Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Van Duyn Home and Hospital, (CCN: 33-5184),

Petitioner

v.

Centers for Medicare and Medicaid Services.

Docket No. C-09-620

Decision No. CR2195

Date: July 23, 2010

DECISION

I sustain the determination of the Centers for Medicare and Medicaid Services (CMS) to impose remedies against Petitioner, Van Duyn Home and Hospital, consisting of:

- Civil money penalties of \$9,650 per day for each day of a period that began on May 29, 2009 and which continued through June 10, 2009;
- Civil money penalties of \$50 per day for each day of a period that began on June 11, 2009 and which continued through July 23, 2009;
- Denial of payment for new Medicare admissions for each day of a period that began on June 4, 2009 and which ended on July 23, 2009; and
- Loss of authority to conduct a nurse aide training, certification, and education program (NATCEP).

I. Background

Petitioner is a skilled nursing facility located in the State of New York. It participates in the Medicare program. Its participation in Medicare is governed by sections 1819 and 1866 of the Social Security Act (Act) and by regulations at 42 C.F.R. Parts 483 and 488. Regulations at 42 C.F.R. Part 498 govern its hearing rights in this case.

CMS determined to impose the remedies that I describe in the opening paragraph of this decision based on deficiency findings that were made at a compliance survey of Petitioner's facility that was conducted on May 29, 2009 (May Survey). The Survey identified deficiencies that consisted of alleged failures by Petitioner to comply with three Medicare participation requirements stated at 42 C.F.R. §§ 483.25(h), 483.75, and 483.75(i). CMS determined that Petitioner's noncompliance with these requirements was so egregious as to comprise immediate jeopardy for residents of Petitioner's facility. "Immediate jeopardy" is defined at 42 C.F.R. § 488.301 as noncompliance that causes, or is likely to cause, serious injury, harm, impairment, or death to a resident.

Petitioner requested a hearing, and the case was assigned to me for a hearing and a decision. The parties exchanged pre-hearing briefs and exhibits, and I scheduled the case for an in-person hearing. The parties then agreed that the case could be heard and decided based on their written exchanges. I cancelled the in-person hearing and allowed the parties to file an additional round of briefs.

CMS filed a total of 35 exhibits, which it identified as CMS Ex. 1 - CMS Ex. 35. Petitioner filed a total of 20 exhibits, which it identified as P. Ex. 1 - P. Ex. 20. I receive all of the parties' exhibits into evidence.

II. Issues, Findings of Fact and Conclusions of Law

A. Issues

The issues in this case are whether:

- 1. Petitioner failed to comply substantially with Medicare participation requirements;
- 2. CMS's determinations of immediate jeopardy level noncompliance are clearly erroneous; and
- 3. CMS's remedy determinations are reasonable.

B. Findings of Fact and Conclusions of Law

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

1. Petitioner failed to comply substantially with Medicare participation requirements.

As I state above, CMS determined that Petitioner failed to comply substantially with three Medicare participation requirements. I discuss each of these noncompliance allegations at subparts a, b, and c of this Finding. I note preliminarily, that the allegations of noncompliance all relate in large measure to the care that Petitioner gave to two of its residents who are identified as Residents # 1 and # 2. I discuss the care that Petitioner gave to these residents in detail in subpart a, and I refer to them as is appropriate in the other subparts of this Finding.

a. Petitioner failed to comply substantially with the requirements of 42 C.F.R. § 483.25(h).

The applicable regulation requires a skilled nursing facility to provide its residents with supervision and assistance to prevent accidents and to protect its residents against accident hazards. It has been the subject of much litigation, and the regulation's requirements are settled. The regulation does not impose strict liability requirements on a facility. It does require a facility to take all reasonable measures to protect its residents against accidents. In practice, that obligation means that a facility must: assess each of its residents to determine what unique aspects of that resident's condition might cause the resident to be vulnerable to accidents and to determine exactly what hazards the resident is exposed to; plan each resident's care in accordance with its assessment of the resident's vulnerabilities; and implement the care plan that it develops for each resident.

Assessment is a core element of a facility's duty to protect each of its residents. To provide protection – and to exhaust all reasonable means of providing protection – a facility must, first and foremost, understand the resident's problems and vulnerabilities. That understanding cannot be obtained without first thoroughly and systematically evaluating the resident. Assessment is the necessary prerequisite to all of the care that the facility subsequently offers or provides to a resident.

CMS alleges that Petitioner failed to meet this requirement. It alleges that Petitioner:

did not conduct appropriate and thorough resident assessments to determine the level of supervision required by the residents to maintain their health and safety. Specifically, the facility failed to have a system in place to ensure that the residents' cognitive and safety needs were assessed prior to allowing them to leave the facility with out on pass [out-on-pass] medical orders.

CMS Ex. 1 at 1.

As I have stated, much of CMS's allegations hinges on the care that Petitioner gave to Residents # 1 and # 2. In reviewing the care that the facility gave to these two residents, I find very few, if any, facts to be in dispute.

Resident # 1 is a relatively young individual, 49 years of age as of the May Survey, who was admitted to Petitioner's facility in November 2008 suffering from a variety of medical problems. His diagnoses on admission included a seizure disorder, a basal ganglia cerebral vascular accident, subdural hematoma, malnutrition, and alcohol abuse. CMS Ex. 1 at 1. At the time of his admission the resident had been living in a homeless shelter. His admission to Petitioner's facility was prompted, at least in part, by his suffering from delirium tremens relating to alcohol abuse and possible seizures. *Id.* at 2. The resident was confined to a wheelchair and needed assistance for transfers from the wheelchair. *Id.*

Petitioner's staff determined that the resident suffered from cognitive as well as physical impairments. He was found by the staff to display moderately impaired cognitive skills for daily decision making and impaired judgment with intermittent agitation. CMS Ex. 1 at 2. The staff determined that the resident needed supervision because of his poor judgment. They noted that the resident was resistant to care, had a history of signing himself out of facilities against medical advice, and had a long history of living on the street. *Id*.

On May 16, 2009, at 1:30 p.m., Resident # 1 left Petitioner's facility without permission and against medical advice. Resident # 2 accompanied him. CMS Ex. 1 at 2. He returned at about six that evening, and Petitioner's staff reported him to be "drunk and loud." *Id.* at 3. On May 17, the following day, the resident became verbally abusive and threatened members of Petitioner's staff when they attempted to retrieve contraband (a lighter) from the resident. *Id.*

The staff discussed the incident with Petitioner's administration. They decided to give the resident a pass to leave the facility conditioned on the following restrictions: the resident would be allowed to leave the facility after breakfast; and he would be required to return to the premises by 4:00 p.m. CMS Ex. 1 at 3.

On May 18, 2009, the resident left the facility and did not return that night. CMS Ex. 1 at 3. The resident spent that night at a homeless shelter. He returned to the facility on the following evening, May 19, 2009, at about 7:30, smelling of alcohol. *Id.* The resident left the facility again on May 20, 2009, accompanied by Resident # 2, telling staff that he would return that evening at about 6:00 p.m. He did not return that evening, rather, spending it at a local homeless shelter. The shelter called Petitioner's facility and notified it that the resident would not be allowed to spend additional nights there. The resident did not return to the facility until May 22, 2009, after he had spent some time in a hospital emergency room being treated for intoxication, a fall with a resulting head laceration, and a seizure. *Id.* at 4. During the periods when the resident was absent from the facility, he did not receive medications that had been prescribed to him to treat his seizures, malnutrition, and alcohol abuse. *Id.* at 5.

The evidence that CMS offered – which Petitioner did not rebut – shows that Petitioner's staff essentially limited their assessment of the resident's ability to be off premises unsupervised to deciding after the May 16 unauthorized absence that the resident should be issued a pass to leave the premises unattended. I infer that the staff decided that the resident should receive a pass, because they agreed that he would leave the premises with or without one. CMS Ex. 1 at 5. The record is devoid of any comprehensive analysis by Petitioner's staff of exactly why the staff thought that giving the resident a pass to leave the premises unsupervised was a reasonable intervention, or necessitated by the resident's contempt for the facility's attempts to provide care for him. Moreover, nothing demonstrates that the staff attempted to develop interventions to dissuade the resident from leaving unescorted or to persuade the resident after he violated the terms of his pass in the days following their issuance of it to him to re-determine whether the issuance of the pass was an appropriate action or whether the resident needed more, and better, protection than he received from Petitioner's staff.

Resident # 2 was admitted to Petitioner's facility on February 23, 2007 with diagnoses that included stroke with left side weakness, right upper extremity amputation, diabetes, and alcohol abuse. CMS Ex. 1 at 6. She, like Resident # 1, was a relatively young individual of 52 at the time of the May survey. Petitioner's staff found the resident to have a moderately impaired cognitive status manifested by poor decision making, a need for supervision, and socially inappropriate and verbally abusive behavior that was not easily altered. *Id.* She had a history of poor impulse behavior. The resident was completely dependent on Petitioner's staff for most aspects of daily care. *Id.* at 6, 9. She used a motorized wheelchair for transportation and she needed to be transferred from her bed to her wheelchair with a mechanical lift. In addition, staff had to feed her, and she was incontinent. *Id.* at 6.

The resident had a physician's order that allowed her to leave the facility on pass with a companion as needed. CMS Ex. 1 at 7. However, no evidence exists that Petitioner's staff comprehensively assessed the resident to determine whether she could leave the facility safely or to determine what protection she might need while off premises. Nor did the staff determine exactly what type of companion the resident might need to protect her while she was off the facility's premises.

On May 16, 2009, Resident # 2 left the facility in the company of Resident # 1 (who left the facility on that occasion against medical advice). The resident was due to return before 4:30 that afternoon when medication would be administered, and her blood sugar would be tested. Petitioner's staff advised her that, the local sheriff would be called if she did not return by 5:00 p.m. CMS Ex. 1 at 7.

The resident did not return by 5:00 p.m. on May 16 but returned at about 6:20 p.m., evidently having consumed alcohol while off premises. An odor of alcohol was on her breath, her eyes were reddened, and her speech was slurred. CMS Ex. 1 at 8.

On May 18, 2009, the resident left Petitioner's premises without signing out. She returned to the facility on that date some time before 4:00 p.m. with a half-full container of an alcoholic beverage in her wheelchair bag. The resident denied that the drink was hers, asserting that it belonged to Resident # 1. *Id*.

No evidence exists that these events prompted Petitioner's staff to reassess Resident # 2 to determine whether she could be safely off Petitioner's premises under the pass conditions that were previously imposed. No effort was made to determine whether more suitable companionship could be arranged for Resident # 2 other than Resident # 1. Nor did Petitioner's staff consider whether interventions might be developed that would dissuade Resident # 2 from leaving Petitioner's premises.

CMS also offered evidence to show that the Petitioner's staff's failures to assess Residents # 1 and # 2 were part of an overall pattern of failure by Petitioner to assess and track residents who sought to leave Petitioner's premises. Petitioner's assistant administrator admitted to a surveyor that no system was in place that told the staff who was permitted to leave the facility on a pass. CMS Ex. 1 at 11. She estimated that about 50 of Petitioner's residents were permitted to leave the facility with a pass. In fact, a total of 218 of Petitioner's residents had such permission. *Id*.

The evidence that CMS offered and which I have discussed is compelling proof that Petitioner was not assessing its residents for risks associated with their leaving the premises unassisted. It is equally compelling proof that Petitioner had no system in place for ascertaining which residents were permitted to leave the facility and under what circumstances they were permitted to leave. The evidence provides more than ample support for a finding that Petitioner failed to comply with the requirements of 42 C.F.R. § 483.25(h) in that it proves that Petitioner was derelict in carrying out its responsibility to assess each of its residents for accident risks and vulnerabilities.

That is graphically illustrated by the evidence relating to Resident # 1. Petitioner's staff knew that this individual was a highly vulnerable, beset by physical infirmities and alcoholism that placed him in danger of serious injury or death any time he left the premises unaccompanied. The resident also obviously suffered from a significantly impaired ability to judge his vulnerabilities on his own and to make rational decisions about risk. His non-cooperativeness accentuated his vulnerabilities. When faced with the resident's insistence on engaging in obviously self-destructive behavior – including leaving the facility unaccompanied and consuming alcohol while away – Petitioner's staff simply threw up their hands and ignored the problems the resident posed. They made no efforts to assess the resident for possibly effective interventions even as they knew that the resident was engaging in behavior that could lead to extremely damaging consequences. Much the same could be said about the way in which Petitioner treated Resident # 2.

In responding to these allegations, Petitioner makes two of its own. First, it insists that it had adequate comprehensive systems in place for assessing and protecting its vulnerable residents. Second, it asserts that CMS seeks to compel it to do something unlawful, namely, to restrict forcibly the freedom of movement of mentally competent residents who wish to leave Petitioner's premises. Neither of these arguments is persuasive.

Petitioner rests its allegation that it had a system in place for assessing those residents who wished to leave the premises in part on the affidavit testimony of Paul Katz, M.D. P. Ex. 21. Dr. Katz testified that:

In my opinion, . . . [Petitioner] clearly had a system for assessing resident safety for out-on-pass orders. The evidence shows that this system was comprehensive, well understood by the staff and effectively implemented with respect to Residents # 1 and # 2. In my opinion, . . . [Petitioner'] resident assessment protocol is reasonable and prudent for the industry and consistent with the applicable regulatory standard.

P. Ex. 21 at 6.

Petitioner also relies on the affidavit testimony of Peter Becker, M.D., Petitioner's medical director, as support for its contention that Petitioner had a protocol in place for assessing those residents who desired to leave the facility's premises. P. Ex. 15. Dr. Becker avers that Petitioner had in place:

policies and practices with clearly defined procedures, which the staff understand and follow in practice, for assessing residents for their capacity for decision-making and their ability to leave the grounds safely.

P. Ex. 15 at 8.

In his affidavit Dr. Becker discusses the approaches that Petitioner and its staff allegedly use to assess residents for the risks they encountered when away from the facility. Dr. Becker lists these approaches as constituting: initial evaluation of each resident upon admission; assessment made by a nurse of each resident who seeks to leave the facility; and consultation between the nurse and the resident's treating physician. P. Ex. 15 at 8-11.

However, and notwithstanding the contentions of these witnesses, Petitioner offered me nothing that memorializes these alleged protocols or that establishes that they were applied in the cases of individual residents. The assertions of Dr. Katz and Dr. Becker are uncorroborated claims, and I find them not to be credible. Petitioner provided me with no facility documentation, such as a policy statement or facility procedures, which sets forth the alleged assessment protocols. Furthermore, nothing exists in the treatment records of Residents # 1 and # 2 that demonstrates the presence and application of the risk assessment protocol that Drs. Katz and Becker contend that Petitioner employed.

I reviewed the care plans (CMS Ex. 16), nursing notes, and social service progress notes that were generated for Resident # 1 (CMS Ex. 19 and CMS Ex. 20), as well as the resident's elopement risk assessment (CMS Ex. 22), to test the credibility of the witnesses' contentions and to determine whether Petitioner at any time comprehensively assessed the risks and vulnerabilities that the resident might be exposed to if away from the facility unaccompanied. I found nothing in any of those exhibits that shows that such assessment was ever made. The resident's care plans document the staff's decision to give the resident a pass to leave the premises. CMS Ex. 16 at 2. They state that, on May 18, 2009, Petitioner's staff discussed with Resident # 1 the circumstances of his behavior and the need for appropriate support for medical concerns. *Id.* But, nowhere in this document is there an assessment or itemization of the risks that the resident would be exposed to while away on pass, nor is there any analysis of how those risks might be ameliorated.

I find the absence of such an analysis to be striking, especially because Petitioner's staff plainly knew or should have known that the resident would be exposed to life-threatening risks while away from the facility. The resident had a propensity to abuse alcohol to the extent that he had suffered from delirium tremens and seizures in the past that were related to his alcohol consumption. Yet, there is literally nothing in the resident's record that addresses the probability that the resident would drink while away from Petitioner's premises and the risks that such behavior posed for the resident's health and safety. Not even the fact that the resident clearly was drinking while away from the facility's premises motivated the staff to assess the risks that the resident faced.

I have also reviewed the affidavit testimony of Petitioner's other witnesses to ascertain whether Petitioner provided any credible evidence of an assessment process to deal with residents who expressed a desire to leave the facility. P. Ex. 16 - P. Ex. 20. I find nothing in these affidavits that supports Petitioner's contentions. Maureen Cerniglia, Petitioner's administrator, essentially repeats the assertions of Dr. Katz and Dr. Becker by contending that Petitioner had in place a system to assess its residents for safety. P. Ex. 17 at 2-3. But, as with the testimony of Dr. Katz and Dr. Becker, Ms. Cerniglia provides no specifics that support her assertions, and she provides no proof that Petitioner assessed Residents # 1 and # 2 for safety when off-premises.

Petitioner argues that no regulation requires an assessment protocol be committed to writing. That is true. But, in the absence of a written protocol, it is incumbent on Petitioner to provide me with some credible evidence showing that a protocol existed, even if it was known to staff only by word of mouth and custom. Petitioner has not offered such evidence. There is certainly none to be found in the treatment records of Residents # 1 and # 2. These records provide no support at all for the witnesses' contentions that unwritten protocols existed. Rather, the records of these residents show that the staff made ad hoc judgments in the residents' cases that were unsupported by any comprehensive analysis of the risks that the residents faced when they left the premises. I am persuaded that the staff essentially concluded that these residents would be intransigent and that, therefore, there was no point in even attempting to assess them comprehensively for off-premises risks.

Petitioner argues also that the fact that 218 of its residents had passes to leave the facility's premises is proof that it had a system in place for assessing those residents. P. Ex. 21 at 13. This assertion is unpersuasive. The fact that Petitioner allowed many of its residents (about one half of its resident census) to leave the facility on passes does not, by itself, establish anything about how or whether Petitioner's staff assessed these residents for safety.

Petitioner puts great emphasis on the right of a resident of a facility to refuse care and on a resident's freedom of choice. Essentially, Petitioner argues that it is powerless to intervene against a resident's wishes, by restricting that resident's freedom to come and go from its facility as he or she pleases, if that is what the resident desires to do. It argues, furthermore, that Resident # 1 was mentally competent to make the decision to spurn care and to leave the premises when he wanted to. Consequently, according to Petitioner, there was literally nothing it could have done lawfully to protect the resident.

I agree with Petitioner that a mentally competent resident has the right to refuse care that is offered to him or her. A facility does not have the authority to hold a resident against his or her will assuming that the resident shows sufficient mental competence to express a desire to leave the premises. However, if a skilled nursing facility is not a prison for mentally competent residents, neither is it a federally subsidized hotel or a group residence. A facility has a duty to attempt every reasonable measure to protect its residents, even if some of them exercise their rights to refuse care.

This case is not about whether Petitioner was required to restrict its residents' freedom of movement. It is about Petitioner's failure to discharge its fundamental obligation to assess the risks that residents faced when they left its premises unaccompanied. Petitioner would not be liable for failing to protect its residents had it taken all reasonable steps to assess and protect them, and the residents, notwithstanding, had rejected the care that was offered to them. The question of whether the residents would have rejected interventions that Petitioner developed for them never arises, because Petitioner failed to make the assessments that were prerequisites to developing meaningful interventions.

For example, in the case of Resident # 1, no evidence exists to show that Petitioner made an effort to develop interventions that might have dissuaded the resident from leaving the premises unaccompanied. Petitioner failed to assess the risks that the resident faced when away from the premises and failed, consequently, to consider what interventions could be offered to the resident short of simply giving him a pass. Moreover, the evidence in this case shows that Petitioner lacked a system even to identify and keep track of its residents who were away on a pass. Essentially, the evidence shows that Petitioner allowed its residents to come and go as they pleased without ever addressing the risks that these residents faced when they were away from the facility. None of these shortcomings by Petitioner implicate residents' rights. Rather, they establish Petitioner's basic failure to acknowledge and perform its obligation to protect its residents.

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

The applicable regulation requires a skilled nursing facility to 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. CMS alleges that Petitioner failed to comply with these regulatory requirements in that it failed to have a system in place to ensure that its residents were assessed to determine their ability to be away from facility premises on pass before being allowed to leave the premises. As support for this assertion, CMS relies on the same evidence that I have discussed at subpart a of this Finding.

I find this evidence to be persuasive. Petitioner's management was responsible for developing and implementing policies and procedures, including those that governed

assessing at risk residents for the hazards they might encounter while away from Petitioner's premises. Petitioner's management manifestly failed to develop such policies. As I discuss at subpart a of this Finding, there were no protocols, policies, or procedures – written or otherwise – governing assessment of at risk residents. The consequence was that staff made ad hoc judgments about what should be done for residents who desired to leave the premises, judgments that were not based on any meaningful assessment of the risks that these residents might face. Furthermore, Petitioner's management failed to have in place any policy that would enable it to track those residents who left the premises. As I discuss above, there was no system in place to account for residents who were out on pass and no master list of those residents who had pass privileges. That absence is underscored by the gross underestimate that Petitioner's Ex. 1 at 11.

Petitioner's arguments in opposition to CMS's assertions are essentially the same as I have discussed at subpart a. Petitioner insists that it had a system in place to assess for safety those residents who sought to leave the facility's premises. As support for this assertion, Petitioner relies on the affidavits of Dr. Katz, Dr. Becker, and Ms. Cerniglia. P. Ex. 15; P. Ex. 17; P. Ex. 21. I have found the testimony of these witnesses not to be credible. No need exists to re-analyze their testimony here.

c. Petitioner failed to comply substantially with the requirements of 42 C.F.R. 483.75(i).

The applicable regulation governs the position of medical director at a skilled nursing facility. In relevant part, it provides that a facility's medical director is responsible for implementation of resident care policies and the coordination of medical care at the facility. CMS alleges that Petitioner's medical director failed to assist with the development and implementation of policies and procedures that provided guidance and direction to facility staff when a resident requested a pass to leave the facility. It alleges additionally that the medical director failed to ensure that Petitioner's staff conducted appropriate and thorough assessments of residents that addressed risk factors to residents' health and safety when out on pass. As support for these assertions, CMS relies on the same evidence as I have discussed at subpart a of this Finding.

I need not re-analyze that evidence. At subpart a, I find that Petitioner failed to develop and implement policies governing assessment of at-risk residents who desired to leave Petitioner's premises. In the absence of a system, Petitioner's staff allowed residents – as is evidenced by the cases of Residents # 1 and # 2 –to leave the premises without evaluation of the risks and hazards that they might face. The consequence of that failure to assess is that no interventions were developed to at least attempt to persuade these residents to remain on premises. The responsibility for developing policies and procedures to assure that residents be assessed appropriately clearly falls within the ambit of the medical director's duties. A facility's medical director is responsible for implementation of a facility's resident care policies. 42 C.F.R. § 483.75(i)(2)(i). Implicit in that requirement is the duty to assure that appropriate policies exist.

The overwhelming evidence is that Petitioner failed to have – much less implement – policies and procedures that assured that residents who left the facility were assessed for the risks that they faced while off-premises. That failure was in part the responsibility of Petitioner's medical director, and, therefore, the evidence establishes noncompliance with the medical director regulation.

Petitioner's arguments in opposition to CMS's allegations are identical to those that I have addressed at subparts a and b of this Finding. I find it unnecessary to address them again. I find them to be as unpersuasive here, as I find them to be unpersuasive elsewhere.

2. Petitioner did not prove CMS's determinations of immediate jeopardy to be clearly erroneous.

Ample evidence in this case exists to support a conclusion that each of the three deficiencies that I find at Finding 1 of this decision was at the immediate jeopardy level of scope and severity. Resident # 1, in particular, was at grave risk of serious injury, harm, or even death when he left Petitioner's premises. The resident is a seriously impaired individual who depends on a wheelchair to ambulate. He abuses alcohol to the extent that he experiences seizures and delirium tremens. It is obvious that this resident will drink when he is on his own and that his drinking will lead to serious and even fatal consequences. The likelihood of serious injury, or worse, to this resident when he is out in public is very high. Thus, when the resident was away from Petitioner's facility between May 20 and May 22, 2009, he became intoxicated, suffered a seizure, lacerated his head, and had to visit a hospital emergency room for treatment of his injury.

A direct link exists between Petitioner's noncompliance with participation requirements and the likelihood that Resident # 1 would suffer serious injury, or worse. Petitioner's failure to assess Resident # 1 for the hazards that he faced while he was away from the premises rendered it impossible for Petitioner to develop and to implement interventions that might have dissuaded the resident from leaving the premises. Petitioner's failure to have policies in place to govern risk assessments meant that the staff was on its own and would at best treat instances like Resident # 1's attempts to leave the premises on an ad hoc basis rather than systematically.

Petitioner has not offered evidence to prove CMS's allegations of immediate jeopardy to be clearly erroneous. Petitioner argues that there was no likelihood of serious injury to any of its residents, because it "had already taken steps to assess the hazards and risks

and to implement reasonable interventions to mitigate them." Petitioner's Pre-Hearing Brief at 16. It asserts that its staff counseled Residents # 1 and # 2 on the risks of their conduct while away from the premises, limited the hours when they would be away, and limited Resident # 1's access to funds. *Id.* "Far from creating a likelihood of serious injury, harm or death, these actions constituted reasonable means to avert such a result." *Id.*

I am not persuaded by these assertions that Petitioner's staff gave meaningful counseling to the residents. How could the staff counsel these residents about the risks that they faced when the staff had not assessed those risks? As for the other interventions – limiting the residents' hours when they could be away and limiting Resident # 1's access to funds – those measures were demonstrated to be ineffective almost the instant that Petitioner implemented them. Resident # 1 simply ignored the time limitations of his pass, and he was able to secure alcohol while off premises despite the limitation of funds that Petitioner's staff imposed. The failure of these interventions should have prompted the staff immediately to reassess what they were doing to protect Resident # 1. However, no reassessment was made.

Petitioner also reiterates its assertion that it had a policy in place to assure that residents who left the premises were adequately assessed for the risks that they might encounter. It contends that it complied with regulatory guidelines by identifying potential risks to residents, implementing appropriate interventions, and monitoring and re-evaluating these measures to ensure the safety of Residents # 1 and # 2. I have found these assertions to be unsupported elsewhere in this decision, and I will not restate my analysis here.

3. CMS's remedy determinations are reasonable.

Petitioner did not challenge the duration of CMS's compliance findings. Therefore, I find that Petitioner was noncompliant with participation requirements, at an immediate jeopardy level of scope and severity, from May 29 through June 10, 2009. I conclude also that Petitioner remained noncompliant, at a level of noncompliance that was less than immediate jeopardy, from June 11 through July 23, 2009. What remains to be determined is whether the remedies that CMS imposed during these periods of noncompliance are reasonable. I find that they are.

a. Denial of payment for new admissions is reasonable as a matter of law.

CMS imposed the remedy of denial of payment for new Medicare admissions for each day of a period beginning on June 4 and running through June 23, 2009. CMS is authorized to impose this remedy based on any finding of substantial noncompliance and for each day that noncompliance persists. 42 C.F.R. § 488.417(a)(1). CMS is authorized

to impose the remedy here, inasmuch as Petitioner did not comply substantially with Medicare participation requirements throughout the June 4 – June 23, 2009 period.

b. CMS's civil money penalty determinations are reasonable.

i. Immediate jeopardy level penalties of \$9,650 per day are reasonable.

Civil money penalties for immediate jeopardy level noncompliance must fall within a range of from \$3,050 to \$10,000 per day. 42 C.F.R. § 488.438(a)(1)(i). Regulatory criteria exist for deciding where within the range a penalty amount should fall. The criteria include: the seriousness of a facility's noncompliance; its compliance history; its culpability; and its financial condition. 42 C.F.R. § 488.438(f)(1) - (4); 488.404 (incorporated by reference into 42 C.F.R. § 488.438(f)(3)).

CMS failed to address the issue of penalty amount in either its pre-hearing or final brief, so I am left to decide this issue without guidance or advocacy from CMS. Petitioner, by contrast, argues that no penalties should be imposed against it, because it denies noncompliance. Additionally, it asserts that its financial condition precludes it from paying the amount of the penalties that CMS determined.

The seriousness of Petitioner's noncompliance is certainly adequate, without consideration of other factors, to sustain an immediate jeopardy level penalty amount of \$9,650 per day. Petitioner housed residents – such as Resident # 1 – who were at grave risk for serious injury, or worse, when they were off premises without Petitioner's support and assistance. Resident # 1, a known alcohol abuser with a history of delirium tremens and seizures, was obviously in harm's way each time he left Petitioner's facility. What happened to him when he was away, his episodes of intoxication, his seizure, and his visit to the hospital, simply confirm that obvious conclusion. Petitioner's failure to assess Resident # 1 for possible risks when he was off premises by himself was, in fact, a symptom of a much greater problem at Petitioner's facility, the absence of policies and procedures to assure that assessments for risk would be done systematically and effectively in the cases of all residents who expressed an interest in leaving Petitioner's premises.

I am not persuaded that Petitioner's financial condition should mitigate in favor of reduction of the penalty amount. I note, preliminarily, that I may not, in any event, reduce the immediate jeopardy level penalty amount to an amount that is less than \$3,050 a day, nor may I reduce the non-immediate jeopardy level penalty amount to less than the \$50 per day that CMS determined to impose. Furthermore, I may not order that a denial of payment for new admissions be waived on grounds of financial hardship. Waiver of a denial of payment is not authorized by regulations. Regulations specifically prohibit an

administrative law judge to reduce civil money penalties below the regulatory minimum amounts.

Nor is there a basis for me to reduce the penalty amount from \$9,650 per day to \$3,050 per day, or to any amount that falls in between these two amounts. Petitioner contends that it will suffer injury if penalties are imposed against it, because it is a publicly operated facility that sustains actual operating losses. P. Ex. 19 at 5. It argues additionally that tight public funds and the prospect of reduced financial support from State and local agencies would make it difficult to recoup the additional impact on its operations of the civil money penalty amounts that CMS has determined to impose. *Id.* at 5-6. However, the fact that Petitioner has sustained operating losses in the past, or that it is expected to do so in the future, serves as no impediment to imposition of penalties. Obviously, Petitioner was able to make up for operating losses in the past – presumably through public contributions – and it has not demonstrated that it will be unable to do so now. Moreover, Petitioner has offered no evidence to show that the penalties will actually jeopardize its survival or its ability to provide care to the residents of the facility.

ii. Non-immediate jeopardy penalties of \$50 per day are reasonable as a matter of law.

Civil money penalties for non-immediate jeopardy level deficiencies must fall within a range of from \$50 to \$3,000 per day. 42 C.F.R. § 488.438(a)(1)(ii). The non-immediate jeopardy level penalty amount of \$50 per day that CMS determined to impose against Petitioner is the minimum that the law permits. It is therefore reasonable as a matter of law.

c. Loss of authority to conduct NATCEP is mandatory.

As a matter of law, CMS must revoke Petitioner's NATCEP for a period of two years. Revocation must occur where: a facility has been subject to an extended survey; or civil money penalties of \$5,000 or more have been imposed. Act § 1819(f)(2)(B(iii)(I)(a), (b). An extended survey is made where a facility has been found to manifest substandard quality of care, and that term includes findings of immediate jeopardy. Here, both of these statutory criteria were met, and, consequently, loss of NATCEP is mandatory.

/s/

Steven T. Kessel Administrative Law Judge