STATE OF FLORIDA
DIVISION OF ADMINISTRATIVE HEARINGS

DEPARTMENT OF HEALTH, BOARD OF MEDICINE,	)	
Petitioner,	)	
vs.	)	Case No. 02-2969PL
ROBERT H. FIER,	)	
Respondent.	)	

RECOMMENDED ORDER

Robert E. Meale, Administrative Law Judge of the Division of Administrative Hearings, conducted the final hearing in Tallahassee, Florida, on October 3, 2002.

APPEARANCES

For Petitioner: Bruce A. Campbell
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For Respondent: Brian A. Newman
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STATEMENT OF THE ISSUES

The issues are whether Respondent deviated from the applicable standard of care in the practice of medicine by inserting the wrong intraocular lens during cataract surgery, in

violation of Section 458.331(1)(t), Florida Statutes, or failed to maintain adequate medical records, in violation of Section 458.331(1)(m), Florida Statutes, and, if so, what penalty should be imposed.

PRELIMINARY STATEMENT

By Administrative Complaint dated June 4, 2002, Petitioner alleged that Respondent is a licensed physician Board Certified in Ophthalmology. The Administrative Complaint alleges that, on October 17, 2000, Respondent scheduled an 80-year-old patient for phacoemulsification cataract surgery of the left eye with an intraocular lens implant at the Treasure Coast Center for surgery in Stuart.

Respondent allegedly placed a lens implant into the patient's eye that bore the wrong refractive power because he inserted a lens that had been intended for a different patient. The operative report allegedly contains standard form language that does not accurately describe the treatment received by the patient.

The Administrative Complaint alleges that, on October 26, 2000, Respondent performed additional surgery on the patient to replace the incorrect lens, which had a refractive power of 20.5, with the correct lens, which had a refractive power of 21.5. The Administrative Complaint alleges that, prior to the

first surgery and after both surgeries, the patient's best corrected visual acuity in the left eye was 20/30.

Count One of the Administrative Complaint alleges that Respondent deviated from the applicable standard of care, in violation of Section 458.331(1)(t), Florida Statutes, by performing cataract surgery on an 80-year-old patient with corrected vision of 20/30, inserting the wrong lens into the patient's eye, or performing the second surgery to provide minimal visual benefit.

Count Two of the Administrative Complaint alleges that Respondent failed to maintain medical records justifying the course of treatment, in violation of Section 458.331(1)(m), Florida Statutes, by preparing an operative report on October 17, 2000, that did not accurately describe the treatment rendered and failing to maintain records that justified the second surgery, given the minimal visual benefit derived from the second surgery.

Based on these alleged violations, the Administrative Complaint seeks the revocation of Respondent's license, or such lesser penalty as the Board of Medicine deems appropriate, and the costs of the investigation and prosecution.

Respondent timely requested a formal hearing.

At the hearing, Petitioner called no witnesses and offered into evidence two exhibits: Petitioner Exhibits 1-2.

Respondent called three witnesses and offered into evidence 17 exhibits: Respondent Exhibits 1-3 and 6-19. The parties offered three joint exhibits: Joint Exhibits 1-3. All exhibits were admitted except Respondent Exhibits 11 and 19, which were proffered.

The court reporter filed the transcript on November 4, 2002. The parties filed proposed recommended orders on November 14, 2002. In its proposed recommended order, Petitioner concedes that it did not prove that Respondent deviated from the applicable standard of care in performing the initial or corrective surgery, so the issues are now whether he deviated from the applicable standard of care in inserting the wrong lens and whether he failed to maintain adequate medical records.

FINDINGS OF FACT

1. At all material times, Respondent has been a licensed physician, holding license number ME 0030598. Respondent graduated from medical school in 1976 and completed a three-year residency in ophthalmology in 1980.

2. Board-certified in ophthalmology since 1981, Respondent is the medical director of the Treasure Coast Center for Surgery in Stuart (Surgery Center). The Surgery Center is an ambulatory surgery center licensed under Chapter 395, Florida Statutes.

3. Since 1980, Respondent has performed over 20,000 surgeries, including over 10,000 cataract surgeries. In that time, he has never previously misidentified a patient, operated on the wrong site, or inserted the wrong lens.

4. This case involves a wrong lens that Respondent inserted into an 80-year-old patient on October 17, 2000. A local optometrist had referred the patient to Respondent for evaluation of cataracts in both eyes. Respondent performed successful cataract surgery on the patient's right eye on August 22, 2000.

5. A cataract is a partial or complete opacification, or clouding, of a natural lens or its capsule. Typically associated with aging, the cataract is a major cause of a slow loss of vision, making it more difficult for the patient to read or drive, especially at night with the glare of lights.

6. Twenty years ago, conventional cataract surgery comprised an intracapsular cataract extraction with the lens implant placed in the front of the eye. In the last 20 years, the predominant mode of cataract surgery comprises an extracapsular cataract surgery or phacoemulsification with the lens implant placed behind the iris of the eye. In the phacoemulsification process, the surgeon, using a smaller incision than that used in the older procedure, dissolves the cataract-involved natural lens using ultrasound and removes the

cataract in smaller pieces than the single-piece removal characteristic of the intracapsular extraction process.

7. The patient was scheduled for phacoemulsification of the cataract-involved lens in her left eye at the Surgery Center as the first patient of the day on October 17, 2000. Respondent handled her case as he handles all of the other cases. Prior to the surgery, Respondent reviews the patient's office chart and brings it, together with the office charts of the other patients scheduled for surgery that day, from his office to the Surgery Center.

8. At the Surgery Center, Respondent delivers the office charts to circulating nurses, who remove each chart, read it to determine the lens to be implanted, find the lens specified in the chart for implantation, and insert the packaged lens into the chart. A nurse then stacks the office charts in a stand in the order of the patients' surgeries scheduled for the day.

9. From the patient's perspective, she is greeted by a receptionist upon arrival. The receptionist pulls the already-prepared materials, including an identification bracelet or armband, and has the patient sign the necessary paperwork.

10. At this point, an admission nurse takes the patient to the preoperative area where the patient lies down on a gurney. The nurse identifies the patient and confirms the eye to be operated on and the procedure to be performed. After verifying

this information, the nurse places the identification bracelet on the patient's wrist. In cases such as this, in which an anaesthesiologist administers the anaesthesia, the anaesthesiologist meets with the patient to confirm the identity of the patient, the eye to be operated on, and the procedure to be performed.

11. The Surgery Center's policy requires: "the attending physician and/or anesthesiologist, along with the responsible nurse, will review the patient's medical record, the armband and the Surgery Schedule to confirm the correct operative site. The operative site will also be confirmed by the patient or parent/guardian." The cited language, as well as the surrounding context, reveals a policy to ensure that the correct site--here, left eye--is the subject of the actual surgical procedure; nothing in the policy explicitly requires anyone to match the correct lens with the patient.

12. After completion of the preoperative procedure, the circulating nurse takes the patient from pre-op. Among the nurse's other duties is to check the patient's bracelet against the office chart and to ask the patient if she is the person named on the office chart and bracelet. Accompanying the patient into the operating room are the office chart and Surgery Center chart. Once in the operating room, the circulating nurse

places the office chart on a side table used by the scrub nurse and the Surgery Center chart with the anaesthesia equipment.

13. Transferred into the operating room, the patient is scrubbed by a scrub nurse, who drapes the patient from just below her knees to above her head with a gown that opens only at the site of the eye to be operated on. The purpose of the gown is to maintain a sterile field, so no one can lift the gown in the operating room, such as to identify the patient by face or bracelet with the name on the chart, without exposing the patient to a risk of infection.

14. When Respondent enters the operating room, he is already scrubbed and wearing gloves. A stand holds the patient's office chart with the packaged lens implant at the side table. Respondent checks the power of the lens, as disclosed on the package, against the power specified on the office chart. In this case, the two powers matched, as the office chart and the lens implant were for another patient. To maintain sterility, Respondent cannot touch a chart while he is in the operating room; if the necessity arises, a nurse may touch the chart.

15. Before proceeding with surgery, Respondent reads the name of the patient on the office chart. Respondent does not verify that the names on the bracelet and either of the charts are the same. Nor does Respondent confirm with the circulating

nurse that she has done so. To check the identity of the patient, Respondent says, "Good morning, Ms. _____. I'd like you to put your chin up for me."

16. However, patients often have fallen asleep from the three preoperative sedatives that they have already received. Respondent conceded that the patient in this case may not have been alert when he addressed her by name. For whatever reason--reduced consciousness, unconsciousness, nervousness, or inability of the patient to hear Respondent or Respondent (or others) to hear the patient--the patient in this case did not effectively communicate to Respondent that she was not the patient whose name he stated.

17. Respondent proceeded with the surgery and implanted the wrong lens into the patient's left eye. Respondent had specified a lens with a 21.5 diopter refractive power and implanted a lens with a 20.5 diopter refractive power. The circulating nurse discovered the error when she went to get the next patient and found the office chart of the patient on whom Respondent had just completed surgery.

18. The next day, when the patient visited Respondent at his office for a routine post-operative examination, Respondent informed her that he had placed the wrong lens in her eye and recommended that he recheck her vision in a few days and then decide whether to perform a corrective procedure.

19. Three days after the initial surgery, Respondent found an increased degree of anisometropia, which is the difference in refraction between the two eyes. At this time, the patient complained to Respondent about imbalance. Respondent advised corrective surgery, and, on October 26, Respondent performed surgery to replace the implanted lens with another lens. Although the initial surgery was sutureless, the corrective surgery required sutures. The corrective surgery was generally successful, although two and one-half months later, the patient was complaining that her left eye was sore to the touch--a complaint that she had not made following the initial surgery to the left eye.

20. Petitioner asserts that Respondent's medical records are deficient in two respects: inaccurately describing the treatment and failing to justify the corrective surgery.

21. Respondent dictates his operative reports prior to surgery, even though they bear the date of the surgery--here, October 17, 2000. To accommodate contingencies, Respondent dictates three conditional notes, one of which itself contains two alternatives. As found in the patient's operative report, these conditional notes state:

> The corneoscleral wound was enlarged, if necessary.
>
> * * *

> If necessary, an interrupted suture was placed for pre-existing against-the-rule astigmatism or to help maintain the water-tightness of the wound. If a suture was placed, the wound was retested to be water-tight.

22. Although Respondent's pre-dictated operative notes for the patient are detailed, they omit a salient element of her surgery--that Respondent inserted a lens of the wrong power. Respondent did not try to conceal this fact. To the contrary, as soon as the nurse informed him of her error, he directed her to attach the sticky label on the lens package, which records the power of the lens, to the patient's chart. He also directed her to prepare an incident report, which prompted Petitioner's investigation.

23. The expert testimony in this case was conflicting. Respondent's expert witness was originally contacted by Petitioner and asked for an opinion on the standard-of-care and medical-records issues described above. The witness opined that Respondent met the applicable standard of care and the medical records justified the course of treatment. Respondent then retained this physician as his expert witness.

24. Respondent's expert witness opined that an ophthalmologic surgeon necessarily must rely to a "large extent" on staff for a "certain amount of identification" before the patient is transferred into the operating room. Respondent's

expert witness did not explain in detail the qualifications inherent in these statements. Finding an error by the Surgery Center in the insertion of the wrong lens, Respondent's expert witness admitted that Respondent had some control over the circulating nurse, but stated that the nurse administrator basically directs the nurses. Expressing no problem with the conditional notes, Respondent's expert witness testified that it is not unusual for a surgeon to predictate an operative report and then change it if something unusual happens.

25. Petitioner retained another expert witness to replace the expert witness who became Respondent's witness. Petitioner's expert witness opined that Respondent failed to meet the applicable standard of care and the medical records did not justify the course of treatment. Petitioner's expert witness opined that it was never within the applicable standard of care to insert the wrong lens and admitted that he was unaware of the procedures of the Surgery Center and Respondent to avoid this occurrence. Petitioner's expert witness explained that the surgeon is the captain of the ship and ultimately bears the responsibility for the insertion of the wrong lens.

26. Petitioner's expert witness also opined that all pre-dictated operative notes were not "the standard of care" and likewise criticized the conditional notes. Petitioner's expert witness admitted that nothing included in or omitted from the

operative notes would adversely affect the future management of the patient's medical care.

27. Respondent's proposed recommended order identifies various deficiencies in the testimony of Petitioner's expert witness, although Respondent's assertion that the expert relied on a not-yet-effective strict-liability statute is not accurate. Most of these deficiencies pertain to the earlier allegations that Respondent failed to meet the applicable standard of care in performing cataract surgery on an 80-year-old patient and in performing the corrective surgery.

28. Citing the recent case of Gross v. Department of Health, 819 So. 2d 997 (Fla. 5th DCA 2002)(Orfinger, J., concurring), Petitioner's proposed recommended order invites the Administrative Law Judge to be guided by common sense in assessing the standard-of-care issue. This invitation may arise from a well-placed concern with the means by which Petitioner's expert reached his conclusion that Respondent deviated from the applicable standard of care. Petitioner's expert witness has opined that the insertion of the wrong lens violates the applicable standard of care, without regard to the safeguards or precautions that a physician may employ to avoid this mishap. In finding a deviation from the applicable standard of care, the Administrative Law Judge relies on inferences and logic not explicitly identified by Petitioner's expert witness.

29. In addressing the standard-of-care issue, Respondent's expert witness adopted the proper approach, which features a close analysis of the facts to determine the reasonableness of the surgeon's acts and omissions. Under that approach, however, the record establishes that Respondent failed to take all reasonable precautions necessary to prevent this mistake.

30. Although the likelihood of the insertion of the wrong lens seems low, based on Respondent's experience, the burden of additional, effective safeguards would be minor. Both parties focused on the location of the bracelet relative to the length of the protective gown. However, an anklet would be in plain view in the operating room because the gown would not extend that far below the patient's knees. Even if the patient identification remains on a wrist bracelet, the surgeon himself could check the patient's name on the bracelet with the name on the office chart just prior to the surgeon and patient entering the operating room. Either practice would add a few seconds to the overall process and would prevent this type of error.

31. On the other hand, the categoric rejection of Respondent's records by Petitioner's expert witness is correct. The date of the operative record is incorrect; it was not dictated on October 17, 2000, but on an earlier date. The three conditions and one alternative present a confused operative history. The operative record fails to indicate if there was a

corneoscleral wound; if there was an interrupted suture; if so, if the suture was for a pre-existing astigmatism or for wound protection; and if there was a suture placed at all. With these conditions and alternative, the operative report fails to memorialize accurately material elements of the surgery.

32. Additionally, the operative report omits an indisputably material element of the surgery--the insertion of the wrong lens. Respondent recorded this fact in an office note a few days later, but never amended his predictated operative report to reflect this important fact.

33. Lastly, the justification for the corrective surgery ultimately was the patient's complaint of imbalance, not the difference in refractive power between the lens implanted and the lens specified. Respondent nowhere recorded any such complaint in any records.

34. Based on the foregoing, Petitioner has proved by clear and convincing evidence that Respondent deviated from the applicable standard of care in inserting the wrong lens and failed to maintain medical records justifying the course of treatment with respect to the deficiencies noted in the operative record and post-operative records preceding the corrective surgery.

CONCLUSIONS OF LAW

35. The Division of Administrative Hearings has jurisdiction over the subject matter. Section 120.57(1), Florida Statutes. (All references to Sections are to Florida Statutes. All references to Rules are to the Florida Administrative Code.)

36. Section 458.331(1)(t) requires that a physician "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." This recommended order refers to this statutory standard as the "applicable standard of care."

37. Section 458.331(1)(m) requires that a physician keep 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, dispenses or administered; and reports of consultations and hospitalizations."

38. Petitioner must prove the material allegations by clear and convincing evidence. Department of Banking and Finance v. Osborne Stern and Company, Inc., 670 So. 2d 932 (Fla. 1996) and Ferris v. Turlington, 510 So. 2d 292 (Fla. 1987).

39. As contended by Respondent, the determination of whether a physician deviated from the applicable standard of

care requires consideration of the factual circumstances of each case. As recently held in Gross v. Department of Health, 819 So. 2d 997 (Fla. 5th DCA 2002), the determination of whether a physician has violated the applicable standard of care is a fact question for the Administrative Law Judge.

40. Although adopting the finding of a violation of the applicable standard of care, as contended by Petitioner's expert witness, this Recommended Order rejects the reliance by Petitioner's expert upon a per se rule of strict liability. This reliance invites judicial correction under the authority of McDonald v. Department of Professional Regulation, 582 So. 2d 660 (Fla. 1st DCA 1991), which overturned an agency's invocation of a presumption of negligence, so as effectively to shift the burden of proof to the licensee.

41. This Recommended Order also disclaims reliance upon the captain-of-the-ship reasoning used by Petitioner's witness. Even if not violative of the statutory and judicial authority cited in the preceding paragraph, the captain-of-the-ship cases emphasize analyses of master-servant relationships. See, e.g., Dohr v. Smith, 104 So. 2d 29 (Fla. 1959)(anaesthecist not employee of surgeon); Vargas v. Dulzaides, 520 So. 2d 306 (Fla. 3d DCA 1988)(per curiam)(surgeon responsible for negligence of uncertified perfusionist who allowed air into heart-lung machine); Fortson v. McNamara, 508 So. 2d 35 (Fla. 2d DCA

1987)(hospital nurse anaesthecist not employee of surgeon); Hudmon v. Martin, 315 So. 2d 516 (Fla. 1st DCA 1975)(hospital scrub nurse negligently filling syringe with improper solution is employee of surgeon, not hospital); and Buzan v. Mercy Hospital, Inc., 203 So. 2d 11 (Fla. 3d DCA 1967)(hospital nurse performing ministerial duty not involving professional skill--counting surgical sponges--is employee of hospital, not surgeon). These cases are unhelpful because they tend, in their analysis of employment arrangements, to be searching for bases for imposing strict liability against physicians under a respondeat superior theory. These cases do not analyze the statutorily mandated criterion of reasonableness that is inherent in determining the applicable standard of care and whether a physician has violated this standard of care.

42. Relying on the Gross concurring opinion and possibly concerned with the means by which its expert found a violation of the applicable standard of care, Petitioner invites the Administrative Law Judge to use common sense in finding a violation of the applicable standard of care. The invitation to use common sense raises the question as to when a factfinder may find a violation of the applicable standard of care without any expert evidence. See, e.g., Dohr v. Smith, 104 So. 2d 29, 32 (Fla. 1959)(where patient lost teeth during intraoperative administration of anaesthesia, "jury could have decided from

common knowledge and experience, regardless of expert testimony, that the patient needlessly suffered from a condition the anesthecist sought to prevent"); Atkins v. Humes, 110 So. 2d 663, 665 (Fla. 1959)(where physician so negligently treated a fracture as to cause a contracture, expert evidence not required "in cases where want of skill or lack of care on the part of the physician or surgeon is so obvious as to be within the understanding of laymen and to necessitate only common knowledge and experience to judge it"). The latitude extended factfinders in finding deviations from the applicable standard of care, without any expert evidence, likely means that a factfinder may subscribe to the ultimate opinion of an expert witness, even though for reasons not explicitly advanced by the expert witness.

43. In its proposed recommended order, Respondent has relied on the Gross decision in which the court sustained factfinding that declined to find a violation of the applicable standard of care by a physician who did not watch the loading of dye into an injector and thus failed to see that the technician had not performed this task, so the injector injected air into the patient, who died as a result of this mistake. However, the Gross facts are distinguishable from the present case.

44. In the present case, the burden imposed upon Respondent is to take reasonable steps, not onerous, to ensure

that the chart and attached lens belong to the semi-conscious patient lying on the gurney awaiting surgery. In Gross, the burden imposed upon the physician was greater, as it required interaction with equipment and a technician in preparation for a surgical procedure using the equipment.

45. Separated far enough from the operating room--such as the faulty periodic maintenance of an oil seal on the dye-injection equipment, misfilling of an oxygen tank with nitrogen, mislabeling of a lens power by the manufacturer, or incorporation of invisible contaminants into the lens by the manufacturer--the ensuing disaster or mishap may not constitute a violation of the applicable standard of care by the physician, who may not reasonably be able to supervise all of these tasks, even though the failure to complete any of them means a poor or disastrous outcome in surgery. Increasing dependence on complicated and elaborate diagnostic and therapeutic equipment and medical supplies, as well as increasing reliance on specialists to manufacture, service, and operate these items, may attenuate the liability of the surgeon, but not in this case.

46. Here, a surgeon failed to incorporate sufficient and relatively easy safeguards to ensure that the chart and attached lens matched the patient lying in front of him. The identification of the patient with her chart is more fundamental

than the supervision of technicians performing various tasks on equipment to be used in surgery. Respondent's failure to identify the patient with her chart violated the applicable standard of care because Respondent himself could have easily ensured that the patient matched the chart.

47. The issue is not as close concerning the medical records. The operative record does not accurately describe the surgery due to the omission of the insertion of the wrong lens and the reliance on three contingencies and one alternative. The operative record thus fails to justify the ensuing course of treatment of the patient. No record documents the patient's complaint about balance after the first surgery. The records thus fail to justify the ensuing course of treatment of the patient. Relying only on the operative record and the absence of any mention of a problem with balance, an informed reader would have no idea why Respondent undertook the corrective surgery. The contrary opinion of Respondent's expert on these records is puzzling and entitled to less deference than that of Petitioner's expert, notwithstanding his description of the problem with the records in terms of the "standard of care." Regardless of the label, Respondent's medical records are inadequate as a description of the first surgery and a justification for the corrective surgery.

48. For a violation of the applicable standard of care, Rule 59R-8.001 provides that the Board of Medicine may impose discipline ranging from revocation to two years' probation and an administrative fine from $1000 to $10,000. For a violation pertaining to medical records, Rule 59R-8.001 provides that the Board of Medicine may impose discipline ranging from two years' suspension followed by probation to a reprimand and an administrative fine of $1000 to $10,000.

49. In its proposed recommended order, Petitioner seeks a fine of $5500 plus costs of the investigation and prosecution, pursuant to Section 456.072(4). Petitioner notes that each incident was a single occurrence, Respondent had practiced 25 years without prior discipline, and the exposure to the patient of injury was slight. The only aggravating factor cited by Petitioner was the element of pecuniary gain in the collection of a fee, even though discounted, for the corrective surgery.

50. Petitioner misconstrues two of the factors. First, the collection of any fee, even a discounted one, for the corrective surgery, although perhaps reflective of poor judgment in retrospect, did not establish that Respondent's motive in performing the corrective surgery was pecuniary. The misidentification of the patient and poor recordkeeping are consistent with a surgery center in which the medical director/surgeon is at least as ambulatory as the patients, but

the record does not establish excessive haste on Respondent's part, so pecuniary gain is not available as an aggravating factor on this basis either.

51. Second, the exposure to injury of an 80-year-old patient to another round of anaesthesia and surgery was not slight. Although the record does not depict this surgery as painful, the record does reveal that the patient emerged from the second surgery with a sore left eye.

52. The long absence of a disciplinary history offsets the pain and discomfort caused the patient who was subjected to the corrective surgery due to Respondent's failure to take reasonable measures to ensure that the correct chart had accompanied the patient into the operating room. On balance, the violation of the applicable standard of care was slighter than the violation concerning the medical records, which were seriously deficient for several reasons. Appropriate penalties would thus be $2500 for the violation of the applicable standard of care and $7500 for the violation concerning the medical records.

53. The Administrative Law Judge will retain jurisdiction to enter additional findings on costs if the parties are unable to reach agreement on this item.

RECOMMENDATION

It is

RECOMMENDED that the Board of Medicine enter a final order finding Respondent guilty of violating Section 458.331(1)(t), Florida Statutes, and Section 458.331(1)(m), Florida Statutes, imposing an administrative fine of $10,000, and remanding the case to the Division of Administrative Hearings for findings concerning costs, pursuant to Section 456.072(4), Florida Statutes, if the parties cannot agree as to an amount.

DONE AND ENTERED this 18th day of December, 2002, in Tallahassee, Leon County, Florida.

ROBERT E. MEALE
Administrative Law Judge
Division of Administrative Hearings
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Filed with the Clerk of the
Division of Administrative Hearings
this 18th day of December, 2002.

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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 must be filed with the agency that will issue the final order in this case.