STATE OF FLORIDA
DIVISION OF ADMINISTRATIVE HEARINGS

AGENCY FOR HEALTH CARE ADMINISTRATION, Petitioner, vs. TAMPA HEALTHCARE ASSOCIATES, LLC, d/b/a HABANA HEALTH CARE CENTER, Respondent.	)	Case Nos. 03-2114 03-3320

RECOMMENDED ORDER

Administrative Law Judge (ALJ) Daniel Manry conducted the administrative hearing of this case on December 8, 2003, in Tampa, Florida, on behalf of the Division of Administrative Hearings (DOAH).

APPEARANCES

For Petitioner: Gerald L. Pickett, Esquire
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For Respondent: R. Davis Thomas, Jr.
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STATEMENT OF THE ISSUES

The issues for determination are whether Petitioner should have changed the status of Respondent's license from standard to conditional; and whether Petitioner should impose administrative fines of $7,500 and recover costs for alleged deficiencies in the care of four residents of a nursing home.

PRELIMINARY STATEMENT

On May 8, 2003, Petitioner issued an Administrative Complaint alleging that Respondent committed certain violations related to the death of a nursing home resident in Respondent's care. On August 6, 2003, Petitioner issued a second Administrative Complaint alleging that Respondent failed to prevent or improve pressure sores of three nursing home residents in Respondent's care. Each Administrative Complaint notified Respondent that Petitioner had changed Respondent's license rating from Standard to Conditional, that Petitioner proposed administrative fines for the alleged violations, and that Petitioner sought to recover costs incurred in its investigation.

Respondent timely requested an administrative hearing for each Administrative Complaint. Petitioner referred the matters to DOAH to conduct the administrative hearings.

DOAH assigned Case Nos. 03-2114 and 03-3320, respectively, to the cases related to the first and second Administrative

Complaints. On October 10, 2003, ALJ Carolyn S. Holifield consolidated Case No. 03-3320 with Case No. 03-2114. DOAH transferred the consolidated cases to the undersigned to conduct the administrative hearing on December 8, 2003.

At the hearing, Petitioner presented the testimony of two witnesses, one of whom appeared by telephone and the deposition transcripts of two witnesses as exhibits in lieu of their live appearance at hearing, and submitted five composite exhibits for admission into evidence. Respondent presented the testimony of two witnesses, and submitted one composite exhibit for admission into evidence. The identity of the witnesses and exhibits and any attendant rulings are set forth in the two-volume Transcript of hearing filed on January 5, 2004.

At the conclusion of the hearing, the ALJ required the parties to file their respective Proposed Recommended Orders (PROs) on January 15, 2004. On January 12, 2004, the parties jointly requested an extension of time to submit their PROs. Petitioner and Respondent timely filed their respective PROs on January 23 and 22, 2004.

FINDINGS OF FACT

1. Petitioner is the state agency responsible for licensing and regulating nursing homes in Florida pursuant to Section 400.23(7), Florida Statutes (2003). Respondent is

licensed to operate a 150-bed nursing home located at 2916 Habana Way, Tampa, Florida 33614 (the facility).

2. Respondent admitted Resident 1 to the facility on March 9, 2001. The admitting diagnoses included tracheal bronchitis, diabetes mellitus, morbid obesity, and acute respiratory failure. From the time Resident 1 entered the facility until her death, Resident 1 lived with a tracheal tube in place.

3. Resident 1 died on March 4, 2003, at 10:20 a.m. in the emergency room at St. Joseph's Hospital in Tampa, Florida. The tracheal tube of Resident 1 was completely occluded with hardened secretions when Resident 1 arrived at the hospital.

4. The emergency room (ER) physician that treated Resident 1 testified by deposition. The ER physician diagnosed Resident 1 with respiratory arrest and death. However, the diagnosis is merely a clinical impression and is not a medical determination of the cause of death. No certain cause of death could be determined without an autopsy, and no one performed an autopsy on Resident 1.

5. The diagnosis made by the ER physician is a clinical impression that is an educated guess. The respiratory arrest suffered by Resident 1 could have been precipitated by various causes including an occluded tracheal tube, a heart attack, or acute respiratory failure. The ER physician did not determine

that the facility committed any negligence and found no evidence of negligence.

6. The ER nurse who assisted the ER physician believed that the facility had been negligent in clearing the tracheal tube of Resident 1. The ER nurse suspected that secretions had been accumulating in the tracheal tube for several days and that the facility did not monitor or clean the tube because the tube was completely occluded when Resident 1 arrived at the hospital. The ER nurse notified Petitioner of her suspicions.

7. On March 11, 2003, Petitioner conducted a complaint investigation of the facility in connection with the death of Resident 1. Petitioner determined that Respondent either had not assessed whether Resident 1 was capable of performing her own tracheal tube care; or had not monitored the respiratory status of Resident 1 between March 2 and March 4, 2003; or both.

8. Petitioner determined that the alleged failure to assess and monitor Resident 1 violated 42 CFR Section 483.25(k)(4) and (5). Florida Administrative Code Rule 59A-4.1288 applies the federal standard to nursing homes in Florida. 42 CFR Section 483.25(k)(4) and (5) requires Respondent to "ensure that residents receive proper treatment and care for . . . tracheostomy care (sic) . . . [and] tracheal suctioning."

9. Petitioner assigned the charged deficiency a severity rating of class "II." In relevant part, Section 400.23(8)(b), Florida Statutes (2003), defines a Class II deficiency as one that has:

> compromised the resident's ability to maintain or reach his or her highest practicable physical, mental and psychosocial well-being, as defined by an accurate and comprehensive assessment, plan of care, and provision of services.

Petitioner determined that a Class II rating was appropriate because the facility's alleged failure to provide Resident 1 with appropriate tracheal tube care harmed Resident 1.

10. Petitioner changed the license rating for the facility from Standard to Conditional within the meaning of Section 400.23(7), Florida Statutes (2003). The change in license rating was effective March 11, 2003, when Petitioner completed the complaint survey of the facility. The Conditional rating continued until April 10, 2003, when Petitioner changed the rating to Standard. Petitioner also proposed an administrative fine of $2500 pursuant to Section 400.23(8)(b), Florida Statutes (2003).

11. The preponderance of evidence shows, by various measures, that Respondent provided Resident 1 with proper treatment and care for her tracheotomy tube within the meaning of 42 CFR Section 483.25(k)(4) and (5). First, it is uncommon

for a person to cough up material in a tracheal tube and have the material gradually accumulate until the tube closes. It is more likely that secretions coughed up will block the tracheal tube immediately. Second, the emergency medical team (EMT) that treated Resident 1 in the facility did not find it necessary to remove or replace the existing tracheal tube in order to obtain an open airway. Rather, EMT personnel administered oxygen through the existing tube. Third, Resident 1 had normal oxygen saturation levels on March 2, 2003. Finally, Resident 1 was experienced in maintaining her tracheal tube, was capable of clearing her own tube, and asked members of the nursing staff to clear the tube whenever Resident 1 needed assistance. On March 4, 2003, Resident 1 complained of shortness of breath rather than a blocked tracheal tube.

12. The ER physician's testimony shows it is uncommon for a person to cough up material in a tracheal tube and have the material gradually accumulate until the tube closes. The ER nurse that suspected secretions had been accumulating in the tracheal tube of Resident 1 for several days had no experience caring for nursing home residents with tracheal tubes.

13. Gradual accumulations of secretions in a tracheal tube are generally associated with a productive cough from causes such as infiltrated pneumonia. There is no evidence that Resident 1 had such a condition. It is more likely that any

material Resident 1 coughed up would have occluded the tracheal tube immediately rather than accumulating over time.

14. EMT personnel that treated Resident 1 in the facility did not find it necessary to remove or replace the existing tracheal tube in order to obtain an open airway. When EMT personnel arrived at the facility, Resident 1 was non-responsive. When confronted with a non-responsive patient, standard protocol requires EMT personnel to ensure an open airway. EMT personnel placed an oxygen "bag" over the existing tube to provide Resident 1 with oxygen. EMT personnel then transported Resident 1 to the hospital emergency room.

15. In the emergency room, the ER physician found the tracheal tube of Resident 1 to be completely blocked with hardened secretions. He removed the tube, replaced it with an open tube, and unsuccessfully attempted to ventilate Resident 1.

16. It is likely the hardened secretions found in the tracheal tube at the emergency room blocked the tube between the time EMT personnel administered oxygen to Resident 1 at the facility and the time the treating physician removed the tracheal tube in the emergency room. A contrary finding would require the trier of fact to speculate that EMT personnel found the tracheal tube to be blocked and administered oxygen to a closed tube; or incorrectly diagnosed Resident 1 with a clear

tracheal tube before administering oxygen. There is less than a preponderance of evidence to support either finding.

17. Sudden deposits of hardened secretions in the tracheal tube of Resident 1 are consistent with medical experience. A person with a tracheal tube may develop calcified secretions in their lung known as concretions that can be coughed into the tube and cause it to become instantly blocked.

18. It is unlikely that the hardened secretions found in the tracheal tube at the emergency room were present before Resident 1 collapsed in the facility. Hardened secretions can be cleared with a suctioning device or by coughing them through the tube and out of the opening near the neck if the resident has sufficient muscle strength.

19. Resident 1 was a cognitively alert, 40-year-old, and physically capable of cleaning her own tracheal tube with a suctioning device. Resident 1 also had sufficient muscle strength to cough some secretions through the opening in her tube. Whenever Resident 1 was unable to clear her tube through the suctioning device or by coughing, she became anxious and immediately notified a nurse, who would then suction the tube and clear it for her.

20. On March 2, 2003, Resident 1 complained to a nurse that she was experiencing shortness of breath. Significantly, Resident 1 did not complain that her tracheal tube was blocked.

21. The nurse on duty at the facility notified the treating physician of Resident 1's complaints, and the physician ordered the nurse to measure the oxygen saturation levels of Resident 1. The oxygen saturation levels were within normal range, at 97 percent.

22. The treating physician then ordered bed rest for Resident 1 and ordered the nurse to give Resident 1 a breathing treatment. Resident 1 had no further problems on March 2, 2003.

23. On March 4, 2003, at approximately 9:30 a.m., Resident 1 summoned a nurse to come to her bedside and told the nurse that she did not feel well. Resident 1 did not complain that her tracheal tube was blocked. Her skin color was gray. She then passed out and fell to the floor.

24. Nursing staff immediately called for EMT assistance, and EMT personnel arrived at the facility at approximately 9:32 a.m. EMT personnel transported Resident 1 to the emergency room at approximately 9:52 a.m.

25. Between March 2 and March 4, 2003, the preponderance of evidence shows that the tracheal tube of Resident 1 was clear. Nursing staff at the facility monitored Resident 1 three times on March 3, 2003. Resident 1 had no breathing difficulties and did not express any complaints or discomfort. Resident 1 took her scheduled medications and meals on March 3, 2003.

26. The nurse on duty during the 11 p.m. to 7 a.m. shift for March 4, 2003, provided oxygen and suctioning, "as needed," to Resident 1. This action would have cleared secretions, if any, that would have been "accumulating" in the tracheal tube of Resident 1.

27. Resident 1 placed her finger over the opening to her tracheal tube when she spoke to the nurse about not feeling well on March 4, 2003. Resident 1 covered her tracheal tube to force air around her vocal cords so that the nurse could hear Resident 1. It would not have been necessary for Resident 1 to cover her tracheal tube if the tube were occluded.

28. The findings in paragraphs 25 through 27 are based on notes prepared by the unit manager on March 4, 2003, in response to the directive of the facility's risk manager. The risk manager was responsible for investigating the incident and required all nurses who had contact with Resident 1 on March 3 and 4, 2003, to document their experiences with Resident 1. The unit manager then placed the accounts in the medical record.

29. Petitioner questions the credibility of the unit manager notes because they are late-filed entries in the medical records. The trier of fact finds the unit manager and her notes to be credible and persuasive.

30. The testimony and notes of the unit manager are consistent with the apparent determination by EMT personnel that

the tracheal tube was clear. In addition, the Medication Administration Record for March 4, 2003, indicates that Resident 1 received a dose of an ordered medication at 6:00 a.m. and did not complain of not feeling well until some time later.

31. If the notes and testimony of the unit manager were disregarded, the trier of fact cannot ignore the administration of oxygen by EMT personnel. The preponderance of evidence shows that the tracheal tube of Resident 1 was clear when EMT personnel administered oxygen.

32. If it were determined that the tracheal tube of Resident 1 were fully occluded at the facility before Resident 1 collapsed on March 4, 2003, such a finding would alter the outcome of this case. Petitioner failed to show by a preponderance of evidence that an occlusion occurred as a consequence of inadequate assessment or monitoring.

33. Resident 1 had normal oxygen saturation levels on March 2, 2003. The preponderance of evidence does not show that facility staff had reason to believe that the tracheal tube of Resident 1 was occluded after March 2, 2003, and failed to take action to clean the tube prior to the time Resident 1 collapsed on March 4, 2003.

34. There is no preprinted or accepted assessment form for nursing homes to use to assess and monitor the ability of Resident 1 to clean her own tracheal tube. The parties agree

that the process involves nothing more than a simple observation of Resident 1 to confirm that she understood and could clean the tracheal tube either by suctioning or coughing.

35. Resident 1 was capable of cleaning her tracheal tube. Relevant orders from the treating physician did not require cleaning to be performed by facility staff. One physician's order indicated that Resident 1 could participate in her own self-care. Another physician's order indicated that Resident 1 was to have "trach care" three times a day, but did not describe the nature and scope of the care or designate who was to provide such care. Another physician's order indicated that Resident 1 was to receive oxygen through her tracheal collar while in bed and "suction trach as needed." However, nothing in the order indicated who was to provide those services.

36. Resident 1 had her tracheal tube for more than a year prior to March 4, 2003. Facility staff routinely observed Resident 1 successfully suctioning and otherwise cleaning her own tracheal tube. Resident 1 also routinely notified staff when she could not remove a blockage in her tube.

37. Facility staff appropriately determined that Resident 1 was capable of performing self-care on her tracheal tube. It was appropriate for facility staff to rely on Resident 1 to inform them if Resident 1 were unable to clean the tube. Her transfer to the hospital on March 4th and her subsequent death

were not the product of any inadequate or erroneous assessment or monitoring of Resident 1.

38. On May 12, 2003, Petitioner conducted another complaint investigation of the facility. Petitioner determined that Respondent failed to provide adequate care for pressure sores for three residents identified in the record as Residents 1A, 4, and 5, in violation of 42 CFR Section 483.25(c). Florida Administrative Code Rule 59A-4.1288 applies the federal requirements for pressure sore care to nursing homes in Florida.

39. Petitioner assigned the charged deficiency a class II rating. Petitioner determined that a Class II rating was appropriate because actual harm or a negative outcome allegedly occurred with each of the residents cited in the deficiency.

40. Petitioner changed the license rating for the facility from Standard to Conditional within the meaning of Section 400.23(7), Florida Statutes (2003). The change in license rating was effective May 12, 2003, and continued until June 16, 2003, when Petitioner changed the rating to Standard.

41. Petitioner also proposes a $5,000 fine against Respondent. The fine is calculated by doubling the prescribed fine of $2,500, based on the alleged deficiency in the survey conducted on March 11, 2003, in accordance with Section 400.23(8)(b), Florida Statutes (2003).

42. For reasons stated in previous findings, Respondent committed no violation in connection with the survey conducted on March 11, 2003. The fine for the alleged deficiency found on May 12, 2003, cannot exceed $2,500.

43. Petitioner alleges that the pressure sore care provided by Respondent for Residents 1A, 4, and 5 violated 42 CFR Section 483.25(c). In relevant part, 42 CFR Section 483.25(c) requires a nursing home to ensure that:

> [a] resident who enters the facility without pressure sores does not develop pressure sores unless the individual's clinical condition demonstrates that they were unavoidable; and a resident having pressure sores receives necessary treatment and services to promote healing, prevent infection, and prevent new sores from developing.

42 CFR Section 483.25(c)

44. Petitioner alleges that Respondent failed to provide Resident 1A with necessary treatment and services to promote healing of an existing pressure sore on the coccyx of Resident 1A. Resident 1A acquired the pressure sore before Respondent admitted Resident 1A to the facility. In April 2003, Resident 1A had surgery to cover the pressure sore with a skin graft taken from her thigh. The surgery required approximately sixty staples to secure the graft.

45. The alleged improper care of Resident 1A is based on several observations made by the surveyor on May 12, 2003. The

surveyor observed that the staples used in the surgical process had not been removed even though a physician's order dated April 16, 2003, directed staff to set up an appointment with the plastic surgeon within two weeks of the date of the order. The surveyor found no evidence that staff had scheduled an appointment or taken any other steps to remove the staples. The surveyor observed that the skin was reddened and growing over some of the areas around the staples. The surveyor also observed Resident 1A positioned on her back in bed in such a manner that her weight was on her coccyx area.

46. The area in question was not a pressure sore. Petitioner has adopted a written definition of a pressure sore in the guidelines that Petitioner requires its surveyors to use in interpreting the federal regulation at issue. In relevant part, the guidelines define a pressure sore as:

> . . . ischemic ulceration and/or necrosis of tissues overlying a bony prominence that has been subjected to pressure, friction or sheer.

47. If the area of concern were the area over the coccyx of Resident 1A, that area would have been over a "bony prominence" within the meaning of definition of a pressure sore. However, it is undisputed that the area of concern for Resident 1A was located in the fleshy part of the buttocks where staples were used to secure the skin flap to the skin. The area

of concern was a surgical wound site, rather than a pressure sore because of its origin and location. The preponderance of evidence shows that the area of concern failed to satisfy the definition of a pressure sore adopted by Petitioner.

48. Section 120.68(7)(e), Florida Statutes (2003), prohibits Petitioner from deviating from its officially stated policy unless Petitioner explains the deviation. Petitioner failed to provide any evidence to explicate legitimate reasons for deviating from its written definition of a pressure sore in this case.

49. Assuming arguendo the staples around the wound site were a pressure sore, the preponderance of evidence shows that Respondent provided necessary treatment to promote healing. Respondent turned and repositioned Resident 1A every two hours in accordance with standard protocol. That schedule included a period during which Resident 1A was on her back in bed, with the head of her bed elevated. The single observation by the surveyor of Resident 1A on her back in bed did not show that Respondent failed to properly turn and reposition Resident 1A.

50. The failure to timely comply with the physician's order for Resident 1A to consult with a plastic surgeon did not deprive Resident 1A of the care necessary to promote healing of a pressure sore. The removal of staples from a skin flap is not an element of required care for a pressure sore. Rather,

removal of staples is part of the established care for a surgical wound site. The failure to timely provide a consult was not a violation of the requirements for care of pressure sores.

51. If the removal of staples were required for treatment of pressure sores, the failure to timely obtain a consult and the failure to timely remove the staples did not cause harm to Resident 1A. The undisputed purpose of the physician's order to see a plastic surgeon was to evaluate whether the staples should be removed from the wound site. Respondent removed the staples from the wound site shortly after the survey with no complications to the resident. The surgical wound site healed in a timely and complete manner. The absence of harm to Resident 1A precludes a rating as a Class II deficiency.

52. Petitioner alleges that Respondent allowed avoidable pressure sores to develop on Resident 4 and failed to provide necessary treatment after the pressure sores developed. During the survey, the surveyor and a nurse, who was a clinical consultant to the facility, twice observed Resident 4 lying on a special air mattress that was not inflated. After the second observation, the surveyor and consultant examined Resident 4 and observed what each determined to be two stage II pressure sores on each of the outer heels of Resident 4, a stage IV pressure

sore on the right toe, two stage II areas on her left side above her rib cage, and a stage II area under her left breast.

53. The surveyor and the nurse-consultant found nothing in the medical record to indicate that these areas had been previously identified by facility staff. Nor did they find any treatment orders for the areas of concern.

54. The areas of concern were not pressure sores. It is undisputed that pressure sores involve deep tissue damage, do not heal quickly, and would have been present a few days later during examination.

55. The director of nursing and the wound care nurse for the facility examined Resident 4 on May 13, 2003, and found no evidence of the areas that caused concern to the surveyor and nurse-consultant on May 12, 2003. The director of nursing asked the treating physician to examine Resident 4 to confirm the director's observations. On May 19, 2003, the treating physician examined Resident 4 and found no areas of concern on Resident 4.

56. Resident 4 had no conditions that placed her at risk for developing pressure sores. The failure to inflate the special air mattress under Resident 4 did not create any risk for pressure sores. The mattress had not been ordered for Resident 4 and was not necessary for her care because Resident 4 was not at risk for developing pressure sores. Resident 4 was

on the mattress because she had moved into a new room, and facility staff had not yet removed the mattress from the bed in the room that was used by the previous occupant.

57. Petitioner alleges that Respondent failed to provide necessary treatment to promote healing of existing pressure sores on Resident 5. Resident 5 had three open areas on his skin: one on each hip and one over the coccyx.

58. The areas on each hip were surgical wounds from hip surgeries prior to admission to the facility. For reasons stated in previous findings, these areas were surgical wound sites and were not pressure sores.

59. It is undisputed that the remaining area on Resident 5 was a stage II pressure sore over the coccyx that was present upon admission to the facility. During the survey, the surveyor and the nurse-consultant observed Resident 5 on a specialty air mattress that contained a number of air chambers. Two of the chambers were not inflated. The surveyor and nurse-consultant determined that the area over the coccyx had worsened to a stage IV pressure sore. Petitioner alleges that Respondent failed to provide necessary care to Resident 5 by failing to properly inflate his specialty air mattress during the survey.

60. Respondent did not fail to properly inflate the air mattress for Resident 5. The level of inflation of that mattress is not determined or set by the facility. Rather, the

manufacturer calculates and sets the level of inflation for the mattress.

61. The alleged failure to properly inflate the air mattress did not cause harm to Resident 5. The director of nursing observed the area of concern the day after the survey and determined it to be a stage II, rather than a stage IV, pressure sore. The clinical records that charted the size and stage of the pressure sore for the month after the survey show that the area was never more than a stage II pressure sore. A stage IV pressure sore would not have improved to a stage II sore within a month. Petitioner failed to show by a preponderance of the evidence that the alleged improper inflation of an air mattress caused the pressure sore on Resident 5 to worsen from a Stage II to a Stage IV pressure sore.

CONCLUSIONS OF LAW

62. DOAH has jurisdiction over the parties and subject matter of this cause pursuant to Sections 120.569 and 120.57(1), Florida Statutes (2003). The parties received adequate notice of the administrative hearing.

63. Petitioner has the burden of proof in these proceedings. The standard of proof, however, varies. Petitioner must show by a preponderance of the evidence that Respondent committed the deficiencies alleged as a basis for

changing Respondent's license rating from Standard to Conditional. Florida Department of Transportation v. J.W.C. Company, Inc., 396 So. 2d 778 (Fla. 1st DCA, 1981); Balino v. Department of Health and Rehabilitative Services, 348 So. 2d 349 (Fla. 1st DCA 1977). Petitioner must show by clear and convincing evidence that Respondent committed the deficiencies alleged as a basis for the proposed administrative fines. Department of Banking and Finance, Division of Securities and Investor Protection v. Osborne Stern and Company, 670 So. 2d 932, 935 (Fla. 1996).

64. Petitioner failed to show by a preponderance of the evidence that Respondent committed any of the alleged deficiencies. In addition, Petitioner failed to show that the alleged deficiencies caused harm to a resident. Beverly Health Care v. Agency for Health Care Administration, 2004 WL 177018, 29 Fla. L. Weekly D316, (Fla. 5th DCA January 30, 2004).

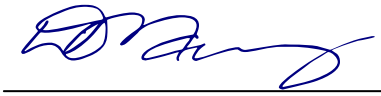
65. The preponderance of evidence does not show the existence of a Class I or II deficiency, or an uncorrected Class III deficiency, within the meaning of Section 400.23(7)(a), Florida Statutes (2003). Similarly, the preponderance of evidence does not show a violation for which Section 400.23(8), Florida Statutes (2003), authorizes Petitioner to impose a fine.

RECOMMENDATION

Based on the foregoing findings of fact and conclusions of law, It is

RECOMMENDED that Petitioner enter a Final Order deleting the disputed deficiencies from the survey reports for March 11 and May 12, 2003; replacing the Conditional ratings with Standard ratings; and dismissing the proposed fines and investigative costs with prejudice.

DONE AND ENTERED this 2nd day of March, 2004, in Tallahassee, Leon County, Florida.



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Filed with the Clerk of the
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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.