STATE OF NEW YORK
DEPARTMENT OF HEALTH

433 River Street, Suite 303 Troy, New York 12180-2299

Richard F. Daines, M.D.
Commissioner

Public

October 15, 2007

CERTIFIED MAIL - RETURN RECEIPT REQUESTED

Daniel Guenzburger, Esq.
NYS Department of Health
90 Church Street – 4th Floor
New York, New York 10007-2919

Ruben Jean Louis Fleurantin, M.D.
324 Scotland Road
South Orange, New Jersey 07079

RE: In the Matter of Ruben Jean Louis Fleurantin, M.D.
& Bay Imaging, P.C.

Dear Parties:

Enclosed please find the Determination and Order (No. 07-226) of the Hearing Committee in the above referenced matter. This Determination and Order shall be deemed effective upon the receipt or seven (7) days after mailing by certified mail as per the provisions of §230, subdivision 10, paragraph (h) of the New York State Public Health Law.

Five days after receipt of this Order, you will be required to deliver to the Board of Professional Medical Conduct your license to practice medicine together with the registration certificate. Delivery shall be by either certified mail or in person to:

Office of Professional Medical Conduct
New York State Department of Health
Hedley Park Place
433 River Street - Fourth Floor
Troy, New York 12180

If your license or registration certificate is lost, misplaced or its whereabouts is otherwise unknown, you shall submit an affidavit to that effect. If subsequently you locate the requested items, they must then be delivered to the Office of Professional Medical Conduct in the manner noted above.

As prescribed by the New York State Public Health Law §230, subdivision 10, paragraph (i), and §230-c subdivisions 1 through 5, (McKinney Supp. 1992), "the determination of a committee on professional medical conduct may be reviewed by the Administrative Review

Board for professional medical conduct." Either the licensee or the Department may seek a review of a committee determination.

Request for review of the Committee's determination by the Administrative Review Board stays penalties other than suspension or revocation until final determination by that Board. Summary orders are not stayed by Administrative Review Board reviews.

All notices of review must be served, by certified mail, upon the Administrative Review Board and the adverse party within fourteen (14) days of service and receipt of the enclosed Determination and Order.

The notice of review served on the Administrative Review Board should be forwarded to:

James F. Horan, Esq., Administrative Law Judge
New York State Department of Health
Bureau of Adjudication
Hedley Park Place
433 River Street, Fifth Floor
Troy, New York 12180

The parties shall have 30 days from the notice of appeal in which to file their briefs to the Administrative Review Board. Six copies of all papers must also be sent to the attention of Mr. Horan at the above address and one copy to the other party. The stipulated record in this matter shall consist of the official hearing transcript(s) and all documents in evidence.

Parties will be notified by mail of the Administrative Review Board's Determination and Order.

Sincerely,

James F. Horan

James F. Horan, Acting Director
Bureau of Adjudication

JFH:cah

Enclosure

STATE OF NEW YORK : DEPARTMENT OF HEALTH
STATE BOARD FOR PROFESSIONAL MEDICAL CONDUCT

IN THE MATTER	
OF	DETERMINATION
RUBEN JEAN LOUIS FLEURANTIN, M.D.	AND
AND	ORDER
BAY IMAGING, P.C.	BPMC #07-226

A Notice of Hearing and Statement of Charges, both dated April 11, 2007, were served upon the Respondents, Ruben Jean Louis Fleurantin, M.D. and Bay Imaging, P.C. **ALAN KOPMAN (CHAIR), PAUL S. CARTON, M.D., AND ROBERT D. SUNSHINE, M.D.,** duly designated members of the State Board for Professional Medical Conduct, served as the Hearing Committee in this matter pursuant to Section 230(10)(Executive) of the Public Health Law. **LARRY G. STORCH, ADMINISTRATIVE LAW JUDGE,** served as the Administrative Officer. The Department of Health appeared by Daniel Guenzburger, Esq., Associate Counsel. The Respondent appeared by *pro* se. Evidence was received and witnesses sworn and heard and transcripts of these proceedings were made.

After consideration of the entire record, the Hearing Committee issues this Determination and Order.

PROCEDURAL HISTORY

Date of Service:	April 19, 2007
Pre-Hearing Conference:	May 10, 2007
Answer Filed:	May 16, 2007
Hearing Dates:	May 18, 2007 July 12, 2007
Witnessed for Department:	Gene Miskin Patient A28/B48 Patient A45/B75 Patient A16/B26 Lisa Saunders Ann C. Cea, M.D.
Witnesses for Respondents:	None
Deliberations Held:	September 7, 2007

STATEMENT OF CASE

Petitioner has charged Respondent Fleurantin individually, and in his capacity as an officer of Bay Imaging, P.C., with seven specifications of professional misconduct. The charges include allegations of failing to provide access to patient information by qualified persons, failing to make relevant records available to the Department of Health within thirty days, willful or grossly negligent failure to comply with substantial provisions of federal law governing the practice of medicine, failure to maintain medical records, negligence on more than one occasion, and gross negligence. The allegations

involve hundreds of patients who were denied access to mammography and other radiological studies performed at facilities owned and operated by Bay Imaging, P.C. Respondent denied the allegations.

At the pre-hearing conference, held on May 10, 2007, the Department filed an Amended Statement of Charges (Exhibit #1A), which made several minor modifications to the number of patients involved. A copy of the Amended Statement of Charges is attached to this Determination and Order in Appendix I.

Respondent appeared *pro se* at the pre-hearing conference and on the first day of hearing. He failed to appear at the second day of hearing, July 12, 2007, and presented no defense to the charges.

Following the close of the hearing, the Department withdrew the Fifth Specification (Failure to Maintain Records).

FINDINGS OF FACT

The following Findings of Fact were made after a review of the entire record in this matter. Numbers in parentheses refer to transcript page numbers or exhibits. These citations represent evidence found persuasive by the Hearing Committee in arriving at a particular finding. Conflicting evidence, if any, was considered and rejected in favor of the cited evidence.

1. Ruben Jean Louis Fleurantin, M.D. (hereinafter "Respondent"), was authorized to practice medicine in New York State by the New York State Education Department's issuance of license number 171144 on July 27, 1987. (Ex. #2).

2. On or about December 16, 2005, Respondent Fleurantin acquired ownership of three radiological facilities that did business under the name of Bay Imaging, P.C. The facilities were located at 1620 Caton Avenue, 9201 4th Avenue, and 2626 East 14th Street, Brooklyn, New York. Respondent Fleurantin inspected the facilities prior to purchase. (T. 30; Ex. #3).

3. Respondent Fleurantin acquired ownership of the facilities through the purchase of one hundred percent of the stock in Respondent Bay Imaging, P.C. ("Bay Imaging") and two other legal entities. Respondent's acquisition of Bay Imaging involved the transfer to him of all the assets and liabilities of the legal entities, including the transfer of the legal responsibility to maintain medical records that had been generated prior to his ownership of the radiology facilities. In paragraph 4(b)(viii) of the "Ownership Transfer Agreement", Respondent Fleurantin represented and warranted to the former owner, Irwin Singer, M.D., that he would maintain medical charts and patient records in accordance with all laws, rules and regulations. (Ex. #3).

4. The Office of Radiological Health of the New York City Department of Health and Mental Hygiene ("ORH") is responsible for regulatory oversight of facilities that use ionizing radiation equipment. The Bay Imaging facilities had such equipment, including mammography, regular x-ray equipment and fluoroscopic equipment. According to Gene Miskin, the Director of the ORH, his office had not encountered problems with the facilities prior to Respondent Fleurantin's ownership of Bay Imaging. (T. 44, 62-63).

5. The ORH issues permits to facilities that use ionizing radiation equipment. The permit for a radiology facility must identify the name of a current physician shareholder. Respondent failed to obtain a permit in his name when he assumed ownership of Bay Imaging. (T. 75-77).

6. In August 2006, the ORH began receiving complaints that Bay Imaging patients were not receiving reports of their mammography studies. Around the same time as patients started complaining, the ORH received a telephone call from a person who identified herself as the Bay Imaging "office manager". This person asked if she could give patients their films because Bay Imaging did not have a radiologist who could interpret mammograms. (T. 44-46, 54-55).

7. On August 18, 2006, the ORH "sealed" the mammography equipment at all three Bay Imaging facilities in order to prevent the further build-up of unread mammography examinations. The ORH sealing order prohibited the use of the mammography equipment. (T. 46, 56-58).

8. In late August 2006, the Federal Drug Administration ("FDA") initiated its own investigation. The FDA is the federal agency responsible for enforcing national mammography standards. The FDA's investigation revealed that there were about eight hundred unread mammography examinations at the three Bay Imaging facilities. (T. 47, 64).

9. In September, 2006, personnel from the ORH, the New York State Department of Health, and the FDA began a series of discussions about how to address the Bay Imaging situation. A conference call with Respondent Fleurantin took place on September 21, 2006. Dr. Finder of the FDA told Respondent that his agency would impose civil penalty fines and de-certify the radiology facilities if he failed to provide patients with their mammography results. Respondent Fleurantin's response was that it wasn't his fault; that the circumstances were beyond his control at that point, but he did indicate that he had hired a radiologist, Dr. Dhanani to read the unread mammography films. (T. 46-50).

10. In response to the continued proliferation of patient complaints, the ORH issued an order on November 3, 2006 requiring Respondents to provide copies of all mammography reports for examinations performed at Bay Imaging from April 1, 2006 to the date that the facilities closed. When Respondents failed to comply with the order, the ORH sent their radiation physicist and field inspectors to the three facilities and copied the reports they were able to find. Approximately two thousand one hundred reports were copied. The ORH forwarded the report to the patient's physician when the report identified a referring physician. (T. 51-52, 64-67).

11. Federal regulations promulgated pursuant to the Mammography Quality Standards Act ("MQSA") require that mammography results be reported to patients or their referring physicians within 30 days of the date of examination. (21 CFR Subchapter I, §900.12(c)(2) and (c)(3) - Official Notice Taken).

12. Respondents failed to communicate mammography results to Patients D1 through D362 and/or their referring physicians within thirty days of their respective examinations. (T. 177-182; Ex. #8A and #8B).

13. Patient D23 underwent mammography and breast ultrasound at Bay Imaging on July 14, 2006. The mammogram and ultrasound were not interpreted until October 22, 2006, over three months after the radiological evaluation. The radiologist who evaluated the studies, Dr. Dhanani, found on the breast ultrasound "a large complex area at the site of a palpable lump with a cystic and a solid component measuring 2.62 by 2.5 by 3.35". Dr. Dhanani classified the finding as suspicious for malignancy. (Ex. #8B, pp. 85-86).

14. This patient most likely had breast cancer. (T. 215-216).

15. The Office of Professional Medical Conduct ("OPMC") obtained reports that ORH personnel copied at Bay Imaging facilities in November, 2006. Three hundred sixty of the reports are from the period of July and August 2006. The mammograms were two, and in some cases, three months old by the time a Bay Imaging radiologist examined them. (T. 177; Ex. #8A and #8B).

16. Dr. Parekh, the other radiologist who interpreted the backlogged mammograms, interpreted the films between October 9 and October 20, 2006. Dr. Parekh read the films through a company called Comp Health. He did not note the date of the interpretation on his reports. Comp Health

employment records establish that Dr. Parekh had a temporary assignment with Bay Imaging from October 9, 2006 through October 20, 2006. (T. 180-181; Ex. #9).

17. Dr. Parekh and Dr. Dhanani reported 77 mammograms as Birad 0, meaning that the radiologists were unable to render a mammography assessment. The Birad system is an internationally accepted system for classifying mammography results. Because the radiologists could not render a diagnosis based on the screening studies, the patients whose mammogram were classified as Birad 0 should have immediately undergone further mammographic evaluation. (T. 208-209; Ex. #8A and #8B).

18. Patient D3's mammography study was classified as Birad 0. Her examination was performed on July 29, 2006, and was interpreted by Dr. Parekh sometime between October 9 and October 20, 2006. Dr. Parekh's finding of a 2 cm. "architectural distortion" in the inferior quadrant required immediate follow-up. (T. 213).

19. The Access to Patient Information Program ("API Unit") of the OPMC assists patients obtain their medical records. Lisa Saunders, a medical conduct investigator assigned to the API Unit since December, 2004, testified regarding her efforts to secure Bay Imaging patients' records.

Ms. Saunders urged patients to write Respondents, and provided patients with current contact information for Respondent Fleurantin. Ms. Saunders also wrote letters directing Respondents to provide records for the various patients who filed complaints with the API Unit, and she was in frequent telephone contact with Respondent Fleurantin and others associated with Bay Imaging. (T. 157-168).

20. Ann Cea, M.D., a radiologist with many years of experience in a variety of practice settings, testified that a reasonable time to respond to a request for radiological records would usually be several days, but in a rare instance up to, but no more than, one month after the request. (T. 222).

21. Patients A1-A63 failed to receive their records within a reasonable time of their written request for records. None of the patients in this category received their records within one month of the date of their request. Thirty-three patients in this group never received their medical records. (T. 167-168; Ex. #5A; Ex. #5B).

22. Access to prior mammography films is extremely important to making a proper interpretation. Mammographers look to see if there is a change in the mammographic appearance in a quadrant of the breast or in the appearance of

a microcalcification. If a mammographer does not have access to a prior film, they may have to order a biopsy to be sure that something suspicious is not cancerous. The comparison of the current mammogram with a prior study may obviate the need for a biopsy. (T. 217-219).

23. Patients B1-B121 failed to receive their mammography records within one month of the date of the request. Thirty-nine patients received their records by the end of April, 2007, and an additional ten patients received their records sometime after April, 2007. Seventy-two of the 121 patients never received their records. (T. 172; Ex. #6A and 6B).

24. Patient B48 had been a satisfied patient of Bay Imaging from 2002 to 2006. The last time she had a mammogram at Bay Imaging was on January 14, 2006. The January 14, 2006 study was interpreted as normal. (T. 83, 92).

25. When Patient B48 learned that Bay Imaging had closed she was quite concerned because she knew that she needed her prior mammogram films. Each time she called the Bay Imaging telephone number, the call went into voice mail. She could not leave a message because the mail box was full. (T. 84).

26. In or about January, 2007, Patient B48 filed a complaint with the New York State Department of Health. Lisa Saunders instructed her to send a letter to Respondent Fleurantin requesting the films. About one week after sending the letter, the patient received a call informing her that someone would call her again the following week to arrange a way for her to pick up the films. She never received another call. (T. 85-86; Ex. #6B, p. 166).

27. On January 20, 2007, Patient B48 went to Regional Radiology in Staten Island for her annual mammogram. The diagnostic impression was "clustered calcifications, right axillary tail". The radiologist noted that prior mammography was not submitted for comparison. The patient was recalled for further evaluation. (T. 87-88; Ex. #10).

28. On January 29, 2007, Patient B48 underwent diagnostic mammography. The diagnostic impression was "suspicious cluster of microcalcifications in the right breast". The radiologist asked B48 if she had her prior films. The radiologist then recommended that the patient see a surgeon for a biopsy. (T. 89; Ex. #11).

29. Patient B48 sent Respondent Fleurantin a second letter in which she stated that her request for her prior films was "urgent". The patient explained in her letter that

she needed her films because of suspicious findings in her recent mammogram and that she was scheduled to undergo a biopsy. Patient B48 never got a response to that letter. (T. 89; Ex. #6B, p. 167).

30. Patient B48 had a biopsy performed under anesthesia on March 6, 2007. The biopsy revealed that the microcalcifications were non-malignant. (T. 90-91).

31. In approximately April 2007, Patient B48 learned from Lisa Saunders that Respondent Fleurantin had made arrangements for patients to pick up their films at 30 Martense Street, Brooklyn, New York. Her husband went to that location. The films could not be located, but her husband filled out another request. Several days later, and months after she had the biopsy, Patient B48 was notified that her films had been found and were available for pick up. (T. 90-92, 94).

32. On January 18, 2007, OPMC sent Respondents a written communication to make available records for numerous patients, including Patients C1 through C69. Respondents failed to provide the records for Patients C1 through C10, C12 through C54, and C56 through 69 within thirty days of the written communication from the Department. (T. 175).

33. As of the date of this hearing, Respondents had failed to provide a meaningful mechanism for Bay Imaging patients to obtain their medical records. (T. 68).

CONCLUSIONS OF LAW

Respondent is charged with six specifications alleging professional misconduct within the meaning of Education Law §6530. This statute sets forth numerous forms of conduct which constitute professional misconduct, but does not provide definitions of the various types of misconduct. During the course of its deliberations on these charges, the Hearing Committee consulted a memorandum prepared by the General Counsel for the Department of Health. This document, entitled "Definitions of Professional Misconduct Under the New York Education Law" sets forth suggested definitions for gross negligence, negligence, gross incompetence, incompetence, and the fraudulent practice of medicine.

The following definitions were utilized by the Hearing Committee during its deliberations:

Negligence is the failure to exercise the care that a reasonably prudent physician would exercise under the circumstances. It involves a deviation from acceptable standards in the treatment of patients. Bogdan v. Med. Conduct

Bd., 195 A. D. 2d 86, 88-89 (3rd Dept. 1993). Injury, damages, proximate cause, and foreseeable risk of injury are not essential elements in a medical disciplinary proceeding, the purpose of which is sole to protect the welfare of patients dealing with State-licensed practitioners. Id.

Gross Negligence is negligence that is egregious, i.e., negligence involving a serious or significant deviation from acceptable medical standards that creates the risk of potentially grave consequence to the patient. Post v. New York State Department of Health, 245 A.D. 2d 985, 986 (3rd Dept. 1997); Minielly v. Commissioner of Health, 222 A.D. 2d 750, 751-752 (3rd Dept. 1995). Gross negligence may consist of a single act of negligence of egregious proportions, or multiple acts of negligence that cumulatively amount to egregious conduct. Rho v. Ambach, 74 N.Y.2d 318, 322 (1991). A finding of gross negligence does not require a showing that a physician was conscious of impending dangerous consequences of his or her conduct.

For the remaining specifications of professional misconduct, the Hearing Committee interpreted the statutory language in light of the usual and commonly understood meaning of the language. (*See*, New York Statutes, §232).

Using the above-referenced definitions as a framework for its deliberations, the Hearing Committee made the following conclusions of law pursuant to the factual findings listed above. All conclusions resulted from a unanimous vote of the Hearing Committee unless noted otherwise.

The Hearing Committee first considered the credibility of the various witnesses, and thus the weight to be accorded their testimony. The Department presented testimony from six witnesses.

Gene Miskin is the director of the Office of Radiological Health, New York City Department of Health and Mental Hygiene. Mr. Miskin testified regarding the investigation of Bay Imaging conducted by his office. Ann Cea, M.D. is a board certified radiologist with a background in mammography. (T. 197-200). Dr. Cea testified regarding the reporting standards under the MQSA, as well as the significance of some of the individual studies at issue.

The Department also presented testimony by Lisa Saunders. Ms. Saunders is a medical conduct investigator employed by OPMC. She testified regarding the Department's efforts to obtain records from Respondents. Lastly, the Department presented three patients (Patients A16, A28 and A45). These patients testified regarding their efforts to obtain their

records from Bay Imaging, and the consequences of their failure to obtain the records in a timely fashion.

The witnesses all testified in a credible fashion, and were not challenged by Respondent Fleurantin. The Committee found all to be credible and gave great weight to their testimony.

As noted previously, Respondent Fleurantin failed to appear for the second day of hearing, and presented no witnesses or documentary evidence in his own behalf.

The basic, underlying facts are beyond dispute. On or about December 16, 2005, Respondent Fleurantin acquired a 100% ownership interest in three Brooklyn-based radiological facilities doing business as Bay Imaging. By September, 2006, Bay Imaging had gone out of business, leaving hundreds of patients without access to their records, including mammography films and reports. Respondent Fleurantin did not claim that the records had been provided. Rather, it is his position that he was just an absentee landlord, and had no responsibility for the records. Moreover, he claimed that he had been sold the practice under false pretenses. (*See*, Exhibit A). We strongly disagree.

In the contract by which Respondent Fleurantin acquired the radiology facilities, Respondent expressly agreed

to maintain all of the medical charts and patient records in accordance with all applicable laws, rules and regulations. (Ex. #3). Respondents then committed professional misconduct as defined by Education Law §6530(40), by failing provide access by qualified persons to patient information in conformance with the standards set forth in Public Health Law §18.

Dr. Cea testified that a reasonable period of time to fulfill a request for records for the purposes of compliance with Section 18 is, at most, no more than a month. Patients A1 through A63 waited many months to get their records. The majority of the patients identified in Appendix A of the Amended Statement of Charges never received a response to their records request. Accordingly, the Committee voted to sustain the first specification.

Education Law §6530(28) requires licensees to respond within thirty days to written communications from the Department of Health and to make available any relevant records with respect to an inquiry or complaint about the licensee's professional conduct. On January 18, 2007, OPMC sent Respondents a letter requesting the records for various patients, including Patients C1 through C69. The Department withdrew charges with respect to Patients C11 and C55. Respondents failed to provide the Department and/or the

remaining 67 patients with records within thirty days of the written request. Accordingly, the Committee voted to sustain the second specification.

The evidence further established that Respondents committed professional misconduct as defined by Education Law §6530(16) by their willful or grossly negligent failure to comply with substantial provisions of federal law governing the practice of medicine. The Mammography Quality Standards Act ("MQSA") is a federal statute that governs all licensees involved in the practice of mammography. The federal regulations promulgated under the MQSA are set forth in 21 CFR Subchapter 1, Part 900. The portions of the regulations pertaining to recordkeeping requirements are found in 21 CFR §900.12(c), and are attached to this Determination and Order in Appendix II.

Patients B1 through B122 requested, in writing, that Respondents provide them with their mammography reports and/or films. The majority of these patients never received their records. Therefore, the Hearing Committee voted to sustain the third specification.

21 CFR §900.12(c)(2) mandates that mammography results be sent to patients within thirty days of the mammographic examination. If the assessment is "suspicious" or "highly

suggestive of malignancy" the facility is required to make reasonable attempts to communicate the results to the patient as soon as possible. Respondents failed to communicate mammography results to Patients D1 through D362 and/or their referring physicians within thirty days of their respective examinations. This demonstrated a willful and grossly negligent failure to comply with the requirements of the MQSA. The Committee therefore voted to sustain the fourth specification.

Respondent's failure to interpret and report mammography results in a timely manner on such a vast scale demonstrated an especially egregious deviation from the standard of care. Their actions resulted in real harm to at least one patient. Patient B48 underwent a biopsy (a surgical procedure performed under anesthesia), because she was unable to obtain prior mammograms to compare against. Patient D23 underwent a mammogram and breast ultrasound on July 14, 2006. The studies were not interpreted until October 22, 2006, at which time a palpable lump was described as suspicious for malignancy. This 40 year old woman most likely had breast cancer, and may have lost precious time due to the delay in interpreting and reporting the results of her studies.

Based on the foregoing, the Hearing Committee unanimously concluded that Respondent's conduct demonstrated

both negligence on more than one occasion (Education Law §6530(3)), as well as gross negligence (Education Law §6530(4)), as defined above. As a result, the Committee voted to sustain the sixth and seventh specifications of professional misconduct.

DETERMINATION AS TO PENALTY

The Hearing Committee, pursuant to the Findings of Fact and Conclusions of Law set forth above, unanimously determined that Respondent Fleurantin's license to practice medicine as a physician in New York State should be revoked. This determination was reached upon due consideration of the full spectrum of penalties available pursuant to statute, including revocation, suspension and/or probation, censure and reprimand, and the imposition of monetary penalties. In addition, the Committee determined that pursuant to Section 1503 of the Business Corporation Law, the certificate of incorporation for Bay Imaging, P.C. should be revoked.

Respondent's massive failure to provide hundreds of patients with their radiological studies upon the failure of his practice represents a heretofore unprecedented level of non-compliance with the standards of practice. He presented no defense to the charges and no evidence which might mitigate the sanction to be imposed. Indeed, in his opening statement to this Committee, he made it clear that he did not believe that he

had any responsibility to these patients. Under these circumstances, no sanction short of revocation will suffice.

ORDER

Based upon the foregoing, **IT IS HEREBY ORDERED THAT:**

1. The First, Second, Third, Fourth, Sixth and Seventh Specifications of professional misconduct, as set forth in the Amended Statement of Charges, (Exhibit #1A) are **SUSTAINED**;

2. Respondent Ruben Jean Louis Fleurantin's license to practice medicine as a physician in New York State be and hereby is **REVOKED**;

3. The Certificate of Incorporation for Bay Imaging, P.C., be and hereby is **REVOKED**;

4. This Determination and Order shall be effective upon service. Service shall be either by certified mail upon Respondent at Respondent's last known address and such service shall be effective upon receipt or seven days after mailing by certified mail, whichever is earlier, or by personal service and such service shall be effective upon receipt.

DATED: Troy, New York
Oct 12, 2007

ALAN KOPMAN (CHAIR)

PAUL S. CARTON, M.D.
ROBERT D. SUNSHINE, M.D.

TO: Daniel Guenzburger, Esq.
Associate Counsel
New York State Department of Health
90 Church Street - 4th Floor
New York, New York 10007-2919

Ruben Jean Louis Fleurantin, M.D.
324 Scotland Road
South Orange, New Jersey 07079

APPENDIX I

NEW YORK STATE DEPARTMENT OF HEALTH
STATE BOARD FOR PROFESSIONAL MEDICAL CONDUCT

IN THE MATTER

OF

RUBEN JEAN LOUIS FLEURANTIN, M.D.

AND

BAY IMAGING, P.C.

AMENDED
STATEMENT
OF
CHARGES

RUBEN JEAN LOUIS FLEURANTIN, M.D. the Respondent, was authorized to practice medicine in New York State on or about July 27, 1987 by the issuance of license number 171144 by the New York State Education Department.

BAY IMAGING, P.C., Respondent, is a professional service corporation organized pursuant to Article 15 of the Business Corporation Law.

FACTUAL ALLEGATIONS

A. On or about December 16, 2005, Respondent Fleurantin acquired ownership and control over three radiological facilities located respectively at 1620 Caton Avenue, 9201 4th Avenue, and 2626 East 14th Street, Brooklyn, New York. Respondent Fleurantin acquired the facilities through the purchase of stock in Respondent Bay Imaging, P.C. ("Bay Imaging") and two other legal entities. The Bay Imaging facilities ceased operating in or about September 2006. The facilities had offered a wide array of radiological services, including MRI, CAT scans, bone density studies, plain x-rays, mammography. At the time of closure, Bay Imaging maintained records of thousands of radiological studies performed both prior to and during the period that Respondent Fleurantin owned the facilities.

1. Respondents Fleurantin and Bay Imaging failed to furnish Patients A1 through A63 with reports and/or films of their radiological evaluations, within a reasonable period of time of the date that the Patients requested their records.
2. Respondents Fleurantin and Bay Imaging willfully and/or gross negligently failed to comply with Mammography Quality Standards Act Regulations Part 900, Subpart B, Section 900.12 (c)(4) by failing to comply with requests for mammograms and/or reports by Patients B1 through B 122.
3. Respondents Fleurantin and Bay Imaging failed to provide the Department of Health with the medical records for Patients C1 through C69 within 30 days of a written request. The written request was delivered to Respondents on or about January 18, 2007.
4. With respect to the patients referred to in factual allegations A1, A2, and A3, Respondents Fleurantin and Bay Imaging failed to maintain records that accurately reflect the evaluation of the patients.
5. Respondents Fleurantin and Bay Imaging willfully and/or gross negligently failed to comply with Mammography Quality Standards Act Regulations Part 900, Subpart B, Section 900.12 (c)(2) by failing to communicate mammography results to Patients D1 through D 362, and/or their referring physicians, within 30 days of their respective examinations.
6. With respect to the Patients referred to in Paragraphs A and A5, Respondents Fleurantin and Bay Imaging deviated from medically accepted standards by failing to cause:

a. Mammography examinations to be interpreted within an appropriate period of time.

b. Mammography results to be communicated to patients and/or their referring physicians within an appropriate period of time.

SPECIFICATION OF CHARGES

FIRST SPECIFICATION

RECORD ACCESS

Respondent is charged with committing professional misconduct as defined in N.Y. Educ. Law § 6530(40) by failing to provide access by qualified persons to patient information in accordance with the standards set forth in Public Health Law Section 18, as alleged in the facts of:

1. Paragraphs A and A1.

SECOND SPECIFICATION

OPMC RECORD REQUEST

Respondent is charged with committing professional misconduct as defined in N.Y. Educ. Law § 6530(28) by failing to respond within thirty days to written communications from the Department of Health and to make available any relevant records, as alleged in the facts of:

2. Paragraphs A and A3.

THIRD AND FOURTH SPECIFICATIONS

FAILING TO COMPLY WITH FEDERAL LAW

Respondent is charged with committing professional misconduct as defined in N.Y. Educ. Law §6530(16) by his willful or grossly negligent failure to comply

with substantial provisions of federal law governing the practice of medicine, as alleged in the facts of:

3. Paragraphs A and A2.

4. Paragraphs A and A5.

FIFTH SPECIFICATION

FAILURE TO MAINTAIN RECORDS

Respondent is charged with committing professional misconduct as defined in N.Y. Educ. Law § 6530(32) by failing to maintain a record for each patient which accurately reflects the care and treatment of the patient, as alleged in the facts of:

5. Paragraphs A and A4.

SIXTH SPECIFICATION

NEGLIGENCE ON MORE THAN ONE OCCASION

Respondent is charged with committing professional misconduct as defined in N.Y. Educ. Law § 6530(3) by practicing the profession of medicine with negligence on more than one occasion as alleged in the facts of two or more of the following:

6. Paragraphs A, A6, A6(a) and/or A6(b).

SEVENTH SPECIFICATION

GROSS NEGLIGENCE

Respondent is charged with committing professional misconduct as defined in N.Y. Educ. Law § 6530(4) by practicing the profession of medicine with gross negligence on a particular occasion as alleged in the facts of the following:

7. Paragraphs A, A6, A6(a) and A6(b).

DATED: May 8, 2007
New York, New York

Roy Nemerson
Deputy Counsel
Bureau of Professional
Medical Conduct

APPENDIX II

21 CFR Section 900.12:

(c) *Medical records and mammography reports—*

(1) *Contents and terminology.* Each facility shall prepare a written report of the results of each mammography examination performed under its certificate. The mammography report shall include the following information:

(i) The name of the patient and an additional patient identifier;

(ii) Date of examination;

(iii) The name of the interpreting physician who interpreted the mammogram;

(iv) Overall final assessment of findings, classified in one of the following categories:

(A) "Negative:" Nothing to comment upon (if the interpreting physician is aware of clinical findings or symptoms, despite the negative assessment, these shall be explained);

(B) "Benign:" Also a negative assessment;

(C) "Probably Benign:" Finding(s) has a high probability of being benign;

(D) "Suspicious:" Finding(s) without all the characteristic morphology of breast cancer but indicating a definite probability of being malignant;

(E) "Highly suggestive of malignancy:" Finding(s) has a high probability of being malignant;

(v) In cases where no final assessment category can be assigned due to incomplete work-up, "Incomplete: Need additional imaging evaluation" shall be assigned as an assessment and reasons why no assessment can be made shall be stated by the interpreting physician; and

(vi) Recommendations made to the health care provider about what additional actions, if any, should be taken. All clinical questions raised by the referring health care provider shall be addressed in the report to the extent possible, even if

the assessment is negative or benign.

(2) *Communication of mammography results to the patients.* Each facility shall send each patient a summary of the mammography report written in lay terms within 30 days of the mammographic examination. If assessments are "Suspicious" or "Highly suggestive of malignancy," the facility shall make reasonable attempts to ensure that the results are communicated to the patient as soon as possible.

(i) Patients who do not name a health care provider to receive the mammography report shall be sent the report described in paragraph (c)(1) of this section within 30 days, in addition to the written notification of results in lay terms.

(ii) Each facility that accepts patients who do not have a health care provider shall maintain a system for referring such patients to a health care provider when clinically indicated.

(3) *Communication of mammography results to health care providers.* When the patient has a referring health care provider or the patient has named a health care provider, the facility shall:

(i) Provide a written report of the mammography examination, including the items listed in paragraph (c)(1) of this section, to that health care provider as soon as possible, but no later than 30 days from the date of the mammography examination; and

(ii) If the assessment is "Suspicious" or "Highly suggestive of malignancy," make reasonable attempts to communicate with the health care provider as soon as possible, or if the health care provider is unavailable, to a responsible designee of the health care provider.

(4) *Recordkeeping.* Each facility that performs mammograms:

(i) Shall (except as provided in paragraph (c)(4)(ii) of this section) maintain mammography films and reports in a permanent medical record of the patient for a period of not less than 5 years, or not less than 10 years if no additional mammograms of the patient are performed at the facility, or a longer period if mandated by State or local law; and

(ii) Shall upon request by, or on behalf of, the patient, permanently or temporarily transfer the original mammograms and copies of the patient's reports to a medical institution, or to a physician or health care provider of the patient, or to the patient directly;

(iii) Any fee charged to the patients for providing the services in paragraph (c)(4)(ii) of this section shall not exceed the documented costs associated with this service.

(5) *Mammographic image identification.* Each mammographic image shall have the following information indicated on it in a permanent, legible, and unambiguous manner and placed so as not to obscure anatomic structures:

(i) Name of patient and an additional patient identifier.

(ii) Date of examination.

(iii) *View and laterality.* This information shall be placed on the image in a position near the axilla. Standardized codes specified by the accreditation body and approved by FDA in accordance with Sec. 900.3(b) or Sec. 900.4(a)(8) shall be used to identify view and laterality.

(iv) *Facility name and location.* At a minimum, the location shall include the city, State, and zip code of the facility.

(v) Technologist identification.

(vi) Cassette/screen identification.

(vii) Mammography unit identification, if there is more than one unit in the facility.