

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

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In the Case of:)	
)	
Kingsville Nursing and Rehabilitation)	Date: August 14, 2008
Center (CCN: 67-5815),)	
)	
Petitioner,)	
)	
- v. -)	Docket No. C-08-177
)	Decision No. CR1832
Centers for Medicare & Medicaid)	
Services.)	
_____)	

DECISION GRANTING SUMMARY DISPOSITION

I grant summary disposition in favor of the Centers for Medicare & Medicaid Services (CMS) and against Petitioner, Kingsville Nursing and Rehabilitation Center, and I sustain the imposition of two per-instance civil money penalties of \$4,000 and \$6,000.

I. Background

Petitioner is a skilled nursing facility doing business in Kingsville, Texas. It participates in Medicare. Its participation in that program is governed by sections 1819 and 1866 of the Social Security Act and by regulations at 42 C.F.R. Parts 483 and 488. Its hearing rights in this case are governed by regulations at 42 C.F.R. Part 498.

A Medicare compliance survey was conducted at Petitioner's premises in September 2007 (September survey). The surveyors concluded that Petitioner was not complying substantially with participation requirements. CMS accepted the surveyors' findings and determined to impose the remedies that I describe in the opening paragraph of this decision.

Petitioner filed a hearing request challenging CMS's determination and the case was assigned to me for a hearing and a decision. The parties filed pre-hearing exchanges of proposed exhibits and pre-hearing briefs. Then, CMS moved for summary disposition and Petitioner opposed the motion.

CMS filed a total of 36 proposed exhibits which it designated as CMS Ex. 1 - CMS Ex. 36. Petitioner filed a total of 98 proposed exhibits which it designated as P. Ex. 1 - P. Ex. 98. I am receiving all of these proposed exhibits into the record of the case and I cite to some of them in this decision for purposes of illustration. However, my decision is based entirely on the undisputed material facts as alleged by the parties.

II. Issues, findings of fact and conclusions of law

A. Issues

The issues in this case are whether:

1. The undisputed material facts establish that 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 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.

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

The regulation that is at issue here mandates that a resident who enters a skilled nursing facility without pressure sores will not develop a pressure sore or sores unless the resident's clinical condition demonstrates that the development of a pressure sore was unavoidable. 42 C.F.R. § 483.25(c)(1). Additionally, it requires a facility to provide necessary treatment and services to any resident having pressure sores, to promote healing, prevent infection, and prevent new sores from developing. 42 C.F.R. § 483.25(c)(2).

The regulation imposes several distinct duties on nursing facilities. First, a nursing facility must *assess* each of its residents in order to determine which of them have pressure sores or are at risk for developing them and also to identify precisely what are the risk factors faced by each resident. Secondly, a facility must *plan* the care of each resident who has a pressure sore or who is at risk for developing one to ensure that it takes all reasonable measures to prevent the development of sores and to promote the speedy healing of those that exist. Finally, a facility must *implement* completely and diligently all of the measures that it has identified as being necessary for each resident who is identified as being at risk for or as having pressure sores.

The case for summary disposition against Petitioner rests on allegations that Petitioner failed to discharge these obligations. First, CMS asserts that Petitioner failed to carry out plan of care directives ordering that residents who were identified as being vulnerable to developing pressure sores be repositioned on a regular basis in order to relieve pressure. CMS identifies the following residents whose care plans required that they be repositioned at two-hour intervals and who, according to CMS, were not repositioned: Residents #s 24, 25, 26 and 11.

CMS contends that it is undisputed that each of these residents, all of whom were essentially helpless, had been identified by Petitioner's staff as being at risk for pressure sores. CMS Ex. 12, at 13; CMS Ex. 13, at 11; CMS Ex. 14, at 14; CMS Ex. 8, at 18. Each of these residents had a care plan that specifically required that the resident be repositioned once every two hours as a pressure sore prevention intervention. *Id.* CMS asserts that a surveyor (and, in the case of Resident # 11, two surveyors) observed each of these residents on multiple occasions over an approximately eight-hour period on September 13, 2007. Two of these residents, Residents #s 24 and 25, were observed to be lying only on their backs throughout the period. CMS Ex. 5, at 22. Residents #s 26 and 11 were observed to be lying only on their backs during the first six hours of the same eight hour period. CMS's motion for summary disposition at 2 - 10. CMS Ex. 5, at 21; CMS Ex. 6, at 52.

According to CMS, these facts comprise irrefutable proof that Petitioner failed to comply with the regulatory requirement that it implement every reasonable intervention to protect the four residents from developing pressure sores. The undisputed facts, according to CMS, establish that Petitioner failed to comply with the very care plans that it had developed to protect these residents.

Second, CMS contends that two of Petitioner's residents, identified in the September survey report as Residents #s 33 and 39, developed pressure sores that Petitioner did not show were clinically unavoidable. According to CMS, the undisputed material facts show that both of these residents had entered Petitioner's facility without pressure sores.

However, on September 20, 2007, Petitioner's staff documented an area of redness on Resident # 33's buttock. CMS Ex. 16, at 15. On the following day, September 21, 2007 Petitioner's staff identified pressure sores on Resident # 33's right hip and buttock. *Id.*, at 16. On that same date, the staff identified a pressure sore on Resident # 39's right leg. CMS Ex. 18, at 47. On the following day, September 22, 2007, the staff identified an additional pressure sore on the resident's right leg and two blisters on the resident's left hip. *Id.*, at 48.

CMS emphasizes that these residents' development of multiple pressure sores is made remarkable by the fact that neither of them had been identified by Petitioner's staff as being at a high risk for development of pressure sores. Indeed, on August 17, 2007 and September 21, 2007 – the day after the staff first documented redness on Resident # 33's buttock and the day before the staff first identified pressure sores on that resident – the staff assessed that resident as being at low risk for developing a pressure sore. CMS Ex. 16, at 14. On multiple occasions during her stay at Petitioner's facility, Resident # 39 had been assessed by the staff as being at low risk for developing pressure sores. CMS Ex. 18, at 44 - 45. On September 21, the date Petitioner's staff first found pressure sores on Resident # 39, Petitioner's staff assessed the resident as being only at moderate risk for developing sores. *Id.*, at 26.

CMS argues that there is nothing in these residents' records to show that they would have inevitably developed pressure sores despite Petitioner's best efforts to prevent them. In light of that, CMS contends that the residents' development of sores is undeniable proof that Petitioner failed to comply with its regulatory obligations.

I find CMS's arguments to be persuasive if not rebutted by Petitioner. In the absence of any dispute of the facts cited by CMS these facts make out a powerful case of noncompliance by Petitioner with the requirements of 42 C.F.R. § 483.25(c).

The facts alleged by CMS concerning the staff's observed failure to reposition Residents #s 24, 25, 26, and 11, are in and of themselves sufficient to establish a failure by Petitioner to comply with the regulation's requirements. Petitioner's staff developed care plans that reflected the staff's assessments of these dependent residents' vulnerabilities. The interventions stated in the plans – including repositioning the residents every two hours – had been determined by the staff to be essential to assuring that these residents not develop pressure sores. Failure by the staff to implement the care plans constituted a failure to take all reasonable measures to protect the residents.

Similarly, the facts relating to Residents #s 33 and 39 would be sufficient if not rebutted to prove that Petitioner failed to satisfy regulatory requirements. Neither of these residents was identified by Petitioner's staff to be particularly vulnerable to developing

pressure sores. Yet both of them developed sores, and indeed, Resident # 33 began showing signs of sores the *day before* Petitioner’s staff assessed the resident as being at low risk for the development of pressure sores. There is a presumption built into the regulations that pressure sores in nursing facilities are avoidable. *See* 56 Fed. Reg. 48826, 48851 (September 26, 1991).¹ It is incumbent on Petitioner to explain why these two residents developed sores in spite of its best efforts to protect them. Petitioner must be found to be deficient in providing care absent facts to show that the sores were unavoidable.

I conclude that Petitioner did not rebut CMS’s assertion of facts and arguments. Petitioner contends that there are disputed material facts concerning its compliance. However, Petitioner has not challenged any of the facts that are elements of CMS’s case. It alleges additional facts which it contends rebut those offered by CMS. For purposes of this decision, I have assumed that all of the facts alleged by Petitioner are true. But the facts alleged by Petitioner do not create a genuine dispute about material facts even assuming that they are true.

First, Petitioner asserts that the medical records for Residents #s 24, 25, 26, and 11 “clearly document that . . . [each] resident was being turned and repositioned every 2 hours on a daily basis, including on September 13, 2007.” Petitioner’s response to CMS’s motion (response) at 4, 5. In fact, Petitioner has not offered any facts from which I might reasonably infer that the four residents whose care is at issue were repositioned during the period when they were being observed.

¹ The preamble to the final regulations state—

Comment: One commenter concurred with the requirement in § 483.25(c) which requires that a resident with pressure sores receive necessary treatment to promote healing and prevent infection or the development of new sores. Two others requested that § 483.25(c)(2) be revised, allowing a facility to be exempted from this requirement by claiming that a resident's clinical condition makes such treatment impossible.

Response: We are not making the requested revision because we believe that the facility should always furnish the necessary treatment and services to prevent the development of pressure sores or, at the least, to promote the healing of sores that have developed.

No employee of Petitioner has averred that he or she repositioned the residents during the time period on September 13, 2007 when the surveyors observed them to be on their backs continuously. Petitioner has offered no witness statements to challenge any of the surveyors' findings about these residents. Nor has Petitioner produced any documentation that specifically shows that residents were being repositioned during the period when they were observed by the surveyors to be lying continuously on their backs. For Resident # 11, Petitioner produced an hourly repositioning schedule for the period from September 14 through 24, 2007. Those are dates that are *after* September 13, the date when the surveyors made their observations of this resident. The document thus says nothing about what happened on September 13.

The other documents that Petitioner relies on are: P. Ex. 78; P. Ex. 79; P. Ex. 82; P. Ex. 85; P. Ex. 87; and P. Ex. 90. These documents consist of activities of daily living flow sheets that are initialed once per shift. They contain markings from which I might infer that members of Petitioner's staff reported having repositioned the residents whose care is at issue during the work shifts on September 13, 2007 and on other dates. But the most I can infer from the markings is that the residents were repositioned *at some time* during a given shift. I cannot infer anything beyond that because the flow sheets contain no charting showing when during a shift the residents were being repositioned. There is nothing in these documents which records the times when residents were repositioned or even how frequently they were repositioned during a shift.

Indeed, there is nothing inconsistent between the exhibits and the surveyors' observations because it is possible that, on September 13, the residents could have been (and in fact, Residents 26 and 11 were) repositioned during *each shift* but not at two hour intervals or during the period when the surveyors saw them lying continuously on their backs.

Petitioner argues also that two of the four residents, Residents #s 26, and 11, were placed on mattresses known as ASAP II air mattresses. According to Petitioner, the manufacturer's instructions for these devices state that their use "may eliminate turning schedules for pressure considerations." P. Ex. 70; P. Ex. 71. But assuming that to be true, it does not derogate from the fact that Petitioner's staff decided that repositioning the two residents was a *necessary element* of their care. The residents' care plans could have been amended to show that repositioning was no longer necessary due to the use of the ASAP II mattress – if staff had concluded that was the case – but they were not. The only reasonable inference that I can draw is that the staff never decided that the need to reposition these two residents was eliminated by use of the ASAP II mattress.

Furthermore, there is nothing in the manufacturer's instructions from which I may infer reasonably that the use of ASAP II mattresses actually eliminated a need for repositioning Residents #s 26 and 11. The instructions do not say that use of the mattress will eliminate

the need for repositioning. They say only that such use *might* eliminate such need. Petitioner has offered absolutely no facts to show that its staff considered these ambiguous instructions and from them addressed the possibility whether the ASAP II mattresses given to Residents #s 26 and 11 would eliminate the need to reposition the residents. Nor has Petitioner offered even a single fact to show that the staff made an informed judgment that repositioning was no longer necessary with the inception of the mattresses' use.

As for the care it gave to Residents #s 33 and 39, Petitioner argues that CMS is now making allegations that were not made in the report of the September survey. It contends that the survey report asserts only that Petitioner failed to identify the sores that these residents manifested. *See* P. Ex. 3, at 2. Petitioner argues that there are no findings in the report to the effect that Petitioner failed to protect residents against developing avoidable pressure sores.

I agree with Petitioner that the report of the September survey does not explicitly allege that Petitioner failed to protect residents against developing avoidable sores. However, the facts on which CMS bases this allegation and which I discuss above were stated explicitly in the September survey report. P. Ex. 3, at 33. Petitioner was on notice of these facts as of the date it received a copy of that report.

There is nothing in the regulations barring CMS from clarifying or even amending its determination of noncompliance pending an appeal of its remedy determination. The only limitations placed on CMS's ability to clarify or amend are those which are posed by considerations of due process. CMS is precluded from amending or making new allegations where to do so would be fundamentally unfair to a facility. Such unfairness might exist where a facility does not have sufficient notice of the new allegations and an opportunity to develop its defenses to them.

Here, Petitioner received ample notice from CMS, in its motion for summary disposition, that it was making the legal argument – based on facts previously disclosed to Petitioner – that Petitioner had contravened the requirements of 42 C.F.R. § 483.25(c) by failing to prevent residents from developing avoidable pressure sores. I discern no prejudice to Petitioner. Petitioner had long been aware of the operative facts and had plenty of time within which to develop a defense to CMS's amended allegations of noncompliance.

Petitioner also contends that CMS's findings of noncompliance concerning the care that was given to these two residents were stricken at an informal dispute resolution proceeding. But, in fact, nothing that CMS now alleges concerning the development of pressure sores by Residents #s 33 and 39 was the subject of the informal dispute resolution. *See* P. Ex. 94.

Petitioner has not provided me with anything that might be construed as a defense on the merits against CMS's allegations concerning the care that Petitioner's staff gave to the two residents. Petitioner has offered no facts to dispute the allegations on which CMS based its motion. It does not deny that Resident # 33 and Resident # 39 developed pressure sores while these residents were under Petitioner's care. Nor does Petitioner deny that its staff had assessed each of these residents as being at low, or at worst, moderate, risk for development of pressure sores right up until the sores were first identified.

Most important, Petitioner has offered no facts whatsoever from which I might infer reasonably that these residents' pressure sores were unavoidable. For example, Petitioner has not even alleged that either of these residents suffered from medical problems that made the development of sores an inevitable consequence despite Petitioner's best efforts to protect them against developing sores. And, furthermore, Petitioner has offered no legal analysis to suggest that, given the undisputed facts, it is not liable for the development of sores by the two residents.

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

The regulation at issue here provides in relevant part that a skilled nursing facility must be administered effectively and efficiently in order to maximize the well-being of each of its residents. CMS's allegations that Petitioner failed to comply substantially with this regulation derive from its assertions of noncompliance that I discuss at subpart a. of this Finding. According to CMS, when viewed in their totality, the instances of Petitioner's noncompliance show that it was not attentive to the key needs of its residents.

I agree with CMS that the undisputed material facts establish a management failure by Petitioner. I infer from these facts that Petitioner's staff neither comprehended nor carried out their responsibilities to protect residents who were at risk for developing pressure sores. That failure reasonably may be attributed to Petitioner's management which had the responsibility for insuring that the staff operated effectively and efficiently to provide care that satisfied the letter and spirit of the Act's requirements and those of implementing regulations.

Petitioner characterizes CMS's noncompliance allegations as mere "conclusory sentences." Petitioner's response at 7. In saying this, Petitioner seems to be arguing that, as a matter of law, findings of noncompliance with the administration requirement may not derive from findings of noncompliance with other regulatory requirements. If this is Petitioner's assertion, I disagree with it. The undisputed facts of this case are sufficient for me to conclude that there was a wholesale failure by Petitioner's staff to carry out its

responsibilities to protect residents who were vulnerable to developing pressure sores. Indeed, it is not reasonable for me to infer otherwise from the facts relied on by CMS. The incidences of noncompliance that I discuss at subpart a. of this Finding were not isolated or random. The undisputed facts establish, rather, a pervasive lack of compliance by Petitioner's staff with regulatory requirements. It is only reasonable that I infer that such a wholesale failure by staff to discharge their responsibilities was caused by a failure of Petitioner's management to assure that the staff was sufficiently trained and appropriately managed to carry out their responsibilities.

Petitioner also makes a series of contentions about the performance of its management. According to Petitioner:

(1) The Director of Nursing ("DON") effectively communicated with the nursing staff with physician order changes; (2) The DON is part of the weekly QA skin committee and is made aware of changes to resident wound conditions; (3) The DON implemented the turning & repositioning schedules for the residents in the facility; (4) The DON and Medical Director were aware of the wounds as evidenced by the clinical records; and (5) The Q/A Assessment Committee, DON and other nurse managers appropriately supervised the nurse staff and provided appropriate oversight training and guidance reasonably necessary to evaluate the care and treatment provided to the residents made the subject of the survey.

Petitioner's response at 8. For purposes of this decision I will assume that all of these contentions are true. But, assuming that, they beg the question raised by the facts asserted by CMS because they exalt form over function.

The issue here is not whether there were communications between Petitioner's nursing director and staff, whether there were meetings of the quality assessment committee, or whether the director of nursing issued directives to staff, and conducted oversight. The issue is whether the management of Petitioner's facility was *effective*. The facts offered by CMS show that regardless of the directives, communications, and meetings that occurred at Petitioner's facility there was an obvious failure to implement residents' care plans and a failure by Petitioner's staff to take appropriate measures to protect residents from developing pressure sores. That failure is ultimately a failure of management because it is a facility's management's responsibility to assure that the staff execute their responsibilities effectively.

I am not suggesting that every error or mistake by a member of a facility's staff translates to a failure of that facility's management to discharge its responsibilities effectively. There are times when errors occur despite the best efforts of a facility's management. But here, the undisputed facts show such a pervasive noncompliance that it is simply not reasonable to infer that the noncompliance was a random event that occurred despite effective management.

Petitioner also cites a series of its exhibits as support for its contention that it was effectively managed. Petitioner's response at 8; *see* P. Ex. 91 - P. Ex. 98. Petitioner has not told me what is in these exhibits that support its contentions. Nevertheless I have read them. The exhibits comprise: records of in-service training; a note from a physician; attendance records for Petitioner's quality assessment committee meetings; the findings of the Texas Health and Human Services Commission concerning Petitioner's informal dispute resolution hearing; affidavits from members of Petitioner's staff and a consultant; and Petitioner's request for informal dispute resolution. I cannot discern anything in these exhibits that creates a dispute as to the material facts relied on by CMS to establish Petitioner's failure to be managed effectively.

Some of these exhibits appear to be irrelevant on their face. For example, P. Ex. 92 is a statement from a physician about a resident whose care is not the subject of CMS's motion. Petitioner has offered no explanation of why this exhibit raises material facts. Others are merely evidence that Petitioner maintained the forms of management but raise no facts to challenge CMS's evidence showing that Petitioner was managed ineffectively. For example, P. Ex. 93 consists of attendance records of Petitioner's monthly quality assurance meetings. The exhibit contains no information concerning what decisions were made at these meetings.

2. CMS's remedy determinations are reasonable.

At issue here are two per-instance civil money penalties: \$4,000 that CMS determined to impose to remedy Petitioner's failure to comply with the requirements of 42 C.F.R. § 483.25(c); and \$6,000 that CMS determined to impose to remedy Petitioner's failure to comply with the requirements of 42 C.F.R. § 483.75. I find that the undisputed material facts establish these two remedies to be reasonable.

Per-instance civil money penalties are authorized by 42 C.F.R. § 488.438(a)(2). This section provides that penalties which are imposed for an instance of noncompliance shall fall within a range of from \$1,000 - \$10,000 per day. The criteria for determining where within this range a per-instance civil money penalty should fall 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 criteria may include: the seriousness of a facility's noncompliance; its compliance history; its culpability for its noncompliance; and its financial condition. *Id.*

CMS argues that each of the penalties that it determined to impose is relatively modest. Respectively, they comprise 40 percent and 60 percent of the maximum allowable per-instance amount. According to CMS, these relatively modest penalties are amply justified by the seriousness of Petitioner's noncompliance.² It contends that each of the two deficiencies related to care that Petitioner gave to residents who were either totally dependent on Petitioner's staff for their daily existence or who were in need of extensive assistance. These residents' helplessness, according to CMS, made it critical that Petitioner's staff be attentive to their needs. Petitioner's failure to provide these residents with the care they needed – literally to survive – put them at grave risk of severe harm.

I agree entirely with CMS's characterization of the seriousness of Petitioner's noncompliance. The seriousness of Petitioner's noncompliance – in and of itself – amply justifies the remedies that CMS determined to impose. The undisputed facts show that residents who were identified by Petitioner's own staff as being extremely vulnerable to the development of pressure sores, who were identified also as needing frequent repositioning as an essential measure to protect against the development of sores, and who were literally incapable of positioning themselves were left by the staff to lie in one position for hours. This noncompliance comprised a blatant disregard for these residents' most basic needs and its egregiousness was compounded by the fact that it involved multiple residents.

Perhaps even more appalling was that Petitioner – after having consistently identified two of its residents as being at low risk for the development of pressure sores – failed to protect them against developing sores. It is simply not consistent with modern nursing practice that a facility fail to take adequate protective measures to prevent its residents from developing avoidable pressure sores. Petitioner's failure to take such actions in two instances is an extremely serious episode of noncompliance.

² In the September survey report, the surveyors concluded that Petitioner's noncompliance with the requirements of 42 C.F.R. §§ 483.25(c) and 483.75 was so egregious as to comprise immediate jeopardy for Petitioner's residents. I am not required to decide here whether that determination was clearly erroneous because a finding of immediate jeopardy is not a necessary element in deciding whether a per-instance penalty is reasonable. 42 C.F.R. § 488.438(a)(2).

The evidence also establishes an extremely serious failure of management to assure that the staff carry out their responsibilities. As I discuss above, at Finding 1.b., the errors and misfeasance of Petitioner's staff were not isolated or random. To the contrary, the undisputed material facts establish a pervasive failure by Petitioner's staff to attend to residents' needs.

I do not find that Petitioner has called into dispute any of the facts relied on by CMS to support its remedy determinations. Petitioner suggests that CMS's arguments in support of its remedy determinations are somehow deficient because CMS has not presented facts or arguments addressing all of the regulatory factors described in 42 C.F.R. §§ 488.438 and 404. I do not find this argument to be persuasive because its premise is incorrect. Where facts that relate to even one of the regulatory factors are sufficient to support a remedy it becomes unnecessary to decide whether there are also facts that might be relevant to another factor or factors.³

Petitioner asserts that CMS neither provided nor pointed to any evidence in its motion that Petitioner had a pattern of or repeated compliance problems or any history of having remedies imposed against it for noncompliance with the requirements of 42 C.F.R. §§ 483.25(c) and 483.75. Assuming this to be true, however, does not derogate at all from the facts that CMS offered establishing the seriousness of Petitioner's noncompliance, facts which I have concluded are in and of themselves sufficient to support the remedies that CMS determined to impose.

Petitioner also asserts that its "degree of culpability in this matter is hotly contested and . . . [Petitioner] believes it is either nonexistent or minimal at best." Petitioner's response at 10. However, CMS's arguments supporting the remedies are not based on Petitioner's culpability but on the seriousness of its noncompliance. Furthermore, Petitioner has not advocated any facts to support its assertion that it has "hotly contested" its culpability. Making a naked assertion is not sufficient to call into question the undisputed material facts on which CMS relies.

³ Petitioner could have offered facts that related to any of the regulatory factors to support an argument that there were disputed material facts as to the reasonableness of the remedy. For example, Petitioner might have offered facts concerning its financial condition as an effort to show that the penalty amounts were unreasonable. But it failed to do so and I am not required to defer a decision until after a hearing on the premise that Petitioner *might* present relevant evidence at a later date.

