# STATE OF FLORIDA DIVISION OF ADMINISTRATIVE HEARINGS

AGENCY FOR HEALTH CARE	)	
ADMINISTRATION,	)	
	)	
Petitioner,	)	
	)	
Vs.	)	Case No. 04-4633
	)	
MANOR CARE OF SARASOTA, INC.,	)	
d/b/a MANOR CARE NURSING	)	
CENTER,	)	
	)	
Respondent.	)	
-	)	

# RECOMMENDED ORDER

Pursuant to notice, a formal hearing was held in this case before Lawrence P. Stevenson, Administrative Law Judge of the Division of Administrative Hearings, on March 23, 2005, in Lakeland, Florida.

# APPEARANCES

For Petitioner: Eric Bredemeyer, Esquire

Agency for Health Care Administration

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For Respondent: Alfred W. Clark, Esquire

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# STATEMENT OF THE ISSUES

Whether Respondent, Manor Care of Sarasota, Inc., d/b/a
Manor Care Nursing Center, committed a Class II deficiency at

the time of a survey conducted on August 10 through 12, 2004, so as to justify the issuance of a "conditional" license and the imposition of an administrative fine of \$2,500.

# PRELIMINARY STATEMENT

An Administrative Complaint dated November 23, 2004, was filed by Petitioner, Agency for Health Care Administration ("AHCA"), against Respondent, Manor Care of Sarasota, Inc., d/b/a Manor Care Nursing Center ("Manor Care"), alleging an isolated Class II deficiency, seeking to change Manor Care's license rating from "standard" to "conditional," and seeking to impose an administrative fine of \$2,500 against Manor Care.

Manor Care denied the allegations and timely requested a formal hearing. The matter was forwarded to the Division of Administrative Hearings ("DOAH") for hearing on December 27, 2004. The case was scheduled for hearing on March 9, 2005. A joint motion for continuance was granted by Order dated February 2, 2005. The Order rescheduled the final hearing for March 23, 2005, when it was held.

At the hearing, AHCA presented the testimony of Barbara Pescatore, a registered nurse ("RN") accepted as an expert registered nurse specialist; Anne Dolan, an RN accepted as an expert in long-term care nursing; and Franklin E. May, Ph.D., accepted as an expert pharmacist and as an expert in pharmacy surveying for long-term care nursing. AHCA's Exhibits A

through K were accepted into evidence. Manor Care presented the testimony of Diane Hinrichs, a licensed practical nurse ("LPN") supervisor at Manor Care; Angela Miguel, an RN supervisor at Manor Care; Jane Sargent-Jefferson, a certified dietary manager ("CDM") at Manor Care; Sharon Broders, an RN and director of nursing at Manor Care; and Nancy Caras, an RN and licensed nursing home administrator at Manor Care. Manor Care's Exhibits 1 through 7 were admitted into evidence.

A Transcript of the hearing was filed at DOAH on April 7, 2005. The parties timely submitted Proposed Recommended Orders, which have been given careful consideration in the preparation of this Recommended Order.

# FINDINGS OF FACT

Based upon the evidence presented at the final hearing, the following relevant findings of fact are made:

1. At all times material hereto, AHCA is the state agency charged with licensing of nursing homes in Florida under Subsection 400.021(2), Florida Statutes (2004), and the assignment of a licensure status pursuant to Subsection 400.23(7), Florida Statutes (2004). AHCA is charged with evaluating nursing home facilities to determine their degree of compliance with established rules as a basis for making the required licensure assignment. AHCA is also responsible for conducting federally-mandated surveys of long-term care

facilities receiving Medicare and Medicaid funds for compliance with federal statutory and rule requirements pursuant to Florida Administrative Code Rule 59A-4.1288.

- 2. Pursuant to Subsection 400.23(8), Florida Statutes (2004), AHCA must classify deficiencies according to the nature and scope of the deficiency when the criteria established under Subsection 400.23(2), Florida Statutes (2004), are not met. The classification of any deficiencies discovered determines whether the licensure status of a nursing home is "standard" or "conditional" and the amount of the administrative fine that may be imposed, if any.
- 3. Surveyors note their findings on a standard prescribed Center for Medicare and Medicaid Services (CMS) Form 2567 entitled, "Statement of Deficiencies and Plan of Correction," which is commonly referred to as a "Form 2567." During the survey of a facility, if violations of regulations are found, the violations are noted and referred to as "Tags." A tag identifies the applicable regulatory standard that the surveyors believe has been violated, provides a summary of the violation, and sets forth specific factual allegations that the surveyors believe support the violation.
- 4. Manor Care is a 178-bed nursing home located at 5511 Swift Road, Sarasota, Florida. Manor Care is licensed as a skilled nursing facility.

- 5. On August 10 through 12, 2004, AHCA's staff conducted a survey at Manor Care. The Form 2567 completed during this survey found the facility in violation of Tag F425. This alleged violation formed the basis of AHCA's Administrative Complaint.
- 6. Tag F425 relates to pharmacy services. The federal regulation with which Manor Care allegedly failed to comply is 42 C.F.R. Section 483.60, which provides in relevant part:

The facility must provide routine and emergency drugs and biologicals to its residents, or obtain them under an agreement described in Sec. 483.75(h) of this part.

- 42 C.F.R. Section 483.75 provides generally that a facility "must be administered in a manner that enables it to use its resources effectively and efficiently to attain or maintain the highest practicable physical, mental, psychosocial well-being of each resident." 42 C.F.R. Section 483.75(h) provides:
  - (h) Use of outside resources.
  - (1) If the facility does not employ a qualified professional person to furnish a specific service to be provided by the facility, the facility must have that service furnished to residents by a person or agency outside the facility under an arrangement described in section 1861(w) of the Act<sup>[1/]</sup> or (with respect to services furnished to NF residents and dental services furnished to SNF residents) an agreement described in paragraph (h)(2) of this section.

- (2) Arrangements as described in section 1861(w) of the Act or agreements pertaining to services furnished by outside resources must specify in writing that the facility assumes responsibility for--
- (i) Obtaining services that meet professional standards and principles that apply to professionals providing services in such a facility; and
  - (ii) The timeliness of the services.
- 7. Resident 10, a female who was 51 years old at the time of the survey, was initially admitted to Manor Care on December 19, 2003, with diagnoses that included diabetes mellitus, arteriosclerotic heart disease, peripheral vascular disease, depression, chronic obstructive pulmonary disease, and cerebral vascular accident with hemiparesis and intercerebral hemorrhage.
- 8. Resident 10 was admitted to Sarasota Memorial Hospital for a surgical procedure on her leg, then re-admitted to Manor Care on August 2, 2004. The hospital's medical impression history and background included status post bilateral iliac angioplasty and stent, hypertension, a history of nicotine addiction, cigarette abuse, status post previous coronary stent, severe osteoarthritis, a history of lumbosacral disk disease with chronic pain syndrome, status post left thoracotomy, lower lobectomy for adenocarcinoma, a history of seizure disorder, and a history of moderate carotid stenosis on the right and left.

- 9. Upon her re-admission to Manor Care on August 2, 2004, Resident 10 had an intravenous morphine pump at 25 mg per day for severe pain and a clonopin pump at 250 mg per day for back pain. She was also prescribed oxycodone (Percocet) "prn," or as needed, for breakthrough pain. Finally, she was prescribed fentanyl citrate (Actiq), a narcotic analgesic, in the form of a lozenge often referred to as a "lollipop," every three hours, as needed, for breakthrough pain. As a potent opiate, fentanyl is a Schedule II controlled substance that is subject to misuse, abuse, and addiction.
- 10. The nurses' notes for August 2, 2004, indicated that Resident 10 was offered Percocet for her pain, but that she declined it.
- 11. On August 3, 2004, the attending physician changed Resident 10's fentanyl prescription from "3 hr. prn" to "q. 2h," meaning from every three hours, as needed, to every two hours regardless of her expressed need.
- 12. Manor Care's pharmaceuticals were provided by an outside pharmacy pursuant to a contract comporting with 42 C.F.R. Section 483.75(h). On August 7, 2004, Manor Care's staff faxed a refill order to the contract pharmacy requesting a refill of Resident 10's fentanyl. During the day shift on August 9, 2004, Diane Hinrichs, the LPN performing the narcotics count, noticed that the fentanyl count was low and that the

pharmacy had not filled the August 7 refill order. She faxed a repeat refill order and phoned the pharmacy, which assured her that the fentanyl would be included in the pharmacy's 4:00 p.m. delivery to Manor Care. When the fentanyl was not delivered at 4:00 p.m., another Manor Care nurse phoned the pharmacy again. The pharmacy assured the nurse that the fentanyl would be included in the next scheduled delivery, at about 2:00 a.m. on August 10, 2004. Shortly before 2:00 a.m., Ms. Hinrichs was back on duty and phoned the pharmacy, asking whether she could obtain the fentanyl at Walgreens or some other alternate source. The pharmacist told her that she could not, but assured her that the fentanyl was "on its way." The fetanyl was not included in the 2:00 a.m. delivery. The duty nurse called the pharmacy immediately, then again at approximately 5:20 a.m., and was again told that the fentanyl was "on its way."

- 13. The last dose of fentanyl in the facility was administered to Resident 10 at midnight on August 9, 2004.

  Resident 10 did not receive fentanyl, as ordered, at 2:00 a.m., 4:00 a.m., and 6:00 a.m. on August 10, 2004. She continued to receive the morphine and clonopin on the intravenous pump throughout the night.
- 14. During the night, Resident 10 was offered Percocet as a substitute for the unavailable fentanyl. She declined the Percocet, stating that "it does not help at all." Manor Care's

medication administration records indicated that Resident 10 had never taken Percocet. As noted above, Resident 10's physician had prescribed Percocet for breakthrough pain.

- 15. The pharmacy delivered the fentanyl at approximately 7:40 a.m. on August 10, 2004, and the nursing staff administered the medication to Resident 10 at about 8:30 a.m. The pharmacy later investigated the situation and informed Manor Care that a pharmacy technician had miscalculated the amount of fentanyl that Manor Care was allowed to keep on hand and had placed the refill order in a "holding bin" for later delivery.
- 16. The Manor Care nursing notes indicate that Resident 10's physician was notified of the unavailability of the fetanyl at some time on August 10, 2004. On August 11, 2004, the physician discontinued his order for Percocet and instead prescribed oral morphine (Roxanol) for Resident 10's breakthrough pain. The physician continued the prescription for fetanyl.
- 17. One of Resident 10's diagnoses was a "history of nicotine addiction, cigarette abuse." Her night and early morning routine was sleep punctuated by frequent trips in her wheelchair to an outdoor gazebo designated by Manor Care as a smoking area. During the early morning hours of August 10, 2004, Resident 10 followed this routine.

- 18. During the early morning hours of August 10, 2004,
  Resident 10 was observed by an experienced RN, Angela Miguel,
  and an experienced LPN, Diane Hinrichs, both of whom were
  familiar with Resident 10's condition, personality, and habits.
  Resident 10 did not complain to either nurse regarding pain
  caused by the missed doses of fentanyl. Neither nurse observed
  Resident 10 to exhibit any behavior indicative of pain.
  Resident 10 appeared to be going about her usual routine of
  sleeping, then going outside to smoke. Under the circumstances,
  neither nurse saw any reason or need to conduct a formal pain
  evaluation of Resident 10.
- 19. Jane Sargent-Jefferson, the food service director, arrived at Manor Care at her usual time of 5:00 a.m. on August 10, 2004. She found Resident 10 asleep in her wheelchair outside in the smoking gazebo, which is adjacent to the Manor Care dining room. Ms. Sargent-Jefferson often found Resident 10 asleep in the gazebo during the early morning hours and would wake up Resident 10 and talk to her. She did so on the morning of August 10, 2004.
- 20. Ms. Sargent-Jefferson testified that "the first thing out of [Resident 10's] mouth" was that "she was mad because her meds had been missed." Ms. Sargent-Jefferson stated that it was not unusual for Resident 10 to be angry and to complain when she

was unhappy. Just the day before, Resident 10 had "stormed out" of the dining room when the chef's salad was not to her liking.

- 21. Ms. Sargent-Jefferson had frequent conversations with Resident 10. On the morning of August 10, 2004, she spoke with Resident 10 on three separate occasions between 5:00 a.m. and noon. Resident 10 did not say that she had been in pain during the previous night. Ms. Sargent-Jefferson testified that Resident 10 "would tell you" if she was in pain. Ms. Sargent-Jefferson observed nothing out of the ordinary in Resident 10's appearance or behavior on the morning of August 10, 2004.
- 22. On the morning of August 10, 2004, AHCA surveyor
  Barbara Pescatore was in the smoking gazebo when she was
  approached by a resident subsequently identified as Resident 10,
  who complained that she had not received prescribed pain
  medication from midnight until 8:30 a.m. Ms. Pescatore
  transferred the inquiry to Anne Dolan, the RN who had been
  assigned to survey the care of Resident 10.
- 23. Ms. Dolan reviewed the facility's records and interviewed the staff. She learned that Resident 10's fentanyl doses were missed at 2:00 a.m., 4:00 a.m., and 6:00 a.m. on August 10, 2004, and that the 8:00 a.m. dose on that date was administered at about 8:30. She further learned the circumstances surrounding the lack of fentanyl in the facility in the early morning hours of August 10, 2004.

- 24. At the hearing, Ms. Dolan, an expert in long-term care nursing, opined that Manor Care and its nurses had an absolute responsibility to ensure that Resident 10 had her medication and had it on time. She testified that at 10:00 p.m. on August 9, 2004, the nursing staff knew that there was only one dose of fentanyl remaining to administer and that it was the staff's responsibility to do whatever was needed to ensure there would be more medication to give Resident 10 after the last dose at midnight. Ms. Dolan testified that missed doses of a routine pain medication can cause unnecessary pain and a delay in the medication's effect when the doses are resumed.
- 25. Ms. Dolan testified that she could see Resident 10 grimacing and wincing when she would feel pain in her leg. She testified that Resident 10's pain was relieved immediately when she received the fetanyl "lollipop." However, Ms. Dolan was not present on the night in question, and the record gives no indication whether Ms. Dolan or any other AHCA surveyor simply asked Resident 10 whether she experienced increased pain when she missed the doses of fentanyl. No direct evidence was presented that Resident 10 expressed pain or complained of pain or discomfort due to the missed doses of fentanyl, either at the time or later.
- 26. Dr. Franklin May, a senior pharmacist for AHCA, offered expert testimony and testified that the nursing staff's actions

during the night of August 9, 2004, evidenced a "very severe" failure to deliver pharmaceutical services. He based this opinion on the fact that the regulations require that medication be provided in a timely manner. Dr. May was not involved in the survey process and did not interview Resident 10. Based on the records he reviewed, Dr. May testified that he could not say whether Resident 10 "needed" the fentanyl for pain between midnight and 8:00 a.m.

- 27. Dr. May opined that when the dose of fentanyl was missed due to its unavailability and Resident 10 refused to take the alternative drug Percocet, the staff nurses should have performed an immediate pain evaluation and contacted the resident's physician for instructions. If the attending physician had been unavailable, then the nurses should have contacted Manor Care's director of medicine for instruction.

  Dr. May emphasized that the staff nurses did not have the discretion to allow the resident to simply miss doses of prescribed medicine.
- 28. The contracting pharmacy's policy and procedure manual set forth the following policy: "When medication orders are not received or unavailable, the licensed nurse will immediately initiate action in cooperation with the attending physician and the pharmacy provider. All medication orders unavailable to the customer will be managed with urgency." The manual sets forth

the following process to implement the policy, in relevant part (emphasis in original):

- 2. If a medication shortage is discovered during normal pharmacy hours:
- 2.1 A licensed nurse calls the pharmacy and speaks to a registered pharmacist to determine the status of the order. If not ordered, place the order or re-order to be sent with the next scheduled delivery.
- 2.2 If the next available delivery causes delay or missed dose in the customer's medication schedule, take the medication from the emergency stock supply to administer the dose.
- 2.3 If medication is not available in the emergency stock supply, notify the pharmacist and arrange for an emergency delivery.
- 3. If a medication shortage is discovered after normal pharmacy hours:
- 3.1 A licensed nurse obtains the ordered medication from the emergency stock supply.
- 3.2 If the ordered medication is not available in the emergency stock supply, a licensed nurse calls the pharmacy's emergency answering service and request to speak with the registered pharmacist on duty to manage the plan of action. Action may include:
  - 3.2.1 Emergency delivery.
  - 3.2.2 Use of emergency (back-up) pharmacy.
- 4. If an emergency delivery is unavailable, a licensed nurse contacts the attending physician to obtain orders or directions which may include:

- 4.1 Holding the dose/doses.
- 4.2 Use of an alternative medication available from the emergency stock supply.
- 4.3 Change in order (time of administration or medication).

\* \* \*

- 6. When a missed dose is unavoidable:
- 6.1 Document missed dose on the Medication Administration Record (MAR) or Treatment Administration Record (TAR):
- 6.1.1 Initial and circle to indicate any missed dose. Document explanation for missed dose according to physicians order: e.g. "hold dose" on back of MAR/TAR and indicate "See nurses notes for explanation."
- 6.2 Document explanation of missed dose
  in the Nurses Notes:
- 6.2.1 Describe circumstance of medication shortage.
  - 6.2.2 Notification of pharmacy and response.
  - 6.2.3 Action(s) taken.
- 29. Manor Care staff did not completely fulfill the requirements of the quoted procedures. The MAR for Resident 10 complied with the documentation requirement that missed doses be initialed and circled, but made no reference to explanatory nurses' notes. The records indicate that the nurses' notes regarding the missed doses were not made contemporaneously, but were completed later in the morning of August 10, 2004. As noted above, the nursing staff made several attempts to have the

pharmacy deliver the fentanyl, but never proceeded to the next step of using a back-up pharmacy or contacting the attending physician because of the attending nurses' observations that Resident 10 was not in pain or discomfort.

30. The federal CMS issues a "State Operations Manual" containing guidelines that are relied upon by surveyors when assessing compliance with regulatory requirements. The State Operations Manual provides, as follows regarding alleged violations of 42 C.F.R. Section 483.60:

A drug, whether prescribed on a routine, emergency, or as needed basis, must be provided in a timely manner. If failure to provide a prescribed drug in a timely manner causes the resident discomfort or endangers his or her health and safety, then this requirement is not met.

- 31. There was no allegation made nor evidence presented that Resident 10's health or safety was endangered by the missed doses of fentanyl. Thus, the issue, as framed by the Guidance to Surveyors documents, is whether Resident 10 experienced "discomfort." The evidence presented at hearing did not establish that Resident 10 experienced pain or more than minimal additional discomfort due to the missed medication.
- 32. At most, the evidence proved that Resident 10 was upset by the fact that she missed doses of fentanyl. She did not tell anyone that she was in pain and displayed few, if any, outward behavioral indications of pain. Resident 10 went about

her normal routine, including sleeping for a time and going outside to smoke cigarettes on the gazebo. Subsequently, in September 2004, Resident 10 was discharged from Manor Care and returned to her own residence.

33. The alleged violation of C.F.R. Section 483.60 was classified by the surveyors as an isolated "Class II" deficiency. Subsection 400.23(8)(b), Florida Statutes (2004), provides, in relevant part:

A class II deficiency is a deficiency that the agency determines 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 resident assessment, plan of care, and provision of services. A class II deficiency is subject to a civil penalty of \$2,500 for an isolated deficiency . . . A fine shall be levied notwithstanding the correction of the deficiency.

- 34. Subsection 400.23(7)(b), Florida Statutes (2004), provides that the presence of one or more Class II deficiencies requires AHCA to assign a conditional licensure status to the facility. Conditional licensure means that a facility "is not in substantial compliance at the time of the survey with criteria established under this part or with rules adopted by the agency."
- 35. Subsection 400.23(8)(c), Florida Statutes (2004), defines a "Class III" deficiency as follows, in relevant part:

A class III deficiency is a deficiency that the agency determines will result in no more than minimal physical, mental, or psychosocial discomfort to the resident or has the potential to compromise the resident's ability to maintain or reach his or her highest practical physical, mental, or psychosocial well-being, as defined by an accurate and comprehensive resident assessment, plan of care, and provision of services. A class III deficiency is subject to a civil penalty of \$1,000 for an isolated deficiency . . . A citation for a class III deficiency must specify the time within which the deficiency is required to be corrected. If a class III deficiency is corrected within the time specified, no civil penalty shall be imposed.

36. Under all the facts and circumstances set forth above, it is found that Manor Care did not provide Resident 10 with her prescribed fentanyl during the late night hours of August 10, 2004. It is further found that though Manor Care's nursing staff made repeated efforts to obtain the fentanyl through its contracted pharmacy and received repeated assurances that the medication was "on its way," Manor Care's nursing staff did not follow all of the procedures set forth in the pharmacy's policy and procedure manual to secure the medication on an urgent basis. However, the evidence did not establish that Resident 10's "ability to maintain or reach . . . her highest practicable physical, mental, and psychosocial well-being" was compromised by the missed doses of fentanyl. At most, Resident 10 suffered "minimal physical, mental, or psychosocial discomfort," and the

alleged violation should have been classified as an isolated Class III deficiency.

#### CONCLUSIONS OF LAW

- 37. The Division of Administrative Hearings has jurisdiction over the parties and subject matter of this case pursuant to Section 120.569 and Subsection 120.57(1), Florida Statutes (2004).
- Enterprises Florida v. Agency for Health Care Administration,
  745 So. 2d 1133 (Fla. 1st DCA 1999). The burden of proof to
  impose an administrative fine is by clear and convincing
  evidence. Department of Banking and Finance v. Osborne

  Stern & Co., 670 So. 2d 932 (Fla. 1996). The burden of proof
  for the assignment of licensure status is by a preponderance of
  the evidence. See 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).3/
- 39. Subsection 400.23(7), Florida Statutes (2004), states in relevant part:
  - (7) The agency shall, at least every 15 months, evaluate all nursing home facilities and make a determination as to the degree of compliance by each licensee with the established rules adopted under this part as a basis for assigning a licensure status to that facility. The agency shall base its

evaluation on the most recent inspection report, taking into consideration findings from other official reports, surveys, interviews, investigations, and inspections. The agency shall assign a licensure status of standard or conditional to each nursing home.

- (a) A standard licensure status means that a facility has no class I or class II deficiencies and has corrected all class III deficiencies within the time established by the agency.
- (b) A conditional licensure status means that a facility, due to the presence of one or more class I or class II deficiencies, or class III deficiencies not corrected within the time established by the agency, is not in substantial compliance at the time of the survey with criteria established under this part or with rules adopted by the agency. If the facility has no class I, class II, or class III deficiencies at the time of the follow-up survey, a standard licensure status may be assigned. . . .
- 40. AHCA has alleged that Manor Care violated 42 C.F.R. Section 483.60, adopted by reference by Florida Administrative Code Rule 59A-4.1288, because Resident 10 did not receive a pain medication on the schedule prescribed by her attending physician.
- 41. Section 400.23, Florida Statutes (2004), provides, in relevant part:
  - (1) It is the intent of the Legislature that rules published and enforced pursuant to this part shall include criteria by which a <u>reasonable and consistent quality</u> of resident care may be ensured and the results of such resident care can be demonstrated

and by which safe and sanitary nursing homes can be provided. It is further intended that reasonable efforts be made to accommodate the needs and preferences of residents to enhance the quality of life in a nursing home . . . .

- (2) Pursuant to the intention of the Legislature, the agency, in consultation with the Department of Health and the Department of Elderly Affairs, shall adopt and enforce rules to implement this part, which shall include <a href="reasonable and fair criteria">reasonable and fair criteria</a>. . . (Emphasis added)
- 42. The emphasized portions of the quoted statute make it clear that Florida Administrative Code Chapter 59A-4, establishing minimum standards for nursing homes, does not impose strict liability on nursing homes. The regulations must be interpreted as requiring nursing homes to make reasonable efforts and to exercise reasonable care to ensure resident safety.
- 43. In similar fashion, the State Operations Manual promulgated by the federal CMS does not impose strict liability on nursing homes for providing medications in a timely manner. Rather, the State Operations Manual provides that the requirements of 42 C.F.R. Section 483.60 are not met only if "failure to provide a prescribed drug in a timely manner causes the resident discomfort or endangers his or her health and safety."

- 44. AHCA did not establish that Resident 10's health or safety was endangered. At most, Resident 10 suffered the "minimal physical, mental, or psychosocial discomfort" associated with a Class III deficiency. A Class III deficiency cannot be the basis for a fine or a "conditional" license unless it is not timely corrected by the nursing home. No evidence was presented that Manor Care's admitted deficiency in providing the fentanyl to Resident 10 was ever repeated. Thus, there was no proof that the deficiency was severe enough to support any penalties.
- 45. Regardless of whether AHCA's burden of proof was the preponderance of the evidence or clear and convincing evidence, AHCA failed to prove that a Class II deficiency existed at Manor Care's facility. Thus, there was no basis for the imposition of either conditional licensure or an administrative fine.

# RECOMMENDATION

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

RECOMMENDED that AHCA enter a final order dismissing the Administrative Complaint.

DONE AND ENTERED this 26th day of August, 2005, in Tallahassee, Leon County, Florida.

LAWRENCE P. STEVENSON

Administrative Law Judge

Division of Administrative Hearings

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Filed with the Clerk of the Division of Administrative Hearings this 26th day of August, 2005.

# ENDNOTES

- 1/ Codified at 42 U.S.C. 1395x(w).
- Ms. Dolan's observations have not been disregarded, but have been considered in light of the facts that fentanyl is potent, highly addictive, and takes effect gradually over the 15 minutes the "lollipop" is consumed and for approximately one hour thereafter, according to the Physician's Desk Reference entry admitted into evidence at the hearing. Thus, it may be inferred that the <a href="immediate">immediate</a> relief Resident 10 appeared to experience when she received the "lollipop" could be related to a psychological, if not physical, dependence on the drug rather than an actual lessening of pain. Such an inference would be consistent with the observations of Manor Care's staff, <a href="i.e.">i.e.</a>, Resident 10 did not appear to be in pain but was angry at not receiving her regular dose of fentanyl and unwilling to accept an alternative pain reliever.
- Manor Care contends that conditional licensure constitutes an even greater penalty on a facility than does the imposition of an administrative fine. The impact of conditional licensure on Manor Care's property interest in its business, while not quantified at the hearing, cannot be denied. Thus, Manor Care urges that the assignment of licensure status be subject to the

same burden of proof as the imposition of an administrative fine: clear and convincing evidence. In at least one Final Order, AHCA has rejected the contention that assignment of licensure status is subject to the clear and convincing evidence standard. Agency for Health Care Administration v. Health Care and Retirement Corporation of America, Case No. 03-2569 (DOAH December 22, 2003)(Final Order June 2, 2004). In this case, it is unnecessary to determine the standard of proof because ACHA failed to prove the material allegations under the preponderance standard.

# 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.