Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Oak Ridge Center,
(CCN: 51-5174),

Petitioner,

v.

Centers for Medicare & Medicaid Services.

Docket No. C-17-71

Decision No. CR4865

Date: June 13, 2017

DECISION

I enter summary judgment in favor of the Centers for Medicare & Medicaid Services (CMS) and against Petitioner, Oak Ridge Center, a skilled nursing facility doing business in West Virginia. I sustain CMS's determinations that Petitioner failed to comply substantially with a Medicare participation requirement and that Petitioner's noncompliance posed immediate jeopardy for residents of its facility. I sustain also CMS's remedy determination consisting of civil money penalties in the amount of $5,900 per day for each day of a period that began on September 15, 2015 and that continued through May 12, 2016.[1]

[1] CMS also imposed civil money penalties of $250 per day for each day of a period that began on May 13, 2016 and that continued through August 29, 2016, basing those penalties on the same noncompliance findings that were the basis for the immediate jeopardy level penalties, albeit at a level of noncompliance at less than immediate jeopardy. Petitioner did not challenge the imposition of this remedy and it is not at issue here.

I. Background

Petitioner requested a hearing to challenge the immediate jeopardy level remedy imposed by CMS. The parties exchanged pre-hearing briefs and exhibits. CMS then moved for summary judgment and Petitioner opposed the motion.

CMS objected to portions of some of Petitioner's exhibits and Petitioner replied to CMS's objections. I rule on CMS's objections in the body of this decision.

In deciding this case I refer to some of the parties' exhibits but only insofar as I discuss undisputed material facts or the absence of such facts.

II. Issues, Findings of Fact and Conclusions of Law

A. Issues

The issues are whether Petitioner's noncompliance with a Medicare participation requirement posed immediate jeopardy for residents of its facility, and whether CMS's remedy determination was reasonable.

B. Findings of Fact and Conclusions of Law

I am mindful of the criteria for imposing summary judgment. In evaluating CMS's allegations and Petitioner's defenses I rely only on material facts that are undisputed. I have considered these facts in the context of Petitioner's arguments and assertions in order to decide whether inferences may be drawn in Petitioner's favor that would support a ruling that summary judgment is not appropriate.

CMS's case against Petitioner centers on its assertion that Petitioner failed to comply substantially, and at an immediate jeopardy level of noncompliance, with the Medicare participation requirement stated at 42 C.F.R. § 483.25. This regulation mandates a participating skilled nursing facility to provide services to each of its residents in order that he or she may attain the highest practicable physical, mental, and psychosocial level of well-being, in accordance with his or her written plan of care.

Petitioner concedes that it failed to comply with this regulation. Inasmuch as noncompliance is not at issue here, the remaining issues pertain to the level of noncompliance and reasonableness of the remedy.

Noncompliance in this case consists of wholesale failure by Petitioner's staff to provide care to diabetic residents consistent with the treatments and services ordered by the residents' physicians. The undisputed facts establish multiple failures by the staff to implement appropriately those aspects of the residents' care plans that addressed the residents' diabetes.

- Staff withheld administering insulin that physicians had prescribed for residents. CMS Ex. 28 at 7-8; CMS Ex. 29 at 10-12.

- Facility staff did not follow the facility's protocol for addressing possible instances of hypoglycemia (low blood sugar) in diabetic residents. CMS Ex. 28 at 8-9; CMS Ex. 29 at 12-13.

- Staff erroneously failed to administer prescribed long-acting insulin to one resident for eight consecutive days. CMS Ex. 28 at 9; CMS Ex. 29 at 13-16.

- On eleven separate occasions Petitioner's staff ignored a physician's order that the physician be notified whenever a resident's blood sugar exceeded a specified level. CMS Ex. 28 at 5-7; CMS Ex. 29 at 14-15.

- Petitioner's staff failed to perform a test measuring blood glucose levels (HGA1c test) as ordered by a resident's physician. CMS Ex. 28 at 10-11; CMS Ex. 29 at 16.

These undisputed failures by Petitioner's staff to provide prescribed care to diabetic residents had consequences. For example, failure by the staff to notify a resident's physician of hyperglycemic blood sugar levels (excess blood sugar) resulted in the resident necessitating emergency treatment for severe hyperglycemia. CMS Ex. 11A at 13; CMS Ex. 11E at 30-31. The staff's failure to administer long-acting insulin to another resident for eight consecutive days caused the resident to experience multiple hyperglycemic episodes during that period. CMS Ex. 14A at 15, 17-18, 60. These episodes were a setback from the resident's previous state in which he had exhibited substantial improvement with controlling his blood sugar levels. CMS Ex. 29 at 14.

The deficient care implicated multiple staff members at Petitioner's facility, it affected multiple residents, and in some instances it constituted failure to provide necessary care over sustained periods of time. CMS Ex. 29 at 8. These failures amounted to a systemic failure by Petitioner's staff to understand the dangers and risks that diabetes posed to residents. The deficiencies resulted in a likelihood of serious harm, injury, or death to Petitioner's residents.

Resistance to insulin and the inability of one's body to produce sufficient insulin is the cause of diabetes in adults (Type 2 diabetes) and it is a common condition among nursing facility residents. CMS Ex. 29 at 5. The failure of one's body to produce adequate insulin or to self-regulate insulin levels may lead to hypoglycemia and/or hyperglycemia. *Id.*

Because individuals who suffer from Type 2 diabetes cannot self-regulate their insulin level, failure by trained personnel to assist these individuals may lead to their suffering from episodes of hypoglycemia and/or hyperglycemia and all of the likely adverse consequences of these episodes. Hypoglycemia (excess amounts of insulin causing low blood sugar levels) may lead to coma or death if allowed to develop and not treated appropriately. CMS Ex. 29 at 5. Hyperglycemia (insufficient amounts of insulin causing high blood sugar levels) may cause immediate medical problems including dehydration, low blood pressure, and altered mental status. *Id.*

Hyperglycemia may not cause the acute problems caused by hypoglycemia, but hyperglycemia may have long-term effects that are devastating to a person suffering from Type 2 diabetes. Excess glucose in the blood stream causes vascular damage, which in turn damages a body's organs. CMS Ex. 29 at 7. Excess blood glucose has the potential to exacerbate and make worse other medical conditions from which an individual suffers. *Id.* Hyperglycemia may cause long-term dysfunction and failure of body organs, especially the kidneys, heart, brain, skin, eyes, nerves, and blood vessels. *Id.*

The term "immediate jeopardy" is defined at 42 C.F.R. § 488.301 to mean noncompliance that causes or is likely to cause serious injury, harm, impairment, or death to a resident. The undisputed facts that I have discussed are more than adequate to prove immediate jeopardy level noncompliance by Petitioner. The staff's systemic failure to provide prescribed care to diabetic residents made it likely that those residents would experience the adverse consequences of Type 2 diabetes. *The Laurels at Forest Glen*, DAB No. 2182, at 6 (2008).

Furthermore, the immediate jeopardy at Petitioner's facility wasn't confined solely to those diabetic residents who were put in harm's way. What is evident from this noncompliance was that Petitioner's staff demonstrated either a persistent inability to comply with physicians' orders or an unwillingness to do so. That also is immediate jeopardy because it establishes that the staff put all residents at risk, whether or not they suffered from diabetes.

Carrying out the orders of a physician is essential at a skilled nursing facility. It distinguishes a skilled nursing facility from a retirement home or a boarding house. The essence of skilled nursing care is that individuals who require skilled nursing care will receive that care as is prescribed by their physicians. Systemic failure by a facility's staff to carry out physicians' orders to provide care is antithetical to the purpose of skilled nursing care.

Where CMS makes a determination of immediate jeopardy level noncompliance, that imposes a burden on Petitioner to prove that the determination is clearly erroneous. *Liberty Commons Nursing & Rehab Ctr.-Johnston,* DAB No. 2031, at 18-19 (2006), *aff'd,* 241 F. App'x 76 (4th Cir. 2007). That is a higher standard than mere preponderance of the evidence. I am mindful that in deciding a motion for summary judgment I do not weigh evidence. I may only grant summary judgment where the moving party must prevail based on the undisputed facts, as supported by whatever evidence the moving party offers. But, I am also mindful that ultimately, a petitioner must surmount a very high barrier if it is to establish that a finding of immediate jeopardy is clearly erroneous. In looking at Petitioner's arguments, therefore, I ask: has it adduced facts which, if established at a hearing, could satisfy me that CMS's immediate jeopardy determination is clearly erroneous?

In this case, Petitioner failed not only to meet that test but it failed to adduce *any* evidence-based facts that would allow me to rule in its favor. To be sure, Petitioner has raised numerous arguments against entry of summary judgment. But, and as I explain, none of them are supported by facts in the exhibits presented by the parties. Indeed, Petitioner's brief in opposition to CMS's motion contains no citations whatsoever to the parties' exhibits. I find Petitioner's arguments to constitute mere unsupported claims. I cannot deny a motion for summary judgment where the party opposing the motion offers no facts that would support its position.

Petitioner's central argument is that times have changed and that the standards and criteria that CMS rely on are outmoded. Thus, Petitioner contends repeatedly that CMS relies on standards that were current in 1987, the year when Congress enacted provisions of the law governing Medicare, asserting that the evolution of modern medicine long ago rendered these standards obsolete. From that, Petitioner contends that more modern and widely accepted criteria for managing diabetes no longer require close monitoring of residents for signs of hyperglycemia (Petitioner says nothing about monitoring for signs of hypoglycemia). It argues that some levels of hyperglycemia in an elderly diabetic individual are okay, that current thinking is that such an individual can tolerate some hyperglycemia. And, from that, Petitioner concludes that its staff really didn't cause much or any harm to its residents or put them in jeopardy when it failed to carry out physicians' orders to monitor residents for hyperglycemia and to notify the physicians when hyperglycemia was present.

Petitioner purports to base its assertions on three documents: The American Medical Directors' Association's "Diabetes Management in the Long-Term Care Setting" (2010); the same organization's "Diabetes Management in the Post-Acute and Long-Term Care Setting" (2015); and The American Diabetes Association's criteria for managing diabetes. P. Ex. 1; P. Ex. 2; P. Ex. 3. These documents are 54 pages, 74 pages, and 11 pages, respectively. Nowhere in its briefs (neither its initial brief nor its opposition to CMS's summary judgment motion) does Petitioner cite to any specific statement in these documents that allegedly supports its contentions.

And, in fact, there is nothing there. I have reviewed them (although Petitioner failed to cite a single passage in any of them that supports its arguments) and I find no language in any of them that even remotely supports Petitioner's contention that modern standards for treating Type 2 diabetes allow a skilled nursing facility to fail or refuse to execute a physician's order to monitor a diabetic resident and to report episodes of hyperglycemia and not put residents at jeopardy. Nothing in those documents suggests that a facility may appropriately fail to administer insulin as prescribed and not put residents at jeopardy. There is not a word in the documents that supports a finding that failure to perform prescribed tests is harmless error. And, most importantly, there is absolutely nothing in these documents that suggests that a physician's assessment of the risks of hyperglycemia in an individual resident and his or her resulting orders to monitor the resident for hyperglycemia and to report incidents of hyperglycemia in that resident may be ignored or overridden by a facility's staff because it is okay under modern standards for treatment of diabetes for the resident to be hyperglycemic.

Petitioner also argues that its experts' testimony supports its central argument. These experts are Steven A. Levenson, M.D. (P. Ex. 30), Holly Estrel, R.N. (P. Ex. 31), and Naushira Pandya, M.D. (P. Ex. 32). The three witnesses filed largely identical affidavits. CMS has argued that these affidavits are predicated on inadmissible hearsay and that I should exclude them for that reason. It argues also that these affidavits contravene my pre-hearing order, in which I directed the parties to reduce all testimony to writing made under oath or affirmation, because large portions of them are statements attributed to third parties whose testimony was not offered by Petitioner in affidavit or declaration form.

I do not hear this case pursuant to the Federal Rules of Evidence and I do not exclude hearsay automatically, even if I have serious reservations about its probative value. Consequently, I do not exclude these exhibits for that reason. That said, large portions of all three exhibits clearly contravene my pre-hearing order. Much of the testimony in these exhibits consists of statements that the declarants attribute to employees of Petitioner's facility, including its director of nursing or nurses who treated the residents whose care is at issue. The statements that the witnesses attribute to these individuals are precisely the kinds of statements and testimony that are covered by my pre-hearing order. Petitioner knew or should have known that it was obligated to offer these statements as

written direct testimony made under oath if it wanted me to consider them. I exclude all of the statements that are attributed to third parties because they violate the pre-hearing order that I issued in this case.[2]

Portions of Dr. Levenson's and Dr. Pandya's affidavits are not based on third-party testimonial statements. These portions refer to the criteria and recommendations contained in P. Ex. 1, P. Ex. 2, and P. Ex. 3. P. Ex. 30 at 3-6; P. Ex. 32 at 3-6. However, although I do not exclude these portions, neither do I find them to be relevant. They offer no facts that challenge CMS's determination because, while the statements of the two experts purport to paraphrase the guidelines and criteria in P. Ex. 1, P. Ex. 2, and P. Ex. 3, they do not cite to *any specific statements in these exhibits* that allegedly support the witnesses' conclusions. In that respect the opinions of Drs. Levenson and Pandya are as flawed as is Petitioner's brief. They are opinions without any foundation in the record and offer no basis for refuting CMS's case for summary judgment.

As I have stated above, I cannot discern anything in P. Ex. 1, P. Ex. 2, or P. Ex. 3 that supports Petitioner's argument that CMS is relying on outmoded and unduly stringent standards of care for monitoring and treating diabetic residents in skilled nursing facilities. Petitioner's witnesses' assertions that these exhibits contain statements that support that argument are meaningless because they fail to refer to a single statement in any of these exhibits that says anything that remotely supports Petitioner's argument.

And, it is evident why these witnesses do not cite to anything in P. Ex. 1, P. Ex. 2, or P. Ex. 3 that supports their opinions as to immediate jeopardy level noncompliance. There is nothing in these documents that provides support. These witnesses' opinions address an argument that CMS does not make and ignore the argument that is central to CMS's case.

Petitioner's contentions notwithstanding, CMS does not assert that some rigid standard of care that was current in the 1980s but that is now obsolete is the basis for finding Petitioner's noncompliance to be at the immediate jeopardy level. Even if Drs. Levenson and Pandya are correct that modern standards of care for treating hyperglycemia are somewhat more relaxed than they were in the 1980s, those opinions avoid confronting what CMS is asserting. The crux of CMS's case is that systemic failure by a facility to provide prescribed care to diabetic residents, consisting of wholesale failure to comply with physicians' orders to administer medication, to monitor blood sugar levels and report findings above prescribed levels, and to conduct prescribed tests, puts residents at a likelihood of serious harm because there are adverse long-term consequences to manifestations of diabetes such as hyperglycemia that are made more likely when that

[2] Petitioner's counsel is a veteran of many hearings before me and is intimately familiar with the terms and requirements of the standard pre-hearing order that I issued in this case and in all other cases involving skilled nursing facilities.

issue isn't properly treated. Nothing that Drs. Levenson or Pandya says addresses that assertion. Neither of these witnesses contends that any of the specific deficiencies that I have discussed and that Petitioner concedes would be permissible or deemed to cause less than serious harm under the ostensible modern guidelines for treating diabetes.

I have considered Petitioner's remaining arguments and find them to be without merit.

Petitioner asserts that: "CMS essentially moves for summary judgment of this appeal on the straightforward argument that any nursing error that involves diabetes care ipso facto represents 'immediate jeopardy' . . . ." Petitioner's Reply at 2. That argument is plainly incorrect. CMS neither alleges nor argues that any nursing error in diabetes care is automatically an immediate jeopardy level deficiency. The gravamen of CMS's case – amply established by undisputed material facts – is that systemic failure to provide *prescribed care* to diabetic residents is immediate jeopardy level noncompliance, because there are dangers inherent in such systemic failure to provide care. This is not a case of a single incident of failure to provide care. Rather, it is a case of many failures that not only endangered residents in the aggregate but that established a wholesale failure by Petitioner's staff to provide care consistent with physicians' orders.

Similarly, Petitioner contends that CMS alleges that: "*whatever* the basis for the nurses' judgments, and *whatever* the likely effect on residents, because the disease in question is diabetes, *any* error or anomaly, or *any* instance where a nurse did not follow a physician's order or a resident's care plan to the letter, exposed *all* of Petitioner's residents to the 'likelihood' of death or serious harm." Petitioner's Reply at 3-4. This is a straw man. It mischaracterizes CMS's argument for the obvious reason that it is far easier to attack the mischaracterized argument than what CMS actually asserts.

Petitioner characterizes its witnesses' opinions as "factual statements" that refute CMS's argument that Petitioner's noncompliance put residents at immediate jeopardy. Petitioner's Reply at 4-5. I have discussed this argument above. The statements by Drs. Levenson and Pandya are not "factual statements." They are opinions that recite no facts and I find them to be irrelevant for that reason and for other reasons that I have discussed. *See* P. Ex. 30; P. Ex. 32.

Petitioner attempts to minimize the failures of its nursing staff to report episodes of diabetic residents' hyperglycemia to the residents' physicians with this argument: "CMS does not address whether this fact – that is that there was *ongoing* interaction and communication between Petitioner's nurses and residents' physicians and their nurse practitioners – is material to Petitioner's compliance . . . ." Petitioner's Reply at 7. Petitioner argues that this asserted "ongoing interaction and communication" somehow substituted for or ameliorated the staff's failure to respond to physicians' orders that they be consulted when residents' blood sugars exceeded prescribed levels.

I am hard put to understand why this would be so and Petitioner doesn't explain it. However, Petitioner has offered no facts whatsoever to establish this alleged "ongoing interaction and communication." It has pointed to nothing – no nurse's notes, no reports of contact, no other documentation whatsoever – that evidences these alleged ongoing interactions and communications.

An unsupported fact assertion is no basis for refuting a motion for summary judgment. Petitioner's naked claim is of no relevance.

Petitioner asserts that CMS failed to identify undisputed material facts. Petitioner's Reply at 10-12. This argument is incorrect. CMS identified precisely what Petitioner's staff failed to do and Petitioner conceded these allegations. Petitioner's Reply at 8. Those undisputed material facts amply justify CMS's argument that immediate jeopardy level noncompliance existed at Petitioner's facility.

Petitioner contends that its witnesses describe material disputes of fact. Petitioner's Reply at 12-17. This is not correct. As I have discussed, Drs. Levenson and Pandya offer opinions about whether CMS is holding Petitioner to unduly stringent care requirements for treatment of diabetes. They purport to base their opinions on the treatment guidelines contained in P. Ex. 1, P. Ex. 2, and P. Ex. 3. But, neither of these witnesses identifies anything specific in these documents that would ostensibly support their opinions. Indeed, neither of these witnesses – nor, for that matter, Petitioner's counsel – ever cites to anything specific in these exhibits that purportedly would support their opinions or that would show that CMS is holding Petitioner to outmoded standards of care.

Furthermore, CMS made very specific allegations of immediate jeopardy. CMS isn't contending that the facility's application of liberalized guidelines for treating hyperglycemia put residents at immediate jeopardy. CMS contends explicitly that failure to carry out physicians' orders for treatment of diabetes, failure to consult with physicians notwithstanding the physicians' express orders to do so, failure to administer medication as prescribed by physicians, and failure to administer tests as prescribed by physicians, put residents at immediate jeopardy. Petitioner's witnesses do not confront these allegations and they cite to absolutely nothing that would refute them.

Finally, Petitioner asserts that CMS mischaracterizes Petitioner's arguments about its noncompliance by contending that Petitioner asserts a "no harm, no foul" argument that attempts incorrectly to minimize the seriousness of the noncompliance. Petitioner's Reply at 18-19. It argues that: "There is a significant logical and legal difference between a plausible risk of harm that does not actually occur, whether fortuitously or otherwise, and an implausible or even impossible chance that some act or omission will cause serious harm." Petitioner's Reply at 18. Whether or not that assertion is correct is

irrelevant. CMS offered undisputed facts showing that the systemic failures by Petitioner's staff to provide requisite care to its residents created a likelihood of harm.

Petitioner offered no arguments or facts to challenge the penalty amount imposed by CMS or the duration of its noncompliance. The penalties of $5,900 per day that CMS determined to impose are well within the range of penalties that may be imposed for immediate jeopardy level noncompliance. 42 C.F.R. § 488.438(a)(1). I sustain them in the absence of any argument or facts to show that they are unreasonable.

____/s/__________________
Steven T. Kessel
Administrative Law Judge