STATE OF FLORIDA
DIVISION OF ADMINISTRATIVE HEARINGS

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

Petitioners,

and

FLORIDA ASSOCIATION OF NURSE ANESTHETISTS,

Intervenor,

vs.

Case No. 00-0951RP

DEPARTMENT OF HEALTH, BOARD OF MEDICINE,

Respondent,

and

FLORIDA SOCIETY OF PLASTIC SURGEONS, INC.; FLORIDA SOCIETY OF DERMATOLOGY, INC.; FLORIDA SOCIETY OF ANESTHESIOLOGISTS, INC.; FLORIDA CHAPTER OF AMERICAN COLLEGE OF SURGEONS, INC.; FLORIDA HOSPITAL ASSOCIATION, INC.; ASSOCIATION OF COMMUNITY HOSPITALS AND HEALTH SYSTEMS OF FLORIDA, INC.; and FLORIDA NURSES ASSOCIATION,

Intervenors.

FINAL ORDER

This case, consolidated with DOAH Case No. 00-1622RP, was heard by William R. Pfeiffer, the assigned Administrative Law Judge of the Division of Administrative Hearings, on July 25-27 and August 7-8, 2000, in Tallahassee, Florida.

APPEARANCES

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STATEMENT OF THE ISSUE

The issue in this case is whether the challenged portions of the proposed amendments set forth in the Fourth Notice of Change for Rule 64B8-9.009, Florida Administrative Code (FAC), published in the Florida Administrative Weekly on February 18, 2000, constitute an invalid exercise of delegated legislative authority.

PRELIMINARY STATEMENT

On February 25, 2000, Petitioners, Florida Academy of Cosmetic Surgery, Inc. (FACS), Charles Graper, M.D., D.D.S., FACS (Graper), and R. Gregory Smith, M.D. (Smith) (collectively Petitioners) filed a Petition for Administrative Determination of the Invalidity of a Proposed Rule (Petition). The Petition was assigned DOAH Case No. 00-0951RP. Leave to intervene was granted to the Florida Society of Anesthesiologists, Inc. (FSA), the Florida Association of Nurse Anesthetists (FACA), the Florida Society of Plastic Surgeons, Inc. (FSPS), the Florida Society of Dermatology, Inc. (FSD), the Florida Hospital Association, Inc., and Association of Community Hospitals and Health Systems of Florida, Inc. (collectively Hospitals), the Florida Nurses Association (FNA) and the Florida Chapter of the American College of Surgery (ACS).

On March 8, 2000, Petitioners FACS, Graper, and Smith filed an Amended Petition for Administrative Determination of the Invalidity of a Proposed Rule in DOAH Case No. 00-0951RP.

On April 17, 2000, the FANA filed a Petition to Challenge Proposed Rule challenging the Fourth Notice of Change. It was assigned DOAH Case No. 00-1622RP and was consolidated with DOAH Case No. 00-0951RP on May 4, 2000.

Contemporaneous with the filing of the challenge to the proposed Rule amendment at issue in this case, Petitioners FACS,

Graper, and Smith also filed challenges to several aspects of the Board's existing Rules related to office-based surgery which are contained in Rule 64B8-9.009, Florida Administrative Code. The challenges to the provisions of the existing Rule were assigned DOAH Case No. 00-1058RX and a formal hearing was conducted in that case on June 14-16, and June 21, 2000, before the undersigned Administrative Law Judge. On September 7, 2000, a Final Order was entered in DOAH Case No. 00-1058RX (Final Order) which invalidated certain portions of the Board's existing Rule including the requirements for hospital staff privileges to perform Level III office surgeries and transfer agreements as a precondition to perform Level II office surgeries if the operating physician did not have hospital staff privileges. Among the proposed Rule changes included in the Fourth Notice of Change was a revision to the recently invalidated rule provision regarding staff privileges.

The Amended Petition for an Administrative Determination of the Invalidity of a Proposed Rule filed in the present case (DOAH Case No. 00-0951RP) by Petitioners seeks a determination that the proposed changes to Rule 64B8-9.009 (6)(b)1.a. are an invalid exercise of delegated legislative authority.

During the hearing in this matter, the parties stipulated that the entire record from the earlier proceeding shall be received into evidence. As documented in the rulemaking record,

the clear intent of the Board was to amend the staff privileges requirement and provide additional alternatives for demonstrating sufficient training and competence to perform Level III office surgery. The argument raised in the earlier proceeding must be evaluated in light of the revisions proposed to the hospital staff privileges requirement by the Fourth Notice of Change. The results of that analysis are set forth in the Findings of Fact and Conclusions of Law below.

A formal administrative hearing on the consolidated proposed rule challenge petitions was held on July 25-27 and August 7-8, 2000. At the hearing, Petitioners FACS, Graper, and Smith presented the testimony of Diana Calderone, M.D.; Douglas D. Dedo, M.D.; Anthony Rogers, M.D.; Peggy Bowen, CRNA; Charles Graper, D.D.S., M.D.; William N. Watson, M.D.; and R. Gregory Smith, M.D. Petitioner FANA presented the testimony of Michael B. Pine, M.D.; Mitchell H. Tobin; Kriston J. Kent, M.D.; Sandra Darlng, CRNA; Maria Garcia-Otero, CRNA, EdD.; Robert Barnes, CRNA; and David Rogers, CRNA. The FNA presented the testimony of Barbara Limpkin. The FSPS, FSD, and FCACS presented the testimony of Michael Polakov; Christopher R. Seymour; Mohammed R. Samiian, M.D.; Dean Livingston Johnston, M.D.; Enrique J. Fernandez, M.D.; and Gary Rosenberg, M.D. The FSA presented the testimony of Stephen Thomas Pyles, M.D.; Joseph Franklin Cassady, Jr., M.D.; Rafael Miguel, M.D.;

Andrew Astrove, M.D.; Lee Bailey Massengill; Marilyn Morris; Thomas Wescott Andrews, M.D.; David Craig Mackey, M.D.; Luis Cajina, M.D.; Enrique Murciano, M.D.; and Alan Levine. The Board presented the testimony of Liz Cloud, Georges El-Bahri, M.D., and R. Gregory Smith, M.D. Petitioners' Exhibits numbered 1, 4, 5, 6, 7, 8, 9, and 10 were received into evidence. FANA's Exhibits numbered 1, 2, 3, 4, and 6 were received into evidence. FSPS' Exhibits numbered 1, 2, 4, 5, 6, and 9 were received into evidence.

The Transcript was filed on September 1, 2000. The parties submitted Proposed Findings of Facts and Conclusions of Law which have been considered by the Administrative Law Judge.

FINDINGS OF FACT

Background

1. Rule 64B8-9.009, Florida Administrative Code, is the Board's Rule governing the standards of care for office surgery. The Rule was first adopted on February 1, 1994 as a Rule 61F6-27.009, Florida Administrative Code. It was transferred to Rule 59R-0.009, Florida Administrative Code, and was amended on May 17, 1994; September 8, 1994; and November 15, 1994, and then was finally transferred to Rule 64B8-9.009, Florida Administrative Code.

2. In February of 1998, the Board directed its Surgical Care Committee to evaluate Rule 64B8-9.009 and to make

recommendations for any modifications or amendments to the Rule. The 1998 Florida Legislature also addressed the issue of office-based surgery and provided that the Board may "establish by rule standards of practice and standards of care for particular practice settings . . . " including office-surgery environments. As discussed below, hearings were conducted by the Board and its Surgical Care Committee to consider changes to the office surgery rule.

The Parties

R. Gregory Smith, M.D., Charles Graper, D.D.S., M.D. and Florida Academy of Cosmetic Surgery

3. Petitioner R. Gregory Smith, M.D., is a licensed medical doctor practicing in Ponte Vedra Beach, Florida. Smith practices cosmetic surgery, plastic surgery, and oralmaxillofacial surgery in his office. Smith has a dental degree from Ohio State University College of Dentistry, a residency in oral and maxillofacial surgery and a degree in medicine.

4. Approximately 30 percent of FACS members use general anesthesia (Level III) in their office surgery procedures. At least one representative of FACS has attended each public rulemaking hearing relating to proposed Rule 64B8-9.009, Florida Administrative Code. FACS actively participated in the rulemaking process, expressing concerns relating to transfer

agreements, hospital privileges, and the requirement for an anesthesiologist in Level III surgery. FACS' purposes include addressing adverse outcomes in the field of cosmetic surgery and implementing recommended approaches to improve patient safety.

5. Petitioner Charles E. Graper, D.D.S., M.D., is a Florida licensed medical doctor and dentist practicing in Gainesville, Florida. Graper received his doctorate in dental surgery from Emory University in 1971, his medical degree from Hahnemann University Medical School in 1983, and received one year of post-graduate training in general surgery at Orlando Regional Medical Center. Graper is Board-certified by the American Board of Oral and Maxillofacial Surgery, Board-certified in general cosmetic surgery, Board-eligible in general plastic surgery, and is a Fellow of the American College of Surgeons.

6. Graper performs in his office cosmetic surgery, functional surgery, and surgery below the head and neck which would not be authorized by his dental license. Graper has been practicing cosmetic surgery for 20 years and has been teaching cosmetic surgery for 15 years. Graper has experience in performing Level III office surgery using general anesthesia.

The Board of Medicine

7. The Board of Medicine (Board) regulates the practice of medicine in Florida, and is the agency that adopted the rule at issue.

The Florida Society of Plastic Surgeons, Inc., Florida Chapter, American College of Surgeons and Florida Society of Dermatologists

8. The FSPS, FCACS, and the FSD are comprised of Florida physicians who practice in the areas of plastic surgery and dermatology.

9. As licensed physicians (M.D.s), members of FSPS, FCACS, and FDS are subject to the regulations promulgated by the Board of Medicine. A substantial number of physician members of the FSPS, the FCACS, and the FSD perform office surgery and are affected by the proposed amendments to Rule 64B8-9.009, Florida Administrative Code.

10. FSPS is a Florida not-for-profit corporation whose 270 members are board-certified plastic surgeons (of the approximately 375 such physicians statewide) licensed in the State of Florida pursuant to Chapter 458, Florida Statutes. FSPS was created and exists for the purposes of promoting plastic surgery as a science and profession. FSPS regularly participates in legislative efforts, rulemaking proceedings, and litigation on behalf of its members, and has participated

throughout the rulemaking process with respect to Florida Administrative Code Rule 64B8-9.009.

11. FCACS is a Florida not-for-profit corporation whose 1400 members are surgeons licensed in the State of Florida pursuant to Chapter 458, Florida Statutes. FCACS was created and exists for the purposes of promoting surgery as a science and profession. FCACS regularly participates in legislative efforts, rulemaking proceedings, and litigation on behalf of its members. Members of the Association, including Petitioner Graper, routinely perform office surgery.

12. FSD is a Florida not-for-profit corporation whose 462 members are board-certified dermatologists licensed in the State of Florida pursuant to Chapter 458, Florida Statutes. FSD was created and exists for the purposes of promoting surgery as a science and profession. FSD regularly participates in legislative efforts, rulemaking proceedings, and litigation on behalf of its members. Members of the Association, including David Allyn, M.D., and Diane Calderone, M.D., routinely perform office surgery.

The Florida Society of Anesthesiologists, Inc., Florida Hospital Association, Inc. and Association of Community Hospitals and Health systems

13. The FSA is a not-for-profit professional membership organization representing approximately 2,000 anesthesiologists

in Florida. FSA members practice in educational institutions, hospitals, ambulatory surgical centers, and physicians' offices.

14. The purpose of the FSA is to provide its members information about anesthesiology and to inform the public about issues related to anesthesiology.

15. The FHA and the ACHHS are nonprofit trade associations which represent over 200 hospitals and health systems. FHA and ACHHS represent member hospitals and health systems on common interests before the branches of government, particularly with respect to regulations that impact the members.

The Florida Nurses Association (FNA)

16. The Florida Nurses Association is a professional association of approximately 7,500 nurses licensed in the state of Florida, including approximately 1,700 advanced registered nurse practitioner (ARNP) members and a substantial number of CRNAs. Among its many purposes, the FNA represents the legal, legislative, and professional practice interests of the members.

The Florida Association of Nurse Anesthetists

17. Petitioner, Florida Association of Nurse Anesthetists (FANA), is a non-profit corporation and professional organization made up of more than 1,600 certified registered nurse anesthetists practicing throughout Florida, many of whom currently provide anesthesia for surgery performed in physicians' offices. As a part of its mission, FANA advocates

its members' interests in legal, legislative, and professional practice issues.

Rule Challenges by FSA and the Hospitals

18. On July 8, 1999, the FSA filed a Petition for Administrative Determination of Invalidity of Proposed Rule challenging portions of the proposed amendments to Rule 64B-8.9009 as set forth in the Second Notice of Change. The FSA's Rule challenge was assigned DOAH Case No. 99-2974RP.

19. Also on July 8, 1999, the Hospitals filed a petition for Administrative Determination of the Invalidity of Proposed Rules challenging portions of the proposed amendments to Rule 64B8-9.009 as set forth in the Second Notice of Change. The Hospitals' Rule challenge was assigned DOAH Case No. 99-2975RP.

20. The Board conducted a third public hearing on the proposed Rule amendments on August 7, 1999.

21. The Board published a Third Notice of Change to the proposed Rule amendments in the August 20, 1999, issue of the Florida Administrative Weekly. None of the changes in the Third Notice of Change related to provisions that were in litigation.

22. On January 12, 2000, the Board, the FSA, and the FSPS filed a Joint Stipulation on provisions of Rule 64B8-9.009, Florida Administrative Code (Joint Stipulation) in DOAH Case No. 99-2974RP. The Joint Stipulation released from FSA's Rule challenge, Case No. 99-2974RP, the majority of the proposed

amendments to Rule 64B8-9.009 and reserved only the proposed amendments to Subsections (1)(e) and (6)(b)1.a. of Rule 64B8-9.009 for challenge.

23. On January 26, 2000, the Hospitals filed a Notice of Partial Voluntary Dismissal in DOAH Case No. 99-2975RP, dismissing their challenge to all proposed amendments to Rule 64B8-9.009, except with respect to Subsections (2)(e), (2)(f), (2)(i), (4)(b)1. and 2. and (6)(b)1.a. and b.

24. In light of the filing of the Joint Stipulation in DOAH Case No. 99-2974RP, and the filing of the Notice of Partial Voluntary Dismissal in DOAH Case No. 99-2975RP, the proposed amendments to Rule 64B8-9.009 were no longer subject to challenge, with the exception of the proposed changes to Subsections (1)(e), (2)(e), (2)(f), (2)(I), (4)(b)1., (4)(b)2., (6)(b)1.a. and (6)(b)1.b. Accordingly, on January 28, 2000, the Board filed the proposed amendments to Rule 64B8-9.009 that were no longer subject to challenge with the Department of State for Adoption. The Board subsequently conducted an additional public meeting and published a fourth notice of change relating to the proposed amendments to Rule 64B8-9.009 still subject to challenge by the FSA and the Hospitals. These changes included the withdrawal of the proposed amendments to Subsection (4)(b)1. which would have changed "transfer agreement" to "transfer protocol." During this public meeting, the Board was informed

that those parts of the Rule no longer being challenged had been filed with the Department of State.

25. On January 28, 2000, the Board filed all of its proposed amendments to Rule 64B8-0.009, with the exception of the amendments to Subsections (1)(e), (2)(e), (2)(f), (2)(i), (4)(b)1. and 2., and (6)(b)1.a-b, for adoption with the Florida Secretary of State. The proposed amendments filed for adoption on January 28, 2000, became effective February 17, 2000.

26. The Board voted to modify some of the proposed amendments to Rule 64B8-9.009 still subject to challenge at its public meeting on February 5, 2000.

27. The FSA filed a Notice of Voluntary Dismissal of its Rule challenge in DOAH Case No. 99-2974RP on February 7, 2000.

28. DOAH case No. 99-2974RP was closed on February 8, 2000.

29. The Hospitals filed a Notice of Voluntary Dismissal of their Rule challenge in DOAH Case No. 99-2975RP on March 9, 2000, and the case was closed on March 10, 2000.

30. The Fourth Notice of Change was published in the February 18, 2000, issue of the Florida Administrative Weekly noticing the changes to proposed amendments to Rule 64B8-9.009 voted on by the Board at its February 5, 2000, meeting.

31. On February 25, 2000, the FACS, Graper, and Smith filed a Petition for an Administrative Determination of the

Invalidity of a Proposed Rule challenging the Board's proposed changes to Subsection (6)(b)1.a. of Rule 64B8-9.009 as published in the Fourth Notice of Change. This petition was assigned DOAH Case No. 00-0951RP.

32. On March 8, 2000, the FACS, Graper, and Smith filed an Amended Petition for an Administrative Determination of the Invalidity of a Proposed Rule in DOAH Case No. 00-0951RP challenging the Board's proposed withdrawal of the proposed changes to Subsection (4)(b)1. of Rule 64B8-9.009 and the proposed changes to Subsection (6)(b)1.a. of Rule 64B8-9.009 as published in the Fourth Notice of Change.

33. The Board held a public hearing on April 8, 2000, in Orlando, Florida, and received testimony concerning the Fourth Notice of Change. At the conclusion of the hearing, the Board voted to adjourn without making any changes in the Fourth Notice of Change.

34. On April 17, 2000, the FANA filed its petition challenging the Board's Fourth Notice of Change. The FANA's petition was assigned DOAH Case No. 00-1622RP.

35. DOAH Case Nos. 00-0951RP and 00-1622RP were consolidated by Order of the Administrative Law Judge issued May 4, 2000.

36. The Fourth Notice of Change states that "[t]he proposed changes to Subsection (4)(b)1., shall be withdrawn."

37. With respect to Subsection (6)(b)1.a. of Rule 64B8-9.009, the Fourth Notice of Change states:

> Proposed Subsection (6)(b)1.a. shall be changed to 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.

38. Petitioners have challenged the Fourth Notice of Change on the following grounds: (1) the requirement that an anesthesiologist be present for all Level III surgeries in physicians' offices will increase the cost and limit surgical procedures and practice opportunities of Petitioners resulting in a substantial adverse financial impact on Petitioners and patients; (2) the Fourth Notice of Change exceeds the Board of

Medicine's rulemaking authority by attempting to regulate nurse anesthetists; (3) the Fourth Notice of Change conflicts with existing statutes governing the practice of nurse anesthetists; (4) the rule is arbitrary and capricious and is not supported by competent evidence and is inconsistent with the law and policies of the federal government and of 49 states; (5) the Fourth Notice of Change is not supported by competent substantial evidence and would not have any measurable effect on patient safety; (6) the Rule was improperly adopted; and (7) that the Fourth Notice of Change conflicted with the existing requirement to provide a choice of anesthesia providers. Each of these arguments is addressed below.

Final Order in DOAH Case No. 00-1058RX

39. The Final Order in DOAH Case No. 00-1058RX invalidated certain existing Rule requirements related to transfer agreements and hospital staff privileges as a precondition for certain office surgeries. Specifically, that Final Order invalidated Subsection (4)(b) of Rule 64B8-9.009, which required a transfer agreement for any physician performing Level II office surgery who did not have staff privileges to perform the same procedure at a licensed hospital.

40. In addition, the Final Order invalidated Subsection (6)(b) of Rule 64B8-9.009 which required a physician performing Level III office surgery to have hospital staff privileges for

the procedure performed in an out-patient setting. As grounds for invalidating the staff privileges requirement, the Administrative Law Judge determined that the Board lacked specific statutory authority to mandate hospital privileges, thereby exceeding its grant of rulemaking authority. The Final Order further determined that the requirement for hospital privileges was arbitrary, deferred credentialing to individual hospitals, and was not supported by competent substantial evidence. During the prior hearing, the parties did not present specific argument related to, nor did the Final Order consider the proposed changes to the staff privileges requirement set forth in the Fourth Notice of Change due to the separate Rule challenge proceedings.

<u>The Proposed Rule Regarding Competency Demonstration</u>

41. Notwithstanding, Subsection 4 of the Fourth Notice of Change proposes to change Subsection (6)(b)1.a. of Rule 64B8-9.009 to include alternatives to hospital staff privileges as a manner of demonstrating sufficient education, training and competency to perform Level III surgery in an office setting. The proposed change provides that a surgeon who seeks to provide Level III surgery in an office setting can demonstrate training as follows:

> 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 <u>or</u> 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 <u>or</u> must be able to demonstrate to the accrediting organization or to the Department comparable background, training, and experience. (emphasis added)

The proposed Rule at issue in this proceeding continues to provide for the same mechanism of hospital privileges, previously invalidated. The provision remains invalid for the reasons articulated in the previous Final Order.

42. However, the proposed Rule also provides office surgeons with two alternative methods for objectively demonstrating sufficient training and competency through certification by a recognized medical specialty board or through direct demonstration to the Board of Medicine. That provision of the proposed Rule, provides significant flexibility and meaningful options to physicians seeking to perform office surgery. The Board demonstrated that the options are an appropriate approach for the Board to utilize in exercising its delegated regulatory authority and responsibility to adopt education and training standards for the office setting. The Petitioners adequately challenged the provisions and the Board proved the validity of the proposed alternatives by a preponderance of the evidence.

Increased Costs

43. Petitioners contend that the anesthesiologist requirement in the Fourth Notice of Change violates Section 120.52(8)(g), Florida Statutes, by imposing regulatory costs on the regulated person which could be reduced by the adoption of less costly alternatives that substantially accomplish the statutory objectives. Petitioners offered credible evidence indicating that the hourly rates charged by anesthesiologists range from 50 to 100 percent higher than the hourly rates charged by CRNAs for similar procedures.

44. Respondent and Intervenor, FSA, on the other hand, demonstrated that hourly rates varied from market to market within Florida and in a few cases, rates for anesthesiologists were approximately the same as for CRNAs.

45. The evidence is clear, however, that the charges for an anesthesiologist are significantly higher than those for CRNAs for similar procedures. Anesthesiologists possess broader expertise, education, and training. As a result, requiring an anesthesiologist for Level III office surgeries will increase the total cost of a typical in-office plastic or cosmetic surgery procedure between five and ten percent.

46. Furthermore, the evidence demonstrated that although some surgeons periodically use anesthesiologists during Level III office surgery for a variety of reasons, including

availability, complexity of procedure, current health of patient and contractual agreements, most surgeons utilize CRNAs due to the considerable cost savings.

47. Petitioners also claimed that the Rule would create a monopoly in the provision of in-office anesthesia for anesthesiologists and would force hundreds of CRNAs out of office practice.

48. The Fourth Notice of Change applies to Level III surgeries, so it is reasonable to conclude that the need for CRNAs to participate in the performance of Level III surgeries under the supervision of an anesthesiologist will be obviated. Their assistance is unnecessary and cost prohibitive.

49. And although nurse anesthetists would still be permitted to provide Level II anesthesia in the office setting under the supervision of the operating surgeon, the proposed Rule imposes a significant increase in the cost of Level III surgeries and severely decreases competition.

Rulemaking Authority and Conflicting Law

50. Petitioners mistakenly contend that the proposed anesthesiologists requirement exceeds the scope of the Board of Medicine's rulemaking authority and conflicts with existing law. The authority for the Fourth Notice of Change is contained in part in Section 458.33(1)(v), Florida Statutes, which states in pertinent part:

> The Board may 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 manual in order to establish grounds for disciplining doctors.

51. Specifically, Petitioners allege that the Fourth Notice of Change constitutes an impermissible attempt by the Board of Medicine to regulate nurse anesthetists and conflicts with Chapter 464, Florida Statutes, which permits nurse anesthetists to practice under the supervision of any physician, osteopath, or dentist.

52. The parties have stipulated that Florida-certified registered nurse anesthetists are licensed only by the Florida Board of Nursing and are subject to discipline only by the Florida Board of Nursing.

53. In mandating that office surgeons use an anesthesiologist during in-office Level III surgery, the proposed Rule does not directly regulate any nurse or certified registered nurse anesthetist and does not subject the CRNA to any discipline by the Board of Medicine or by the Board of Nursing. Thus, the Rule on its face does not conflict with the

delegated legislative authority to the Board of Medicine for rulemaking in Section 458.331(1)(v).

Federal Law, Scientific Evidence, Arbitrary and Capricious, Competent Substantial Evidence

54. Petitioners contend that the Fourth Notice of Change requiring an anesthesiologist be present during Level III surgery is inconsistent with the laws and policies of the federal government and 49 states, contrary to the overwhelming weight of scientific evidence, arbitrary and capricious, and not supported by competent substantial evidence.

55. There is no evidence that the Fourth Notice of Change is inconsistent with the laws and policies of the federal government. There is no federal law or rule which prohibits any state from establishing its own rules governing the rights of various practitioners to administer or supervise the administration of anesthesia in any particular setting. Federal government regulations defer to state law on this subject unless a state establishes a lower standard of care.

56. While it is insignificant whether any other state currently requires an anesthesiologist to be present for the administration or supervision of general anesthesia in an office setting, some states have considered such requirements, including Pennsylvania and New Jersey.

57. With respect to the scientific evidence presented by the parties, it is clear that there is a lack of competent and substantial evidence to demonstrate an increased level of safety for general anesthesia patients who undergo surgery under the care of an anesthesiologist as opposed to a CRNA.

58. CRNAs are advanced registered nurse practitioners. In addition to their nursing training, CRNAs must have at least one year of experience in a critical care setting (such as working in a hospital intensive care unit) prior to beginning their two-to-three year master's level anesthesia training. Nurse anesthetists typically are trained side by side with physician anesthesia residents, use the same textbooks, and are taught by the same instructors.

59. Unlike physician anesthesiologists who receive a general medical-surgical license that may not require any level of training or expertise in the administration of anesthesia, CRNAs must pass a national certifying examination in anesthesia as a condition of state licensure. In addition, CRNAs must complete 40 hours of continuing anesthesia education every two years, and must be recertified every two years to retain their state license.

60. The evidence suggests that the safety of office surgery is comparable to that of hospitals and ambulatory surgery centers. Moreover, under the existing Rule, the office

surgeon and patient determine the most appropriate anesthesia provider and setting based on the individual patient's needs.

61. The direct testimony and scientific evidence indicate no significant difference in patient outcomes based on whether anesthesia is administered by an anesthesiologist or CRNA. Hence, Florida law and the existing standard of care in Florida permits a surgeon to supervise a CRNA in the office setting. Nearly forty percent of the 1600 CRNA members of FANA provide anesthesia in physicians' offices.

62. Furthermore, the evidence indicates that anesthesiologist supervision of CRNAs in hospitals is extremely inconsistent. "Supervision" as defined by various hospitals requires the anesthesiologists to be within five to thirty minutes of the hospital. Anesthesiologists are often absent for extended periods and typically "supervise" several operating rooms simultaneously. In fact, Federal Medicare regulations permit an anesthesiologist to receive payment for the "medical direction" of as many as four CRNAs at the same time.

63. Moreover, several smaller and often rural hospitals and ambulatory surgical centers in Florida do not have anesthesiologists on staff. CRNAs provide the anesthesia services in those venues.

64. Dr. David Mackey, an anesthesiologist, testified that he had reviewed information on 28 deaths related to office

surgery which occurred between 1987 and 1999. Dr. Mackey concluded that there have been nine deaths resulting from office surgery in the past 12 years in which anesthesia was a cause of death. However, Dr. Mackey was able to confirm that a CRNA provided the anesthesia in only two of the nine cases.

65. Office surgeons and related professional societies agree that an office-based surgeon may safely supervise a CRNA. Currently, there are three national accrediting organizations that may accredit office surgery facilities: Joint Commission on Accreditation for Ambulatory Healthcare Organizations; American Association for Accreditation of Ambulatory Surgery Facilities; and Accreditation Association for Ambulatory Health Care. Rule 64B8-9.0091, Florida Administrative Code. None of these accrediting organizations requires that CRNAs be supervised by an anesthesiologist.

66. No other state currently requires anesthesiologist supervision of CRNAs in an office setting. In fact, Florida's Joint Committee of the Boards of Nursing and Medicine identify specific medical acts that may be performed by ARNPs, and the level of physician supervision required for such acts. Section 464.003(a)(c), Florida Statutes. The Joint Committee does not require anesthesiologist supervision of CRNAs in any setting.

67. The U.S. Armed Forces do not require anesthesiologist supervision of CRNAs in any practice setting. And the American

Society of Anesthesiologists' has published its own "Recommended Scope of Practice for Nurse Anesthetists" which provides for CRNAs to administer anesthesia under the supervision of the operating surgeon.

Studies of Anesthesia Outcomes and Medical Error

68. Michael B. Pine, M.D., a Board-certified cardiologist, former chief of cardiology at Cincinnati Medical school, and a former professor of medicine at Harvard Medical School and two other medical schools, testified as an expert in healthcare quality assessment and improvement. Dr. Pine has served as a healthcare quality assessment and improvement consultant to the JCAHO, the Health Care Financing Administration (HCFA), the American Medical Association (AMA), the American Osteopathic Association, the Hospital Research and Educational Trust of the American Hospital Association, the American Association of Oral and Maxillofacial Surgeons, the American Association of Nurse Anesthetists, Blue Cross/Blue Shield, and Anthem, among others. Dr. Pine characterized his career transition from clinician to consultant as moving from "dealing with diseased individuals to dealing with diseased organizations to help them assess their problems in delivering health care and help them improve and get better."

69. Dr. Pine assisted in the development of clinical indicators for JCAHO, including indicators in anesthesia care.

He has worked with the federal Health Care Financing Administration (HCFA) to measure hospital mortality and adjust for patient severity as an indicator of hospital quality. Dr. Pine's consulting experience includes evaluating outcome data for individual practitioners, groups of providers, and whole systems.

70. Dr. Pine testified that the classic study in anesthesia mortality was a 1950's study by Beecher and Todd of 600,000 anesthetic administrations which were followed by about 8,000 deaths, 325 of which were ultimately determined to be anesthetic related. The study reflects an anesthesia mortality rate of about 1:2,500. In the Beecher and Todd study, nurse anesthetists performed twice as many cases as anesthesiologists, but the number of deaths involving nurse anesthetists was virtually the same as the number of deaths involving anesthesiologists. Beecher and Todd initially hypothesized that the greater mortality rate for anesthesiologists could be explained by the severity of illness of the patients seen by anesthesiologists rather than nurse anesthetists, but after correcting for the difference in severity of illness, they discovered the nurse anesthetists had actually treated patients who were slightly more sick. Beecher and Todd were unable to explain why physician anesthesiologists, who anesthetized only

half as many patients as nurse anesthetists, were involved in an equal number of deaths.

71. Dr. Pine testified that a later study, the Bechtoldt, measured outcomes associated with two million anesthetics in North Carolina between 1969 and 1976. The mortality rate was approximately 1:24,000; a mortality rate ten times better than the rate reflected in the Beecher and Todd study 20 years earlier. The Bechtoldt study compared the outcomes of anesthesiologists working alone, nurse anesthetists working alone, and CRNAs and anesthesiologists working together, the surgeon or dentist administering anesthesia him/herself, and deaths in which no provider could be identified. Bechtoldt concluded that:

> When we calculated the incidence of anesthetic related deaths for each group which administered the anesthetic, we found that the incidence among the three major groups - the CRNA, the anesthesiologist, and the combination of both - to be rather similar. Although the CRNA working alone accounted for about half the anesthesia-related deaths, the CRNA working alone also accounted for about half the anesthetics administered.

72. A 1980 study by Forrest of 17 hospitals and about 10,0000 patents was one of the first studies to make a formal adjustment for the sickness severity of the patients. Using conservative statistical methods, Forrest concluded that "there were no significant differences in outcomes" between the

hospitals that predominately used anesthesiologists and the hospitals that predominately used nurse anesthetists.

73. Anesthesia safety continued to improve as indicated by a British study in the early 1980's, that used a procedure similar to that used by Beecher and Todd in the 1950's. The British study looked at 485,000 surgeries in which anesthesia was provided. There were 4000 deaths, only 3 of which were determined to be anesthetic related, reflecting an anesthesia mortality rate of 1:185,000.

74. The Institute of Medicine report entitled "To Err is Human," published in 1999, reflects an even better anesthesia mortality rate of 1:200,000 to 1:300,000 cases. The Institute of Medicine report states:

> The gains in anesthesia are very impressive and were accomplished through a variety of mechanisms including improved monitoring techniques, the development and widespread adoption of practice guidelines and other systemic approaches to improving errors . . . . the success of anesthesia, was accomplished through a combination of technological changes, new monitoring equipment, standardization of existing equipment, information-based strategies including the development and adoption of guidelines and standards, application of human factors to improve performance such as the use of simulators for training, formation of the Anesthesia Patient Safety Foundation to bring together stakeholders form different disciplines, physicians, nurses, manufacturers, to create a focus for action and having a leader who would serve as a champion for the cause.

75. Dr. Pine also addressed the recent study regarding anesthesia by Silber published in June 2000. This study examined 7,665 deaths following 217,000 hospital procedures for which medical bills were submitted to HCFA for Medicare reimbursement. The study attempted to characterize the type of anesthesia provider based on whether an anesthesiologist submitted a bill for providing anesthesia or supervising the anesthesia. The study assumed that a CRNA administered the anesthesia if either the CRNA billed for it, or if no bill was located. Moreover, instead of reviewing deaths that occurred within 48 hours after the surgery, the study counted all deaths which occurred within 30 days following surgery, and ignored any non-anesthesia related complications and deaths which were included in the 7,665 death toll. Conversely, the 7,665 deaths in 217,000 procedures produce a mortality rate of 1:28, nearly 100 times greater than the mortality rate in the 1950 Beecher and Todd study, and nearly 10,000 times what the 1999 Institute of Medicine study reflected as the anesthetic mortality rate. The greatly inflated and inconsistent death rate is highly questionable and provides little scientific support for the Board's proposed rule.

76. With respect to Petitioners' argument relating to arbitrary and capricious mandate, the proposed Rule would not

permit office-based surgeons to provide a choice of anesthesia provider for Level III office surgeries, since only one anesthesia provider is necessary or justified for Level III office surgery, and the proposed rule mandates the participation of an anesthesiologist. It is unreasonable and not economically feasible for the surgeon or the patient to pay for an anesthesiologist and a CRNA for the same procedure.

77. Based on the current Rule's "choice of anesthesia provider" requirement in subsection (2)(b) of the existing Rule, the proposed anesthesiologist mandate for Level III surgery is inconsistent, confusing and illogical to the reasonable person.

CONCLUSIONS OF LAW

Jurisdiction

78. The Division of Administrative Hearings has jurisdiction over this proceeding. Section 120.56, Florida Statutes. Each of the rule challenges in this consolidated proceeding was properly filed, having complied with the requirements of Section 120.56, Florida Statutes.

Standing

79. Pursuant to Section 120.56(1)(a), Florida Statutes, "any person substantially affected by a rule or a proposed rule may seek an administrative determination of the invalidity of the rule on the ground that the rule is an invalid exercise of delegated legislative authority." In order to meet the

substantially affected test, the Petitioner must establish that, as a consequence of the proposed rule, it will suffer injury in fact and that the injury is within the zone of interested to be regulated or protected. Lanque v. Florida Department of Law Enforcement, 751 So. 2d 94 (Fla. 1st DCA 1999). Petitioners Smith and Graper have standing to challenge the proposed rule.

80. In addition, the Florida Association of Nurse Anesthetists (FANA) and the Florida Nurses Association (FNA) have standing to challenge the proposed rule. Should the Fourth Notice of Change become law, a significant number of CRNAs who are members of FANA and FNA will be displaced from their businesses and from their jobs, creating a potential injury sufficient to meet the highest possible requirement of potential injury set forth in State Board of Optometry v. Florida Society of Ophthalmology, 538 So. 2d 878 (Fla. 1st DCA 1989).

81. Moreover, should the proposed amendments become law, Petitioners will be substantially affected due to the supply of anesthesiologists available for office surgeries, the added cost of such services, the disruption to their practices, and the restriction of their ability to make the best patient care choices for each individual patient. Similarly, the Intervenors Florida Society of Plastic Surgeons, Florida Society of Dermatology, and Florida Chapter, American College of Surgeons, each have standing on behalf of their members. Finally, each of

the association parties meets the criteria for association standing as set forth in Florida Home Builders Association v. Department of Labor and Employment Security, 412 So. 2d 351 (Fla. 1982), as each has shown that (1) a substantial number of its members are affected; (2) that the subject matter is within the association's general scope of interest and activity; and (3) that the relief sought is appropriate for the association to receive on behalf of its members.

82. Respondent, the Florida Society of Anesthesiologists states similarly demonstrated that it is substantially affected by the proposed rule.

83. In addition, the Florida Hospital Association, Inc., and the Association of Community Hospitals and Health Systems of Florida, Inc., have standing to participate in this proceeding.

Burden of Proof

84. The parties have stipulated that the rule revision included in the Fourth Notice of Change are proposed rules. As a result, "the burden of persuasion is on the agency to establish the validity of the proposed rule once it has been properly challenged." St. Johns River Water Management Dist. V. Consolidated-Tomoka Land Co., 717 So. 2d 72 (Fla. 1st DCA 1998). Hence, the Petitioners have the burden of establishing a factual basis for the objections to the rule and the Board has the burden of demonstrating by a preponderance of the evidence that

the proposed rule is a valid exercise of delegated legislative authority.

Standard for Determining the Invalidity of a Rule

85. A rule is an invalid exercise of delegated legislative authority if:

> (a) The agency has materially failed to follow the applicable rulemaking procedures or requirements set forth in Chapter 120;
>
> (b) The agency has exceeded its grant of rulemaking authority, citation to which is required by Section 120.54(3)(a)1;
>
> (c) The rule enlarges, modifies, or contravenes the specific provisions of law implemented, citation to which is required by Section 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.

Section 120.52(8), Florida Statutes.

86. While Section 458.331(1)(v), Florida Statutes, does not authorize the Board of Medicine to regulate or restrict the practice of nursing, the proposed rule does not regulate CRNAs, Item 4 of the Fourth Notice of Change, as it relates to the

mandatory presence of an anesthesiologist, and does not contravene Subsection (c) of Section 120.52(8), Florida Statutes.

The Proposed Rule is Arbitrary and Capricious

87. In order to avoid a finding of invalidity, a rule may not be arbitrary or capricious. Section 120.52(8)(e), Florida Statutes; Grove Isle, Ltd. v. State Department of Environmental Regulation, 454 So. 2d 571 (Fla. 1st DCA 1984); General Telephone Co. of Florida v. Florida Public Service Commission, 446 So. 2d 1063 (Fla. 1st DCA 1984).

88. A rule is considered arbitrary when it is "not supported by facts or logic . . . ." Agrico Chem. Co. v. Department of Environmental Protection, 365 So. 2d 759, 763 (Fla. 1st DCA 1978). A rule is capricious where it is irrational and adopted without thought or reason. See id. If an agency's decision is justifiable under any analysis that a reasonable person would use to reach a decision of similar importance, the agency's decision is neither arbitrary or capricious. See Dravo Basic Materials Co. v. Department of Transp., 602 So. 2d 632, 634n.3 (Fla. 2d DCA 1992).

89. A proposed rule amendment that clearly contradicts a section of the existing rule is inherently illogical.

90. In the case at bar, Subsection (2)(b) of the existing Rule clearly provides 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." However, because two anesthesia providers are unnecessary to perform a single office procedure, it is not reasonable to expect that both an anesthesiologist and a CRNA will be employed for the same procedure.

91. Therefore, the economic burden placed upon the physician and/or the patient of having two anesthesia providers is unreasonable and violative of Section 455.517, Florida Statutes. The relationship between Subsection (2)(b) and the proposed regulation mandating the presence of an anesthesiologist during Level III surgeries also creates an internal inconsistency violative of 120.52(8)(e).

92. Moreover, it is inconceivable that the informed consent section of the rule with which the newly proposed rule provision conflicts is not representative of the intent of the Board of Medicine because the informed consent provision was filed for final adoption only eight days before the proposed rule provision mandating the participation of an anesthesiologist at Level III was adopted by the Board.

93. While the Respondents suggested during the hearing that an anesthesiologist might be willing to lower his charges for anesthesia services if a physician would give the

anesthesiologist the exclusive contract to provide anesthesia services in the office (like the exclusive contracts often given to hospitals), a surgeon may reasonably conclude that he is prohibited from entering into such an agreement by the informed consent requirement.

The Proposed Rule is Not Supported by Competent Substantial Evidence

94. Competent substantial evidence has been described as such evidence as a reasonable person would accept as adequate to support a conclusion. Agrico Chem. Co., 365 So. 2d at 763; see also De Groot v. Sheffield, 95 So. 2d 912, 915 (Fla. 1957)(defining "competent substantial evidence" as "such evidence as will establish a substantial basis of fact from which the fact at issue can be reasonably inferred" and "such relevant evidence as a reasonable mind would accept to support a conclusion.").

95. Documentation considered by the Board in adopting the Fourth Notice of Change and transcripts of numerous days of hearings and meeting conducted by the Board over a 22-month period was admitted into evidence. Based on the full record, there was insufficient scientific medical evidence to support the anesthesiologist mandate for Level III surgery.

96. The proposed regulation mandating the presence of an anesthesiologist during Level III surgeries "is not supported by

competent substantial evidence." Section 120.52(8)(f), Florida Statutes. While there can be no doubt as to the value of the medical school education which anesthesiologists possess and CRNAs lack, the evidence simply does not provide justification for the elimination of CRNAs from the Level III office surgery marketplace. Adverse incidents and deaths, albeit rarely, have occurred during Level III office surgeries while an individual CRNA and an anesthesiologist were providing the anesthesia. However, there is no evidence suggesting that they occur with more frequency under a CRNA's direction. In summary, there is no reliable data demonstrating that Level III office surgery is safer with an anesthesiologist than with a CRNA.

Rulemaking Procedures and Requirements of Chapter 120

97. Petitioners and their Intervenors allege that the Fourth Notice of Change is an "invalid exercise of delegated legislative authority" because the Board failed to follow the applicable rulemaking procedures or requirements of Chapter 120, Florida Statutes. Specifically, Petitioners contend that the Board improperly withdrew the amendments to Rule 64B8-9.009 and proceeded with adoption of the remaining portions of the rule with the Department of State on January 28, 2000. Petitioners contend that rulemaking should have been re-initiated.

98. Section 120.52(8)(a), Florida Statutes, provides that a rule is invalid if the agency has materially failed to follow

the rulemaking procedures of Chapter 120. Applying the standard that clear and unambiguous language must be given its plain, ordinary meaning, "materially" means: "with regard to matter and not to form, to a significant extent or degree." Webster's Third New International Dictionary (1968). The purpose of the steps in the rulemaking process is to ensure that interested persons are aware of the intentions of rulemaking agency, and are given an opportunity to provide substantive input regarding the proposed regulation. Petitioners and their Intervenors have not demonstrated that they were unaware of any portion of the rulemaking process for the instant rule and, indeed, participated in both public and private meetings regarding the rule. The only alleged "failure" by the Board was action taken consistent with the policy of the agency charged with the responsibility to determine if rulemaking procedures have been followed.

99. Section 120.54(3)(e)3., Florida Statutes, states: "At the time a rule is filed, the agency shall certify that the time limitations prescribed by this paragraph have been complied with, that all statutory requirements have been met, and that there is no administrative determination pending on the rule." Section 120.54(3)(e)4., Florida Statutes, further requires the Department of State to reject any rule "upon which an

administrative determination is pending." Section 120.54(3)(e)4., Florida Statutes (1999).

100. The evidence demonstrated that the amendments to Rule 64B8.9.009 filed for adoption with the Department of State on January 28, 2000, were no longer subject to challenge by the FSA and the Hospitals due to the Joint Stipulation and the Notice of Parial Voluntary Dismissal. The amendments to Rule 64B8-9.009 were filed for adoption after consultation with the BAC and JAPC and pursuant to the BAC's policy that unchallenged portions of the proposed rule. Thus, the Board followed applicable rulemaking procedures and requirements of Chapter 120 in adopting amendments to Rule 64B8-9.009 that became effective February 17, 2000, and in proposing the Fourth Notice of Change.

The Proposed Level III Anesthesia Rule is Invalid Because It Unreasonably Restricts Competition

101. In Section 455.517, Florida Statutes, the Florida Legislature has expressed its intent that unreasonable restrictions should not be placed on regulated professions by either the Department of Health or its regulating boards, specifically providing:

> (4)(a) Neither the department nor any board thereof 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.

102. While it is apparent that the proposed rule with regard to the mandatory presence of an anesthesiologist during Level III office surgeries "restricts competition" and places a restriction "on the ability of individuals (i.e., CRNAs) who seek to practice or who are practicing a profession or occupation to find employment," the issue is whether the Board acted unreasonably. Based on the lack of credible scientific evidence supporting the Board's conclusion regarding patient safety and its subsequent rule promulgation, the restrictions are unreasonable and violate Section 455.517, Florida Statutes.

CONCLUSION

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

ORDERED

1. The portion of the first sentence relating to hospital privileges is invalid.

2. The Board proved by a preponderance of the evidence that the remaining portion of the first sentence of proposed

Rule 64B8-9.009(6)(b)1.a. is a valid exercise of delegated legislative authority pursuant to Section 120.56 and is therefore determined to be valid.

3. The second sentence of proposed Rule 64B8-9.009(6)(b)1.a. is valid.

4. The third sentence is invalid.

5. The valid portions of the Rule are as follows:

1. Training required.

a. The surgeon 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.

DONE AND ORDERED this 16th day of November, 2000, in Tallahassee, Leon County, Florida.

WILLIAM R. PFEIFFER
Administrative Law Judge
Division of Administrative Hearings
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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 one copy of a notice of appeal with the Clerk of the Division of Administrative Hearings and a second 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.