

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Meadow Park Care Center
(CCN: 03-5127),

Petitioner

v.

Centers for Medicare and Medicaid Services.

Docket No. C-09-327

Decision No. CR2294

Date: December 16, 2010

DECISION

Petitioner, Meadow Park Care Center (Petitioner or facility), is a long-term care facility located in Prescott, Arizona, that participates in the Medicare program. Based on a survey completed December 30, 2008, the Centers for Medicare and Medicaid Services (CMS) determined that the facility was not in substantial compliance with Medicare requirements and that its deficiencies posed immediate jeopardy to resident health and safety. CMS has imposed against the facility a per instance civil money penalty (CMP) of \$10,000 and denied payment for new admissions for two days (January 27-28, 2009). Petitioner timely appealed CMS's determination.

CMS moves for summary judgment, which Petitioner opposes.

For the reasons set forth below, I find that CMS is entitled to summary judgment. The facility was not in substantial compliance with Medicare program requirements, and the penalty imposed is reasonable.

I. Background

The Social Security Act (Act) sets forth requirements for nursing facility participation in the Medicare program and authorizes the Secretary of Health and Human Services to promulgate regulations implementing those statutory provisions. Act §1819. The Secretary's regulations are found at 42 C.F.R. Part 483. To participate in the Medicare program, a nursing facility must maintain substantial compliance with program requirements. To be in substantial compliance, a facility's deficiencies may pose no greater risk to resident health and safety than "the potential for causing minimal harm." 42 C.F.R. § 488.301.

The Secretary contracts with state survey agencies to conduct periodic surveys to determine whether skilled nursing facilities are in substantial compliance. Act § 1864(a); 42 C.F.R. § 488.20. The regulations require that each facility be surveyed once every twelve months and more often, if necessary, to ensure that identified deficiencies are corrected. Act § 1819(g)(2)(A); 42 C.F.R. §§ 488.20(a); 488.308.

Here, following a complaint investigation survey completed December 30, 2008, CMS determined that the facility was not in substantial compliance with program requirements and that its deficiencies posed immediate jeopardy to resident health and safety. Specifically, CMS determined that the facility was not in substantial compliance with 42 C.F.R. §§ 483.25, 483.25(h), 483.25(l), and 483.35(d)(3). CMS also determined that the deficiencies cited under section 483.25(h) (Tag F323 – supervision/accident prevention) posed immediate jeopardy to resident health and safety. CMS Ex. 4.

CMS subsequently found that the facility returned to substantial compliance on January 29, 2009. CMS Ex. 5.

Based solely on the deficiencies cited under section 483.25(h), CMS imposed a \$10,000 per instance CMP. Based on all of the deficiencies cited, CMS denied payment for new admissions, effective January 27, 2009. CMS Ex. 4 at 2.

Petitioner timely appealed, and the matter was assigned to Administrative Law Judge (ALJ) Alfonso J. Montano. When Judge Montano left the Civil Remedies Division, the matter was reassigned to me. On July 27, 2010, I issued a ruling and order delineating the issues before me and directing the parties to submit additional written arguments and the written direct testimony of any proposed witness. Ruling and Order (July 27, 2010).

The parties have filed "readiness reports" and pre-hearing briefs. (CMS Br.; P. Br.). In response to my order, CMS filed a motion for summary judgment (MSJ) and memorandum in support (MSJ Br.), and Petitioner filed "Written Arguments" (P. Arg.).

Petitioner filed a response to CMS's MSJ (P. Response). CMS has submitted 29 exhibits (CMS Exs. 1-29). Petitioner has submitted 20 exhibits (P. Exs. 1-20).¹

II. Issues

I consider whether summary judgment is appropriate.

On the merits, the only issues before me are: 1) whether, at the time of the December 2008 survey, the facility was in substantial compliance with 42 C.F.R. §§ 483.25, 483.25(h), 483.25(l), and 483.35(d)(3); and 2) if the facility was not in substantial compliance with section 483.25(h), is the penalty imposed – \$10,000 per instance – reasonable.

I have the authority to review all of the deficiency findings, because CMS bases its two-day denial of payment for new admissions (DPNA) on all of the deficiencies cited. *See Schowalter Villa*, DAB No. 1688 (1999). However, since I find that the facility was not in substantial compliance with 42 C.F.R. § 483.25(h), I need not review the remaining deficiencies. So long as the facility was not in substantial compliance, CMS has the authority to impose any of the penalties listed in 42 C.F.R. § 488.406, which include imposing a DPNA. Act § 1819(h); 42 C.F.R. § 488.402; *see Claiborne-Hughes Health Ctr.*, No. 09-3239 at 11 (6th Cir. 2010).

Petitioner raises the following additional issues, which I have no authority to review:

- Petitioner challenges the immediate jeopardy finding. An ALJ may review CMS's scope and severity findings (which include a finding of immediate jeopardy) only if a successful challenge would affect the range of the CMP, or if CMS has made a finding of substandard quality of care that results in the loss of approval of a facility's nurse aide training program. 42 C.F.R. § 498.3(b)(14); 42 C.F.R. § 498.3(d)(10); *Cedar Lake Nursing Home*, DAB No. 2344 at 9 (2010); *Evergreen Commons*, DAB No. 2175 (2008); *Aase Haugen Homes*, DAB No. 2013 (2006). Here, the penalty imposed is a per instance CMP, for which the regulations provide only one range (\$1,000 to \$10,000), so the level of noncompliance does not affect the range of the CMP. 42 C.F.R. § 488.438(a)(2). Nor does CMS's scope and severity finding affect approval of

¹ Petitioner did not mark P. Ex. 16 (Affidavit of Heather Easterday) nor P. Ex. 17 (Affidavit of Sheila Perry), which are attached to Petitioner's "First Amended . . . Proposed Prehearing Exhibit List & Witness List" and were submitted with a letter dated August 30, 2010. On October 4, 2010, Petitioner filed a revised P. Ex. 11 with its "Second Amended Proposed Prehearing Exhibit List and Witness List." I am marking P. Ex. 16 and P. Ex. 17 and substituting the revised P. Ex. 11 for the copy of P. Ex. 11 filed earlier.

the facility's nurse aide training program. Where, as here, the facility has been assessed a CMP of \$5,000 or more, the state agency may not approve its nurse aide training program. Act § 1819(f)(2)(B); 42 C.F.R. § 483.151(b)(2)(iv).

- Petitioner also suggests that CMS did not apply correctly the relevant factors for determining the amount of the CMP. It is well-settled that, in reaching a decision on the reasonableness of the CMP, I may not consider CMS's internal decision-making processes. Instead, I consider *de novo* whether the record evidence concerning the relevant regulatory factors supports the finding that the amount of the CMP is at a level "reasonably related to an effort to produce corrective action by a provider with the kind of deficiencies found and in light of the other factors involved." *Barn Hill Care Ctr.*, DAB No. 1848 at 21 (2002); *Cnty. Nursing Home*, DAB No. 1807 at 22 *et seq.* (2002); *Emerald Oaks*, DAB No. 1800 at 9 (2001); *CarePlex of Silver Spring*, DAB No. 1683 at 8 (1999).
- Finally, although Petitioner complains about the conduct of the survey, survey performance does not relieve a facility of its obligation to meet all requirements for program participation nor invalidate adequately documented deficiencies. 42 C.F.R. § 488.318(b).

III. Discussion

Summary judgment. Summary judgment is appropriate when a case presents no issue of material fact, and its resolution turns on questions of law. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247-48 (1986); *Livingston Care Ctr. v. United States Dep't of Health and Human Servs.*, 388 F.3d 168, 173 (6th Cir. 2004). *See also Illinois Knights Templar Home*, DAB No. 2274 at 3-4 (2009) (*citing Kingsville Nursing Ctr.*, DAB No. 2234 at 3-4 (2009)). The moving party may show the absence of a genuine factual dispute by presenting evidence so one-sided that it must prevail as a matter of law, or by showing that the non-moving party has presented no evidence "sufficient to establish the existence of an element essential to [that party's] case, and on which [that party] will bear the burden of proof at trial." *Livingston Care Ctr.*, 388 F.3d 168, 173 (*quoting Celotex Corp. v. Catrett*, 477 U.S. 317, 323-24 (1986)). To avoid summary judgment, the non-moving party must then act affirmatively by tendering evidence of specific facts showing that a dispute exists. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586 n.11 (1986); *see also Vandalia Park*, DAB No. 1939 (2004); *Lebanon Nursing and Rehab. Ctr.*, DAB No. 1918 (2004).

To defeat an adequately supported summary judgment motion, the non-moving party may not rely on the denials in its pleadings or briefs, but must furnish evidence of a dispute concerning a material fact

Illinois Knights Templar, DAB No. 2274 at 4; *Livingston Care Ctr.*, DAB No. 1871 at 5 (2003).

In examining the evidence for purposes of determining the appropriateness of summary judgment, I must draw all reasonable inferences in the light most favorable to the non-moving party. *Brightview Care Ctr.*, DAB No. 2132 at 2, 9 (2007); *Livingston Care Ctr.*, 388 F.3d at 168, 172; *Guardian Health Care Ctr.*, DAB No. 1943 at 8 (2004); *but see Cedar Lake*, DAB No. 2344 at 7; *Brightview*, DAB No. 2132 at 10 (entry of summary judgment upheld where inferences and views of non-moving party are not reasonable). However, drawing factual inferences in the light most favorable to the non-moving party does not require that I accept the non-moving party's legal conclusions. *Cedar Lake*, DAB No. 2344 at 7; *Guardian*, DAB No. 1943 at 11 ("A dispute over the conclusion to be drawn from applying relevant legal criteria to undisputed facts does not preclude summary judgment if the record is sufficiently developed and there is only one reasonable conclusion that can be drawn from those facts.").

Program requirements. Under the statute and the "quality of care" regulation, each resident must receive, and the facility must provide, the necessary care and services to allow a resident to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the resident's comprehensive assessment and plan of care. Act § 1819(b); 42 C.F.R. § 483.25. To achieve this, the facility must, among other requirements, "ensure" that each resident's environment remains as free of accident hazards as possible. 42 C.F.R. § 483.25(h)(1). It must take "reasonable steps to ensure that a resident receives supervision and assistance devices designed to meet his assessed needs and to mitigate foreseeable risks of harm from accidents." *Briarwood Nursing Ctr.*, DAB No. 2115 at 5 (2007); *Guardian*, DAB No. 1943 at 18 (citing 42 C.F.R. § 483.25(h)(2)). The facility must anticipate what accidents might befall a resident and take steps to prevent them. A facility is permitted the flexibility to choose the methods it uses to prevent accidents, but the chosen methods must constitute an "adequate" level of supervision under all the circumstances. *Briarwood*, DAB No. 2115 at 5; *Windsor Health Care Ctr.*, DAB No. 1902 at 5 (2003); *see Burton Health Care Ctr.*, DAB No. 2051 at 9 (2006) (holding that determining whether supervision/assistive devices are adequate for a particular resident "depends on the resident's ability to protect himself from harm").

A. CMS is entitled to summary judgment, because the undisputed evidence establishes that the facility lacked smoking assessments for nine of its residents who were smokers, and these residents' care plans did not address safe smoking. Without proper assessments and care plans, the facility could not identify actual or potential hazards and thus did not comply with 42 C.F.R. § 483.25(h).²

² My findings of fact/conclusions of law are set forth, in italics and bold, in the discussion captions of this decision.

The regulation explicitly requires that resident safety needs be assessed. 42 C.F.R. § 483.25(h) (“[T]o meet his *assessed* needs. . . .”); *Briarwood*, DAB No. 2115; *see* 42 C.F.R. § 483.20 (“The facility must conduct initially and periodically a comprehensive, accurate, standardized, reproducible assessment of each resident’s functional capacity.”). As Surveyor Rena Castro, RN, noted, the facility must assess the resident to identify any actual or potential accident hazard related to the resident’s physical or mental status and to determine if the resident requires an assistive device or higher level of supervision to ensure his/her safety while smoking. Without an assessment, we cannot know if the facility considered such issues as: Can the resident safely hold a cigarette and dispose of the ashes? Will the resident remain conscious, alert, and aware while smoking? Can the resident sense a cigarette burning his/her fingers? Does the resident require a smoking apron? Does the resident require verbal cues? CMS Ex. 27 at 9-10 (Castro Decl. ¶¶ 31, 32).

CMS alleges that nine of the facility’s residents who were smokers (Residents 8, 9, 10, 11, 12, 13, 14, 15, and 16) lacked smoking assessments, and their care plans did not address safe smoking. Initially, it seemed that Petitioner did not challenge this finding, since nowhere in its hearing request, readiness report,³ or pre-hearing brief did it mention smoking assessments or care planning. None of its exhibits include timely smoking assessments or care plan provisions that address smoking safety.⁴

Responding to CMS’s MSJ, Petitioner claims, for the first time, that it “does dispute whether Residents 8, 9, 10, 11, 12, 13, 14, 15, and 16 were accurately assessed as capable of smoking under supervision.” P. Response at 3. Petitioner points out that facility policy authorized the resident’s attending physician, prior to or at the time of admission, to determine whether he/she was a responsible smoker and to determine what, if any, restrictions should be placed on his/her smoking privileges. Those restrictions would be noted in the resident’s care plan. P. Response at 4; CMS Ex. 13 at 1, 4, 5; P. Ex. 11 at 2; P. Ex. 20 at 1. According to Petitioner, all nine of the cited residents were “alert, oriented, and capable of being directed and supervised”; their physicians had designated

³ Judge Montano’s order of March 20, 2009, directed the parties to file “readiness reports.” In those reports, each party was required to identify legal issues and factual disputes, summarizing its position and describing the proof it planned to introduce for each proposition.

⁴ Petitioner submits one “evaluation for smoking safely” and three portions of care plans that were developed at the time of the survey, apparently in response to surveyor concerns. P. Ex. 7 at 61; P. Ex. 10 at 9; P. Ex. 20 at 4, 5.

them as responsible and ordered “NO restrictions on their ability to smoke.” P. Response at 3-5 (emphasis in original).⁵

Petitioner accurately refers to one provision of its smoking policy, which authorized a resident’s attending physician and the facility’s DON to determine, prior to or upon admission, whether a resident was a responsible or “non-responsible” smoker, and to restrict the individual’s smoking privileges. Restrictions were to be noted on the resident’s care plan “so that all personnel may be alert to smoking restrictions.” Non-responsible smokers were not permitted to smoke except under the direct supervision of a responsible staff member, family member, visitor, or volunteer worker. “Direct supervision” had to be provided throughout the entire smoking period. CMS Ex. 13 at 1, 4, 5. The facility policy also provided that “[s]moking restrictions concerning the classification of residents as responsible and non-responsible shall be made at least quarterly by the director of nursing services, the attending physician, and/or the care planning team.” All reclassifications were to be noted on the care plan. CMS Ex. 13 at 1, 5.

As noted above, to defeat CMS’s MSJ, Petitioner must do more than deny the allegations; it must *furnish evidence* of specific facts, showing that a dispute exists. While Petitioner claims that – consistent with facility policy – an attending physician assessed each of these residents for smoking safety, it has come forward with no evidence to support that claim. Indeed, based on the evidence presented, the only reasonable conclusion that can be drawn from undisputed facts is that, prior to the survey, the facility did not assess its residents for smoking safety and did not include in its resident care plans interventions designed to assure resident safety while smoking. At the same time, facility staff imposed unauthorized and unplanned smoking restrictions as a behavior management tool.

As the following discussion shows, virtually all of the cited residents suffered conditions or displayed behaviors that, at a minimum, needed to be considered in planning how he/she could smoke safely.

Resident 15 (R15) offers a stark example of the problems associated with the facility’s failure to assess and plan for a smoking resident’s safety. The facility’s own documents establish the following undisputed facts.

R15 was admitted to the facility on June 21, 2001, and readmitted on August 9, 2007. At the time of the survey, he was 64 years old. Among other impairments, he suffered from

⁵ But Petitioner also claims that, notwithstanding the physicians’ instruction, the facility restricted the smoking privileges of these purportedly responsible smokers, allowing them to smoke only during planned smoking times, while under the “direct care supervision” of facility staff. P. Response at 5.

a seizure disorder, schizoaffective disorder, hypoxemia (low blood oxygen), hypertension, chronic obstructive pulmonary disease (COPD), atrial flutter, and alcoholism. CMS Ex. 11 at 5. Subsequent assessments identified memory problems and said that his cognitive skills for daily decision-making were moderately impaired; he was easily distracted and had periods of altered perception or awareness of surroundings. CMS Ex. 11 at 8. He exhibited behavioral symptoms: wandering; verbal abuse; physical abuse; and socially inappropriate or disruptive behavior. CMS Ex. 11 at 10. He suffered from delusions and hallucinations. He had an unsteady gait. He experienced shortness of breath. CMS Ex. 11 at 15. His medications included antipsychotics and antianxiety drugs. CMS Ex. 11 at 18-19. He required oxygen therapy. CMS Ex. 11 at 19.

R15's assessment does not even mention smoking. CMS Ex. 11 at 6-22.

A report of a physical examination, dated September 4, 2008, lists schizophrenia, dementia, mental retardation, coronary artery disease, atrial flutter, COPD, and congestive heart failure among R15's conditions. It says that the resident had a grand mal seizure in 2006, and that his medications included the antidepressant Zoloft, the antipsychotic Seroquel, and the antianxiety drug Lorazepam. This document does not establish that R15's attending physician assessed him for smoking safety at the time of his admission, as called for in the facility's policy, and as Petitioner claims. First, the report shows that the physician examined R15 more than a year after his readmission, and Petitioner has not provided evidence of any earlier examination. Second, even though the report mentions that R15 smokes cigarettes, it includes no assessment of his ability to do so safely. P. Ex. 10 at 1-2.

Nurses' progress notes cite the resident's memory problems, impaired decision-making ability, and incoherent speech. They say that he has lower extremity weakness and uses a wheelchair. They note auditory and visual hallucinations and angry outbursts. They say that he is up all night one or two nights per week. P. Ex. 10 at 3. He endangers staff and other residents by "run[ning]" his wheelchair in the hallways at a high rate of speed. P. Ex. 10 at 4.

R15's clinical records establish that staff frequently deprived R15 of cigarettes in response to his behavioral outbursts – but they did so in the absence of a care plan to authorize it. For example:

- On October 23, 2008, he was on the patio talking to himself, yelling at others, and throwing furniture. The nurse told him that he would lose his cigarette if the furniture were not picked up. P. Ex. 10 at 6.
- On October 25, he threw a plastic cup at another resident, so he lost his cigarette. He then became angry and was "verbal[ly] scolding" the nurse. P. Ex. 10 at 6.

- On October 31, he threw coffee on another resident, went outside yelling, and then returned inside yelling and striking out at staff. He threw a cup at one of the nurses. Staff withheld his 3:30 p.m. cigarette because of his increased agitation. P. Ex. 10 at 5.
- Staff also withheld cigarettes for less serious infractions. On November 6, he refused to change his underwear, and staff denied him cigarettes. He became “very angry” at losing his cigarettes, so he blocked the door and backed another resident into a corner. P. Ex. 10 at 5.
- On December 20, 2008, he refused his scheduled shower, so he lost his cigarette break, which was followed by an angry outburst. P. Ex. 10 at 7.
- On December 30, 2008, R15 was on the patio when a nurse aide went out to smoke. He asked her for a “puff,” and, when she refused, he “kicked, hit and punched” her. Staff took away his next scheduled cigarette and told him that losing the cigarette would help him to remember not to hit, kick, or punch anyone. P. Ex. 10 at 7.

None of these facts are in dispute. The only reasonable conclusion that can be drawn from them is that R15 was not and could not have been a “responsible smoker”; no physician or anyone else ever assessed him to be a “responsible smoker.” To keep him and other residents and staff safe required care planning, particularly if staff were going to withhold cigarettes as a means of controlling his behaviors.⁶

At the time of the survey, the facility drafted a care plan. The plan sets as a goal that R15 will be free of injury related to smoking and directs that: 1) he be monitored “at all times” while smoking; 2) his oxygen tank be turned off and his nasal cannula removed before he leaves the building to smoke; 3) his doctor be notified of his “needs and changes when appropriate”; and 4) staff monitor him “to ensure that he puts out the cigarette [at] the proper time.” P. Ex. 10 at 9. The plan does not authorize staff to withhold cigarettes in response to the resident’s behavior.

Resident 16 (R16) was admitted to the facility on October 25, 2004, and readmitted on May 8, 2008. He was 65 years old at the time of the survey, and his diagnoses included schizophrenia, Alzheimer’s disease, and COPD. CMS Ex. 12 at 5. According to his assessment, he had memory problems, and his cognitive skills were moderately impaired. He had periods of altered perception or awareness of surroundings and episodes of

⁶ I see no evidence that cigarette-withholding was a particularly effective method of control. In fact, the above-cited incidents suggest that the opposite is true – withholding cigarettes only escalated his behaviors. In any event, an adequate assessment and care plan should address the potential effectiveness of such a strategy.

disorganized speech. CMS Ex. 12 at 8. He wandered and exhibited “socially inappropriate/disruptive” behaviors. CMS Ex. 12 at 10. He was on seven antipsychotic medications. CMS Ex. 12 at 19. Nothing in the record suggests that R16’s physician, the facility’s DON, or anyone else assessed R16 for smoking safety, although, at the time of the survey, staff drafted a care plan for R16 that is virtually identical to that drafted for R15. P. Ex. 20 at 5.⁷

Resident 8 (R8) was a 73-year-old man, admitted to the facility on May 2, 2006, suffering from COPD, depressive disorder, alcoholic cirrhosis, and other impairments. CMS Ex. 9 at 1. The admission documents that are a part of this record do not mention his smoking status. CMS Ex. 9 at 1.

Petitioner submits clinical records for R8 but points to nothing that suggests that his physician, the DON, or anyone else ever assessed his ability to smoke safely. A history and physical, dated December 12, 2008 (more than two-and-a-half years after his admission), mentions that he is “+ smoker,” but does not answer the form’s questions about the resident’s neurological condition (is he alert and oriented, confused/agitated, or lethargic/unresponsive?). Although barely legible, and Petitioner offers no interpretation, a physician’s note seems to say that R8 is still smoking and was advised to quit. P. Ex. 3 at 1. Nursing progress notes mention that he has an unsteady gait and uses a walker. P. Ex. 3 at 4, 6, 8, 10. He was apparently taking a variety of prescription medications, including: the antidepressant, Zoloft; the narcotic, Lortab (Vicodin); and a muscle relaxant, Roboxin. P. Ex. 3 at 2-3.

Resident 9 (R9) was admitted to the facility on December 9, 2006, and readmitted on August 17, 2008. At the time of the survey, he was 63 years old. According to the admissions summary, his diagnoses included schizoaffective disorder and depression. The summary says nothing about smoking. CMS Ex. 9 at 2. Petitioner submits a report of a history and physical, dated April 5, 2009, which says that R9 is a smoker, but nothing in the report suggests that the physician assessed his abilities to smoke safely. P. Ex. 4 at 1. Physician progress notes, dated May 15, 2008, list as R9’s major problems chronic schizoaffective disorder, chronic bronchitis, Parkinson’s Disease, and tobacco use disorder. He also suffered from nicotine addiction and alcoholism. The physician

⁷ At the same time, a staff member also filled out a document titled “Evaluation for Smoking Safely,” which is signed by the staff member and the resident. Petitioner does not explain this document. It asks only three questions (Is the resident able to light his own cigarette? Is the resident able to hold and dispose of ashes properly? Does the resident know fire and safety standards and understand proper location of smoking areas?). All of the questions are answered affirmatively. The document then says that staff have concluded that the resident is incapable of smoking safely, so they have the right to “begin monitoring and assisting [him] on all smoke breaks.” P. Ex. 20 at 4.

describes him as “well medicated” and “subdued.” R9’s history included a November 2007 fall with head injury and seizure. He had a long list of medications, including: Risperdal, an atypical antipsychotic; Vicodin; Depakote, an anti-seizure medication; and Benadryl, an antihistamine. P. Ex. 4 at 2-3. Nurses’ progress notes say that his thinking ability (“disordered thinking/delirium”) varies and that his hands shake. P. Ex. 4 at 4, 5, 6, 10, 12.

Progress notes also describe incidents of confusion and aggressive behavior and indicate that R9 was once prescribed Ativan, an anti-anxiety medication. P. Ex. 4 at 8-9.

But nothing in R9’s records suggests any assessment or care planning to address smoking safety.

Resident 10 (R10) was admitted to the facility on August 28, 2003, and readmitted November 15, 2007. At the time of the survey, he was 75 years old, suffering from, among other diseases, schizophrenia, diabetes, septicemia, and venous thrombosis; his feet had been amputated. His admission summary does not mention smoking. CMS Ex. 9 at 3. An annual physical, dated December 12, 2008, includes no identifiable mention of smoking. P. Ex. 5 at 1.

Treatment notes record two falls, one resulting in a head injury, and a separate incident in which he hit his ear against the cross-bar of his Hoyer lift, suffering a laceration. P. Ex. 5 at 2-3. According to nurses’ progress notes, his decision-making ability was impaired, and his thinking ability varied. He was confined to a wheelchair, needed a Hoyer lift for transfers, and was dependent on staff for transfer, locomotion, and activities of daily living. P. Ex. 5 at 4, 6, 8. According to one comment, he “goes out for smoke breaks [with] supervision.” P. Ex. 5 at 7.

Nothing in R10’s records shows that he was assessed for smoking safety or that his care plan addressed the issue.

Resident 11 (R11) was a 77-year-old woman, admitted to the facility on December 7, 2006. Her diagnoses included anxiety, depression, hypertension, and dementia. She had fractured her ankle. Her admission summary does not mention her smoking status. CMS Ex. 9 at 4. A December 12, 2008 report of a physical says “+ smoker” but does not include any assessment of her smoking capabilities. P. Ex. 6 at 1.

Nurses’ progress notes describe R11’s decision-making ability as “impaired.” She used a wheelchair and experienced weakness in her lower extremities. P. Ex. 6 at 3, 5. Other progress notes describe her as “very confused.” They mention that she “smokes during day.” In one incident, she rolled her wheelchair over and skinned her knee and hand. On another occasion, she was found sitting on the dining room floor. P. Ex. 6 at 2.

I see no evidence that anyone assessed R11 for smoking safety or that her care plan addressed the issue.

Resident 12 (R12) was admitted to the facility on December 15, 2008, with a fractured femur. She also suffered from COPD. She used a wheelchair or walker for locomotion. Her admission documents mention that she is a smoker and had a physician's order for oxygen. CMS Ex. 10 at 1-3, 5, 19; P. Ex. 7 at 3, 4, 8. She was described as "extremely frail" with mild pursed-lip breathing, cyanotic-colored ears, and clubbing of her digits. She had an enlarged heart. P. Ex. 7 at 2. She was prescribed Lortab (Vicodin), among other medications, and her use of the drug was considered "high." CMS Ex. 10 at 7; P. Ex. 7 at 31.⁸

Mentally, she appears to have been more competent than some of the other residents discussed here (CMS Ex. 10 at 3, 19, 20), but that does not mean that she was a responsible smoker. *See* P. Ex. 12 (in which a staff member describes a shouting match between R12 and another resident, making the smoking session "very chaotic"). In any event, Petitioner has produced no evidence that facility staff assessed her for smoking safety or addressed the issue in her care plan prior to the time of the survey.

During the survey, staff added safe smoking to R12's care plan. The plan is virtually identical to that developed for R15 and R16, except that it authorizes the use of cigarettes as a behavior management device. Instead of instructing staff to ensure that she put her cigarette out at the proper time (as called for in R15's and R16's plans), it says that, if she becomes anxious or displays "manipulating behavior," staff is to calm her down before giving her a cigarette and explain that she must remain calm or she will not be given a cigarette. P. Ex. 7 at 61.

Resident 13 (R13) was admitted to the facility on March 24, 2005, and readmitted on March 12, 2008. She was 64 years old at the time of the survey and suffered from osteoarthritis and joint pain in her ankle and left leg. She had had a cerebral vascular accident (stroke) and suffered from peripheral vascular disease and hypotension, among other ailments. CMS Ex. 9 at 5.

In May 2008, R13 was hospitalized with septic shock. P. Ex. 8 at 1- 3.

According to progress notes, she used a wheelchair and required assistance to transfer. Nurses' progress notes describe her decision-making ability as "impaired" and indicate that she has lower extremity weakness. P. Ex. 8 at 5-7, 9, 11, 13.

Her records do not even indicate that she is a smoker, much less contain any smoking assessments or smoking care plan.

⁸ Shortly after the survey, medical staff recommended that she decrease her use of Lortab.

Resident 14 (R14) was admitted to the facility on April 30, 2007, suffering from dementia. She was a 69-year-old woman at the time of the survey. CMS Ex. 9 at 6. According to a physician's report, dated July 24, 2008, dementia was her only diagnosis. P. Ex. 9 at 1. Nurses' progress notes characterize her decision-making ability as "severely impaired" and indicate that her thinking ability varies. She had an unsteady gait and ambulated with a walker. She had behavioral problems, wandering into other resident rooms. P. Ex. 9 at 2, 4. A comment dated November 10, 2008, describes her as alert and agitated, confused, with an impaired short-term memory. The note says that she is becoming combative and aggressive. P. Ex. 9 at 5. Petitioner points to nothing, and I found nothing in any of the records that refers to her smoking.

Thus, Petitioner has not come forward with evidence establishing a factual dispute as to whether the facility assessed these residents for smoking safety or developed care plans based on such an assessment. Without smoking assessments, the facility could not identify any actual or potential accident hazards posed by the residents' physical or mental limitations and could not determine what, if any, assistive devices or supervision the residents would require to ensure their smoking safety and the safety of others, as required by 42 C.F.R. § 483.25(h). *See* CMS Ex. 27 at 9 (Castro Decl. ¶ 31). The facility was therefore not in substantial compliance with 42 C.F.R. § 483.25(h), and CMS is entitled to summary judgment.

B. CMS is entitled to summary judgment that the facility was not in substantial compliance with 42 C.F.R. § 483.25(h), because the undisputed evidence establishes that facility staff did not safely handle and store oxygen cylinders.

The facility policy for oxygen safety required staff to store oxygen cylinders "in racks with chains, sturdy portable carts and/or approved stands." They could not be left free-standing but had to be "securely fastened at all times." The policy also prohibited "[s]moking, open flames and spark producing devices" in oxygen storage areas or areas where oxygen was in use. CMS Ex. 13 at 2.

CMS has come forward with evidence establishing that facility staff did not follow – indeed, could not follow – the facility's policy for safe storage of oxygen cylinders.

On December 30, 2008, at 3:35 p.m., Surveyor Jean Lapour, RN, observed residents smoking on the patio of the "behavioral unit." She saw a nurse aide remove the oxygen cylinder from R15's wheelchair and lean it against the wall, approximately four feet away from the resident. The nurse aide left the cylinder "completely unsecured." Another resident, R16, was in the area, near the unsecured cylinder. CMS Ex. 28 at 4 (Lapour Decl. ¶ 12). Surveyor Lapour did not see any storage racks or stand on the patio or anywhere near the door inside the behavioral unit, so she concluded that staff were unable to comply with the facility's oxygen safety policy and the standard of care for oxygen safety. CMS Ex. 28 at 5 (Lapour Decl. ¶ 14).

Surveyor Lapour asked the nurse aide about her oxygen cylinder storage practices. The aide said that she always removed the oxygen cylinder and put it against the wall unsecured. She said that she had never been trained in oxygen safety and smoking, although she knew that leaving the oxygen unsecured could cause it to “explode or blow up and be dangerous.” CMS Ex. 28 at 6 (Lapour Decl. ¶ 16); CMS Ex. 16 at 3.

At a different location and time, Surveyor Rena Castro, RN, observed a scheduled, supervised smoking session on the facility’s open patio at 7:48 p.m. on December 29, 2008. She saw the nurse aide who was supervising the session remove an oxygen cylinder from a resident’s wheel chair. Holding the cylinder by the regulator,⁹ the aide carried it down the hall to the nursing station and placed it on the floor, unsecured. CMS Ex. 27 at 4 (Castro Decl. ¶¶ 12, 13). Surveyor Castro saw no storage racks or stand on the smoking patio or near the nursing station, which meant that the staff was unable to comply with the oxygen safety policy and the standard of care for safe cylinder storage. CMS Ex. 27 at 5 (Castro Decl. ¶ 17).

According to Surveyor Castro (and as reflected in the facility’s policy) leaving an oxygen cylinder on the floor, unsecured, creates a hazardous situation. If the cylinder falls or is hit, “it can take off like a rocket,” injuring anyone who is hit by the projectile. Further, oxygen is combustible. If a cylinder explodes, the highly compressed oxygen gas could feed a fire if any sparks or flames are in the area. CMS Ex. 27 at 5 (Castro Decl. ¶ 15). Surveyor Lapour concurred:

If the cylinder hits the ground, particularly a hard surface such as a patio, it can release oxygen and create sparks that could start a fire and/or cause an explosion. There is no real “safe distance” from an unsecured cylinder, so even though the oxygen cylinder was leaned up against the wall some 4 or 5 feet away from the closest resident, that did not mitigate the potential for harm if the cylinder was knocked over and combusted from the sparks and pressurized oxygen in the cylinder.

CMS Ex. 28 at 5 (Lapour Decl. ¶ 15).

Petitioner has not come forward with evidence establishing a dispute over any of these facts. In its response to CMS’s MSJ, Petitioner asserts that “the closest oxygen tank to

⁹ The regulator was attached to the top of the cylinder with a wrench to ensure that it was securely closed. The regulator is used to control the rate at which oxygen leaves the cylinder. It also reflects the amount of pressure that the contents are under. CMS Ex. 27 at 4-5 (Castro Decl. ¶ 14).

any cigarette was Resident #15's oxygen tank, which was approximately five feet away from the [r]esident's cigarette." P. Response at 6. I need not accept this assertion of fact, because it is unsupported. Nevertheless, the statement is generally consistent with Surveyor Lapour's sworn statement that the cylinder was placed about four feet away from R15. CMS Ex. 28 at 4 (Lapour Decl. ¶ 12). In light of R15's behaviors – "running" his wheelchair, throwing furniture and other objects, striking out – five feet seems a dangerously short distance between his lit cigarette and an unsecured oxygen cylinder.

Petitioner also disputes CMS's assertion that, contrary to its policy and the standard of care, the facility improperly allowed smoking in an oxygen storage area, claiming "[t]he smoking patio is not an 'oxygen storage area[.]'" P. Response at 7. But Petitioner has not challenged Surveyor Lapour's statement that a nurse aide regularly stored R15's oxygen cylinder on the smoking patio while R15 and others were smoking. The only reasonable conclusion to draw from this undisputed fact is that staff turned the patio into an oxygen storage area during the smoking sessions.

Finally, in her affidavit, the facility's administrator, Sheila Perry, says that facility staff followed the facility's policy for oxygen safety and kept oxygen containers "a safe distance from any open flame or spark." P. Ex. 17. These are not statements of fact; they are conclusions (unsupported by any facts).

Thus, Petitioner presents no evidence suggesting a dispute over the dispositive surveyor observations: staff left oxygen cylinders completely unsecured; the facility had no racks or stands available for cylinder storage during smoking sessions; at least one staff member stored oxygen on a smokers' patio during smoking sessions; at least one staff member, who handled oxygen cylinders, was not aware of the policy for oxygen storage and had not been trained in oxygen safety/smoking.¹⁰ Nor does Petitioner challenge any of the surveyor statements regarding the importance of securing the oxygen cylinders. *See Cedar Lake*, DAB No. 2344 at 8-9 (citing *Woodland Vill. Nursing Ctr.*, DAB No. 2053 at 9 (2006)); *Lakeridge Villa Health Care Ctr.*, DAB No. 1988 at 22 (2005) (holding that a facility's failure to follow its own policies can constitute a deficiency under 42 C.F.R. § 483.25).

The facility's failure to secure the cylinders and to keep them away from smoking residents put residents and staff at considerable risk and, by itself, shows that the facility was not in substantial compliance with 42 C.F.R. § 483.25(h).

¹⁰ Another nurse aide told Surveyor Castro that she had never been in-serviced on the facility's smoking policies or proper supervision techniques. CMS Ex. 27 at 6-7 (Castro Decl. ¶ 21). Petitioner has not come forward with documents, affidavits, or any other evidence of staff training to dispute this assertion.

Other incidents. CMS alleges other incidents of purported noncompliance. Surveyor Castro observed R12 enter the smoking patio with her oxygen running. According to Surveyor Castro, the nurse aide present was then about to light R12's cigarette when the surveyor intervened. CMS Ex. 27 at 6 (Castro Decl. ¶ 19). Petitioner denies that the aide was going to light the cigarette but admits that R12 entered the smoking patio with her oxygen in use while other residents were smoking. Petitioner argues that R12 was returning from an outside appointment, her actions were "beyond [staff's] control," and staff quickly told her to turn off her oxygen, which she did. P. Response at 8; P. Ex. 12 (Montoya Decl.); P. Ex. 16 at 1 (Easterday Decl.); P. Ex. 17 (Perry Decl.).

CMS also charges that a staff member responsible for supervising smokers left the smoking patio to return residents to the facility. CMS Ex. 27 at 8 (Castro Decl. ¶ 26). Petitioner admits that the staff member walked some residents back into the facility, while others were still smoking, but argues that the distance was only "a few" feet, took a very short time, and the smoking residents were visible through glass doors. P. Response at 9-10; P. Ex. 17 at 1 (Perry Decl.).¹¹

CMS also claims that a staff member responsible for their supervision was not adequately observing the smokers, because she sat looking at her cell phone, punching in keys. CMS MSJ at 14; CMS Ex. 27 at 8 (Castro Decl. ¶ 25). Petitioner concedes that the staff member "was punching keys on her phone" but argues (without citation to any evidence) that she "was within a few feet" of the smoking residents and that "her eyes and ears were supervising [them] at all times." P. Response at 10.

Because I find that CMS's determination of substantial noncompliance and the penalty imposed are more than justified by: 1) the absence of smoking assessments and care plans, and 2) the facility's failure to secure safely the oxygen cylinders, I need not consider whether CMS is entitled to summary judgment based on these additional cited incidents.

C. The penalty imposed is reasonable.

I next consider whether the CMP is reasonable by applying the factors listed in 42 C.F.R. § 488.438(f): 1) the facility's history of noncompliance; 2) the facility's financial condition; 3) factors specified in 42 C.F.R. § 488.404; and 4) the facility's degree of culpability, which includes neglect, indifference, or disregard for resident care, comfort or safety. The absence of culpability is not a mitigating factor. The factors in 42 C.F.R. § 488.404 include: 1) the scope and severity of the deficiency; 2) the relationship of the deficiency to other deficiencies resulting in noncompliance; and 3) the facility's prior history of noncompliance in general and specifically with reference to the cited deficiencies.

¹¹ According to Administrator Perry, the distance was twenty feet.

In reaching a decision on the reasonableness of the CMP, I consider whether the evidence supports a finding that the amount of the CMP is at a level reasonably related to an effort to produce corrective action by a provider with the kind of deficiencies found, and in light of the above factors. I am neither bound to defer to CMS's factual assertions, nor free to make a wholly independent choice of remedies without regard for CMS's discretion. *Barn Hill*, DAB No. 1848 at 21 ; *Cnty. Nursing Home*, DAB No. 1807 at 22 *et seq.*; *Emerald Oaks*, DAB No. 1800 at 9; *CarePlex of Silver Spring*, DAB No. 1683 at 8.

CMS has imposed a \$10,000 per instance CMP, which is currently the maximum per instance penalty (\$1,000-\$10,000). 42 C.F.R. §§ 488.408(d)(iv), 488.438(a)(2). On the other hand, the penalty is modest considering what CMS might have imposed. *See Plum City Care Ctr.*, DAB No. 2272 at 18-19 (2009) (Even a \$10,000 per instance CMP can be "a modest penalty when compared to what CMS might have imposed.").

CMS does not contend that the facility's history justifies a higher CMP. Petitioner has not argued that its financial condition affects its ability to pay the penalty. With respect to the other factors, I find that the scope and severity of the deficiencies more than justify a \$10,000 penalty. Staff's mishandling of oxygen cylinders created a very dangerous situation, putting at risk virtually every resident, staff member and visitor. Because it did not assess its residents for smoking safety, the facility could not even begin to identify the level of supervision or any assistive devices necessary to keep them safe. This failure evidences serious disregard for resident safety, for which the facility is culpable.

IV. Conclusion

The undisputed facts establish that the facility was not in substantial compliance with Medicare requirements governing the prevention of accidents, 42 C.F.R. § 483.25(h). Given the scope and severity of the deficiencies and the facility's culpability, the \$10,000 CMP is reasonable. Because the facility was not in substantial compliance with Medicare requirements, CMS had the authority to impose the DPNA.

/s/
Carolyn Cozad Hughes
Administrative Law Judge