STATE OF FLORIDA
DIVISION OF ADMINISTRATIVE HEARINGS

DEPARTMENT OF HEALTH, BOARD OF MEDICINE,	)	
Petitioner,	)	
vs.	)	Case No. 08-1074PL
GERARD ROMAIN, M.D.,	)	
Respondent.	)	

RECOMMENDED ORDER

On August 8, 2008, a formal administrative hearing in this case was held in Tampa, Florida, before William F. Quattlebaum, Administrative Law Judge, Division of Administrative Hearings.

APPEARANCES

For Petitioner: Elana J. Jones, Esquire
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For Respondent: Dale R. Sisco, Esquire
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STATEMENT OF THE ISSUES

The issues in this case are whether the allegations of the Amended Administrative Complaint are correct, and, if so, what penalty should be imposed.

PRELIMINARY STATEMENT

By Administrative Complaint dated July 16, 2007, the Department of Health (Petitioner) alleged that Gerard Romain, M.D. (Respondent), violated Subsections 458.331(1)(t), 458.331(1)(q), and 458.331(1)(m), Florida Statutes (2005). The Respondent disputed the allegations and requested a formal administrative hearing. By letter dated February 29, 2008, the Petitioner forwarded the matter to the Division of Administrative Hearings, which scheduled and conducted the hearing. Without objection, the Administrative Complaint was amended on July 28, 2008, to correct patient identification and statutory reference.

At the hearing, the Petitioner presented the testimony of one witness and had Exhibits numbered 1, 2, 4, and 5 admitted into evidence. The Respondent presented no testimony or exhibits.

The hearing Transcript was filed on August 21, 2008. Both parties filed Proposed Recommended Orders that have been considered in the preparation of this Recommended Order.

FINDINGS OF FACT

1. The Respondent is a licensed physician in the State of Florida, holding license number ME 81249.

2. At all times material to this case, the Respondent was board-certified in family medicine. The Respondent held no

board certification at the time of the administrative hearing, and, according to his response to the Petitioner's First Request for Admissions, the family medicine certification expired in July 2007.

3. On February 8, 2006, the Respondent prescribed hydrocodone (10/325, generic Norco, 10mg.) to Patient M.R. through an internet service called ERMeds.com.

4. On June 26, 2006, the Respondent prescribed hydrocodone (Hydro/APAP 10/325, generic Norco, 10/325) to Patient M.R. through the internet service called ERMeds.com.

5. Hydrocodone is a Schedule II controlled substance listed in Chapter 893, Florida Statutes.

6. Hydrocodone/APAP is hydrocodone combined with acetaminophen, and the combined drug is a Schedule III controlled substance listed in Chapter 893, Florida Statutes.

7. Both hydrocodone and hydrocodone/APAP have high potential for abuse and addiction.

8. The prescriptions issued to Patient M.R. contained the Respondent's identification including address and DEA number on the prescription form, as well as the Respondent's electronic facsimile signature.

9. The Respondent had no contact with Patient M.R. either before or after the prescription was issued to Patient M.R.

10. The Respondent conducted no health evaluation of Patient M.R. The Respondent did not obtain or review any medical information related to Patient M.R.

11. The Respondent testified during deposition that a physician's assistant for whom the Respondent was the supervising physician was responsible for gathering and reviewing medical information from the patient.

12. According to the Respondent's response to the Petitioner's First Request for Admissions, the physician's assistant obtained patient history, including current medications and complaints, and the "information was available to Respondent at the time the prescriptions were authorized."

13. According to the Respondent's response to the Petitioner's First Request for Admissions, a completed medical questionnaire was available for the Respondent's review.

14. There is no evidence that the Respondent reviewed any information or questionnaire regarding the patient's medical history or complaint either before or at the time the prescriptions were authorized.

15. The Respondent did not know and never met the physician's assistant and was unable to recall the last name of the physician's assistant.

16. There is no evidence that the Respondent had any discussion with any physician's assistant related to

Patient M.R. either before or at the time the prescriptions were authorized.

17. At the hearing, the Petitioner presented the testimony of Bernd Wollschlaeger, M.D., a Florida-licensed physician holding board certification in family practice.

18. Dr. Wollschlaeger testified that a physician must evaluate a patient, take a patient's medical history, review any available medical records, and document the findings and diagnosis in a contemporaneous record prior to issuing a prescription for hydrocodone to a patient.

19. Based upon the Respondent's deposition testimony and the responses to the Petitioner's First Request for Admissions, it is clear that the Respondent failed to evaluate Patient M.R. in any respect prior to issuing the prescriptions for hydrocodone to the patient.

20. The Respondent reviewed no medical history or records related to Patient M.R.

21. The Respondent failed to diagnose any medical condition that would support prescribing hydrocodone to Patient M.R.

22. The Respondent failed to document any medical information related to Patient M.R. in any written record.

CONCLUSIONS OF LAW

23. The Division of Administrative Hearings has jurisdiction over the parties to and the subject matter of this proceeding. §§ 120.569 and 120.57, Fla. Stat. (2008).

24. The Petitioner is the state agency charged with regulating the practice of medicine. § 20.43 and Chapters 456 and 458, Fla. Stat. (2008).

25. The Administrative Complaint charges the Respondent with violations of Subsection 458.331(1), Florida Statutes (2005), which provides in relevant part as follows:

> (1) The following acts constitute grounds for denial of a license or disciplinary action, as specified in s. 456.072(2):
>
> * * *
>
> (m) Failing to keep legible, as defined by department rule in consultation with the board, medical records that identify the licensed physician or the physician extender and supervising physician by name and professional title who is or are responsible for rendering, ordering, supervising, or billing for each diagnostic or treatment procedure and that justify the course of treatment of the patient, including, but not limited to, patient histories; examination results; test results; records of drugs prescribed, dispensed, or administered; and reports of consultations and hospitalizations.
>
> * * *
>
> (q) Prescribing, dispensing, administering, mixing, or otherwise preparing a legend drug, including any controlled substance,

other than in the course of the physician's professional practice. For the purposes of this paragraph, it shall be legally presumed that prescribing, dispensing, administering, mixing, or otherwise preparing legend drugs, including all controlled substances, inappropriately or in excessive or inappropriate quantities is not in the best interest of the patient and is not in the course of the physician's professional practice, without regard to his or her intent.

* * *

(t) Notwithstanding s. 456.072(2) but as specified in s. 456.50(2):

1. Committing medical malpractice as defined in s. 456.50. The board shall give great weight to the provisions of s. 766.102 when enforcing this paragraph. Medical malpractice shall not be construed to require more than one instance, event, or act.

2. Committing gross medical malpractice.

3. Committing repeated medical malpractice as defined in s. 456.50. A person found by the board to have committed repeated medical malpractice based on s. 456.50 may not be licensed or continue to be licensed by this state to provide health care services as a medical doctor in this state.

Nothing in this paragraph shall be construed to require that a physician be incompetent to practice medicine in order to be disciplined pursuant to this paragraph. A recommended order by an administrative law judge or a final order of the board finding a violation under this paragraph shall specify whether the licensee was found to have committed "gross medical malpractice," "repeated medical malpractice," or "medical malpractice," or any combination thereof,

and any publication by the board must so specify.

26. Subsection 456.50(1)(g), Florida Statutes (2005), defines medical malpractice as follows:

> "Medical malpractice" means the failure to practice medicine in accordance with the level of care, skill, and treatment recognized in general law related to health care licensure. Only for the purpose of finding repeated medical malpractice pursuant to this section, any similar wrongful act, neglect, or default committed in another state or country which, if committed in this state, would have been considered medical malpractice as defined in this paragraph, shall be considered medical malpractice if the standard of care and burden of proof applied in the other state or country equaled or exceeded that used in this state.

27. The Petitioner has the burden of proving by clear and convincing evidence the allegations set forth in the Administrative Complaint against the Respondent. Department of Banking and Finance v. Osborne Stern and Company, 670 So. 2d 932, 935 (Fla. 1996); Ferris v. Turlington, 510 So. 2d 292 (Fla. 1987).

28. Clear and convincing evidence is that which is credible, precise, explicit, and lacking confusion as to the facts in issue. The evidence must be of such weight that it produces in the mind of the trier of fact the firm belief of conviction, without hesitancy, as to the truth of the

allegations. Slomowitz v. Walker, 429 So. 2d 797, 800 (Fla. 4th DCA 1983). In this case, the burden has been met.

29. The evidence clearly and convincingly establishes that the Respondent committed medical malpractice and violated Subsection 458.331(1)(t), Florida Statutes (2005), by prescribing medications to Patient M.R. without obtaining or reviewing any medical information related to the patient. The evidence establishes that the Respondent failed to practice medicine with the level of care, skill, and treatment which is recognized by a reasonably prudent similar physician as being acceptable and appropriate under similar conditions and circumstances.

30. The evidence clearly and convincingly establishes that the Respondent violated Subsection 458.331(1)(q), Florida Statutes (2005), by inappropriately prescribing hydrocodone, a controlled substance, to Patient M.R. without obtaining or reviewing any medical information related to the patient.

31. The evidence clearly and convincingly establishes that the Respondent violated Subsection 458.331(1)(m), Florida Statutes (2005), by failing to keep any medical records to justify the course of treatment. The evidence establishes that the Respondent kept no records at all related to Patient M.R.

32. The Respondent asserts that a physician's assistant was responsible for obtaining medical information from the

patient, performing a medical evaluation of the patient, diagnosing the patient's medical condition, issuing the prescription, and documenting the information. The documentation was supposedly maintained by the owners of the ERMeds Internet website. There is no credible evidence to support the exculpatory assertions, and they have not been credited.

33. Paragraphs 13 through 15 of the Amended Administrative Complaint alleged that, on September 23, 2006, Patient M.R. was taken to a hospital emergency department after being found by his wife cold and unresponsive"; that attempts to resuscitate the patient were unsuccessful; and that on September 28, 2006, an autopsy identified the cause of death as "acute hydrocodone intoxication."

34. The Petitioner presented no evidence whatsoever to support the allegations of paragraphs 13 through 15. Further, there is no credible evidence that the patient received or ingested the medication identified on the prescriptions at issue in this proceeding.

35. Dr. Wollschlaeger testified based upon his review of materials provided to him by the Respondent, which included a number of emails, all of which were hearsay. During cross-examination, it became apparent that some of the documents reviewed by Dr. Wollschlaeger lacked any information identifying

either the patient or the internet website relevant to this proceeding. The testimony specifically related to the email documents has been disregarded.

36. Dr. Wollschlaeger also testified as to his understanding of the manner in which medication prescriptions can be obtained through the internet. His testimony in this regard was corroborated by the deposition testimony and admissions of the Respondent concerning the operation of ERMeds. Accordingly, Dr. Wollschlaeger's opinions related to the standard of care applicable to a physician issuing or authorizing prescriptions through an internet-based service are credited.

37. The Respondent has not been the subject of any prior disciplinary proceedings. Florida Administrative Code Rule 64B8-8.001 sets forth the disciplinary guidelines applicable to the statutory violations relevant to this proceeding.

38. Florida Administrative Code Rule 64B8-8.001(2) provides that the penalty for a first offense of Subsection 458.331(1)(m), Florida Statutes, ranges from a reprimand to denial or two years' suspension followed by probation, and an administrative fine from $1,000.00 to $10,000.00.

39. Florida Administrative Code Rule 64B8-8.001(2) provides that the penalty for a first offense of Subsection 458.331(1)(q), Florida Statutes, ranges from a one-year period of probation to revocation or denial and an administrative fine from $1,000.00 to $10,000.00.

40. Florida Administrative Code Rule 64B8-8.001(2) provides that the penalty for a first offense of Subsection 458.331(1)(t), Florida Statutes, ranges from a one-year period of probation to revocation or denial and an administrative fine from $1,000.00 to $10,000.00.

41. Florida Administrative Code Rule 64B8-8.001(3) provides as follows:

> Aggravating and Mitigating Circumstances. Based upon consideration of aggravating and mitigating factors present in an individual case, the Board may deviate from the penalties recommended above. The Board shall consider as aggravating or mitigating factors the following:
>
> (a) Exposure of patient or public to injury or potential injury, physical or otherwise: none, slight, severe, or death;
>
> (b) Legal status at the time of the offense: no restraints, or legal constraints;
>
> (c) The number of counts or separate offenses established;
>
> (d) The number of times the same offense or offenses have previously been committed by the licensee or applicant;

(e) The disciplinary history of the applicant or licensee in any jurisdiction and the length of practice;

(f) Pecuniary benefit or self-gain inuring to the applicant or licensee;

(g) The involvement in any violation of Section 458.331, F.S., of the provision of controlled substances for trade, barter or sale, by a licensee. In such cases, the Board will deviate from the penalties recommended above and impose suspension or revocation of licensure.

(h) Where a licensee has been charged with violating the standard of care pursuant to Section 458.331(1)(t), F.S., but the licensee, who is also the records owner pursuant to Section 456.057(1), F.S., fails to keep and/or produce the medical records.

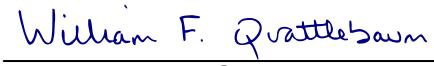
(i) Any other relevant mitigating factors.

42. In this case, the Respondent twice prescribed Schedule II and III medications to a patient with whom he had no interaction. The Respondent failed to review any medical information related to the patient prior to the prescriptions being issued. There is no credible evidence that any physician's assistant obtained any medical information from the patient or conducted any medical evaluation of the patient on behalf of the Respondent. The issuance of two prescriptions for hydrocodone under these circumstances exposes the patient and public to potential injury.

RECOMMENDATION

Based on the foregoing Findings of Fact and Conclusions of Law, it is RECOMMENDED that the Department of Health enter a final order finding Gerard Romain, M.D., in violation of Subsections 458.331(1)(m), 458.331(1)(q), and 458.331(1)(t), Florida Statutes (2005), and imposing a penalty as follows: a reprimand; a three-year period of probation, the first year of which shall include a prohibition on issuing prescriptions for Schedule II and III controlled substances; an administrative fine of $20,000.00; and such additional continuing education and community service requirements as the Department of Health determines appropriate.

DONE AND ENTERED this 23rd day of September, 2008, in Tallahassee, Leon County, Florida.



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Filed with the Clerk of the
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this 23rd day of September, 2008.

COPIES FURNISHED:

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NOTICE OF RIGHT TO SUBMIT EXCEPTIONS

All parties have the right to submit written exceptions within 15 days from the date of this Recommended Order. Any exceptions to this Recommended Order should be filed with the agency that will issue the Final Order in this case.