Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:	)	
	)	
Venetian Gardens (CCN: 36-6348),	)	Date: June 1, 2009
	)	
Petitioner,	)	
	)	
- v. -	)	Docket No. C-08-722
	)	Decision No. CR1956
Centers for Medicare & Medicaid Services.	)	
	)	

DECISION GRANTING SUMMARY JUDGMENT TO CENTERS FOR MEDICARE & MEDICAID SERVICES

I grant summary judgment to the Centers for Medicare & Medicaid Services (CMS) sustaining its determination to impose the following remedies against Petitioner, Venetian Gardens:

- A civil money penalty of $4150 to remedy Petitioner's noncompliance with Medicare participation requirements on May 17, 2008; and

- Civil money penalties of $100 per day for each day of a period that began on May 18 and which ran through July 17, 2008 to remedy Petitioner's noncompliance with Medicare participation requirements during that period.

I. Background

Petitioner is a skilled nursing facility doing business in the State of Ohio. It participates in the Medicare program. Its participation in Medicare is governed by sections 1819 and 1866 of the Social Security Act and by implementing regulations at 42 C.F.R. Parts 483 and 488. Its right to a hearing in this case is governed by regulations at 42 C.F.R. Part 498.

CMS determined to impose the remedies that I describe at the inception of this decision based on findings of noncompliance with Medicare participation requirements that were made during compliance surveys conducted at Petitioner's facility on May 28 (May survey) and June 18 (June survey), 2008. Petitioner requested a hearing and the case was assigned to me for a hearing and a decision. The parties exchanged proposed exhibits and filed pre-hearing briefs.

I scheduled an in-person hearing. However, CMS moved for summary judgment as to two of the noncompliance findings that were made at the May survey and one of the noncompliance findings that was made at the June survey. The two May survey findings are Petitioner's alleged failures to: provide one of its residents with adequate supervision and assistance devices in order to prevent accidents as is required by 42 C.F.R. § 483.25(h)(2); and complete a required interdisciplinary team assessment to determine whether that resident could safely self-administer medications as is required by 42 C.F.R. § 483.10(n). Petitioner opposes CMS's motion concerning these two deficiency findings.

The June survey finding about which CMS has moved for summary judgment is Petitioner's alleged failure to comply with the consultation and notification requirements of 42 C.F.R. § 483.10(b)(11). Petitioner is no longer contesting this latter finding of noncompliance and, therefore, I do not address it in this decision except where I discuss the reasonableness of CMS's remedy determinations.

CMS filed a total of 24 proposed exhibits which it designated as CMS Ex. 1 – CMS Ex. 24. Petitioner filed a total of 15 proposed exhibits which it designated as P. Ex. 1 – P. Ex. 15. Petitioner attached an additional exhibit to its brief in opposition to CMS's motion for summary judgment which it designated as P. Ex. A. I am receiving all of these exhibits into the record of this case and I cite to some of them in this decision. However, I make no evidentiary findings from these exhibits. I base my fact findings solely on the undisputed material facts as averred by the parties.

II. Issues, findings of fact and conclusions of law

A. Issues

The issues in this case are whether the undisputed material facts establish that:

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

2. CMS's determination of immediate jeopardy is not clearly erroneous.

3. CMS's remedy determinations are reasonable.

B. Findings of fact and conclusions of law

I make findings of fact and conclusions of law (Findings) to support my decision in this case. I set forth each Finding below as a separate heading.

1. The undisputed material facts establish that Petitioner failed to comply substantially with Medicare participation requirements.

I find the following facts to be undisputed.

Shortly after midnight on May 18, 2008 an individual who is identified in the May survey report as Resident # 79, a resident of Petitioner's facility, was struck and killed by an automobile while he operated his motorized wheelchair, alone and unsupervised, on a State highway near Petitioner's facility. CMS Ex. 5, at 1-4. At the moment of impact Resident # 79 was in the right of way and not on the shoulder or berm of the highway. *Id.* at 4. Local authorities reported that, prior to the accident, they had received calls about a person in a motorized wheelchair swerving in the roadway. *Id.*

Resident # 79 was a 56-year old individual who suffered from ailments which included end stage Parkinson's disease with tremors. CMS Ex. 9, at 26, 65, 71. The resident also had psychological problems which included anxiety and mania. *Id.* at 14, 23. He was profoundly physically impaired. His condition was so compromised that he required total care from Petitioner's staff for most activities of daily living. *Id.* at 26. Resident # 79 was assessed as having uncontrollable movements and poor coordination. *Id.* at 28, 63. He was incapable of ambulating independently and was dependent on a wheelchair for mobility. His impairments were of such severity that his balance was unsteady even when he sat. *Id.* at 34, 51. Petitioner's staff determined that the resident needed assistance for locomotion while in a wheelchair. *Id.* at 28. His motor control was so limited that when he attempted to use a recumbent bicycle in physical therapy, he required maximum assistance from Petitioner's staff to place his feet on the pedals. *Id.* at 74. The staff found the resident to be at risk for sustaining falls. *Id.* at 63-64.

The care plan that Petitioner's staff developed for Resident # 79 on December 17, 2007 and continued after March 30, 2008 acknowledges the resident's severe impairments. It states that he "requires 24 hour care and supervision . . . ." CMS Ex. 9, at 13.

Resident # 79 often left Petitioner's facility alone and unaccompanied by members of the staff or of his family. CMS Ex. 9, at 1-3. Petitioner's staff was aware that the resident would leave the facility without being supervised or assisted. *Id*. at 18; Petitioner's brief in opposition to CMS's motion for summary judgment (brief in opposition) at 5. Petitioner's staff maintained a sign out sheet for those residents who left the premises. CMS Ex. 9, at 1-3. On December 20, 2007 Resident # 79 signed an agreement in which he promised that he would provide the staff with an approximate time of return whenever

he signed himself out of the facility. *Id.* at 72. Resident # 79 would often sign himself out of the facility but without stating his destination or the time when he was expected to return to the premises. *Id.* at 1-3. At other times he would state various destinations that were off the premises of the facility and which could only be reached by traveling on a public highway. *Id.* On the evening of May 17, 2008, the resident signed himself out at 7:50 p.m. without stating a destination or an expected time of return. CMS Ex. 9, at 3; CMS Ex. 5, at 4.

There are no records showing that Petitioner's staff assessed Resident # 79 in order to determine whether the December 17, 2007 or the March 30, 2008 care plans should be modified or re-written so as to provide supervision or assistance to the resident when he left the premises. There are no records showing that Petitioner's staff ever systematically assessed the risks that Resident # 79 exposed himself to when he traveled alone from the facility in his motorized wheelchair. Nor are there records showing that Petitioner's staff discussed with the resident's physician the fact that the resident was leaving the facility unaccompanied and the risks that he was encountering by doing so.

Resident # 79 used a model of motorized wheelchair known as the Quantum 6000. CMS Ex. 4. This vehicle has a top speed of 6.5 miles per hour. *Id.* at 4; P. Ex. 3, at 6. The manufacturer has provided safety warnings to the chair's users. CMS Ex. 4 at 2-3. For example, the manufacturer warns about the risks of using the chair while under the influence of medications and counsels against using the chair at all while under the influence of alcohol. *Id.* at 3. The manufacturer also warns against the user reaching, leaning, or bending while driving the chair. *Id.* It specifically counsels that a user should "practice bending and reaching in the presence of a qualified healthcare professional." *Id.* at 2. There are no facility records which show that Petitioner's staff trained Resident # 79 to avoid these possible hazards associated with using the chair while he was away from the facility. *See* CMS Ex. 9, at 12. Nor are there records showing that the facility staff assessed Resident # 79 for the risks associated with the use of the chair, planned interventions designed to minimize those risks, or discussed those interventions with the resident.

Petitioner's staff allowed Resident # 79 to take medications with him and to self-administer those medications when he was outside of the facility unsupervised. P. Ex. 3, at 10, ¶ 12. Among the resident's medications were controlled substances for pain including Percocet and Oxycodone (Oxycontin). CMS Ex. 9, at 81, 87. There is no record that Petitioner's staff conducted an interdisciplinary team assessment in 2008 to determine whether it was safe for Resident # 79 to self-administer medications.

2. The undisputed material facts establish that Petitioner failed to comply substantially with Medicare participation requirements.

a. The undisputed material facts establish that Petitioner failed to comply substantially with the requirements of 42 C.F.R. § 483.25(h)(2).

The facts that I discuss above establish that Petitioner failed to provide Resident # 79 with adequate supervision and assistance devices to prevent accidents as required by section 483.25(h)(2). Petitioner's staff knew that the resident was a gravely impaired individual with serious balance and positioning issues. The staff concluded that the resident needed constant care and supervision. Indeed, the resident's care plan in effect at the time of his death was premised on that conclusion. But, in spite of that knowledge, Petitioner's staff did very little to protect the resident against the risks he encountered when he left the facility unaccompanied. The minimal assistance that the staff did provide to the resident – such as warning the resident to be safe when he left the facility unattended, or urging him to watch out for traffic on such occasions, or putting a flag and reflective tape on the resident's motorized wheelchair – were at best half measures.

Indeed, the undisputed facts establish a wholesale disregard by Petitioner's staff of the resident's safety and welfare. It should have been evident to the staff that any individual – but especially one as physically impaired as was Resident # 79 – would encounter very serious hazards if he or she traveled alone at night on a public highway in a motorized wheelchair with a maximum speed of 6.5 miles per hour. But, Petitioner's staff ignored these hazards. The staff did not assess the risks that the resident was encountering. Indeed, and judging from the absence of any facility records documenting those risks, the staff appeared to ignore them completely. They planned no interventions to protect the resident when he was outside of the facility by himself. Nor did the staff document discussing with the resident comprehensively the risks that he encountered or the protections that might have been available to him.

While some nurses notes document that safety was at least discussed with the resident on some occasions, the instructions appear to be superficial and sporadic. P. Ex. 4, at 26 ("be aware of the traffic and please be careful"); P. Ex. 4, at 28 ("instructed [resident] on safety, & weather pt states 'I understand I won't be gone [longer than a] 1/2 hr at the most' pt signed out. Appropriate clothing on"); P. Ex. 4, at 30 ("[resident] signed out [resident] was educated on safety & states understanding"); P. Ex. 4, at 31 ("[resident] signed out, educated re: safety, traffic & weather [resident] stated he understands"); P. Ex. 4, at 39 ("[resident] signed out per protocol. [E]ducated [resident] re: safety. Verbalizes understanding"). Other nurses notes document that he left the facility but do not mention safety instruction. P. Ex. 4 at 28, 32. One social service note dated May 15, 2008 indicates that Resident # 79's social service designee spoke with him "about the safety of being on the highway [with] scooter. Res. Stated he follows all traffic rules."

P. Ex. 10, at 3. Resident # 79 signed the sign out log 31 times from March through May 2008; Petitioner has provided only six instances of cursory instruction about safety while the resident was outside the facility.

Moreover, because staff did not assess the risks that the resident might encounter and care plan for them, any safety instructions would have been ad hoc and would not have had the benefit of care planned interventions and options for the resident. Nothing in the record shows that the resident ever received instruction on the risks associated with operating the wheelchair in general much less at night on a public highway.

A skilled nursing facility is not simply a federally-compensated hotel for sick and impaired residents. The facility owes a duty of care to each of its residents. That duty includes protecting each resident against all known or knowable accident hazards. Petitioner's first obligation in providing care to Resident # 79 was to assess him to identify each and every risk that was specific to his condition. The staff failed to make that assessment because it failed to consider what unique risks might be encountered by the resident if he left the premises unsupervised in his motorized wheelchair. The records are simply devoid of any evidence that Petitioner's staff focused on and addressed that issue.

Second, Petitioner was obligated to plan the resident's care so as to address all identified or identifiable risks. There was a patent failure in planning Resident # 79's care because the care plan – while it stated that the resident needed 24-hour supervision – failed to discuss at all how the resident would be protected when he was off premises.

Finally, the facility had a duty to implement all reasonable protective measures in order to prevent the resident from having foreseeable accidents. There was a complete failure of Petitioner's staff to perform that duty. The staff ignored the obvious risks posed by the resident's use of a motorized wheelchair with a maximum speed of 6.5 miles per hour, often at night, on a public highway. These risks were exacerbated by the resident's severely impaired physical condition, his uncontrollable movements, his poor coordination, and his loss of balance. The facility's records reveal only minimal and sporadic efforts by the staff to counsel him about safety hazards or to offer the resident assistance. Thus, the staff would occasionally warn the resident to be safe while he was away from the facility. But, nothing in the facility's records show any comprehensive planning for the resident's safety. For example, there is no documentation that the staff offered to drive the resident to destinations away from the facility so as to avoid the hazards the resident would encounter by using his motorized wheelchair alone.

I have considered Petitioner's arguments in opposition to CMS's motion and I find them to be without merit. I conclude that they are irrelevant or incorrect as a matter of law even if I assume Petitioner's fact contentions to be true.

In opposing CMS's motion, Petitioner asserts repeatedly that it provided assistance and support to Resident # 79 consistent with regulatory requirements. Below, I discuss Petitioner's assertions in detail and I explain why, even assuming their truth, they do not support a finding that Petitioner provided the resident with requisite assistance and supervision. It is true, as I discuss, that Petitioner did provide some sporadic assistance and support to the resident. The staff would, on occasion, warn the resident to be safe or careful while he was away from the facility. There appeared to have been some discussions with the resident about how to operate his motorized wheelchair safely. And, the staff did equip the chair with reflective tape and a flag. But, these measures pale in comparison to the hazards faced by the resident when he was away from the facility alone. What is singularly lacking in the facts alleged by Petitioner is anything showing that its staff ever *comprehensively* identified these risks and attempted to deal with them. In short, the measures undertaken by Petitioner – assuming everything that Petitioner asserts to be true – were half measures at best. Petitioner's staff should have known that the assistance that it offered to the resident was woefully inadequate given the risks he encountered every time he left the facility.

Petitioner contends that the proximate cause of Resident # 79's death was not any compliance failure by the facility. According to Petitioner:

> the death resulted because of the misfeasance of an inattentive, drugged and handicapped driver, Mr. . . ., who hit what he thought to be a dog with his 14-year-old, dilapidated car on a clear night on an open, flat road devoid of any other traffic.

Petitioner's brief in opposition at 5. This argument is irrelevant even assuming the truth of the facts alleged by Petitioner concerning the circumstances of Resident # 79's death. It does not matter to my decision that the negligence of another individual may have caused the resident's death. The issue before me is whether Petitioner and its staff failed comprehensively to address hazards to Resident # 79 that should have been addressed. The hazards encountered by this profoundly impaired individual traveling at a maximum speed of 6.5 miles per hour in the vehicle right of way on a public highway at night were present whether or not his death was caused by the negligence of someone else. Indeed, Petitioner's noncompliance would be just as evident even if *there had never been an accident* and the resident was presently alive.

Petitioner also asserts that what is really at issue in this case is that Resident # 79 was:

> a competent person, with free-will and civil rights, including the right to refuse care, be left alone, and, most importantly, to come and go as he pleased . . . .

Petitioner's brief in opposition at 5-6.

As support for these assertions Petitioner relies on advice that the State of Ohio's public ombudsman's office allegedly gave to Petitioner's consultant. According to the consultant, that office advised her that it would have had a "big problem" if Petitioner had attempted to restrict the resident's freedom to leave Petitioner's facility as he pleased. P. Ex. 3, at 10, ¶ 11. And, according to Petitioner, the ombudsman's office advised the consultant that, even on the night of the resident's death, the facility "appropriately recognized [the resident's] right to leave the facility as he chose."[1] *Id.*

Petitioner's arguments and the reported conversation between the consultant and the State of Ohio's ombudsman are irrelevant. This case is not about the resident's right to refuse care nor is it about the resident's civil rights. What is at issue here is Petitioner's obligation to offer supervision and assistance to its residents. That duty exists *even if* a resident, such as Resident # 79, exercises his or her free will and decides to decline that which Petitioner offers. *Koester Pavillion*, DAB No. 1750, at 28 (2000). Moreover, had Resident # 79 actually rejected Petitioner's offer to provide care, the resident's care plan should have documented that. 42 C.F.R. § 483.20(k)(1)(ii). Where a resident refuses to accept care that is offered by a facility the facility has the burden of documenting that refusal. *Innsbruck HealthCare Center*, DAB No. 1948, at 7-8 (2004).

The resident's care plan is devoid of any reference to a possible refusal by the resident to accept supervision and/or assistance while away from the facility. Petitioner's nursing notes are similarly devoid of such a reference. But, even assuming that Petitioner's staff counseled the resident about the risk of leaving the facility alone, that advice did not excuse Petitioner from assessing the resident, planning his care, and at least offering to implement that which they had planned. I emphasize: Petitioner has come forward with absolutely nothing to show that its staff ever comprehensively assessed the risks that Resident # 79 faced when out of the facility alone, nor has it offered anything to show that Petitioner planned the resident's care in light of those risks.

Petitioner contends that there were standing orders by a physician that allowed the resident to leave the facility unaccompanied and with his medications. As support for this assertion Petitioner relies on a physician's orders dated December 2007 and February 2008. Petitioner's brief in opposition at 7-8; P. Ex. 4, at 15, 18-19. Petitioner also offers an April 2009 affidavit from the resident's former treating physician. P. Ex. A, at 2.

---

[1] The asserted communication with the ombudsman occurred after the resident's fatal accident. There are no facts to show that Petitioner's staff consulted with the ombudsman while the resident was alive and engaging in his unsupervised trips from the facility. Nor are there facts to describe exactly what was the substance of any communications between the consultant and the ombudsman. For example, it is unknown whether the consultant described the extent of the resident's impairments and the circumstances under which he was out alone from the facility.

For purposes of this decision I am accepting as true Petitioner's contention that the resident's physician ordered that the resident could leave the facility unaccompanied and with his medications.[2] However, that has no bearing on the outcome of this case. The risks to Resident # 79 resulting from him being out of the facility alone were evident. Petitioner's staff was required to assess those risks and to plan interventions to protect the resident even if the physician authorized the resident being outside alone.

Petitioner asserts that its staff gave training to the resident and that the resident was made aware on numerous occasions how to operate his motorized wheelchair. "In fact," according to Petitioner, "safety precautions/training and instructions were provided so often that [Resident # 79] protested the frequency with which they were given." Petitioner's brief in opposition at 9. Petitioner contends, additionally, that the resident expressed awareness and an understanding of this training and the operating instructions and safety directions attendant with his wheelchair use as well as the risks involved with using the wheelchair. *Id.*

However, Petitioner cites to nothing in the resident's treatment record to support these assertions and, in fact, the exhibits offered by Petitioner consisting of the resident's treatment record provide no facts to show that the staff gave Resident # 79 anything more than cursory instructions about the hazards of operating his motorized wheelchair. There is no documentation showing that the staff ever discussed with the resident the inherent safety risks of operating the wheelchair while on a public highway at night. Nor is there anything to show that the staff ever discussed with Resident # 79 the risks that he would encounter if he operated the wheelchair away from the facility while under the influence of controlled substances.

The sole support offered by Petitioner for its assertion that its staff gave safety training to the resident is in an affidavit offered by Petitioner's consultant, an individual who was not involved in providing direct care to the resident. P. Ex. 3, at 3-5, 14. But, what the consultant cites as support for her conclusion consists only of sporadic warnings to the resident to be careful or to watch out for traffic while away from the facility.

---

[2] There are facts from which one easily could infer a different conclusion. On March 21, 2008 the physician issued an order which authorized the resident to leave the facility, with a pass, and accompanied by his family. CMS Ex. 7, at 1. This order comes later in point of time than those relied on by Petitioner and it would be reasonable for me to infer that the physician, recognizing the resident's severe limitations, envisioned him leaving the facility only in the company of a family member. I do not decide this question because I rely only on the undisputed facts. However, the fact that this latter order was in the resident's record certainly should have, at the very least, put the staff on notice of a possibility that the physician did not want the resident leaving the facility unaccompanied and the staff clearly should have addressed this possibility in its assessment and care plan for the resident.

I make no credibility finding about the consultant's assertions.[3] For purposes of this decision I accept as true her assertion that the resident received training from Petitioner's staff in the use of his motorized wheelchair to the extent that it is supported by the exhibits which the consultant cites. But, such training was clearly inadequate to address the risks that the resident encountered when he left Petitioner's premises alone and at night. Sporadically warning the resident to watch out for traffic when he was away from the facility or to be safe or careful does not approach the comprehensive support and assistance that this resident was entitled to receive. Petitioner has cited to nothing to show that the staff ever *comprehensively* discussed with Resident # 79: the hazards of traveling unaccompanied on a state highway; the risks of driving a motorized wheelchair in the dark on a road that was made for vehicles traveling at a much faster pace than 6.5 miles per hour; the risks of using the chair outside of the facility's premises while under the influence of controlled substances including Oxycontin; or the inherent dangers resulting from the resident's greatly impaired physical condition.

Petitioner contends that Resident # 79 frequently signed himself out of the facility in accordance with the facility's protocol. Petitioner's brief in opposition at 10. It contends that the protocol allowed for documentation about the safety instructions that were given to the resident concerning his use of his motorized wheelchair. *Id.*

There is no factual basis for me to conclude that Resident # 79 complied with Petitioner's sign out protocol. However, even if Petitioner's assertion of compliance by the resident is true, it is irrelevant. The facility resident sign out sheet, cited by Petitioner in support of its contention, very clearly shows that Resident # 79 often left the facility without complying with the facility's sign out protocol. CMS Ex. 9, at 1-3. He had agreed to state his destination and expected time of return whenever he signed himself out. *Id.* at 72. But, the resident frequently signed himself out without stating his destination or the expected time of his return. Indeed, on May 17, 2008, the evening of the resident's death, he signed himself out without stating his destination or the expected time of his return. *Id.* at 3.

Furthermore, Petitioner has not provided any explanation of its sign out protocol. Petitioner's consultant states that the protocol "*allowed* for documentation about Resident # 79's use and safety instruction for his wheelchair." P. Ex. 3, at 5 (emphasis added). The consultant's declaration cites to nursing notes where staff provided cursory safety

---

[3] The consultant's affidavit is filled with similar unsupported assertions of fact. *See* P. Ex. 3. The absence of corroboration of the statements by a consultant, who was not involved in providing care to the resident, and who was not present at Petitioner's facility on a daily basis when care was being provided to Resident # 79, raises obvious questions about her credibility. I make no credibility findings in this decision because I am issuing summary judgment in favor of CMS. Rather, I am assuming the consultant's statements to be true even if they find no support in the record of the resident's care.

instruction to the resident, such as "be safe", when he left the facility but does not explain what the protocol actually requires. *See* discussion above. The consultant does not assert that the protocol requires any particular safety instructions (e.g., regarding time of day, weather conditions, mode of transportation, medication) or safety instruction each time a resident leaves the facility.

Petitioner would be noncompliant even if Resident # 79 had followed the facility's sign out protocol to the letter. The fact that the resident may have told the staff where he was going and when he expected to return to the facility did not compensate for the facility's failures to: assess the risks to the resident of his being away unaccompanied; plan comprehensive interventions to protect the resident; and to at least offer those interventions to the resident. The staff's knowledge that the resident was out on a public highway in his motorized wheelchair at night absent any meaningful and comprehensive attempt to ameliorate the obvious hazards that the resident encountered did nothing whatsoever to reduce the risks to the resident from such activity.

Petitioner asserts that it protected Resident # 79 by adding reflective tape and a flag to the resident's wheelchair. Regardless of how many reflectors or flags Petitioner put on the resident's wheelchair those steps do not take the place of supervision, particularly when the resident's care plan specifically called for 24 hour supervision. Reflectors and flags may have provided added safety to the resident, but they are not, given the hazards that were faced by the resident, meaningful assistive devices and adding them to his wheelchair falls far short of the regulation's requirement for comprehensive assessment, planning, and assistance.

Petitioner contends that, had it provided Resident # 79 with the supervision and assistance required by 42 C.F.R. § 483.25(h)(2), it would have had to make "a Hobbesian choice of facing a lawsuit for invasion of privacy and/or false imprisonment and a survey finding of want of substantial regulatory compliance for failing to abide by resident's rights laws." Petitioner's brief in opposition at 13. The choice posited by Petitioner is a false choice. The regulation does not put a facility in the position of having to decide whether to comply by violating a resident's rights. Petitioner could have complied completely with regulatory requirements without violating the resident's rights by assessing the resident's needs, planning his care, and offering him appropriate interventions. Discharging those regulatory obligations would not have infringed at all on the resident's rights including his right to reject that which Petitioner's staff might have offered to him.

Petitioner argues that to hold it liable for noncompliance with the requirements of 42 C.F.R. § 483.25 would be to violate a rule of reason governing application of that regulation. It contends that the regulation, in not imposing a strict liability standard on a facility, only requires a facility to do that which is practicable. According to Petitioner, it would have been impracticable for the facility to provide Resident # 79 with one-on-one

supervision or other interventions that would have assured his safety when he was away from Petitioner's premises. Therefore, according to Petitioner, it should not be held accountable for whatever might possibly have occurred to the resident during his absences from the premises.

Petitioner is correct in asserting that the regulation does not require a facility to accomplish the impossible. For example, the facility could not force Resident # 79 to do something that was against his will. However, there were many things that Petitioner could have done – and did not do – to protect the resident consistent with the facility's duties under the regulation. All of these things were practicable and reasonable. The facility could have done a comprehensive assessment of the risks faced by the resident when he left the facility. It could have discussed those risks in detail with the resident and documented those discussions, including the resident's reactions and his own comments in response to that which was told to him by the facility's staff. It could have developed interventions designed to protect the resident and offered those interventions to the resident. For example, if the resident expressed a desire to visit a commercial establishment off the facility's premises the staff might have attempted to find a way to drive the resident there. Or, it could have offered to accompany him. What is singularly lacking in this case are facts showing that Petitioner's staff conceived of or offered any assistance to Resident # 79.

b. The undisputed material facts establish that Petitioner failed to comply substantially with the requirements of 42 C.F.R. § 483.10(n).

The undisputed material facts provide overwhelming support for my conclusion that Petitioner failed to comply substantially with regulatory requirements in allowing Resident # 79 to self-medicate. The regulation states that:

> An individual resident may self-administer drugs if the interdisciplinary team, as defined by § 483.20(d)(2)(ii), has determined that this practice is safe.

The regulations define an interdisciplinary team as consisting of the resident's attending physician, a registered nurse with responsibility for the resident, and other appropriate staff in disciplines as determined by the resident's needs, and to the extent practicable, the participation of the resident, the resident's family or the resident's legal representative. 42 C.F.R. § 483.20(k)(2)(ii).[4]

[4] There is a misprint in the reference at 42 C.F.R. § 483.10(n) to 42 C.F.R. § 483.20(d)(2)(ii). A skilled nursing facility's interdisciplinary team is defined at 42 C.F.R. § 483.20(k)(2)(ii) and not 42 C.F.R. § 483.20(d) (subsection (d) addresses maintenance and use of comprehensive assessment records).

There are no facts showing that Petitioner had an interdisciplinary team conduct an assessment of Resident # 79 in order to determine whether it was safe to allow the resident to self-administer drugs, including the controlled substances Percocet and Oxycontin, while he was away from Petitioner's premises unaccompanied. Nor is there anything to show that an interdisciplinary team even considered the possibility that the resident's self administration of medications including controlled substances during periods – including nights – when he operated his motorized wheelchair on a public highway might be dangerous to the resident's safety.

Petitioner argues that there was "no safety issue" associated with allowing Resident # 79 to self-administer medications. Petitioner's brief in opposition at 15. Petitioner premises that assertion on alleged facts that the resident was not cognitively impaired, that he had well-functioning arms, hands, and fingers, and that he was physically capable of administering medication to himself. *Id.* But, these asserted facts do not excuse Petitioner's failure to comply with regulatory requirements. There was an explicit regulatory duty, which Petitioner ignored, to have an interdisciplinary team evaluate the safety factors and risks associated with allowing the resident to self-medicate *before* the resident began doing so. Such evaluation needed to be updated periodically in order to take into account any changes in the resident's condition. The record of this case is devoid of any facts showing that Petitioner's staff accomplished this duty.

Furthermore, the resident's physical capabilities and even his cognitive state were not the only things that Petitioner's staff needed to take into consideration in agreeing to allow the resident to self-medicate. For example, Petitioner's staff knew or should have known that the manufacturer of the resident's motorized wheelchair had warned against the use of the chair while a patient was under the influence of medications. Petitioner's staff certainly needed to address that issue, among many other things, in the context of an interdisciplinary review.

Nor is it sufficient to assert that the resident's physician approved the resident's self-medication. A purpose of requiring an interdisciplinary team to evaluate the issue of self-medication by a resident is to give the physician input that might otherwise be missing when the physician exercises his or her judgment. A facility's staff serves as the eyes and ears of a physician who is not on premises and attending to a resident 24 hours per day. But, the record of this case is devoid of any facts showing that Petitioner's staff performed that function. For example, there are no facts in this case to show that Resident # 79's physician was aware that the resident was using his motorized wheelchair to travel alone and at night on a public highway. [5] Yet, precisely those facts should have

---

[5] The resident's treating physician avers in her affidavit that:

been considered by an interdisciplinary team and brought to the physician's attention in order to determine whether it would have been safe for Resident # 79 to self-medicate while away from Petitioner's premises.

3. The undisputed material facts establish CMS's determination of immediate jeopardy level noncompliance not to be clearly erroneous.

CMS determined that Petitioner's noncompliance with the requirements of 42 C.F.R. § 483.25(h)(2) was so egregious as to comprise immediate jeopardy for residents of Petitioner's facility. An immediate jeopardy level deficiency is one that causes, or is likely to cause, one or more residents of a facility to suffer serious injury, harm, impairment, or death. I find that the undisputed material facts of this case overwhelmingly support my conclusion that the noncompliance was at the immediate jeopardy level of scope and severity.

The undisputed facts establish an overwhelming likelihood that Resident # 79 would suffer serious injury, harm, impairment or death as a consequence of Petitioner's failure to offer him reasonable assistance and supervision. It should have been obvious to Petitioner's staff that an individual as impaired as was Resident # 79 was flirting with disaster every time he drove his motorized wheelchair alone on a state highway. Yet, and despite that knowledge of looming disaster, Petitioner's staff did nothing to assess the risk, plan to ameliorate it, and offer reasonable interventions to the resident.

Petitioner has offered no facts which, if true, would establish the determination of immediate jeopardy to be clearly erroneous. Petitioner argues that the facts of the resident's accidental death on May 18, 2008 are relevant to deciding whether or not Petitioner's noncompliance was at the immediate jeopardy level. "[O]therwise," according to Petitioner, "one is left to conclude that the mere fact that [Resident # 79] was out of the Facility, alone, supports not only the deficiency finding but also its scope and severity." Petitioner's brief in opposition at 11. Petitioner goes on to argue that the resident's fatal accident was due entirely to the negligence of the driver of the vehicle which struck the resident.

> I was the attending physician to Resident 79 . . . Thus, I am specifically familiar with the conditions, behaviors and diagnoses for Resident 79.

P. Ex. A, at 1. Assuming these representations to be true they do not amount to saying that her knowledge of the resident's condition and behaviors was equal to that of Petitioner's staff. The physician does not aver that she was with the resident throughout the day as were members of the staff. Nor does she aver that she was aware that the resident was leaving the facility alone on his motorized wheelchair to travel on a public highway.

My finding of immediate jeopardy rests on the likelihood that Petitioner's failure to offer reasonable assistance and supervision to Resident # 79 would result in at least serious injury and not on facts showing that this failure actually caused the accident of May 18. The *likelihood* of serious injury or worse was high even if Petitioner's failure to offer supervision and assistance to the resident was not the proximate cause of the May 18 accident.[6]

Immediate jeopardy does not exist here based on the "mere fact" that Resident # 79 left Petitioner's facility alone on the evening of May 17, 2008. It rests on the facility's failure to assess the risks and hazards that the resident faced when he went outside alone, its failure to plan reasonable interventions, and its failure to offer them to the resident.

4. The undisputed material facts establish CMS's remedy determinations to be reasonable.

There are two remedies that are at issue here: a one-day civil money penalty of $4150 to remedy Petitioner's immediate jeopardy level noncompliance on May 17, 2008; and civil money penalties of $100 per day for each day of a period running from May 18 through July 17, 2008 to remedy Petitioner's non-immediate jeopardy level noncompliance during this period. The undisputed material facts establish these remedies to be reasonable.

a. The undisputed material facts establish that a one-day civil money penalty of $4150 to remedy Petitioner's immediate jeopardy level noncompliance is reasonable.

Civil money penalties for immediate jeopardy level noncompliance fall within a range of a minimum of $3050 to a maximum of $10,000 per day. 42 C.F.R. § 488.438(a)(1)(i). There are regulatory factors which govern the amount of a civil money penalty falling within this range. These factors include: the seriousness of the noncompliance; a facility's compliance history; its culpability for the noncompliance; 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)).

The undisputed material facts of this case establish that the seriousness of Petitioner's immediate jeopardy level noncompliance is more than sufficient to justify the one-day $4150 civil money penalty that CMS determined to impose. Petitioner's noncompliance was egregious. It should have been obvious to the staff that Resident # 79 was at grave

---

[6] That is not to say that the circumstances of the accident – if they were the consequence of Petitioner's failure to provide supervision and assistance to the resident – would be irrelevant. It is, however, unnecessary that I address those circumstances in order to decide this case.

danger every time he exited Petitioner's premises alone. As I have discussed he was a profoundly physically impaired individual operating a piece of equipment that was patently unsafe to operate on a public highway at night. Petitioner's staff knew or should have known that the resident's impairments gravely compromised his ability to be away safely from the facility by himself. They knew or should have known also that the circumstances under which he was away from the facility – alone, at night, under the influence of controlled substances including Oxycontin, and operating a motorized wheelchair with a maximum speed of 6.5 miles per hour on a public highway among much faster moving motor vehicle traffic – was a recipe for disaster. But, despite that, Petitioner failed categorically to discharge its obligations to assist and protect this resident.

The $4150 civil money penalty is, in fact, a pittance when compared to the seriousness of Petitioner's noncompliance. To begin with, it is near the bottom of the range of penalties that may be imposed for immediate jeopardy level noncompliance. Also, CMS has, in its discretion, opted not to impose any penalties for the weeks in which the staff failed to protect Resident # 79 while he engaged in identical behavior to that which he was engaging in on the night of his death. In short, Petitioner is fortunate that CMS did not elect to impose a much greater civil money penalty than that which it determined to impose.

Petitioner has offered no argument or facts to show the penalty amount to be unreasonable. Mainly, it argues that the undisputed material facts do not establish immediate jeopardy level noncompliance. I have addressed that issue at Finding 2 of this decision.

Petitioner has not contended that it lacks the wherewithal to pay the penalty. It asserts that CMS has not offered any facts concerning Petitioner's compliance history. However, and as I have discussed, the seriousness of the noncompliance in and of itself justifies the penalty amount. Facts showing a poor compliance history might provide additional support for the penalty but such facts are unnecessary here. And, Petitioner has offered nothing to show that a reduction of the penalty amount might be justified in light of its compliance history.

b. The undisputed material facts establish that civil money penalties of $100 per day for each day of a period that began on May 18 and which continued through July 17, 2008 to remedy Petitioner's non-immediate jeopardy level noncompliance are reasonable.

Civil money penalties for non-immediate jeopardy level noncompliance fall within a range of from $50 to $3000 for each day of noncompliance. 42 C.F.R.

§ 488.438(a)(1)(ii). The same regulatory factors for deciding on a penalty amount within this range apply here as apply to immediate jeopardy level penalties.

The undisputed material facts show that Petitioner's non-immediate jeopardy level noncompliance persisted through July 17, 2008. CMS determined that Petitioner did not attain full compliance with the requirements of 42 C.F.R. §§ 483.25(h)(2) and 483.10(n) until that date. Petitioner has offered no facts showing that it corrected these deficiencies at any time earlier than July 18. CMS Ex. 1, at 1-2.[7]

Petitioner argues that its noncompliance with the requirements of 42 C.F.R. § 483.10(n) necessarily ended with the death of Resident # 79 on May 18, 2008. I disagree. The noncompliance lies in the staff's failure to comprehend the necessity for performing the assessment required by the regulation as a prerequisite for allowing *any* resident – not just Resident # 79 – to self-medicate. The failure to perform that assessment in Resident # 79's case illustrates the staff's lack of understanding of its obligations. But, the resident's death, without any facts showing corrective action by Petitioner, does not establish that the staff had recognized the error of their ways and corrected the deficiency.

I find that the penalty amount is amply justified by the undisputed facts showing the seriousness of Petitioner's noncompliance. Indeed, the seriousness of Petitioner's noncompliance as is demonstrated by the failure of Petitioner to perform the required assessment of Resident # 79's ability to self-medicate before allowing him to do so would very easily justify a much higher daily penalty amount than $100.

A daily penalty amount of $100 is a minimal penalty, comprising only three percent of the maximum allowable non-immediate jeopardy daily penalty amount. Petitioner does not argue that the amount is unreasonable assuming that it was deficient during the May 18–July 17, 2008 period. Petitioner does not assert that it lacks the resources to pay the penalty nor does it contend that there are facts showing that a penalty amount of $100 per day – assuming noncompliance – would be unreasonably high.

This resident was already at great risk of life and limb when he made his unaccompanied excursions away from the facility in a motorized wheelchair. Combining those excursions with unsupervised consumption of medications, including controlled substances, clearly greatly exacerbated the risk to the resident. Yet, there are no facts to show that Petitioner's staff was sensitive to this heightened risk. Rather, the staff simply

---

[7] Petitioner's noncompliance during this period also included noncompliance with the requirements of 42 C.F.R. § 483.10(b)(11), beginning on June 18, 2008 (the date of the June survey) and continuing through July 17, 2008. As I discuss in the introduction to this decision, Petitioner is not challenging this noncompliance. Its plan of correction for this deficiency specified that compliance would be attained on July 18. CMS Ex. 14.

handed medications over to the resident without having an interdisciplinary team look at the possible adverse implications. That level of noncompliance, coupled with Petitioner's continued noncompliance with the requirements of 42 C.F.R. § 483.25(h)(2) and its noncompliance during part of the May 18–July 17 period with the requirements of 42 C.F.R. § 483.10(b)(11), demonstrates that $100 per day is truly a minimal penalty amount.

/s/
Steven T. Kessel
Administrative Law Judge