could not have compared FLACS's

"internal" quality assurance program and processes with the "internal" quality assurance programs and processes of the national accrediting agencies.

29. During the hearing, the Board presented expert testimony about quality assurance programs in general. The expert testified that a generic quality assurance program for healthcare providers requires the following: (a) identification of positive outcomes that one desires; (b) identification of undesired negative outcomes based on the service and risk profile of the facility; (c) evaluation of accrued adverse incidents to identify trends; and (d) identification of ways to prevent future problems.

30. The Board's quality assurance expert based his testimony on the standards published by the Center for Medicare and Medicaid Services (CMS). The description of a quality assurance program in the CMS document forms a skeleton for national accreditation programs such as the AAAASF, JACHO, and the Accreditation Association for Ambulatory Health Care (AAAHC). The rule does not reference CMS, JACHO, AAAASF, or AAAHC as having established models for an "internal" mandatory quality assurance program that the Board would approve.

31. FLACS's office quality improvement plan compares favorably to the one established by AAAASF in some respects. For instance FLACS requires its accredited physicians and

offices to perform a random chart screen of five cases on a quarterly basis. AAAASF requires a minimum of six cases per surgeon utilizing a facility or two percent of all cases in a group practice every six months.

32. AAAASF requires its clients to engage in a peer review process at least every six months. The review is done by a recognized peer review organization or a medical doctor other than the operating room surgeon. FLACS does not require peer review evaluations due to concerns that peer review documents would be subject to discovery in legal proceedings in Florida.

Rule 64B8-9.0092(4)(c)--Ongoing Anesthesia-related Accreditation and Quality Assurance Processes Involving the Active Participation of Anesthesiologists

33. Florida Administrative Code Rule 64B8-9.0092(4)(c) requires an accrediting organization to have "ongoing anesthesia-related accreditation and quality assurance processes involving the active participation of anesthesiologists." The Board did not base its denial on FLACS's anesthesia-related accreditation standards and quality assurance processes required by Florida Administrative Code Rule 64B8-9.0092(4)(b). Instead, the denial is based upon the requirement for "active participation of anesthesiologists."

34. The Board has no standards that describe or define the "active participation of anesthesiologists." There is no

evidence that shows how the Board applied this requirement to FLACS's application. There are no forms or instructions to provide guidance for an applicant attempting to show the ongoing active participation of anesthesiologists. There is no evidence regarding the participation of anesthesiologists in ongoing anesthesia-related accreditation and quality assurance processes of national accreditation agencies.

35. FLACS has an Anesthesia Review Committee, which is made up of three participating anesthesiologists, FLACS's inspectors, and FLACS's Executive Director. The committee meets quarterly to discuss current issues involving office surgery anesthesia, any anesthesia incidents involving FLACS's accreditees, new pharmacological agents available for outpatient anesthesia and, when available, additional information such as incident reports involving anesthesia mishaps of physicians who are not FLACS's accreditees.

36. The Anesthesia Review Committee keeps written minutes. FLACS's Board of Directors reviews the minutes during regularly scheduled meeting.

37. The Anesthesia Review Committee is responsible for updating FLACS's Anesthesis Parameters of Care on an annual basis. They also attend FLACS's educational meeting to update members on current practice in outpatient/office surgery anesthesia.

38. The Board's quality assurance expert testified that he could not determine exactly how FLACS's anesthesiologists participated, i.e. what they did and how they came to conclusions. The expert could not say whether the participation of FLACS's anesthesiologists resembled the participation of anesthesiologists in the programs of national accreditation agencies. The expert acknowledged that for a relatively small number of physician's offices with a small number of anesthesia-related problems occurring within those offices, an evaluation of such problems on a quarterly basis might be quite adequate.

CONCLUSIONS OF LAW

39. The Division of Administrative Hearings has jurisdiction over the parties and the subject matter of this proceeding pursuant to Section 120.56, Florida Statutes (2005).

40. FLACS has the burden of proving, by a preponderance of the evidence, that Florida Administrative Code Rules 64B8-9.0092(2)(f), 64B8-9.0092(4)(a), and 64B8-9.0092(4)(c) are invalid exercises of delegated legislative authority as to the objection raised. See § 120.56(3)(a), Fla. Stat.

41. Section 120.56(1)(e), Florida Statutes, provides in pertinent part that "[h]earings held under this section shall be de novo in nature."

42. The parties have agreed and the facts establish that FLACS has standing to bring this rule challenge. FLACS's

application was denied in part based on the Board's reliance upon the challenged rules.

43. Section 120.52(8), Florida Statutes, provides as follows in relevant part:

> (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:
>
> * * *
>
> (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 vest 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.
>
> * * *
>
> 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 provision setting forth general legislative intent or policy. Statutory language granting rulemaking authority shall be construed to extend no further than implementing or interpreting the specific powers and duties conferred by the same statute.

44. Paragraphs (b) and (c) of Subsection 120.58, Florida Statutes, are somewhat similar, but have been held to impose different requirements upon agency rulemaking. Paragraph (8)(b) relates to the adequacy of the grant of rulemaking authority, while paragraph (8)(c) and the "flush left" language relate to the limitations imposed by an agency's enabling statutory authority, which is being implemented. See St. Johns Water Management District v. Consolidated - Tomoka Land Company, 717 So. 2d 72, 81 (Fla. 1st DCA 1998); The Sierra Club v. St. Johns Water Management District, DOAH Case No. 01-0583RP at p. 19 (Final Order, June 16, 2001). The "flush left" language has been described as "a set of general standards to be used in determining the validity of a rule in all cases." See Southwest Florida Water Management District v. Save the Manatee Club, 773 So. 2d 594, 597-598 (Fla. 1st DCA 2000).

45. Florida Administrative Code Rule 64B8-9.0092 states as follows in pertinent part:

> (1) Definitions.

* * *

(b) "Approved accrediting agency or organization" means nationally recognized accrediting agencies: American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF), Accreditation Association for Ambulatory Health Care (AAAHC) and Joint Commission on Accreditation of Healthcare Organization (JACHO). Approved organizations also include those approved by the Board after submission of an application for approval pursuant to this rule.

* * *

(2) Application. An application for approval as an accrediting organization shall be filed with the Board office at 4052 Bald Cypress Way, Bin #C)#, Tallahassee, Florida 32399-3252, and shall include the following information and documents:

* * *

(f) Copies of all incident reports filed with the state.

* * *

(4) Requirements. In order to be approved by the Board, an accrediting organization must comply with the following requirements:

(a) The accrediting agency must have a mandatory quality assurance program approved by the Board of Medicine.

(b) The accrediting agency must have anesthesia-related accreditation standards and quality assurance processes that are reviewed and approved by the Board of Medicine.

(c) The accrediting agency must have ongoing anesthesia-related accreditation and quality assurance processes involving the active participation of anesthesiologists.

Petitioner challenges the validity of Florida Administrative Code Rules 64B8-9.0092(2)(f), 64B8-9.0092(4)(a), and 64B8-9.0092(4)(c).

Section 120.52(8)(b), Florida Statutes

46. FLACS argues that the Board exceeded its rulemaking authority contrary to Section 120.52(8)(b), Florida Statutes, in the following ways: (a) in Florida Administrative Code Rule 64B8-9.0092(2)(f) by requiring an application to include incident reports; (b) in Florida Administrative Code Rule 64B8-9.0092(4)(a) by mandating an requirement for an approved quality assurance program; and (c) in Florida Administrative Code Rule 64B8-9.0092(4)(c) by requiring that an applicant have ongoing anesthesia-related processes involving the active participation of anesthesiologists.

47. The Board does not cite to Section 458.309(1), Florida Statutes, as specific authority for the challenged rules. Section 458.309(1), Florida Statutes, states as follows:

> 458.309 Rulemaking authority.--
> (1) The board has authority to adopt rules pursuant to ss. 120.536(1) and 120.54 to implement the provisions of the chapter conferring duties upon it.

Instead, the Board cites the specific authority of Section 458.309(3), Florida Statutes, which states as follows:

> (3) All physicians who perform level 2 procedures lasting more than 5 minutes and all level 3 surgical procedures in an office

setting must register the office with the department unless that office is licensed as a facility pursuant to chapter 395. The department shall inspect the physician's office annually unless the office is accredited by a nationally recognized accrediting agency or an accrediting organization subsequently approved by the Board of Medicine. The actual costs for registration and inspection or accreditation shall be paid by the person seeking to register and operate the office setting in which the office surgery is performed.

48. Section 120.54(1)(a), Florida Statutes, states as follows:

> 120.54 Rulemaking.--
> (1) GENERAL PROVISIONS APPLICABLE TO ALL RULES OTHER THAN EMERGENCY RULES.--
> (a) Rulemaking is not a matter of agency discretion. Each agency statement defined as a rule by s. 120.52 shall be adopted by the rulemaking procedure provided by this section as soon as feasible and practicable.

49. Any standards that the Board uses to approve or disapprove applicants would constitute rules as defined by Section 120.52(15), Florida Statutes, which states as follows in relevant part:

> (15) "Rule" means each agency statement of general applicability that implements, interprets, or prescribes law or policy or describes the procedure or practice requirements of an agency and includes any information not specifically required by statute or by an existing rule. . . .

50. By locating Section 458.309(3), Florida Statutes, in a statutory section entitled "Rulemaking Authority," the Legislature has necessarily given the Board explicit authority to promulgate the challenged rules. Any other interpretation of the statute would mean that the Board could not establish the standards to be employed when granting or denying approval of office surgery accrediting organizations without violating Section 120.54(1)(a), Florida Statutes.

<u>Section 120.52(8)(c) and the "Flush Left" Language</u>

51. FLACS argues that Florida Administrative Code Rules 64B8-9.0092(2)(f), 64B8-9.0092(4)(a) and 64B8-9.0092(4)(c) enlarge, modify, or contravene the specific provisions to be implemented contrary to Section 120.52(8)(c), Florida Statutes, and the "flush left" language, quoted above. The challenged rules cite Section 458.309(3), Florida Statutes, as the law implemented.

52. Specifically, FLACS asserts that Section 458.351(4), Florida Statutes, and Florida Administrative Code Rule 64B8-9.001(1)(a), quoted above in the Findings of Fact, require physicians to file adverse incident reports. FLACS takes the position that Section 458.309(3), Florida Statutes, does not refer to incident reports or give the Board the power or duty to force accrediting organizations to comply with Section

458.351(4), Florida Statutes, by requiring them to file copies of incident report with their applications.

53. FLACS also asserts that Section 458.309(3), Florida Statutes, does not give the Board the power or duty to mandate the implementation of quality assurance programs or the active participation of anesthesiologist in anesthesia-related accreditation and quality assurance processes.

54. In Section 458.309(3), Florida Statutes, the Legislature did not limit the Board's discretion to decide what applicants must include with their applications or what they must show to achieve approval of their accreditation processes. The Legislature's decision not to spell out the contents of applications or to list all standards the Board must apply before approving applications does not mean that the challenged rules violate Section 120.58(c), Florida Statutes. Section 458.309(3), Florida Statutes, gives the Board the specific power and duty to exercise its discretion in this regard.

Section 120.52(8)(d), Florida Statutes

55. FLACS argues that Florida Administrative Code Rules 64B8-9.0092(2)(f), 64B8-9.0092(4)(a) and 64B8-9.0092(4)(c) violate Section 120.58(8)(d), Florida Statutes, because they are vague, fail to establish adequate standards for agency decisions, and vest unbridled discretion upon the Board.

56. As to Florida Administrative Code Rule 64B8-9.0092(2)(f), FLACS is correct that the rule does not specifically identify incident reports as defined in Section 458.351(4), Florida Statutes, and Florida Administrative Code Rule 64B8-9.001(1)(a). However, FLACS had no trouble identifying the incident reports when it filed two such reports with its application. There is nothing vague about the term "incident reports" in the medical community.

57. The requirement for applicants to file incident reports is very straightforward. If the reports are filed, the accreditation organization meets the requirement and the Board would have no discretion to find otherwise.

58. The requirement for an applicant to include incident reports with its application does not violate Section 120.58(d), Florida Statutes. In fact, FLACS did not assert this argument in its Proposed Final Order.

59. In considering whether Florida Administrative Rules 64B8-9.0092(4)(a) and 64B8-9.0092(4)(c) are vague, one must construe the terms "quality assurance program" and "ongoing anesthesia-related accreditation and quality assurance processes involving the active participation of anesthesiologist" in accordance with the meaning assigned to the terms by the class of persons within the purview of the rule and within the context of the subject matter of the rule. See Southwest Florida Water

Management Dist. v. Charlotte County, 774 So. 2d 903, 915-916 (Fla. 2nd DCA 2001). Given that the challenged rules are meant to regulate office surgery accreditation organizations, the terms must be given the meaning assigned them by individuals who operate such organizations.

60. During the hearing, the Board presented expert testimony that the term "quality assurance program" is judged by a national standard, which originates from CMS and its deemed national healthcare accrediting programs (AAAASF, AAAHC, and JACHO). The Board's expert also opined that the national accrediting agencies express the national standards for quality assurance in different ways. In other words, they do not mirror each other in every detail.

61. It might be possible to determine the national standard for quality assurance programs of office surgery facilities by examining the programs that national accrediting agencies require of their accredited practices. One cannot use the same process to determine the national standard for an "internal quality assurance program" or "ongoing anesthesia-related accreditation and quality assurance processes involving the active participation of anesthesiologists" because the "internal" quality assurance programs and processes of the national accrediting agencies are proprietary.

62. In any event, having a national standard, implemented by national accrediting agencies in different ways, does not eliminate the problem here. In Section 458.309(3), Florida Statutes, the Legislature created three inspection methods for office surgery facilities: (a) inspection by DOH; (b) inspection by a nationally recognized accrediting agency; and (c) inspection by an accrediting organization approved by the Board. In making a distinction between national agencies and state-approved organizations, the Legislature authorized the Board to establish office surgery inspection standards, i.e. something other than the national experience per se. However, the challenged rules do not inform applicants whether the Board wants them to use the quality assurance program and processes of a particular national agency as a model, to select parts of the programs and processes from each of the named national agencies, or to design quality assurance programs and processes based entirely on Florida's experience and independent of the national standard.

63. The challenged rules are open-ended and do not provide sufficient information for applicants to know whether their "internal" quality assurance programs and processes are adequate. Accordingly, Florida Administrative Code Rules 64B8-9.0092(4)(a) and 64B8-9.0092(4)(c) are vague and enable the

Board to exercise unbridled discretion in violation of Section 120.52(8)(d), Florida Statutes.

Section 120.52(8)(e), Florida Statutes

64. FLACS argues that Florida Administrative Code Rule 64B8-9.0092(2)(f) is arbitrary and capricious because it requires applicants to file incident reports in violation of Section 120.52(8)(e), Florida Statutes. FLACS asserts that the rule is invalid for the following reasons: (a) the rule enables the Board to deny an application for failing to include incident reports, even though the Board is in possession of the reports and knows which agency or organization accredited the office; (b) there is no statutory requirement for an accrediting organization to file such report; and (c) there is no way for an applicant to know for certain when a physician's office has filed an incident report.

65. FLACS's argument that it is arbitrary or capricious to require applicants to file incident reports is without merit for several reasons. First, the Board uses the requirement as a cross-reference to ensure that physicians are filing the reports with the state. The requirement is important to ensure that every adverse incident reported to an accrediting organization is also reported to CSU.

66. Second, accrediting organizations need to be aware of adverse events that occur in the offices they inspect. Without

such knowledge, accrediting organizations would not be aware of the need to take action to prevent reoccurrence of the event. Regardless of the type of quality assurance programs or processes that applicants employ "internally" or impose on their accredited offices, a minimal requirement would be knowledge of adverse events occurring in those offices.

67. Third, the challenged rule is not arbitrary or capricious because there is no statutory requirement for applicants to file physicians' adverse incident reports. As discussed above, the Board has the power and duty to decide the contents of applications, including incident reports, where consideration of such documents is an important part of evaluating applications, i.e. to ensure that applicants are aware of what is going on in their accredited offices.

68. FLACS has requested an award of fees and costs pursuant to Section 120.595(3), Florida Statutes, which states as follows:

> (3) CHALLENGES TO EXISTING AGENCY RULES PRUSUANT TO section 120.56(3).--If the court or administrative law judge declares a rule or portion of a rule invalid pursuant to s. 120.56(3), a judgment or order shall be rendered against the agency for reasonable costs and reasonable attorney's fees, unless the agency demonstrates that its actions were substantially justified or special circumstances exist which would make the award unjust. An agency's are "substantially justified" if there was a reasonable basis in law and fact at the time

> the actions were taken by the agency. If the agency prevails in the proceedings, the court or administrative law judge shall award reasonable costs and reasonable attorney's fees against a party if the court or administrative law judge determines that a party participated in the proceedings for an improper purposed as defined by paragraph (1)(e). No award of attorney's fees as provided by this subsection shall exceed $15,000.

69. The undersigned reserves jurisdiction to determine the question of an award of fees and costs in this case, pending a motion for such relief and the opportunity for the parties to present facts related to the request.

ORDER

Based on the foregoing Findings of Fact and Conclusions of Law, it is

ORDERED:

1. That the challenge to Florida Administrative Code Rule 64B8-0092(2)(f) is dismissed.

2. That Florida Administrative Code Rules 64B8-9.0092(4)(a) and 64B8-9.0092(4)(c) are invalid exercises of delegated legislative authority.

DONE AND ORDERED this 8th day of August, 2005, in Tallahassee, Leon County, Florida.

SUZANNE F. HOOD
Administrative Law Judge
Division of Administrative Hearings
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Filed with the Clerk of the
Division of Administrative Hearings
this 8th day of August, 2005.

ENDNOTE

1/ The Exhibits and Transcript in DOAH Case No. 04-3249 are located with the record in DOAH Case No. 05-0402RX.

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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 Appeal with the agency clerk of the Division of Administrative Hearings and a copy, accompanied by filing fees prescribed by law, with the District Court of Appeal, First District, or with the District Court of Appeal in the Appellate District where the party resides. The notice of appeal must be filed within 30 days of rendition of the order to be reviewed.