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RULE ADOPTIONS
LAW AND PUBLIC SAFETY
DIVISION OF CONSUMER AFFAIRS
STATE BOARD OF MEDICAL EXAMINERS
Minimum Standards for the Performance of New or
Novel Procedures in the Office Setting

37 N.J.R. 4277(b)

Adopted New Rule: N.J.A.C. 13:35-6.7

Minimum Standards for the Performance of New or Novel Procedures in the Office Setting

Proposed: October 4, 2004 at 36 N.J.R. 4367(a).

Adopted: April 13, 2005 by the Board of Medical Examiners, Bernard Robins, M.D., President.

Filed: September 27, 2005 as R.2005 d.360, with substantive and technical changes not requiring additional public notice and comment (see N.J.A.C. 1:30-6.3).

Effective Date: November 7, 2005.

Expiration Date: March 17, 2010.

Summary of Agency-Initiated Changes:

There was a typographical error in N.J.A.C. 13:35-6.7(d)4 as the rule was proposed. The term "sacrifice" in this rule should have been "scientific." The Board has corrected this error upon adoption.

Federal Standards Statement

The adopted new rule will require licensees who perform new or novel procedures in an office setting to establish a procedural protocol that provides for protections of human subjects consistent with FDA guidelines set forth in 21 CFR § 50 (2004). The Board does not believe that there are any other Federal laws or standards applicable to this adopted new rule.

Full text of the adoption follows (additions to proposal indicated in boldface with asterisks *thus*; deletions from proposal indicated in brackets with asterisks *[thus]*):

13:35-6.7 Minimum standards for the performance of new or novel procedures in the office setting

(a) This section contains minimum standards for the performance of new or novel procedures as defined in (b) below which are performed in the office setting and are not performed under the jurisdiction of an Institutional Review Board (IRB) which complies with the requirements of the Federal Food and Drug Administration.

(b) The following words and terms when used in this section shall have the following meanings, unless the context indicates otherwise:

"Diagnostic or therapeutic modality" means a modality intended for use in the diagnosis of disease or conditions in humans or in the cure, mitigation, treatment or prevention of disease in humans or a modality intended to affect the structure of or any function of the human body.

"Generally recognized as safe and effective" means there exists substantial evidence by means of at least two well-

controlled clinical studies that the new or novel procedure will have the effect that is represented and the procedure does not pose a significant risk to the physical or emotional health of the patient and has a low reported incidence of adverse reactions or significant side effects.

"New or novel procedure" means a diagnostic or therapeutic modality performed by a Board licensee that:

1. Is not yet generally recognized as safe and effective by experts in the field who are qualified by scientific training and experience to evaluate the safety and effectiveness of the procedure for its intended use and poses a potential risk of physical or emotional harm to a patient; or
2. Is a new application of a procedure which has been generally recognized as safe and effective for its traditional use but is not yet generally recognized as safe and effective by experts in the field who are qualified by scientific training and experience to evaluate the safety and effectiveness of the procedure for its new application and the new application poses a potential risk of physical or emotional harm to a patient.

"New or novel procedure" does not include responses to emergent and unexpected issues that arise during surgery or the use of a medication that has been approved by the Food and Drug Administration (FDA), even if the medication is being used for a purpose not specifically approved by the FDA.

"Office setting" means a location at which medical, surgical or podiatric services are rendered and is not licensed by the New Jersey Department of Health and Senior Services.

(c) A licensee shall not perform a procedure in an office setting that is generally recognized as ineffective and unsafe by experts in the field who are qualified by scientific training and experience to evaluate the safety and effectiveness of the procedure for its intended use.

(d) A licensee shall establish a procedural protocol prior to performing a new or novel procedure in the office setting. The protocol shall at a minimum:

1. Provide for protection of human subjects consistent with FDA guidelines set forth in 21 C.F.R. § 50 (2004) available from the United States Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857-0001, which are incorporated by reference herein, and as may be amended and supplemented;
2. Ensure the procedure is performed by physicians qualified by training, education, or experience to perform such procedure;
3. Ensure the physician performing the procedure is able to demonstrate the scientific merits of the procedure;
4. Ensure the procedure is supported by adequate and well-controlled animal studies or the weight of the *[sacrifice]* *scientific* and medical literature;
5. Contains provisions for pre-operative screening;
6. Delineate specific diagnoses for which the procedure is indicated;
7. Delineate specific contraindications to the procedure, if any;
8. Provide for fully informed consent in accordance with prevailing New Jersey law, including full explanation of risks, benefits, alternative treatments and likely outcome without treatment;
9. Provide for and demonstrate operator and staff training, experience, and ongoing competency;
10. Provide for a period of post procedure observation and management commensurate with the complexity, invasiveness and risks of the procedure and any concomitant anesthesia;
11. Provide for written discharge instructions, follow-up and any associated aftercare;

12. Maintain documentation of complete care rendered in accordance with Board rules, N.J.A.C. 13:35-6.5, and maintain records of any associated morbidity, mortality and clinical outcomes;

13. Ensure that procedures are described with specificity including use of pharmaceutical agents and their dosages, anticipated side effects, and projected short and long-term treatment; and

14. Where applicable, ensure compliance with the rules regarding surgery and anesthesia services performed in an office setting (N.J.A.C. 13:35-4A).

(e) A licensee shall provide the Board with a procedural protocol upon request in order to ensure that the licensee has complied with the requirements of (d) above.

(f) If the requirements of (d) above cannot be met, a licensee may request Board approval to perform a new or novel procedure. Such request shall include a statement identifying which protocols in (d) above cannot be met and the reason therefor. The Board shall not approve a request under this subsection unless the licensee demonstrates to the satisfaction of the Board that:

1. The procedure may be effective for its intended use and will not expose patients to an unreasonable and significant additional risk of illness or injury;
2. The procedure is intended to treat a serious or immediately life-threatening disease and no comparable or satisfactory therapeutic alternatives are available to treat that stage of the disease in the intended patient population and there is a reasonable likelihood that death will occur within a matter of months or premature death is likely without early intervention;
3. The procedure is under investigation in controlled clinical trials or all clinical trials have been completed but not yet reported; and
4. The licensee has provided to the Board all information known to the licensee, regarding the studies referred to in (f)3 above.