Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

John J. Kane Regional Center - McKeesport
(CCN: 39-5640),

Petitioner

v.

Centers for Medicare and Medicaid Services.

Docket No. C-10-843

Decision No. CR2383

Date: June 15, 2011

DECISION

I sustain the determination of the Centers for Medicare and Medicaid Services (CMS) to impose two per-instance civil money penalties of $3,000 against Petitioner, John J. Kane Regional Center.

I. Background

Petitioner is a skilled nursing facility in McKeesport, Pennsylvania. 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 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 against Petitioner the remedies that I describe in the opening paragraph of this decision. CMS based its remedy determination on Petitioner's alleged failure to comply with two Medicare participation requirements stated at 42 C.F.R. §§ 483.10(b)(11) and 483.13(c). Petitioner requested a hearing, and the case was assigned to me for a hearing and a decision.

I held a hearing by videoconference on April 4, 2011. I heard the cross-examination and redirect testimony of witnesses whose written direct testimony had been submitted previously as exhibits. I also received into evidence the parties' exhibits (Ex.) that were identified as CMS Ex. 1 – CMS Ex. 22 and P. Ex. 1 – P. Ex. 14.

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; and

2. 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.

a. Petitioner failed to comply substantially with the requirements of 42 C.F.R. § 483.10(b)(11).

The applicable regulation mandates a facility to consult immediately with a resident's treating physician about either an accident involving the resident that results in injury and has the potential for requiring physician intervention or a significant change in the resident's physical, mental, or psychosocial status. The purpose of the regulation plainly is to assure that sick and vulnerable individuals receive care that they are unable to provide for themselves.

CMS's allegations of noncompliance all relate to the care that Petitioner gave to a resident who is identified as Resident # 1. On the morning of April 1, 2010, this resident fell from her wheelchair. CMS Ex. 6 at 1, 13.[1] She did not complain initially of pain. However, beginning at about two o'clock on the afternoon of April 1, the resident voiced complaints of hip and back pain. *Id.* at 1. Her complaints escalated over the ensuing one and one-half days. On the evening of April 1, Resident # 1 demanded that Petitioner's

[1] It appears that the resident may have fallen two times on that date. Nursing notes for April 1, 2010 do not precisely describe the fall, or falls, that the resident sustained, but they make reference to two falls. CMS Ex. 6 at 6.

staff transport her to a hospital. *Id.* at 2. She continued to complain of pain during the day of April 2, 2010 and complained that her pain medications were not helping her. *Id.* On the evening of April 2, the resident again insisted that she be transported to a hospital. *Id.* The resident then called 911 and requested that she be taken to a hospital because she had a broken hip. *Id.* This request was subsequently cancelled, and I infer that it was facility staff that cancelled the request after speaking with the resident.

The resident continued to complain of severe hip and back pain. Some time before 8:00 on the evening of April 2, Resident # 1 again called 911. At 8:00 p.m., emergency medical technicians arrived and transported the resident to a local hospital. She was admitted that evening and diagnosed to be suffering from a broken hip. Subsequently, the resident underwent surgery to repair the fracture. CMS Ex. 10 at 1, 4, 5, 7.

Dr. James Campagna, the resident's treating physician, saw the resident at about 9:00 a.m. on the morning of April 1, 2010, shortly after the resident had sustained her fall. At that time the resident was not complaining of pain. The physician directed Petitioner's staff to monitor the resident for continued pain. CMS Ex. 6 at 13. But, and despite these instructions and the resident's escalating and persistent complaints of hip and back pain, Petitioner's staff never again consulted with the Dr. Campagna about the resident's condition between the morning of April 1 and the resident's hospitalization on the evening of April 2.

The evidence conclusively establishes that Petitioner failed to consult with Resident # 1's physician in contravention of regulatory requirements. Petitioner's failure to respond to Resident # 1's escalating complaints of pain – including its failure to consult with the resident's treating physician about those complaints – is a grossly inappropriate response to the resident's condition in contravention of professionally recognized standards of care. CMS Ex. 12 at 6. The resident's escalating complaints of pain in conjunction with her fall on April 1, 2010 constituted a significant change in her condition that necessitated immediate consultation by Petitioner's staff. In fact, the resident herself was demanding physician intervention due to her pain. The fact that the resident was making these complaints in the aftermath of a fall should have put the staff on notice that there was at least a possibility of a serious injury underlying the resident's complaints.

Petitioner's defense to the evidence that I have addressed is to argue that Resident # 1 was a chronic complainer and a person who engaged in drug seeking behavior. Petitioner asserts that the resident's constant complaints and attempts to obtain pain medication created a fog that obscured the resident's complaints after her fall on April 1, 2010. For example, the resident complained of back pain on March 25, 2010. P. Ex. 3 at 3. The resident had also had previous falls, on July 15, August 11, and apparently, on August 12, 2009. Resident # 1 was assessed after these falls and found to be uninjured. Petitioner asserts that it should be excused from failing to respond to the resident inasmuch as her complaints were, essentially, normal behavior for her. Additionally, Petitioner argues

that it had developed an objective approach to measure the resident's pain in collaboration with the resident's treating physician that obviated the necessity for physician consultation after the April 1 fall.

Petitioner's arguments notwithstanding, this is not a case about a resident who merely complained consistently of pain. The event that was the source of the resident's complaints beginning April 1 was an obvious departure from the baseline and should have put Petitioner's staff on notice that there was a significant change in the resident's condition. The resident fell. The resident's fall was a signal event that should have alerted any responsible staff of a possibility of an injury that required medical attention. Second, and shortly after the fall, the resident uttered complaints of pain that were entirely consistent with an injury that was caused by a fall. The complaints soon escalated in seriousness and intensity, the resident complained that her pain medications were ineffective, and the resident demanded to be transferred to a hospital. Most significantly, the right-sided hip pain that Resident # 1 complained of after her April 1, 2010 fall was a new complaint, one that had not been voiced previously by Resident # 1. *See* CMS Ex. 6.[2] So, even if the resident was a chronic complainer, she was voicing something new after the April 1 fall, and it was consistent with an injury that could have resulted from the fall.

Thus, the fact that the resident may have been a chronic complainer, or that she may have fallen in the past without sustaining injury, did not justify Petitioner and its staff from treating her complaints after April 1 as being anything less than serious. What is evident is that the resident sustained a fall on April 1 that plainly could have caused (and, indeed, did cause) the resident to sustain a serious injury. The resident's complaints of pain in the wake of the accident were entirely consistent with a serious injury. CMS Ex. 12 at 6; CMS Ex. 13 at 14. The staff was obligated to treat the resident's complaints in conjunction with her fall as a significant change and to consult with the resident's physician irrespective of the resident's history.

Petitioner relies on the testimony of Dr. Campagna to support its contention that there was no significant change in Resident # 1's condition that necessitated physician consultation. P. Ex. 13; Tr. at 54-112. In his direct testimony, Dr. Campagna avers that there was no significant change in Resident # 1's condition after her fall on April 1 because there was no major decline in the Resident's status. P. Ex. 13 at 3. That

[2] There is, however, a psychiatric report dated March 25, 2010, in which the psychiatrist notes that the resident complained of "chronic pain, lower back and hip." P. Ex. 3 at 3. The report does not document the complaint with any specificity. For example, it does not specify which hip the resident was complaining about. I find this vague and generalized complaint of pain to be distinguishable from the specific complaints that the resident voiced beginning on April 1. Nothing in the resident's treatment record shows that the resident had previously made complaints of this type or specificity.

testimony ignores what is obvious from the record of this case, that Resident # 1 voiced escalating complaints of pain and that those complaints were made in close conjunction with the resident's fall on April 1. In light of that, I find Dr. Campagna's testimony not to be credible.

His testimony is not credible in another important respect. When asked whether it was acceptable for Resident # 1 to complain of unremitting pain for a period of nearly 36 hours after sustaining a fall, Dr. Campagna asserted that this was indeed acceptable given the resident's previous history. Tr. at 108. In effect, Dr. Campagna advocated the theory that a resident such as Resident # 1 could effectively be ignored by a facility's staff even in the situation where there was an apparent cause-effect relationship between an accident and the resident's subsequent complaints. Petitioner has offered no nursing standard of care that would support this theory.

Indeed, Dr. Campagna's testimony is squarely refuted by professionally accepted standards of nursing care. As he conceded during his cross-examination, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) designated pain as a fifth vital sign that requires monitoring and assessment with the same vigilance as with all other vital signs. Tr. at 92-93; CMS Ex. 15 at 1-7. Allowing the resident's complaints – for a period of about 36 hours – to go unaddressed, as Dr. Campagna advocated, is wholly contrary to this standard.

Petitioner contends additionally that it had implemented a system for assessing the resident's pain. This system, it asserts, enabled the staff to assess the resident objectively and without regard to the resident's complaints of pain. According to Petitioner, it was necessary to utilize this system in light of the fact that Resident # 1 was a chronic complainer. Petitioner argues that the objective system that it had put into place for Resident # 1 was implemented pursuant to Dr. Campagana's orders and that this, effectively, entitled the staff to ignore the resident's complaints of pain on April 1 and 2, 2010.

The objective system that Petitioner contends it implemented in providing care to Resident # 1 is known as the "FLACC" scale.[3] The FLACC scale is a system that was developed for assessing pain in preverbal children. Tr. at 71-72, 151. Petitioner has provided no evidence explaining how this scale would have worked effectively in assessing the pain that Resident # 1 may have experienced given that the resident is not a child and is perfectly capable of expressing herself (to the extent that she was capable of calling 911 and asking for assistance). Furthermore, Petitioner has not shown that its staff utilized it on April 1 and 2, 2010 to assess the resident's pain. Petitioner has provided no documentation showing that an assessment using the FLACC scale was done

[3] I can find no definition of the acronym in Petitioner's briefs. I take notice that "FLACC" stands for "face, legs, cry, consolability, activity." Tr. at 123.

at any time on these dates.[4] So, even if I were to assume that the FLACC scale might have been an effective mechanism for assessing Resident # 1's pain, there is nothing in the record of this case to show that Petitioner's staff utilized it to assess the resident's pain at a time when the resident plainly needed such an assessment.

b. Petitioner failed to comply substantially with the requirements of 42 C.F.R. § 483.13(c).

The applicable regulation requires a facility to develop and implement written policies and procedures that prohibit mistreatment, neglect, and abuse of residents. CMS alleges that Petitioner neglected to provide necessary care to Resident # 1. It alleges that Petitioner failed to follow both applicable nursing standards of care and its own policy in providing care to Resident # 1.

The evidence is conclusive that Petitioner failed to follow applicable nursing standards of care and its internal policies in addressing Resident # 1's complaints of pain. The staff failed to assess the resident's pain. They failed to precisely document the resident's pain and essentially ignored her escalating complaints. They failed to complete documentation that was required by Petitioner's policy. And, the staff failed to notify the resident's physician about her complaints, also in contravention of facility policy.

Nursing standards of care require that a resident's complaints of pain be assessed by a skilled nursing facility's professional staff. CMS Ex. 12 at 6. Those standards are incorporated by Petitioner into its own policies for assessing and addressing pain. CMS Ex. 7, at 15-16, 18-24. Assessing complaints of pain means that a staff must, first and foremost, listen to what a resident is saying and, then, attempt to do all that is appropriate to alleviate the resident's complaints. CMS Ex. 12 at 7. There are certain discrete elements that should be documented when pain is assessed. These include: measuring the intensity of pain using a standardized scale; documenting the frequency, pattern, and description of pain; documenting duration of pain; assessing precipitating factors, such as movement or touch; documenting the resident's response to pain medication; evaluating other approaches to ameliorating pain when medication is ineffective; documenting nonverbal responses to pain; and describing a history of the resident's pain and related factors. *Id.* at 8.

Petitioner's staff failed to comply with these requirements and the applicable standard of nursing care, as well as Petitioner's policy governing assessment and management of pain. There is very little documentation of the resident's complaints in the resident's record, and the record contains none of the assessments mandated by the applicable

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[4] In fact, I find nothing in the record to show that use of the FLACC scale was actually ordered for Resident # 1.

standard of care. Indeed, between 10:30 p.m. on April 1 to 12:30 p.m. on April 2, Petitioner's staff failed to make any documentation of the resident's complaints. CMS Ex. 6 at 2; CMS Ex. 12 at 8.

As I have discussed, there is also no evidence that Petitioner utilized the alternative system that it contends it put into place for measuring Resident # 1's pain – the FLACC scale – to document the resident's pain on April 1 and April 2. Nor is there evidence that this system would have effectively supplanted the requirements of the professionally recognized standard for assessing pain in a resident, even if it had been used.

Petitioner utilized a pain assessment form to document residents' pain. CMS Ex. 6 at 34. The elements of the form essentially track the requirements of the applicable standard of care for assessing pain. For example, the form requires that the staff document the intensity of a resident's pain on a scale of from 1-10. The form requires that the duration of pain, its quality, the type of pain, and the effects of pain be documented. It requires the staff to document observed behavior in a resident who is experiencing pain. It also requires the staff to make note of a resident's activity and emotional status. *Id.* Petitioner's staff failed to utilize this form to assess Resident # 1's complaints of pain on April 1 and 2, 2010. Nursing notes fail to demonstrate any assessments that addressed the elements of this form. *See* Tr. at 120, 128-30, 132-34.

Petitioner also had a pain management policy that required nurses to notify a resident's physician if medication was ineffective in controlling pain. CMS Ex. 7 at 21; CMS Ex. 12 at 3. On April 2, 2010, Resident # 1 complained that her pain medication was not helping her. CMS Ex. 6 at 2. Petitioner's staff failed to notify Dr. Campagna of this complaint and thereby violated Petitioner's pain management policy.

Petitioner argues that its liability for failing to comply with the requirements governing implementation of policies addressing pain assessment and management depends on whether it contravened requirements governing consultation with Resident # 1's treating physician. Petitioner reasons that it cannot be held liable for violating the regulation governing neglect, if it, in fact, complied with the regulation governing physician consultation.

This reasoning is incorrect. A facility may fail to implement policies preventing neglect of residents even in a situation where the issue of physician consultation is not implicated. Here, Petitioner's liability stands independently from its liability for violating the consultation requirement. It would have been obligated to implement its policies governing pain assessment and management even if effective implementation of those policies established no reason to consult with Resident # 1's physician. Moreover, and as I have found, Petitioner did violate regulatory requirements governing physician consultation.

Petitioner then argues that there is no evidence that the resident ever complained of "severe pain" until 7:39 p.m. on April 2, 2010. P. Brief at 13. That is debatable – the resident's complaints of pain clearly escalated throughout April 1 and 2, 2010 – but even if it is true, it provides Petitioner with no excuse for failing to implement its pain assessment and management policy and contravening professionally recognized standards of care for managing the resident's pain. The policy should have been implemented, and the resident's pain should have been thoroughly assessed even if the resident had only voiced complaints of mild pain.

Finally, Petitioner argues that CMS would have had it contravene the Resident # 1's physician orders in assessing and managing the resident's pain. I can discern no basis for this argument. There is nothing in the record of this case to suggest that Dr. Campagna ever ordered Petitioner to disregard professionally recognized standards of nursing care or Petitioner's own policies in assessing and managing Resident # 1's complaints of pain. As I have discussed, there is not even evidence that Petitioner systematically implemented the FLACC scale – certainly not with respect to the events of April 1 and 2, 2010 – to address the resident's complaints of pain.

2. CMS's remedy determinations are reasonable.

At issue here are two per-instance civil money penalties, each in the amount of $3,000. I find these penalties to be reasonable.

Per-instance civil money penalties are authorized by 42 C.F.R. § 488.438(a)(2). The regulation allows for a penalty ranging from $1,000 to $10,000 for each instance of noncompliance. The penalties that CMS determined to impose fall substantially beneath the midpoint of that range.

Regulatory factors for deciding what is reasonable are 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 include: the seriousness of a facility's noncompliance; its compliance history; its culpability; and its financial condition.

Here, CMS relies on the seriousness of Petitioner's noncompliance to justify the penalty amounts. I agree with CMS. The noncompliance in this case was serious. The two civil money penalties that CMS determined to impose are actually quite modest when considered in the context of Petitioner's noncompliance.

The evidence establishes that Petitioner's staff were indifferent to the resident's injuries and complaints of pain following the fall that she sustained on April 1, 2010. The resident suffered for two days with a fractured hip before being provided medical attention that ultimately necessitated surgery. During this period, her complaints of pain were disregarded or even ignored by Petitioner's staff. The staff failed to: assess the

resident's complaints; listen to her assertions that her medication had become ineffective; and communicate any of the resident's problems to her treating physician. The resident's problems would have continued to go unattended had the resident not on her own volition intervened and called 911. The staff's inattention to the resident comprised blatant violations of regulatory requirements, applicable nursing standards of care, and Petitioner's own policies.

Petitioner has not provided evidence or argument to show that the penalties are unreasonable. It argues that CMS has the "burden of proof" to establish that the penalty amounts are reasonable. It is unnecessary for me to address this argument because the overwhelming evidence clearly supports the penalties that CMS determined to impose. I have considered all of Petitioner's arguments to defend its actions and those of its staff and for the reasons I discuss above, at Finding 1, I find them to be without merit.

/s/
Steven T. Kessel
Administrative Law Judge