

UNITED STATES OF AMERICA  
BEFORE THE FOOD AND DRUG ADMINISTRATION  
DEPARTMENT OF HEALTH AND HUMAN SERVICES 2719 10:07

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In the Matter of )  
 )  
ECUMED HEALTH GROUP ) ADMINISTRATIVE COMPLAINT  
a corporation, ) FOR CIVIL MONEY PENALTY  
 )  
and )  
 )  
AMADOR REYES, ) FDA Docket: 2004H-0322  
JUAN C. CARRAI, )  
RICHARD W. STONE, M.D., and )  
ERLINDA E. ENRIQUEZ, M.D., )  
individuals. )  
\_\_\_\_\_)

Complainant, the Center for Devices and Radiological Health, Food and Drug Administration ("FDA"), United States Department of Health and Human Services, by Michael N. Varrone, attorney for Complainant, respectfully represents as follows:

INTRODUCTION

1. This action is brought by FDA under the Mammography Quality Standards Act of 1992 ("MQSA"), 42 U.S.C. § 263b, which authorizes the imposition of civil money penalties against persons and facilities that provide screening and/or mammography services in violation of the MQSA, after the opportunity for a hearing provided in accordance with 42 U.S.C. § 263b(h) (3) and (4).

JURISDICTION

2. FDA has subject matter jurisdiction, as delegated by the Secretary of Health and Human Services to the Commissioner of Food and Drugs, over this action and personal jurisdiction over

the parties ("Respondents"), pursuant to 42 U.S.C. § 263b. Pursuant to 42 U.S.C. § 263b(h)(4) and the implementing regulations, 21 C.F.R. Part 17, the authority to conduct an administrative civil penalty hearing and assess a civil penalty is vested in an Administrative Law Judge, appointed in accordance with 5 U.S.C. § 3105.

#### RESPONDENTS

At all relevant times:

3. Respondent Ecumed Health Group, Inc. ("EHG" or "the firm"), a corporation, was organized under the laws of the State of Florida and was doing business at 687 East 9th Street, Hialeah, Florida 33010. EHG was engaged in the business of conducting mammography examinations, and it owned and operated a mammography facility within the meaning of 42 U.S.C. § 263b(a)(3).

4. Respondent Amador Reyes was president and co-owner of EHG. Mr Reyes was the most responsible person at the firm and was responsible for all operational decisions.

5. Respondent Juan C. Carrai was the vice-president and co-owner of EHG, as well as the registered radiologic technician. Mr. Carrai had authority over all mammography and x-ray operations conducted at EHG.

6. Respondent Richard W. Stone, M.D., was the lead interpreting physician at EHG from October 30, 2000, through at

least January 31, 2002. As lead interpreting physician, Dr. Stone was responsible for ensuring adequate clinical image quality at EHG. He also was responsible for maintaining EHG's certification under the MQSA.

7. Respondent Erlinda E. Enriquez, M.D., was the lead interpreting physician at EHG from at least September 11, 2002, through May 6, 2003. During this period, Dr. Enriquez was responsible for ensuring adequate clinical image quality at EHG. She also was responsible for obtaining EHG's certification under the MQSA.

#### RELEVANT LAW

8. The MQSA provides that no mammography facility may conduct a mammography examination or procedure unless it possesses a certificate that has been issued or renewed under the MQSA. See 42 U.S.C. § 263b(b) (1).

9. To obtain or renew a certificate, the MQSA, and its implementing regulations, 21 C.F.R. Part 900, require a facility to apply to, and be accredited by, an FDA-approved accreditation body. See 42 U.S.C. § 263b(d) (1) (A) (iv); 21 C.F.R. § 900.11(a), (b) (i). Once FDA receives notification of the accreditation body's decision to accredit a facility, FDA may issue a certificate to the facility or renew the facility's existing certificate. See 21 C.F.R. § 900.11(b) (1) (ii).

10. Where a previously certified facility has allowed its certificate to expire, as in this case, the facility may apply to an accreditation body to have its certificate reinstated. See 21 C.F.R. § 900.11(c). A facility applying for reinstatement shall submit to an accreditation body, among other things, a corrective action plan ("CAP") that details how the facility has corrected the deficiencies that led to the lapse of its certificate. See 21 C.F.R. § 900.11(c)(1)(iii). FDA may then issue a provisional certificate to the facility once the accreditation body notifies FDA that the facility has corrected, or is in the process of correcting, the deficiencies that led to the lapse of its certificate. See 42 U.S.C. § 263b(c)(2); 21 C.F.R. § 900.11(c)(2). Once a facility receives a provisional certificate, it may lawfully perform mammography services while completing the requirements of certification. See 21 C.F.R. § 900.11(c)(3). However, a provisional certificate can only be effective for up to 6 months from the date of issuance. See 21 C.F.R. § 900.11(b)(2)(ii).

11. Under 42 U.S.C. § 263b(h)(3)(A), FDA may assess civil money penalties in an amount not to exceed \$10,000 for a failure to obtain a certificate as required by section 263b(b).

12. In addition, under 42 U.S.C. § 263b(h)(3)(D), FDA may assess civil money penalties in an amount not to exceed \$10,000 for each violation of, or for aiding and abetting a violation of,

any provision of the MQSA by an owner, operator, or any employee of a facility required to have a certificate.

#### VIOLATIONS

13. On June 8, 2001, FDA issued provisional MQSA certification to EHG. This provisional certificate allowed EHG to perform mammography while conducting additional testing in order to obtain full MQSA certification of its facility. The provisional certificate expired on December 8, 2001. The expiration date was clearly indicated on the certificate.

14. On June 11, 2001, the American College of Radiology ("ACR"), an FDA-approved accreditation body, issued testing materials to EHG for its mammography unit.

15. On July 31, 2001, ACR sent a letter to EHG explaining that EHG's testing was delinquent. ACR had not received any of the required testing materials from EHG, including clinical and phantom images.

16. By letter addressed to Dr. Stone, dated September 14, 2001, ACR notified Respondents that EHG's certificate would soon expire. The letter explained that EHG could not legally conduct mammography if EHG's MQSA certificate expired. The letter also explained that, without certification, EHG could be subject to sanctions or fines by FDA.

17. In an attempt to complete the requirements of certification, Respondent Dr. Stone submitted testing results

from EHG's mammography unit to ACR. ACR received this testing data on October 2, 2001.

18. FDA advised Respondents by letter addressed to Dr. Stone, dated November 1, 2001, that EHG's MQSA certificate would expire on December 8, 2001, unless EHG was reinstated for accreditation. The letter also stated that EHG could not perform mammography services once EHG's MQSA certificate expired:

19. By letter to Respondent Dr. Stone dated November 14, 2001, ACR informed Respondents that EHG failed to qualify for accreditation as a mammography facility because ACR's examination of EHG's clinical image quality testing showed that EHG's mammography unit failed to comply with ACR's standards for clinical image quality. The letter also reminded Respondents that they may not lawfully conduct mammography when the firm's MQSA certificate expired.

20. EHG's certificate expired on December 8, 2001.

21. On December 12, 2001, ACR received Respondents' appeal of the November 14, 2001 ACR letter denying EHG accreditation for the failure of the mammography unit to pass.

22. By letter addressed to Dr. Stone, dated January 4, 2002, ACR informed Respondents that it had denied their appeal. ACR again found that EHG's mammography unit failed to comply with ACR's standards for clinical image quality. This letter also

notified Respondents that for EHG to provide mammography services it must apply for provisional reinstatement.

23. On or around June 18, 2002, EHG inquired about reinstatement. ACR subsequently sent EHG information that EHG needed to complete to obtain provisional reinstatement.

24. On October 14, 2002, ACR received EHG's application for reinstatement, signed by Respondent Dr. Enriquez. On or around October 16, 2002, ACR informed Respondents that it could not be provisionally reinstated until it submitted a sufficient CAP.

25. On or around November 21, 2002, ACR discussed with Respondents the testing information EHG still needed to submit to ACR to complete its CAP and gain provisional reinstatement. ACR was told that EHG was not performing mammography.

26. On May 5, 2003, EHG submitted additional testing information to ACR.

27. On May 6, 2003, ACR notified FDA that Respondents' application was successfully complete for review, and that EHG was eligible for provisional reinstatement. Therefore, on May 6, 2003, FDA issued an interim notice to EHG. This interim notice served as EHG's certification to conduct mammography services until it received a provisional certificate.

28. Between and including December 9, 2001, and May 5, 2003, EHG was not certified to conduct mammography examinations or procedures.

29. Between and including December 9, 2001, and May 5, 2003, Respondents conducted, or aided and abetted in the conduct of, up to 1201 mammography examinations, although EHG did not have a certificate, in violation of 42 U.S.C. § 263b(b)(1). Respondents conducted these examinations on the patients and dates listed on Attachment A.

30. Because of the numerous letters FDA and ACR sent to Respondents, Respondents knew or should have known that the performance of mammography after the expiration date constitutes continuing violations of the MQSA.

31. Because the expiration date of the provisional certificate was clearly indicated on the certificate, Respondents knew or should have known that the performance of mammography after the expiration date constitutes continuing violations of the MQSA.

32. Petitioner seeks to assess civil money penalties against each Respondent pursuant to 42 U.S.C. § 263b(h)(3)(A), for failure to obtain a certificate, and 42 U.S.C. § 263b(h)(3)(D), for each mammography examination conducted on a patient while the facility did not have a certificate, in violation of section 263b(b)(1).

AMOUNT OF PENALTY

33. Petitioner seeks to impose penalties in the amount of \$1,211,000.00 against EHG; \$1,211,000.00 against Amador Reyes; \$1,211,000.00 against Juan C. Carrai; \$55,000.00 against Dr. Richard W. Stone; and \$663,000.00 against Dr. Erlinda Enriquez.

34. The penalty sought against each Respondent under 42 U.S.C. § 263b(h)(3)(A), for failure to obtain a certificate, is \$10,000.

35. The penalty sought against Respondents EHG, Amador Reyes, and Juan C. Carrai under 42 U.S.C. § 263b(h)(3)(D), for each of the 1201 mammography examinations that they conducted, or aided and abetted in the conduct of, while the facility was uncertified in violation of section 263b(b)(1), is \$1000 per violation.

36. The penalty sought against Respondent Dr. Richard W. Stone under 42 U.S.C. § 263b(h)(3)(D), for each of the 45 mammography examinations that he conducted, or aided and abetted in the conduct of, while the facility was uncertified in violation of section 263b(b)(1), is \$1000 per violation.

37. The penalty sought against Respondent Dr. Erlinda Enriquez under 42 U.S.C. § 263b(h)(3)(D), for each of the 653 mammography examinations that she conducted, or aided and abetted in the conduct of, while the facility was uncertified in violation of section 263b(b)(1), is \$1000 per violation.

INSTRUCTIONS FOR FILING AN ANSWER

38. To obtain a hearing, each Respondent must file an answer, pursuant to 21 C.F.R. § 17.9, with the Division of Dockets Management (HFA-305), Food and Drug Administration, Room 1061, 5630 Fishers Lane, Rockville, MD 20852, within 30 days of the date of service of this Complaint. The failure to file an answer by any Respondent within 30 days of service of the Complaint may result in the imposition of the proposed penalty and assessment against such Respondent, as provided by 21 C.F.R. § 17.11. Respondents may retain counsel to represent them in this proceeding.

39. Pursuant to 21 C.F.R. § 17.9, Respondents' answer(s), if filed, must admit or deny each of the allegations made in this Complaint and must include the following: all defenses on which each Respondent intends to rely; all reasons (if any) why each Respondent contends that the penalty and assessment should be less than the amount requested by this Complaint; and the name, address, and telephone number of each Respondent's counsel (if any).

PRAYER FOR RELIEF

Based on the violations described in this Complaint,  
COMPLAINANT PRAYS THAT THE PRESIDING OFFICER FIND THAT:

1. Each of the allegations in this Complaint is true;

2. Respondents violated, or aided and abetted in violations of, 42 U.S.C. § 263b(b) (1) by operating a facility without a certificate;

3. Respondents EHG, Amador Reyes, and Juan C. Carrai violated, or aided and abetted in violations of, 42 U.S.C. § 263b(b) (1) by conducting 1,201 mammography examinations while EHG was uncertified;

4. Respondent Dr. Richard W. Stone violated, or aided and abetted in violations of, 42 U.S.C. § 263b(b) (1) by conducting 45 mammography examinations while EHG was uncertified;

5. Respondent Dr. Erlinda Enriquez violated, or aided and abetted in violations of, 42 U.S.C. § 263b(b) (1) by conducting 653 mammography examinations while EHG was uncertified;

6. Civil money penalties should be assessed against each Respondent pursuant to 42 U.S.C. § 263b(h) (3) (A) for failure to obtain a certificate as required by section 263b(b);

7. Civil money penalties should be assessed against EHG, Amador Reyes, and Juan C. Carrai pursuant to 42 U.S.C. § 263b(h) (3) (D) for conducting, or aiding and abetting in the conduct of, 1201 mammography examinations while EHG was uncertified, in violation of section 263b(b) (1);

8. Civil money penalties should be assessed against Dr. Richard W. Stone pursuant to 42 U.S.C. § 263b(h) (3) (D) for conducting, or aiding and abetting in the conduct of, 45

mammography examinations while EHG was uncertified, in violation of section 263b(b) (1);

9. Civil money penalties should be assessed against Dr. Erlinda Enriquez pursuant to 42 U.S.C. § 263b(h) (3) (D) for conducting, or aiding and abetting in the conduct of, 653 mammography examinations while EHG was uncertified, in violation of section 263b(b) (1);

10. Each and every affirmative defense, if any, presented by Respondents is not meritorious;

11. The appropriate amount of the civil penalty for which Respondent EHG is liable, considering Respondent EHG's ability to pay, and efforts, or lack thereof, to comply with the law, is \$1,211,000.00;

12. The appropriate amount of the civil penalty for which Respondent Reyes is liable, considering Respondent Reyes's ability to pay, and efforts, or lack thereof, to comply with the law, is \$1,211,000.00;

13. The appropriate amount of the civil penalty for which Respondent Carrai is liable, considering Respondent Carrai's ability to pay, and efforts, or lack thereof, to comply with the law, is \$1,211,000.00;

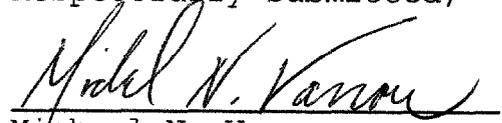
14. The appropriate amount of the civil penalty for which Respondent Stone is liable, considering Respondent Stone's ability to pay, and efforts, or lack thereof, to comply with the

law, is \$55,000.00;

15. The appropriate amount of the civil penalty for which Respondent Enriquez is liable, considering Respondent Enriquez's ability to pay, and efforts, or lack thereof, to comply with the law, is \$663,000.00.

DATED: 19<sup>th</sup> day of July, 2004.

Respectfully submitted,



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