Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Omni Manor Nursing Home,
(CCN: 36-5433),

Petitioner,

v.

Centers for Medicare & Medicaid Services.

Docket No. C-08-760

Decision No. CR2213

Date: August 12, 2010

DECISION GRANTING SUMMARY JUDGMENT TO CENTERS FOR MEDICARE AND MEDICAID SERVICES

I grant summary judgment to the Centers for Medicare and Medicaid Services (CMS) sustaining CMS's determination to impose civil money penalties against Petitioner, Omni Manor Nursing Home, of $550 per day for each day of a period beginning on April 24, 2008 and running through May 21, 2008.

I. Background

Petitioner is a skilled nursing facility in Youngstown, 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 hearing rights are governed by regulations at 42 C.F.R. Part 498.

A compliance survey of Petitioner's facility was conducted on April 24, 2008 (April Survey). The surveyors who conducted this survey found that Petitioner had failed to

comply substantially with several Medicare participation requirements.[1] CMS concurred with these findings and imposed the civil money penalties that I describe in the opening paragraph of this decision.[2]

Petitioner requested a hearing and the case was assigned to Alfonso J. Montano, an administrative law judge of the Departmental Appeals Board Civil Remedies Division. The case was developed extensively before Judge Montano. CMS filed 24 proposed exhibits that it identified as CMS Ex. 1 – CMS Ex. 24. Petitioner filed 47 proposed exhibits that it identified as P. Ex. 1 – P. Ex. 47.

During the course of pre-hearing development the case was narrowed to a single issue, that being the date when Petitioner attained substantial compliance with Medicare participation requirements. In other words, Petitioner does not challenge the noncompliance findings made by the surveyors at the April Survey and concurred in by CMS, nor does it assert that the $550 daily civil money penalty amount that CMS determined to impose is unreasonable. It argues only that it attained substantial compliance with participation requirements on a date that is earlier than that which CMS found to be the date of compliance (April 29, 2008 versus May 22, 2008).

CMS moved for summary judgment on the issue of duration of noncompliance and Petitioner opposed the motion. With its opposition Petitioner filed two additional exhibits that it identified as P. Ex. 48 (Trexler Declaration) and P. Ex. 49. Judge Montano permitted the parties a second round of briefing on the merits of CMS's motion. On June 21, 2010, he issued a ruling denying the motion.

The case was then transferred to me for a hearing and a decision. On August 3, 2010, I vacated Judge Montano's ruling denying the motion for summary judgment and advised the parties that I would reconsider the motion.

I receive into the record of this case CMS Ex. 1 – CMS Ex. 24 and P. Ex. 1 – P. Ex. 49.

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[1] There was also a Life Safety Code survey that found noncompliance. The noncompliance that was found at this survey is no longer at issue and I do not address it in this decision.

[2] Additionally, and by virtue of CMS's noncompliance findings, Petitioner lost the authority to conduct nurse aide training, certification, and education (NATCEP). The loss of authority to conduct NATCEP is not challenged.

II. Issues, findings of fact and conclusions of law

A. Issue

The issue in this case is the duration of Petitioner's noncompliance with Medicare participation requirements.

B. Findings of fact and conclusions of law

In deciding a motion for summary judgment, I apply the principles of Rule 56 of the Federal Rules of Civil Procedure. Summary judgment is appropriate where a case rests on issues of law or on application of law to undisputed facts. I may not enter summary judgment where there are disputed issues of material fact. A "material fact" is one which may affect the outcome of a case. In deciding whether a dispute exists as to a material fact, I must draw all reasonable inferences in favor of the party opposing the motion for summary judgment.

In this case I find that CMS is entitled to summary judgment as a matter of law. There is no dispute that, as of April 24, 2008, Petitioner failed to comply substantially with several Medicare participation requirements. Nor is there any dispute that CMS determined that Petitioner attained compliance with these requirements effective May 22, 2008. Petitioner contends that there are facts showing that it actually attained compliance on April 29, 2008. However, and as I explain in detail, the facts offered by Petitioner would not establish compliance on a date that is earlier than May 22, 2008 because they are legally insufficient to prove compliance. Consequently, I sustain CMS's determination.

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

1. ***As a matter of law and given the nature of Petitioner's noncompliance, Petitioner may not establish compliance at a date that is earlier than the date of an on-site revisit survey of Petitioner's facility.***

It is undisputed that Petitioner's noncompliance as of April 24, 2008 included several instances in which the manner in which the quality of care that Petitioner's staff provided residents was inadequate. These deficiencies included Petitioner's failure to comply substantially with the requirements of 42 C.F.R. §§ 483.25; 483.25(d); 483.25(g)(2); 483.25(h); 483.25(m)(1); and 483.65(a). Specifically, Petitioner's staff failed to:

- Provide one of its residents with necessary care and services in order to maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with that resident's comprehensive assessment and plan of care. CMS Ex. 5 at 5-8. Petitioner's staff delayed providing the resident with treatment for the resident's respiratory problems even as the resident's medical condition rapidly deteriorated and failed to improve. *Id.*;

- Provide proper urinary incontinence care to a resident by failing to remove a resident's Foley catheter timely. CMS Ex. 5 at 10-15;

- Ensure that a resident who was being fed by a gastrostomy tube received medications administered using the correct technique. CMS Ex. 5 at 15-16;

- Ensure that the facility was free of accident hazards in that they failed to secure potentially dangerous items (spray disinfectant and razors) in a shower room that was accessible to independently mobile, but cognitively impaired residents. CMS Ex. 5 at 16-18;

- Ensure that Petitioner had a medication administration error rate of less than five percent. CMS Ex. 5 at 18-21; and

- Establish and maintain an infection control program designed to provide a safe, sanitary, and comfortable environment and to prevent the development and transmission of disease and infection, by failing to provide proper incontinence care to a resident.

The undisputed facts establish that these deficiencies share a feature in that each involved a failure by Petitioner's nursing staff to comply with recognized standards of nursing care. The noncompliance thus was, in every single instance, one of human error in providing care.

Where CMS imposes a remedy to address a deficiency or deficiencies that remedy will continue in effect until:

> The facility has achieved substantial compliance, as determined by CMS or the State based upon a revisit or after an examination of credible written evidence that it can verify without an on-site visit; . . . .

42 C.F.R. § 488.454(a)(1). The regulation does not specify the circumstances where a revisit is necessary or where CMS might be able to verify written evidence of compliance without revisiting a facility. That issue was addressed in the Secretary's comments in the preamble to the Part 488 regulations:

> There are other cases in which documentation cannot confirm the correction of noncompliance, and in these cases an on-site revisit is necessary. For example, one of the requirements for Infection Control is that personnel must handle, store, process and transport linens so as to prevent the spread of infection as specified in § 483.65. If a deficiency is cited for a violation of this requirement and a civil monetary penalty is imposed, submitting written documentation would not confirm the correction of the violation. An on-site revisit to observe personnel behavior is necessary in this case to confirm that the facility is, in fact, back in substantial compliance with this regulatory provision.

59 Fed. Reg. 56207 (November 10, 1994). The preamble clarifies the regulation by defining the circumstances in which documentation alone will not serve to establish compliance. Deficiencies that involve staff members' providing care to residents are not deficiencies that normally can be certified as corrected based solely on a review of documents because documents alone cannot prove that staff is actually providing care according to professionally recognized standards of care. For such deficiencies, observation of performance is a critical element of certifying compliance.[3]

The deficiencies that I describe above all fall into the category of deficiencies that cannot be certified as having been corrected based solely on documents. Each of these deficiencies is, at bottom, a failure by Petitioner's staff to provide care to residents in accord with professionally recognized standards of care. For example, Petitioner's staff was found to have failed to provide a resident with proper incontinence care. Retraining the staff in the correct performance of incontinence care certainly is a critical part of correcting this deficiency. But, retraining alone is not sufficient. There must be proof that the staff absorbed the information provided by the retraining and that they are applying it in practice. That aspect of compliance cannot be established simply by documents but requires observation.

Thus, and as a matter of law, Petitioner could not establish compliance with the deficiencies that I describe in this Finding based solely on documents representing that its staff had been retrained or even that they were performing according to professionally recognized standards of care. What was minimally necessary to establishing compliance was that the staff be observed actually providing the care implicated in the deficiencies and providing it according to professionally recognized standards of care. Certification

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[3] There are some deficiencies where correction can be certified based on documents. For example, a Life Safety Code deficiency might be based on the failure of a specific piece of equipment at a facility. In that circumstance, a facility might be able to prove compliance by offering written proof that the faulty piece of equipment had been repaired or replaced.

of that required a revisit to the facility. In this case the revisit occurred on May 22, 2008 and that date is as a matter of law the earliest date on which CMS could have certified Petitioner as compliant.

Petitioner makes several arguments in opposition to CMS's motion and to the analysis that I have just given. I find them to be without merit.

Petitioner argues that it "corrected each deficiency through a variety of in-service training, counseling, education and investigation," citing as support for this contention the affidavit of Paulette Trexler, Petitioner's quality assurance director. Petitioner's Memorandum in Opposition to CMS's Motion for Summary Judgment (Petitioner's brief in opposition) at 2; P. Ex. 48. However, and as is evident from Ms. Trexler's affidavit, all of the evidence cited by Petitioner is in the form of documents that it or its staff generated. In other words, Petitioner relies precisely on documentary evidence that is as a matter of law insufficient to prove compliance. Indeed, on close examination it becomes obvious that Petitioner's contention that it attained compliance earlier than the May 22, 2008 revisit rests entirely on documents which Petitioner offers to show that staff members were retrained or that policies were written and implemented. P. Ex. 49.[4]

Petitioner contends that "there is no evidence submitted by CMS to support that it actually conducted the types of investigatory and monitoring activities supposedly underpinning the 'comments' made by the Secretary to the 'Preamble to 42 CFR Part 488.'" Petitioner's brief in opposition at 3. In effect, Petitioner argues that the surveyors did a poor job at the revisit and, therefore, their findings should not control. This argument misses the point. Whether the surveyors did a good job or a bad job on May 22, 2008 is not an issue in this case. As a matter of law, CMS is entitled to rely on the revisit findings and to assume that, if the surveyors conclude that compliance has been attained, that the surveyors performed the revisit correctly. Thus, a survey's finding may not be invalidated by the argument that the surveyors did not follow survey protocol or that they did a poor job. 42 C.F.R. § 488.318(b).

Moreover, if Petitioner's argument were followed to its logical conclusion it would mean only that there is insufficient evidence to prove that Petitioner attained compliance as of the revisit. That conclusion benefits Petitioner not at all because it does not permit me to infer that Petitioner attained compliance prior to the revisit.

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[4] It would have been insufficient as a matter of law even if Petitioner had provided affidavits of individuals certifying that they had observed personally staff providing care consistent with regulatory requirements because the regulations make it plain that CMS or its delegate, a State survey agency, must make that observation in order for it to have meaning. 42 C.F.R. § 488.454(a)(1).

Petitioner then attacks CMS's argument that the preamble to the Part 488 regulations provides guidance as to the regulations' interpretation. "Necessarily, a Preamble is not law. It is, by its nature and definition, something preliminary, not interpretative, and nothing which constitutes enforcement." Petitioner's brief in opposition at 3. I agree that the preamble to the regulations does not have the legal effect of the regulations themselves. But, Petitioner is incorrect in arguing that the preamble has no value as an interpretive document. It is, in fact, the Secretary's guidance as to how she wants the regulations to be interpreted and applied and is, therefore, a highly influential policy statement.

But, according to Petitioner, even if the preamble has some interpretive value it gives no meaningful guidance in this case. That is so, Petitioner contends, because: "The Preamble mentioned by CMS says nothing about any tag at issue. Not one." Petitioner's brief in opposition at 3-4. That assertion is incorrect inasmuch as the example cited in the preamble is 42 C.F.R. § 483.65, governing infection control, and Petitioner contravened this regulation. More to the point, however, Petitioner's argument distorts the meaning of the preamble and the guidance that it gives.

The preamble language that I have cited in this decision is not – as Petitioner seems to assert – intended to list those regulatory sections for which onsite surveys must be held in order to verify compliance. Rather, and using 42 C.F.R. § 483.65 as an example, it lays out a principled basis for deciding when a resurvey is necessary in order to verify compliance. It explains that a resurvey is always necessary when noncompliance involves failure by facility staff to provide care in accordance with accepted standards of care. As I discuss above, all of the deficiencies that I address in this decision are deficiencies that involve precisely the types of human error that necessitate a resurvey in order to verify compliance with participation requirements.

Petitioner also asserts that its plan of correction establishes that compliance with participation requirements was attained by April 29, 2008, five days after the April Survey. Petitioner's brief in opposition at 4. I have explained already why Petitioner's documents cannot establish compliance with participation requirements. Furthermore, a plan of correction, by definition, is not evidence that a facility has attained compliance. It is merely a promise by a facility to attain compliance. It does not document what a facility has done to attain compliance; rather, it documents what a facility pledges to do.

In this case, Petitioner's plan of correction does not even promise that compliance will be attained by April 29, 2008. Although it lists "4/29/08" as the completion date of proposed corrective actions, the plan actually describes corrective actions that would require as much as a month to complete. CMS Ex. 5 at 5-6, 14, 15, 17, 21, 24. For example, in pledging to correct its noncompliance with the requirements of 42 C.F.R. § 483.25, Petitioner asserts that corrective actions:

> will be monitored through chart audits on residents exhibiting a change in condition by Assistant DON [director of nursing], Clinical Director, QA [quality assurance] Nurse 5 x week x 2 weeks then 3 x week x 2 weeks then randomly thereafter.

CMS Ex. 5 at 5. In addressing the same deficiency, Petitioner avers that discharge records would be reviewed for one month. *Id.* at 6.

Petitioner avers that State survey agency staff told Petitioner that they would certify that compliance was attained by April 29, 2008. Petitioner's brief in opposition at 4. That assertion is irrelevant. It is not a State survey agency or its employees, but CMS that determines when compliance is attained.

Finally, Petitioner argues that it is unfair to make compliance contingent on a revisit. It raises the question of the situation in which CMS or a State survey agency unreasonably delays conducting the revisit, thereby causing penalties to accrue by virtue of the delay even though the facility's staff is providing care consistent with applicable standards of care. I do not need to consider that issue here because, in this case, the State survey agency actually revisited Petitioner prior to the dates when Petitioner represented that it would attain compliance with participation requirements. *See* CMS Ex. 5 at 5-6, 14, 15, 17, 21, 24.

2. Petitioner attained compliance with participation requirements effective May 22, 2008. Therefore, CMS may impose a civil money penalty of $550 per day for each day of a period that began on April 24, 2008 and ran through May 21, 2008.

As a matter of law Petitioner could not attain compliance prior to the revisit of May 22, 2008. Consequently, CMS is authorized to impose a civil money penalty of $550 a day for each day of the period that began on April 24, 2008 and ran through May 21, 2008.

/s/
Steven T. Kessel
Administrative Law Judge