

STATE OF FLORIDA
DIVISION OF ADMINISTRATIVE HEARINGS

FLORIDA ACADEMY OF COSMETIC)
SURGERY, INC.,)
)
Petitioner,)
)
vs.) Case No. 04-3249
)
DEPARTMENT OF HEALTH, BOARD OF)
MEDICINE,)
)
Respondent.)
_____)

RECOMMENDED 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
Post Office Box 623
Tallahassee, Florida 32302-0623

For Respondent: Edward A. Tellochea, Esquire
Office of the Attorney General
Department of Legal Affairs
The Capitol, Plaza Level 01
Tallahassee, Florida 32399-1050

STATEMENT OF THE ISSUE

The issue is whether Respondent properly denied Petitioner's application for approval as an office surgery accrediting organization pursuant to Section 459.309(3), Florida Statutes, and Florida Administrative Code Rule 64B8-9.0092.

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 recommended orders.

FLACS filed its Proposed Recommended Order on June 21, 2005. The Board filed its Proposed Recommended 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," purports to establish requirements that FLACS must meet in order to achieve the Board's approval to operate 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. The Board approved FLACS as an 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 agenda for the Board's next scheduled meeting.

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.

Uncorrected "Prior Errors"

9. After FLACS submitted its January 2003 "renewal" application, the Board's staff met several times with FLACS to discuss and "work out" problems that the Board had with FLACS's office surgery accrediting procedures. These meetings, which took place between January 2003 (when FLACS filed its renewal application) and August 2003 (when the Board denied the renewal application,) were supposed to result in changes to FLACS's inspection procedures and to alleviate the Board's concerns about FLACS' renewal application.

10. Apparently FLACS successfully implemented some changes between the time that the Board denied FLACS's renewal application in August 2003 and the time that the Board issued the June 2004 Final Order in DOAH Case No. 03-3349. There is no evidence in the instant case that FLACS committed the following prior violations: (a) failed to provide DOH with accreditation reports and corrective action plans required by Florida Administrative Code Rule 64B8-9.0092(4)(e); and (b) awarded accreditation retroactive to the inspection date.

11. Despite FLACS's effort to make needed changes in its inspection processes, it failed to do so on several occasions. First, on May 23, 2004, FLACS inspected the office of Anthony Rogers, M.D. Even though Dr. Rogers had one crash cart deficiency (missing the drug isuprel), FLACS's facility

inspection form indicates that Dr. Rogers passed the inspection. FLACS did not receive confirmation that Dr. Rogers was in 100 percent compliance with the Board's rules regarding the mandated crash cart medications until May 27, 2004. FLACS accredited Dr. Rogers on that date based on a packing slip/boxed content list, showing receipt of the isuprel.

12. Second, FLACS inspected the office of Rodolfo Binker, M.D., on May 22, 2004. FLACS's facility inspection form indicates that Dr. Binker passed the inspection even though he was missing intubation forceps (McGill). FLACS did not receive confirmation that Dr. Binker's monitoring and emergency equipment included intubation forceps (McGill) until May 24, 2004. FLACS accredited Dr. Binker that same day based on an invoice, showing that the forceps had been ordered and shipped to Dr. Rogers. The invoice does not indicate the date that Dr. Rogers received the forceps.

13. Third, FLACS prefers for physicians who fail an inspection to verify compliance with the Board's rules by providing FLACS with a packing slip, showing receipt of the missing drugs or equipment. However, the evidence indicates that one of FLACS's inspectors sometimes accepts purchase orders/invoices, which do not show actual receipt of the missing items.

14. Fourth, there is no evidence that FLACS failed to advise DOH about conditions in any physician's office that posed potential immediate jeopardy to patients as required by Florida Administrative Code Rule 64B8-9.0092(4)(f). FLACS's application states that "[a]ll deficiencies, including those which pose potential immediate jeopardy, will be immediately reported to the Department of Health and the Board." However, as a practical matter, FLACS does not believe it is necessary to make such a report as long as it notifies the Board by telephone for any circumstance that it believes constitutes an "immediate threat" to a patient and provides the Board with copies of all inspection materials, facility surveys, and compliance materials on all FLACS accreditations. In other words, unless a patient is in immediate danger, FLACS will leave it to DOH and the Board to review all documentation and determine whether a physician's office poses a "potential immediate threat."

15. Finally, Bruce Hirshman, D.O, is an anesthesiologist who participates in FLACS's ongoing anesthesia-related accreditation and quality assurance processes. At some point in time, FLACS accredited Dr. Hirshman's office surgery facility. As of June 3, 2003, FLACS was aware that Dr. Hirshman had not registered with the Board of Osteopathic Medicine and advised him to do so. FLACS took no further action regarding

Dr. Hirshman's failure to register until May 2005. FLACS's May 5, 2005, letter to Dr. Hirshman, stated as follows in relevant part:

As of April 28, 2004, the Florida Academy of Cosmetic Surgery was informed by Ms. Rina Palladino at the Florida Board of Osteopathic Medicine that you had not registered with the Florida Board of Osteopathic Medicine to perform office surgery. The Florida Academy of Cosmetic Surgery is withdrawing your accreditation .
. . .

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

16. Florida Administrative Code Rule 64B8-9.0092(2)(f) requires an application for approval as an office surgery accrediting organization to include copies of all incident reports that accredited physicians file 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.

17. 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.

18. 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, and Florida Administrative Code Rule 64B8-9.001(1)(a). FLACS's application specifically references adverse incident reports as defined by Section 458.351, Florida Statutes. FLACS provided two such adverse incident reports with its new application: (a) one filed by Fabio Arturo Castro, M.D., from an incident that occurred on November 24, 2003; and (b) one filed by Kurt S. Dangl, M.D., from an incident that occurred on September 25, 2003.

19. The new application did not include the following incident reports that FLACS included with its January 2003 renewal application: (a) one filed by Robert Gregory Smith, M.D., from an incident that occurred on August 16, 2001; and (b) one filed by Rafael A. Fleites, M.D., from an incident that occurred on March 9, 2002.

20. As of July 12, 2004, DOH had received a total of nine (9) office incident reports from doctors' offices that are, or were at the time the incidents occurred, accredited by FLACS. FLACS's accredited physicians did not provide it with the following incident reports: (a) one filed by Michael Patipa, M.D., from an incident that occurred on March 29, 2004; (b) one filed by Constantino F. Mendieta, M.D., from an incident that occurred on February 2, 2004; (c) one filed by Edward J. Gross, M.D., from an incident that occurred on July 22, 2003; (d) one filed by Timothy Fee, M.D., from an incident that occurred on November 11, 2003; and (e) one filed by Ramiro Morales, Jr., M.D., from an incident that occurred on April 9, 2002. The Board's staff discovered that FLACS's application did not provide copies of these five incident reports by reviewing individual physician office registration files.

21. 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.

22. Most important, FLACS can make quarterly public record requests for the reports 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 physicians and office surgery facilities.

23. 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 Organization (JACHO) and American Association for Accreditation of Ambulatory Surgical Facilities (AAAASF), have provisions in their accreditation manuals related to adverse incidents.

24. 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.

25. 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 timeframe. 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.

26. 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.

27. 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 timeframe.

28. 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.

29. 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.

30. 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.

31. 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.

32. 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 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 own policies to improve the accreditation process.

33. 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.

Rules 64B8-9.0092(4)(a) and 64B8-9.0092(4)(c)

34. Florida Administrative Code Rules 64B8-9.0092(4)(a) and 64B8-9.0092(4)(c) were declared invalid in Florida Academy of Cosmetic Surgery, Inc. v. Department of Health, Board of Medicine, DOAH Case No. 05-0402RX (Final Order, August 8, 2005). For the reasons set forth below in the Conclusions of Law, it is unnecessary to report facts related to a mandatory quality assurance program or the ongoing anesthesia-related accreditation and quality assurance processes involving the active participation of anesthesiologists.

CONCLUSIONS OF LAW

35. The Division of Administrative Hearing has jurisdiction over the parties and the subject matter of this

proceeding pursuant to Sections 120.569 and 120.57(1), Florida Statutes (2005).

36. FLACS has the burden of proving by a preponderance of the evidence that it is entitled to approval as an office surgery accrediting organization. See Florida Department of Transportation v. J.W.C. Company, Inc., 396 So. 2d 778 (Fla. 1st DCA 1981).

37. In Florida Academy of Cosmetic Surgery, Inc. v. Department of Health, Board of Medicine, DOAH Case No. 05-0402RX (Final Order, August 8, 2005), the undersigned concluded that Florida Administrative Code Rules 64B8-9.0092(4)(a) and 64B8-9.0092(4)(c) were invalid exercises of delegated legislative authority. Consequently, the Board is precluded from relying upon these rules as a basis for denial of FLACS's present application.

38. Section 458.309(3), Florida Statutes, 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.

39. Section 458.309(3), Florida Statutes, gives the Board authority to approve office surgery accrediting organizations and broad discretion to establish criteria for such approval. However, the statute in its substance does not include a reference to "mandated quality assurance program" or an "ongoing anesthesia-related accreditation and quality assurance processes involving the active participation of anesthesiologists." There is no other statute that addresses the requirements relative to office surgery accrediting organizations. Without the rules held invalid or some statutory language regarding the requirements, the Board cannot deny FLACS's application based on inadequate quality assurance program and/or processes. Accordingly, quality assurance programs and processes are not discussed here.

PRIOR ERRORS

40. One reason for denial of FLACS's application was its failure to correct errors it made when participating in accrediting activities in the past. The relevant period is between the time that the Board denied FLACS's renewal application in August 2003 and the time that the Board issued the June 2004 Final Order in DOAH Case No. 03-3349.

41. There is no evidence that FLACS failed to provide copies of accreditation reports and corrective action plans to the Board in violation of Florida Administrative Code 64B8-9.0092(4)(e), which states as follows:

(e) The accrediting organization shall obtain authorization from the accredited entity to release accreditation reports and corrective action plans to the Board. The accrediting organization shall provide a copy of any accreditation report to the Board office within 30 days of completion of accrediting activities. The accrediting organization shall provide a copy of any corrective action plans to the Board office within 30 days of receipt from the physician office.

FLACS appears to have corrected this past violation.

42. Florida Administrative Code Rule 64B8-9.0092(4)(f) provides as follows:

(f) If the accrediting agency or organization finds indications at any time during accreditation activities that conditions in the physician office pose a potential immediate jeopardy to patients, the accrediting agency or organization will immediately report the situation to the Department.

43. There is no evidence of a situation where FLACS actually failed to report conditions in a physician's office that posed a "potential immediate jeopardy to a patient." However, FLACS admits that its current policy is to notify the Board by telephone as to any "immediate threat" to a patient and otherwise to file all inspection materials with the Board so

that the Board can make the determination whether conditions in a physician's office pose a "potential immediate threat."

FLACS's current policy clearly does not comply with Florida Administrative Code Rule 64B8-9.0092(4)(f) and constitutes a basis for denying FLACS's application.

44. Florida Administrative Code Rule 64B8-9.0092(4)(g) states that "[a]n accrediting agency or organization shall send to the Board any change in its accreditation standards within 30 calendar days after making the change." FLACS has not corrected its prior violations of this rule.

45. After allegedly changing its standards, policies and procedures to address the Board's concerns, FLACS ignored its written accreditation standard, which requires accredited physicians and offices to be in total compliance with all statutes and rules. On at least two occasions FLACS gave passing grades on inspections even though the inspections revealed at least one deficiency for each office. FLACS allowed one physician to remain accredited without being registered from June 2003 through May 2005. FLACS admits that it sometimes relies on purchase order/invoices to verify a physician's compliance with the Board's rules even though the documents do not show receipt of the deficient items. FLACS obviously was not operating under its approved accreditation standards. The

failure to do so constitutes a basis for denial of FLACS's application.

INCIDENT REPORTS

46. Florida Administrative Code Rule 64B8-9.0092(2)(f) requires an application to include copies of all incident reports filed with the state. FLACS provided two such reports with its January 2003 renewal application and two reports with the instant application. FLACS failed to provide copies of another five incident reports that its accredited physicians had filed with the Board.

47. FLACS argues that the Board cannot disapprove the application for failing to include all nine incident reports that FLACS's accredited physicians filed with the Board. In support of this argument, FLACS relies on Section 120.60, Florida Statutes, which states as follows in relevant part:

(1) Upon receipt of an application for a license, an agency shall examine the application and, within 30 days after such receipt, notify the applicant of any apparent errors or omissions and request any additional information the agency is permitted by law to require. An agency shall not deny a license for failure to correct an error or omission or to supply additional information unless the agency timely notified the applicant within this 30 day period.

* * *

(3) Each applicant shall be given notice either personally or by mail that the agency intends to grant or deny, or has granted or denied, the application for license. The notice must state with particularity the grounds or basis for the issuance or denial of the license, except when issuance is a ministerial act

48. In this case, FLACS's application did not contain any apparent omissions on its face. The Board discovered the failure to include all nine incident reports only after the Board's staff reviewed the registration files of FLACS's accredited offices.

49. One of the most important reasons for requiring applications to include copies of incident reports is to demonstrate that the applicants have been diligent in their efforts to review the negative outcomes in accredited offices, to prevent future adverse incidents, and to make improvements in the accreditation process. Informing FLACS that it needed to supplement its application with copies of incident reports might make the application "complete" but would not change the reality that FLACS was unaware of at least five adverse incidents during the critical time for FLACS to determine whether it needed to make changes in its policies or procedures.

50. FLACS cannot be sure that physicians are sending it copies of incident reports unless it makes a public records record to the Board or DOH on at least a quarterly basis. There

is no persuasive evidence that FLACS made such a request during the time that it operated as an approved accrediting organization or before it filed its new application. Under the circumstances of this case, the Board did not violate Section 120.60, Florida Statutes, and was justified in denying FLACS's application.

RECOMMENDATION

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

RECOMMENDED:

That the Board issue a Final Order denying FLACS's application for approval as an office surgery accrediting organization.

DONE AND ENTERED this 9th day of August, 2005, in Tallahassee, Leon County, Florida.



SUZANNE F. HOOD
Administrative Law Judge
Division of Administrative Hearings
The DeSoto Building
1230 Apalachee Parkway
Tallahassee, Florida 32399-3060
(850) 488-9675 SUNCOM 278-9675
Fax Filing (850) 921-6847
www.doah.state.fl.us

Filed with the Clerk of the
Division of Administrative Hearings
this 9th 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.

COPIES FURNISHED:

Alfred W. Clark, Esquire
Post Office Box 623
Tallahassee, Florida 32302-0623

Edward A. Tellochea, Esquire
Office of the Attorney General
Department of Legal Affairs
The Capitol, Plaza Level 01
Tallahassee, Florida 32399-1050

Larry McPherson, Executive Director
Board of Medicine
Department of Health
4052 Bald Cypress Way
Tallahassee, Florida 32399-1701

NOTICE OF RIGHT TO SUBMIT EXCEPTIONS

All parties have the right to submit written exceptions within 15 days from the date of this Recommended Order. Any exceptions to this Recommended Order should be filed with the agency that will issue the Final Order in this case.