STATE OF FLORIDA
DIVISION OF ADMINISTRATIVE HEARINGS

TAMPA HEALTH CARE CENTER, Petitioner, vs. AGENCY FOR HEALTH CARE ADMINISTRATION, Respondent.	)	Case No. 01-0734

RECOMMENDED ORDER

A formal hearing was held in this case before Daniel M. Kilbride, Administrative Law Judge, Division of Administrative Hearings, on May 24, 2001, in Tampa, Florida.

APPEARANCES

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For Respondent: Patricia J. Hakes, Esquire
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STATEMENT OF THE ISSUES

Whether Petitioner was in violation of 42CFR 483.25(l)(1), 42CFR 483.60(d), Rules 59A-4.112(5) and 59A-4.1288, Florida Administrative Code, at the time of its annual survey in July 2000, and, if so, whether those violations were uncorrected at

the time of resurvey in September 2000, in order to justify the issuance of a Conditional licensure rating.

PRELIMINARY STATEMENT

The Agency for Health Care Administration (Respondent) conducted an annual survey on July 27, 2000, and a follow-up survey on September 5, 2000, of Petitioner's premises.

Based on these survey results, and pursuant to Subsection 400.23(7)(b), Florida Statutes, the facility was assigned a conditional licensure rating effective September 9, 2000, which continued until the facility's receipt of a standard license on December 1, 2000. The conditional rating was based on Respondent's determination that Petitioner had deficiencies in the first survey and uncorrected deficiencies in the second survey relating to (1) administration of unnecessary drugs, in that their use was not adequately monitored, and (2) failure to properly label drugs.

Petitioner filed a petition under Section 120.57, Florida Statutes, challenging the conditional license and this matter was referred to the Division of Administrative Hearings. Following discovery, a formal administrative hearing was held on May 24, 2001. At the hearing Respondent presented testimony from four witnesses, Barbara Bearden, R.N.; Katherine Benson, R.N.; Trish Gold, Health Facility Evaluator; and Marie Maisel, R.N., and offered two exhibits which were admitted in evidence.

Petitioner's witnesses were Pam Johnson, a pharmacist, and Cheryl Cobb-Tullos, R.N., and Petitioner's six exhibits were admitted into evidence. During the testimony of Maisel, Petitioner moved for the admission of the witness' deposition, dated May 14, 2001. Said motion was denied. Following the hearing, Petitioner filed a motion to submit deposition, dated August 6, 2001, seeking re-consideration of this tribunal's ruling at the hearing. Upon further consideration, pursuant to Section 90.803(18)(d), Florida Statutes, and Florida Rules of Civil Procedure 1.330 and 1.390; Lee v. Department of Health and Rehabilitation Services, 698 So. 2d 1194, 1200 (Fla. 1997); Costa v. School Board of Broward County, 701 So, 2d 414 (Fla. 4th DCA 1997), said motion is granted and the deposition of the witness, Marie Maisel, taken on May 14, 2001, is admitted in evidence.

A Transcript of the hearing was filed on June 6, 2001. The parties filed a motion for extension of time to file their post-hearing submittals. The motion was granted, and both parties filed Proposed Recommended Orders on August 6, 2001. Both parties' proposals have been give careful consideration in the preparation of this Recommended Order.

FINDINGS OF FACT

1. Tampa Health Care Center (Petitioner) is a licensed nursing home in Tampa, Florida.

2. Pursuant to Chapter 400, Florida Statutes, Respondent surveys Petitioner to determine whether it is in compliance with applicable laws and regulations. If there are deficiencies, it determines the level of deficiency. When Respondent conducts a survey of a nursing home, it issues a survey report, commonly called by its form number, a "2567." The particular regulation, and the allegedly deficient practices which constitute a violation of that regulation, are cited in a column on the left side of the paper. After receiving the 2567, the facility is required to develop a plan of correction which is put in the right hand column corresponding to the alleged deficiency. The facility is required to develop this plan regardless of whether it agrees that it is in violation of any regulations, and it is prohibited from being argumentative.

3. Respondent conducted its annual survey of Petitioner, ending July 27, 2000, and issued a 2567 survey report noting certain deficiencies. The deficiencies are designated as tag numbers. Among those noted were Tag F329, which is the shorthand reference to 42 C.F.R. Subsection 483.25 (1)(1), and Tag F431, which incorporates 42 C.F.R. Subsection 483.60(d). Respondent rated these deficiencies as Class III deficiencies.

4. Respondent conducted a follow-up survey on September 5, 2000, and determined that the deficiencies under tags F329 and

F431 were uncorrected, and, as a result, issued a Conditional rating to the facility.

5. On December 2000, Respondent conducted another follow-up survey and determined that all deficiencies had been corrected and therefore issued a Standard license to Petitioner effective that date.

6. The 2567 constitutes the charging document for purposes of issuing a Conditional license. No other document was offered to describe the offenses, or deficiencies, which resulted in imposition of the Conditional license. The parties stipulated at the hearing that Tags F329 and F431 were the only ones at issue in this proceeding.

7. In conducting its survey, Respondent uses a document developed by the Health Care Financing Administration (HCFA), called the State Operations Manual. It indicates guidance on how are to interpret regulations.

TAG F 329

8. The 2567 from the July survey asserts, under Tag F 329, that the facility "failed to monitor psychotropic medications for 5 of 5 sampled residents." The regulation states that residents are to be "free from unnecessary drugs," and elaborates that a drug given without adequate monitoring is considered unnecessary. The guidelines establish that monitoring is expected only for residents on psychotropic

medications. Therefore, for a violation to occur, there must first be a resident who is receiving psychotropic medications, and secondly, a lack of monitoring of the use of that drug.

9. Respondent alleged and put on evidence that certain residents (numbers 1, 9, 19, and 21) identified in the July survey did not have "behavior monitoring records" in their files. Specific forms are not mandatory, and evidence of monitoring can be documented elsewhere in a resident's clinical record. Monitoring can be documented in nurses' notes, and those notes were not thoroughly reviewed, as Respondent's surveyors only had limited time for the survey.

10. Respondent presented no evidence that Residents 9, 19, or 21 were receiving psychotropic medications.

11. Petitioner presented evidence of numerous systems in place to monitor residents, including those receiving psychotropic medications. Residents are given a complete clinical assessment within 24 hours of admission; there is then a 14-day more thorough observation and assessment process, culminating in the development of care plans which address particular issues and direct staff to care for residents in particular ways. Nurses regularly document issues or concerns in nurses notes; a physician visits the residents at least once a month, which, as all drugs are ordered by the physician, includes review of the resident's medication. If necessary, a

psychiatric evaluation is completed. Once a week a transdisciplinary team meets to discuss any residents "at risk," which includes those receiving psychotropic medications.

12. Additionally, a consultant pharmacist reviews all residents' medications once a month. This review is to determine how well the resident is doing on the drug regimen. It includes reviewing nurses' notes, physicians' notes, the medication administration record, the record of dosages taken on an "as needed" basis, and discussions with nursing staff. The pharmacist reviews whether there are medications administered in excessive doses, in excessive duration, without adequate monitoring, without adequate indications for use, or in the presence of adverse consequences.

13. With regard to the September survey, Respondent alleged in the Form 2567 that "Residents numbers 3, 4, 9, 11, and 13 lacked Behavior Monitoring Forms in their records" and that all were on psychotropic medications which required monitoring. Respondent presented the testimony of Barbara Bearden who stated that Residents 3 and 4 were on psychotropic medications, and that there were no behavior monitoring forms. With regard to Resident 4, Respondent asserted that there was no assessment of behaviors in any records after August 14. Bearden acknowledged that both Residents 3 and 4 received reasonable doses, and that there was no reason to believe the level of

medication was too high. Respondent's witness also asserted that there was no "AIMS" assessments, no initial assessment, and no indication of the reason for or effectiveness of the medications. These matters were not alleged in the charging document, which only asserted the lack of behavior monitoring forms. During her testimony, Respondent's witness acknowledged that there was no standard to determine how often there should be behavior monitoring.

14. Marie Maisel testified for Respondent regarding Residents 9, 11, and 13. With regard to Resident 9, she testified that the resident received Restoril, a sleeping medication, and also Zoloft, an anti-depressant, and that there was no "systematic behavior monitoring." Sleeping medications do not require behavior monitoring, according to the State Operations Manual, and at deposition, the surveyor indicated that the only medication the resident received was Restoril. Petitioner therefore had no notice of the additional allegation regarding Zoloft and this fact cannot be considered.

15. With regard to Resident 11, Maisel testified that the resident received Risperdal, a psychotropic medication, and that, in her opinion, the behavior monitoring was not adequate.

16. At hearing the surveyor testified that Resident 13 was receiving Haldol and there was no systemic behavior monitoring. However, the witness acknowledged that when her deposition was

taken, she did not know why Resident 13 had been cited. Petitioner therefore had no notice of these allegations regarding Resident 13.

17. Petitioner presented evidence, including excerpts from the resident's clinical record, that Resident 3 had been assessed for drug use, and that behaviors were monitored. The resident had been admitted less than three weeks before the September survey, which means that an initial assessment had been performed, as well as the complete 14-day assessment, just prior to survey. Respondent admitted that it would be inappropriate to reduce medication soon after admission. There was a care plan which addressed the resident's use of Risperdal, and another which addressed the resident's ability to function with the activities of daily living. These care plans directed staff to monitor the resident's condition and behavior. Numerous nursing notes documented the resident's condition and behaviors.

18. Resident 3 was not noted in the pharmacist's monthly report, meaning the review revealed no problems with medications. Furthermore, the resident's medications were significantly reduced while in Petitioner's care, and her condition improved dramatically, from being nearly comatose, to being alert and oriented, and needing only limited assistance with mobility.

19. Resident 4 had been admitted just a month before the survey and had also just undergone an extensive assessment process. Her medications were also reduced from those she had been receiving on admission, and nurses notes clearly documented her condition and behaviors throughout the period up to the survey. These notes document not only the monitoring of behaviors, but the reason and need for the medication, as she exhibited combative behaviors. Resident 4 also did not appear on the pharmacist's report.

20. With regard to Resident 9, Petitioner presented evidence that there was a care plan specifically addressing the resident's use of Zoloft, that there were other care plans which addressed behaviors and condition which required that the resident be monitored, and that there was periodic consideration of reductions. Resident 9 did appear on the pharmacist's report, suggesting consideration of a reduction in dosage; thus demonstrating the effectiveness of the system.

21. Resident 11 had a care plan addressing her use of Risperdal, which required monitoring and other interventions. Monthly nursing summaries reflected that she was monitored, as did nursing notes. Generally, nurses notes indicate when there are problems or unusual occurrences, not when everything is routine.

22. Petitioner also presented evidence with regard to Resident 13's use of Haldol, which showed the reason for its use (wandering, verbal abusiveness), numerous efforts to reduce the dosage, review by the pharmacist, a care plan to address its use, which required monitoring, and monthly summaries summarizing her condition and behaviors.

23. Respondent presented sufficient evidence to show that Residents 3, 4, 9, 11, and 13, cited in the September survey, were appropriately monitored and were not receiving unnecessary drugs.

TAG F431

24. Respondent charged in the September 2000 survey that several insulin vials in the medication room were not marked with the date they were opened. The regulation under Tag F431, 42 C.F.R. Subsection 483.60(d), requires that drugs be labeled "in accordance with currently accepted professional principles" and "the expiration date when applicable." The surveyor guidelines indicate that the critical elements of labeling are the name of the drug and its strength. Additionally, the guidelines advise that drugs approved by the Federal Drug Administration (F.D.A.) must have expiration dates on the manufacturer's container.

25. Respondent's witness acknowledged that all insulin had the manufacturer's expiration date. Although there is a chance

of contamination after opening a vial of insulin, it was acknowledged that it is customary to have a policy allowing use for six months after opening.

26. Petitioner has a policy of discarding insulin 60 days after opening. While it is customary to write the opening date on the vial, a failure to do so will only reduce the amount of time it can be used, because of other systems in place. The pharmacy which dispenses the insulin puts a dispensing date on it, and the pharmacist reviews, monthly, stored medications. Within every three months, all medications are checked, and if there is no date of opening, the pharmacist looks to the dispensing date. If the vial was dispensed more than 60 days prior, it is given to the nurse for discarding. Instead of being able to be used for six months beyond the date opened, the medication is discarded sixty days, or at most ninety days, after it was dispensed.

27. Writing the date opened on the vial is not an item encompassed by the regulation as explicated in the guidelines. Furthermore, there is no potential for harm, as there are redundant systems in place.

CONCLUSIONS OF LAW

28. The Division of Administrative Hearings has jurisdiction over the parties and subject matter of this cause,

pursuant to Section 120.569 and Subsection 120.57(1), Florida Statutes.

29. Subsection 120.569(1), Florida Statutes, applies to all proceedings in which the substantial interests of a party are determined by an agency. Subsection 120.57(1), Florida Statutes, applies in those proceedings involving disputed issues of material fact.

30. A facility is substantially affected by a conditional rating and/or an administrative fine. For example, Section 408.35, Florida Statutes, governing certificates of need, provides that an applicant's ability and record of providing quality of care are among the criteria for competitive review. Additionally, a facility cannot for the Gold Seal program if it has had a conditional rating within the previous thirty months, Section 400.235, Florida Statutes. A conditional rating can substantially affect the reputation of a facility in the community and have a negative impact on staff morale and recruiting. See Spanish Gardens Nursing & Convalescent Center (Beverly Health & Rehab Svcs., Inc.) v. Agency for Health Care Administration, 21 FALR 132 (AHCA, 1998).

31. Respondent is authorized to license nursing home facilities in the State of Florida, and pursuant to Chapter 400, Part II, Florida Statutes, is required Respondent to "at least every 15 months, evaluate all nursing home facilities and make a

determination as to the degree of compliance . . ." Respondent's evaluation must be based on the most recent inspection report, taking into consideration findings from other official reports, surveys, interviews, investigations and inspections. It must assign either a standard or conditional licensure rating to each facility after it is surveyed. Subsection 400.23(7)(b), Florida Statutes.

32. Subsection 400.23(7)(b), Florida States (Supp. 2000), provides:

> "[C]onditional 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, . . . If the facility comes into substantial compliance at the time of the follow-up survey, a standard licensure status may be assigned."

33. Subsection 400.23(8)(c), Florida Statutes (Supp. 2000), provides:

> "Class III deficiencies are those which Respondent determines to have an indirect or potential relationship to the health, safety or security of nursing home facility residents, other than class I and class II deficiencies. A class III deficiency shall be subject to a civil penalty . . . for each and every deficiency. . . ."

34. Conditional licensure is authorized by law for facilities with class III deficiencies which are not corrected. Subsection 400.23(7)(b), Florida Statutes.

35. Tag 329 incorporates:

> (a) 42 C.F.R. 483.25(l)(1) which states that each resident's drug regimen must be free from unnecessary drugs. An unnecessary drug is any drug when used: . . . (iii) without adequate monitoring.
> (b) Rule 59A-4.1288, Florida Administrative Code, which requires that nursing homes which participate in Title XVIII or XIX must follow 42 C.F.R. 483.

36. Tag 431 incorporates:

> (a) 42 C.F.R. 483.60(d) which requires that drug and biologicals used in the facility must be labeled in accordance with currently accepted professional principles.
>
> (b) Rule 59A-4.112(5), Florida Administrative Code, which requires that drugs and biologicals be labeled in accordance with currently accepted professional principles.
>
> (c) Rule 59A-4.1288, Florida Administrative Code, which requires that nursing homes which participate in Title XVIII or XIX must follow 42 C.F.R. 483.

37. Respondent has the burden of proving by a preponderance of the evidence the basis of changing Petitioner's licensure rating to Conditional and the basis for imposing an administrative fine. 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).

38. In the instant case, Respondent alleges that it was proper to issue Petitioner a Conditional licensure on September 5, 2000, because Class III deficiencies cited in the July survey were allegedly uncorrected at the time of the September survey. Under Section 400.23, Florida Statutes, a Conditional license can be imposed for Class III deficiencies only if they are not corrected within the time frame established by Respondent. Accordingly, it is Respondent's burden to establish by at least a preponderance of evidence the existence of the deficiencies cited by the surveys of both July and September 2000.

39. The only charges made by Respondent under Tag F329 relate to adequate monitoring and the absence of certain forms which could be used to monitor residents' behavior. However, there was agreement that use of these forms is not required by the regulation, and there was also a lack of evidence about what monitoring is "adequate." In the light of evidence presented by Petitioner that various systems existed to ensure that residents were monitored and that the particular residents noted in the September survey had considerable documentation of monitoring, Respondent failed to demonstrate a violation of this regulation.

40. Respondent's assertion that Petitioner did not fulfill its "plan of correction" to the July survey is without probative value of the underlying question of whether Petitioner complied with the regulation. The evidence was unrefuted that Petitioner had no choice, even if it disagreed with the assertions, about submitting a plan of correction to address the allegations.

41. Petitioner is entitled to a succinct and understandable statement of the charges. See Cottrill v. Department of Insurance, 685 So. 2d 1371, 1372 (Fla. 1st DCA 1996). As the charges are made through the 2567, the allegations of that document are what must be proven, and what Petitioner is required to defend. Though details may be filled in through discovery, if those details are withheld in discovery, they may not be added at hearing. This is relevant to the allegations regarding Residents 9 and 13 from the September survey. The charging document stated only that they "lacked Behavior Monitoring Forms in their records" and received psychotropic medications. The type of medication was not named.

At deposition, Respondent offered the information that Resident 9 received only a sleeping pill, not covered by the regulation, and that it was not known why Resident 13 had been cited. There was an agreement between counsel that this witness' deposition would be used in lieu of live testimony, yet Petitioner presented the witness at hearing, and at hearing she

added previously undisclosed information regarding those two residents. That information, presented at hearing without prior notice in spite of Petitioner's efforts to obtain it, cannot be used to support Respondent's charges in this case. Respondent bears the responsibility for identifying the specific grounds for the proposed agency action. Agency for Health Care Administration v. Beverly Health and Rehabilitation Center-Coral Trace, 22 FALR 673 (AHCA 1999). It cannot, consistent with the Administrative Procedures Act and fundamental due process, fail to provide specifics in the charging document, withhold them during discovery, and then produce them at hearing.

42. Respondent charges, under Tag F431 in the September survey, that Petitioner violated this regulation because "opened insulin vials were not dated with the date opened." This allegation does not state a violation of the regulation as it is written. Furthermore, the guidance given to surveyors does not suggest this as a requirement, requiring only manufacturer's expiration dates for F.D.A. approved drugs.

43. Additionally, there is no potential for any harm if a vial is not labeled on the date opened, as the only result is discarding the insulin sooner rather than later, based on the date of dispensation. The law, Section 400.23, Florida Statutes, requires that a nursing home be in substantial compliance. Federal Regulations, adopted in Florida through the

same statute, Section 400.23, Florida Statutes, define minor deficiencies, with which a facility remains in substantial compliance, as those with "no greater risk to resident health or safety than the potential for causing minimal harm," 42 C.F.R. Section 488.301. Though the use of contaminated insulin could obviously cause harm, this is not the question. The issue is whether the failure to put an opening date on the vial has potential, other than the most speculative and conjectural, to result in harm from use of contaminated insulin. See discussion of foreseeability in Washington Manor v. AHCA, DOAH Case Nos. 00-4035 and 4735, Recommended Order, dated May 7, 2001, p. 33. There is no reasonably foreseeable harm from the failure to document insulin with date of opening; therefore, even if this were required by the regulation, a failure to do so does not equate to lack of substantial compliance. Respondent failed to demonstrate that Petitioner was not in substantial compliance with this regulation.

RECOMMENDATION

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

RECOMMENDED that the Director of the Agency for Health Care Administration enter a final order revising the July 27 and September 5, 2000, survey reports by deleting the deficiencies described under Tags F329 and F431, and issuing a Standard

rating to Respondent to replace the previously issued Conditional rating.

DONE AND ENTERED this 22nd day of August, 2001, in Tallahassee, Leon County, Florida.

DANIEL M. KILBRIDE
Administrative Law Judge
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Filed with the Clerk of the
Division of Administrative Hearings
this 22nd day of August, 2001.

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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.