Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Golden Living Center - Superior,
(CCN: 52-5370),

Petitioner,

v.

Centers for Medicare & Medicaid Services.

Docket No. C-15-2887

Decision No. CR4514

Date: January 28, 2016

DECISION

I grant summary judgment in favor of the Centers for Medicare & Medicaid Services (CMS), sustaining its determination to impose civil money penalties of $5100 against Petitioner, Golden Living Center – Superior, for each day of a period that began on January 26 and that ran through February 9, 2015.[1]

I. Background

Petitioner is a skilled nursing facility in Superior, Wisconsin. It requested a hearing in order to challenge the remedies that I cite in this decision's opening paragraph. CMS moved for summary judgment and Petitioner opposed the motion. CMS moved for leave to file a sur-reply brief, and I granted the motion.

[1] CMS imposed additional remedies against Petitioner including additional civil money penalties. These were not contested by Petitioner and for that reason it is unnecessary that I make specific noncompliance findings concerning these additional remedies. I find CMS's determination to impose these additional remedies to be administratively final.

CMS filed a total of 43 proposed exhibits, identified as CMS Ex. 1 – CMS Ex. 43, as part of a pre-hearing submission in this case. Petitioner filed 15 proposed exhibits, identified as P. Ex. 1 – P. Ex. 15. I am making all of these exhibits part of the record for purposes of ruling on CMS's motion for summary judgment.

II. Issues, Findings of Fact and Conclusions of Law

A. Issues

The issues are whether undisputed facts prove that:

1. Petitioner failed to comply substantially with the requirements of 42 C.F.R. § 483.65.

2. Petitioner's noncompliance was so egregious as to comprise immediate jeopardy for Petitioner's residents.

3. CMS's determination to impose civil money penalties of $5100 per day is reasonable.

B. Findings of Fact and Conclusions of Law

CMS asserts that Petitioner failed to comply substantially with the requirements of 42 C.F.R. § 483.65. This regulation establishes a skilled nursing facility's duty to protect its residents against the spread of infection. In relevant part, this regulation states that a skilled nursing facility must:

> Establish and maintain an infection control program designed to provide a safe, sanitary, and comfortable environment and to help prevent the transmission of disease and infection.

CMS alleges that Petitioner failed to comply with this regulation because it failed to implement its own protocols for dealing with influenza infection. These policies were entitled "Influenza Outbreak Guideline" and "Influenza Outbreak Antiviral Procedures." P. Ex. 2 at 1-4, 5-7. Specifically, CMS asserts that Petitioner adopted infection protocols that ought to have been triggered when even one of its residents developed influenza. *Id.* at 1. The protocols commanded Petitioner's staff to implement its outbreak management procedures immediately based on a resident developing the signs and symptoms of influenza. The staff was told not to wait for a confirmed diagnosis before implementing the protocols and to implement infection control measures "as soon as the influenza is suspected." *Id.* at 3. The protocols included the following requirements in the event of a suspected case of influenza:

- The staff was instructed to call Petitioner's medical director and to request orders for prophylactic and anti-viral medications for residents according to current recommendations. The protocols called for considering providing anti-viral medication to members of the staff as well.

- The protocols directed that staff not be moved around Petitioner's facility. Designated staff members were instructed to stay only in their regularly scheduled work area and were told not to go from floor to floor within the facility.

- If several residents in a particular wing of the facility had influenza, then the staff was instructed to cancel all activities and serve all residents their meals in their rooms.

Id. at 3-4.

These protocols also included a treatment regimen that would be implemented with an influenza outbreak. The staff would administer prophylactic doses of antiviral drugs (Tamiflu or Relenza) to residents within 48 hours of the manifestation of signs or symptoms of influenza. P. Ex. 2 at 6. Petitioner's protocols also referred its staff to a Centers for Disease Control (CDC) website for additional guidance on dealing with an influenza outbreak. *Id.* at 7. The CDC advises entities such as Petitioner that all residents of an entire facility should receive antiviral medications as soon as an influenza outbreak is determined or when two residents become ill within 72 hours and one of the residents has confirmed influenza. CMS Ex. 13 at 6-7.

CMS contends that five residents of Petitioner's facility tested positive for influenza between January 22 and February 4, 2015. CMS asserts that the following residents developed signs and symptoms of influenza during this period and ultimately tested positive for influenza: Residents #s 11, 12, 13, 15, and 20. CMS's Memorandum in Support of its Motion for Summary Judgment at 9-11 and citations contained therein. CMS argues that, during this period, Petitioner failed to apply its own protocols for dealing with an influenza outbreak and failed to follow the CDC guidelines that it had incorporated into its protocols.

Specifically, CMS asserts that:

- Petitioner failed to provide prophylactic Tamiflu treatment to all of its residents before February 2, 2015, more than 10 days after the first case of influenza became apparent and well after the point that several of Petitioner's residents were diagnosed with influenza. CMS Ex. 20 at 1; CMS Ex. 21 at 6. CMS notes that this contention is buttressed by the admission of Petitioner's medical director, who acknowledged not ordering prophylactic Tamiflu administration to residents until February 2, 2015, after five confirmed cases of influenza had occurred. P. Ex. 13

at 12-13. This statement is confirmed, according to CMS, by an admission by Petitioner's director of nursing. P. Ex. 11 at 15.

- Between January 22 and February 6, 2015, Petitioner's management allowed at least one member of its staff to move between the area of the facility where the influenza outbreak had occurred, Petitioner's Alzheimer's unit, and other parts of the facility. CMS Ex. 17.

- After January 22, residents in the Alzheimer's unit continued to engage in small group activities and were not isolated. P. Ex. 10 at 3; P. Ex. 11 at 11; P. Ex. 14 at 1-2.

The facts as asserted by CMS, if unchallenged, plainly establish noncompliance by Petitioner with its own influenza protocols. These facts show that Petitioner had adopted protocols that called for implementation of specific measures with the appearance of even a single case of influenza at its facility. These protocols included prophylactic administration of antiviral medications to all residents; restriction of staff movement from the area in which an outbreak occurred; and suspension of group activities during an outbreak. The facts as alleged by CMS show that Petitioner implemented none of these measures at its facility after the January 22 outbreak of influenza.

These facts also establish that Petitioner failed to comply substantially with the requirements of 42 C.F.R. § 483.65. The regulation does not contain specific protocols for dealing with influenza outbreaks. Rather, it imposes on skilled nursing facilities the duty to develop their own protocols and, importantly, to maintain them. Here, there is no question that Petitioner developed detailed protocols for addressing an influenza outbreak. But, the facts offered by CMS show that Petitioner failed to implement those protocols at the critical moment when an outbreak occurred. That is noncompliance with the regulation's requirement that a facility maintain its infection controls.

Petitioner has thrown up a series of arguments in opposition to CMS's motion. I find them to be without merit. Most significantly, I find that Petitioner has adduced no facts whatsoever to contradict those offered by CMS.

Petitioner starts off by contending that CMS's allegations of noncompliance are "murky." Petitioner's Reply to CMS's Motion for Summary Judgment at 2. By that, Petitioner evidently means that there is some vagueness or lack of clarity to CMS's arguments and fact contentions. I find no basis for Petitioner's assertion. To the contrary, what CMS alleges is crystal clear. From the outset of this case CMS has not varied in its central argument: Petitioner developed infection control protocols for addressing an influenza outbreak but failed to implement them when an outbreak occurred at its facility. There is absolutely nothing unclear about that. Nor is there anything unclear or uncertain about the facts and evidence relied on by CMS. The protocols that CMS identifies in its motion

are Petitioner's protocols. They are stated explicitly in Petitioner's own exhibits and Petitioner has not asserted that CMS identified them inaccurately or incompletely. There is no dispute that several residents of Petitioner's facility developed influenza during the period running from January 22 through February 6, 2015. Nor is there any dispute that Petitioner: failed prior to February 2, 2015, to administer prophylactic antiviral medication to its residents; allowed at least one member of its staff to move from the Alzheimer's unit where the infected residents resided to other parts of its facility; and continued small group activities in the Alzheimer's unit during the outbreak. All of these failures to act or actions contravened Petitioner's protocols.

Next, Petitioner asserts that CMS impermissibly expanded or modified its allegations of noncompliance beyond those which are stated in the survey report that is the basis for CMS's remedy determinations. *See* CMS Ex. 1. I disagree with Petitioner's premise. The survey report states explicitly that Petitioner: "did not ensure that it had an effective control program consisting of recognizing and preventing outbreaks (including appropriate precautions and timely use of Tamiflu) . . . during an outbreak . . . ." *Id.* at 32-33. That is an accurate if somewhat broadly stated summary of CMS's contentions about Petitioner's noncompliance. While Petitioner undoubtedly had an infection control program, its program was not effective because it failed to implement it. Therefore, Petitioner did not have an effective control program, as the survey report stated. Moreover, the report recites in great detail the specific fact contentions on which CMS bases its assertions. *Id.* at 31-64.

Furthermore, Petitioner's argument notwithstanding, there is nothing in the regulations at 42 C.F.R. Part 498, which govern hearings in cases involving CMS, that precludes CMS from modifying, expanding on, or even raising additional, allegations of noncompliance during the pendency of a case. The requirement of due process defines the boundaries of what a party may argue in a Part 498 hearing. A party may amend or supplement its allegations if it provides its adversary with notice and if the adverse party has the opportunity to defend against and rebut the amendment or supplement. *Livingston Care Ctr.*, DAB No. 1871 (2003), *aff'd*, *Livingston Care Ctr. v. U.S. Dep't of Health and Human Servs.*, 388 F.3d 168 (6th Cir. 2004). Petitioner has not made a showing that it was surprised by any of CMS's allegations nor has it shown that it was denied the opportunity to present evidence and argument in opposition to whatever it is that CMS is contending.

The central component of Petitioner's defense is that CMS has failed to enunciate any standard to which Petitioner may be held accountable. Petitioner repeatedly points out that 42 C.F.R. § 483.65 fails to identify specific infection control requirements applicable to influenza outbreaks. Petitioner asserts additionally that CMS has not at any time identified an objective standard that defines the necessary elements of influenza control. Thus, according to Petitioner, CMS's entire case collapses because CMS has not and cannot identify any criteria pursuant to which Petitioner may be held accountable.

Indeed, according to Petitioner, if any party merits summary judgment in its favor it is Petitioner, due to CMS's failure to identify an applicable legal standard.

This argument is a red herring. CMS did not identify a binding and objective standard for influenza control because the regulation governing infection control at skilled nursing facilities is not predicated on inflexible and rigid standards. Instead, the regulation vests responsibility in skilled nursing facilities to develop their own standards and protocols consistent with professionally recognized standards of nursing care. That is evident from the plain language of 42 C.F.R. § 483.65. Moreover, the regulation takes into account the likelihood that professional standards of care will evolve with time. Putting a specific objective requirement in the regulations undercuts the statutory purpose of assuring that skilled nursing facilities have the flexibility to adapt their protocols to changed circumstances. *Omni Manor Nursing Home*, DAB No. 1920, at 11 (2004), *aff'd*, *Omni Manor Nursing Home v. Thompson*, 151 F. App'x 427 (6th Cir. 2005).

A skilled nursing facility is granted discretion to develop and implement infection control protocols including those that deal with influenza outbreaks. Once those protocols are in place a facility is required to maintain them – that is to say, it is required to implement its protocols and to assure that they are working. *Barbourville Nursing Home*, DAB No. 1962 (2005), *aff'd, Barbourville Nursing Home v. U.S. Dep't of Health and Human Servs.*, 174 F. App'x 932 (6th Cir. 2006).

Now, it is conceivable that a facility's infection control protocols could be so inadequate as to fail to meet generally accepted nursing standards. In that event, CMS could impose a remedy against a facility for failing to adopt meaningful protocols. But, that is not what CMS alleges here. CMS does not challenge the theoretical efficacy of Petitioner's protocols. Indeed, it refers to them as "comprehensive" and notes that these protocols accorded with recommendations adopted by the CDC. What CMS is contending is that Petitioner failed to *implement* its protocols and thus, failed to "maintain" them as is required by the governing regulation. The undisputed material facts support CMS's contention. Petitioner would have complied with regulatory requirements had it but implemented the protocols that it developed.

In a variation on its argument Petitioner also contends that there exist a multitude of protocols – published by the CDC and other entities – that address influenza outbreaks. It seems to say that it is unfair to cite Petitioner for noncompliance if CMS does not identify specifically which of these protocols Petitioner failed to comply with and explain why failure to comply with one protocol, as opposed to some other, amounts to a deficiency.

That argument is another red herring. As I have stated, it isn't CMS's duty to establish protocols for influenza control, nor is it CMS's duty to pick and choose among those that exist and hold skilled nursing facilities accountable for complying with whichever is CMS's preferred protocol. The regulatory obligation to establish and maintain an

influenza prevention protocol falls squarely on Petitioner. It could choose between existing protocols or devise protocols of its own so long as those protocols comported with professionally recognized standards of care. But, once it opted for specific infection control protocols, Petitioner was obligated to follow them. Petitioner's failure is that it violated the protocols that it adopted.

Petitioner argues that CMS has offered no rationale that would support the conclusion that it was obligated to follow its influenza protocols rather than its more general infection control protocols. The infection control protocols are less stringent, according to Petitioner, and CMS has not established any basis for requiring Petitioner to conform its procedures to the more demanding influenza protocols. I find that argument to be without merit. Petitioner obviously drafted and implemented its influenza protocols to deal with the specific problems that are unique to an influenza outbreak. Influenza is a highly infectious and extremely dangerous disease in a community such as the one housed at Petitioner's facility and Petitioner's protocols recognize that. To now excuse it from having to follow those protocols in the event of an actual outbreak – as Petitioner advocates – would render them meaningless.

Petitioner argues also that it followed its influenza protocols for the most part. It contends that its failure to follow only a few of these protocols should be weighed against its compliance with the vast majority of them. I also find this argument to be without merit. The three failures by Petitioner to comply with its protocols clearly were serious. For example, allowing at least one member of its staff who worked with influenza-infected residents to work also in other parts of Petitioner's facility could have spread infection widely among a community of highly vulnerable individuals. Consequently, the failures by Petitioner were serious even if Petitioner complied with other aspects of its protocols.

Petitioner argues that, if it did not follow its protocols, that is because its management and medical director made reasoned judgments as to whether the protocols should be applied strictly in the context of the outbreak at Petitioner's facility. In support of that argument Petitioner cites to the affidavit of Dr. Mark Boyce, Petitioner's medical director, in which he avers that he exercised his professional judgment in deciding not to administer Tamiflu immediately to all residents when influenza was detected at Petitioner's facility. P. Ex. 13 at 8, 12.

I make no findings as to the credibility of Dr. Boyce's assertions. For purposes of this decision I accept as true his claim that he made a judgment call in deciding to defer administering Tamiflu to Petitioner's residents. But, that determination clearly contravened Petitioner's protocols and absent some documented and contemporaneous decision to revise or modify the protocols, constituted noncompliance with regulatory requirements to maintain its protocol. This is not a case in which Petitioner modified its protocols based on documented clinical experience. Petitioner has offered no evidence

whatsoever of that. There is nothing at all in the record of this case showing that Petitioner's management reviewed the protocols and decided to modify them based on reasoned medical judgment. At best, Petitioner can say only that its management decided to ignore its influenza protocols because it concluded that this would be an appropriate course of action, without documenting the reasons for that conclusion. That decision – to ignore the protocols in the case of an actual outbreak of influenza – plainly violated the regulatory requirement that infection control protocols be maintained once adopted.

Dr. Boyce's explanation is that he made a professional judgment that Tamiflu should not be administered until at least three cases of influenza were diagnosed at Petitioner's facility. Nothing in the record shows that Petitioner had revised its protocols to reflect that judgment. At the time of the outbreak the protocols demanded that Petitioner's staff provide Tamiflu to residents within 48 hours of the *first* diagnosis of influenza. Dr. Boyce's ad hoc decision to ignore that specific requirement violated those protocols.

Petitioner also cites to studies that suggest that prophylactic Tamiflu administration may be ineffective to prevent the spread of influenza. From these it suggests that Petitioner should not be penalized for violating its own protocols. That is a kind of "no harm, no foul" defense in which Petitioner essentially argues that it should not be penalized even if it failed to comply with its responsibilities. I find that argument to be without merit. Petitioner always had the option of modifying or re-writing its influenza protocols if it concluded that they were obsolete or ineffective. But, that's not what it did here. Rather, it violated its protocols without documenting a reason for doing so and then gave an after the fact explanation for its violation. That is not permitted.

Petitioner asserts repeatedly that it in fact complied with the letter of its influenza protocols. Notwithstanding, it admits or fails to rebut the facts that CMS asserts are undisputed. As I have discussed, Petitioner concedes that it did not order administration of Tamiflu to its residents as was required by its protocols. Likewise, Petitioner does not deny CMS's assertion that Petitioner allowed at least one member of its staff who was assigned to Petitioner's Alzheimer's unit to move to other parts of the facility during the influenza outbreak. Petitioner argues that it limited its staff to working on the Alzheimer's unit "to the extent feasible." Petitioner's Reply to CMS's Motion for Summary Judgment at 22. But, Petitioner's protocols do not call for limiting staff movement during an outbreak to the extent that is feasible. They *prohibit* staff movement. P. Ex. 2 at 4 ("Do not move your staff around the building.").

Petitioner asserts that it took additional measures to assure that staff did not communicate influenza such as not allowing ill staff to work. I am accepting all of Petitioner's representations as true for purposes of deciding whether to issue summary judgment, but those representations do not gainsay the fact that Petitioner explicitly violated its protocols by allowing at least one member of its staff to move between the Alzheimer's unit with its infected residents and other parts of Petitioner's facility.

Petitioner's response to CMS's contention that the staff continued to hold small group activities in the Alzheimer's unit during the influenza outbreak is unavailing. In response, Petitioner explains that it canceled some group activities, but continued to permit "sensory activities" for small groups of residents who had not shown signs of influenza. Petitioner's medical director states that "the Center's influenza policy provides that in the case of an influenza outbreak, all services, including therapy, can be provided on the Unit . . . ." P. Ex. 13 at 10. His statement directly conflicts with Petitioner's written policy. P. Ex. 2 at 4 ("Cancel all activities/serve all meals in rooms if several residents have influenza in a particular wing."). All activities means all activities, not some activities and not activities for only the sick residents. Petitioner's actions were an express violation of its protocols.

According to Petitioner, it implemented all sorts of actions in order to curb the spread of influenza at its facility. *See, e.g.*, P. Ex. 11 at 10-12. These actions, apparently, are what Petitioner means when it argues that it complied with its protocols. However, although some of those actions may have been in compliance with the protocols, that compliance does not negate the noncompliance that CMS asserts and that is established by undisputed facts.

A skilled nursing facility's noncompliance with a Medicare participation requirement is so egregious as to comprise immediate jeopardy for the facility's residents where the noncompliance causes or is likely to cause serious injury, harm, impairment, or death to a resident. 42 C.F.R. § 488.301. CMS determined that Petitioner's noncompliance with 42 C.F.R. § 483.65 was at the level of immediate jeopardy. Petitioner has not responded to this assertion. It offered no argument, either in its initial brief or in its opposition to CMS's motion for summary judgment, that CMS's determination of immediate jeopardy was incorrect. I sustain CMS's determination as unchallenged. Furthermore, I find the immediate jeopardy determination to be well supported by the undisputed material facts.

Influenza can be – and often is – a deadly event for elderly individuals, particularly the frail, debilitated, and demented residents of Petitioner's Alzheimer's unit. For individuals such as these, influenza often produces a mortality rate of ten percent or more. CMS Ex. 40 at 7. Among the residents of Petitioner's facility who contracted influenza during the 2015 outbreak, three of them were hospitalized and one received palliative care. CMS Ex. 1 at 33-34; CMS Ex. 23 – CMS Ex. 27. These facts are overwhelming proof that acts or omissions that might facilitate the spread of influenza in a nursing facility place residents of that facility at immediate jeopardy.

Petitioner's failure to implement its own influenza protocols could have facilitated the spread of influenza at Petitioner's facility and thus jeopardized Petitioner's residents. At the very least, allowing at least one member of its staff who had been exposed to the virus and who possibly had become infected to work in other parts of the facility outside of the Alzheimer's unit put residents at risk. So also did allowing small group activities among possibly infected residents within the Alzheimer's unit to continue.

Petitioner also did not challenge the reasonableness of CMS's determination to impose civil money penalties of $5100 for each day of the period running from January 22 through February 9, 2015. It never argued, either in its initial brief or its opposition to CMS's motion for summary judgment, that these penalty amounts and the duration of the penalties were unjustified, assuming that it was noncompliant at the immediate jeopardy level. Therefore, I sustain these remedies as being unchallenged.

But, I also sustain them because the undisputed material facts establish them to be entirely reasonable. Regulations governing the imposition of civil money penalties for noncompliance state that CMS may impose daily penalties ranging from $3050 to $10,000 for immediate jeopardy level noncompliance. 42 C.F.R. § 488.438(a)(1)(i). Penalty amounts within this range are determined based on evidence pertaining to factors that include: the seriousness of a facility's noncompliance; its culpability; its compliance history; and its financial condition. 42 C.F.R. §§ 488.438(f)(1)-(4), 488.404 (incorporated by reference into 42 C.F.R. § 488.438(f)(3)).

CMS cites three reasons for imposing penalties of $5100 per day (which, as CMS notes, are only about one-half of the maximum penalty amounts allowed by regulation). First, Petitioner's noncompliance was serious. The undisputed material facts establish that Petitioner's noncompliance put residents at jeopardy for contracting influenza, an illness that is often fatal in populations of frail and elderly individuals. Second, Petitioner demonstrates substantial culpability for its noncompliance. Its management was responsible not only for implementing the influenza protocols but for understanding the risks attendant to not implementing them. And, yet, it blatantly disregarded several of the protocols' explicit requirements. Finally, Petitioner has a poor compliance history. It had been found substantially noncompliant for health or Life Safety Code requirements at every survey cycle conducted at its facility since 2004 – a more than ten-year history of substantial noncompliance. These reasons – in the absence of any opposition by Petitioner – amply justify the penalty amounts.

Finally, I note that Petitioner makes other arguments concerning burden of proof. These issues have long been settled, and I have no authority to reopen them. More important, "burden of proof" is not an issue that is germane to summary judgment. I do not weigh the evidence here. In issuing summary judgment I decide the case based on the existence of facts that are not in dispute.

/s/
Steven T. Kessel
Administrative Law Judge