Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Bloomfield Care Center,
(CCN: 16-5326),

Petitioner,

v.

Centers for Medicare & Medicaid Services.

Docket No. C-14-10

Decision No. CR3231

Date: May 15, 2014

DECISION

I sustain the determination of the Centers for Medicare & Medicaid Services (CMS) to impose a per-instance civil money penalty of $7,950 against Petitioner, Bloomfield Care Center.

I. Background

Petitioner is a skilled nursing facility located in Bloomfield, Iowa, that participates in the Medicare program. Following a survey of the facility completed on July 23, 2013, CMS determined that Petitioner failed to comply substantially with a Medicare participation requirement that is stated at 42 C.F.R. § 483.25(h)(1) and (2). The regulation requires that a skilled nursing facility be free of accident hazards and that each resident of a facility receives adequate supervision and assistance devices to prevent accidents. As a remedy, CMS determined to impose a $7,950 per-instance civil money penalty against Petitioner.[1] Petitioner requested

---

[1] In its pre-hearing brief CMS asserts that it imposed the per-instance civil money penalty and "other sanctions" against Petitioner. CMS's pre-hearing brief at 4. It never describes these "other sanctions." Petitioner has not described them either,

a hearing. CMS moved to impose sanctions against Petitioner on the ground that the hearing request was inadequate. I denied that motion but directed Petitioner to file an amended and more detailed hearing request. Petitioner did so. CMS then moved again to impose sanctions against Petitioner and renewed that motion subsequently in its final brief. I deny it.

The parties filed pre-hearing exchanges including proposed exhibits. The proposed exhibits included the written direct testimony of several witnesses. The parties advised me that they did not wish to cross-examine each other's witnesses. I accepted final briefs from the parties and I am deciding this case based on their written exchanges. CMS filed exhibits that are identified as CMS Ex. 1 – CMS Ex. 8. Petitioner filed exhibits that are identified as P. Ex. 1 – P. Ex. 36. I receive these exhibits into evidence.

II. Issues, Findings of Fact and Conclusions of Law

A. Issues

The issues are: whether Petitioner failed to comply substantially with the requirements of 42 C.F.R. § 483.25(h)(1) and (2); and whether the per-instance civil money penalty of $7,950 is reasonable.

B. Findings of Fact and Conclusions of Law

The central facts of this case are uncomplicated. As of July 2013 Petitioner had four residents who it had determined were at risk for eloping the facility. It had equipped each of these residents with a Wanderguard bracelet. The four residents who were equipped with this device included a resident who is identified as Resident # 1.

A Wanderguard is an alarm device. In an operating Wanderguard system a resident who wears the bracelet will trigger an audible alarm if he or she approaches an exit door that is wired to the system. *See* P. Ex. 2 at 92-93; CMS Ex. 2 at 10. In that way the staff will be notified that someone wearing a Wanderguard is in close proximity to an exit and will be alerted to the possibility that the resident needs to be retrieved and/or redirected.

Petitioner had equipped its main exit door with two alarm systems. The first system was an alarm that sounded when the exit door was opened. Pressing a

---

and neither CMS nor Petitioner has offered any argument about them. I have no idea as to what these "other sanctions" might be, if they exist at all, and so, I do not address them in this decision.

button next to the alarmed door would deactivate that alarm. The second system was the Wanderguard system. Individuals who were not equipped with a Wanderguard bracelet could exit Petitioner's facility without triggering the primary alarm simply by pushing the deactivation button next to the door. Alternatively, one could leave the facility without triggering the primary alarm by walking with someone else who had pushed the deactivation button. However, a person equipped with a Wanderguard bracelet would trigger the secondary Wanderguard alarm system even if he or she managed to get through the exit door without triggering the primary alarm.

In May and June 2013 Petitioner remodeled the front entrance to its facility. The front entrance of the facility was closed. The construction crew removed the Wanderguard system from the front door. CMS Ex. 2 at 6 - 7. As part of the reconstruction an alternate entrance to the facility was established by Petitioner's dining room that staff, residents, and facility visitors would use while construction was ongoing. *Id.* This entrance was not equipped with a Wanderguard system although Petitioner's management had assumed that it would be. *Id.* at 7.

Evidently, there was a lack of communication between the construction crew and Petitioner's management, because the failure to relocate the Wanderguard system to the new exit door was not brought to management's attention. CMS Ex. 2 at 6 - 7. As a result, no directives were issued to install the system at the new exit door. No information was communicated from management to Petitioner's staff about the failure to install the Wanderguard system. None of the residents' care plans were amended to account for the failure to install the Wanderguard system and, in fact, all four of the residents who wore Wanderguard bracelets continued to wear them. *See* CMS Ex. 2 at 7. No extra or special security measures were put into place for any of the residents in lieu of the Wanderguard system.

Petitioner argues that its staff knew that the Wanderguard alarm system no longer functioned even if management did not and even if no written directives were issued concerning the system's removal. *See* P. Ex. 24 at 14. I find this argument to be without evidentiary support. There is not any statement from any of Petitioner's staff averring that the staff was informed that the Wanderguard system had not been relocated to the new exit. Furthermore, the assertion that the staff knew that the Wanderguard system had been removed and not reinstalled is belied by the fact that the residents' care plans were not modified and by the fact that the four residents continued to wear Wanderguard bracelets. It would make no sense to continue to equip these residents with these bracelets if the staff knew that the system was no longer in place.

Petitioner now asserts that its management made a conscious decision to discontinue use of the Wanderguard system during construction. Petitioner's final

brief at 3 - 4. According to Petitioner, it "determined that the Wanderguard was not necessary given its [a temporary exit door's] high visibility and highly trafficked surroundings." Petitioner's final brief at 3, *citing* P. Ex. 8 at 2, ¶¶ 6 – 8. I find this assertion to be unsupported. The exhibit cited by Petitioner, a declaration by Resident # 1's treating physician, does not address the question of removal of the Wanderguard system at all and says nothing about what management did or did not decide to do.

What is apparent is that Petitioner had relied on the Wanderguard system to protect four of its residents from the possibility of elopement, the system was disconnected and not reinstalled unbeknownst to Petitioner's management and staff, and no changes were made to the residents' care plans to provide these residents with anti-elopement protections in lieu of the defunct Wanderguard system. And, most importantly, Petitioner's staff continued to care for the four elopement-prone residents without knowing that their Wanderguard bracelets no longer protected them.

These developments put the four elopement-prone residents at grave risk because Petitioner's staff was relying on a defunct system to protect them. Clearly, staff could have been lulled into a false sense of security because it would have assumed that the Wanderguard alarm would be triggered when these residents approached the new exit door when, in fact, the alarm had never been reinstalled.

Resident # 1 was an elderly, demented individual who needed assistance for many of the activities of daily living. CMS Ex. 2 at 9, 48, 52, 55-56, 72, 76. She had short- and long-term memory deficits and severe cognitive limitations. *Id.* at 44, 55, 76. Petitioner's staff assessed her to be an elopement risk and her care plan provided that she would wear alarms that would be checked daily by Petitioner's staff for functionality. *Id.* at 76. The resident had attempted to elope Petitioner's facility on numerous occasions. *Id.* at 86, 87, 88, 90.

On July 3, 2013, staff noted apparent elopement attempts by the Resident between 9:00 and 9:15 a.m. CMS Ex. 2 at 21, 25, 26. The staff intercepted these attempts. However, at 9:40 a.m. on July 3, Petitioner's staff received a call from a hospital about two-tenths of a mile away from the facility. The resident had been found in the hospital parking lot. *Id.* at 9. Satellite images show that the facility and the hospital are separated by a street and by a wooded area. CMS Ex. 6.

Although the evidence does not establish the precise circumstances of the resident's elopement, it is entirely reasonable to infer that the resident eloped successfully *as a direct consequence of the Wanderguard system's discontinuation and the facility's staff's not putting measures in place to protect the resident in lieu of the Wanderguard system.* That inference is reasonable because, had the

Wanderguard system been working, an alarm would have triggered the moment that the resident came into proximity with the exit door. That would have alerted Petitioner's staff to an elopement in process and the resident would have been intercepted.

The question is whether this security breach that enabled the elopement of Resident # 1 and that put other residents at risk comprised substantial noncompliance with the requirements of 42 C.F.R. § 483.25(h)(1) and (2). I find that there was substantial noncompliance. Although it is true that the system was discontinued unbeknownst to Petitioner's management and staff, that is no excuse. Petitioner's management and its staff had a duty to know whether the system functioned and they also had a duty to put into place whatever additional protective measures were necessary the instant that they learned that the system was not functioning.

The regulation imposes on a facility the duty to take all reasonable measures to assure that foreseeable hazards are eliminated or protected against. That is not a strict liability standard but it does impose on a facility a substantial burden of making sure that no stone is unturned in order to protect residents. Here, Petitioner's management should have known – even if it did not know – that the Wanderguard system was not working. The act of reconstructing the entranceway and the necessary disconnection of alarm systems in order to perform that work was enough to put management on notice that the Wanderguard system might be disabled and non-functioning. Management and staff should have followed up with the construction crew to assure that the system was reinstalled at the new temporary exit. Furthermore, it would have been simple to test the Wanderguard system while construction was ongoing and afterward. All management and/or staff needed to do was to put a Wanderguard bracelet in close proximity with the new exit. A failure of the alarm to sound in that circumstance could only mean that the system was down or that the bracelet itself was dysfunctional.

Petitioner advances a variety of arguments to assert that it was, in fact, in compliance with regulatory requirements. I find these arguments to be without merit.

Petitioner argues that its front entrance was uniquely situated and that its location justified that only it be equipped with a Wanderguard system. Petitioner's final brief at 1 – 2. From that assertion Petitioner would evidently have me infer that there never was a need to install a Wanderguard system on the replacement exit by the facility's dining room. That inference is not reasonable. First, Petitioner's management intended that the Wanderguard system be installed at the new exit. CMS Ex. 2 at 7. Second, Petitioner's staff obviously assumed that the Wanderguard system *had been* installed at the replacement exit. Otherwise, the

four residents' care plans, which assumed that the residents were protected by Wanderguard bracelets, would be meaningless, as would be the fact that these residents continued to wear the bracelets.

Petitioner then argues that it barricaded its front entrance while construction was taking place, making that entrance inaccessible to residents and obviating the need for a Wanderguard system at that entrance. Petitioner's final brief at 2. That may be so, but it says nothing about the need for a Wanderguard system elsewhere in Petitioner's facility.

Petitioner then avers affirmatively that a Wanderguard was unnecessary at the new entrance because it was located in a highly trafficked and visible location and that its management consciously decided that no Wanderguard system was needed. Petitioner's final brief at 3 – 4. The evidence belies that assertion. As I discuss above, the exhibit cited by Petitioner to support this assertion provides no support for the assertion that management consciously decided not to install the Wanderguard system at the new exit. *See* P. Ex. 8 at 2, ¶¶ 6 – 8. Moreover, Petitioner's management actually thought that the Wanderguard system had been transferred to the new exit. CMS Ex. 2 at 7. So did Petitioner's staff, based on their continued use of the bracelets.

Petitioner then argues that it was not foreseeable that residents would need a Wanderguard system to protect them because all of the facility's doors had alarms. Petitioner's final brief at 4. This argument is simply unsupported. The evidence shows that Petitioner's staff *had* determined that Resident # 1 and three other residents needed additional protection in addition to the push-button alarms that had been placed on exit doors. Some of these residents were assessed as needing Wanderguard bracelets and others wore those devices even though no formal assessments of need were present in these residents' treatment records. I infer that staff assessed these residents as needing to wear the devices even if they did not memorialize those assessments in writing.

Petitioner then accuses CMS of ignoring Resident # 1's history and manner of elopement attempts in concluding that the failure of the Wanderguard system put the resident at risk. Petitioner's final brief at 5 – 6. According to Petitioner, during previous elopement attempts the resident had always pushed on alarmed doors, thereby triggering the alarm systems and alerting staff to an elopement attempt. It argues that, given this history, the Wanderguard was simply unnecessary. But, Petitioner's own care planning for Resident # 1 and for three other residents belies this argument. The fact is that Petitioner's staff had assessed all of these residents as needing alarms. The staff made that determination, it wrote care plans that reached that conclusion, and the staff acted on their determination by putting Wanderguard bracelets on four of its residents. Why

would Petitioner go to the trouble of purchasing the system and equipping its residents with the bracelets if, in fact, they were unnecessary to begin with?

Next, Petitioner argues that it was entirely unforeseeable that someone, perhaps a visitor, would let Resident # 1 elope the premises. And, from this, it argues that the Wanderguard would have been pointless because the resident would have escaped whether or not she was wearing a functioning bracelet. Petitioner's final brief at 6 – 7. It is speculative to assert, as Petitioner does, that someone let Resident # 1 elope. But, assuming that scenario to be true, a functioning Wanderguard bracelet would have been *extremely important* in that circumstance. A Wanderguard bracelet is not a barrier to elopement. Rather, it sounds an alarm when a person wearing a functioning bracelet elopes. If a visitor had let Resident # 1 exit the premises and the resident was wearing a functioning alarm, the alarm would have sounded, immediately alerting the staff to the resident's departure. That would have enabled the staff to retrieve the resident instantly rather than after she'd traversed a street and/or a wooded area and entered a parking lot two-tenths of a mile from the facility.

Petitioner asserts that Resident # 1's cognitive impairments precluded the resident from deactivating the alarm on the new entrance door by pushing the alarm button. Petitioner's final brief at 7 – 8. Thus, according to Petitioner, there was no need for the facility to install additional security devices on its doors. This argument is simply a red herring. The issue here is not whether the resident could or could not deactivate the primary alarm system by pushing the alarm button. The Wanderguard system is entirely separate from the push button deactivation of the primary alarm. Petitioner's staff determined that Resident # 1 needed the Wanderguard bracelet because she was at risk for eloping despite the presence of the primary alarm. And, obviously, she got out of the facility on July 3, 2013, even though the primary alarm system was installed and operating on that date.

Petitioner then argues that it had a "multitude of interventions in place to prevent reasonably foreseeable accidents." Petitioner's final brief at 9. From this, it contends that the Wanderguard system was superfluous. *Id.* at 9 – 14. These interventions, according to Petitioner, included interventions that were applicable generally to all residents and interventions that were specifically designed to protect Resident # 1. The interventions included: push-button deactivated alarms on all exit doors; its Wanderguard system on the original front door; consistent staffing; the use of walkie-talkies by staff so that the staff members could communicate with each other; and many more interventions that Petitioner implemented after Resident # 1 eloped. *Id.* Petitioner also makes the ingenious argument that the reason that the four residents continued to wear Wanderguard bracelets after the system was discontinued was that the bracelets alerted Petitioner's staff to the fact that the residents were elopement risks. *Id*. at 9.

None of the interventions that were in place prior to Resident # 1's elopement substituted for a functioning Wanderguard system. That is made obvious by the fact that the staff determined that Resident # 1 and three other residents *needed to wear Wanderguard bracelets*. Obviously, Petitioner's staff had no confidence that the other pre-elopement interventions cited by Petitioner – the push-button alarm system, consistent staffing, and staff use of walkie-talkies – were sufficient, individually or collectively, to protect the four residents.

As for the interventions put into place after the resident eloped, they may have adequately protected the resident against future elopements, but they certainly had no bearing on what happened on July 3, 2013. Indeed, one could say reasonably that the fact that these interventions were found to be necessary after the fact is evidence that something should have been done prior to the elopement to protect the resident in lieu of a Wanderguard bracelet.

CMS argues that the $7,950 per-instance civil money penalty is justified by Petitioner's allegedly immediate jeopardy-level noncompliance. Additionally, it asserts that the amount of the penalty, assuming that there is immediate jeopardy-level noncompliance, may not be questioned because the penalty determination is an act of discretion by CMS that is not reviewable.

These arguments are both incorrect as a matter of law. Civil money penalties of up to $10,000 per instance of noncompliance may be imposed without any finding of immediate jeopardy-level noncompliance. 42 C.F.R. § 488.408(d)(1)(iv). For that reason I make no finding as to whether Petitioner's noncompliance was at the immediate jeopardy level.

It is also utterly incorrect to assert, as CMS does, that the reasonableness of the penalty amount is immune from review. A principal purpose of a hearing to challenge the imposition of a civil money penalty may be to challenge the reasonableness of the penalty amount. In determining whether a penalty amount is reasonable I must consider the penalty independently from CMS in light of the regulatory factors stated at 42 C.F.R. §§ 488.438(f) and 488.404 (incorporated by reference into 42 C.F.R. § 488.438(f)(3)). These factors may include the seriousness of the noncompliance, a facility's compliance history, and its financial condition.

Neither side has made arguments about the reasonableness of the penalty amount. CMS, evidently relying on its wrong interpretation of the regulations, chose to rest on its incorrect assertion that its penalty amount determination is a discretionary act that is immune from review. Petitioner has not explained why it did not challenge the penalty amount. I sustain the penalty amount in this case without further analysis because Petitioner did not challenge it. I find that it has waived its

possible arguments as to this issue. Had Petitioner challenged the amount I would have ordered CMS to brief the issue of its reasonableness.

/s/

Steven T. Kessel
Administrative Law Judge