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RULE ADOPTION

LAW AND PUBLIC SAFETY

DIVISION OF CONSUMER AFFAIRS

STATE BOARD OF MEDICAL EXAMINERS

SURGICAL AND ANESTHESIA STANDARDS IN PHYSICIANS OFFICES;
ALTERNATIVE PRIVILEGES; COMPLIANCE TIMETABLES;
PROHIBITION ON THE USE OF ANESTHETIC AGENTS OUTSIDE
OF ANESTHETIZING LOCATIONS; REVISIONS OF STANDARDS FOR
NON-INVASIVE SPECIAL PROCEDURES; EMERGENCY CONVERSION TO
GENERAL ANESTHETIC BY CRNAS

Adopted Amendments: N.J.A.C. 13:35-4A.2, 4A.3, 4A.6, 4A.7, 4A.8, 4A.9, 4A.10, 4A.11 and 4A.17

Adopted New Rule: N.J.A.C. 13:35-4A.12

Proposed: November 19, 2001 at 33 N.J.R. 3870(a).

Adopted: November 13, 2002 by the State Board of Medical Examiners, William V. Harrer, M.D., President.

Filed: November 18, 2002 as R.2002 d.404, with substantive and technical changes not requiring additional public notice or comment (see N.J.A.C. 1:30-6.3).

Authority: N.J.S.A. 45:1-15 and 45:9-2.

Effective Date: December 16, 2002.

Expiration Date: September 20, 2004.

Summary of Hearing Officer's Recommendations and Agency Responses:

A public hearing on the proposal was held on December 7, 2001 at the Novotel Hotel in Lawrenceville, New Jersey. William V. Harrer, M.D., presided at the hearing to receive testimony. The Board responses to comments received on the proposal reflect Dr. Harrer's recommendations and the Board's acceptance of those recommendations. At the outset of the proceeding, pursuant to N.J.S.A. 52:4B-4(g), Dr. Harrer summarized the nature of the provisions of the rule proposal as follows:

The rule establishes the mechanism by which those who do not hold current hospital privileges can submit credentials to the Board for review in order to obtain privileges to perform surgery or administer anesthesia in an office setting. Dr. Harrer reviewed the information required in support of an application for privileges. Dr. Harrer noted that the standards for practitioners seeking privileges to administer or supervise the administration of conscious sedation are less demanding (than the standards applied to the use of general or regional anesthesia). He also pointed to the fact that separate and additional standards must be met by those applicant licensees seeking privileges to utilize lasers in the performance of surgery or special procedures in the office setting.

With the exception of certain specific procedures such as liposuction, where the Board has been made aware through its investigation of untoward results, procedures done with local anesthesia will not trigger the need

to obtain these privileges, thus emphasizing that the Board is applying these standards to those procedures where it believes patients may be at greatest risk.

The practice of pre-anesthetizing patients (prior to their arrival at the office) is not acceptable, therefore, the practitioner who performs surgery should not prescribe or advise patients to take an anesthetic agent prior to their arrival.

Lastly, should a situation occur where a patient under conscious sedation experiences a change in medical condition requiring an emergency conversion to general anesthesia, a CRNA, even if under the supervision of a practitioner not privileged to supervise general anesthesia, would be authorized to make the conversion.

A copy of the transcript can be obtained from, and the public hearing record may reviewed by contacting, William V. Roeder, Executive Director, Board of Medical Examiners, PO Box 183, 140 East Front Street, Trenton, N.J. 08625.

The following individuals testified at the public hearing:

Gary M. Brownstein, M.D., American Society of Plastic Surgeons (ASPS)

Mr. Adrian Hochstadt, JD, Director of Public Affairs, Accreditation Association for Ambulatory Health Care (AAAHC)

Larry Lanier, Assistant Director for Government Affairs, American Academy of Dermatology Association (AADA), Dermatological Society of New Jersey

Naomi Lawrence, M.D., American Society for Dermatologic Surgery (ASDS), American Academy of Dermatology Association, (AADA), South Jersey Academy of Dermatology

Antonio Luciano, C.R.N.A.

Ervin Moss, M.D., New Jersey Society of Anesthesiologists

Steven Norwitz, M.D., The New Jersey Society of Plastic Surgeons

Angela M. Richman, C.R.N.A., President of New Jersey Association of Nurse Anesthetists

Alma Saravia, Esq., General Counsel to New Jersey Association of Nurse Anesthetists (NJANA)

Murray F. Treiser, M.D.

Sharon Velez

In addition, the Board received written comments on the proposal from the following:

Robert Richard Abel, M.D.

Deborah A. Chambers, C.R.N.A., MHSA, President, American Association of Nurse Anesthetists (AANA)

Cheryl S. Citron, M.D., President, Dermatological Society of New Jersey

Richard A. D'Amico, M.D., P.A., F.A.C.S., Radiological Society of New Jersey

Linda M. DeLamar, C.R.N.A., MSN, MS

John D. Fanburg, Esq., Counsel to Radiological Society of New Jersey

Robert A. Herbstman, M.D.

Robert W. Hobson, II, M.D., President, New Jersey Chapter, American College of Surgeons

Satwant G. Keswani, M.D., President, Essex County Medical Society

David E. Lipson, M.D., F.A.C.S.

Edward Luce, M.D., F.A.C.S., President, American Society of Plastic Surgeons (ASPS)

Antonio Luciano, C.R.N.A.

Stephen H. Mandy, American Society for Dermatologic Surgery (ASDS)

Helen Mate, DPM, Podiatric Liaison Officer, New Jersey Podiatric Medical Society

Ervin Moss, M.D., Executive Medical Director, New Jersey State Society of Anesthesiologists

Steven B. Norwitz, M.D., F.A.C.S., New Jersey Society of Plastic Surgeons (ASPS)

Matthew Olivo, M.D., South Jersey Academy of Dermatology

Margaret E. Parsons, M.D., American Academy of Dermatology Association (AADA), Chair, Government Affairs Committee

Patricia Polansky, Executive Director, New Jersey State Board of Nursing

Angela Richman, C.R.N.A. individually and on behalf of New Jersey Association of Nurse Anesthetists (NJANA)

Peter T. Richman, C.R.N.A.

Thomas R. Russell, M.D., F.A.C.S., Executive Director, American College of Surgeons (ACS)

Alma L. Saravia, Esq., General Counsel to New Jersey Association of Nurse Anesthetists (NJANA)

Joseph W. Sokolowski, Jr., M.D., Chair, Medical Review & Accrediting Council, Inc. (MRAC)

Carolyn T. Torre, R.N., MA, APN, C., Director of Practice, New Jersey State Nurses Association

Murray F. Treiser, M.D.

Summary of Testimony Presented at Public Hearing and Response of Hearing Officer, as Adopted by the Board:

1. COMMENT: Ervin Moss, M.D., Executive Medical Director for the New Jersey State Society of Anesthesiologists, complimented the Board for what is accomplished in the proposal and testified that it "is unduplicated in the United States" and "no other state, to [his] knowledge, has offered an alternate pathway for those who do not wish to practice in hospitals."

RESPONSE: The Board appreciates the support and assistance of the anesthesia community.

2. COMMENT: Addressing the definition of "complication," Dr. Moss indicated that his organization supports the revision in this regulation requiring the reporting of any hospital admission.

RESPONSE: The Board welcomes the support for its proposed amendment to the definition of

"complication" which will omit the 24 hour stay requirement for an admission to the hospital. This language had been a Board initiated change to the original regulation. The Board believes that there is a need for the best data collection possible in the first few years that this regulatory initiative will be in place. Reporting all hospital admissions will simplify the reporting standard and enhance full data collection. Incident reporting does not assume that anesthesia caused the incident and the Board is confident that incident reporting will not prevent practitioners from referring patients to hospitals when necessary for any length of time.

3. COMMENT: Addressing N.J.A.C. 13:35-4A.6(f) and 4A.7(i), Dr. Moss expressed support for the prohibition on prescribing an anesthetic agent to be administered before arrival at the office and suggested that reference to chloral hydrate be added as an example of such an anesthetic agent.

RESPONSE: The Board appreciates the support for the revision to the existing regulation to prohibit the prescription of anesthetic agents to be administered prior to arrival at the office but declines to list a specific example. Listing chloral hydrate could unintentionally emphasize this one drug over all of the others that practitioners are also prohibited from prescribing for administration prior to arrival or outside of the office.

4. COMMENT: Dr. Moss also testified in support of the proposed revision of N.J.A.C. 13:35-4A.12(f)1 and 4 and (g), specifically endorsing those provisions allowing, during review of applications for alternative privileges, for a personal interview, inspection of the office, and a period of observation.

RESPONSE: The Board appreciates the support.

5. COMMENT: Dr. Moss, for the New Jersey State Society of Anesthesiologists, testified that a charge, as allowed by N.J.A.C. 13:35-4A.12(e), for the application process to be borne by the applicant is reasonable.

RESPONSE: The Board agrees and acknowledges the support.

6. COMMENT: Dr. Moss also testified in support of the exclusion of liposuction, breast augmentation, and reduction or removal of implants from the definition of minor surgery, noting that such a change would prove beneficial to patients.

RESPONSE: The Board acknowledges the commenter's support.

7. COMMENT: Addressing the revised definition of "complication" appearing at N.J.A.C. 13:35-4A.3, Dr. Moss expressed support for inclusion of wound infections, thus making such events reportable.

RESPONSE: The Board appreciates the support.

8. COMMENT: Commenting on N.J.A.C. 13:35-4A.12(b)2iii, Dr. Moss testified that the wording of the section should be changed from "certification in Advanced Cardiac Life Support" (ACLS) to "updated training in ACLS" since the American Heart Association only certifies that the health provider has taken their program and does not certify the ability of that provider to properly administer ACLS. Dr. Moss further suggested, in supplemental written commentary, that when children are operated upon in an office setting, Pediatric Advanced Life Support (PALS) should be required.

RESPONSE: The Board agrees to a change in N.J.A.C. 13:35-4A.12(b)2iii to replace the phrase "Current certification in Advanced Cardiac Life Support or Pediatric Advanced Life Support" with the phrase "Satisfactory evidence that the applicant is Advanced Cardiac Life Support trained with updated training from a recognized accrediting organization." The Board notes that the phrase "Advanced Cardiac Life Support trained" is already defined in the rules at N.J.A.C. 13:35-4A.3, including Pediatric Advanced Life Support (PALS).

9. COMMENT: Dr. Moss suggested a revision to the definition of "special procedures" as it appears in N.J.A.C. 13:35-4A.3. Specifically, he noted that in the example referring to a pediatric MRI, the use of the word "sedative" in a dose sufficient to "cause the patient to sleep or not to move" could engender confusion.

Elsewhere in the rule, the term used is "conscious sedation"; he suggests that the difference in terms could be relied upon by a radiologist seeking to avoid the rules applicable to "conscious sedation."

RESPONSE: The Board agrees that the clarification provided through addition of the words "conscious sedation" instead of "a sedative dose of medication adequate to cause the patient to sleep or not to move" is consistent with its intention and accordingly has made the change in the definition of "special procedure" at N.J.A.C. 13:35-4A.3 on adoption.

10. COMMENT: Commenting further on the definition of "special procedure" at N.J.A.C. 13:35-4A.3, Dr. Moss further noted that, while the routine use of benzodiazepines to relieve anxiety is exempt from the Board's regulation, for patient safety, the regulation should be more specific and limit the exemption to the use of "oral" benzodiazepines. Dr. Moss explained that when benzodiazepines are given intravenously, the result is conscious sedation.

RESPONSE: The Board agrees the word "oral" before "benzodiazepine" provides clarification and limitation of the exemption and notes that such clarification is consistent with the current definition of "conscious sedation." Conscious sedation does not include "a pre-procedure oral dose of a benzodiazepine designed to calm the patient." This technical change is consistent with the Board's original intent.

11. COMMENT: Dr. Moss also suggested adding to "special procedures" specific reference to the invasive techniques used in pain management, more specifically the use of a needle to perform a therapeutic block; implantation of a dorsal column stimulator; and implementation of a pump for narcotics. He suggests that there are complications in pain management practice, as evidenced by a sizable number of malpractice suits involving pain management.

RESPONSE: The purpose of the original regulation and the regulation here proposed are more focused on the levels of anesthesia during the performance of surgery and special procedures than they are on "pain management." In the future, the Board expects to address issues relating to pain management and, at that time, more specialized attention will be given to this issue. Of course, some pain management strategies will also be governed by N.J.A.C. 13:35-7.6, the Board's rule concerning controlled substances.

12. COMMENT: Dr. Moss also offered additional clarifying language for the definition of "complications" set forth at N.J.A.C. 13:35-4A.3, by suggesting adding "neurological damage" as an example after "temporary loss of function."

RESPONSE: The use of the broad phrase "temporary loss of function" is intended to encompass more events not already included in the definition of complication, even where the cause is not known within 48 hours of surgery. Including this example could have the unintended result of limiting events that would otherwise be included because of listing the specific cause (neurological damage) of the "temporary loss of function."

13. COMMENT: Because Dr. Moss is concerned that conscious sedation is not without risk (citing two instances of deaths occurring while patients were under conscious sedation), he suggested that the definition of "complication" be broadened to include a decrease in oxygen saturation to below 90, or the need for narcotic antidotes. Even if not reportable complications, Dr. Moss suggested that disclosure of such incidents as part of the privileges application forms of those seeking privileges to administer or supervise administration of conscious sedation should be required.

RESPONSE: To maintain reliable consistency in terminology, the reporting of "complications" in the application process (N.J.A.C. 13:35-4A.12) is intended to track the same "complications" as referenced in the definitions (N.J.A.C. 13:35-4A.3). Therefore, the Board will not specifically add the suggested language. At the same time, the Board agrees with the importance of quality measures and quality improvement and expects to expand that focus in this area when the alternative privileging procedures are in place.

14. COMMENT: Dr. Moss noted that pursuant to N.J.A.C. 13:35-4A.6(b)1, the transfer agreements from an office to a hospital may unfairly expose a surgeon on call to malpractice and that the doctors with alternative

privileges for an office practice should arrange to have other doctors in their specialty involved with transfer from office to a hospital.

RESPONSE: The requirement for a written transfer agreement from office to hospital is unchanged in this proposal. Physicians on call in the hospital would be expected to meet the same standard of care, and, therefore, have no greater exposure to malpractice, with a patient transferred under a transfer agreement as in any other circumstance arising at the hospital. When this regulation, including the alternative privileging process, becomes fully effective, the Board will continue to be attentive to various issues that have been identified. If practitioners fail to make arrangements for transfer to those hospitals with the availability of appropriate specialty coverage, the Board will revisit the issue.

15. COMMENT: Gary M. Brownstein, M.D., representing the American Society of Plastic Surgeons (ASPS), commended the Board's "precedent-setting work that will be a model for state medical boards across the nation." He indicated that the Society endorsed the definition of minor surgery and the exclusion of liposuction, breast augmentation, breast reduction, and removal of breast implants from the definition of minor surgery.

RESPONSE: The Board thanks the Society for its support.

16. COMMENT: Dr. Brownstein stressed that "the criteria by which practitioners seek alternative privileging must be clearly defined and as rigorous as the process used in hospitals." He expressed a fear that if the process is not "adequately defined and administered," inadequately qualified practitioners will inadvertently obtain access to office-based surgery.

RESPONSE: The Board agrees that clearly defined and rigorous criteria are necessary, and welcomes the opportunity presented through the alternative privileging process to bring important improvements to patient safety in what has been unregulated access to office-based surgery. The Board believes that the rules appropriately focus on both specific education and training required and the accompanying log and patient record documentation necessary to evaluate clinical competence in the privileges requested.

17. COMMENT: Dr. Brownstein urged the Board to take steps to assure that those performing surgery in the office setting meet the educational and training standards for surgeons in surgery or a surgical subspecialty. Specifically, he noted the need for the Board to assure that applicants for alternative privilege have proof of:

--Graduation from an accredited medical school;

--Graduate training or residency in surgery or a surgical subspecialty approved by the ACGME;

--Certification by the Board-recognized American Board of Medical Specialties;

and

--Completion of continuing education credits throughout medical career (CME).

He emphasized that the training must be in the procedures, as well as in the area of anatomical expertise.

RESPONSE: The Board is in general agreement with these requirements identified with the inclusion of similar requirements recognized by the American Osteopathic Association (AOA) and American Podiatric Medical Association (APMA) and expects that it will be requiring applicants to provide the type of detail that Dr. Brownstein has identified on the privilege request form that it will design. The Board also notes that with passage of P.L. 2001, c.307, all licensees will soon be required to fulfill the requirements of 100 hours of Category I or Category II Continuing Medical Education as a condition of renewal of license. These credits may be the same or additional to those that may be required by specialty boards.

18. COMMENT: Dr. Brownstein strongly urged that a surgeon who requests privileges must be able to

document training and experience for the specific procedures he or she is requesting and, even though surgeons have extensive surgical backgrounds, they should not be able to take a weekend course, for example, in cataract surgery or radial keratotomy and then be permitted to perform this type of eye surgery in their offices; basic training in ophthalmology is essential.

RESPONSE: The Board agrees that requests for privileges are to be evaluated based on education, training and demonstrated current competency for the requested procedures. It is the Board's intention that applications for privileges to perform various procedures within a particular specialty would be expected to be approved for those procedures where the applicant demonstrates current competency in procedures of an equal or greater complexity (than those sought) and that require the same or substantially similar level of procedural skill and technique and a knowledge of the same anatomical areas.

19. COMMENT: Dr. Brownstein further encouraged the Board to implement procedures to assure that a surgeon's graduate education includes specific training for requested procedures. He offered a specific example; he suggested that a surgeon requesting privileges for liposuction, whose residency training did not include liposuction, should be required to successfully complete an eight-hour approved course for a Category I CME; three hours of hands-on for a bioskill cadaver training; and successful completion of a comprehensive instructional program on fluid replacement. He further suggests that the surgeon be proctored for the first three cases dealing with liposuction.

RESPONSE: The Board agrees that acceptable training in a procedure for which privileges are requested must be documented. It is the Board's intention to require that training include adequate coverage of necessary anatomy, physiology and technique for the procedure. In liposuction, the Board agrees that, to assure patient safety, applicant review would be expected to include, for example, documented surgical training, which would include training in fluid balance and in a bioskills cadaver laboratory.

20. COMMENT: Dr. Brownstein stressed the importance of accreditation of the surgical facility where plastic surgery procedures are performed and urged the Board to require accreditation for all surgical facilities including office-based surgical facilities. The American Society of Plastic Surgeons (ASPS) requires that surgery performed under anesthesia only be undertaken in facilities that meet the standards set by the American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF) or the Accreditation Association for Ambulatory Health Care (AAAHC) or the Joint Commission on Accreditation of Healthcare Organizations (Joint Commission). He also noted that the ASPS appreciated the Board's hard work and encouraged the Board to consider mandating office-based surgery accreditation.

RESPONSE: The Board has developed standards which apply to a wide range of specialties and it recognizes that these standards must be clearly defined and properly administered. There has been recognition that facility or premises standards would not go far enough in achieving the reform that patients have a right to expect. Board jurisdiction is not premises-based but focuses on the licensees over whom the Board has jurisdiction. The Board has, therefore, placed obligations on its licensees to meet certain standards which are largely comparable to those which the accrediting bodies would recognize.

21. COMMENT: Steven B. Norwitz, M.D., President of New Jersey Plastic Surgery Society, emphasized, from a patient safety perspective, the importance of the individual seeking to do any surgical procedures in an office setting having proper surgical training credentials. He stressed that this should entail certification by a surgical specialty board recognized by the American Board of Medical Specialties (ABMS).

RESPONSE: The Board agrees that surgical training is necessary and that it must be evidenced by certification in the surgical field by ABMS or American Osteopathic Association (AOA) or other certification entity demonstrated by the applicant to have standards of comparable rigor; or successful completion of an ACGME/AOA accredited residency training program in the surgical field or another supervised program in residency or fellowship or equivalent in another field and active participation in the examination process leading to such certification in the surgical field.

22. COMMENT: Dr. Norwitz argued that State in-office regulations should have the same requirements as

those for State-licensed hospitals because the public is entitled to the same assurances by the State Medical Board of safety in the outpatient setting.

RESPONSE: The Board agrees. The goal of this initiative has been and continues to be to upgrade equipment, skills and protocols that must be in place in the office setting so that patients undergoing surgery and receiving anesthesia services in practitioner offices receive the same high quality of care available in New Jersey hospitals and ambulatory care facilities. In addition, every procedure that is appropriate for the hospital or ambulatory care setting will not be appropriate for the office setting.

23. COMMENT: Dr. Norwitz identified the "critical importance" of the rules that the Board must provide regular inspections of these locations where surgical procedures are to be conducted to ensure that the location meets the standards of a recognized accrediting organization such as AAAASF, AAAHC, or the Joint Commission.

RESPONSE: The Board agrees that locations need to meet high standards and supports national accreditation standards. As noted below, other commenters support premises regulation similar to the approach of the Medical Board of California; however, the Board jurisdiction is not premises-based but focuses on the licensees over whom the Board has jurisdiction.

24. COMMENT: Dr. Norwitz testified that since the Board already has rules in place governing the inspection of outpatient surgical facilities, the Board should consider enlisting the services of one of the existing nationally recognized accrediting organizations that already conducts these inspections and enforces the rules at outpatient surgical facilities.

RESPONSE: The Board appreciates this suggested approach but it does not at present undertake routine inspection of offices. After the alternative credentialing mechanism is implemented, the Board may consider whether there are elements of accreditation that may need to be incorporated into this initiative.

25. COMMENT: Dr. Norwitz emphasized the need for comprehensive surgical training. Dr. Norwitz noted that a practitioner not trained in surgery cannot be taught principles and practices of surgery in a one-year fellowship. He stated, "There's a lot more involved in surgery per se than just the technical operation."

RESPONSE: The Board generally agrees with this position and intends that privileges for surgical procedures will require surgical training of the type obtained in a surgical residency.

26. COMMENT: Alma Saravia, General Counsel for the New Jersey Association of Nurse Anesthetists (NJANA), offered testimony on behalf of that organization as well as the American Association of Nurse Anesthetists. She asserted that, although the NJANA supports 90 percent of the provisions of the entire initiative, it remained distressed at the Board's mandate that certified registered nurse anesthetists (CRNAs) must be supervised by an anesthesiologist or a physician with anesthesia training. She argued that no empirical medical evidence has been cited by the Board in support of this provision. She maintained that no hospital and no state has adopted regulations comparable to those promulgated by the Department of Health and Senior Services since they were adopted decades ago. She testified that 39 states have no supervision requirement concerning nurse anesthetists in the relevant practice acts.

RESPONSE: The comments of Ms. Saravia focus on provisions of the existing, but not yet implemented, rules in subchapter 4A which rules are not part of this rulemaking. The requirement for CRNA supervision by a privileged physician is unchanged and there is no provision in law in this State which authorizes independent practice by CRNAs. Any change to sections not proposed for amendment at this time would be a substantive change requiring reproposal. As factual clarification for accuracy or completeness of the record, the Board notes that an analysis of laws in the 50 states and the District of Columbia in 2001, provided by the American Society of Anesthesiologists, shows that 27 states require supervision or direction, 10 additional states require physician supervision or direction in hospitals and 12 additional require collaboration, protocols, guidelines or policies and procedures. These statistics indicate that as many as 49 states impose some physician direction of CRNAs pursuant to statute, regulation, protocol, guideline or policy and

procedure.

27. COMMENT: Ms. Saravia described N.J.A.C. 13:35-4A.8, which permits a CRNA to convert conscious sedation to general anesthesia if necessary for the safety of a patient, as paradoxical. She notes that if a CRNA can be deemed qualified to assist in emergency conversion, she should not need to have anesthesiologist supervision to administer general anesthesia. This is because, if she does need to have anesthesiologist supervision to administer general anesthesia, the requirement then mandates that there be two physicians in the office at which general anesthesia is used which would, in turn, eliminate the need for a CRNA.

RESPONSE: The proposed amendment to N.J.A.C. 13:35-4A.8 of the existing rules was suggested by the CRNAs. It removes any regulatory barrier to an unanticipated but necessary conversion from conscious sedation, administered by a CRNA, to general anesthesia. The conversion from conscious sedation to general anesthesia, in that case, is envisioned by the Board to occur in emergency circumstances. The emergency essentially makes such conversion preferable to no action.

28. COMMENT: The proposal's Economic Impact statement states that the Board has not received any information about the number of CRNAs that would be impacted by this rule. The NJANA argued that, under standards established by the New Jersey Supreme Court, the law does not recognize numbers (of persons affected) as material for considering the validity of regulation.

RESPONSE: The Board did not receive conclusive statistics of the number of CRNAs who now participate in the administration of general, regional or conscious sedation anesthesia in the office setting although the NJANA asserted that the impact of the rule on its membership will be substantial. The Board responds below to written information submitted.

29. COMMENT: Ms. Saravia further objects to the rule provision which would require a physician electing to use a CRNA to administer and monitor conscious sedation to regularly obtain eight hours of training, while those electing to work with an anesthesiologist need not satisfy that requirement. She claims that this disparity will induce surgeons to hire an anesthesiologist. She stated that it is improper to favor one licensee over another. The position of the NJANA is that the rule could have said that any physician offering conscious sedation must have the training, including those who choose to work with an anesthesiologist. With respect to general anesthesia, she notes that the physician working with a CRNA would need to regularly obtain 60 CME hours. In practice, she maintains that only anesthesiologists will satisfy this standard and thus the rule will require two physicians to be in the office. As such, she argues that it is economically impractical for a practitioner to employ an anesthesiologist and a CRNA where one is doing general anesthesia.

RESPONSE: As noted above, many of the comments of Ms. Saravia focus on provisions of the existing rules in subchapter 4A, which rules are not part of this rulemaking. The requirement for CRNA supervision by a privileged physician is unchanged and there is no provision in law in this State which authorizes independent practice by CRNAs. Any change to sections not proposed for amendment at this time would be a substantive change requiring reproposal. In this case, the regulatory provisions implicated by the comment involve both unchanged subsections of the existing rule and the proposal. Provisions that are not part of the rulemaking but which are identified in the comment impose continuing medical education training in anesthesia requirements on a physician to supervise a CRNA. In this regard, the Board considers that the requirement of eight hours of continuing medical education for a physician supervising a CRNA in the context of N.J.A.C. 13:35-4A.10 (conscious sedation), or in the context of N.J.A.C. 13:35-4A.9 (regional anesthesia), would be an unlikely inducement for a physician to hire an anesthesiologist. The requirement of 60 hours of continuing medical education in the context of N.J.A.C. 13:35-4A.8 for those supervising CRNAs in general anesthesia is more substantial and those using general anesthesia in the office may determine to use an anesthesiologist. The relevant point in this rulemaking is the privileging standard in N.J.A.C. 13:35-4A.12 that imposes anesthesia training requirements on physicians who seek to administer or supervise the administration of general anesthesia in an office. The training and experience necessary to obtain privileges to administer

general anesthesia are contained in N.J.A.C. 13:35-4A.12(a) and represent the Board's intent to assure that a patient's safety is protected in an office to the same degree as it is in a hospital or ambulatory care facility. The Board believes that the burden of the provision is outweighed by benefits achieved in patient safety, assuring that practitioners are knowledgeable concerning the general anesthesia used on their patients.

30. COMMENT: Ms. Saravia indicates that the NJANA supports national accreditation standards that are mandated to be met by facilities, rather than focusing on licensees who provide the anesthesia, as is in place, she states, in California.

RESPONSE: As noted above, in response to Dr. Norwitz' and Dr. Brownstein's comments, the Board also supports national accreditation standards. Premises- standards, however, do not address all necessary patient protections.

31. COMMENT: Ms. Saravia stated that she had previously provided information to the Board (October 3, 2000) concerning CRNA qualifications and training; background concerning a legal challenge to a rule in Florida; and her concern that there is a lack of empirical evidence to support the Board's apparent conclusion that there is a difference in outcomes. She further noted that she had provided alternate regulatory language, and that the Board has not responded or incorporated her suggestions in this rulemaking.

RESPONSE: The issues concerning supervision of CRNAs go beyond this rulemaking. The statutory requirement for supervision by a privileged physician is unchanged and there is no provision in law in this State which authorizes independent practice by CRNAs. For accuracy and completeness of the record, the Board did not receive alternative regulatory language that was directed to the alternative privileges proposal. In addition, for accuracy and completeness of the record, the legal challenge identified by Ms. Saravia, was then appealed and the Florida Appeals Court reversed the Administrative Law Judge, upholding the Florida Board rule requiring anesthesiologist supervision of certified registered nurse anesthetists for certain types of office surgeries. Florida Bd of Medicine v. Florida Academy of Cosmetic Surgery, Inc., 808 So.2d 243, 261 (Fla. Dist. Ct. App. 2002). While the Board has attempted to be attentive to various issues that have been identified by many interested parties, it has focused its resources on moving this initiative forward.

Certain recurring points were made at the public hearing by CRNAs in support of their opposition to physician supervision of CRNAs. Notably, even though the requirement for physician supervision of CRNAs is beyond the scope of this rulemaking, for accuracy and clarity, the arguments that there is not a basis in the literature or in training differences to support physician supervision of CRNAs warrant comment.

Statistical Evidence in the Literature: The Board acknowledges the hospital based outcome studies which have been provided and notes that, in the hospital setting, anesthesiologists are generally present. The Board is not aware that there have been appropriately designed studies of general and regional anesthesia provided in office surgery settings (in contrast to hospital and ambulatory care settings). The Board recognizes that there is no conclusive outcome based determination possible for office settings from existing literature of which it is aware. There is an inherent difficulty drawing meaningful conclusions from studies that are not designed for and conducted in the office setting. Moreover, patient safety in the hospital setting differs from the private office, in part, because the hospital has immediately available anesthesiologists who can readily be present in the event of an emergency. The Board has never contended that there is a higher complication rate with CRNAs; it has determined to require responsible physicians to be knowledgeable and capable of responding to all types of emergencies, not only those limited to anesthesia related problems, but also to those complications relating to physiological systems that may arise as a consequence of anesthesia or other factors. More importantly, the Board understands that outcome evidence may be considered one aspect of the issue, at the same time, the Board is aware there is no provision of law in this State which authorizes independent practice by CRNAs. Administration of anesthesia is the practice of medicine and, as such, physician direction is required and appropriate. Existing Department of Health and Senior Services rules require such oversight in the hospital and in ambulatory care facilities. The rules strike a balance, recognizing the valuable role that CRNAs can and do play.

Training Differences: The Board does expressly note, however, that it does not accept the NJANA's position that there is no difference in the training of physicians and CRNAs. As was stated in comments on behalf of the American Association of Nurse Anesthetists, CRNAs engage in the practice of nursing and are trained in nursing, not medicine. From the start, the training, and, therefore, the practice capabilities, of physicians and nurses are quite different. The Board takes notice that training for a physician (using the anesthesiologist, as the example) includes the following: four years of science-intensive pre-medical undergraduate education; four years of medical school, studying the fundamental science of the human condition (biochemistry, biophysics, anatomy, pharmacology, physiology and pathology). In addition, extensive clinical instruction and experience in medical diagnosis and therapy are received by medical students before the award of a medical degree or an osteopathic degree. After medical school, there are four years of residency training. This training includes one year of clinical medicine; two years of clinical anesthesiology; and one year of concentrated study and experience in connection with the most serious complications. Following residency training, certification by the American Board of Anesthesiology (ABA) requires that physicians take an oral and written certification examination to become a Board certified anesthesiologist. A physician may also become Board certified in the subspecialties of pain management or critical care management. Anesthesiologists may complete additional residency training in order to specialize in any of the following: critical care medicine, pain management, pediatric anesthesia, obstetric anesthesia, neuroanesthesia, cardiothoracic anesthesia, anesthesia for outpatient surgery, recovery room care and regional anesthesia. In addition to the basic training, recertification and continuing education is required. After 10 years of being Board certified, an anesthesiologist must become recertified. A Board certified anesthesiologist who subspecialized in either critical care medicine or pain management must also become recertified. The credentialing requirements, examination and passing standard are the same as that for certification. (This applies to all certificates issued by the ABA on or after January 1, 2000. Those physicians holding a certificate prior to January 1, 2000 may voluntarily elect to apply to the ABA for recertification. However, the ABA will not alter the status of their certification if they do not recertify.)

Although CRNAs receive many hours of training, as reflected in the materials that have been provided to the Board, the basic nursing training is not the same as physician training. The CRNAs subsequent instruction in anatomy, physiology, pathophysiology, biochemistry, chemistry, physics and pharmacology is limited and focused on administration of anesthetics. In addition, the Board believes that training in administration of anesthesia and anesthesia-related complications is not the only training issue. The Board has recognized that, in the office setting, complications may arise in the course of surgery and anesthesia. Such complications will require the knowledge, expertise and experience of plenary licensed physicians to manage the disturbance in physiology and organ function to which the entire body may be subjected and which will extend beyond the limited focus of anesthesia effects.

32. COMMENT: Angela Richman, CRNA, testified as the President of New Jersey Association of Nurse Anesthetists, representing over 350 nurse anesthetists in the State. She stated that any CRNA who is working in a hospital has already been granted hospital privileges to give anesthesia. She further stated that CRNAs, like anesthesiologists, are fully qualified through training and education to give anesthesia and resolve anesthesia-related complications. She noted that, upon graduating from an accredited nurse anesthesia program, CRNAs must pass a national certification exam and must go through a recertification process. Ms. Richman opposes the requirement that a CRNA must be supervised by an anesthesiologist or a physician with special training. She noted that 65 percent of all anesthetics in this country are provided by CRNAs who, she said, are experts in anesthesia care. She stated that the medical literature indicates there is no difference in patient outcomes by anesthesia providers. She maintains that the rule unreasonably limits the ability of CRNAs to be employed in a physician's office. Ms. Richman expressed her dismay with the requirement that a surgeon (with no specific training in anesthesia) providing conscious sedation with a CRNA is required to obtain eight hours of training, while no such training requirement is in place for the surgeon providing conscious sedation alone. An eight-hour course will not enable a surgeon to handle an airway or to intubate a patient as well as a CRNA could. She requests a revision to the June 15, 1998 rules on anesthesia and office practice so a physician may choose equally between a CRNA and an anesthesiologist.

RESPONSE: At the outset, it should again be noted that many of the comments of Ms. Richman, like those

of Ms. Saravia and the others speaking on behalf of CRNAs, go to issues not germane to the current proposal. The Board incorporates its points above concerning statistical evidence in the literature and training differences and notes that the remedy the speaker seeks cannot be accomplished through this rulemaking proceeding. Many of the comments are directed to provisions of subchapter 4A which are not part of this rulemaking and are unchanged. Any change to sections not proposed for amendment at this time would be a substantive change requiring reproposal. Nonetheless, certain additional recurring points, beyond statistical evidence and training, were made in opposition to physician supervision and warrant clarifying correction or comment, even though beyond the scope of the rulemaking.

The Board first notes that the reference to 65 percent of anesthetics appears to be incomplete and, therefore, misleading because it does not include the equally relevant data concerning the cases in this statistic in which the CRNA are under physician supervision and which also involve anesthesiologists. Although the source of her data was not specifically identified in Ms. Richman's submission, other written submissions from the American Society of Anesthesiologists (ASA) and the New Jersey Society of Anesthesiologists suggest that the statistics are from the Centers for Medicare and Medicaid Services (CMS), formerly the Health Care Financing Administration (HCFA), and that the statistics provided by Ms. Richman are incomplete. For example, additional, contextual, statistical information provided by the ASA asserts that more complete Medicare figures for 1999 show that a total of 9,721,571 Medicare anesthesia claims were paid and 6,098,604 were paid on claims by doctors (not counting medically directed CRNAs). While, nationwide, CRNAs may be involved with much of the anesthesia delivered, ASA offered figures identified as based on 1999 Medicare data, that 72 percent of the Medicare claims made by CRNAs involved CRNAs under medical direction and the number of non-medically directed CRNA claims were equal to 9.7 percent of the total Medicare anesthesia claims paid. In addition, the information provided by the American Association of Nurse Anesthetists includes the fact that approximately "80 percent of Certified Registered Nurse Anesthetists work as partners in care with anesthesiologists" (from "Nurse Anesthetists and Anesthesiologists Practicing Together").

Other arguments were made by Ms. Richman in opposition to physician supervision of CRNAs. The Board is, however, constrained to adhere to the Medical Practice Act and to read the exemption for nurses at N.J.S.A. 45:9- 21(k) to envision physician direction. As noted above in response to Ms. Saravia, there is no provision of law in this State which authorizes independent practice by CRNAs.

In response to Ms. Richman's comment concerning continuing education for physician supervisors, the Board notes that requirements for a physician seeking privileges to administer and supervise the administration of conscious sedation appear in N.J.A.C. 13:35-4A.12(b)2. The Board's intention with respect to safeguarding patient safety in the provision of general anesthesia in an office, as previously noted in response to Ms. Saravia's comment above, is equally apt here. In addition, pursuant to N.J.A.C. 13:35-4A.10, conscious sedation may be administered in an office only by a physician privileged by a hospital or the Board and who, during every consecutive three- year period beginning July 1, 2001, completes at least eight Category I or II hours. This provision requires that the eight hours be fulfilled by the physician who is administering or supervising administration of conscious sedation. The Board seeks to assure that the physicians be knowledgeable and competent to ensure patient safety.

33. COMMENT: Ms. Richman applauds the Board's attempts to provide a safe environment for patients in an office setting.

RESPONSE: The Board thanks Ms. Richman for her comment.

34. COMMENT: Antonio Luciano, of the New Jersey Association of Nurse Anesthetists, agreed with the comments of Ms. Saravia and Ms. Richman and asked that the Board reconsider the anesthesia guidelines.

RESPONSE: The Board thanks Mr. Luciano for his participation and reiterates its responses above.

35. COMMENT: Tracy Castleman of the New Jersey Association of Nurse Anesthetists supported the remarks of the other nurse anesthetists.

RESPONSE. The Board thanks Ms. Castleman for her participation and reiterates its responses above.

36. COMMENT: Ms. Valez, a liposuction patient, provided the hearing officer and other members of the Board with an account of her experiences with unregulated office-surgery. She testified that she had called a hospital to ask about her surgeon and was told they had no complaints about his work. She testified that she had not known that the physician did not do surgery in the hospital but performs surgery only in the office setting. He had no anesthesiologist in the room. She had liposuction on her knees, thighs, and stomach. She suffered complications and allowed the surgeon to do more liposuction and she is now badly scarred. She provided some details about her scarring and problems.

RESPONSE: The Board appreciates the comments of Ms. Valez and her support for regulation of practitioners of office-based surgery and special procedures.

37. COMMENT: A representative of the American Academy of Dermatology Association (AADA), Larry Lanier, commended the Board for its commitment to patient safety and safe medical offices in New Jersey. He noted that the AADA is also committed to patient safety and that dermatologists have an excellent record of patient safety. He said the AADA has worked with medical boards across the country on rules and guideline language.

RESPONSE: The Board thanks the AADA for its support and participation in this process.

38. COMMENT: In addressing the issue of collection of adverse incident data, Mr. Lanier, for AADA, testified that since such data collection is not always mandatory, it is accomplished with difficulty. He noted, however, that in the area of higher levels of anesthesia, especially general anesthesia, when multiple forms of anesthesia are used for one procedure, and when there is bundling of procedures (multiple procedures are performed at one time), and, in particular, when the procedures are aggressive and invasive, there seems to be a higher incidence of adverse patient outcomes in offices. Mr. Lanier also said that the AADA had "seen very, very few complications and no mortality associated with local anesthesia including what [AADA] call[s] pure tumescent anesthesia, even in cases of liposuction."

RESPONSE: The Board appreciates the data derived from the AADA experience and welcomes the outcome studies that may become available to AADA. The anecdotal information concerning more recent reports of outcomes using local pure tumescent anesthesia is appreciated and will contribute to the Board's ongoing development of statistical information, improving understanding of necessary procedural safeguards in the office setting. The Board intends its rule to tip the balance in favor of patient safety when weighing necessary equipment, skills and protocols that must be in place in the office setting.

39. COMMENT: Mr. Lanier suggested that liposuction, when using pure tumescent anesthesia or lipo injection, should be considered minor surgery and exempted from the provisions of this rule, since these procedures are not generating significant complications.

RESPONSE: The Board understands and appreciates the position of the AADA. The inclusion in this rule of liposuction of whatever type and with whatever anesthetic is intended to assure that qualified physicians safely offer liposuction to appropriate patients in their practice. The Board generally intends that privileges for surgical procedures will require surgical training of the type obtained in a surgical residency. The Board is confident that the procedures and practitioner training and clinical competence requirements in the office setting are justified by the interests of patient safety and protection.

40. COMMENT: Mr. Lanier noted that a Florida Administrative Law Judge overturned portions of a rule promulgated by the Florida Medical Board that required mandatory hospital privileges and mandatory written hospital transfer agreements.

RESPONSE: The Board appreciates this information and notes that the referenced decision was subsequently overturned by the District Court of Appeals of Florida which found that the Board of Medicine had the

authority to require a transfer agreement with a licensed hospital. The Board is not aware of any problems with the transfer agreement requirement at this time, and believes it to be a vitally important safeguard. Unlike Florida, as this proposal illustrates, the Board has provided a mechanism for physicians who do not hold hospital privileges to continue to provide service, once their training and experience has been established.

41. COMMENT: Mr. Lanier suggested modeling New Jersey's rule after the scheme in operation in California. He maintained that in California a physician who has privileges or a written hospital transfer agreement with an acute care facility within a reasonable proximity or with a physician who has admitting privileges at that facility is authorized to practice.

RESPONSE: The comment is directed to provisions of subchapter 4A which are not part of this rulemaking. The requirement for a written transfer agreement from office to hospital is unchanged. Any change to sections not proposed for amendment at this time would be a substantive change requiring reproposal. When these rules, including the alternative privileging process, become fully effective the Board will continue to be attentive to various issues that have been identified.

42. COMMENT: Mr. Lanier supports utilizing an office accreditation policy as another pathway to achieve patient safety.

RESPONSE: The Board also supports national accreditation standards. There has, however, been recognition that facility or premises standards would not go far enough in achieving the reform that patients have a right to expect. Board jurisdiction is not premises-based but focuses on the licensees over whom the Board has jurisdiction. The Board has, therefore, placed obligations on its licensees to meet certain standards which are largely comparable to those which the accrediting bodies would recognize.

43. COMMENT: Mr. Lanier extended the AADA's offer to be helpful and supportive and help with data information.

RESPONSE: The Board appreciates the AADA participation and assistance.

44. COMMENT: Speaking on behalf of the American Society for Dermatologic Surgery, the American Academy of Dermatology Association and the South Jersey Academy of Dermatology, Dr. Naomi Lawrence testified that data has shown that the greatest cause of patient mortality in office related procedures is as a result of the use of general anesthesia in the office setting. She advocated a ban on the use of general anesthesia in medical offices.

RESPONSE: The comment is directed to provisions of subchapter 4A which is not part of this rulemaking. This rule proposal did not address the types of anesthesia services presently allowed under the rules. Any change to sections not proposed for amendment at this time would be a substantive change requiring reproposal. The Board appreciates the concern with general anesthesia in the office and believes that it has fashioned the appropriate safeguards in the requirement pertaining to personnel, equipment and training.

45. COMMENT: Dr. Lawrence described her training in detail, noting that she had three years of residency training in dermatology and three years of experience in a liposuction clinic. She noted that liposuction is specifically mentioned as part of a dermatologist's training on the website for the American Board of Medical Specialties (ABMS). She further noted that the dermatologists and dermatologic surgeons had commissioned an independent outcome study group to do outcome study on liposuction surgery performed by dermatologic surgeons. She reported that the study showed excellent safety statistics ("over seven years, over 63,000 cases without a single death and an adverse incident record of .72 per thousand").

RESPONSE: The Board appreciates the participation of Dr. Lawrence and the dermatology community in this initiative, but notes that it was unable to confirm at the ABMS website or links the training identified.

46. COMMENT: Dr. Lawrence objected to the grouping of liposuction with the other procedures such as

breast augmentation and reduction and removal of breast implants. She noted that liposuction is generally performed under local anesthesia, with minimal oral sedation. She noted that there is a distinction between liposuction utilizing tumescent anesthesia and the procedure when performed under general anesthesia.

RESPONSE: The Board acknowledges that there are differences between general anesthesia and tumescent local anesthesia. At the same time, the Board understands that the high levels of lidocaine used in the tumescent technique present a real risk in the office setting. There seems to be agreement in the literature that peak serum levels of lidocaine may not be reached until 10 to 12 hours after injection. In the office setting, a patient could have gone home before peak levels were reached. In the interest of patient safety, and in view of the risks of lidocaine toxicity, the Board believes that the office setting is not the appropriate location for "off-label" use of drugs. Toxic levels may be reached with this technique if anything goes wrong. Beyond the manufacturer maximum recommended dose, the procedure would be properly done in the hospital with an overnight stay so that appropriate care is available should any problems arise when peak serum levels are reached.

47. COMMENT: Addressing her comments to the definition of minor surgery, Dr. Lawrence testified that tumescent anesthesia has been proven safe and effective. She further noted that scientific journals have found the use of the anesthetic lidocaine to be safe. She specifically questioned the Board's reference within the rules to manufacturer recommended dosages. She suggested that manufacturers do not always anticipate the usages to which their products will be put. She specifically objected to the proposed language ("maximum manufacturer recommended dose of local or topical anesthesia"), which would make it unlawful to utilize lidocaine in a way that is proven to be safe and effective. She recommends language be modified from "maximum manufacturer recommended dose" to "no more than the maximum safe dosages of local or topical anesthesia."

RESPONSE: As noted above, the office setting presents limitations to some procedures. The literature provided presents issues of data reliability (questionnaires which are essentially self reporting), relatively low numbers of responses and mixture of office and hospital settings. To the extent that dosage is provided in a recognized reference text, or the Physician's Desk Reference, the Board would look to those standards as well if they deviate from a manufacturer's literature. The Board, however, does not agree that the language should be so vague as to permit a dosage that would vary according to technique.

48. COMMENT: With respect to N.J.A.C. 13:35-4A.12(d), Dr. Lawrence objected to the language which she thought would allow someone to take a weekend course and be certified to do laser surgery. She expressed concern that those who had laser surgery as part of a residency training program would in fact have more difficulty establishing experience. In response to a question from a Board member, she acknowledged that she has surgical privileges in a hospital.

RESPONSE: The Board appreciates this comment and accepts the identification of the need for further clarity in the intended meaning of N.J.A.C. 13:35- 4A.12(d). The Board envisions that those seeking privileges can establish eligibility through documentation from the program director of an accredited residency training program attesting to the training in specific laser therapy during residency training or a demonstration of successful completion of a laser training program sponsored by an ACCME or AOA accredited provider of Category I CME documenting laser care, physics and clinical indications for utilization of the specific laser and successful performance of laser procedures using the specific laser under direct clinical supervision.

49. COMMENT: Dr. Murray Treiser testified that he has been a licensed plastic surgeon in New Jersey since 1985, that he has an operating room in his office and has probably been involved with as many as 10,000 operations. He is opposed to the position that CRNAs should not be able to perform in-office anesthesia. He testified that, in his licensed facility, all the physicians and nurses are ACLS certified and no patients with significant medical problems are operated on in the office. His position is that a patient should have a right and the option to rely on his advice on the best person to provide anesthesia. As supervising physician, it is his responsibility to choose the appropriate procedures and anesthesia provider. He testified that no decision

is made on an economic basis.

RESPONSE: The Board acknowledges the high standards in patient selection this practitioner identified but does not believe that patients' or practitioners' choices are unreasonably restricted. The safeguards incorporated into these rules provide the minimum standard and allow administration of anesthesia by privileged anesthesiologists and physicians and CRNAs under proper supervision. The protection of the public necessitates certain equipment, training and experience. Once those baseline requirements are fulfilled, the range of choices is the same.

50. COMMENT: Adrian Hochstadt, Director of Public Affairs for the Accreditation Association for Ambulatory Health Care (AAAHC), commended the Board for its precedent setting endeavor, noting that AAAHC was very interested in the alternative privileging process and looks forward to working with the Board. The AAAHC offered assistance and cooperation, noting that if New Jersey chooses to use an accreditation mechanism, AAAHC would be ready, able, and willing to work with the Board in implementing whatever mechanism is developed.

RESPONSE: The Board appreciates the interest of AAAHC.

Summary of Written Public Comments and Agency Responses:

Comments to Provisions Not Part of the Rulemaking--Physician Supervision of CRNAs

51. COMMENT: Many CRNAs commented proposing elimination of physician supervision of CRNAs, citing statistical and other jurisdiction information in support of that proposition and also pointing to CRNA training to support their position.

RESPONSE: These rules focus on surgical and anesthesia standards. It continues to be the Board's view that the administration of anesthesia is the practice of medicine and, as such, physician direction is required and appropriate. Physicians supervising anesthesia practice must be knowledgeable and competent to ensure patient safety. The proposed amendments do not change the original rules; and the Board cannot make these changes through this adoption. The requirement for CRNA supervision by a privileged physician is unchanged and there is no provision in law in this State which authorizes independent practice by CRNAs. Any change to sections not proposed for amendment at this time would be a substantive change requiring reproposal.

52. COMMENT: The NJSNA asserts that a CRNA with education and experience does not need physician supervision. They submit that CRNAs are fully qualified through their education and must undergo rigorous clinical and academic training. It was explained that nurse anesthesia programs are at the graduate level and include, for example, 90 hours of basic and advanced principles of anesthesia and require a Bachelor of Science in nursing with at least one year in a critical care setting, with mandatory certification and recertification processes in place.

RESPONSE: The Board thanks NJSNA for its comment and refers NJSNA to the Board's comments to the recurring point on training differences, contained in the prior section summarizing agency responses to comments at the public hearing. The comments are directed to provisions of subchapter 4A which are not part of this rulemaking. The requirement for CRNA supervision by a privileged physician is unchanged and there is no provision in law in this State which authorizes independent practice by CRNAs. Any change to sections not proposed for amendment at this time would be a substantive change requiring reproposal.

53. COMMENT: The Executive Director of the New Jersey Board of Nursing (Nursing Board) noted, on behalf of the Nursing Board, the extent to which CRNA training and experience "may be comparable to the additional specialized but limited training" that would now be required (by the proposed rule) of non-anesthesiologist physicians who would be supervising CRNAs. The Nursing Board also remarked on studies indicating a shortage of anesthesiologists that may affect New Jersey and that patient safety is its "paramount concern."

RESPONSE: The Board thanks the Nursing Board for its comments. The Board recognizes CRNA training in administration and monitoring of anesthesia as evidenced by the retention of the role of CRNAs particularly in the administration of conscious sedation, where the surgeon can supervise the CRNA while attending to patient responsibilities. Specific studies indicating a shortage of anesthesiologists were not identified; however, through press reports last month, the Board is aware that a national survey of large hospital administrators identified that many hospitals need additional anesthesiologists on staff and Medicare payment rates for anesthesia care may relate to the anesthesiologist shortfall. That survey also showed, according to an American Society of Anesthesiologists press release (and consistent with figures contained in materials submitted with the American Association of Nurse Anesthetists written comment), that 74 percent of the responding hospital administrators use anesthesiologists and anesthesia nurses working together and the remainder use anesthesiologists only. The Board acknowledges that the hospital experience nationwide, as reflected in this survey, indicates an expressed need for additional anesthesiologists.

54. COMMENT: Many CRNAs provided data concerning their acceptance across the country. The AANA asserts that 39 states do not require CRNA supervision by physicians and 30 states do not require CRNA supervision in hospitals.

RESPONSE: As noted above in response to the NJANA testimony at the public hearing and for factual clarification for accuracy or completeness of the record, the Board repeats here that an analysis of laws in the 50 states and the District of Columbia in 2001, provided by American Society of Anesthesiologists, shows that 27 states require supervision or direction, 10 additional states require physician supervision or direction in hospitals and 12 additional require collaboration, protocols, guidelines or policies and procedures. These statistics indicate that as many as 49 states impose some physician direction of CRNAs pursuant to statute, regulation, protocol, guideline or policy and procedure.

55. COMMENT: No other state requires anesthesiologist supervision of a CRNA in the office. A Florida rule requiring anesthesiologist supervision for certain anesthesia cases is not in effect because of legal challenges to the decision of an Administrative Law Judge (ALJ). In addition, anesthesia supervision requirements will increase the cost of health care for in-office medical/surgical procedures. The issue was litigated in Florida and the Administrative Law Judge held that the requirement for anesthesiologist supervision of a CRNA was not necessary and increased costs. The appellate court, in reversing the ALJ in part, did not refute the ALJ factual findings of increased cost.

RESPONSE: As factual clarification for accuracy or completeness of the record, the Board notes that the Florida Appeals Court reversed the Administrative Law Judge. The Florida Appeals Court acknowledged that even if it restricted competition, a Board rule requiring anesthesiologist supervision of certified registered nurse anesthetists for certain types of office surgeries was not unreasonable where "competent substantial evidence" supported the Board's determination and "the proposed provision has no effect whatsoever on the ability of CRNAs to administer anesthesia in hospitals, ambulatory surgical centers, and level I and II office surgeries." Florida Bd of Medicine v. Florida Academy of Cosmetic Surgery, Inc., 808 So. 2d 243, 261 (Fla. Dist. Ct. App. 2002). The apparent referenced appellate court neither refuted nor agreed with any ALJ factual findings on cost. The court did not review nor did it rule on the merits of a cost argument. A rule challenge on cost in Florida must comply with statutory requirements for certain submissions by a "substantially affected party" and the required submission was not made. The court found the ALJ in error to rule on the requirement for anesthesiologists on the basis of cost. 808 So. 2d at 258.

56. COMMENT: The Centers for Medicare and Medicaid Services (CMS) (formerly Health Care Financing Administration) adopted a regulation removing the physician supervision requirement from Medicare regulations. The regulation was changed to allow states to opt out of the supervision requirement.

RESPONSE: As factual clarification for accuracy or completeness of the record, the Board notes that it is aware that the supervision requirement had been removed in a rule published in January 2001 (under the previous Federal Administration), that rule was then stayed (while reviewed by the current Federal Administration), and that, subsequently, the CMS reinstated the supervision requirement in a rule proposal

published in July 2001. The Board takes notice that the final rule (adopted in November 2001) maintains the supervision requirement while allowing, in some circumstances, governors whose state law permits unsupervised practice by CRNAs to opt out of the requirement. A governor can only opt out of the supervision requirement if the state law allows and, after consultation with the Board of Nursing and the Board of Medicine concerning access to and quality of anesthesia services, if the governor finds it to be in the best interest of the state's citizens.

57. COMMENT: The President of the AANA noted that the Federal government does not require anesthesiologist supervision for CRNAs to be directly reimbursed for their services or for hospitals and ASCs to participate in Medicare programs.

RESPONSE: As factual clarification for accuracy or completeness of the record, the Board notes that the Federal position on direct reimbursement of CRNAs for their services appears to be quite separate from the Federal position on supervision of CRNAs. Direct reimbursement is understood to be direct payment to CRNAs for their services as contrasted with payment to a physician for a "bundle" of services, including services by a CRNA. Supervision of CRNAs does not address payment of CRNAs at all. Supervision is a requirement imposed on hospitals participating in Medicare and Medicaid by the CMS final rule which was promulgated on November 13, 2001. The final rule maintained the physician supervision requirement as a condition of participation in Medicare and Medicaid unless a Governor seeks the exemption from the requirement consistent with state law.

58. COMMENT: Several months after the comment period closed, the NJANA submitted on May 22, 2002 the final Report of the Special Committee on Outpatient Surgery from the Federation of State Medical Boards (FSMB). The NJANA noted that the FSMB considered comments from the American Association of Nurse Anesthetists and found "anesthesia preference" language was not warranted. The NJANA also said that the report "does not specify physician supervision of a CRNA unless a state requires such supervision."

RESPONSE: Although the comment period had closed, the Board had not yet published the comments and responses when the NJANA's submission of its letter and the final FSMB Report was received. Accordingly, the Board reviewed the late submission. (The draft and final FSMB Reports were also available to the Board as a member of FSMB.) As factual clarification for accuracy or completeness of the record, the Board notes that it reads the Report differently than the NJANA. First, the final Report actually does specify that supervision is required and supervision may be avoided only if state law specifically allows. In addition, the final Report language essentially tracks the framework of the Board's proposed rules by providing for supervision by an anesthesiologist or the operating physician as does the regulation. The Report provides:

In those cases in which a non-physician administers the anesthesia, the individual must be under the supervision of an anesthesiologist or the operating physician, unless state law permits otherwise.

The rule for supervision requirement, in the Board's view, appropriately varies between anesthesiologist or operating physician depending upon the relative risk presented to the patient by general or regional anesthesia or by conscious sedation.

59. COMMENT: The President of the American Association of Nurse Anesthetists (ANNA), cites the Pennsylvania State Medical Board's proposed October 1996 regulations (ultimately not adopted by the Pennsylvania Board) requiring supervision and Pennsylvania IRRC's (Independent Regulatory Review Commission) "objective" findings of no justification for this and a resulting increased cost of care. Additionally, CRNAs are properly trained in the administration of anesthesia.

RESPONSE: As factual clarification for accuracy or completeness of the record, the Board notes that its research disclosed that the proposed Pennsylvania regulation was deemed withdrawn because the Pennsylvania Board did not publish its final rulemaking within the two-year period required by applicable law. The Pennsylvania Board was deluged with over 2,000 letters, mostly form letters, provided to nurses by the nursing lobby. The Pennsylvania Board was required to address every comment and simply could not do so within the two-year time frame.

60. COMMENT: One commenter noted that no other state has such a supervision rule. Illinois has regulations requiring certain CME in sedation and anesthesia for office based surgeons working with CRNAs but is not as restrictive and it is being challenged in court.

RESPONSE: The comments are directed to provisions of subchapter 4A which are not part of this rulemaking. The requirement for CRNA supervision by a privileged physician is unchanged and there is no provision in law in this State which authorizes independent practice by CRNAs. Any change to sections not proposed for amendment at this time would be a substantive change requiring reproposal. The issue of other State supervision requirements has been discussed in response to testimony of NJANA and written comments of AANA. In addition, the activities, regulations and statutory initiatives in other states (including California and Rhode Island) do not relate to existing New Jersey law or to the subject of the proposed rulemaking.

61. COMMENT: The American Medical Association (AMA) circulated a resolution dated December 1, 2001 which provides that the AMA resolves to inform states of the AMA policy position that requires physician supervision of CRNAs for anesthesia services in Medicare participating hospitals, and ambulatory surgery centers, and critical access hospitals. The commenter believed it reasonable to apply this policy in New Jersey practitioner offices because New Jersey holds the office operating room to the same standards as surgery centers.

RESPONSE: The comments are directed to provisions of subchapter 4A which are not part of this rulemaking. The requirement for CRNA supervision by a privileged physician is unchanged and there is no provision in law in this State which authorizes independent practice by CRNAs. Any change to sections not proposed for amendment at this time would be a substantive change requiring reproposal.

62. COMMENT: The AANA notes that the July 2000 Pennsylvania Silber study was recently discredited by Federal viewers on January 18, 2001. The Silber study favored anesthesiologist supervision of CRNAs.

RESPONSE: As factual clarification for accuracy or completeness of the record, the Board notes that HCFA's review of comments to the December 19, 1997 proposed rule concerning anesthesia services, contained discussion of the July 2000 article by Dr. Silber and others at the University of Pennsylvania. HCFA found the study "not relevant to the policy determination at hand because it did not study CRNA practice with and without physician supervision" (66 FR 4677). HCFA noted design issues and its disagreement with the article's policy conclusion. Id. HCFA also made the point that there "are no studies published within the last 10 years that are specific to the issue of the final rule, namely provision of anesthesia care by CRNAs practicing without physician supervision" (66 FR 4676). The January 18, 2001 rule was delayed twice and was then withdrawn to be superceded by the final rule of November 13, 2001. That operative rule maintained the current requirement of physician supervision of CRNAs unless the Governor determines that an exemption is consistent with State law and in the best interest of the State residents. (66 FR 56762).

63. COMMENT: Several commenters alluded to studies that show no significant difference in anesthesia outcomes based on whether the anesthesia provider is a CRNA or an anesthesiologist. Specifically referenced was a 1994 Minnesota Department of Health study, which concluded there are no studies, national or statewide, which conclusively show a difference in patient outcomes based on type of anesthesia provider.

RESPONSE: As factual clarification for accuracy or completeness of the record, the Board refers to its response above and to the HCFA statement in January 2001 that there are no studies published within the last 10 years that are specific to the issue of provision of anesthesia care by CRNAs practicing without physician supervision (66 FR 4676). The comments are also directed to provisions of subchapter 4A which are not part of this rulemaking. The requirement for CRNA supervision by a privileged physician is unchanged and there is no provision in law in this State which authorizes independent practice by CRNAs. Any change to sections not proposed for amendment at this time would be a substantive change requiring reproposal. In addition, the topic has been addressed at length in the response to the testimony of the NJANA.

64. COMMENT: By requiring physician supervision of CRNAs, the Board seems to be attempting to

legislate a monopoly for anesthesiologists to the detriment of CRNAs and the public.

RESPONSE: The comment is directed to provisions of subchapter 4A which are not part of this rulemaking. Although the commenter seems to be raising issues outside those of patient safety to lend support to their argument against physician supervision of CRNAs in office practice, the requirement for CRNA supervision by a privileged physician is unchanged and there is no provision in law in this State which authorizes independent practice by CRNAs. Any change to sections not proposed for amendment at this time would be a substantive change requiring reproposal. It must be noted that the rule in no way displaces CRNAs from office practice. The rule contemplates a continuing role for CRNAs, particularly in the provision of conscious sedation, which is believed to be the bulk of office anesthesia.

65. COMMENT: CRNAs are the main anesthesia service providers for our Armed Forces and act in an unsupervised environment.

RESPONSE: The comment is directed to provisions of subchapter 4A which are not part of this rulemaking. Although the commenter seems to be raising issues outside those of patient safety to lend support to their argument against physician supervision of CRNAs in office practice, the requirement for CRNA supervision by a privileged physician is unchanged and there is no provision in law in this State which authorizes independent practice by CRNAs. Any change to sections not proposed for amendment at this time would be a substantive change requiring reproposal.

66. COMMENT: CRNAs are well qualified and do not need physician supervision. There are many more physician anesthesia related malpractice payments made in an average year than nurse anesthesia related malpractice payments.

RESPONSE: The comment is directed to provisions of subchapter 4A which are not part of this rulemaking. Although the commenter seems to be raising issues outside those of patient safety to lend support to their argument against physician supervision of CRNAs in office practice, the requirement for CRNA supervision by a privileged physician is unchanged and there is no provision in law in this State which authorizes independent practice by CRNAs. Any change to sections not proposed for amendment at this time would be a substantive change requiring reproposal. The Board also directs the commenter's attention to its extensive discussion in response to testimony of Ms. Saravia and Ms. Richman.

67. COMMENT: CRNAs object strongly to the requirement that surgeons working with CRNAs possess advanced anesthesia training and education since they contend that CRNAs are just as qualified as anesthesiologists to give anesthesia and resolve anesthesia related complications. One CRNA said she was taught and trained along with her medical counterpart anesthesia residents for 24 months.

RESPONSE: The Board considers the requirement of eight hours of continuing medical education for a physician in the context of conscious sedation to be appropriate. The requirement of 60 hours of continuing medical education for those supervising CRNAs in general or regional anesthesia is of course more substantial and relates to the increased risks. The Board believes that one anesthesia trained physician needs to be present in the office setting. The provisions addressing this provide benefits in patient safety, assuring that practitioners are knowledgeable concerning the anesthesia used on their patients.

68. COMMENT: The Board has exceeded its jurisdiction by regulating CRNAs and effectively barring them from practicing in office settings in New Jersey. CRNAs practice nursing, not medicine and the Board has no authority to regulate a nursing specialty.

RESPONSE: The Board's position is that administration of anesthesia is the practice of medicine. This rule addresses the requirements imposed on the Board's licensees. Beyond that, the comment is directed to provisions of subchapter 4A which are not part of this rulemaking. The requirement for CRNA supervision by a privileged physician is unchanged and there is no provision in law in this State which authorizes independent practice by CRNAs. Any change to sections not proposed for amendment at this time would be a substantive change requiring reproposal.

69. COMMENT: The regulations illegally favor one professional licensee over another by mandating that a physician offering conscious sedation in an office setting must have special training if the physician is working with a CRNA but not if the physician is working with an anesthesiologist, thereby creating a two-tiered system; therefore, the proposal would have been better drafted if it required any physician to have special training, not only physicians working with CRNAs.

RESPONSE: In the interest of patient safety, the rules require anesthesia training of the physician so that there will be one physician with training in anesthesia present when conscious sedation is administered in the office. This requirement for one anesthesia-trained physician is satisfied by the surgeon trained in anesthesia who is working with a CRNA and this requirement is also satisfied by an anesthesiologist. As was stated in response to comments considered above, for patient safety it is necessary to assure that one physician be knowledgeable and capable of responding to all types of emergencies--those that may be anesthesia related problems, as well as those complications relating to physiological systems that may arise as a consequence of anesthesia. Because a CRNA is not trained as a physician, the presence of a CRNA with a physician untrained in anesthesia does not satisfy the minimal safety standard set forth above.

70. COMMENT: By requiring that physicians trained in anesthesiology supervise CRNAs, the Board is violating Federal anti-trust laws by effectively granting a monopoly over anesthesiology practice in office settings.

RESPONSE: As was noted in prior responses, in the interest of patient safety, the rules require anesthesia training of the physician so that there will be one physician with training in anesthesia present when conscious sedation is administered in the office. This requirement of one physician with anesthesia training is also satisfied for all anesthesia services by an anesthesiologist. The requirement for CRNA supervision by a privileged physician is unchanged and there is no provision in law in this State which authorizes independent practice by CRNAs. The rules allow and assume that CRNAs will continue to play a critical role in the administration of anesthesia.

71. COMMENT: Some CRNAs commented that the rule requiring physician supervision of CRNAs will drive up health care costs with no improvement in patient safety and this type of "nurse bashing" will ensure that the current nursing shortages will continue to exist because nurses will migrate to friendlier states like Pennsylvania and New York.

RESPONSE: The comments are directed to provisions of subchapter 4A which are not part of this rulemaking. The requirement for CRNA supervision by a privileged physician is unchanged and there is no provision in law in this State which authorizes independent practice by CRNAs. The Board has not received data to support the speculative assertion of an increase in health care costs as a result of its efforts to assure patient safety in the office. As stated earlier, this issue arose in the Florida case involving CRNAs and statutorily required submissions to support the argument were not provided. The Board has consistent high regard for nurses and CRNAs and is encouraged by the high percentage of CRNAs that work with anesthesiologists, as was reported above in materials submitted by AANA.

72. COMMENT: By requiring physician supervision of a CRNA, the Board's rules unreasonably limit the ability of a CRNA to be employed in a physician's office and the Board should allow a physician to choose equally between a CRNA and an anesthesiologist.

RESPONSE: The comment is directed to provisions of subchapter 4A which are not part of this rulemaking. The requirement for CRNA supervision by a privileged physician is unchanged and there is no provision in law in this State which authorizes independent practice by CRNAs. Any change to sections not proposed for amendment at this time would be a substantive change requiring reproposal. The commenter is referred to the previous response to the testimony concerning physician choice.

Comments in General Support of the Regulatory Initiative

73. COMMENT: Many commenters commended the Board's effort to enhance patient safety in the office setting. Representatives of the American College of Surgeons and its New Jersey chapter, the American Society of Plastic Surgeons, the American Academy of Dermatology Association (AADA) and the Dermatological Society of New Jersey, the New Jersey State Society of Anesthesiologists, the New Jersey Podiatric Society and individual practicing physicians and CRNAs commended the Board for its commitment to patient safety in New Jersey and its willingness to provide guidelines for office practices. Many commenters specifically recognized that the requirements for training in Advance Cardiac Life Support would benefit New Jersey patients.

RESPONSE: The Board is appreciative of the active participation and input of many groups during the development of this regulatory initiative.

Comments to Prefatory Statements

74. COMMENT: With respect to the Summary, one commenter noted that retrobulbar blocks are an anesthetic technique and not an anesthetic agent as was referenced in the Summary.

RESPONSE: The Board acknowledges this clarification and the inaccurate reference to retrobulbar block as an anesthetic "agent" in the Summary of the proposal. In the rule proposal, however, the Board did specifically separate out this technique and limits the use of this technique (the administration of this minor conduction block) to physicians credentialed in a hospital or by the Board.

75. COMMENT: The NJANA objected to the assertion in the Economic Impact statement that no estimate of the impact of the rules on its membership had been provided. It was claimed that on April 16, 1998, the NJANA supplied member survey data to BME indicating that a significant percent of them provide general anesthesia in an office. In addition, the NJANA maintains that it is irrelevant whether one or 100 CRNAs are affected by this requirement.

RESPONSE: The information provided to the Board was not conclusive. In an April 16, 1998 letter to the Board, Ms. Saravia wrote that the NJANA has approximately 400 members and the NJANA surveyed its members, asking for response to "a series of questions about the physicians' offices in which they practice as nurse anesthetists and to identify the type of anesthesia they administer." Ms. Saravia reported that 37 members responded to the survey, with 22 identifying general anesthesia and 15 identifying "several different types of anesthesia techniques." In addition, Ms. Saravia wrote that the number of CRNAs doing office anesthesia is now 80, without reference to the type of anesthesia. The very limited response number does not seem to support predictions of substantial industry impact.

76. COMMENT: Similarly, the NJANA objected to reference in the Jobs Impact statement that the Board indicated that it did not have any idea how many physicians employ CRNAs in an office. The NJANA supplied the Board with data a few years ago on the number of CRNAs that work in offices. In addition, the number of CRNAs affected is not relevant because the policy is not lawful.

RESPONSE: Again, the survey information provided in Ms. Saravia's 1998 letter as to this point was far from conclusive. The Board recognizes the importance of factual information concerning physician office practice in New Jersey and supports the efforts of Mr. Joel Cantor, Director for the Rutgers Center for State Health Policy, to obtain data to help develop policy and program initiatives in this area.

N.J.A.C. 13:35-4A.3 Definitions

COMMENT: With respect to the definition of "anesthesiologist" contained in the current rule, the New Jersey State Society of Anesthesiologists (NJSSA) points out that there are very few anesthesiologists in practice that meet the Fellow in the College criteria (a Fellow in the American College of Anesthesia prior to 1982 can be accepted to hold the rank of Chief of Anesthesia along with the American Boards; Fellowship prior to 1982 was by exam). Also, the American Board of Anesthesiology no longer accepts certification from overseas certifying boards as an equivalent of the American Boards.

RESPONSE: The comment is directed to a provision of subchapter 4A which is not part of this rulemaking. The definition is unchanged. Any change to sections not proposed for amendment at this time would be a substantive change requiring reproposal.

78. COMMENT: An anesthesiologist suggests further defining the term "anesthetic agents." He suggests adding "or strongly depressant drugs such as chloral hydrate." This would make clear the applicability of requirements appearing at N.J.A.C. 13:35-4A.6(f)1 and 2, 4A.7(i)1 and 2 and 4A.10(a)3.

RESPONSE: The comment is directed to a provision of subchapter 4A which is not part of this rulemaking. The definition is unchanged. Any change to sections not proposed for amendment at this time would be a substantive change requiring reproposal.

79. COMMENT: With respect to the definition of "complication," the New Jersey State Society of Anesthesiologists asserts that temporary or permanent loss of function is not considered a usual outcome of a procedure. Dr. Moss suggests adding as an example of "temporary loss of function," neurological damage such as ulnar nerve palsy from poor positioning of the arm.

RESPONSE: This example would be expected to be readily apparent as a "temporary loss of function" and specific reference would not be necessary for understanding.

80. COMMENT: The New Jersey State Society of Anesthesiologists also suggests adding a listing of indicators for Quality Improvement studies in offices (as related to complications in conscious sedation) to the definition of "complication." Specifically, it was suggested that the following incidents should be added: fall in oxygen level under 90 percent; incidence of use of reversal agents; prolonged recovery time; and length of stay after reversal agent.

RESPONSE: The identification of indicators that do not rise to the level of "complications" has merit for individual quality improvement. For purposes of reviewing applicants for privileges in conscious sedation, the balance struck in the rule addresses reporting through designation of specific complications as well as hospitalization. At this time, the explicit indicators review suggested is beyond the regulatory scope of the reporting requirement.

81. COMMENT: The New Jersey State Society of Anesthesiologists noted it agreed with the Board's requirement of reporting all admissions to hospitals.

RESPONSE: The Board thanks the commenter for its support.

82. COMMENT: The South Jersey Academy of Dermatology expressed concern with respect to the definition of minor surgery insofar as it excludes liposuction and lipo-injection performed under tumescent anesthesia, and thus makes such procedures subject to the requirements set forth in the rule.

RESPONSE: The Board intends that these rules ensure the safety of the patient in the office setting not only with respect to the dose of local or topical anesthesia but, in the case of liposuction, for example, performed using any technique involving "excessive manipulation or removal of tissue" in the office setting.

83. COMMENT: A representative of the American Academy of Dermatology Association (AADA), comments that certain procedures such as tumescent anesthesia utilize an anesthetic (lidocaine) at levels different from that recommended by manufacturers. She explained that such use is not a misutilization of the medication, just a new use, not anticipated by the manufacturer. Therefore, the Association recommends that the language be modified to say " ... no more than the maximum safe dose of local or topical anesthesia ... " The President of the American Society for Dermatologic Surgery, objects to the language that "minor surgery" is "surgery ... performed on a patient who has received no more than the maximum manufacturer recommended dose of local or topical anesthesia ... " and suggests it would be sufficient to revise the rule to read " ... no more than the maximum safe dosages of local or topical anesthesia ... " since there is published

data citing safe and effective use of lidocaine, for example, at levels different than that which manufacturers recommend. It is noted that doctors may commonly identify new uses of medications that were not anticipated by the manufacturer.

RESPONSE: The commenter is referred to the above Response to testimony of Dr. Lawrence concerning the maximum safe dose. The Board recognizes that individual dose varies based on procedure, patient response and degree of anesthesia required. At the same time, the rule is directed to the "maximum manufacturer recommended dose" which would not be safely exceeded regardless of the procedure. It is not the Board's intention to suggest that a safe dose would never differ from a manufacturer recommendation.

84. COMMENT: Representatives of the Dermatological Society of New Jersey, the American Society for Dermatologic Surgery, and the American Academy of Dermatology Association (AADA) all objected to the inclusion of liposuction and lipo-injection in the same category as breast augmentation or reduction and removal of breast implants. They maintain that liposuction, as performed with pure tumescent anesthesia and with appropriate levels of aspirate, does not involve either extensive manipulation or removal of tissue. It was reported that data shows no significant adverse incidents resulting from liposuction performed with pure tumescent anesthesia. It was further noted that the Florida Board of Medicine categorized tumescent liposuction as "minor surgery." The Dermatological Society of New Jersey also maintains that lidocaine in tumescent anesthesia, is used in doses beyond manufacturer recommendations but is safe. It also suggested that the language be revised to " ... no more than the maximum safe doses of local or topical anesthesia ... " and further that liposuction performed under pure tumescent anesthesia, and lipo-injection, be exempt from the regulation and be considered "minor surgery" and specifically exclude from the definition of "minor surgery" liposuction using multiple forms or higher levels of anesthesia.

RESPONSE: The Board acknowledges that the proposed rules identify a range of very different procedures. The Board notes that despite the difference in the procedures, in the interest of patient protection, its intention is to assure that those procedures that involve manipulation of tissue or removal of tissue, even using local anesthesia, are subject to the same standards of training and skill in an office as in a hospital. As no form of liposuction is being considered "minor surgery" for purposes of these rules, liposuction using multiple forms and higher levels of anesthesia will not be "minor surgery."

85. COMMENT: The American Academy of Dermatology Association (AADA) also requests that the Board exclude from the definition of "minor surgery," any other invasive procedure as performed in conjunction with liposuction.

RESPONSE: The Board agrees with this suggestion but understands that it would be relevant only in the context that was requested, specifically excluding pure tumescent liposuction from "minor surgery." Because the liposuction procedure was not excluded from minor surgery, the safeguards of the regulation will be in place during other invasive procedures performed in conjunction with liposuction. Specific exclusion of these procedures from "minor surgery" would therefore not appear to be necessary.

86. COMMENT: The New Jersey State Society of Anesthesiologists commends the Board for recognizing that liposuction or lipo-injection, breast augmentation or reduction and removal of breast implants are not to be considered "minor surgery" even when performed under local anesthesia.

RESPONSE: The Board thanks the commenter for the support.

87. COMMENT: A representative of the South Jersey Academy of Dermatology supports stringent regulation for procedures requiring general anesthesia, but takes the position that there should be little or no regulation for procedures in which the patient remains alert and responsive, including liposuction under "purely tumescent" anesthetic technique.

RESPONSE: The Board appreciates the support for the regulation for procedures performed under general anesthesia. The Board intends that the amount of regulation of other anesthesia services and assurance of education, training and skill is only so that the patient in the office setting is protected as much as in the

hospital.

88. COMMENT: An attorney representing the Radiological Society of New Jersey comments that under "minor surgery," the word "tranquilization" is misspelled and under "special procedure," the word "anesthetic" is misspelled.

RESPONSE: The Board thanks the commenter and has made the correction to tranquilization upon adoption but notes that the word "anesthetic" (where misspelled) was in the proposal for deletion.

89. COMMENT: With respect to "special procedure," the New Jersey State Society of Anesthesiologists addressed the use of the term "sedative" with regard to pediatric MRI. The Board should use "conscious sedation" because using the word "sedative" could justify the use of chloral hydrate which has been implicated in pediatric MRI deaths and could thus exempt radiologists from the requirements as they apply to conscious sedation.

RESPONSE: As noted above in the discussion concerning the testimony received at the public hearing, the Board agrees that, in the interest of clarity, the definition of "special procedure" be amended to use the term "conscious sedation" instead of "sedative dose."

90. COMMENT: The New Jersey State Society of Anesthesiologists suggested that the definition of "special procedure" be clarified so that the use of benzodiazepines for relief of patient anxiety does not implicate the requirement to become privileged. It was suggested that the word "oral" precede the word benzodiazepines so the IV route of administration is not used since that would make it moderate or conscious sedation.

RESPONSE: As noted in a Response above to the testimony received at the public hearing, the Board has made the requested clarification.

N.J.A.C. 13:35-4A.6 Surgical Standards

91. COMMENT: (N.J.A.C. 13:35-4A.6(c)) The Board limits in-office procedures to healthy patients--those with physical status classifications of ASA I or II (general or regional anesthesia) or ASA I, II or III (conscious sedation). CRNAs routinely treat patients in the hospital with less favorable health conditions, requiring only that the anesthesiologist be immediately available. Yet the Board limits CRNAs in the office by allowing CRNA treatment of healthy patients only if the physician meets Board standards. The Board is creating a two-tier approach as between offices and the hospital and is requiring a stricter standard of care.

RESPONSE: As the comment recognizes, in a hospital, an anesthesiologist must be immediately available when a CRNA is providing anesthesia services. The Board believes that patient protection, when general or regional anesthesia is being administered, requires no less in the office setting. The capabilities of an office are more limited than those at a fully staffed hospital and the Board limits patients who are appropriate candidates for anesthesia services and special procedures in an office through physical status classification. The Board believes that patient safety requires that the properly trained personnel include an anesthesiologist to be available in the office setting where patients are under general or regional anesthesia or receiving certain special procedures.

92. COMMENT: (N.J.A.C. 13:35-4A.6(a)) The American Society for Dermatologic Surgery and the American Academy of Dermatology Association (AADA), in addressing the issue of hospital privileges being used as a method for credentialing office-based surgical procedures, cite adverse patient incident data in Florida showing that 99 percent of physicians who reported adverse incidents held hospital privileges. They opine, therefore, that it is not an indicator of safe medical offices.

RESPONSE: The Board appreciates the additional data offered and believes that the statistics provided may be particularly relevant to the question of the relevant hospitals' renewal periods for privileges. The issue identified may be a subject for consideration in the future; however, for now, the Board will rely on the hospital credentialing process.

93. COMMENT: The American Society for Dermatologic Surgery (ASDS) and the American Academy of Dermatology Association (AADA) advise that the ASDS and AADA support Board-approved privileging only if applicants are subject to review by a committee of peers to ensure fair treatment.

RESPONSE: It has been and will continue to be the Board's intention to do all it can to assure that review of applicants is accomplished through a fair process, which includes reviewers for relevant practice fields.

94. COMMENT: One commenter expressed concern that use of hospital privileges "as a primary indicator of safe medical offices may actually place the patient in greater jeopardy than to completely disregard its standard." She strongly suggested that physicians seeking Board privileges be subject to review by a committee of their peers, specifically other physicians who are certified by a National Medical Specialty Board recognized by ABMS in the same medical specialty as the applicant.

RESPONSE: As noted above, the Board continues to be of the view that maintenance of current hospital privileges does provide assurance that credentials have undergone review. As to those who seek privileges from the Board, it is expected that there will be a review of physicians seeking privileges by certified knowledgeable physicians.

95. COMMENT: (N.J.A.C. 13:35-4A.6(b)) The New Jersey State Society of Anesthesiologists suggests that where a surgeon does not have hospital privileges, he should have an arrangement with a specialist in his own field to handle any hospitalized complications.

RESPONSE: The comment is directed to a provision of subchapter 4A which is not part of this rulemaking. The transfer agreement section is unchanged. Any change to sections not proposed for amendment at this time would be a substantive change requiring reproposal.

96. COMMENT: Representatives of the Dermatological Society of New Jersey, the American Society for Dermatologic Surgery, and the American Academy of Dermatology Association (AADA), in addressing the language mandating that all privileged practitioners have written transfer agreements with a licensed hospital, suggest adopting the language of the California Medical Board which requires "a written transfer agreement with an acute care facility within reasonable proximity or with another physician who had admitting privileges at that facility.... " All of the above commenters mention the Florida Administrative Law Judge overruling sections of the Florida Medical Board's rule requiring a written transfer agreement.

RESPONSE: The comment is directed to a provision of subchapter 4A which is not part of this rulemaking. The required written transfer agreement with a licensed hospital is unchanged. Any change to sections not proposed for amendment at this time would be a substantive change requiring reproposal. The Board notes that the Florida Court of Appeals, finding the Administrative Law Judge determination on transfer agreements to be in error, upheld the requirement for transfer agreements.

97. COMMENT: The representative of the AADA also noted that the Florida ALJ decision which had overturned the portions of a rule promulgated by the Florida Board that required mandatory hospital privileges and mandatory written hospital transfer agreements. He suggested modeling the New Jersey rule after California's, which requires the physician to have privileges or a written hospital transfer agreement with an acute care facility within a reasonable proximity or with a physician who has admitting privileges at that facility.

RESPONSE: The comment is directed to a provision of subchapter 4A which is not part of this rulemaking. The required written transfer agreement with a licensed hospital is unchanged. Any change to sections not proposed for amendment at this time would be a substantive change requiring reproposal.

98. COMMENT: (N.J.A.C. 13:35-4A.6(f)) The New Jersey State Society of Anesthesiologists noted its agreement with the Board's position as to the danger of the administration of potent drugs prior to admission to a facility.

RESPONSE: The Board appreciates the support.

99. COMMENT: (N.J.A.C. 13:35-4A.6(f)) A commenter from the Radiological Society of New Jersey noted that the rule should be modified to make it clear it is permissible for a practitioner who performs surgery to prescribe the anesthetic agent prior to arrival at the office, but not acceptable for that practitioner to prescribe that the anesthetic agent be administered, taken or ingested prior to the arrival at the office.

RESPONSE: The Board intended the language "prior to the arrival at the office" at N.J.A.C. 13:35-4A.6(f)1 to modify "to be administered." Thus, the language is intended to mean that it is permissible to prescribe the anesthetic agent prior to arrival at the office. It is not permissible to prescribe that the anesthetic agent be administered (or taken) prior to arrival at the office.

100. COMMENT: The Radiological Society of New Jersey also suggest that N.J.A.C. 13:35-4A.6(f)2 and 4A.7(i)2 should be modified to clarify that patients should not be anesthetized for the office procedure prior to arrival at the office, but if a patient arrives at the office for a scheduled or urgent procedure (that is, in less than life-threatening circumstances), already anesthetized or sedated for some other reason, then the physician should be permitted to proceed with the office procedure.

RESPONSE: The Board understands the Society's comment to be directed to that limited situation which may arise only in the radiology context. The situation is where a hospital or licensed health care facility is responsible for transport of a patient to whom an anesthetic agent had been prescribed or administered, under the care of appropriate hospital or other licensed health care facility licensed personnel during transport, to a radiology practice for a radiological procedure or procedures unavailable in the hospital or licensed health care facility. The Board agrees to the clarification to the extent that a patient arriving at the office is in the company of medical personnel from an acute care facility. The language of both paragraphs has been amended to provide for such an exception to the prohibition on acceptance of a "patient to whom an anesthetic agent for the surgery (other than minor surgery) or special procedure has been prescribed or administered."

101. COMMENT: The NJSSA suggests that the language should make clear that this prohibition applies to "special procedures" as well as "surgery" because MRIs have been implicated in over sedation outside the facility.

RESPONSE: The Board agrees that this prohibition applies both to surgery and special procedures and notes that the reference is included in N.J.A.C. 13:35-4A.6(f)2 and 4A.7(i)2.

102. COMMENT: A commenter recommends that the Board modify the rules so that a prior prescription for and use of EMLA cream (a local anesthetic) is not precluded. Patients apply this cream between 90 to 120 minutes before their scheduled appointments and this saves them the time and inconvenience of waiting in the office for the cream to take effect.

RESPONSE: The regulation, as proposed, would not apply to the circumstances the commenter described concerning prior prescription and use of EMLA cream. Both N.J.A.C. 13:35-4A.6(f)1 and 4A7(i) deal with an "anesthetic agent" which is defined in N.J.A.C. 13:35-4A.3 as "any drug or combination of drugs administered with the purpose of creating conscious sedation, regional anesthesia or general anesthesia."

N.J.A.C. 13:35-4A.8 and 4A.9 Administration of general anesthesia and regional anesthesia

103. COMMENT: (N.J.A.C. 13:35-4A.8) The requirement for Board general anesthesia privileges effectively limit this to anesthesiologists. Economically, an office will not need both a CRNA and an anesthesiologist. The regulation did not give notice to health care providers that they could not ever be credentialed to continue performing general anesthesia in the office.

RESPONSE: Several commenters have expressed that patient protection demands that the standards in an office for personnel, including education and training, be on par with the standards in a hospital. In a

hospital, an anesthesiologist must be immediately available when a CRNA is providing anesthesia services. The Board believes that patient protection, when general or regional anesthesia is being administered, requires no less in the office setting.

104. COMMENT: The AADA comments that available data as to office procedure indicate a very high percentage of adverse patient incidents that occur in conjunction with the use of general anesthesia in office-based surgeries. The AADA, therefore, requests that the Board ban the use of general anesthesia in the office setting.

RESPONSE: The Board believes, through implementation of required education and training of personnel, the monitoring of patients and mandatory equipment, that it has taken a balanced approach to assure patient safety when its licensees are providing such office procedures.

105. COMMENT: New Jersey hospital/ambulatory care center regulations should not be a model for the regulation. In a hospital, the supervision requirement is a physician who is "immediately available" and who may be concurrently responsible for patient care if there can be attendance to supervisory duties without jeopardizing patient safety. In hospitals the anesthesiologist can be "on call." Supervision is different in an office and there would be no need for both a CRNA and an anesthesiologist.

RESPONSE: The Board agrees that supervision is different in the office setting but believes that the required personnel are necessary in the interest of patient safety. As the comment recognizes, in a hospital, an anesthesiologist must be immediately available when a CRNA is providing anesthesia services. The Board believes that patient protection, when general or regional anesthesia is being administered, requires no less in the office setting. The capabilities of an office setting are more limited than those at a fully staffed hospital.

106. COMMENT: Both the President of the American Association of Nurse Anesthetists (AANA) and the Director of Practice of the NJSNA object to the non-anesthesiologist education requirement for general and regional anesthesia which effectively requires a physician who administers these types of anesthesia or who supervises a CRNA who administers them to be an anesthesiologist.

RESPONSE: As noted in earlier response to the testimony of Ms. Saravia and reiterated here, the Board considers that the requirement of eight hours of continuing medical education for a physician supervising a CRNA in the context of N.J.A.C. 13:35-4A.9 (regional anesthesia), would be an unlikely inducement for a physician to hire an anesthesiologist. The Board considers the requirement of 60 hours of continuing medical education for those supervising CRNAs in general anesthesia is of course more substantial and relates to the increased risks. The provisions addressing this provide benefits in patient safety, assuring that practitioners are knowledgeable concerning the anesthesia used on their patients. The relevant point in this rulemaking is the privileging standard in N.J.A.C. 13:35-4A.12 that imposes anesthesia training requirements on physicians who seek to administer or supervise the administration of general anesthesia in an office. The training and experience necessary to obtain privileges to administer general anesthesia are contained in N.J.A.C. 13:35-4A.12(a) and represent the Board's intent to assure that a patient's safety is protected in an office to the same degree as it is in a hospital or ambulatory care facility. The Board believes that the burden of the provision is outweighed by benefits achieved in patient safety, assuring that practitioners are knowledgeable concerning the general anesthesia used on their patients.

107. COMMENT: The Director of Practice of the NJSNA asserts that the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), an accrediting agency of hospitals in the U.S., has established standards for office-based practice which do not require that CRNAs be anesthesiologist supervised. She noted that the lack of supervisory requirement for purposes of Medicare reimbursement for CRNAs and the CMS allowing governors the flexibility to opt out of supervisory regulations under certain circumstances.

RESPONSE: JCAHO standards are subordinate to State standards. The Federal rule requires supervision unless, after consideration of state law and access to and quality of anesthesia services, a Governor certifies that it is in the state citizens' best interests to opt out of the supervision requirement.

108. COMMENT: The American Association of Nurse Anesthetists (AANA) suggests removing the provisions of the rules that prohibit physicians from concurrently supervising the administration of anesthesia and performing surgery (other than for minor surgery).

RESPONSE: The comments are directed to provisions of subchapter 4A which are not part of this rulemaking. The requirement that prohibits physicians from concurrently supervising the administration of anesthesia and performing surgery (other than for minor surgery), in the first sentence of N.J.A.C. 13:35-4A.8(b) and in 4A.9(b), is unchanged. Any change to subsections not proposed for amendment at this time would be a substantive change requiring reproposal.

109. COMMENT: NJSNA also objected to anesthesiologist supervision since the regulation allows a CRNA to convert a patient to general anesthesia in an emergency situation, even in the absence of an anesthesiologist, noting that in an emergency, tension is high and skills are put to the test; therefore, in a routine case, CRNAs should certainly be allowed to administer general anesthesia without such supervision.

RESPONSE: The proposed amendment to N.J.A.C. 13:35-4A.8, suggested by the CRNAs, removes any regulatory barrier to a necessary conversion from conscious sedation administered by a CRNA to general anesthesia. The necessary conversion from conscious sedation to general anesthesia is envisioned by the Board to occur only in emergency circumstances when the best interests of the patient are at stake. The emergency essentially makes such conversion preferable to no action.

110. COMMENT: The New Jersey State Society of Anesthesiologists also noted opposition to the provision which would allow conversion in emergency situations.

RESPONSE: The Board believes that the regulatory barrier identified by the CRNAs was a valid concern. The Board had not intended to suggest rigidity in life threatening circumstances and believes that all concerned would be expected, in such circumstances, to do what is in the patient's best interest. This emergency safeguard provision is provided for emergency situations. It is not, nor is it expected to be viewed as, anything to countenance non-compliance with the regulatory scheme.

N.J.A.C. 13:35-4A.10 Administration of conscious sedation; authorized personnel

111. COMMENT: The President of the American Association of Nurse Anesthetists (AANA) notes that there is no more need for surgeons who work with CRNAs during the administration of conscious sedation to possess advanced training or education in anesthesia than there is when surgeons work with anesthesiologists. She questioned the provision that a physician's completion of a course in conscious sedation would bring him or her up to par with a CRNA's education and experience in that area. The organization maintains that the provisions would discourage office-based surgeons from working with CRNAs because to receive Board privileges requires a physician to demonstrate clinical experience plus (1) either be Board certified in anesthesia, critical care medicine, or emergency medicine or (2) be ACLS or PALS certified and have taken a course in conscious sedation. Also, regarding conscious sedation, AANA's position is that it should only be administered by qualified anesthesia providers and the person administering it should not be the person performing the operative procedure. Conscious sedation may end up being converted to deep sedation and loss of consciousness and the CRNAs are better trained than surgeons to respond to emergency situations requiring, for example, airway management, administration of emergency fluids and drugs and basic or advanced life support techniques. Eight hours of CME every three years and being ACLS certified and having taken a course in conscious sedation is not sufficient.

RESPONSE: The proposed amendment and rule do not change the original rules, but the Board notes its position that physicians should be knowledgeable concerning the anesthesia services that are provided in connection with the surgical procedures they are performing. The Board considered both the types of procedure involved and the relative risks to the patient, arriving at what the Board views as the appropriate balance between anesthesia providers and necessary training to be required of the practitioner administering or supervising the administration of conscious sedation (as compared with regional and general anesthesia).

112. COMMENT: There is no mandate in N.J.A.C. 13:35-4A.10, Administration of conscious sedation; authorized personnel, for such a physician to employ either a CRNA or an anesthesiologist. For conscious sedation, the rule allows a physician to perform the procedure and the anesthesia himself.

RESPONSE: The commenter is correct that the rule does not require the otherwise qualified physician to employ either a CRNA or an anesthesiologist; however, the use of conscious sedation requires, in addition to the required education and training for the physician to obtain hospital credentials or Board privileges, that monitoring be done by a physician (not the practitioner performing the surgery or special procedure), CRNA or registered professional nurse or physician with training, under the supervision of a privileged or credentialed physician.

113. COMMENT: An attorney representing the Radiological Society of New Jersey comments that the CME requirement is more stringent than that required to obtain privileges to administer conscious sedation at many hospitals. If this is not required for the hospitals to obtain JCAHO certification, then it should not be required of physicians in their private offices.

RESPONSE: The circumstances presented in an office and the staffing available are not the same as in a hospital. The Board believes that the balance must be struck with patient safety paramount. The CME requirements are not overly burdensome in that light.

114. COMMENT: An attorney representing the Radiological Society of New Jersey commented that the requirement that physicians be "continuously present in the procedure room" should be modified for radiologists who should be required to be "immediately available" in the office suite because there are certain radiological procedures where it would not be appropriate or safe for the radiologist to be present in the room during the procedure.

RESPONSE: The Board agrees that there should be language acknowledging that there are circumstances when a practitioner would move outside of the radiology field for brief moments. Clarifying language has been added to N.J.A.C. 13:35-4A.10(a)3 which states: "Continuously present in the procedure room" does not require that a practitioner remain in the procedure room in violation of human exposure safety standards regularly employed during radiological procedures.

N.J.A.C. 13:35-4A.11 Administration of minor conduction blocks; authorized personnel

115. COMMENT: The AANA comments that the proposed amended rule provides that retrobulbar blocks may only be administered by physicians privileged by a hospital or through the alternative privileging program. This discriminates against CRNAs and the Board cites no justification for this restriction.

RESPONSE: Safe use of this anesthetic technique requires knowledge and training of both anesthesia and the specific area of the anatomy. The precision and skill required to safely perform a retrobulbar block is gained through physician specialty training. This expertise is particularly important because the technique is performed very close to the patient's eye. Patient safety in and around the eye is paramount and is the basis for the Board's determination of appropriate personnel.

N.J.A.C. 13:35-4A.12 Alternative privileging procedure

116. COMMENT: A number of commenters emphasized the need to ensure that surgeons meet educational and training standards. A number thought the Board's criteria should be the same as those used by State-licensed hospitals. One strongly opined that a surgeon who requests privileges must be able to document training and experience for the specific procedures. The alternative privilege criteria must be strict and clearly defined and must require residency training in surgery and training in procedures for which the privileges are requested, including, the doctor being able to document training and education experience in that special procedure. Another commenter noted that surgeons must always have an in-depth knowledge of all necessary medical areas and their training should include four years of training and certified by the ABMS. This is especially important in an office setting where immediate consultation with another surgeon

is not possible in the event of a complication. A surgeon cannot be trained in a short period of time. Commenters emphasized, from a patient safety perspective, the important of the individual seeking to do any surgical procedures in an office setting (and applying for alternative credentialing) having proper surgical credentials (and being able to document training and experience in the specific procedures for which he or she is requesting the privileges). This entails certification by a surgically specialized ABMS recognized Board. Further, the individual must provide proof of certification for that area of surgical privileges he or she is requesting. Stated simply, State in-office regulations should have the same requirements as State-licensed hospitals. One commenter suggested that a surgeon requesting privileges for liposuction, might need to be proctored for the first three cases dealing with liposuction.

RESPONSE: The Board agrees and believes that the standards it is proposing are consistent with the suggestions offered by the commenters.

117. COMMENT: The Dermatological Society of New Jersey offered its view that a physician's ability to practice medicine should be determined by education and training as credentialed by the appropriate national medical specialty board as recognized by the ABMS and this certification should be the mechanism used for credentialing of "privileging" of physicians and should be the "alternate pathway" recognized by the Board.

RESPONSE: The Board agrees that education and training are essential to the privileging process. The Board also believes that the privileging process should also include an evaluation of clinical experience, through attestations, clinical competence as determined through a review of a patient log and, where appropriate for privileges sought, any necessary additional training appropriate to certain procedures or techniques.

118. COMMENT: The President of the Essex County Medical Society opined that for patient safety purposes, we should not accept less than that required in licensed hospitals, that is, a surgeon must have completed a surgical training program recognized by the ACGME and the ABMS and be operating only within his or her scope of training and anatomic expertise.

RESPONSE: The Board agrees with the commenter's opinion.

119. COMMENT: Some writers felt that facility accreditation is an important component of standard of care. A number of surgical subspecialists and their organizations stressed the importance of accreditation of the surgical facility where plastic surgery procedures are performed and urged the Board to require accreditation for all surgical facilities including office-based surgical facilities. A few commenters urged that the Board must provide regular inspections of these locations where surgical procedures are to be conducted to ensure that the location meets the standards of a recognized accrediting organization. One suggested that since the Board already has rules in place governing the inspection of outpatient surgical facilities, the Board should consider enlisting the services of one of the existing nationally recognized accrediting organizations that already conducts these inspections and enforces the rules at outpatient surgical facilities.

RESPONSE: As noted previously, the Board's authority is not facility-based. The Board, however, does believe that the standards established by these organizations are important safeguards and in many respects such standards are addressed in the Board's proposal.

120. COMMENT: The President of the American Society of Plastic Surgeons (ASPS) encourages the Board to require that surgeons operating in office-based surgical facilities be accredited by nationally recognized accrediting agencies.

RESPONSE: Such organizations typically accredit premises not the practitioners and, thus, have a different focus than that vested in the Board.

121. COMMENT: The American Academy of Dermatology Association (AADA) notes that physician credentialing beyond licensure by the Board and certification by a national medical specialty board recognized by the ABMS is not necessary in regard to procedures performed under Level I anesthesia.

RESPONSE: The Board believes that the rule incorporates the appropriate reduced level of safeguards for the circumstances that can arise with Level I anesthesia.

122. COMMENT: The President of New Jersey Association of Nurse Anesthetists asserted that the Board should not be in the business of granting or denying privileges; that is the function of a "credentialing" body.

RESPONSE: The Board appreciates the valuable function of the various recognized credentialing bodies and notes that the purpose of the alternative privileging initiative is to address those practitioners who have elected not to submit to the review of such credentialing entities, such as hospitals. This rule derives from the need and the Board's responsibility to assure patient protection in the areas not already the subject of other review.

123. COMMENT: One plastic surgeon stressed that physicians who have not completed a surgical residency cannot be considered to be equally trained to provide the appropriate standard of competency and safety expected by the public and which is provided by completion of a surgical residency training program, followed by certification in a surgical subspecialty by a recognized board of the ABMS. He urges the Board to set the standard for surgery in office-based settings at a level consistent with the minimum years of surgical training required by Board eligibility in a surgical subspecialty.

RESPONSE: This view is largely consistent with the Board's approach in this initiative.

124. COMMENT: The Dermatological Society of New Jersey cites the overall safety record of dermatologists and comments that the Board's broad-based rules are unfair and unreasonable.

RESPONSE: The implementation of the alternative privileging mechanism will focus on evidence of training and experience with clearly articulated criteria, to be applied fairly to those seeking privileges.

125. COMMENT: (N.J.A.C. 13:35-4A.12(a)3ii) An attorney representing the Radiological Society of New Jersey commented regarding the patient log that such a log may not be available to an applicant who only recently joined a practice and may not be able to obtain a patient log from his or her prior practice. An alternative mechanism should be established. For example, the physician could be "grandfathered" until his privileges are up for renewal, two years later.

RESPONSE: The Board believes that a patient log is necessary for appropriate review of an applicant's experience. The Board believes that individual practices will cooperate in allowing physicians access to the log information for the limited purpose of application for privileges. If it is shown that this is not the case, the Board will revisit the issue only as to what is necessary to gain access to the log information.

126. COMMENT: (N.J.A.C. 13:35-4A.12(b)1) An attorney representing the Radiological Society of New Jersey does not understand the text "with the applicant's practice of patients for which privileges are requested except as specifically excluded from practice." He suggests clarification.

RESPONSE: The language intends to limit the information to results for all age groups that the practitioner treats. If the practice is limited to children, then adult patients would be considered "specifically excluded from practice."

127. COMMENT: (N.J.A.C. 13:35-4A.12(a)3i) An attorney representing the Radiological Society of New Jersey commented that since many doctors practicing outside of residency for any length of time are not typically under the "personal observation" of another physician when they perform procedures, no more than one or two references should be required.

RESPONSE: The Board believes that an important element of clinical review is gained through observation. The implementation of this process may require that typical practices be amenable to some change to allow the necessary personal observation to occur. In the interest of patient protection in the private office, the Board recognizes that observation of complex procedures assists in assurance of competence. The Board also

expects that procedures of lesser complexity that require the same or substantially similar level of procedural skill and technique in the same anatomical area(s), would not also require observation.

128. COMMENT: An attorney representing the Radiological Society of New Jersey suggests a provision in the regulation requiring the Board to oversee the reviewing entity to ensure that it does not perform in an arbitrary or capricious manner.

RESPONSE: The Board retains full responsibility for the privileging or denial of privileges process. The Board is fully confident that applicant submissions will be fully and fairly reviewed and that the process will be reasoned and fair.

129. COMMENT: A representative of the Medical Review and Accrediting Council, Inc. (MRAC) comments that physicians applying for new privileging should be assured of a timely review and should have access to information on the status of their application in the review process. The Board is unlikely to be sufficiently staffed and, therefore, should delegate the function to an outside entity to provide the most efficient process and support services to potential applicants. He predicts a large volume of applicants and suggests that the reviewing entity have sufficient medical background to efficiently and fairly process applicants and make recommendations and should meet a high standard of performance in communicating with the applicant so as to avoid applicants directly complaining and making information requests to the Board, that is, define the qualifications of the reviewing entity in the regulations. The reviewing entities should possess medical expertise and a unique knowledge of the diversity of the New Jersey practice environment.

RESPONSE: The Board does envision outsourcing the preparation of the summary report and will select entities pursuant to a process by which it can be assured the selected organization can fulfill the responsibilities identified. In practice, the Board will probably rely on the recommendations of the preliminary report, but it will retain the ultimate decision-making.

130. COMMENT: The New Jersey State Society of Anesthesiologists suggested that because CRNAs can administer anesthesia without the same alternate privilege requirements demanded of physicians, CRNA's employers should be responsible for verification of the CRNA's credentials. Possible verification suggestions include: (1) obtaining recommendation letters from surgeons and facilities who have worked with the CRNA over the last two years; (2) verification of the CRNA's malpractice coverage and malpractice records and disciplinary action history; (3) obtaining a list of cases performed in the last year to ensure the CRNA wishing to practice in an office setting is not applying directly after conclusion of training and without any field experience.

RESPONSE: This suggestion is beyond the scope of the proposal and it is not the intention of the Board to become involved with the establishment of credentialing standards of this type. Nonetheless, the Board notes that, pursuant to N.J.A.C. 13:35-4A.4(b)1, practitioners are required to ensure that healthcare personnel providing patient services in the office possess the required qualifications and are currently licensed, registered or certified, as applicable.

N.J.A.C. 13:35-4A.17 Compliance timetables

131. COMMENT: One commenter urged the Board to rely on independent accrediting organizations to ensure standards are being met.

RESPONSE: The Board appreciates the confidence in the accrediting organizations and agrees that they perform an important function. At the same time, Board jurisdiction is not premises-based but focuses on the licensees over whom the Board has jurisdiction. The Board has therefore placed obligations on its licensees to meet certain standards which are largely comparable to those which the accrediting bodies would recognize.

Appendix

A number of the submissions were accompanied by extensive supporting documentation which is part of record of rulemaking before the agency. These materials are available for review at the Board office.

Deborah A. Chambers, C.R.N.A., MHSA, President, AANA

Appendix A

1. The AANA's Standards for Office Based Anesthesia Practice

Appendix B

1. Jan. 18, 2001 Federal Register Rule (Vol. 66, No. 12, pp. 4674-4687)

Appendix C

1. AANA's Quality of Care in Anesthesia

2. Published Paper Not About Nurse Anesthesia: "Pennsylvania Study" Examining Post Operative Physician Care which analyzes the Pennsylvania study titled Anesthesiologist Direction and Patient Outcomes (2000; 93:152-163)

3. Michael Pine, M.D., M.B.A., January 5, 1999, "Annotated Bibliography of Selected References on the Quality of Anesthesia Care by Anesthesiologists and Nurse Anesthetists"

4. Education News, December 1998, Vol. 66, No. 6, Lorraine M. Jordan, C.R.N.A., PhD, Robert E. Oshel, PhD, Nurse anesthetist malpractice and the National Practitioner Data Bank

Appendix D

AANA Journal, Legal Briefs, Mitchell H. Tobin, JD, Gene A. Blumenreich, JD, April 1992, Vol. 60, No. 2, New Jersey's hospital anesthesia standards

Appendix E

1. State of Florida, Division of Administrative Hearings, November 16, 2000, Florida Administrative Law Judge decision

2. AANA article in NewsBulletin, Vol. 54, No. 11, December 2000, Judge Finds Florida Board of Medicine's Anesthesia Rule Invalid

Appendix F

Comments of the (Pennsylvania) Independent Regulatory Review Commission on State Board of Medicine Regulation No. 16A-493 Administration of Anesthesia, December 18, 1996 (cited for not supporting C.R.N.A. supervision)

Appendix G

AANA's Scope and Standards for Nurse Anesthesia Practice

Appendix H

AANA's Position Statement titled Qualified Providers of Conscious Sedation

Appendix I

1. AANA's Qualifications and Capabilities of the C.R.A.
2. AANA's Education of Nurse Anesthetists in the United States
3. AANA's Nurse Anesthetists . . . At A Glance

Appendix J

1. AANA Journal Legal Briefs, Gene A. Blumenreich, JD, February 1998, Vol. 66, No. 1, The overlap between the practice of medicine and the practice of nursing
2. AANA Journal Legal Briefs, Gene A. Blumenreich, JD, June 1990, Vol. 58, No. 8, The administration of anesthesia and the practice of medicine
3. AANA Journal Guest Editorial, Ira P. Gunn, MLN, C.R.N.A., FAAN, Joseph Nicosia, JD, Mitchell Tobin, JD, April 1987, Vol. 55, No. 2, Anesthesia: A practice of nursing

Appendix K

1. NY Supreme Court decision November 25, 2001 dealing with administrative agencies exceeding their jurisdiction in regulating office anesthesia

Gary M. Brownstein, M.D., American Society of Plastic Surgeons (ASPS)

1. "Guidelines for the Development of Model Legislation for Mandatory Accreditation of Office-based Surgery Facilities"

Ervin Moss, M.D., New Jersey State Society of Anesthesiologists

1. Centers for Medicare and Medicaid Services (CMS) rule published November, 2001
2. AMA Resolution 220 issued December, 2001
3. Internal memo of the ASA (American Society of Anesthesiologists) dated August 20, 2001
4. "Nurse Anesthetist Scope of Practice: Analysis of the Laws of the Fifty States and the District of Columbia" prepared for the ASA in January, 2001

Steven Norwitz, M.D., President of the New Jersey Plastic Surgeon Society

1. American Society of Plastic Surgeons (ASPS) "Statement on Liposuction" June 24, 2000
2. "From My Perspective" by Thomas R. Russell, MD, FACS, Volume 86, Number 3, March 2001, Bulletin of the American College of Surgeons (ACS)
3. "Avoidance of Disaster in Liposuction" By: Arthur W. Perry
4. "Editorial Comment on Avoidance of Disaster in Liposuction by Arthur W. Perry" By: Robert Parsons, M.D.

Matthew Olivo, M.D.

1. "Safety of Tumescent Liposuction in 15,336 Patients" National Survey Results by: C. William Hanke, MD, Gerald Bernstein, MD, Stephen Bullock, BS
2. "Does the Location of the Surgery or the Specialty of the Physician Affect Malpractice Claims in

Liposuction?" By William P. Coleman, III, MD, C. William Hanke, MD, Patrick Lillis, MD, Gerald Bernstein, MD, and Rhoda Narins, MD

3. "Tumescent Technique Chronicles" Local Anesthesia, Liposuction, and Beyond, By Jeffrey A. Klein, MD, January 23, 2002

Patricia Polansky, MS, RN, CNAA, Executive Director, Board of Nursing

December 4, 2001, Federation of State Medical Boards (FSMB), Report of the Special Committee on Outpatient Surgery--Draft Report

Thomas Russell, M.D., Executive Director, American College of Surgeons

1. "Guidelines for Optimal Ambulatory Surgical Care and Office-based Surgery" 3rd Edition

2. "Surgical Training Requirements" (chart) (Source: AMA Graduate Medical Education Directory 2001-2002 and ABMS Training Requirements for Board Certification)

Alma Saravia, Esq., General Counsel, New Jersey Association of Nurse Anesthetists, January 26, 2002

Exhibit A--(Superior Ct. NJ--App. Div., NJANA v. NJ BME) Appellant's Brief dated 12-28-98;

Exhibit B--(Superior Ct. NJ--App. Div., NJANA v. NJ BME) Amicus Curiae Letter Brief of NJ State Nurses Association dated 1-28-99;

Exhibit C--(Superior Ct. NJ--App. Div., NJANA v. NJ BME) On Appeal from N.J.A.C. 13:35-4A, Amicus Curiae Brief of AANA;

Exhibit D--(Superior Ct. NJ--App. Div., NJANA v. NJ BME) On Appeal from N.J.A.C. 13:35-4A, Appellant's Reply Brief dated 5-10-99;

Exhibit E--(Superior Ct. NJ--App. Div., NJANA v. NJ BME) argued 222-00, decided 3-2-00, On appeal from the BME, appeal dismissed;

Exhibit F--Timeline of All Correspondence To & From the BME and attaching all correspondence from 11-19-90 through 3-26-00 (not itemized here since there is SO much of it and it's an attachment to an attachment);

Exhibit G--Fed. Register Jan. 18, 2001 (Vol. 66, Number 12) [pages 4674-4687] Dept. HHS--HCFA Final Rule, Effective March 19, 2001 "Medicare and Medicaid Programs; Hospital Conditions of Participation: Anesthesia Services" (Final rule changes physician supervision requirement for C.R.N.A.s furnishing anesthesia services in hospitals, CAHs and ASCs. State laws will determine which professionals are permitted to administer anesthetics and the level of supervision required);

Exhibit H--Dec. 10, 1998 letter from Maris A. Lown, R.N. (Board of Nursing) to Alma Saravia indicating Nursing Board will regulate nursing practice by C.R.N.A.s;

Exhibit I--November 17, 1998 letter from Linda R. Williams, C.R.N.A., JD, President, American Association of Nurse Anesthetists (addressing the pre- proposal "Surgical and Anesthesia Standards in Physician's Offices; Alternative Credentials; Compliance Timetables," October 19, 1998;

Exhibit J--Nov. 16, 2000 Press Release regarding Florida ALJ decision; Decision attached.

Exhibit K--Legal Briefs, "New Jersey's hospital anesthesia standards," Mitchell H. Tobin, JD AANA Director of State Governmental Affairs, Gene A. Blumenreich, JD, AANA General Counsel, Powers & Hall, Journal of the American Association of Nurse Anesthetists, Vol. 60/No. 2, April 1992; Alma Saravia, Esq.,

General Counsel, New Jersey Association of Nurse Anesthetists, May 22, 2002 (received after January 27, 2002 end of comment period but before Board response to comments)

Exhibit A--Federal of State Medical Boards "Report of the Special Committee on Outpatient Surgery" April 2002;

Exhibit B--March 13, 2001 letter from American Hospital Association; Federation of American Hospitals; Premier, Inc.; and VHA Inc. and "ACFA rule gives hospitals flexibility in supervision of nurse anesthetists" from AHA News, January 22, 2001;

Exhibit C--March 19, 2001 Final rule. Medicare and Medicaid Programs; Hospital Conditions of Participation: Anesthesia Services 42 CFR Parts 416, 482, and 485; May 8, 2002 American Association of Nurse Anesthetists Press Releases (January 18, 2001 rule removes physician supervision requirement); American Association of Nurse Anesthetists Capitol Corner (November 13, 2001 physician supervision required unless State law and governor opt out); April 19, 2002 American Association of Nurse Anesthetists Press Releases FAQ;

Exhibit D--April 22, 2002 American Association of Nurse Anesthetists Press Releases (four Midwest states opt out of Federal physician supervision requirement);

Exhibit E--American Association of Nurse Anesthetists, anesthesiapatientsafety.com, "Nurse Anesthetist Qualifications and Capabilities," "History of Nurse Anesthetists," "Education of Nurse Anesthetists in the United States"; American Association of Nurse Anesthetists about AANA, aana.com, "Nurse Anesthetists and Anesthesiologists Practicing Together," "Nurse Anesthetists at a Glance," "A Career in Nurse Anesthesia," "Education of Nurse Anesthetists in the United States";

Exhibit F--American Association of Nurse Anesthetists, AnesthesiaPatientSafety.com, "Nurse Anesthetists at a Glance."

Summary of Changes Upon Adoption:

1. There is a change in N.J.A.C. 13:35-4A.3 in the definition of "minor surgery" to correct the spelling of "tranquilization."
2. There is a change in N.J.A.C. 13:35-4A.3 in the definition of "special procedure" to clarify the meaning of the sedative dose contemplated in the proposed language by changing it from "a sedative dose of medication adequate to cause the patient to sleep or not to move" to "conscious sedation." The more specific reference is consistent with other examples used in the definition.
3. There is a change in N.J.A.C. 13:35-4A.3 in the definition of "special procedure" to clarify the example of benzodiazepine as a medication to reduce anxiety by specifying that it is oral benzodiazepine.
4. There is a change in N.J.A.C. 13:35-4A.6(b) to clarify that the standards for performing surgery and special procedures in an office apply to any practitioner, and include the requirement of having privileges from a hospital or from the Board. The word "privileged" is changed to "any."
5. There is a change in N.J.A.C. 13:35-4A.6(b)1 to clarify that a transfer agreement must be with a hospital that has acute care capabilities because there may be specialized hospitals that are not prepared to address the kind of emergencies that could arise from in-office anesthesia, surgery or special procedures. The transfer agreement with a hospital with acute care capabilities is an important part of assuring patient safety.
6. There is a change in N.J.A.C. 13:35-4A.6(f)2 to provide an exception to the rule's intended limitation on the administration of anesthetic agents for surgery or special procedures before arrival at the office. The exception allows the practitioner to accept a patient for surgery or special procedure even though the patient has received an anesthetic agent before arrival as long as the patient is in the company of medical personnel

from an acute care facility.

7. There is a change in N.J.A.C. 13:35-4A.7(i)2 also to provide an exception to allow the practitioner to accept a patient for surgery or special procedure even though the patient has received an anesthetic agent before arrival as long as the patient is in the company of medical personnel from an acute care facility.
8. There is a change in N.J.A.C. 13:35-4A.10(a)3 to clarify that the requirement to be "continuously present in the procedure room" does not require a practitioner to remain in the procedure room contrary to human exposure safety standards regularly employed during radiological procedures.
9. There is a change in N.J.A.C. 13:35-4A.12(b)1 to clarify the reference to patients specifically excluded from practice. The attestation as to the number of procedures does not include patient groups (ages) specifically excluded from the applicant's practice.
10. There is a change in N.J.A.C. 13:35-4A.12(b)2iii to correct the inaccurate reference to "certification" in advanced cardiac life support and required specific training (as is defined in N.J.A.C. 13:35-4A.3) and assure that the training is regularly updated.
11. The Board has made a change to conform all of the subsections of N.J.A.C. 13:35-4A.7 with subsection (a) such that the supervision refers to both administration and monitoring of anesthesia services. The phrase "and monitoring" is added to subsections (e), (f), (g), (h) and (i). The word "or" is changed to "and" in paragraph (b).
12. The Board has made a change to conform reference to anesthesia services in N.J.A.C. 13:35-4A.7(f) with N.J.A.C. 13:35-4A.7(a). The word "services" is added after "anesthesia."
13. The Board has made a clarifying change to N.J.A.C. 13:35-4A.7(f) to make internal references consistent. The word "setting" is changed to "area."
14. The Board has made a change in reference to the overstay setting to conform N.J.A.C. 13:35-4A.7(g)3 with paragraph (f), deleting the term "special overnight" in favor of uniform terminology.
15. The Board has made a change to conform N.J.A.C. 13:35-4A.12(a) with N.J.A.C. 13:35-4A.8 and 4A.9 such that supervision refers to both administration and monitoring of general or regional anesthesia.
16. The Board has made a change to conform N.J.A.C. 13:35-4A.12(a) and (b) with N.J.A.C. 13:35-4A.8, 4A.9 and 4A.10 such that supervision refers to both administration and monitoring of general or regional anesthesia or conscious sedation.
17. The Board has made a technical correction to N.J.A.C. 13:35-4A.3 in the part of the definition of "minor conduction block" that specifies what is not included, such that the incorrect reference to "brachial anesthesia" is corrected to "brachial plexus anesthesia."

Federal Standards Statement

A Federal standards analysis is not required for the adopted amendments and new rule. There are no Federal practice standards or requirements that directly affect the particular subject of this rulemaking. The adopted amendments and new rule are consistent with the Federal recognition, as reflected in the rules of the Health Care Financing Administration pertaining to reimbursement by the Medicare and Medicaid programs, that determinations pertaining to standards of professional practice are reserved to the states. (See 42 CFR 416, 482 and 485.)

Full text of the adoption follows:

<< NJ ADC 13:35-4A.2 >>

13:35-4A.2 Scope

(a) This subchapter establishes policies and procedures and staffing and equipment requirements for practitioners and physicians who perform surgery (other than minor surgery), special procedures and administer anesthesia services in an office setting.

(b) For purposes of this subchapter, the standards set forth at N.J.A.C. 13:35-4A.6 do not apply to those performing non-invasive special procedures, such as non-invasive radiologic procedures. However, the standards set forth at N.J.A.C. 13:35-4A.7, including the privileging standards set forth at (a) above, do apply to the anesthesia services provided in connection with all special procedures, whether invasive or non-invasive.

<< NJ ADC 13:35-4A.3 >>

13:35-4A.3 Definitions

The following words and terms, when used in this subchapter, shall have the following meanings, unless the context clearly indicates otherwise.

... "Complications" means an untoward event occurring at any time within 48 hours of any surgery, special procedure or the administration of anesthesia services which was performed in an office setting including, but not limited to, any of the following events: paralysis, nerve injury, malignant hyperthermia, seizures, myocardial infarction, renal failure, significant cardiac events, respiratory arrest, aspiration of gastric contents, cerebral vascular accident, transfusion reaction, pneumothorax, allergic reaction to anesthesia, wound infections requiring intravenous antibiotic treatment or hospitalization, unintended return to an operating room or hospitalization, death or temporary or permanent loss of function not considered to be a likely or usual outcome of the procedure.

... "Minor conduction block" means the injection of local anesthesia to stop or prevent a painful sensation in a circumscribed area of the body (that is, local infiltration or local nerve block), or the block of a nerve by direct pressure or refrigeration. Minor conduction blocks include, but are not limited to, retrobulbar blocks, peribulbar blocks, pudendal blocks, digital blocks, metacarpal blocks and ankle blocks. "Minor conduction block" does not include regional anesthesia that affects larger areas of the body, such as brachial <<+plexus+>> anesthesia or spinal anesthesia.

"Minor surgery" means surgery which can safely and comfortably be performed on a patient who has received no more than the maximum manufacturer recommended dose of local or topical anesthesia, without more than minimal pre-operative medication or minimal intra-operative <<-tranquilization->> <<+tranquilization+>> and where the likelihood of complications requiring hospitalization is remote. Minor surgery specifically excludes all procedures performed utilizing anesthesia services as defined in this section. Minor surgery also specifically excludes procedures which may be performed under local anesthesia, but which involve extensive manipulation or removal of tissue such as liposuction or lipo-injection, breast augmentation or reduction, and removal of breast implants. Minor surgery includes the excision of moles, warts, cysts, lipomas, skin biopsies, the repair of simple lacerations, or other surgery limited to the skin and subcutaneous tissue. Additional examples of minor surgery include closed reduction of a fracture, the incision and drainage of abscesses, certain simple ophthalmologic surgical procedures, such as treatment of chalazions and non-invasive ophthalmologic laser procedures performed with topical anesthesia, limited endoscopies such as flexible sigmoidoscopies, anoscopies, proctoscopies, arthrocenteses, thoracenteses and paracenteses. Minor surgery shall not include any procedure identified as "major surgery" within the meaning of N.J.A.C. 13:35-4.1.

... "Privileges" means the authorization granted to a practitioner or physician by a hospital licensed in the jurisdiction in which it is located to provide specified services or alternatively by the Board pursuant to N.J.A.C. 13:35- 4.12, such as surgery or the administration or the supervision of administration of one or

more types of anesthetic agents or procedures.

... "Regional anesthesia" means the administration of anesthetic agents to a patient to interrupt nerve impulses without loss of consciousness and includes epidural, caudal, spinal and brachial anesthesia. Regional anesthesia does not include minor conduction blocks as defined in this section.

"Special procedure" means patient care which requires anesthesia services because it involves entering the body with instruments in a potentially painful manner, or requires the patient to be immobile, for a diagnostic or therapeutic procedure. Examples of special procedures include diagnostic or therapeutic endoscopy or bronchoscopy performed utilizing conscious sedation or general anesthesia; invasive radiologic procedures performed utilizing conscious sedation; pediatric magnetic resonance imaging performed utilizing <<-a sedative dose of medication adequate to cause the patient to sleep or not to move->> <<+conscious sedation+>>; or manipulation under anesthesia (MUA). The term special procedure does not include a procedure which only requires medication to reduce anxiety such as <<-a->> <<+oral+>> benzodiazepine unless the dose given is intended to provide conscious sedation. ...

<< NJ ADC 13:35-4A.6 >>

13:35-4A.6 Standards for performing surgery and special procedures in an office; privileges necessary; pre-procedure counseling; patient records; recovery and discharge

(a) A practitioner who performs surgery (other than minor surgery) or special procedures in an office shall be privileged to perform that surgery or special procedure by a hospital. If a practitioner is not privileged but wishes to perform surgery or special procedures in an office, the practitioner shall apply to the Board pursuant to N.J.A.C. 13:35-4A.12 to seek Board-approved privileging.

(b) Before <<-a privileged->> <<+any+>> practitioner may perform surgery (other than minor surgery), or special procedures, the practitioner shall have:

1. A written transfer agreement with a licensed hospital <<+with acute care capabilities+>> which can be reached within 20 minutes during all hours in which surgery or special procedures are performed in the office, if the hospital where the practitioner is privileged is not reachable within 20 minutes or if the practitioner is privileged by the Board; and

2. A written policy for handling emergency transport to a hospital at which the practitioner is privileged through 9-1-1 call or a written transfer agreement with a licensed ambulance service which assures immediate transport of patients experiencing complications to the hospital which the practitioner has established a transfer agreement. The written transfer agreement shall be posted in the office and all health care personnel in the office shall specifically be informed of the procedure to be followed.

(c) A practitioner who performs surgery (other than minor surgery) or special procedures in an office shall provide pre-procedure counseling and preparation as follows:

1. The practitioner shall appropriately assess, or review a referring physician's assessment of, the physical condition of the patient on whom surgery or a special procedure is to be performed. The practitioner shall refer a patient who, by reason of pre-existing medical or other conditions, are at undue risk for complications (for example, morbidly obese patients; patients with severe cardiac, pulmonary, airway or neurological problems; substance abusers) to an appropriate specialist for a pre-procedure consultation or to another treatment setting or other appropriate facility for the performance of the surgery or the special procedure. Only patients with an American Society of Anesthesiologists (ASA) physical status classification of I or II are appropriate candidates for an office surgery or special procedure for which general or regional anesthesia are to be used. Patients with an ASA physical classification of I, II or III are appropriate candidates for conscious sedation.

2.-6. (No change.)

(d) A practitioner who performs surgery (other than minor surgery) or special procedures in an office shall ensure the following during recovery and prior to discharge:

1.-4. (No change.)

(e) A practitioner who performs surgery (other than minor surgery) or special procedures in an office shall prepare a patient record which shall include the following:

1.-6. (No change.)

(f) No practitioner who performs surgery (other than minor surgery) or special procedures in an office shall:

1. Prescribe, or advise a patient to take, an anesthetic agent to be administered prior to arrival at the office or outside of the anesthetizing location; or

2. Accept for <<-treatment->> <<+the performance of surgery or a special procedure+>> a patient to whom an anesthetic agent had been <<- prescribed or->> administered <<+for that surgery or special procedure+>> prior to arrival at the office or outside of the anesthetizing location, other than in life threatening circumstances<<+, unless the patient is accompanied by medical personnel from an acute care facility+>>.

<< NJ ADC 13:35-4A.7 >>

13:35-4A.7 Standards for administering or supervising the administration of anesthesia services in an office; pre-anesthesia counseling; patient monitoring; recovery; patient record; discharge of patient

(a) A practitioner who administers or supervises the administration and monitoring of anesthesia services in an office shall be privileged by a hospital to provide the particular anesthesia service. If a practitioner is not privileged but wishes to administer or supervise the administration of anesthesia services, the physician shall apply to the Board pursuant to N.J.A.C. 13:35-4A.12 to seek Board-approved privileging.

(b) A practitioner who administers or supervises the administration <<- or->> <<+and+>> monitoring of anesthesia services in an office shall provide pre-anesthesia counseling and preparation as follows:

1. Any patient to whom anesthesia services are to be provided shall be appropriately screened by the individual administering anesthesia services. Patients who, by reason of pre-existing medical or other conditions, are at undue risk for complications (for example, morbidly obese patients; patients with severe cardiac, pulmonary, airway or neurological problems; substance abusers) shall be referred to an appropriate specialist for a pre-procedure consultation or to another treatment setting or other appropriate facility. Only patients with an ASA physical status classification of I or II are appropriate candidates for an office surgery or special procedure for which general or regional anesthesia are to be used. Patients with an ASA physical classification of I, II or III are appropriate candidates for conscious sedation.

2.-9. (No change.)

(c)-(d) (No change.)

(e) A practitioner who administers or supervises the administration <<+and monitoring+>> of anesthesia services in an office shall establish within that office a recovery area and ensure that recovery services are provided as follows:

1.-7. (No change.)

(f) A practitioner who administers or supervises the administration <<+and monitoring+>> of anesthesia <<+services+>> may allow a patient dischargeable to home pursuant to N.J.A.C. 13:35-4A.4(a)9 and 4A.6(d) to remain in the office for a period not to exceed 23 hours in <<- a->> <<+an+>> overstay area, if

the patient may benefit from additional care. The overstay area shall be staffed by at least one registered professional nurse or physician assistant for each two patients in the overstay <<-setting->> <<+area+>>, the patient's vital signs shall be taken and recorded at least every four hours and a physician shall be able to reach the office within 20 minutes. Appropriate sleeping accommodations, as well as food, shall be provided for the patient.

(g) A practitioner who administers or supervises the administration <<+and monitoring+>> of anesthesia services in an office shall ensure the following prior to discharge:

1.-2. (No change.)

3. That before the patient leaves the office or is transferred to the <<- special overnight->> <<+over+>> area, the physician shall evaluate the patient and shall review and sign the post-anesthesia record; and

4. (No change.)

(h) A practitioner who administers or supervises the administration <<+and monitoring+>> of anesthesia services in an office shall ensure that a patient record is prepared which contains the following:

1.-6. (No change.)

(i) No practitioner who administers or supervises the administration <<+and monitoring+>> of anesthesia services in an office shall:

1. Prescribe, or advise a patient to take, an anesthetic agent to be administered prior to arrival at the office or outside of the anesthetizing location; or

2. Accept for <<-treatment->> <<+the performance of surgery or a special procedure+>> a patient to whom an anesthetic agent had been <<- prescribed or->> administered <<+for that surgery or special procedure+>> prior to arrival at the office or outside of the anesthetizing location, other than in life threatening circumstances<<+, unless the patient is accompanied by medical personnel from an acute care facility+>>.

<< NJ ADC 13:35-4A.8 >>

13:35-4A.8 Performance of general anesthesia; authorized personnel

(a) General anesthesia shall be administered and monitored in an office only by the following individuals:

1. A physician privileged by a hospital or the Board pursuant to N.J.A.C. 13:35-4A.12 to provide general anesthesia services and who, during every consecutive three-year period beginning July 1, <<-(yet unspecified date one year after the adoption)->> <<+2004+>>, completes at least 60 Category I hours of continuing medical education in anesthesia which either meet the criteria for credit towards the Physician's Recognition Award of the American Medical Association or have been approved by the American Osteopathic Association; or

2. A certified registered nurse anesthetist (CRNA), under the supervision of a physician qualified under (a)1 above.

(b) The administration and monitoring of general anesthesia shall be provided by an individual who meets the requirements of (a) above and who is at all times present in the anesthetizing location and who is not the practitioner performing the surgery or special procedure. This subsection shall not be construed to preclude the conversion of conscious sedation to general anesthesia in an emergency to protect the health of the patient, even if there is no physician present who would be qualified to administer and monitor general anesthesia pursuant to (a)1 above.

(c)-(d) (No change.)

<< NJ ADC 13:35-4A.9 >>

13:35-4A.9 Administration of regional anesthesia; authorized personnel

(a) Regional anesthesia shall be administered and monitored in an office only by the following individuals:

1. A physician privileged by a hospital or the Board pursuant to N.J.A.C. 13:35-4A.12 to provide regional anesthesia and who, during every consecutive three-year period beginning July 1, <<-(yet unspecified date one year after adoption)->> <<+2004+>>, completes at least eight Category I hours of continuing medical education in anesthesia exclusively, or in anesthesia as it relates to the physician's field of practice, which either meet the criteria for credit towards the Physician's Recognition Award of the American Medical Association or have been approved by the American Osteopathic Association; or

2. A certified registered nurse anesthetist (CRNA), under the supervision of a physician qualified under (a)1 above.

(b)-(d) (No change.)

<< NJ ADC 13:35-4A.10 >>

13:35-4A.10 Administration of conscious sedation; authorized personnel

(a) Conscious sedation shall be administered in an office only by the following individuals:

1. A physician privileged by a hospital or the Board pursuant to N.J.A.C. 13:35-4A.12 to provide conscious sedation and who, during every consecutive three-year period beginning July 1, 2001, completes at least eight Category I or II hours of continuing medical education in any anesthesia services, including conscious sedation exclusively, or in anesthesia as it relates to the physician's field of practice, which either meet the criteria for credit towards the Physician's Recognition Award of the American Medical Association or have been approved by the American Osteopathic Association;

2. A certified registered nurse anesthetist (CRNA), under the supervision of a physician qualified under (a)1 above; or

3. A registered professional nurse or physician assistant, who is trained and has experience in the use and monitoring of anesthetic agents, at the specific direction of a physician qualified under (a)1 above, but only for the purpose of administering through an established intravenous line, a specifically prescribed supplemental dose of conscious sedation which was selected and initially administered by the physician who remains continuously present in the procedure room. <<+"Continuously present in the procedure room" does not require that a practitioner remain in the procedure room in violation of human exposure safety standards regularly employed during radiological procedures.+>>

(b)-(e) (No change.)

<< NJ ADC 13:35-4A.11 >>

13:35-4A.11 Administration of minor conduction blocks; authorized personnel

(a) Minor conduction blocks (with the exception of retrobulbar blocks) shall be administered in an office for surgery or special procedures only by the following individuals:

1. A practitioner;

2. A certified registered nurse anesthetist (CRNA); or

3. A certified nurse midwife, an advanced practice nurse or physician assistant who has training and experience in the administration of minor conduction blocks.

(b) Retrobulbar blocks shall be administered in the office only by a physician privileged by a hospital or by the Board pursuant to N.J.A.C. 13:35-4.12.

<< NJ ADC 13:35-4A.12 >>

13:35-4A.12 Alternative privileging procedure

(a) A practitioner who seeks to provide or supervise the administration <<+ and monitoring+>> of general or regional anesthesia, as well as conscious sedation, in an office, but does not hold privileges at a licensed hospital to do so, shall submit to the Board an application for these privileges. To be eligible to apply for these privileges, an applicant shall meet the following criteria and submit an application that documents the applicant's fulfillment of these criteria:

1. Demonstration of clinical experience, through an attestation as to the number of procedures for which general or regional anesthesia was provided by the applicant in the last two years for all age groups of patients within the applicant's practice for which privileges are requested;
2. Any one of the following:
 - i. Current certification in anesthesiology granted by the American Board of Anesthesiology or the American Osteopathic Board of Anesthesiology or any other certification entity that the applicant demonstrates has standards of comparable rigor;
 - ii. Successful completion of a residency training program in anesthesiology accredited by the Accreditation Council on Graduate Medical Education (ACGME) or the American Osteopathic Association (AOA); or
 - iii. Supervised training in residency, fellowship or other equivalent experience in another field and active participation in the examination process leading to certification in anesthesiology; and
3. Possess clinical competence to perform the anesthesia services or procedures authorized by the requested privileges, with such competence confirmed by the following:
 - i. Three references submitted directly by plenary licensed physicians addressing the applicant's current competence based on personal knowledge obtained either during a residency training completed during the two years preceding the application or through personal observation during the two years preceding the application;
 - ii. Submission of a log listing all patients for whom the applicant provided any of the anesthesia services in an office setting or licensed ambulatory care facility setting for which privileges have been requested during the two years preceding the date of the application. The log shall include a patient number, the type of anesthesia service provided, the surgery or special procedure performed and the date(s) of service. Patient names and other identifying data shall be redacted. The applicant shall maintain a list or other means to identify the patient, based on the number included in the log;
 - iii. Identification of any patients in the log who have experienced complications relating to the applicant's provision of anesthesia services in an office setting or licensed ambulatory care facility setting and their resulting outcomes; and
 - iv. Submission of no fewer than five patient records or charts (or the pertinent portions thereof with patient names redacted) which have been identified and requested by the Board or other reviewing entity, designated pursuant to (e) below, along with a completed case summary form for each submitted case, utilizing such

forms as are provided in the application materials.

(b) A practitioner who seeks to administer or supervise the administration <<+and monitoring+>> of only conscious sedation in an office, but does not currently hold clinical privileges at a licensed hospital to do so, shall submit to the Board an application for this privilege. To be eligible to apply for this privilege, an applicant shall meet the following criteria and submit an application that documents the applicant's fulfillment of these criteria:

1. Demonstration of clinical experience, through an attestation as to the number of procedures for which conscious sedation was provided by the applicant in the last two years for all age groups with<<+in+>> the applicant's practice of patients for which privileges are requested, except <<+age groups+>> as <<+are+>> specifically excluded from <<+ the applicant's+>> practice;

2. Any one of the following:

i. Current certification in anesthesiology granted by the American Board of Anesthesiology or the American Osteopathic Board of Anesthesiology or any other certification entity the applicant demonstrates has standards of comparable rigor;

ii. Current certification in Critical Care Medicine or Emergency Medicine by a specialty board or certifying entity recognized by the American Board of Medical Specialties ("ABMS") or the American Osteopathic Association ("AOA") or any other certification entity the applicant demonstrates has standards of comparable rigor; or

iii. <<-Current certification in Advanced Cardiac Life Support or Pediatric Advanced Life Support->> <<-Satisfactory evidence that the applicant is advanced cardiac life support trained with updated training from a recognized accrediting organization<<+ and either:+>>->>

(1) Successful completion of an educational home study program, with a test of basic knowledge obtained from the Board; or

(2) A course in conscious sedation offered by a licensed hospital or for continuing medical education credits; and

3. Submission of a list of all patients who have experienced complications relating to the applicant's provision of conscious sedation in an office setting or licensed ambulatory care facility setting and their resulting outcomes. Patient names and other identifying data shall be redacted. The applicant shall maintain a list or other means to identify the patient, based on the number included in the log.

(c) A practitioner who seeks to perform surgery (other than minor surgery) or special procedures in an office, but does not hold privileges at a licensed hospital to perform these procedures shall submit to the Board an application for these privileges, including a completed privilege request form appropriate to the privileges requested. To be eligible to apply for this privilege, an applicant shall meet the following criteria and submit an application that documents the applicant's fulfillment of these criteria:

1. Demonstration of clinical experience, through an attestation as to the number and type of procedures performed by the applicant in the last two years for all age groups of patients for which privileges are requested;

2. Any one of the following:

i. Current certification in the field(s) of practice in which the privileges are sought granted by a specialty board or certifying entity recognized by the American Board of Medical Specialties (ABMS), the American Osteopathic Association (AOA), the American Podiatric Medicine Association (APMA) or any other certification entity that the applicant demonstrates has standards of comparable rigor;

ii. Successful completion of an Accreditation Council for Graduate Medical Education (ACGME) or the American Osteopathic Association (AOA) residency or fellowship training program in the field(s) of practice in which privileges are sought; or

iii. Supervised training in a residency or fellowship training or other equivalent experience in another field and active participation in the examination process leading to certification in the practice field(s) in which privileges are sought; and

3. Possess clinical competence to perform the procedures authorized by the requested privileges, with such competence confirmed by the following:

i. Three references submitted directly by plenary licensed physicians (or licensed podiatrists as to podiatric applicants) addressing the applicant's current competence based on personal knowledge obtained either during a residency training completed during the two years preceding the application or through personal observation during the two years preceding the application;

ii. Submission of a log listing all patients for whom the applicant has performed surgery or special procedures in an office setting or licensed ambulatory care facility setting for which privileges have been requested during the two years preceding the date of the application. The log shall include a patient number, the surgery or special procedure performed and the indications for that procedure and the date(s) of service. Patient names and other identifying data shall be redacted. The applicant shall maintain a list or other means to identify the patient, based on the number included in the log;

iii. Identification of any patients in the log who have experienced complications relating to the applicant's performance of surgery or special procedures in an office setting or licensed ambulatory care facility setting and their resulting outcomes; and

iv. Submission of no fewer than five patient records or charts (or the pertinent portions thereof with patient names redacted) which have been identified and requested by the Board or other reviewing entity, along with a completed case summary form for each submitted case, utilizing such forms as are provided in the application materials.

(d) A practitioner who seeks to utilize laser surgery techniques in an office, but does not hold privileges at a licensed hospital to do so, shall submit to the Board an application, which shall include:

1. Certification of successful completion of an accredited laser training program, in which the curriculum includes instruction in laser care, physics and clinical indications for utilization of the specific laser; or

2. Documentation from the program director of an accredited residency training program which the applicant has successfully completed, attesting to the inclusion of training in the specific laser therapy for which privileges are being sought during residency training.

(e) The Board may delegate to a reviewing entity the responsibility to conduct a preliminary review of an application to ascertain whether the applicant has met the criteria established in (a) through (d) above, which review shall be undertaken at the expense of the applicant. The Board shall thereafter review the summary report including any recommendation concerning the applicant prepared by the reviewer and make a decision on the application for privileges.

(f) If the Board or any entity or person to which the Board may delegate the preliminary application review finds that the applicant has not submitted sufficient information upon which a determination as to the applicant's current competence may be made, the Board or the reviewing entity may require:

1. A personal interview;

2. The submission of a representative sample of patient records substantiating the experience of the applicant;

3. The submission of any patient records relating to an identified complication;
4. An inspection of the office, which may include a review of additional patient records and written policies and procedures; and/or
5. The submission of such additional information as may be necessary to determine an applicant's clinical competence to perform the privileges requested.

(g) Upon review of the summary report prepared by the Board or the reviewing entity, the Board may take any of the following actions:

1. Grant all or some of the privileges requested;
2. Condition its approval of all or some of the privileges requested on the applicant's successful completion of additional training;
3. Condition its approval of all or some of the privileges on the applicant's successful completion of a period of observation;
4. Deny all or some of the privileges requested; and/or
5. Require such additional information as may be necessary to act on the application.

(h) Practitioners who have been granted privileges through the alternative privileging procedure of this section shall submit a renewal application to the Board within two years from the date on which privileges were granted. Practitioners shall notify the Board within 21 days should there be any change in the information provided in the application and renewal.

<< NJ ADC 13:35-4A.17 >>

13:35-4A.17 Compliance timetables

(a) A practitioner who does not hold privileges at a hospital and, as of <<- (the effective date of this rule)->> <<+December 16, 2002+>>, was offering and elects to continue offering or chooses to begin offering anesthesia services or surgery or special procedures in the office setting, shall submit an application to the Board seeking approval pursuant to the alternative privileging process set forth at N.J.A.C. 13:35-4A.12, no later than <<-one year after (the effective date of this rule)->> <<+December 16, 2003+>>. Notwithstanding any other provision in this subchapter, a practitioner who has submitted an application for alternative privileging pursuant to this subsection, may continue to offer services for which privileges have been requested until such time as the Board acts upon that application.

(b)-(c) (No change.)