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FILED

MARCH 22, 2005

**NEW JERSEY STATE BOARD
OF MEDICAL EXAMINERS**

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STATE OF NEW JERSEY
DEPARTMENT OF LAW & PUBLIC SAFETY
DIVISION OF CONSUMER AFFAIRS
BOARD OF MEDICAL EXAMINERS

IN THE MATTER OF THE APPLICATION)
OF) Administrative Action
)
 STEVEN J. BIER, M.D.) **MODIFIED CONSENT ORDER**
)
 TO PRACTICE MEDICINE AND SURGERY)
 IN THE STATE OF NEW JERSEY)
)

This matter was opened to the New Jersey State Board of Medical Examiners ("Board") upon receipt of a February 19, 2005 petition for the Board to reexamine the method for Dr. Bier to reestablish his credentials pursuant to the Mammography Quality Standards Act ("MQSA").

On or about July 2, 2001 Dr. Bier, a Radiologist, whose New York Medical license had been temporarily suspended on May 30, 2000, entered into a Consent Agreement and Order (NY Order) with the State of New York, Department of Health, State Board for Professional Misconduct ("New York Board") which imposed a one-year suspension of his license commencing retroactively on May 30, 2000 and terminating on May 30, 2001. In the NY Order, Dr. Bier did not contest the First Specification of the Amended Statement of

Charges, charging Steven Bier, M.D., P.C., the Professional Corporation Respondent, with the failure to maintain a record for certain patients which accurately reflected the evaluation and treatment of the patient in violation of New York Education Law §6530(32). Due to the fact that Dr. Bier's license had been suspended for one year, he acknowledged in the NY Order that he did not currently meet the qualifications to be an "interpreting physician" as set forth in Sections 900.2(u) and 900.12 of the rules and regulations of the Federal Drug Agency promulgated in 21 CFR Part 900 pursuant to the Federal Mammography Quality Standards Act. As a consequence, according to the NY Order Dr. Bier is not allowed to independently interpret mammographic examinations until he reestablishes his qualifications pursuant to 21 CFR 900.12(a)(1)(iv). Pursuant to the NY Order, Dr. Bier agreed to reestablish his qualifications under the option set forth in 21 CFR 900.12(a)(1)(iv)(A)(1) by multi-reading mammographic examinations under the direct supervision option defined in 21 CFR 900.2(o)(1). Dr. Bier is required to submit to the Director of the Office of Professional Medical Conduct for prior written approval the name and curriculum vitae of a proposed supervising interpreting physician who qualifies under 21 CFR 900.12(a)(1) as an interpreting physician. Under the NY Order Dr. Bier was given an option to practice radiology for one year only in a hospital licensed under New York State Public Health Law Article 28 or work in a non-mammographic facility while he successfully completes specified volumes from the American College of Radiology

Professional Self-Evaluation Series and fifty hours of continuing medical education credits. Dr. Bier also agreed to have a three year practice monitoring period in the event he operates a mammographic facility.

The Board considered all of the documents submitted and is satisfied that Dr. Bier may be released in New Jersey from the requirement, set forth on page three of the New York Order, to interpret no more than 15 mammograms per week when he reestablishes his qualifications to be an interpreting physician. This release will be effective only in the State of New Jersey. The Board is satisfied that the letters submitted by Andrew Novick, M.D., Chairman, Radiology Department, Newark Beth Israel Medical Center and Brian A. Krivisky, M.D., Board of Trustees, Past President of Medical Staff Southwest Florida Regional Medical Center, Former Chairman of Radiology, recommending the Board follow the Federal government standards set forth in the MQSA provide a basis for this modification. Specifically, the Federal standard requires a physician reestablishing qualifications to interpret or multi-read at least 240 examinations under the direct supervision of an interpreting physician and to accomplish this within the six months immediately prior to resuming independent interpretation.

The parties being desirous of resolving this matter, and it appearing that Dr. Bier has read the terms of the within Order, he understands their meaning and effect and consents to be bound by them, and it further appearing that the Board finds that the within Order is adequately protective of the public interest, and it

therefore appearing that good cause exists for the entry of the within Order,

IT IS on the 22ND Day of MARCH 2005,

AGREED AND ORDERED THAT:

1. The New Jersey Board of Medical Examiners continues to grant Steven J. Bier, M.D., licensure to practice medicine and surgery in the State of New Jersey based on his agreement to abide by the conditions set forth in paragraphs two (2) through seven (7) of this Consent Order.
2. Dr. Bier agrees that he shall not independently interpret mammographic examinations in this State until such time as he reestablishes his qualifications pursuant to the Federal Drug Agency rules and regulations promulgated in 21 CFR Part 900.12 (a)(1)(iv)(A)(1) and (3) attached hereto and made a part hereof.
3. Dr. Bier shall submit to the Board for prior approval the name and curriculum vitae of a proposed Supervising Interpreting Physician who qualifies under 21 C.F.R. 900.12(a)(1) as an interpreting physician who shall not be a family member, personal friend, former employee or independent contractor, or person or entity with whom there is or has been a professional relationship or any other person or entity, who could be deemed in the sole discretion of the Board, to have a potential conflict of interest while carrying out supervision responsibilities.
4. Dr. Bier shall be responsible to request and assure that the Supervising Interpreting Physician submits to the Board bi-monthly progress reports and a final report regarding Dr. Bier's fulfillment of the Federal requirements outlined above prior to his resuming independent interpretation of mammograms. Prior to Dr. Bier resuming independent interpretation of mammograms, he shall submit a written request for the removal of supervision by the Supervising Interpreting Physician and a modification of this Order. The Board shall review the final report of the Supervising Interpreting Physician in this educational credentialing process, and determine whether it is appropriate to permit Dr. Bier to commence the independent interpretation of mammograms in New Jersey. The reports shall be submitted to William Roeder, Executive Director, State Board of Medical Examiners, 140 East Front Street, P.O. Box 183, Trenton, NJ, 08625-0183.
5. In the event Dr. Bier operates a mammographic facility in this State, he agrees to enter into a three (3) year practice monitoring period with the Board. Prior to operating a mammographic facility, Dr. Bier shall contact the Board in writing

to request guidance regarding the structure of the monitoring program.

6. In the event Dr. Bier accepts an offer of employment or intends to commence the practice of medicine in the State of New Jersey, he shall provide the Board with at least fourteen (14) days prior written notice of his intention to commence the practice of medicine in the State of New Jersey and provide details pertaining to his employment position and completion of the MQSA requirements. This notice shall be submitted to William Roeder, Executive Director, State Board of Medical Examiners, 140 East Front Street, P.O. Box 183, Trenton, NJ, 08625-0183.

7. Any failure by Dr. Bier to comply with the terms and conditions of this Consent Order shall constitute professional misconduct as defined by N.J.S.A. 45:1-21(e).

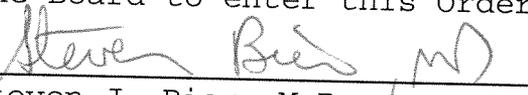
8. This Order is in effect until further Order of the Board.

NEW JERSEY STATE BOARD OF MEDICAL EXAMINERS

By: 

Bernard Robins, M.D., F.A.C.P.
President

I have read and understand
the within Order and agree
to be bound by its terms.
Consent is hereby given to
the Board to enter this Order.



Steven J. Bier, M.D.

mammographic modality.

(D) Units earned through teaching a specific course can be counted only once towards the 15 required by paragraph (a)(1)(ii)(B) of this section, even if the course is taught multiple times during the previous 36 months.

(iii) Exemptions.

(A) Those physicians who qualified as interpreting physicians under paragraph (a)(1) of this section of FDA's interim regulations prior to April 28, 1999 are considered to have met the initial requirements of paragraph (a)(1)(i) of this section. They may continue to interpret mammograms provided they continue to meet the licensure requirement of paragraph (a)(1)(i)(A) of this section and the continuing experience and education requirements of paragraph (a)(1)(ii) of this section

(B) Physicians who have interpreted or multi-read at least 240 mammographic examinations under the direct supervision of an interpreting physician in any 6-month period during the last 2 years of a diagnostic radiology residency and who become appropriately board certified at the first allowable time, as defined by an eligible certifying body, are otherwise exempt from paragraph (a)(1)(i)(D) of this section.

(iv) Reestablishing qualifications. Interpreting physicians who fail to maintain the required continuing experience or continuing education requirements shall reestablish their qualifications before resuming the independent interpretation of mammograms, as follows.

- (A) Interpreting physicians who fail to meet the continuing experience requirements of paragraph (a)(1)(ii)(A) of this section shall.
- (1) Interpret or multi-read at least 240 mammographic examinations under the direct supervision of an interpreting physician, or
- (2) Interpret or multi-read a sufficient number of mammographic examinations, under the direct supervision of an interpreting physician, to bring the physician's total up to 960 examinations for the prior 24 months, whichever is less.
- (3) The interpretations required under paragraph (a)(1)(iv)(A)(1) or (a)(1)(iv)(A)(2) of this section shall be done within the 6 months immediately prior to resuming independent interpretation.

(B) Interpreting physicians who fail to meet the continuing education requirements of paragraph (a)(1)(ii)(B) of this section shall obtain a sufficient number of additional category I continuing medical education credits in mammography to bring their total up to the required 15 credits in the previous 36 months before resuming independent interpretation.

(2) Radiologic technologists. All mammographic examinations shall be performed by radiologic technologists who meet the following general requirements, mammography requirements, and continuing education and experience requirements:

(i) General requirements.

(A) Be licensed to perform general radiographic procedures in a State; or

(B) Have general certification from one of the bodies determined by FDA to have procedures and requirements adequate to ensure that radiologic technologists certified by the body are competent to perform radiologic examinations; and

(ii) Mammography requirements. Have, prior to April 28, 1999, qualified as a radiologic technologist under paragraph (a)(2) of this section of FDA's interim regulations of December 21, 1993, or completed at least 40 contact hours of documented training specific to mammography under the supervision of a qualified instructor. The hours of documented training shall include, but not necessarily be limited to:

(A) Training in breast anatomy and physiology, positioning and compression, quality assurance/quality control techniques, imaging of patients with breast implants;

(B) The performance of a minimum of 25 examinations under the direct supervision of an individual qualified under paragraph (a)(2) of this section; and

(C) At least 8 hours of training in each mammography modality to be used by the technologist in performing mammography exams; and

(iii) Continuing education requirements

(A) Following the third anniversary date of the end of the calendar quarter in which the requirements of paragraphs (a)(2)(i) and (a)(2)(ii) of this section were completed, the radiologic technologist shall have