## **Department of Health and Human Services**

### DEPARTMENTAL APPEALS BOARD

#### **Civil Remedies Division**

Oaks of Mid City Nursing and Rehabilitation Center (CCN: 19-5368),

#### Petitioner

v.

Centers for Medicare and Medicaid Services.

Docket No. C-10-695

Decision No. CR2254

Date: September 29, 2010

### **DECISION**

At the heart of this case lies an appalling dereliction of responsibility by Petitioner, Oaks of Mid City Nursing and Rehabilitation Center. Petitioner, a skilled nursing facility that participates in the Medicare program, admitted an individual who I refer to as Resident # 2 with the implicit promise that it would provide her with care that satisfied Medicare participation requirements and complied with professionally recognized standards of nursing care. But, Petitioner and its staff failed to provide the most basic care to Resident # 2, an insulin dependent diabetic who suffered from other serious problems as well. Most notably, the staff failed to test the resident's blood sugar to assess the effects of insulin on her. They failed to do so even after they knew that the resident was prone to suffering from episodes of life-threatening low blood sugar.

The Centers for Medicare and Medicaid Services (CMS) determined to terminate Petitioner's participation in the Medicare program, based on Petitioner's noncompliance with Medicare participation requirements, and to impose other remedies as well. The evidence overwhelmingly supports CMS's determination to terminate Petitioner's participation, and I sustain that determination. It also supports my sustaining additional

remedies consisting of three per-instance civil money penalties of \$3,500, \$3,500 and \$3,000.

## I. Background

Petitioner does business in the State of Louisiana. Its participation in Medicare is governed by sections 1819 and 1866 of the Social Security Act (Act) and by implementing regulations at 42 C.F.R. Parts 483 and 488. Its hearing rights in this case are governed by regulations at 42 C.F.R. Part 498.

Petitioner filed a hearing request (actually, three hearing requests), and the case was assigned to me for a hearing and a decision. I held an in-person hearing in Baton Rouge, Louisiana on August 11, 2010. At the hearing, I received exhibits from CMS that are identified as CMS Ex. 24 – CMS Ex. 35, CMS Ex. 37 – CMS Ex. 38, CMS Ex. 40, CMS Ex. 42, CMS Ex. 46, and CMS Ex. 48 – CMS Ex. 50. I received exhibits from Petitioner that are identified as P. Ex. 1 – P. Ex. 6, P. Ex. 10, P. Ex. 12 – P. Ex. 13, P. Ex. 15, P. Ex. 17 – P. Ex. 19, P. Ex. 21, and P. Ex. 23 – P. Ex. 24. I heard the cross examination of several of CMS's witnesses whose written direct testimony is in evidence in the form of statements made under oath.

## II. Issues, Findings of Fact, and Conclusions of Law

### A. Issues

The issues are whether:

- 1. Petitioner failed to comply substantially with Medicare participation requirements;
- 2. CMS's determination to terminate Petitioner's participation in Medicare is authorized by law; and
- 3. CMS's civil money penalty determinations are reasonable.

## **B.** Findings of Fact and Conclusions of Law

The findings of noncompliance that I address in this decision were made at a survey of Petitioner's facility that took place on March 5, 2010 (March 5 Survey). There was a previous survey that was conducted on February 4, 2010 (February 4 Survey). Prior to the hearing, I ruled the February 4 Survey findings to be irrelevant for two reasons. First, because CMS did not impose any remedies against Petitioner that are based on the February 4 Survey noncompliance findings. Second, because the noncompliance

findings made at the March 5 Survey are, if sustained, sufficient to justify all of the remedy determinations that CMS made.

I make the following findings of fact and conclusions of law (Findings).

# 1. Petitioner failed to comply substantially with the requirements of 42 C.F.R. § 483.25.

A skilled nursing facility must ensure that each of its residents receives the necessary care and services to attain or maintain his or her highest practicable physical, mental, and psychosocial well-being, in accordance with the resident's comprehensive assessment and plan of care. 42 C.F.R. § 483.25. The meaning of the regulation could not be plainer. A skilled nursing facility's duty to each of its residents includes doing whatever is necessary and within reason to assure that the resident's medical problems are addressed and, if possible, resolved. Services provided to residents must comport with professionally recognized standards of nursing care.

Petitioner failed to comply with this requirement in providing care to Resident # 2. Petitioner's staff failed to clarify gaps and ambiguities in the resident's physician's orders, and they failed to provide the resident with care that was critical to protecting her from life threatening medical complications. Most egregiously, the staff failed to monitor the resident's blood glucose levels even after it became apparent that the resident was suffering from potentially life threatening episodes of hypoglycemia. Without such monitoring, Petitioner's staff had no way of knowing whether the resident's blood glucose levels were abnormally elevated, depressed, or fluctuating dangerously, and had no way of knowing whether, and how, to protect the resident against these possibilities.

The failures by Petitioner's staff to obtain clear instructions from Resident # 2's physician concerning monitoring of her blood glucose level and to monitor the resident's blood glucose level put the resident at grave risk for adverse consequences. The evidence overwhelmingly proves that this was a resident with labile blood sugar who was in great danger. Petitioner's staff knew – or should have known – about the risk that the resident faced. Yet, the staff failed completely to take even simple measures to protect her.

Resident # 2 was admitted to Petitioner's facility from a local hospital on February 4, 2010. At the time of her admission, the resident was relatively young, aged 58, but she was gravely ill. The resident suffered from more than one potentially life threatening illness including: end stage renal failure for which she received kidney dialysis; chronic obstructive pulmonary disease; and insulin dependent diabetes. CMS Ex. 28 at 1, 8.

The resident was admitted with physician's orders that were ambiguous in some respects and inconsistent, or simply confusing, in others. The document that contains these orders is a Statement of Medical Status form (SMS). CMS Ex. 28 at 139-40. Petitioner argues

that the document does not contain a physician's orders, because it is allegedly not headed with the caption "physician's orders." But that argument ducks the reality that the document states a physician's instructions for treating Resident # 2 and is signed in more than one place by a physician. *Id.* Petitioner's argument is also wrong as a matter of fact, because the SMS actually contains a statement that it is a physician admission and order form. *Id.* at 140. Furthermore, the credible and unrebutted testimony of Debra Franklin, one of the surveyors who participated in the March 5 Survey, is that Petitioner treated the SMS as containing a physician's orders. Tr. at 113-15.

The SMS contains a form completed by the resident's physician in which a box entitled "Glucose Monitoring" was checked. CMS Ex. 28 at 139. I infer from this information that the resident's physician intended that Petitioner's staff would monitor the resident's blood glucose level. Although there is no formal order telling the staff to monitor the resident's blood glucose level, any reasonable facility staff would interpret that statement as calling for monitoring to occur. Moreover, and as I discuss below, the professionally recognized standards of care governing skilled nursing facilities require that a resident such as Resident # 2 have her blood glucose level monitored.

The form is, however, ambiguous in that it does not give Petitioner's staff explicit instructions concerning blood glucose level monitoring. It does not tell Petitioner's staff how frequently, or at what times of the day, to monitor the resident's blood glucose level, nor does it tell the staff for how long such monitoring should continue. Nor does the SMS contain any instructions telling the staff what to do in the event that the resident's blood sugar became abnormally low or high.

Petitioner's staff should have sought clarification of this order. They did not. They did not contact the physician who signed the SMS to ask for clarification. Nor did they consult with Petitioner's medical director to determine whether, and how, this order should be clarified.

Failure by Petitioner's staff to obtain precise directions concerning glucose monitoring for Resident # 2 deprived the resident of care that was necessary to treat her diabetes. The professionally recognized standard of nursing care governing diabetic residents who are admitted to a skilled nursing facility requires that these individuals have their blood glucose level monitored regularly. Tr. at 159-60. It was *critically important* that the staff have – and that it followed – precise directions to monitor Resident # 2's blood glucose level. Without such directions, the staff was without guidance as to how often, and under what circumstances, to perform blood glucose monitoring. Failure to monitor the resident's blood glucose rigorously would put the resident at risk of developing potentially life-threatening hypo- or hyperglycemia.

In the credible words of Dr. Larry Johnson, an expert physician, who testified on behalf of CMS:

The standard of care is when a patient is newly admitted to the nursing home, you must follow their blood sugars scrupulously. You don't - - you cannot be sure, even though they came from the hospital and their blood sugars appeared to be normal, what will happen when they enter long-term care. So the standard of care is once they enter your facility, you start from the belief that we must prove the patient is stable before we then cut back the number of finger sticks, and it's demonstrated that the patient is truly stable.

Tr. at 165-66. Why was it so important that the resident's blood glucose level be stable? Because blood sugar that is too high or too low could endanger her life. For example, hypoglycemia (low blood sugar) is associated with seizures, loss of consciousness, brain damage, and death. Tr. at 162.

Not only did the staff fail to seek clarification about how and when to monitor the resident's blood glucose level, but they failed to conduct any meaningful systematic blood glucose level monitoring in violation of Petitioner's own internal policy governing care of diabetic residents. That policy directed the staff to monitor the blood glucose levels of diabetic residents to prevent the development of complications. CMS Ex. 28 at 141, 143; *see* CMS Ex. 37 at 8. The staff checked the resident's blood glucose on February 4 and 5, 2010, the first two dates of the resident's stay at the facility. CMS Ex. 28 at 113. Each of these readings showed that the resident's blood sugar was above the normal blood glucose level of 70-100 mg/dl. *Id.*; CMS Ex. 50 at 2. On February 6, 2010, the third day of the resident's stay, the staff checked the resident's blood glucose level and found that it had dropped to a level that is consistent with hypoglycemia. CMS Ex. 28 at 135; Tr. at 106. The staff treated the resident's low blood sugar by giving her sweets. CMS Ex. 28 at 135. The staff did not consult with the resident's physician concerning the decline in blood glucose level nor did they investigate the reasons for the sudden drop.

The staff thus knew no later than February 6, 2010 that Resident # 2 had a labile blood glucose level and that she was prone to developing hypoglycemia that could be life threatening if not detected and treated effectively. In a shockingly blatant violation of standards of nursing care and Petitioner's own policy, the staff failed completely to monitor and document the resident's blood glucose level after the episode of February 6. CMS Ex. 28 at 141, 143; CMS Ex. 37 at 8. No blood glucose readings were taken of Resident # 2 during the ten following days, and, during that period, Petitioner's staff never discussed the resident's fluctuating blood glucose level with a physician. The staff had no way of knowing whether the resident's blood sugar was dangerously low or high. Tr. at 164-65. The staff continued to administer insulin to the resident without assessing

whether the insulin was effective in controlling the resident's blood sugar, or whether the insulin was producing adverse or even potentially lethal effects.

On February 17, 2010, Resident # 2 was found by Petitioner's staff to be unresponsive to touch and verbal stimuli. CMS Ex. 28 at 131. The staff checked the resident's blood glucose level and obtained a reading of 24 mg/dl, a potentially lethal level of hypoglycemia. *Id.* The resident was given orange juice with sugar in it. A few minutes afterward, the resident's blood glucose level was again checked, and, although it had improved marginally, the resident remained dangerously hypoglycemic. *Id.* The resident's physician then ordered that the resident be transferred to the local emergency room. The resident was revived at the hospital. During her stay, she complained to a hospital physician that neither her blood sugar nor blood pressure was monitored at Petitioner's facility. *Id.* at 55.

Resident # 2 was discharged from the hospital back to Petitioner's facility on March 1, 2010. CMS Ex. 28 at 3. Once again, no specific orders were given to monitor the resident's blood glucose level, and, once again, Petitioner's staff failed to request clarification from the resident's physician. P. Ex. 3 at 35.

As of March 1, 2010, Petitioner's staff was not only aware that Resident # 2 was prone to becoming hypoglycemic, they knew that the resident had experienced hypoglycemia that could have caused her death. Incredibly, the staff continued not to monitor the resident's blood glucose level and thus continued to violate professionally recognized standards of care and Petitioner's policy. No readings were made on March 1.

On March 2, 2010, the day after the resident returned to the facility, she showed neurological signs consistent with hypoglycemia. CMS Ex. 28 at 127. These signs prompted the staff to check the resident's blood sugar, and the resident was found to be dangerously hypoglycemic with a reading of 32 mg/dl. *Id.* The staff attempted to reverse the hypoglycemia, but, shortly afterwards, the resident became unresponsive and her blood sugar dropped to a lethal reading of 10 mg/dl. *Id.* The resident was then transferred to the emergency room, where she was pronounced dead.

The staff's failures to protect Resident # 2 from the adverse consequences of her diabetes, and from unmonitored administration of insulin, were not the only failures by Petitioner to provide the resident with care that met professionally recognized standards. Petitioner's staff also failed to clarify admission orders concerning the nutrition that Resident # 2 was to receive, failed to assess and monitor the resident's nutritional status, and failed to adjust the resident's diet, when it became evident that the resident was not only eating poorly but that she rejected the diet that she had been given. This failure is significant, if for no other reason, because giving the resident a controlled diet was necessary to managing her labile blood glucose level.

Petitioner's failure to clarify orders concerning the resident's nutritional regime, to monitor and assess the resident's eating behavior and her intake and output, to adjust her diet in order to encourage her to eat more, and to consult with the resident's nephrologist about her diet, all put the resident at great risk for harm. As was attested to by Dr. Johnson:

The facility's failure to monitor Resident # 2's meal consumption was a perfect storm of multiple missed opportunities to provide adequate nutrition to Resident # 2 given her multiple diagnoses and receipt of long-acting insulin. Taking insulin without having proper nutrition increases the risk of hypoglycemic episodes as insulin extracts sugar in the blood. When diabetic patients, including those receiving long-acting insulin, eat poorly, that information must be communicated to the nursing staff, the dietician, and the physician to reduce the risks of hypoglycemia. In addition, nutrition alternatives must be offered to the patient and recorded as intake. The facility failed to adequately assess, monitor and address Resident # 2's poor appetite.

#### CMS Ex. 50 at 3.

There was a negative synergy between Petitioner's failure to monitor Resident # 2's blood glucose level and its failure to address her nutritional needs. This resident was an obvious candidate for life threatening consequences of hypoglycemia. That risk was exacerbated by Petitioner's failure to address the resident's nutritional problems, even while its staff was administering regular doses of long-acting insulin to her. And, it was made even greater by the fact that the staff did not make any effort to monitor the resident's blood glucose level, even after the resident had experienced hypoglycemia.

On her admission to Petitioner's facility on February 4, 2010, Resident # 2 had orders that she receive a 2,200 calorie American Diabetic Association diet, consisting of pureed food. CMS Ex. 28 at 108, 111. These orders also made reference to feeding the resident via a PEG tube. *Id.* at 111. I take notice that a PEG tube is a mechanism that enables feeding an individual through a tube that is inserted directly into the resident's digestive tract. However, the SMS made no reference to feeding the resident by mouth. Rather, it only contained a physician's order that the resident receive food via a PEG tube at 200 cc's per hour. *Id.* at 140.

The tube feeding instructions contained an obvious error. The quantity of food that was ordered administered by PEG tube greatly exceeded that which Resident # 2 would have been able to tolerate. Tr. at 172-73. An experienced nurse should have noticed the error and sought clarification of the order from the physician who issued it. *Id.* No one on Petitioner's staff sought immediate clarification of this order.

The errors and ambiguities in the resident's nutrition orders were compounded by the instructions that Petitioner gave its own staff for feeding Resident # 2. The staff was instructed that the resident be fed by "PEG – nothing by mouth" even though the resident had been prescribed a 2,200 calorie diet of pureed food. CMS Ex. 28 at 120. The staff evidently disregarded this instruction without attempting to reconcile it with conflicting instructions.

Petitioner's staff did notice, at least during the early part of Resident # 2's stay, that the resident was eating poorly. The resident complained to Petitioner's staff that she did not like pureed food. On February 8, 2010, the staff sent a fax to the resident's treating physician telling him that the resident was a dialysis patient and that she had been eating "very poor since admission." CMS Ex. 28 at 106. The fax contained the statement: "New tube feeding order to supplement diet please," which, I infer, was a request for a tube feeding order to replace that with which the resident had been admitted. The fax also requested the physician to "please advise." *Id.* The physician responded by instructing Petitioner's staff to contact the resident's nephrologist for orders concerning tube feeding the resident.

There is no evidence that Petitioner's staff actually consulted with the nephrologist. The resident visited a nephrologist on February 9, 2010, while receiving dialysis, but there is no evidence that this visit was the product of, or prompted, a consultation between the nephrologist and Petitioner's staff or with Petitioner's medical director. Tr. at 177. Petitioner's staff did not document whether the resident actually was fed by PEG tube, and they did not document that they monitored the resident's food consumption. The record is, in fact, devoid of evidence of any ongoing systematic assessment by Petitioner's staff of the resident's nutritional status.

Furthermore, Petitioner's staff failed to comply with instructions that it monitor Resident # 2's intake of food and fluids and output of waste. The staff was specifically instructed to monitor intake and output. CMS Ex. 28 at 120. No monitoring was done aside from monitoring on two shifts on February 4, 2010, the date of the resident's admission to the facility. *Id.* at 112. The staff not only contravened the instructions that they had been given, but they violated Petitioner's policy requiring measurement of intake and output of a resident such as Resident # 2, an individual whose meal consumption needed to be assessed on an ongoing basis. CMS Ex. 37 at 9; CMS Ex. 50 at 3.

Petitioner did not offer evidence to challenge directly the facts that establish its noncompliance. It did not offer any evidence showing that its staff sought clarification of the physician's orders for Resident # 2 or that the staff routinely monitored the resident's blood glucose level. Nor did it offer proof establishing that it addressed the resident's nutritional problems or that it monitored the resident's intake and output. It did not explicitly deny that the staff's failure to monitor the resident's blood glucose level, and the resident's intake and output, directly contravened Petitioner's own policies.

Instead, Petitioner sought to: disparage the opinion of CMS's expert; make claims that unique standards of care applicable in Louisiana excused its treatment of Resident # 2; and contend that it is not liable for noncompliance, because nothing it did, or failed to do, actually harmed the resident. I find these defenses, individually and collectively, to be without merit.

Petitioner attacks the credentials and credibility of CMS's expert physician, Dr. Johnson, by asserting that he is not licensed to practice in Louisiana and that he does not have experience as a medical director of a skilled nursing facility in that State. Petitioner's Post-Hearing Brief at 13-15. Petitioner argues that, to be truly expert in discussing nursing care in Louisiana, one must be intimately familiar with what Petitioner contends are standards of nursing care that apply uniquely to that State. I find unpersuasive this challenge to Dr. Johnson's credentials and credibility. Dr. Johnson is eminently qualified to testify about the issues he addressed in this case. He is an associate professor of geriatric medicine at the University of Arkansas, he is a diplomate of the American Board of Family Medicine with additional credentials in geriatric medicine, and he is the medical director of a skilled nursing facility. CMS Ex. 49 at 1.

I am not persuaded by Petitioner's argument that there are some unique "Louisiana" standards of care or legal requirements governing care provided in Louisiana nursing facilities that differentiate that State from the remainder of the United States and which insulate Petitioner from being held to be noncompliant with Medicare participation requirements. First, and contrary to Petitioner's contentions, this case is not about the allegedly unique nursing standards that apply in the State of Louisiana. Medicare is not a State program. It is a federal program, and the standards it expects that participating providers adhere to are universally recognized standards of care. Dr. Johnson made it absolutely clear in his testimony that the standards of care that he identified – and that he concluded Petitioner had contravened – were universally applicable.

Moreover, Petitioner offered no persuasive evidence to support its claims that there are unique "Louisiana" standards of care or laws governing nursing care that apply to the issues in this case. In particular, I find no evidentiary support for Petitioner's contention that, in Louisiana, a nurse must have an explicit physician's order before testing a patient's blood glucose level.

Petitioner asserts, "Dr. Johnson's expectation that nurses in a Louisiana nursing home setting 'can do a finger stick at any time she feels that it is important to the care of patient' is not only incorrect but illegal and may subject him to sanctions by the Louisiana State Board of Medical Examiners." Petitioner's Post-Hearing Brief at 14 (citations to Dr. Johnson's hearing testimony omitted). Petitioner cites to no legal authority whatsoever to support its contention that Louisiana law prohibits nurses from

monitoring blood glucose levels on their own volition, when circumstances require that it be done.

Petitioner asserts additionally, relying on the testimony of its expert physician, Dr. Charles A. Cefalu, that, apart from what the law may require, the applicable standard of care "in Louisiana" is that nursing home staff do not routinely check a diabetic resident's blood glucose level absent an order from the resident's attending physician to do so. P. Ex. 2 at 2. I find this assertion not to be credible. Petitioner has offered me nothing concrete aside from Dr. Cefalu's unsupported opinion to prove that Louisiana's allegedly unique nursing standards would prohibit a nurse from checking a resident's blood sugar on his or her own volition. The assertion is also not credible in light of the fact that glucose level testing kits are commonly available in most pharmacies as over-the-counter items. I take notice that many diabetics routinely check their own blood glucose level. Tr. at 85-86. It strikes me as bizarre that a nurse could not do for a patient what a patient may do on his or her own behalf. Moreover, Dr. Cefalu's assertion is belied by the fact that Petitioner's staff did check Resident # 2's blood glucose level on several occasions. Petitioner has not explained why the staff would have done this if nursing standards or Louisiana law actually prohibited them from doing so in the absence of an express physician's order.

The better explanation is that no such prohibition exists. The weight of the evidence supports a conclusion that in Louisiana, as elsewhere, a nurse may check a patient's blood glucose level without a specific physician's order for blood glucose monitoring. Tr. at 83-84; 123-24.

But, Dr. Cefalu's testimony – even assuming it to be true – does not provide a defense to Petitioner. Routine blood glucose level testing was mandated by the resident's condition. Petitioner cannot hide behind the argument that there was no express order for such testing. If the staff labored under the impression that they could not monitor the resident's blood glucose without a physician's order that they do so, then they should have obtained that order.

Furthermore, and as I discuss in more detail above, it is plain that Dr. Brust, the physician who discharged Resident # 2 to Petitioner's facility, assumed that the staff would perform routine blood glucose testing. That is the only reasonable inference that I can draw from the physician's checking a box on the SMS referring to glucose monitoring. CMS Ex. 28 at 139.

I note also that Dr. Cefalu hedges his testimony by stating that routine blood glucose testing should not be done without a physician's order "unless an acute episode of hypoglycemia is suspected and as represented by clinical symptoms of the resident." P. Ex. 2 at 3. In fact, that, or something very much like that involving Resident # 2, occurred on February 6, 2010. Yet, that event not only prompted no effort by Petitioner's

staff to clarify the orders concerning Resident # 2, but it was followed by the staff's total disregard of the resident's blood glucose level and the possibility that the resident's labile blood sugar might be endangering her.

Dr. Cefalu and Petitioner also seek to make an issue of the fact that the resident's blood glucose level, arguably, was not closely monitored during the resident's hospital stays. P. Ex. 2 at 3. Their theory is that Petitioner should not be accountable for failing to monitor the resident's blood glucose level, if other institutions engage in similar misfeasance. I disagree. Petitioner's failure to discharge its obligations to the resident is not excused by the possible misfeasance of other entities. Inadequate care by a hospital – assuming that occurred – is no justification for inadequate care by Petitioner. Tr. at 185.

Petitioner argues as a primary defense that it should be held blameless for the care that it gave to Resident # 2 on the ground that there is no proof that the care that its staff gave to the resident – or rather, as is demonstrated graphically by the evidence in this case, the staff failed to give – actually harmed her. According to Petitioner, nothing that its staff did, or did not do, for the resident was the proximate cause of her decline and death. Petitioner contends that the real cause of the Resident's death was sepsis and not hypoglycemia. *See* P. Ex. 2 at 3.

I find this defense to be without merit both as a general proposition and in the specific context of this case. Taken to its logical end, Petitioner's "no harm, no foul" theory would excuse even the most egregious failure to provide care consistent with regulatory requirements and professionally recognized standards, unless that failure caused actual harm to residents. Using Petitioner's analysis, a facility could simply warehouse its sick and debilitated residents, provide them with no care whatsoever, collect Medicare reimbursement for keeping them, and not be liable for any deficiencies absent proof that its deficient conduct was the proximate cause of actual harm.

This is not a medical malpractice case. The issue before me is not whether Petitioner caused Resident # 2 to experience hypoglycemia and to die – although one easily could infer that conclusion from the evidence of record notwithstanding Dr. Cefalu's testimony – but whether Petitioner's conduct potentially could have caused the resident, or other similarly situated residents, to experience harm. *See* Tr. at 189-90. As I have explained, the failure of Petitioner to provide care of professionally mandated quality to Resident # 2 put that individual at enormous risk for harm.

Consistent with its "no harm, no foul" theory, Petitioner argues that Resident # 2 exhibited no signs or symptoms of hypoglycemia during the period between February 6 and February 17, 2010. Petitioner asserts that it violated no standard of care by failing to monitor the resident's blood glucose level during this period, because there is no evidence that the resident suffered any harm from the failure to monitor her. However, Petitioner's duty to provide the resident with care that satisfied professionally recognized

standards was not relieved by the fortuitous absence of observable signs or symptoms of hypoglycemia. One monitors a newly admitted insulin dependent resident's blood glucose level, because the risk of damage to the resident is so high in the absence of monitoring. Failure to monitor Resident # 2 meant that Petitioner's staff had no way of knowing whether the resident was suffering from hyper- or hypoglycemia that was not apparent from observation of the resident and had no way of knowing whether the administration of insulin to her was efficacious or actually harmful. Tr. at 164-65.

Petitioner argues also that it had no duty to be proactive in assuring that Resident # 2 received care that complied with professionally recognized standards. Thus, in referring to Resident # 2's return to Petitioner's facility from the hospital on March 1, 2010, Petitioner asserts:

When a resident returns to a nursing home from the hospital, the staff is entitled to presume the resident's medical status is stable.

Petitioner's Post-Hearing Brief at 8. Consistent with this argument, Petitioner believes that its staff had no duty to assure that ambiguous physician orders for Resident # 2 be clarified. Nor, in Petitioner's eyes, did the staff have a duty to obtain orders that were not sent, but which should have been sent, on the resident's behalf.

Petitioner's theory is simply wrong. The Act and implementing regulations do not allow a Medicare-participating skilled nursing facility to be a passive recipient of beneficiaries. The essence of 42 C.F.R. § 483.25 is that a facility must be aggressive in protecting the health and welfare of its residents. Consistent with its duty to its residents, a facility must clarify any admitting orders that are ambiguous, and it must obtain orders where none have been issued but where they are necessary. Here, it was absolutely necessary that the admission orders for Resident # 2 be clarified and, if necessary, supplanted with orders that precisely addressed the resident's problems. Petitioner failed utterly to do that which it was required to do.

Petitioner cites to the testimony of Barbara Anthony, R.N., a consultant, and Dr. Cefalu, as support for its theory that nursing standards of care allow a facility to presume that a newly admitted resident is medically stable. Petitioner's Post-Hearing Brief at 8; *see* P. Ex. 1 at 3; P. Ex. 2 at 2. In fact, neither of these witnesses avers that professionally recognized standards of nursing care allow a facility to presume that a newly admitted resident is medically stable. Neither witness addressed the issue of what standards of care generally govern a facility's obligation to a newly admitted resident.

Consistent with its theory that it had no obligation to aggressively protect Resident # 2, Petitioner contends Resident # 2 did not have a history of hypoglycemia on her admission to Petitioner's facility. Petitioner asserts that an absence of a history of hypoglycemia would relieve it of a duty to monitor the resident's blood glucose level. This argument

fails for two reasons. First, it is factually incorrect. Petitioner's records for Resident # 2 state quite clearly that the resident had suffered from hypoglycemia. CMS Ex. 28 at 8. Petitioner contends that this entry is erroneous, but it has not offered credible evidence to explain why its entry was in error. But, assuming for argument's sake that Petitioner's assertion of a clerical error is correct, Petitioner's staff was clearly on notice by February 6, 2010, just two days after the resident's admission, that Resident # 2 was vulnerable to experiencing hypoglycemia. Notice was given to the staff by the resident's dramatically lowered blood glucose level on that date.

Second, Petitioner's argument ignores that its staff was obligated to monitor the resident's blood glucose level and to assure that the resident was stable, even if the resident had *no previous history* of hypoglycemia. Tr. at 166-68.

Petitioner argues additionally that performing regular blood glucose level monitoring of Resident # 2 would not have protected the resident. This is so, according to Petitioner, because the effects of long acting insulin, such as that which was administered to the resident, do not peak until a substantial period of time has elapsed after administration of the medication. Thus, it contends that episodes of hypoglycemia that occurred hours after administration of insulin would not have been detected by blood glucose monitoring done shortly after the insulin was administered.

There are two obvious logical flaws in this argument. First, Petitioner's staff had no way of knowing what the resident's *baseline* blood glucose level was, if they did not regularly monitor it. Consequently, they had no way of determining whether the insulin that they were administering to the resident was appropriate, insufficient, or too potent. Second, there is no rule – and Petitioner has certainly identified none – which prescribes when during the course of a day, or in relation to the administration of insulin blood glucose, monitoring should be performed. Presumably, a physician would have taken into account that the resident was being administered long acting insulin, and the physician's assessment would be reflected in his or her orders for the timing of monitoring. But, Petitioner's staff never consulted with a physician about that issue and, therefore, had no way of knowing what the physician would have wanted them to do.

Petitioner also makes a "no harm, no foul" argument concerning its failure to monitor the resident's nutrition. Again, relying on the testimony of Dr. Cefalu, Petitioner contends that the resident must have been receiving adequate nutrition during her stay at its facility – despite the absence of evidence showing that Petitioner sought to address the resident's nutritional issues – because the resident did not lose weight during this period. P. Ex. 2 at 2.

It is true that the resident did not lose weight during her stay. But, Petitioner's assertion from that fact that the resident could not have been harmed by the staff's failure to address her nutritional problems is belied by the weight of the evidence relating to

Resident # 2. First – and notwithstanding Dr. Cefalu's contention that there is no evidence that the resident had a poor appetite – the evidence shows that the resident's appetite was, indeed, poor. CMS Ex. 28 at 106; CMS Ex. 35 at 6; Tr. at 173-76. In fact, the resident complained about the diet she was receiving.

More important, the fact that the resident's weight was stable is not, by itself, proof that the resident was nourished adequately or that her nutrition was regulated in a way that would minimize the risks caused by her diabetes and the administration of insulin to the resident. Resident # 2 suffered from renal failure, and she received kidney dialysis. The resident's condition, and the treatment she received for it, meant that her body weight was not a good marker for her nutritional status. Tr. at 195-96. That is because the goal of a nephrologist treating a dialysis patient such as Resident # 2 is to keep the resident's weight as stable as is possible. *Id.* That is done by giving, or withholding, fluid from the resident. *Id.* Consequently, one cannot reasonably infer that the resident was receiving adequate nutrition from the fact that her weight remained stable during her stay at Petitioner's facility.

Petitioner argues also that it had "processes in place to monitor meal consumption and intake and output, when clinically indicated, as evidenced by the fact that no other residents were identified relative to this issue." Petitioner's Post-Hearing Brief at 2. But, and assuming the presence of "processes," that availed Resident # 2 nothing, because none of these "processes" were used to protect her.

Additionally, Petitioner contends that nurses' notes of February 5, 8, and 9, 2010 show that the resident was receiving meals and fluids from Petitioner's staff. Petitioner's Post-Hearing Brief at 2. However, CMS has not alleged that Petitioner's staff failed to offer food and drink to Resident # 2. The problem that CMS identified, about which Petitioner offered no meaningful response, is that the staff failed to address the resident's poor appetite, either by assessing the resident for possible adjustment to her diet, consulting meaningfully with a physician about the resident's nutrition, or offering the resident meal choices that the resident might have found to have been more palatable.

In any event, the fact that the resident did not lose weight is no excuse for Petitioner's failure to attend to the resident's nutritional needs. The reason why it is critically important that an insulin dependent diabetic resident like Resident # 2 receive adequate and regular quantities of nutrition is that missed, or partially consumed, meals may lead to adverse reactions to insulin administration. And, of course, the risk of such an adverse reaction was magnified in this case, because Petitioner's staff did not monitor the resident's blood glucose level.

2. Petitioner failed to comply substantially with the requirements of 42 C.F.R. § 483.20(k)(3)(ii).

A skilled nursing facility must have qualified personnel provide services to each of its residents in accordance with the resident's written plan of care. 42 C.F.R. § 483.20(k)(3)(ii). CMS alleges that, in several respects, Petitioner failed to provide services to its residents that were in accord with the residents' plans of care. The evidence strongly supports CMS's assertion.

a. Petitioner's professional staff failed to administer insulin and/or check blood glucose levels of Residents # 1, # 3, and # 6, in accordance with these residents' physicians' orders and with their plans of care.

The evidence establishes a pattern of failure by Petitioner's staff to provide care consistent with these diabetic residents' plans of care and physician orders. In the case of Resident # 1, the resident had orders to receive blood glucose checks ("Accuchecks") before meals, and at bedtime, and to receive insulin at regularly prescribed intervals. CMS Ex. 27 at 31-34. However, Petitioner's staff frequently failed to administer insulin to the resident per the physician's order. On 18 of 28 days in February 2010, Petitioner's staff failed to administer insulin as directed. *Id.* at 5-6. There were also two instances when the staff failed to perform blood glucose level checks as the resident's physician directed. CMS Ex. 46 at 3. In March 2010, the resident did not receive insulin on two of three days that were reviewed. *Id.* 

In the case of Resident # 3, the evidence proves that the resident did not receive insulin as prescribed on four out of the 28 days in February 2010. CMS Ex. 46 at 4. On one occasion in February 2010, Petitioner's staff failed to check the resident's blood glucose level as directed. *Id.* As concerns Resident # 6, the evidence establishes that Petitioner's staff failed on six instances in January and February 2010 to administer insulin, or to check the resident's blood glucose level, as had been directed. CMS Ex. 32 at 3-4; 21-27; CMS Ex. 42 at 6.

b. Petitioner's professional staff failed to clarify the physician's orders for Resident # 2.

I have discussed at Finding 1 the failure of Petitioner's staff to clarify the physician's orders that were issued for Resident # 2, and it is not necessary that I re-explain my conclusions here. The failure to provide clear orders for the resident put the onus on Petitioner and its staff to obtain clarification, or even additional orders. It is not possible for a facility to prepare and implement a meaningful plan of care for a resident, if it does not have clear instructions from the resident's physician concerning the care that the

resident is to receive. Failure by Petitioner and its staff to obtain clarification for Resident # 2 constituted noncompliance with the requirements of 42 C.F.R. § 483.20(k)(3)(ii), because it meant that Petitioner could not possibly prepare and implement a meaningful plan of care for the resident.

## c. Petitioner's defenses are without merit.

Petitioner offered no evidence to refute that which I have discussed. It does not deny that its professional staff failed to administer insulin as prescribed, failed to perform blood glucose checks, and failed to clarify the physician orders that were issued for Resident # 2.

Petitioner contends that, as a matter of law, the allegations of noncompliance are invalid, because there is no proof that the staff that provided care to the residents were not professionally qualified persons. That may be true, but CMS's allegations do not focus on the staff's qualifications but on their failure to provide care consistent with the residents' physicians' orders and care plans. The regulation applies equally to staff qualifications and to compliance with plans of care.

Additionally, Petitioner contends that care involving "only" three of its residents is at issue. That is not true. CMS's allegations relate to the care that Petitioner gave to four of its residents. But, whether the allegations involve three or four residents is irrelevant. Evidence involving failure to provide care consistent with regulatory requirements involving only a single individual might be enough to prove noncompliance with the regulation. Here, the evidence of noncompliance is compelling and unrebutted.

As a variation on the preceding argument, Petitioner asserts that its population of diabetic residents was but a subset of its total resident census. It contends that failure to provide care to these residents in accord with professionally recognized standards of nursing care has no significance, when considered in light of the non-diabetic resident population, which was unaffected by this misfeasance. I find this argument to be wholly unpersuasive. The obvious answer is that the manner in which Petitioner treated its diabetic residents meant that any resident of Petitioner's facility suffering from diabetes was at grave risk of harm. That is enough to find noncompliance. Moreover, it is reasonable to generalize from the staff's slovenly disregard of professionally recognized standards of care, and Petitioner's own written policy in their treatment of diabetic residents, and to conclude that *all* of Petitioner's residents were at risk for being treated with indifference to professionally recognized standards of care. That inference is reasonable given the pervasiveness and egregiousness of Petitioner's misfeasance as respects diabetic residents.

Petitioner suggests that withholding of insulin from residents by Petitioner's staff constitutes a permissible exercise of discretion. What Petitioner argues, in effect, is that

the staff could legitimately countermand physicians' orders. However, the staff was not vested with such discretion. If a member of Petitioner's staff determined that deviating from the physician's orders was appropriate, that staff member should have consulted with the physician before doing so. Tr. at 61-63.

Finally, Petitioner argues that there was something unique about the relationship between Petitioner's staff and the residents' treating physician, in that the physician was also Petitioner's medical director. The suggestion is, apparently, that the staff's unilateral departure from orders, and their failure to consult with the residents' physician, is justified by this special relationship. No such justification exists. Petitioner offered no proof that professionally recognized standards of nursing care would allow nursing staff to contravene a physician's explicit orders, based on some inchoate relationship of trust between the staff and the physician.

## 3. Petitioner failed to comply substantially with the requirements of 42 C.F.R. § 483.75.

A skilled nursing 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, and psychosocial well-being of each of its residents. 42 C.F.R. § 483.75. CMS asserts that Petitioner failed to comply with this regulation, arguing that the failures by Petitioner to comply with other regulations were a product of failures by Petitioner's management to develop and implement policies and procedures to assure efficient and effective operation of the facility.

The evidence strongly supports CMS's assertion. There was an obvious failure on the part of Petitioner's management to assure that the staff operated effectively and efficiently. The deficient care that Petitioner gave to Resident # 2 is graphic proof of the ineffectiveness with which Petitioner was managed. As I have stated, the failure by Petitioner's staff to monitor this resident's blood glucose level – both as a matter of protocol governing a newly admitted insulin dependent diabetic resident, and as a matter of urgency in the face of the resident's labile blood glucose level – is a shocking dereliction of the duty of care that Petitioner owed to the resident. That misfeasance persisted over a period of several weeks. At no time during this period did Petitioner's supervisory staff notice anything untoward in the care that was being given to the resident. No review took place, no corrections were made, and no protocols were determined to have been violated. This is an obvious failure by Petitioner's management to have in place meaningful supervision of its staff or systems that would detect and stop improper care.

The failure of Petitioner's management is also evident in the staff's lack of comprehension of what was required by professionally recognized standards of nursing care. When queried as to why she failed to administer insulin to Resident # 1 pursuant to

the express written order of the resident's physician, one of Petitioner's nurses stated that she was exercising "nursing judgment." Tr. at 62-63. However, the professionally recognized standard of care requires a nurse to consult with a resident's physician if he or she believes that it would be inappropriate to follow the physician's order. Tr. at 191. As I discuss at Finding 2, Petitioner's staff breached this standard of care on multiple occasions. Petitioner's management was clueless as to these repeated breaches and had no system in place to detect and correct them. Nor did it have in place any system to train its staff to follow the applicable professionally recognized standard of nursing care.

Petitioner has offered no affirmative proof to establish that it was effectively and efficiently managed, and it has not rebutted the evidence that I have just discussed.

# 4. Petitioner failed to comply with the requirements of 42 C.F.R. §§ 483.20 and 483.20(b).

A skilled nursing facility is required to conduct initially for each of its residents and periodically a comprehensive, accurate, standardized, reproducible assessment of that resident's functional capacity. 42 C.F.R. § 483.20. In performing the comprehensive assessment, the facility must comply with the detailed and explicit requirements of 42 C.F.R. § 483.20(b). The comprehensive assessment must be completed within 14 days of a resident's admission to the facility and must be done again after a significant change in a resident's condition and periodically. 42 C.F.R. § 483.20(b)(2)(i)-(iii).

CMS alleges that Petitioner contravened these requirements, because it failed to make ongoing assessments of Resident # 2's condition. CMS offered no direct proof that Petitioner failed to complete the document envisioned by 42 C.F.R. § 483.20, *i.e.*, it did not offer a copy of a document entitled "comprehensive assessment" and attack the alleged deficiencies in the document. Rather, CMS argues that the failure by Petitioner to perform basic and ongoing assessments of Resident # 2 is, constructively, a failure to comply with the comprehensive assessment requirement. I agree.

There is a difference between the requirement that a resident's needs and condition be assessed on an ongoing basis and the requirement that a facility perform a "comprehensive assessment" of that resident. The former requirement is a requirement that is subsumed within the regulation governing quality of care at a facility. Failure to assess a resident's condition on an ongoing basis and to react to every significant change in that resident's condition clearly comprises noncompliance with the requirement of 42 C.F.R. § 483.25 that a facility give a resident all that is needed to assure that the resident attains the highest possible level of functioning. But, a failure to conduct these necessary ongoing assessments is at least technically different from a failure to conduct the comprehensive assessment that 42 C.F.R. § 483.20 requires.

As the regulation describes, a comprehensive assessment is a formal document that embodies the facility's staff's overall evaluation of a resident. Obviously, the comprehensive assessment includes assessments of each of the resident's problems, strengths, and weaknesses. But, and as opposed to the requirement for ongoing assessments, a comprehensive assessment is a document that must only be executed periodically, or after a significant change in a resident's condition.

Resident # 2 was in Petitioner's facility for barely enough time to trigger the comprehensive assessment requirement. She resided at the facility from February 4-17 and on March 1-2, 2010. It is unclear to me whether Petitioner's staff even met and considered writing the document that the regulation required.

However, it would not have been possible for the staff to have written a comprehensive assessment in compliance with regulatory requirements. The staff's continuous and ongoing failures to monitor the resident's blood glucose level and her nutrition meant that the staff was not collecting any of the information that they needed to write a comprehensive assessment. Consequently, any document that the staff prepared for Resident # 2, or that it could have prepared for this resident, would have been effectively meaningless where it addressed the resident's diabetes or the status of her nutrition.

I find that Petitioner failed to comply with the comprehensive assessment requirement – not because it failed to dot all of the i's and cross all of the t's in the comprehensive assessment form required by 42 C.F.R. § 483.20 – but because it would have been impossible for Petitioner ever to have prepared a document that complied with regulatory requirements, given its failure to perform basic assessments and monitoring of Resident # 2. Failure to perform the ongoing assessments and monitoring demanded by Resident # 2's condition is, in the context of this case, a failure to comply with the comprehensive assessment requirement, because it is a failure to perform the basic building blocks of a comprehensive assessment.

I base my finding of Petitioner's noncompliance with the comprehensive assessment requirement solely on its failure to perform the functions necessary for completing a comprehensive assessment of Resident # 2.

## 5. CMS may terminate Petitioner's participation in Medicare.

The Secretary of the United States Department of Health and Human Services, or her delegate, CMS, may terminate the participation of any skilled nursing facility, if that facility is not fully complying with Medicare participation requirements. Act § 1866(b)(2)(A); 42 C.F.R. § 488.456(b)(1). Any noncompliance that is substantial will suffice to authorize termination of participation. It is unnecessary, for example, to justify termination that noncompliance be so egregious as to place residents of a facility in a state of immediate jeopardy. *Id*.

Petitioner was not complying substantially with four Medicare participation requirements as of the March 5 Survey. Findings 1-4. Any one of these failures to comply authorized CMS to terminate Petitioner's participation in Medicare.

Petitioner attacks CMS's determination by contending that: CMS followed policies that were not specifically authorized by regulations; its determination was at variance with the policies and practices of the Louisiana State survey agency; and it treated Petitioner disparately from other skilled nursing facilities in Louisiana that had manifested deficiencies in the past. None of these arguments are relevant.

Petitioner's arguments fail, because they attack CMS's exercise of discretion as opposed to its authority to act. At bottom, the question of whether to terminate a facility's participation in Medicare for noncompliance with participation requirements is a matter of discretion for CMS. I have no authority to question CMS's exercise of discretion or to hear arguments from Petitioner challenging that exercise of discretion. A skilled nursing facility may not appeal CMS's choice of a remedy, including those factors considered in selecting the remedy. 42 C.F.R. § 488.408(g)(2).

## 6. Per-instance civil money penalties of \$3,500, \$3,500, and \$3,000 are reasonable.

CMS determined to impose three civil money penalties against Petitioner as remedies in addition to termination of Petitioner's participation in Medicare. The three proposed penalties are as follows:

- A per-instance civil money penalty of \$3,500 to remedy Petitioner's noncompliance with 42 C.F.R. §§ 483.20 and 483.20(b);
- A per-instance civil money penalty of \$3,500 to remedy Petitioner's noncompliance with 42 C.F.R. § 483.25; and
- A per-instance civil money penalty of \$3,000 to remedy Petitioner's noncompliance with 42 C.F.R. § 483.75.

The three penalties at issue are per-instance civil money penalties. CMS may impose a per-instance civil money penalty, ranging from \$1,000 to \$10,000, for each instance of noncompliance by a skilled nursing facility. 42 C.F.R. \$ 488.438(a)(2). Where within that range a penalty amount should fall depends on the presence of evidence relating to factors for determining penalty amounts set forth at 42 C.F.R. \$ 488.438(f)(1) – (4) and 488.404 (incorporated by reference into 42 C.F.R. \$ 488.438(f)(3)). These factors may include: the seriousness of a facility's noncompliance; its compliance history; its culpability; and its financial condition.

CMS determined that Petitioner's noncompliance with 42 C.F.R. §§ 483.20, 483.25, and 483.75 was at the immediate jeopardy level. An immediate jeopardy level deficiency is one that causes, or is likely to cause, serious injury, harm, impairment, or death to a resident. 42 C.F.R. § 488.301. I find it unnecessary to address the question of immediate jeopardy, because a finding of immediate jeopardy is not necessary to deciding whether any of the three penalties is reasonable. There is no requirement that noncompliance be at the level of immediate jeopardy to justify a per-instance civil money penalty. And, as I find above, at Finding 5, a finding of immediate jeopardy level noncompliance also is unnecessary to deciding whether CMS is authorized to terminate Petitioner's participation in Medicare.

That having been said, it is apparent that Petitioner's noncompliance was extremely serious. The failure to provide routine blood glucose level monitoring to Resident # 2, coupled with Petitioner's other failures to treat this resident consistent with professionally recognized standards of nursing care, put this resident at great risk for harm or worse. Petitioner's noncompliance jeopardized this resident's life. And, as I have concluded, that failure was not just a failure by individual members of Petitioner's staff to provide needed care to the resident, it was a failure to perform basic assessments of the resident and a failure by Petitioner's management to develop and implement policies and systems that would prevent such misfeasance from occurring.

I find the three penalties of \$3,500, \$3,500, and \$3,000 are justified by the seriousness of Petitioner's noncompliance, and I sustain them. Indeed, they represent only a small fraction of what CMS might have imposed against Petitioner, given that this noncompliance extended over a period of time at least covering Resident # 2's stay at the facility.

Petitioner asserts that CMS failed to take into consideration its financial condition in determining to impose civil money penalties. However, it is not CMS's duty under the regulations to research a facility's financial condition, before determining to impose penalties. A facility may argue as an affirmative defense to a penalty that it would be damaged unreasonably, if it were made to pay it. But, it is the facility's responsibility to offer evidence as to its financial condition. It is in possession of information concerning its financial condition, information that CMS does not have access to.

Here, Petitioner has offered nothing except to contend that termination of its participation would put it out of business and that, therefore, it would be unable to pay the penalty amounts. It has not offered any evidence showing its income stream, its resources, or its financial reserves. I conclude that Petitioner has not made a credible case that it lacks the wherewithal to pay the extremely modest civil money penalties that I sustain.

7. Petitioner's other arguments are without merit or are beyond the scope of my authority to hear and decide.

During the course of this case, Petitioner made arguments, which raise claims and contentions that are collateral to the merits. I addressed all of these arguments in prehearing rulings, or during the in-person hearing. I discuss some of my rulings in more detail here.

a. I have no authority to rule on Petitioner's claim of estoppel. In any event, Petitioner has established no basis for a claim of estoppel, even assuming that its assertions are true.

Perhaps the collateral argument that Petitioner made most strenuously is its assertion that CMS is estopped from terminating its participation in Medicare. To support its estoppel claim, Petitioner contended that:

- CMS originally opted to allow Petitioner to file a plan of correction to rectify its noncompliance then reversed course and terminated Petitioner's participation, without giving Petitioner the opportunity to correct. Petitioner argues, citing 42 C.F.R. § 488.456, that CMS must either terminate a facility's participation upon determining noncompliance *or* give the facility an opportunity to file a corrective action plan. According to Petitioner, the regulation does not afford CMS the opportunity to change its determination, once it has determined which of the two courses of action it will follow.
- CMS erroneously determined that Petitioner was a "special focus facility" and based its determination to terminate Petitioner's participation on that determination, when, in fact, Petitioner had "graduated" from special focus status effective March 25, 2010. Thus, according to Petitioner, CMS unfairly determined to terminate its participation based on a status that Petitioner did not, in fact, occupy after March 25, 2010.
- Representatives of CMS and/or the State of Louisiana were dishonest in explaining how the determination to terminate Petitioner's participation came to be made.

All of these arguments ultimately relate to CMS's exercise of discretion in choosing to terminate Petitioner's participation in Medicare. As I explain at Finding 5, Petitioner may not challenge CMS's exercise of discretion, and I have no authority to hear arguments relating to such a challenge. Petitioner's arguments are irrelevant, because they are beyond the scope of my authority.

The arguments also are incorrect as a matter of law. Petitioner is simply wrong in asserting that 42 C.F.R. § 488.456 requires CMS to make an irrevocable choice of remedy. There is nothing in the regulation that suggests that, and Petitioner has offered no authority to support its claim.

Furthermore, Petitioner has offered nothing that would establish grounds for estoppel even assuming that its assertions are true and assuming further that I had the authority to consider them. See Heckler v. Cmty. Health Servs. of Crawford County, Inc. 467 U.S. 51 (1984). CMS's authority in this case is clearly spelled out by the Act and implementing regulations, and Petitioner, as a Medicare participant, was responsible for knowing what those regulations say. The regulations put Petitioner on notice that, if CMS overruled the State agency and determined to terminate Petitioner's participation in Medicare, CMS's determination would control. 42 C.F.R. § 488.452(b)(1). Furthermore, Petitioner did not offer evidence to prove that it was actually harmed, if, in fact, CMS told Petitioner that it would have an opportunity to correct its noncompliance and then changed its determination.

# b. Petitioner was not entitled to discovery. Moreover, the discovery that it sought was for information that is irrelevant.

Petitioner contended that I denied it due process, because I refused to allow it to take discovery. The discovery envisaged by Petitioner includes depositions of Louisiana and CMS personnel and other individuals in this Department, possibly including the Secretary. Petitioner never completely explained the purpose of these depositions but, evidently, sought them in order to generate evidence that might buttress its estoppel argument.

There is nothing in the Act, or in the regulations governing hearings at 42 C.F.R. Part 498, that allows a party to take discovery. The depositions that Petitioner sought to take are not authorized, and, for that reason, I denied Petitioner's request.

Petitioner notes that the regulations at Part 498 are silent on the subject of discovery and argues that discovery ought to be allowed in that it is not expressly prohibited. I find that argument to be without merit. There is no constitutional or statutory right to take discovery in a case involving CMS. The regulations expressly define the rights of the parties.

There are other regulations of this Department governing hearings that expressly confer a limited right of discovery on parties. For example, the regulations at 42 C.F.R. Part 1005, governing hearings before the Inspector General (I.G.), confer narrowly limited discovery rights that do not include the taking of depositions. 42 C.F.R. § 1005.7. The I.G. regulations that allow limited discovery stand in sharp contrast to the regulations that do not explicitly allow it, such as the Part 498 regulations. What is clear from reading the

Part 1005 regulations is that the Secretary has determined to allow discovery in only certain types of cases and, then, under very limited and tightly controlled circumstances. The only reasonable conclusion one can draw in comparing the Part 1005 regulations with the Part 498 regulations is that the Part 498 regulations do not specifically discuss discovery, because the Secretary did not intend to grant discovery rights to the parties.

Moreover, the discovery sought by Petitioner is irrelevant, because it arguably relates to an issue – Petitioner's estoppel claim – that I have no authority to hear and decide. I would have denied Petitioner's request as irrelevant, even if the regulations authorized me to grant discovery.

### c. I did not deny Petitioner due process at the hearing.

At the hearing of this case Petitioner objected strenuously to my receiving nearly all of CMS's exhibits on the ground that they contained hearsay. It argued that, if hearsay is prohibited by rules of evidence such as the Federal Rules of Evidence, it should be prohibited also in hearings conducted pursuant to the regulations at Part 498.

Petitioner's argument is wrong on more than one count. First, the Part 498 regulations expressly allow administrative law judges to receive evidence that might not be admissible under rules of evidence governing trials in courts of law. 42 C.F.R. § 498.61. The administrative law judge thus has broad authority to admit evidence and that authority certainly extends to admitting hearsay.

The obvious difference between an administrative hearing conducted pursuant to the Part 498 regulations and a trial in a federal court is that the administrative hearing is not a jury trial. Rules that are designed to shield possibly unsophisticated lay jurors from evidence that may be tainted are unnecessary in an administrative hearing, where the administrative law judge is able to make fact and credibility findings based on his or her experience hearing and deciding many cases of the same type.

I routinely admit hearsay evidence. That is not to say that I assume uncritically that all hearsay evidence is credible. I often find it to be unpersuasive if its provenance is questionable or if it is not corroborated by other evidence.

Most of the evidence that Petitioner objected to as containing hearsay would, in fact, be exempt from exclusion under the Federal Rules of Evidence. The vast majority of the documents that Petitioner objected to are copies of Petitioner's own resident treatment records generated by Petitioner's staff, or associated documents that were in Petitioner's files and that the surveyors obtained during the March 5 Survey. These documents would be admissible under either the business record or admission exceptions in the Federal Rules of Evidence.

Finally, Petitioner established no prejudice resulting from my admitting documents that CMS obtained from Petitioner's files. For example, CMS Ex. 28 consists of excerpts of treatment records pertaining to Resident # 2. The exhibit contains documents primarily from two sources: records generated by Petitioner's staff relating to the care that the resident received during her stay at Petitioner's facility; and records from a local hospital. All of these records were obtained by surveyors from Petitioner's own files. Petitioner was provided a copy of these records by CMS counsel weeks before the hearing. It had ample time to show specific inaccuracies in these documents or to demonstrate that they were incomplete. However, Petitioner made no showing to that effect. Instead, its counsel objected in general terms, claiming that he did not know where the exhibit came from or what it contained. That is not a credible objection to records that were copied from documents in Petitioner's own files.

/s/ Steven T. Kessel Administrative Law Judge