

STATE OF FLORIDA
DIVISION OF ADMINISTRATIVE HEARINGS

DEPARTMENT OF HEALTH,)
BOARD OF MEDICINE)
)
Petitioner,)
vs.) Case No. 01-4664PL
)
STEVEN PLISKOW, M.D.,)
)
Respondent.)
_____)

RECOMMENDED ORDER

Pursuant to notice, a formal hearing was held in this case on February 6 and 7, 2002, in West Palm Beach, Florida, before Patricia Hart Malono, a duly-designated Administrative Law Judge of the Division of Administrative Hearings.

APPEARANCES

For Petitioner: Sarah D. Cyrus, Esquire
Ephraim D. Livingston, Esquire
Agency for Health Care Administration
Post Office Box 14229, Mail Stop 39A
Tallahassee, Florida 32317-4229

For Respondent: Alexander Barker, Esquire
Adams, Coogler, Watson, Merkel,
Barry & Kellner, P.A.
1555 Palm Beach Lakes Boulevard
Suite 1600
Post Office Box 2069
West Palm Beach, Florida 33402-2069

STATEMENT OF THE ISSUE

Whether the Respondent committed the violations alleged in the Administrative Complaint dated October 22, 2001, and, if so, the penalty that should be imposed.

PRELIMINARY STATEMENT

In a three-count Administrative Complaint dated October 22, 2001, the Department of Health ("Department") charged Steven Pliskow, M.D., with violations of three provisions of the Florida Statutes governing the practice of medicine. These alleged violations involved the treatment provided C.B., a patient in a weight loss clinic operated in 1996 and 1997 by Dr. Pliskow and others.

The allegations in the Administrative Complaint are as follows:

(a) In Count I, the Department charged that Dr. Pliskow had violated Section 458.331(1)(t), Florida Statutes, by practicing medicine below the accepted standard of care, specifically by (1) failing to complete a physical examination and/or obtain a complete history of C.B. prior to starting her on a weight loss program; (2) failing to provide adequate supervision to an Advanced Registered Nurse Practitioner ("A.R.N.P.") and personally reviewing C.B.'s chart; and (3) failing to document in C.B.'s medical records justification for the course of treatment and dosage of medication.

(b) In Count II, the Department charged that Dr. Pliskow had violated Section 458.331(1)(m), Florida Statutes, by failing to keep written medical records justifying the course of treatment and dosage of medication provided to C.B.

(c) In Count III, the Department charged that Dr. Pliskow had violated Section 458.331(1)(1)(q), Florida Statutes, by prescribing a legend drug outside the course of his professional practice, specifically by failing to document in C.B.'s medical records her course of treatment and dosage of medication.

Dr. Pliskow timely disputed the facts alleged in the Administrative Complaint and requested an administrative hearing. The Department forwarded the matter to the Division of Administrative Hearings for assignment of an administrative law judge, and the final hearing was held, pursuant to notice, on February 6 and 7, 2002.

At the hearing, the Department presented the testimony of Amy Windham, records custodian from Delray Medical Center; patient C.B.; Ira Fine, M.D., C.B.'s primary care physician; and Kevin Holthaus, M.D., the Department's expert witness. Petitioner's Exhibits 3, 4, and 13 were offered and received into evidence; Petitioner's Exhibit 12 was offered and rejected, but was not proffered. Petitioner's Exhibit 3 was received

subject to a hearsay objection, and its use is governed by the limitation of the use of hearsay evidence in Section 120.57(1)(c), Florida Statutes (2001).

Dr. Pliskow testified on his own behalf and presented the testimony of Mark Multach, M.D., his expert witness, and Kimberly Payne, an A.R.N.P. who worked in the weight loss clinic. Respondent's Exhibits 1, 4, 5, and 6 were offered and received into evidence. In addition, prior to the final hearing, Dr. Pliskow filed Respondent's Request to Take Judicial Notice, in which he requested that official recognition be taken of the opinion in Alvarez v. Smith, 714 So. 2d 652 (Fla. 5th DCA 1998); Sections 464.003 and .012, Florida Statutes (1995); and Rules 64B8-35.001 and .002, Florida Administrative Code. The motion was granted at the hearing, and official recognition has been taken of these documents.

The four-volume transcript of the proceedings was filed with the Division of Administrative Hearings on February 25, 2002, and the parties timely filed proposed findings of fact and conclusions of law, which have been considered in the preparation of this Recommended Order.

FINDINGS OF FACT

Based on the oral and documentary evidence presented at the final hearing and on the entire record of this proceeding, the following findings of fact are made:

1. The Department is the state agency responsible for the investigation and prosecution of complaints involving physicians licensed to practice medicine in Florida. See Section 455.225, Florida Statutes. The Board of Medicine is the entity responsible for regulating the practice of medicine in Florida and for imposing penalties on physicians found to have violated the provisions of Section 458.331(1), Florida Statutes. See Section 458.331(2), Florida Statutes.

2. Dr. Pliskow is, and was at the times material to this proceeding, a physician licensed to practice medicine in Florida, having been issued license number ME 0054211, and he is Board-certified in Obstetrics, Gynecology, and Forensic Medicine. At the times material to this proceeding, Dr. Pliskow practiced obstetrics and gynecology with three other physicians, Dr. Ackerman, Dr. Herbst, and Dr. Aqua, under the name "Advanced Women's Healthcare."

3. In 1996, Dr. Pliskow, Dr. Ackerman, and Dr. Herbst established the Comprehensive Weight Loss & Nutrition Center ("Center") as a separate corporation. Kimberly Payne, an A.R.N.P., was the administrative director of the Center, and, in addition to administrative duties, her job responsibilities included supervision of the nursing staff working in the Center, direct patient care, and staff training. The four physicians

practicing at Advanced Women's Healthcare were the designated supervising physicians for staff of the Center.

4. Bariatrics is the subspecialty dealing with the medical treatment of obesity, and the four physicians supervising the Center, as well as Nurse Payne, were members of the American Society of Bariatric Physicians. As members of this organization, the physicians and Nurse Payne received two monthly journals, a biweekly newsletter, a monthly magazine, and faxes and e-mails containing updates on standard-of-care issues, medication changes, updates from the Federal Drug Administration, and suggested treatment changes and recommendations. The organization also provided educational programs and training opportunities for its members.

5. In accordance with the recommendations of the American Society of Bariatric Physicians, the Center's weight loss program included a behavior modification program; a diet providing between 1200 and 1400 kilocalories per day; and an exercise program designed for each of its patients. In addition, if the patient was an appropriate candidate, the Center prescribed anorectic medications, including the combination of the drugs Phentermine and Fenfluramine commonly known as "Phen/Fen."

I. Weight Loss Protocol

6. At the times material to this proceeding, A.R.N.P.s were allowed under Florida law to practice independently under the general supervision of a physician who was accessible to them if they needed a consultation or evaluation of a patient. See Sections 464.003(3)(c) and 464.012(3), Florida Statutes (1995); Rule 64B8-35.002, Florida Administrative Code. Among other things, A.R.N.P.s were allowed to perform physical examinations of patients, to take medical histories, to initiate treatment programs, to prescribe certain types of drugs, and to evaluate patients for signs and symptoms of side effects associated with medications. A.R.N.P.s could not, however, prescribe drugs that were classified as controlled substances.

7. Nurse Payne, and another A.R.N.P. subsequently hired to work at the Center, practiced under the general supervision of Dr. Pliskow, Dr. Ackerman, Dr. Herbst, and Dr. Aqua and in accordance with a protocol setting forth the respective duties of the A.R.N.P.s and of the physicians in the various areas of practice at Advanced Women's Healthcare. The protocol was filed with the appropriate state agency.

8. Section Four of the protocol dealt with weight loss. Pursuant to the general guidelines, the A.R.N.P.s working at the Center were "responsible for the assessment and management of overweight individuals in a comprehensive weight reduction

program including nutritional counseling, exercise management, and use of anorectic medications when appropriate." Patient selection criteria were as follows:

A. Any individual who is over their ideal body weight may participate in the nutrition and exercise portions of the program.

B. In order to qualify to participate in the medication portion of the program, the individual must meet the following criteria:

1. Between the ages of 18 and 65 (any person between the ages of 61 and 65 must have medical clearance from their PCP [primary care physician]).

2. Minimum of 20% over ideal body weight.

3. No present history of heart disease, uncontrolled hypertension, cardiac arrhythmia, glaucoma, uncontrolled diabetes, hyperthyroidism, psychotic illness, drug or alcohol abuse, pregnancy, breastfeeding, or impending surgery requiring general anesthesia.

4. Any deviation from these criteria requires collaboration with physician.

9. The following was the General Condition of the weight loss protocol:

The A.R.N.P. should consult with the physician on all patients exhibiting abnormal findings which might affect their weight loss management and refer for physician evaluation as needed.

II. Patient C.B.

10. Patient C.B. learned of the Center's weight loss program from her daughter, who had participated in the program and taken weight loss medication. C.B. had an initial consultation at the Center on October 23, 1996. At the time, as recorded on the Center's Weight Reduction Intake Form, C.B. was 62 years of age, her weight was 165 pounds, her height was five feet and four inches, she had a medium frame, her blood pressure was 138/82, and her pulse was 72 beats per minute. The intake form also included her body measurements as of October 23, 1996.

11. As part of the initial consultation, C.B. completed the Center's Weight Reduction Program Questionnaire, in which she stated that she considered her ideal weight to be 135 pounds, that her biggest obstacle to losing weight was staying on a diet, and that she was interested in using medication in her weight loss program. C.B. indicated that she had no limitations on exercise and played tennis regularly. She disclosed her current medications, and she indicated that she did not then, nor had she ever, had the following conditions: heart disease, irregular heartbeat, high blood pressure, glaucoma, diabetes, psychotic illness, or alcohol or drug abuse.

12. Nurse Payne reviewed the Weight Reduction Program Questionnaire with C.B. and completed the intake form. She noted on the intake form that C.B.'s ideal weight was between

120 and 135 pounds, that her weight goal was 135 pounds, and that her body mass index ("BMI") was 28.¹ Nurse Payne reviewed with C.B. the information C.B. provided on the questionnaire, including her medical history, current medications, and drug allergies, and Nurse Payne noted on the intake form that C.B. reported arthritis as her only significant medical history.

13. Nurse Payne and C.B. discussed the 1200-calorie exchange diet that was part of the program, and Nurse Payne developed an exercise plan for C.B. that included walking in the pool twice each week and incorporated C.B.'s usual routine of playing tennis three times each week. Nurse Payne noted on the intake form that Dr. Ira Fine was C.B.'s primary care physician.

14. Nurse Payne also discussed medication options with C.B., including the benefits and risks of medications. The intake form included a printed section on medications, in which the first entry was "Pondimin² 20 mg. po bid and Phentermine 37.5 mg. po qd" and the second entry was "Other." Nurse Payne indicated on the intake form that C.B. would be started on "Phen/Fen pending medical clearance [by] Dr. Fine & EKG." Nurse Payne also advised C.B. that she would need to obtain medical clearance from Dr. Fine before medication would be prescribed.

15. During the initial consultation on October 23, 1996, Nurse Payne provided C.B. with a Consent for Diet Program form

and discussed with C.B. in detail the information in the consent form. The consent form contained descriptions of both Phentermine and Fenfluramine, together with the contraindications to their use, and Nurse Payne provided C.B. with an excerpt from the Physician's Desk Reference for Phentermine and the packet insert for Pondimin.³ C.B. signed the consent form on October 23, 1996.

16. A blood specimen was drawn from C.B. on October 23, 1996, and Nurse Payne scheduled C.B. for an EKG on October 26, 1996. Nurse Payne telephoned Dr. Fine's office on October 25, 1996, and spoke with "Betty" about medical clearance for C.B. to participate in the weight loss program; she specifically told Dr. Fine's office the program would include the use of Phen/Fen. Nurse Payne was later advised by Dr. Fine's office that Dr. Fine had medically cleared C.B. to participate in the Center's weight loss program.⁴

17. Once medical clearance was obtained for a patient and the results of the blood work and EKG were received, the standard procedure at the Center was for the A.R.N.P. to present the patient's chart to one of the supervising physicians.⁵ The physician would review the test results and the patient's medical history and determine whether it was appropriate to prescribe medications for the patient. If so, the physician wrote the prescriptions, which were then given to the patient.

Neither Dr. Pliskow nor Nurse Payne can recall specifically that this procedure was followed in C.B.'s case, but there is nothing in the record to indicate a deviation from this procedure with respect to C.B.

18. C.B. was cleared for participation in the weight loss program and for the use of Phen/Fen based the results of her blood work and her EKG and on the criteria set out in the weight loss protocol: Her primary care physician had given medical clearance; her weight was 20 percent above her ideal body weight; and she had reported no present history of the conditions identified in paragraph II.B.3 of the protocol. Her blood pressure and pulse were normal. The results of her EKG showed no significant abnormality, and there was nothing in the results of the blood work done on October 23, 1996, that would prevent C.B. from participating in the weight loss program or from taking Phen/Fen.

19. C.B.'s initial prescriptions for Phen/Fen were written on October 28, 1996 and, as noted in her chart, were for Pondimin in the dosage of "20 mg. [milligrams] po [orally] bid [twice daily]" and for Phentermine in the dosage of "37.5 mg. [milligrams] po [orally] qd [daily]." ⁶ The medications and dosage prescribed for C.B. remained the same throughout the time she participated in the Center's weight loss program, and no further notations regarding dosage was included in her chart.

20. C.B. initially visited the Center each week; in late November 1996, the frequency of her visits was decreased to once every two weeks, and then, in early February 1997, to once every four weeks. At each visit, a member of the nursing staff at the Center would note C.B.'s blood pressure, pulse, and weight on the progress forms in her chart, together with the amount of weight lost since her last visit. The chart also contained the notes of Nurse Payne or the other A.R.N.P. working at the Center reporting on C.B.'s success in staying on the diet and exercise plans; noting that her medication was "P/F"; and summarizing C.B.'s general progress, anything unusual she reported, and the plan she would follow until the next visit. C.B. also completed at each visit a Follow-Up Questionnaire in which she was asked to report whether, since her last visit, she had experienced chest pain, shortness of breath, dizziness, light-headedness, visual problems, palpitations, abdominal pain, bowel changes, fatigue, difficulty sleeping, depression, irritability, difficulty concentrating, memory loss, tremors, or increased appetite.

21. The Center's standard procedure was for the A.R.N.P. meeting with the patient to discuss the answers in the questionnaire with the patient and to question the patient regarding any problems he or she might be having with the program. Once the A.R.N.P. had examined the patient and

completed the patient's progress report, the A.R.N.P. would take the chart to the supervising physician, who would review the chart and write the prescriptions for Phen/Fen. None of the prescriptions for Phen/Fen dispensed at the Center were pre-signed.

22. Patients in the weight loss program received new prescriptions for Phen/Fen at each visit to the Center. Because Phentermine and Fenfluramine are controlled substances, there could be no refills on a prescription, so the prescriptions were written for a sufficient number of pills to last until the patient's next visit to the Center. Although the prescriptions were written and signed by one of the supervising physicians, the physicians did not sign the patient's chart.

23. After the supervising physician wrote the prescriptions, the A.R.N.P. would take the prescriptions to the patient, who could have them filled at the pharmacy in the offices of Advanced Women's Healthcare or at a pharmacy elsewhere. There is nothing in the record to indicate that this practice was not followed with respect to the prescriptions issued to C.B.⁷

24. On November 4, 1996, her first visit after beginning the program, C.B. reported one episode of light-headedness. Otherwise, C.B. reported none of the symptoms identified in the questionnaire and reported no problems with the program. Had

C.B. reported experiencing anything abnormal, Nurse Payne would have called in one of the physicians supervising the Center for a consultation.

25. C.B. participated in the Center's weight loss program through April 7, 1997, which was the date of her last visit. C.B. lost weight on the Center's program at a slow but steady rate, usually between one and four pounds between visits, until, on April 7, 1997, she weighed 141 pounds. C.B.'s treatment with Phen/Fen ended before May 1997, when the Florida Board of Medicine published stricter limitations on the use of these medications.⁸

26. Although Dr. Pliskow was not present in the office on October 28, 1996, when C.B.'s first prescriptions for Phen/Fen were written, he was present in the office during four of C.B.'s ten visits to the Center. Because at least one other physician was also present in the office during these four visits, Dr. Pliskow may or may not have reviewed C.B.'s chart and written her prescriptions.⁹

III. Summary

27. The evidence presented by the Department is not sufficient to support a finding that Dr. Pliskow practiced medicine below the level of care considered acceptable by a reasonably prudent physician under similar circumstances or to support a finding that Dr. Pliskow failed to document in C.B.'s

medical records justification for the course of her treatment in the weight loss program and the dosage of the medications prescribed for her.

28. The evidence is not sufficient to establish clearly and convincingly that the prevailing standard of care required the physician supervising the Center's A.R.N.P.s personally to perform a physical examination of C.B. prior to her being cleared for receiving medication as part of her weight loss program or personally to obtain C.B.'s medical history. Rather, it was appropriate for Nurse Payne and the other A.R.N.P. working at the Center to perform physical examinations and to take medical histories of persons seeking to participate in the Center's weight loss program.

29. In addition, the evidence is not sufficient to establish clearly and convincingly that it was inconsistent with the prevailing standard of care for the Center's supervising physicians to rely on C.B.'s primary care physician to provide medical clearance for her to participate in the weight loss program. Dr. Fine was familiar with C.B.'s overall medical condition as a result of his examination of her on September 12, 1996, and he was, therefore, competent to assess the overall risks of her participation in a weight loss program incorporating the use of anorectic medications. Furthermore, the evidence fails to establish that it was inconsistent with

the prevailing standard of care to rely on the verbal medical clearance conveyed to Nurse Payne through Dr. Fine's office; rather, the persuasive evidence suggests that it was the normal practice for clearance to be given in this manner.¹⁰ And, significantly, Dr. Fine's medical clearance was not the only basis for C.B.'s clearance to take anorectic medications: C.B.'s vital signs were recorded on the intake form by the Center's nursing staff, and Nurse Payne compiled C.B.'s medical history from C.B.'s answers to questions on the Weight Loss Program Questionnaire and from discussions with C.B.; an EKG and extensive blood work were ordered for C.B., and a physician reviewed C.B.'s chart and the results of these tests before writing C.B. prescriptions for anorectic medications.¹¹

30. The evidence is not sufficient to establish that the physicians practicing at Advanced Women's Healthcare failed to provide the appropriate level of supervision to the A.R.N.P.s who worked in the Center. A.R.N.P.s are independent practitioners, and they are subject only to the general supervision of a physician. The evidence failed to establish that the prevailing standard of care for physicians supervising A.R.N.P.s required anything more than that the physician be available for consultation. At least one physician was available in the Advanced Women's Healthcare offices at all times for consultation and/or patient evaluation if an A.R.N.P.

working at the Center determined that a patient was experiencing any complications or if a patient reported any unusual symptoms.

31. The evidence is not sufficient to establish clearly and convincingly that the type and scope of information collected during C.B.'s regular visits to the Center and the on-going care provided to C.B. were not appropriate under the prevailing standard of care for monitoring patients on weight loss programs such as C.B.'s. The prescriptions for C.B.'s weight loss medications were written by a physician at each of C.B.'s visits, but only after the physician reviewed her chart, which included the A.R.N.P.'s progress notes and C.B.'s answers on the Follow-Up Questionnaires she completed at each visit, to determine whether it was appropriate to continue C.B. on anorectic medications.¹² The evidence also fails to establish that the prevailing standard of care required a supervising physician to sign a chart prepared by an A.R.N.P. to indicate that it had been reviewed.¹³

32. The evidence is not sufficient to establish that C.B. was not an appropriate candidate for a weight loss program using Phen/Fen under the prevailing standard of care in 1996 and early 1997.¹⁴ Adequate justification for the treatment of C.B. with anorectic medications was included in C.B.'s medical records: She was considered obese by 1996 standards because her weight of 165 pounds was more than 20 percent higher than her ideal body

weight of 120-to-135 pounds and because her BMI was 28 and she wanted to lose weight. In addition, nothing in the medical history C.B. provided to Nurse Payne or in her tests results indicated that she would be an inappropriate candidate for anorectic medications, and she reported no complications during her follow-up visits.¹⁵

33. The evidence is not sufficient to establish clearly and convincingly that the dosages of Phen/Fen prescribed for C.B. were inappropriate or excessive under the prevailing standard of care in 1996 and early 1997. Rather, the dosages prescribed for C.B. were in the lower range of dosages recommended at the time by the American Society of Bariatric Physicians and in the medical literature in general for the use of Phentermine and Fenfluramine in combination.¹⁶ The dosage of both medications was printed on the intake form completed during C.B.'s initial visit to the Center, and the dosages did not change during the time C.B. participated in the Center's weight loss program; in accordance with normal practice, no further notations were made regarding dosages in C.B.'s chart. New prescriptions were written each time C.B. visited the Center, and no refills were permitted, which is also in accordance with the standard practice in dispensing controlled substances.

CONCLUSIONS OF LAW

34. The Division of Administrative Hearings has jurisdiction over the subject matter of this proceeding and of the parties thereto pursuant to Sections 120.569 and 120.57(1) and Section 456.073(6), Florida Statutes (2001).

35. In its Administrative Complaint, the Department has charged Dr. Pliskow with having violated three provisions of Section 458.331(1), Florida Statutes, as follows:

(m) Failing to keep legible . . . medical records 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) . . . [T]he failure to practice medicine with that level of care, skill, and

treatment which is recognized by a reasonably prudent similar physician as being acceptable under similar conditions and circumstances. . . .

36. The Department seeks to impose penalties against Dr. Pliskow that include suspension or revocation of his license and/or the imposition of an administrative fine. Therefore, the Department has the burden of proving by clear and convincing evidence that Dr. Pliskow committed the violations alleged in the Administrative Complaint. Department of Banking and Finance, Division of Securities and Investor Protection v. Osborne Stern and Co., 670 So. 2d 932 (Fla. 1996); and Ferris v. Turlington, 510 So. 2d 292 (Fla. 1987).

37. In Evans Packing Co. v. Department of Agriculture and Consumer Services, 550 So. 2d 112, 116, n. 5 (Fla. 1st DCA 1989), the court defined clear and convincing evidence as follows:

[C]lear and convincing evidence requires that the evidence must be found to be credible; the facts to which the witnesses testify must be distinctly remembered; the evidence must be precise and explicit and the witnesses must be lacking in 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 or conviction, without hesitancy, as to the truth of the allegations sought to be established. Slomowitz v. Walker, 429 So. 2d 797, 800 (Fla. 4th DCA 1983).

See also Walker v. Florida Department of Business and Professional Regulation, 705 So. 2d 652, 655 (Fla. 5th DCA 1998)(Sharp, J., dissenting).

38. The Department specifically alleged in its Administrative Complaint that the basis for the charge that Dr. Pliskow violated Section 458.331(1)(m), Florida Statutes, was his failure "to document justification for the course of treatment and the dosage of Patient C.B.'s medication in the medical records." On the basis of the findings of fact herein, the Department failed to prove by clear and convincing evidence that Dr. Pliskow violated Section 458.331(1)(m), Florida Statutes, as charged in the Administrative Complaint. The medical records kept by the Center include all of the information necessary to justify placing C.B. on Phen/Fen as part of her weight loss program in 1996 and early 1997. In addition, the medical records kept by the Center for C.B. identified the medication prescribed for her, as well as the dosages initially prescribed on October 28, 1996, which is sufficient since there was no change in the dosages prescribed.

39. The Department specifically alleged in its Administrative Complaint that the basis for the charge that Dr. Pliskow violated Section 458.331(1)(q), Florida Statutes, was his failure "to document justification for the course of treatment and the dosage of C.B.'s medication in the medical

records." Based on the findings of fact herein and for the reasons stated in the immediately preceding paragraph, the Department failed to prove by clear and convincing evidence that Dr. Pliskow violated Section 458.331(1)(q), Florida Statutes, as charged in the Administrative Complaint.

40. The Department specifically alleged in its Administrative Complaint that the basis for the charge that Dr. Pliskow violated Section 458.331(1)(q), Florida Statutes, was his failure "to complete a physical examination and/or obtain a complete history of Patient C.B. prior to starting her on a weight loss regime"; "to provide adequate supervision of the A.R.N.P. and personally reviewed [sic] Patient C.B.'s chart"; and "to document justification for the course of treatment and the dosage of Patient C.B.'s medication in the medical records." Based on the findings of fact herein, the Department failed to prove by clear and convincing evidence that Dr. Pliskow violated Section 458.331(1)(t), Florida Statutes, as charged in the Administrative Complaint. As set forth in paragraph 38, above, the medical records of the Center included sufficient information to justify C.B.'s treatment and medication dosages. The prevailing standard of care did not require the supervising physician of an A.R.N.P. personally to perform a physical examination of C.B. or personally to compile her medical history. Finally, Nurse Payne and the other

A.R.N.P. at the Center were adequately supervised in a manner consistent with the prevailing standard of care, with the requirements of the protocol for the Center on file with the Department, and with the parameters within which A.R.N.P.s practiced in Florida, as set forth in Sections 464.003 and .012, Florida Statutes (1995); and in Rules 64B8-35.001 and .002, Florida Administrative Code.

RECOMMENDATION

Based on the foregoing Findings of Fact and Conclusions of Law, it is RECOMMENDED that the Board of Medicine enter a final order dismissing in its entirety the Administrative Complaint against Steven Pliskow, M.D.

DONE AND ENTERED this 30th day of April, 2002, in Tallahassee, Leon County, Florida.

PATRICIA HART MALONO
Administrative Law Judge
Division of Administrative Hearings
The DeSoto Building
1230 Apalachee Parkway
Tallahassee, Florida 32399-3060
(850) 488-9675 SUNCOM 278-9675
Fax Filing (850) 921-6847
www.doah.state.fl.us

Filed with the Clerk of the
Division of Administrative Hearings
this 30th day of April, 2002.

ENDNOTES

^{1/} Ideal weight range and BMI were calculated using a chart produced by the American Society of Bariatric Physicians.

^{2/} Pondimin is a brand name of Fenfluramine.

^{3/} The package insert contains the same information found in the Physician's Desk Reference.

^{4/} Dr. Fine did a comprehensive routine physical examination of C.B. on September 12, 1996, during her first visit to his office. This examination included taking a medical history of her and her family, a social history, a review of her current medications, and a examination of all of her organ systems. The only abnormality Dr. Fine discovered during his examination was a mild to moderate systolic heart murmur, which he rated as a "one-to-two over six" murmur.

Dr. Fine did not perform a special examination in late October 1996 for the purpose of clearing C.B. for a weight loss program. In Dr. Fine's opinion, however, based on his examination in September 1996, there was no medical reason she could not participate in a weight loss program involving the use of Phen/Fen. Dr. Fine noted that, at the time, the medical profession was not aware of any problems with prescribing Phen/Fen as part of a weight loss program.

^{5/} The supervising physicians at any given time were those present in the offices of Advanced Women's Healthcare, which were next door to the Center's offices.

^{6/} Dr. Pliskow was in surgery and not in the Advanced Women's Healthcare offices on the morning of October 28, 1996, when C.B. received her first prescription for Phen/Fen.

^{7/} C.B. testified that either Nurse Payne or the other A.R.N.P. working at the Center provided the prescriptions to her. C.B. does not know who filled out the prescriptions and signed them, but she testified that the prescriptions were signed by a medical doctor.

^{8/} Fenfluramine was removed from the market in late 1997.

^{9/} Dr. Pliskow cannot recall specifically reviewing C.B.'s chart or writing prescriptions for her during the time she was a

patient at the Center. It was not his practice to initial the charts of the Center's patients when he reviewed them, nor did he note the medication and dosage prescribed on the chart unless the medication or dosage was changed. Dr. Pliskow testified that he attempted to obtain the prescriptions themselves from the pharmacy that operated on the Center's premises to verify the identity of the physician(s) who signed the prescriptions and the dosage prescribed, but the pharmacy refused to release the records.

¹⁰/ Dr. Fine could not recall ever having sent a copy of his medical records to another physician in the context of clearing a patient for a medical procedure, and both he and Dr. Multach testified that they were not aware of any requirement that a primary care physician do so.

¹¹/ The results of C.B.'s EKG and blood work were not among the documents the Department provided its expert witness, Dr. Holthaus. Consequently, Dr. Holthaus's opinion that Dr. Pliskow failed to do an adequate physical examination before clearing C.B. for the use of anorectic medications was based, at least in part, on his incorrect assumption that C.B. had had no EKG or blood work done as part of her evaluation at the Center. His opinion on this point is, therefore, not credited.

¹²/ Dr. Holthaus testified that "an encounter" with a patient taking anorectic medications should minimally include an extensive examination into the patient's cardiovascular, gastrointestinal, neurological, and psychological status; renal function; electrolyte level; and orthostatic changes. Dr. Holthaus did not state that such an examination was the prevailing standard of care at the times material to this proceeding, and it must be inferred from the context of his testimony that he was expressing his opinion and beliefs and describing the manner in which he conducted his practice, rather than describing the objective standard of care acceptable to a reasonably prudent physician under circumstances similar to those in which C.B. was treated at the Center.

¹³/ Dr. Holthaus first testified that the standard of care for supervising A.R.N.P.s required the supervising physician to sign the chart. Dr. Holthaus later conceded that the chart prepared by a physician's assistant had to be reviewed and signed but that this was not a requirement for charts prepared by an A.R.N.P.

^{14/} Dr. Holthaus first testified that C.B. was not an appropriate candidate for anorectic medications because her BMI was not sufficiently high; he later testified that she was marginally qualified as a candidate because her weight was more than 20 percent over her ideal body weight; and he finally conceded that C.B. did qualify under the guidelines in place at the time she participated in the Center's weight loss program. Although C.B. may not have qualified for the use of anorectic medications under the stricter standards published by the Florida Medical Association, these standards were not published until after C.B. stopped participating in the Center's program.

^{15/} C.B. testified that she was not aware that she had a heart murmur until after she stopped visiting the Center and so did not include this in her medical history. In Dr. Holthaus's opinion, C.B. was a high-risk patient for anorectic medications because a patient with a heart murmur "by definition may have some abnormality within their heart," and the use of anorectic medications could potentially cause "cardiovascular stress." Dr. Pliskow, Dr. Fine, and Dr. Multach each testified that a "one-to-two over six" heart murmur, which is by definition one that is barely audible, would not preclude C.B. from participating in the medication portion of the Center's weight loss program. According to Dr. Multach, Dr. Pliskow's expert witness, in 1996 there were no known adverse effects of Phen/Fen on the heart, and Dr. Fine did not consider C.B.'s heart murmur an impediment to her participation in the weight loss program. The testimony of Dr. Multach, Dr. Pliskow, and Dr. Fine on this point is credited as more persuasive than that of Dr. Holthaus.

Dr. Holthaus testified that he believes that C.B.'s age of 62 years placed her at a high risk for the use of anorectic medications, but he did not explain the basis for this opinion. Moreover, he did not opine that her age disqualified her from taking such medications.

Dr. Holthaus's testimony that the results of C.B.'s EKG indicated an abnormality is not credited. Dr. Holthaus examined the EKG results for the first time at the hearing, and his description of the perceived abnormality was vague and inconclusive. Both Dr. Pliskow and Dr. Multach testified that there were no significant abnormalities shown on the results of C.B.'s EKG, and their opinions are credited as more persuasive than the opinion of Dr. Holthaus.

^{16/} Dr. Holthaus initially testified that the dosages of Phen/Fen prescribed for C.B. at the Center were excessive given her age and what he considered her marginal qualification for anorectic medication. He did not, however, identify what he considered to be the appropriate dosages, and, later in his testimony, he conceded that the dosages prescribed for C.B. were not greater than the dosages considered appropriate under the prevailing standard of care.

COPIES FURNISHED:

Alexander Barker, Esquire
Adams, Coogler, Watson, Merkel, Barry & Kellner, P.A.
1555 Palm Beach Lakes Boulevard, Suite 1600
Post Office Box 2069
West Palm Beach, Florida 33402-2069

Sarah D. Cyrus, Esquire
Agency for Health Care Administration
Post Office Box 14229, Mail Stop 39A
Tallahassee, Florida 32317-4229

William W. Large, General Counsel
Department of Health
4052 Bald Cypress Way, Bin A02
Tallahassee, Florida 32399-1701

Mr. R. S. Power, Agency Clerk
Department of Health
4052 Bald Cypress Way, Bin A02
Tallahassee, Florida 32399-1701

Ms. Tanya Williams, Executive Director
Board of Medicine
Department of Health
4052 Bald Cypress Way
Tallahassee, Florida 32399-1701

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.