STATE OF FLORIDA DIVISION OF ADMINISTRATIVE HEARINGS

AGENCY FOR HEALTH	CARE)			
ADMINISTRATION,)			
)			
Petitioner,)			
)			
vs.)	Case	Nos.	04-4506
)			05-0388
RULEME CENTER,)			
)			
Respondent.)			
)			

RECOMMENDED ORDER

Pursuant to notice, the Division of Administrative

Hearings, by its designated Administrative Law Judge, P. Michael

Ruff, held a final hearing in the above-styled case on

February 9, 2005, in Tavares, Florida. The appearances were as

follows:

APPEARANCES

For Petitioner: Thomas J. Walsh, II, Esquire

Agency for Health Care Administration

525 Mirror Lake Drive, 330G St. Petersburg, Florida 33702

For Respondent: Alfred W. Clark, Esquire

117 South Gadsden Street, Suite 201

Post Office Box 623

Tallahassee, Florida 32302-0623

STATEMENT OF THE ISSUES

The issues to be resolved in this proceeding concern whether the Respondent should be subjected to administrative

fines and a conditional licensure for alleged violations of 42 Code of Regulation (CFR) Section 483.20(k)(3)(i) and 42 CFR Section 483.25, adopted by reference in Florida Administrative Code Rule 59A-4.1288.

PRELIMINARY STATEMENT

This cause arose when the Agency issued a "Notice of Assignment of Conditional Licensure Status" which was transmitted to the Respondent on or about October 20, 2004. In that "charging document" the Agency seeks to assign a conditional licensure status to the Respondent (Ruleme) commencing July 29, 2004 (Case No. 04-4506). Through an Administrative Complaint filed January 26, 2005, the Agency seeks to impose administrative fines in the total amount of \$20,000.00, based upon two purported "Class I deficiencies," pursuant to Section 400.23(a), Florida Statutes (2004), and seeks to impose a "six month survey cycle fee" of \$6,000.00 in accordance with Section 400.19(3), Florida Statutes (2004).

A formal proceeding was requested by Ruleme in both cases and the two cases were consolidated by Order of February 3, 2005. In Count I of its Administrative Complaint the Agency contends that Ruleme failed to ensure that services provided by its facility met professional standards of quality by failing to document in accord with professional standards, and in violation of the facility's policy and procedures requiring notification of

a resident's physician upon significant change in the condition of a resident. In Count II, it is alleged that Ruleme did not ensure that the resident (Resident 14) received necessary care and services to attain or maintain the highest practicable physical, mental, and psycho-social well-being, in accordance with the comprehensive assessment and plan of care in that the facility failed to provide nursing services meeting professional standards of practice. Specifically, the Agency contends that nursing services provided to Resident 14 were not documented in accordance with professional standards and in violation of the facility's policies and procedures, and that the Respondent failed to properly monitor the resident, who had experienced an incident of respiratory distress. The monitoring failures purportedly included the failure to observe the resident at appropriate intervals, the failure to assess the effectiveness of the prescribed treatment, the failure to monitor the resident's diabetic status and the failure to adequately monitor the resident's vital signs.

Ruleme contested the Agency's intent to assign a conditional licensure status by its Petition for Formal Proceeding dated November 2, 2004 (Case No. 04-4506), and the imposition of the intended administrative fines and six-month survey cycle, with fine, in its petition filed January 27, 2005. (Case No. 05-

0388). The consolidated cases that came before the undersigned for formal proceeding and hearing.

The cause came on for hearing as noticed. The testimony of three witnesses was presented by the Agency: Ms. Marsha Lisk, a registered nurse specialist, accepted as an expert in professional nursing standards and practices and long-term nursing care; Ms. Denise Godfrey, an Agency surveyor and Public Health Nutrition Consultant; and Mr. Steven Burgin, an Agency surveyor. The Agency presented a Composite Exhibit that was admitted into evidence by stipulation of the parties.

Ruleme presented the testimony of three witnesses:

Ms. Laura Runnels, a Licensed Practical Nurse (LPN), Dr. Braxton

Price, M.D. qualified as an expert in long-term care, by

stipulation of the parties, and Ms. Joyce Kadziolka-Long, the

Administrator of the Ruleme facility. Ruleme introduced a

Composite Exhibit which was admitted into evidence upon

stipulation of the parties. Upon conclusion of the proceeding

the parties requested a transcript thereof and the opportunity to

submit proposed recommended orders. The Proposed Recommended

Orders were timely submitted, after one stipulated extension of

time, and have been considered in the rendition of this

Recommended Order.

FINDINGS OF FACT

1. The Agency for Health Care Administration (AHCA); is the state agency charged with licensing nursing homes in Florida under Section 400.021(2), Florida Statutes (2004), and the assignment of licensure status pursuant to Section 400.23(7), Florida Statutes (2004). The Agency is thus charged with evaluating nursing home facilities to determine their degree of compliance with rules as a basis for making required licensure assignments. Additionally, it is responsible for conducting federally-mandated surveys of long-term care facilities which receive Medicare and Medicaid funds in order ascertain compliance with federal statutory and regulatory rule requirements. The federal requirements are made applicable to Florida Nursing Home Facilities by Florida Administrative Code Rule 59A-4.1288, which states in pertinent part,

[N]ursing Homes that participate in Title XVIII or XIX must follow certification rules and regulations found in 42 CFR 483, Requirements for Long Term Care Facilities, September 26, 1991, which is incorporated by reference.

2. Ruleme is a licensed nursing facility with long-term care facility located in Eustis, Florida. Section 400.23(8), Florida Statutes (2004), requires AHCA to classify deficiencies according to their nature and scope under the criteria established in Section 400.23(2), Florida Statutes (2004). The

classification of any deficiencies is determative of whether the licensure status of a nursing home is standard or conditional licensure and relates to the amount of administrative fine that may be imposed.

- 3. Surveyors of nursing homes note their findings on a standard form prescribed by the "Center for Medicare and Medicaid Services" (CMS), Form 2567. That form is entitled "Statement Deficiencies and Plan of Correction." It is commonly referred to as a "2567 form." When a nursing home facility is surveyed, if violations are found, the violations are reported as "tags." A numbered "tag" identifies the applicable regulatory standard that the surveyors believe has been violated. It provides a summary of the violation, sets forth specific factual allegations that the surveyors believe support a violation and indicates the federal scope and severity of the non-compliance or violation.
- 4. The Agency alleged that Ruleme was not in compliance with certain of those requirements, two of which are significant in this proceeding; 42 CFR Section 483.20 (Tag F281) (Count I), for failing to meet professional standards of quality; and 42 CFR Section 483.25 (Tag F309) (Count II), for failing to provide the necessary care and services to attain or maintain a resident's highest practicable physical, mental, and psycho-social well-being. As to each, the Agency alleged that the deficient practices were of an isolated scope because the deficiencies

alleged were only determined with regard to one resident out of 42 residents who were the subjects of the Ruleme survey at issue.

- 5. The Agency determined that the facility allegedly did not comply with the state requirements of Section 400.23(7) and (8), Florida Statutes (2004), and Florida Administrative Code Rule 59A-4.1288. Under the Florida classification system, it classified the federal Tag F281 and Tag 309 deficiencies as state Class I deficiencies of isolated scope.
- 6. On or about July 26, 2004, the Agency conducted a licensure recertification survey of Ruleme Center. Resident 14 was a lady with a diagnosis of diabetic mellitus requiring insulin coverage; congestive heart failure; end-stage failure to thrive; hypertension; a history of colon cancer and gastric resection; gastric reflux disease; depression, and osteoporosis. The resident was verbal and aware and had a history of non-compliance with medications. Her recent prescription for psychotropic medication (haldol) seemed to have calmed her mood somewhat. The resident had also executed a "DO NOT RESUSCITATE" (DNR) order as well as a Living Will.
- 7. The resident's medication orders included "accuchecks" to be conducted three times daily to monitor blood sugar levels, related to diabetes, with a concomitant sliding scale for the administration of insulin, depending upon the blood sugar count. Further medications included an order for glucagan to be

administered on an "as needed" basis for hypoglycemia, and phenergan, to be administered as needed for nausea and vomiting. In order to address the gastro-reflux disease, three medications were prescribed: metoclapramide, protonix, and sucralfate.

- 8. The medication administration records (MAR) for this resident reflected that on July 26, 2004, she had refused the prescribed and offered medications for gastro-reflux disease. The MAR reflected that the 11:30 a.m., check of the blood sugar revealed a blood sugar count of 236. Two units of insulin were prescribed and administered for this. At 4:30 p.m. the next prescribed time for monitoring of blood sugar, the resident refused to have her blood sugar test conducted. At 9:00 p.m. that night, the last daily-prescribed time for blood sugar testing, the blood sugar test revealed a blood sugar reading of 222. Two insulin units were prescribed for such a reading. The MAR however does not reflect whether the prescribed insulin was administered to the resident or not.
- 9. Resident 14 vomited at some time between 11:00 and 11:30 p.m., on July 26, 2004. The CNA on duty cleaned the resident elevated the head of her bed to a 45 degree angle and notified the LPN on duty, Nurse Laura Runnels of the event. Nurse Runnels documented in the resident's chart at 11:30 p.m., the following:

Patient vomited a large amount of emesis, contained food particles.

Nurse Runnels then directed a CNA to take vital signs of the resident. The resident's vital signs were recorded as: blood pressure, 88 systolic over 46 diastolic; pulse of 124 beats per minute; temperature of 96.1 and respiration at 30 breaths per minute. Nurse Runnels also listened to the resident's lung sounds with a stethoscope.

10. At 12:00 a.m., July 27, 2004, Nurse Runnels entered the following note in the nurses' note:

Patient moaning in bed, raspy, gurgling breath signs. States she does not feel well but can't pinpoint what it is that doesn't feel well. Will continue to monitor.

11. Nurse Runnels telephoned Dr. Braxton Price, the treating physician and medical director of Ruleme. After waiting approximately 10 minutes for a return call she then paged Dr. Price on his pager. He then returned her call and she explained that the resident had vomited and communicated the resident's vital signs. She also indicated to the doctor that the congestion in the resident's lungs was low in the lungs. Nurse Runnels told the doctor that she did not feel suctioning would be effective. Dr. Price apparently agreed with that assessment and ordered that the resident be administered oxygen. Nurse Runnels and a CNA then provided the administration of oxygen as ordered by Dr. Price.

- 12. After the administration of oxygen, the resident's anxiety and restlessness seemed to alleviate. Nurse Runnels believed the patient had stabilized and she thereafter was sleeping. Nurse Runnels conducted visual checks of Resident 14 three times from midnight until 3:50 a.m., when the patient was observed to have expired. She conducted the visual checks each time noting that the resident appeared to be sleeping, by standing in the patient's room and observing the patient. The room was lit by a single light located over a sink across the room from the patient's bed.
- 13. No further entries were made by Nurse Runnels on the nursing notes until 3:50 a.m., on July 27, 2004, at which time she noted, "CNA reported [resident] didn't seem to [be] breathing, when I checked for breath sounds there were none, no heart sounds/pulse. M.D. and family notified."
- 14. Dr. Price executed the resident's death certificate.

 He stated that the cause of death was senescence, a term roughly meaning death as a natural result of the aging process. It was a cause of death accepted by the medical examiner.
- 15. Nurse Runnels did not document the care or services provided to the resident from the midnight entry she made until the resident's death at approximately 3:50 a.m. There was an absence of documentation concerning her consultation with Dr. Price, his order for administration of oxygen or the

monitoring Nurse Runnels conducted. Documentation is a critical responsibility for the provision for professional nursing services, as it is the basis for future decisions regarding patient care by all the care providers who treat a patient at any one time and for subsequent care providers of the patient, as, for instance, those on the following shift.

16. Ruleme's physician notification policy requires that, upon the observance of a significant change in the medical condition of a resident, a nurse must contact the physician, report the nursing assessments and observations, complete a physician's notification and nurse's note prior to contacting the physician, document the reason for notification, obtain new orders from the physician and transcribe these to the MAR or treatment administration record (TAR), and update the resident's care plan. A significant change is defined as respiration above 30 breaths per minute and a pulse in excess of 120 beats per minute. When Nurse Runnels decided to contact the physician Dr. Price, Resident 14's respirator rate was 30 breaths per minute with a pulse of 124 beats per minute. This was a significant change under this policy. Although not documented, in fact Nurse Runnels observed the significant change in the resident's condition, did promptly contact Dr. Price, and reported to him her nursing assessment and observations. She obtained new orders from the physician, the administration of

oxygen, and promptly carried them out, particularly, but she acknowledged in her testimony that she failed to document these matters after 12:00 a.m., on the night in question. Later entries to the relevant records regarding Resident 14 would have been a standard and accepted practice in the provision of professional nursing services.

- 17. The resident was diabetic. Her blood sugar was checked according to normal procedure at approximately 9:00 p.m., on the evening in question. Her blood sugar at that time resulted in a reading of 222. That would indicate the need for the provision of approximately two units of insulin. The records, however, do not reflect whether she received any insulin at that time and it is presumed that she did not. A reading of 222 is not substantially elevated, and the failure to provide insulin at that time would not likely result in any health crisis. The resident thereafter, however, vomited and expelled food. This could have resulted in a decline in her glucose or sugar level. Further readings were apparently not taken, or at least not documented, so it is not known whether her glucose levels declined markedly thereafter on the evening in question.
- 18. A hypoglycemic condition can result in sweating and decline in consciousness and, if low enough, can result in a lapse into unconsciousness. Conversely, a hyperglycemic condition, with excessively high blood sugars can result in

irritability, dry skin, and possibly mental confusion.

Hyperglycemia was unlikely to result because the resident had vomited and expelled food from her digestive system which would more likely result in a lowering of glucose levels in her blood. In any event, Nurse Runnels knew of the diabetic condition and knew of the vomiting which had occurred shortly after the beginning of her shift at 11:00 p.m. She apparently had been told that the resident had vomited earlier that evening, on the proceeding shift, although that was not confirmed and was not documented at the time it occurred. She did not, however, check the resident's blood sugar and did not review the resident's MAR to determine the status of the blood sugar levels. In fact, the physician's orders provided for the last daily blood sugar reading to be taken at 9:00 p.m.

19. Although she monitored and observed the resident three or four times between 11:30 p.m., and 3:50 a.m., these were visual observations only and she did not touch the resident. They were conducted in a dimly lit room while the resident appeared to be sleeping. This reduced the opportunity for Nurse Runnels to adequately assess the resident's status concerning such indicators as changes in temperature, sweating, confusion or irritability, or reduced consciousness. In fact, some of these factors would not have been observed because the resident was sleeping.

- 20. Nurse Runnels did not conduct or cause to be conducted further checks of the resident's vital signs after the vital signs were taken at approximately midnight. Two of the four vital signs, respiration and pulse, were above the level which would require that the facility, through its staff, assess a resident, monitor vital signs, initiate appropriate medical interventions, document all assessments, and contact a physician. Although the physician was contacted and his orders were followed, further checks of blood pressure, pulse, and respiration were apparently not made. Nurse Runnels indicated that she did not wish to awaken the resident because she appeared to be stable and was sleeping comfortably after the administration of oxygen. She had a history of being irritable and even combative if awakened from sleep to have medication administered or tests performed. However, respiration and pulse are vital signs that require minimal intrusion on the resident. It would even be possible to check them while the resident was sleeping comfortably. In view of the fact that the resident had had elevated pulse and respiration prior to administration of oxygen, and substantially low blood pressure, at approximately 12:00 a.m., proper professional nursing practice would dictate that the vital signs be checked periodically after that time.
- 21. Nurse Runnels did not check, or cause to be checked,
 Resident 14's oxygenation level after oxygen was administered in

accord with the physician's orders. Proper professional standards of nursing practice would dictate that the oxygenation level be checked to determine if the administration of oxygen was providing the desired effect on the patient. Professional standards of nursing practice require the assessment of the patient on an ongoing basis, including the assessment of any prescribed treatment to ensure its effectiveness. Nurse Runnels did not undertake such an assessment concerning the provision of oxygen to this resident.

22. Nurse Runnels did not administer or required to be administered the prescribed phenegran medication designed to alleviate nausea and vomiting. Nurse Runnels had been told verbally that the resident had experienced an episode of vomiting once earlier in the evening on the previous shift, as well as the one which Nurse Runnels knew had occurred on her own shift. determined, however, that the medication should not be administered, unless two episodes of vomiting occurred and did not consider the information of the earlier episode as being reliable since it had not been charted by the duty nurse at that time. However, when she reported the vomiting episode on her shift to the physician and the gurgling noises she heard in the resident's lungs thereafter, the physician did not order the provision of the anti-nausea medication and, after the administration of oxygen the resident appeared to be stable and

resting comfortably. Thus, it has not been demonstrated that the failure to administer the anti-nausea medication was a departure from proper professional standards of nursing practice and with the facility's polices and procedures under these circumstances. The resident had no nausea or vomiting after the event around 11:30 p.m., and one of the side effects of the anti-nausea medication is sedation and interference with mental alertness. The anti-nausea medication was not shown to be needed and would be inappropriate for the resident who was comfortable and no longer nauseous, given that the sedative side effect could have had a deleterious effect on the patient's blood pressure and respiration. The physician did not order the administration of the anti-nausea medication.

23. AHCA contends that Resident 14 should have been monitored more frequently. AHCA's expert witness, Ms. Lisk, suggested that monitoring should have been every 15 to 30 minutes, and indeed Dr. Price, Resident 14's physician, gave a similar estimate. After oxygen was administered at approximately 12:30 to 12:45 a.m., Resident 14 became calm, her breathing was no longer labored although audible lung sounds remained. She appeared comfortable and sleeping with no signs of distress each time she was monitored by Nurse Runnels and the CNA. Nurse Runnels checked on the resident three more times after oxygen was administered. Additionally, the CNA assigned to Resident 14

checked on the resident at least every 30 minutes. The CNA and the LPN did not check on the resident at the same time; therefore the resident was monitored at intervals averaging less than 30 minutes. Although the evidence reflects that Nurse Runnels could recall little about any discussion she might have had about the resident's care with the CNA, the evidence shows she regarded the CNA as one of significant experience, knowledge, and judgment. She trusted the CNA's ability to properly monitor the resident.

- 24. Ms. Marsha Lisk is a registered nurse and was accepted as an expert witness in the professional standards of nursing and long-term nursing care. She opined that the professional standards of nursing require that a nurse document care and observation, assess a patient both before and after a treatment is provided, and regularly monitor a patient who has exhibited signs or symptoms that require medical attention.
- 25. Dr. Price was accepted as an expert in long-term care. He established that Resident 14 was a frail, 84-year-old female in poor physical condition. She had numerous health problems which included congestive heart failure, deep vein thrombosis (blood clots) and "end-stage failure to thrive." Any of these three conditions can cause death. In consideration of these three life-threatening diagnoses, Dr. Price considered the incident on the night in question to be an "end-of-life event" for Resident 14. The Living Will and DNR Order limited the

available interventions for her care, even if it were known specifically that the cardiopulmonary systems was failing during those hours. The treatments for these life-threatening diagnoses would, in the doctor's expert opinion, be considered extraordinary means of treatment which would be prohibited by the Living Will and the DNR order. In his expert opinion he considered that there was "nothing else to do" for the resident.

- 26. The Agency's expert did not know or establish the cause of the resident's death. In the absence of the knowledge of the cause of death it is not possible to attribute her death to the action or inaction of the Respondent's staff, and the expert did not testify that the staff's conduct "caused" or was "likely to cause" death or serious harm to the resident. Dr. Price certified on the death certificate that the "immediate cause (final disease or condition resulting in death)" was due to "senescence" which had been experienced "for months." By this he meant that the death was due to multiple causes and body failure due to the resident's advanced age. The death certificate shows that the "probable manner of death" was "natural." Dr. Price's expert opinion, which is accepted, was that the facility staff had not failed to do something which resulted in a serious and immediate threat to Resident 14.
- 27. The Agency's surveyors must access the effect of an alleged violation on the resident and assign a "classification"

to the violation. In this instance they classified the violations as Class I. A Class I violation is one which "has caused or is likely to cause serious injury, harm, impairment, or death to a resident." See § 400.23(8)(a), Fla. Stat. The survey team determined not that there was a potential for harm but that actual harm, in effect the death, resulted because the physician was not notified of the resident's condition or because of the charged failures in professional nursing care involving monitoring, documenting, and assessing. The physician was notified however, and there is no evidence that any action or inaction by the staff "caused the death." AHCA expert Ms. Lisk opined that the failure to meet professional nursing standards would "increase the potential" for harm, injury, or death. did not testify or establish however, that staff action or inaction had "caused" or were "likely to cause" serious injury or death. The potential for an event does not rise to the level of a likelihood of an event. Webster's New Word Dictionary of the American Language, Second College Edition, 1978, defines "likely" as "probable" (at page 819) and defines "potential" as "possible", "latent" or "unrealized" (at page 1114). There is no persuasive evidence that staff inadequacies in conforming to professional nursing standards were a probable cause of the resident's death.

- 28. The gravamen of Count I of the complaint and Tag F281 concern the alleged failure to notify the resident's physician as a basis for that violation. The evidence establishes however, that the physician was notified, gave orders, and that his orders were followed by the staff. The staff monitored and assessed the resident at 15 to 30-minute intervals and found her in no distress and resting comfortably. To the extent that failure to document, monitor, or access is charged in this count and concerns this Tag, there is no persuasive evidence that establishes how the failure to document the physician notification process caused or was likely to cause the resident's death.
- 29. Count II of the complaint and Tag F309 of Form 2567L alleges that "necessary care and services" were not provided. The evidence concerning the staff's alleged inadequacies related to failure to document, monitor properly, or to assess properly (i.e. perform additional vital sign checks and oxygen checks, etc.). There is no persuasive evidence, however, which describes how the failure to perform documentation, assessment, or monitoring properly, or any nonconformance to nursing standards under the circumstances of this resident and this incident, caused or were likely to cause Resident 14's death, serious injury, harm, or impairment.

CONCLUSIONS OF LAW

- 30. The Division of Administrative Hearings has jurisdiction of the subject matter of and the parties to this proceeding. §§ 120.569 and 120.57(1), Fla. Stat. (2004).
- 31. The regulatory and statutory authority relied upon by the Agency in this proceeding is as follows:
- 32. 42 CFR Section 483.20, resident assessment, which states in pertinent part:

The facility must conduct initially and periodically a comprehensive, accurate, standardized, reproducible assessment of each resident's functional capacity. . . .

- (K) The services provided or arranged by the facility must . . .
- (I) Meet professional standards of quality.
- 33. 42 CFR Section 483.25, quality of care, states in relevant part:

Each resident must receive and the facility must provide the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the comprehensive assessment and plan of care.

34. Section 400.23(7), Florida Statutes, 2004, states in relevant part:

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.
- 35. Section 400.23(8)(a), Florida Statutes, (2004), states in relevant part:

A Class I deficiency is a deficiency that the agency determines presents a situation in which immediate corrective action is necessary because the facility's non-compliance has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident receiving care in the facility. A Class I deficiency is subject to a civil penalty of \$10,000.00 for a isolated deficiency. . .

36. Florida Administrative Code Rule 59A-4.1288, states in relevant part:

Nursing homes that participate in Title XVIII or XIX must follow certification rules and regulations found in 42 CFR 483, requirements for long-term care facilities, September 26, 1991, which is incorporated by reference.

- 37. The Agency is required to prove the alleged violations and the justification for an administrative fine by clear and convincing evidence. Department of Banking and Finance v.

 Osborne Stern, 670 So. 2d 932 (Fla. 1996); Latham v. Florida

 Commission on Ethics, 694 So. 2d 83 (Fla. 1st DCA 1997);

 Heritage Health Care and Rehabilitation Center-Naples v. AHCA,

 DOAH Case No. 99-1892 (AHCA 1999).
- Numerous recommended and final orders entered by AHCA have followed the standard of proof of a preponderance of the evidence, when AHCA is seeking to impose a conditional licensure status on a nursing home facility. In this case the Respondent proved that its operations would be negatively affected in terms of its reputation as a facility providing quality of care and in terms of its ability to retain and to hire competent professional staff, if a conditional licensure status were imposed. Therefore, it established that it would be penalized by the imposition of a conditional license. Thus, it would seem, as the Respondent contends, that removing a standard license held without strictures and replacing it with a conditional license would be an Agency act with is "penal in nature and implicates significant property rights." See Gulfview Nursing Home v. AHCA, 859 So. 2d 581 (Fla. 1st DCA 2003); Gulfcrest Nursing Home v. AHCA, 662 So. 2d 1330 at 1332 (Fla. 1st DCA 1995). See also discussion in Recommended Order

in AHCA v. Health Care and Retirement Corporation of America,
DOAH Case No. 03-2569, Conclusions of Law 82-86, Recommended
Order entered December 22, 2003 (exceptions to Recommended Order
granted and Final Order entered June 2, 2004). Regardless of
the legal logic of the Respondent's position, however, even if
the standard of proof is by preponderance of the evidence for
imposition of conditional licensure, the Agency failed to prove
the alleged violations. If no violations are proven (only
charged as Class I violations), then conditional licensure
cannot be imposed.

39. Count I of the complaint Tag F281 of the notice allege a violation of 42 CFR Section 483.20(k)(3)(i) and are based upon the essential alleged fact that Resident 14's physician was not notified of her condition by the staff. Additionally, Count I and Tag F281 set forth the pertinent regulatory requirements regarding documentation of physician notification and the circumstances surrounding it, but did not specifically allege that the documentation requirements concerning physician notification were not complied with. While AHCA cited the regulation concerning the requirement services that provided by the facility must meet "professional standards of quality," it did not allege what services provided or not provided constituted a failure to meet professional standards of quality. Rather, at final hearing, AHCA supported the violation alleged

in Count I and Tag F281 by evidence of the LPN's failure to adequately monitor, assess, and document the care and assessment maintains should have been done and should have been documented. The essential fact alleged as constituting a violation in this count really concerns the alleged lack of notification to the physician of the resident's condition and change of condition as was documented in the nurse's note at approximately 11:30 p.m., and 12:00 a.m., on the evening in question. This alleged fact was simply not proven. It was established that the Respondent staff member, the LPN, did indeed notify the physician promptly upon observing the change in the resident's condition, involving respiratory distress, including elevated breathing rate, pulse rate, and lowered blood pressure. Upon the physician's being notified, he gave orders to the LPN and the evidence shows that those orders were carried out. Although these events, including the physician's orders and the fact that the physician was notified was not documented, and should have been under the regulations, that element of the Agency's position is not supported by factual allegations in this above portion of the Administrative Complaint.

40. Count II of the Administrative Complaint and Tag F309 of the notice allege violation of 42 CFR Section 483.25, alleging a "failure to provide necessary care and services."

Count II and Tag F309 do not clearly allege and identify the

"care and services" which it maintains were not provided.

Substantial detail is alleged of the events concerning Resident

14. Although factual allegations detailing all contended

deficiencies are not made in this count, it is possible to infer

some or most of them based upon the detailed narrative taken

from the survey report and inserted in Count II of the

Administrative Complaint. The Agency sought to support this

alleged violation in Count II and Tag F309 with the same

evidence of alleged failure to properly monitor, assess, and

document the medical situation concerning Resident 14 that was

offered in support of Count I.

41. An agency is limited in its evidence to the allegations made in its administrative complaint, the charging document. See Tampa Health Care Center v. Agency for Health Care Administration, DOAH Case No. 01-0734 (August 2001).

"Notice of intent to assign conditional licensure status constitutes the charging document which . . . only matters placed in issue by the notice of intent to assign conditional licensure status were considered during the hearing and in the preparation of this recommended order." See Vista Manor v.

Agency for Health Care Administration, DOAH Case No. 00-0547 (September 2000). "Evidence of any alleged deficiency not contained in the expressed terms of the charging document are

not relevant and material to the allegations in the charging document."

- 42. AHCA has found that it cannot find a Respondent guilty of a violation "based on evidence of facts not alleged in the administrative complaint" and that "to do so would negate the right to an administrative hearing to contest the allegations in an administrative complaint, and it would eviscerate fundamental principles of due process (citations omitted)." AHCA v. Lake

 Mary Health Associates, Inc., DOAH Case No. 04-0335, Recommended Order at paragraph 24, entered June 8, 2004; Final Order entered August 25, 2004.
- 43. If it be assumed <u>arguendo</u> that the allegations of fact made in the Administrative Complaint were sufficiently specific to accord with principles of notice pleading, which is not the case with regard to Count I at least, AHCA did not prove a violation of either regulation. The Respondent proved that it did monitor and assess the resident and provide all the care and services which were ordered by the resident's attending physician. The resident's physician, who testified at final hearing as an expert in long-term care, demonstrated through his testimony that none of the additional forms of assessment or additional instances of such assessment which AHCA argued would be appropriate (oxygen saturation assessment, blood sugar test, and more frequent assessment of vital signs), as well as

additional documentation by the LPN on duty, would have provided any information which would have changed his orders for this resident, given what he knew of the resident's medical circumstances, unless the resident were in distress. After the administration of oxygen, which was provided at the physician's order and as a result of the LPN properly reporting the resident's medical situation to him, the resident was not thereafter in distress. The physician established that although such information may have been interesting, it would not have resulted in any change in his orders and treatment of the resident, knowing what he knew of the resident's medical circumstances. Indeed, given the resident's underlying diagnoses, particularly the diagnosis of cardiopulmonary failure or congestive heart failure, Dr. Price established that any additional orders which he might have given, if additional assessments were made would have had to involve "extraordinary measures" which the resident's DNR and Living Will had already effectively precluded. The administration of oxygen was already being provided which would have been the ordered treatment if an oxygen saturation assessment had shown a deficient oxygen level. In the doctor's words, there was "nothing else to be done."

44. AHCA's contention through the testimony of its expert witness, that the Respondent's monitoring of Resident 14 was inadequate does not sufficiently address the fact that the

resident was monitored approximately every 15 to 30 minutes by the assigned CNA and the LPN. The LPN monitored the resident at least three times between 12:30 a.m. and 3:50 a.m., and the CNA monitored the resident in between those observations or no less frequently than every 30 minutes. Thus, the resident was monitored by one or the other of these staff personnel at least every 15 minutes to 30 minutes which the evidence in this case established was appropriate under the circumstances of this resident. When the resident was monitored after the provision of oxygen at around 12:30 a.m., the resident was observed to be resting comfortably and not in distress.

45. Although AHCA's testimony describes assessments and monitoring which it contends should have been done or done more frequently, it did not establish any preponderant evidence that the care and services it contends were not provided, or were not provided frequently enough caused or were likely to cause death. AHCA in essence contends that some unspecified knowledge which might have been gleaned concerning the resident's condition from more frequent assessments or the institution of an oxygen saturation assessment or blood sugar assessment might have resulted in some provided care not specified in the evidence. That does not sufficiently address the fact, established by the DNR status and the Living Will and the physician's expert testimony, which is accepted, that any care which might have

been possible as a result of such additional unspecified knowledge, would not have made any difference or would have constituted "extraordinary measures," which the physician and the staff were not at liberty to provide. As established by Dr. Price, what occurred with the resident was clearly an "end of life event" and there was really nothing more that could have been done for the resident with her diagnoses, medical history, and medical condition.

- 46. Even if AHCA had established that there were care and services which should have been provided but were not and that professional nursing standards were not met, which last was partly true, at least, in terms of documentation deficiencies, no preponderant evidence was presented by AHCA that these deficiencies "caused or [were] likely to cause death or serious harm to the resident" as required by Section 400.23(8)(a), Florida Statutes.
- 47. The Agency has the burden of proof in this proceeding and the standards of proof may differ because of two sanctions being involved, a conditional license and the imposition of a fine for an alleged Class I deficiency. In the fine case the Agency must prove by clear and convincing evidence that the deficiencies existed. Department of Banking and Finance

 Division of Securities and Investor Protection v. Osborne Stearn and Co., supra. "Clear and convincing evidence" requires that

evidence:

. . . must be found to be credible, the facts to which the witnesses testified must be distinctly remembered, the testimony must be precise and explicit and the witnesses must be lacking confusion as to the fact in issue. The evidence must be of such a weight that it produces in the mind of the trier of fact a firm belief or conviction, without hesitancy, as to the truth of the allegations sought to be established.

Inquiry concerning Judge Davey, 645 So. 2d 398, 404 (Fla. 1994)
(quoting Slomowitz v. Walker, 429 So. 2d 77, 800 (Fla. 4th DCA
1983)).

- 48. The Agency must demonstrate by clear and convincing evidence both the existence of a violation and that the deficiency/violation is properly classified. <u>Id.</u>; <u>Agency for Health Care Administration v. Blue-Haven Retirement, Inc.</u>, DOAH Case No. 02-4170 (Final Order pending).
- 49. If the deficiency exists and it is a Class I deficiency, a fine is appropriate. A Class I deficiency is what has been alleged in this proceeding. If either one of these elements is not established by clear and convincing evidence, then the Agency cannot levy the fine. This issue is also raised in Beverly Enterprises, Inc.,-Eastbrooke v. Agency for Health Care Administration, 20 FALR 873, 880 (Final Order March 12, 1998) where the secretary found that the Agency has the burden of proof to show by the evidence that each of the allegations is

true in order to establish a deficiency.

50. Here the evidence presented, especially the testimony of the physician, which is accepted, establishes that Resident 14 died a natural death at the end of what the physician established was an "end of life" event, in accordance with the resident's right to choose that no extraordinary means be employed to prolong her life. The Agency did not prove, even by a preponderance of the evidence, a Class I deficiency within the meaning of Section 400.23(7)(b), Florida Statutes, which would authorize a conditional license, or any violation under Section 400.23(8), Florida Statutes, which would authorize an administrative fine. Therefore, the Agency has shown no basis for levying a fine or imposing a conditional license on Ruleme.

RECOMMENDATION

Based on the foregoing Findings of Fact, Conclusions of
Law, the evidence of record, the candor and demeanor of the
witnesses, and the pleadings and arguments of the parties, it
is, therefore,

RECOMMENDED that a final order be entered by the Agency for Health Care Administration, dismissing the Administrative Complaint and the notice and determining that the alleged violations have not been established.

DONE AND ENTERED this 17th day of June, 2005, in Tallahassee, Leon County, Florida.

S

P. MICHAEL RUFF
Administrative Law Judge
Division of Administrative Hearings
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Filed with the Clerk of the Division of Administrative Hearings this 17th day of June, 2005.

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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.