STATE OF FLORIDA
DIVISION OF ADMINISTRATIVE HEARINGS

DEPARTMENT OF HEALTH, BOARD OF MEDICINE,	)	
Petitioner,	)	
vs.	)	Case Nos. 12-0666PL
NEELAM T. UPPAL, M.D.,	)	
Respondent.	)	

RECOMMENDED ORDER

On June 19, 2012, a disputed fact administrative hearing was held in this case by video teleconference in Tallahassee and St. Petersburg, Florida, before J. Lawrence Johnston, Administrative Law Judge, Division of Administrative Hearings (DOAH).

APPEARANCES

For Petitioner: Elana J. Jones, Esquire
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For Respondent: Michael R. D'Lugo, Esquire
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STATEMENT OF THE ISSUE

The issue in this case is whether the Board of Medicine should discipline Respondent under section 458.331(1)(g), Florida Statutes (2006),[1/] for failures to perform statutory or legal obligations allegedly revealed during an inspection of her medical practice on March 17, 2007. Respondent denies the charges and also defends on the ground of laches.

PRELIMINARY STATEMENT

On March 12, 2008, Petitioner, the Department of Health (DOH), filed the Administrative Complaint resulting from the inspection on March 17, 2007. Respondent timely disputed the facts and requested a hearing. The matter was not referred to DOAH until February 12, 2012, after failed attempts to settle this and another administrative complaint against Respondent (for allegedly facilitating the unlicensed practice of medicine by her medical assistant). (The other administrative complaint also was referred to DOAH and was consolidated with this case, but later was severed and closed, and jurisdiction was relinquished to allow the Board of Medicine to reconsider probable cause.)

At the final hearing on June 19, 2012 (which was governed by the parties' Second Amended Joint Pre-hearing Stipulation), DOH called Benjamin Simpkins, Karen Hanzal, and Mary Mayleben, Pharm.D., as witnesses and had Petitioner's Exhibits 1 through 5,

7, and 8 admitted in evidence. Respondent testified and had Respondent's Exhibits 1, 15, 17, and 22 admitted in evidence.

On June 22, DOH moved unopposed for leave to file an Amended Administrative Complaint to correct two minor errors, which was granted.

The Transcript of the final hearing was filed on July 11. On August 10, the parties filed proposed recommended orders, which have been considered.

FINDINGS OF FACT

1. Respondent holds license ME 59800, which allows her to practice medicine in Florida, subject to regulation by DOH and the Board of Medicine. In March 2006, it was noted on Respondent's license that she was a dispensing practitioner, meaning that she could sell or dispense medication. Her medical office at the time was at 5840 Park Boulevard in Pinellas Park.

2. Respondent has been practicing medicine in Florida since 1998. She has not been disciplined by the Board of Medicine. Her practice treats patients for infectious diseases. She often is referred patients who cannot be treated effectively by their regular internists.

3. Although licensed as a dispensing practitioner, Respondent actually has not been operating as a dispensing practitioner. She was not purchasing medications for resale to her patients. (She sometimes gives her patients free samples.)

Rather, Respondent stores at her office medications purchased by her patients in large quantities to save money. Sometimes, patients bring their medications to Respondent; sometimes, an online pharmacist sends her patients' medications directly to Respondent's medical practice. Respondent keeps the medications in her office until the patients come in for treatment by infusion or injection. If enough of a reusable medication remains after infusion or injection, Respondent will store the left-over medication, sometimes in a refrigerator or freezer, for subsequent reuse. Respondent has no wholesale contracts for medications and is not affiliated with any manufacturer of medications.

4. Respondent's medical office is in a two-story building. The patient lobby and reception area, Respondent's personal office, and several infusion and examination rooms are on the first floor. The second floor is used to store medications. Every three to four weeks, an employee sweeps the office for expired medications and puts them in storage on the second floor. A biohazard removal service comes to the office once a month to remove and dispose of discarded sharps, used non-reusable medications, and expired medications.

5. DOH conducted a routine inspection of Respondent's medical practice in February 2007. The practice was rated satisfactory in all 28 elements of the inspection, including:

clean and safe dispensing area; proper storage of medications requiring refrigeration; expiration/discard date of prescription labels provided in written form; no controlled substances; and outdated medications removed from stock satisfactorily. Respondent's medical practice also was subject to periodic Medicaid inspections and biohazard inspections that were passed satisfactorily.

6. At some time before March 17, 2007, DOH received a complaint that Respondent's patients were being seen and treated by unlicensed medical assistants on Saturdays when Respondent was not present. On Saturday, March 17, 2007, Pinellas Park police and DOH inspectors "raided" the practice. After making sure it was safe to discontinue and postpone patient treatments, DOH ordered all patient treatment to stop and ordered all patients to leave the building. The police officer took photographs of the medical practice. The inspection and photographs resulted in the charges leveled against Respondent in this case. (They also resulted in charges that Respondent facilitated the unlicensed practice of medicine, but DOAH jurisdiction over those charges was relinquished to allow the Board of Medicine to reconsider probable cause.)

Findings as to Count I

7. Count I of the Amended Administrative Complaint alleges that Respondent violated Florida Administrative Code Rule 64B16-

28.110 by failing to remove expired and deteriorated medications from her stock of medications at least every four months and by selling or dispensing expired medications.

8. On March 17, 2007, there were some expired and deteriorated medications at Respondent's medical practice. The deteriorated medications were partially or almost completely used medications. In some cases, it was unclear whether the expiration date was a prescription expiration or a medication expiration.

9. One medication bore an expiration date of 1994. There was no rational explanation for how that date came to be on the medication since Respondent was in New Jersey then and was not practicing medicine in Florida until 1998.

10. Except for possibly the mysterious medication bearing the 1994 expiration date, there was no proof that any medications were expired for more than four months. To the contrary, the evidence was that there were no expired medications in storage as of February 7, 2007.

Findings as to Count II

11. Count II of the Amended Administrative Complaint alleges that Respondent violated section 499.005(1), Florida Statutes, by storing medications in a freezer that were not supposed to be stored that way, or by possessing legend drugs for which she could not produce pedigree papers.

12. The evidence proved that Respondent stored medications in a freezer that were labeled "refrigerate." The evidence did not prove that those medications were not allowed to be stored in a freezer, or that storage in a freezer would adulterate the medication or render it unfit for use. To the contrary, there was evidence that, for at least one of the medications being stored in a freezer (ceftriaxone, generic for Rocephin), freezing can extend the useful life of the medication for up to 26 weeks. As DOH points out, it cannot be assumed that the same is true of another medication (Azactam) found in a freezer at Respondent's medical practice and labeled "refrigerate." But DOH did not prove that the useful life of Azactam cannot be extended by freezing.

13. DOH proved that Respondent could not produce pedigree papers for any of the medications found at Respondent's medical practice on March 17, 2007. It would not be expected that Respondent would have pedigree papers for medications purchased by her patients from other pharmacies and stored at Respondent's office for their convenience. Those pedigree papers would be held by the pharmacies that sold the medications to the patients. Since Respondent was not acting as a dispensing practitioner, she was not receiving pedigree papers and did not even know what they were on March 17, 2007.

Findings as to Count III

14. Count III of the Amended Administrative Complaint alleges that Respondent violated rule 64B8-9.0075 by leaving a syringe, or allowing a syringe to be left, on the counter in the reception area of her office, or by storing or allowing medications to be stored in a refrigerator with uneaten food in a McDonald's bag.

15. Respondent herself was not physically present at her medical office on March 17, 2007, which was a Saturday, before the arrival of the police and DOH inspectors.

16. There was a syringe left on the counter in the reception area of Respondent's office that was photographed by the police officer and seen by him and the DOH inspectors. There was no evidence as to the circumstances of how or when the syringe came to be there. It is possible that it was left there by someone who was interrupted in the provision of medical services by the raid that morning. It was not proven that, as a result of the syringe left on the counter, Respondent was not providing appropriate medical care under sanitary conditions.

17. On March 17, 2007, medications were being stored in a refrigerator with a McDonald's bag that had food in it. There was no evidence as to the circumstances of how or when the bag of food came to be in the refrigerator, but it was unlikely that it was placed there because of the raid that day, and it was

inappropriate to store medications in the refrigerator with the food bag.

18. There was other evidence that Respondent's medical practice was not providing patients with appropriate medical care under sanitary conditions. Open vials and injection and infusion devices lay on unsanitary shelves and other surfaces. Refrigerators and freezers where used medications and infusion and injection devices were being stored were not cleaned appropriately. Floors were not cleaned appropriately. However, those items were not specifically charged in the Amended Administrative Complaint.

Findings as to Count IV

19. Count IV of the Amended Administrative Complaint alleges that Respondent violated section 456.057, Florida Statutes, by maintaining patient records in an unlocked file cabinet in an examination room, or by maintaining medical records (or allowing them to be maintained) in plain view of anyone who approached the reception area of Respondent's office.

20. DOH proved that there were records stored in an unlocked cabinet in one of Respondent's examination rooms, but it was not proved that they were patient records. Neither the police officer nor any inspector looked at the records to ascertain what they were. Respondent testified that they were administrative records, not confidential patient records.

21. There were patient files left lying on the shelf of the half-door between the patient lobby and waiting area and the reception desk of Respondent's medical practice. There also were open files on the reception desk that possibly could have been seen and read (upside down) by someone standing at the counter in front of the reception desk. These files were photographed by the police officer and seen by him and the DOH inspectors. There was no evidence as to the circumstances of how or when the files got there. It is possible that they were left there by someone who was interrupted in the provision of medical services by the raid that morning.

Respondent's Defenses

22. Respondent contends that the photographs taken at her office on March 17, 2007, were "staged"--i.e., that the charges were trumped up by moving or placing items to be photographed (including the McDonald's bag) to make it appear that Respondent was in violation when she was not. The police or DOH investigators did not stage the photographs. Respondent herself testified that she did not believe her medical assistant and other office staff would have done so. That leaves only her medical assistant's boyfriend, who may have been there on March 17, 2007. No plausible reason was given why the boyfriend would have done such a thing (although it is conceivable that he might have placed a McDonald's bag in the refrigerator).

23. Part of Respondent's case that violations were staged was the hearsay of a patient who was there on March 17, 2007. Respondent testified that, when she arrived at the office during the raid, the patient told her she was being "set up," that he saw patient files being placed in open view on countertops and saw someone enter the back door with coffee and food that was placed in the refrigerator. She says he told her that he would testify to what he saw in her defense.

24. Respondent also contends that laches bars the Amended Administrative Complaint because the employee assigned to monitor and discard expired medications and the patient whose hearsay claimed Respondent was set up have died. There was no evidence as to when these individuals died, or why Respondent was unable to preserve their testimony before they died.

25. The Administrative Complaint was filed in March 2008. Respondent requested a disputed fact hearing in April 2008. No evidence was presented at the hearing as to why the matter was not referred to DOAH until February 2012. DOAH files, which can be officially recognized, indicate that at least some of the delay related to settlement negotiations and the consideration of settlement proposals through August 2008.

26. In October 2008 and again in 2011, Respondent's office computer systems malfunctioned, resulting in the loss of digital patient appointment records for March 2007. No evidence was

presented at the hearing as to how DOH is responsible for this loss or how the loss of patient appointment records prejudiced Respondent in the presentation of her defense.

CONCLUSIONS OF LAW

27. Section 458.331(1)(g) authorizes the Board of Medicine to discipline a Florida-licensed physician who fails to perform any statutory or legal obligation placed upon a licensed physician.

28. Because it seeks to impose license discipline, DOH has the burden to prove its allegations by clear and convincing evidence. See In re Davey, 645 So. 2d 398, 405 (Fla. 1994); Dep't of Banking & Fin. v. Osborne Stern & Co., Inc., 670 So. 2d 932 (Fla. 1996); Ferris v. Turlington, 510 So. 2d 292 (Fla. 1987).

29. Count I of the Amended Administrative Complaint alleges that Respondent violated rule 64B16-28.110. That rule governs pharmacies and dispensing practitioners and states:

> Persons qualified to do so shall examine the stock of the prescription department of each pharmacy at a minimum interval of four months, and shall remove all deteriorated pharmaceuticals, or pharmaceuticals which bear upon the container an expiration date which date has been reached, and under no circumstances will pharmaceuticals or devices which bear upon the container an expiration date which has been reached be sold or dispensed to the public.

30. DOH did not prove either that Respondent did not have a qualified person examine prescriptions at least every four months and remove all deteriorated and expired pharmaceuticals, or that Respondent sold or dispensed expired medications to the public.

31. Count II of the Amended Administrative Complaint alleges that Respondent violated section 499.005(1), Florida Statutes, by storing medications in a freezer that were not supposed to be stored that way, or by possessing legend drugs for which she could not produce pedigree papers. Expired drugs are, by definition, adulterated; so are legend drugs for which the required pedigree paper is nonexistent, fraudulent, or incomplete. § 499.006(9)-(10), Fla. Stat.

32. DOH did not prove either that Respondent stored medications in a freezer that were not supposed to be stored that way, or that Respondent did not have pedigree papers that she was supposed to have.

33. Count III of the Amended Administrative Complaint alleges that Respondent violated rule 64B8-9.0075 by leaving a syringe, or allowing a syringe to be left, on the counter in the reception area of her office, or by storing or allowing medications to be stored in a refrigerator with a bag of fast food. The rule requires licensed physicians to ensure that their patients are provided appropriate medical care under sanitary conditions.

34. DOH proved that on March 17, 2007, a syringe was on the counter in the reception area and that medications were stored in a refrigerator with a bag of fast food. DOH did not prove the circumstances of how or when either the syringe or the bag of fast food came to be where they were on March 17, 2007. As a result, the syringe did not clearly prove inappropriate provision of medical care under less-than-sanitary conditions. On the other hand, the storage of medications alongside a food bag in a refrigerator did prove a violation.

35. There was other evidence that Respondent's medical practice was not providing patients with appropriate medical care under sanitary conditions. However, those items were not specifically charged in the Amended Administrative Complaint, and discipline cannot be based on them. See Trevisani v. Dep't of Health, 908 So. 2d 1108 (Fla. 1st DCA 2005); Aldrete v. Dep't of Health, Bd. of Med., 879 So. 2d 1244 (Fla. 1st DCA 2004); Ghani v. Dep't of Health, 714 So. 2d 1113 (Fla. 1st DCA 1998); Willner v. Dep't of Prof'l Reg., Bd. of Med., 563 So. 2d 805 (Fla. 1st DCA 1990).

36. Count IV of the Amended Administrative Complaint alleges that Respondent violated section 456.057 by maintaining patient records in an unlocked file cabinet in an examination room, or by maintaining medical records in plain view of anyone who approached the reception area.

37. It was proven that during the raid on Respondent's medical practice on March 17, 2007, medical records were left in places where they could be seen, but they could have been left there by someone who was interrupted in the provision of medical services by the raid that morning. For that reason, the alleged violation was not proven.

38. Respondent did not prove her defense that she was set up. She also did not prove her defense of laches.

39. Technically, laches does not apply to administrative license discipline cases. See Farzad v. Dep't of Prof'l Reg., Bd. of Med., 443 So. 2d 373 (Fla. 1st DCA 1983). Procedural delays contrary to statute can result in dismissal if the delays impair the fairness of the proceedings or the correctness of the action taken and prejudice the licensee. See Carter v. Dep't of Prof'l Reg., Bd. of Optometry, 613 So. 2d 78 (Fla. 1st DCA 1993). In this case, under section 456.073(2), DOH was to have completed the report of its initial investigative findings and recommendations concerning probable cause within six months of March 17, 2007, but there was no evidence that the delay prejudiced Respondent in any way. No evidence was presented at the hearing as to why the referral to DOAH was delayed from April 2008 until February 2012. DOAH files, which can be officially recognized, indicate that at least some of the delay was related to settlement negotiations and proposals.

40. The alleged unfairness was due to the death of two witnesses. No evidence was presented as to when the two witnesses died, or why Respondent was unable to preserve their testimony. For these reasons, dismissal is not an appropriate consequence of the delay in referring the matter to DOAH.

41. Respondent also asserted that the loss of digital patient appointment records during the delay in referring the matter to DOAH resulted in unfairness to Respondent. No evidence was presented at the hearing as to whether Respondent was prejudiced in any way from the loss of digital patient appointment records during the delay in referring the matter to DOAH. In any event, it was Respondent's duty to maintain these records. See §§ 458.331(1)(g) & (m) & 456.057, Fla. Stat.; Fla. Admin. Code R. 64B8-10.002.

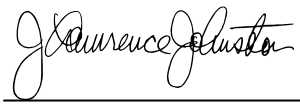
42. Under rule 64B8-8.001(g), the recommended ranges of penalties for the proven violation alleged in Count III are from a letter of concern to revocation and an administrative fine from $1,000 to $10,000. Based on the severity of the offense and the potential for patient harm, the lower quartile of the penalty range is appropriate. Consideration of the aggravating and mitigating factors in paragraph (3) of the rule makes a penalty at the low end of the range appropriate in this case.

RECOMMENDATION

Based on the foregoing Findings of Fact and Conclusions of Law, it is

RECOMMENDED that the Board of Medicine enter a final order: finding Respondent guilty of one of the violations alleged in Count III of the Amended Administrative Complaint, but not guilty of the other charges; issuing a letter of concern; and imposing a $1,000 fine.

DONE AND ENTERED this 4th day of September, 2012, in Tallahassee, Leon County, Florida.



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Filed with the Clerk of the
Division of Administrative Hearings
this 4th day of September, 2012.

ENDNOTE

[1/] All statutory references are to the 2006 Florida Statutes, which were in effect at the time of the alleged violations. Likewise, all rule references are to the revision of the Florida Administrative Code in effect at the time of the alleged violations.

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.