Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Doylestown Health Care Center
(CCN: 365695),

Petitioner

v.

Centers for Medicare and Medicaid Services.

Docket No. C-10-967

Decision No. CR2412

Date: August 11, 2011

DECISION

Petitioner, Doylestown Health Care Center (Petitioner or facility), is a long-term care facility, located in Doylestown, Ohio, that participates in the Medicare program. Investigating a complaint, state surveyors found that, for almost two weeks, facility staff did not monitor the blood coagulation levels of a resident taking anti-coagulant medication. When the resident's nose started bleeding, staff waited hours before contacting a physician. Based on these findings, 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 imposed against the facility a per instance civil money penalty (CMP) of $6,000. Petitioner appeals, and CMS moves for summary judgment.

For the reasons set forth below, I grant summary judgment. The undisputed facts establish that the facility was not in substantial compliance with Medicare requirements and that the $6,000 CMP is reasonable. I have no authority to review the immediate jeopardy finding.

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, responding to a complaint, surveyors from the Ohio Department of Health (state agency) visited the facility and, on July 12, 2010, completed a partial extended survey. Based on their findings, CMS determined that the facility was not in substantial compliance with 42 C.F.R. § 483.25(l), which protects residents from "unnecessary drugs." CMS also determined that the facility's noncompliance posed immediate jeopardy to resident health and safety. CMS Exs. 1, 2.

CMS has imposed against the facility a per instance CMP of $6,000. CMS Ex. 1.

Petitioner timely requested a hearing, and CMS now moves for summary judgment.

CMS submitted a motion for summary judgment and memorandum in support (CMS Br.), along with 15 exhibits (CMS Exs. 1-15). Petitioner submitted a memorandum in opposition to summary judgment (P. Br.) and 3 exhibits (P. Exs. 1-3).

II. Issues

I consider whether summary judgment is appropriate.

On the merits, the only issues before me are: 1) was the facility in substantial compliance with 42 C.F.R. § 483.25(l); and 2) if the facility was not in substantial compliance, is the penalty imposed -- $6,000 per instance – reasonable.

I discuss below why I lack the authority to review CMS's finding of immediate jeopardy.

III. Discussion

A. CMS's scope and severity finding is not reviewable in this forum.[1]

Petitioner challenges CMS's determination that the facility's deficiencies posed immediate jeopardy to resident health and safety. In making this challenge, however, Petitioner may not have recognized the differences between a per instance and a per day penalty. *See* P. Br. at 4, 6 (discussing the upper and lower ranges for per day penalties); CMS Ex. 1 (declaring that the "enforcement remedy that went into effect" was a CMP "of $6,000 per instance").

An Administrative Law Judge (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), (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). For a per instance penalty, the regulations provide only one range ($1,000 to $10,000), so the level of noncompliance here does not affect the range of the CMP. 42 C.F.R. § 488.438(a)(2).

Neither party mentions whether the facility even has a nurse aide training program. But, assuming that it does, CMS's scope and severity finding would not affect its approval. By statute and regulation, if, as here, CMS imposes a penalty of $5,000 or more, the state agency cannot approve a facility's nurse aide training program. Act § 1819(f)(2)(B); 42 C.F.R. § 483.151(b)(2)(iv). The facility loses its approval without regard to any finding of immediate jeopardy.

Thus, because the immediate jeopardy finding here does not affect the range of the CMP or cause the facility to lose approval of its nurse aide training program (if it has one), the finding is not reviewable.

In its brief, CMS lays out the regulatory criteria for review of its scope and severity determinations. CMS Br. at 9-10. It also recognizes that imposing a $6,000 penalty triggers the nurse aide training prohibition. CMS Br. at 10 n.2. Remarkably, CMS then disregards these provisions and lists the immediate jeopardy determination among the issues presented for my review. But CMS's inexplicable concession on this jurisdictional

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

issue simply does not give me review authority that the regulations plainly preclude. I therefore decline to review the immediate jeopardy finding.[2]

B. CMS is entitled to summary judgment because the undisputed evidence establishes that facility staff did not monitor a resident's anti-coagulant medication nor respond appropriately to its adverse consequences, as required by 42 C.F.R. § 483.25(l).

Summary judgment. Summary judgment is appropriate when a case presents no issue of material fact, and its resolution turns on questions of law. *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247-48 (1986); *Livingston Care Ctr. v. U.S. 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 and Rehab. 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 at 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); s*ee 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).

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[2] In any event, immediate jeopardy exists if a facility's noncompliance has caused, or is likely to cause, "serious injury, harm, impairment or death to a resident," and the finding must be upheld unless "clearly erroneous." 42 C.F.R. §§ 488.301, 498.60(c). As the following discussion shows, the uncontroverted facts here establish that facility staff did not monitor a resident's blood levels as ordered and did not respond for hours when her nose started to bleed. She ended up hospitalized with blood levels so dangerously high that they could have been fatal. Thus, even if I had the authority to review the immediate jeopardy determination, I see no scenario under which Petitioner could prevail on that issue.

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 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 (upholding entry of summary judgment 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 that end, each resident's drug regimen must be free from unnecessary drugs. Unnecessary drugs are defined as any one or combination of the following: drugs used in excessive doses (including duplicate drug therapy); drugs used for an excessive duration; drugs that are not adequately monitored; drugs used without adequate indications for their use; and drugs whose adverse consequences indicate that they should be reduced or discontinued. 42 C.F.R. § 483.25(l)(1).

Anti-coagulant drugs. Anti-coagulant drugs, such as Coumadin (Warfarin), help to inhibit the formation of blood clots and are often prescribed to individuals who have experienced inappropriate blood clotting, such as those who have had heart attacks, strokes, or deep vein thrombosis (DVT), which is the formation of a blood clot in a deep vein. *See* CMS Ex. 13 at 3 (Patterson Decl. ¶¶ 11, 12); CMS Ex. 14; *see also* www.coumadin.com. Unfortunately, bleeding is a major complication associated with anti-coagulants. CMS Ex. 14 at 1. For individuals administered these drugs, blood levels must be monitored carefully to assure that they are within a safe and therapeutic range. If the levels are too high, the resident risks bleeding complications; if the levels are too low, clotting and/or stroke could result. The need for careful monitoring is even more pronounced when the resident is prescribed additional medications, because Coumadin interacts with many other drugs in dangerous, even fatal, ways. *See* CMS Ex. 10 at 39; CMS Ex. 13 at 4, 6 (Patterson Decl. ¶¶16, 19, 29); CMS Ex. 14; *see also* www.coumadin.com.

A specific test, referred to as PT/INR (prothrombin time/international normalized ratio) evaluates the ability of blood to clot properly. CMS Ex. 13 at 4 (Patterson Decl. ¶ 15); CMS Ex. 14. The INR is the ratio of an individual's prothrombin time to a control (*i.e.*,

normal) sample -- the higher the INR, the greater the chance of bleeding. A very low INR suggests the risk of a blood clot. Normal ranges for a healthy person are 0.9 to 1.3; for people on Coumadin, desirable ranges may be 2.0 to 3.0. However, many factors – such as patient age, gender, and manner of administration – can affect the test results, so the physician generally determines an acceptable range for each individual patient. According to the manufacturer, an INR above 4.0 exposes the patient to a higher risk of bleeding without providing any additional therapeutic benefit. In a black box warning, the manufacturer cautions that Coumadin can cause major or fatal bleeding.[3] Risk factors for bleeding include an INR greater than 4, and the patient's age (65 or older). *See* CMS Ex. 14; *see also* www.coumadin.com.

Resident 99 (R99). This case centers around the treatment provided to one of the facility's residents, identified as R99. Facility documents, which are unchallenged, establish that R99 was an alert and relatively healthy 91-year-old woman, who lived with her children until May 2010, when she fell and broke her hip. She was hospitalized and, following surgical repair of the hip, transferred to the facility on May 19, 2010 (a Wednesday). CMS Ex. 7 at 1, 10; CMS Ex. 8 at 1.

Among other ailments, R99 had a history of DVT. CMS Ex. 7 at 1; CMS Ex. 13 at 3 (Patterson Decl. ¶ 10). Even before her hospitalization and surgery, R99 took a relatively small dose (0.5 mg. daily) of Coumadin. CMS Ex. 7 at 1, 4, 6, 10. While she was still hospitalized, Richard F. Rose, M.D., her then-attending physician, increased the Coumadin dosage to 3 mg. daily. CMS Ex. 7 at 3, 8, 9. At the same time, Dr. Rose ordered PT/INR testing, and the test was performed on May 19, prior to R99's hospital discharge. CMS Ex. 7 at 3; CMS Ex. 8 at 2. Although the PT result was high, 23.2 (reference range: 11.5-14.6), her 2.01 INR was within a desirable range. CMS Ex. 8 at 2.

The May 21, 2010 PT/INR test that did not happen. At the time of her transfer to the facility, Freeland Oliverio, M.D., who was the facility's medical director, became R99's attending physician. He continued the order for Coumadin and ordered PT/INR testing weekly "on Fridays." CMS Ex. 8 at 1, 15, 19. The parties agree that the facility did not provide these tests on Friday, May 21 or Friday, May 28. CMS Br. at 3; P. Br. at 8, 11.

According to CMS, the facility should have tested R99 on May 21, two days after Dr. Oliverio ordered the Friday tests, and this position is certainly compatible with the plain language of the physician's order. Petitioner, on the other hand, maintains:

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[3] The United States Food and Drug Administration (FDA) mandates that pharmaceutical companies include within a drug's package insert information about its adverse effects. The "black box warning" is the strongest warning required by the FDA, and its use indicates that the drug carries significant – even life-threatening – adverse effects.

> [t]here were no indications by R99's orthopedic doctor (Dr. Rose) or from Dr. Oliverio . . . that R99's PT/INR needed to be drawn two days after her admission to [the facility] on May 21, 2010; rather the physician's order was for weekly PT/INR, and R99's PT/INR had already been tested that week on May 19, 2010.

P. Br. at 8.[4] From this, Petitioner suggests that I infer that Dr. Oliverio ordered PT/INR testing beginning May 28, nine days after R99's hospital test, so the facility committed no error when it failed to test on May 21. I disagree.

First, even if the record were otherwise silent on when the testing was supposed to begin (which it is not), drawing every reasonable inference in the light most favorable to Petitioner does not mean that I accept Petitioner's interpretation of Dr. Oliverio's order; it means that the order is ambiguous. But a physician's order should not lend itself to more than one interpretation; in reading and implementing it, no one should have to guess its meaning. If facility staff do not understand an order, they must clarify it with the physician. *Cedar Lake Nursing Home*, DAB No. 2390 at 12 (2011); *Oaks of Mid City Nursing and Rehab. Ctr.*, DAB No. 2375 at 9-10 (2011); *Emerald Oaks*, DAB No. 1800 at 44-45 (2001).

Moreover, the record is not otherwise silent on when the testing was supposed to begin. CMS has come forward with evidence -- the facility's own documents and statements from staff -- establishing that the PT/INR testing was supposed to begin on Friday, May 21. Staff, however, did not follow the facility's procedures for insuring that blood tests

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[4] Petitioner attempts to bolster this, and most of its other arguments, by citing the written declaration of Paulette Trexler, RN-BC (P. Ex. 3). RN Trexler's declaration does not create disputes of material fact. Rather, she reiterates some of the evidence contained in the facility's documents (which the parties do not dispute) and then offers some of Petitioner's legal arguments. As noted above, I am not bound to accept "conclusions to be drawn from applying relevant legal criteria to undisputed facts." *Guardian*, DAB No. 1943 at 11. Moreover, RN Trexler's declaration is offered with precious little foundation. She declares that she has "personal knowledge," but that knowledge was apparently derived from review of the resident's records and "follow-up information received from Dr. Oliverio after May 31, 2010." She does not specify what information came from what source, nor the means by which she obtained her "follow-up information."

were performed as ordered, and the responsible staff members were subsequently disciplined for their failings.

An employee documentation form describes a May 19, 2010 "incident" involving Registered Nurse (RN) Amanda Norris. The document says that R99 was admitted with orders for PT/INR to be drawn weekly and that "[l]abs were scheduled to be drawn on 5/21/10 and 5/28/10." RN Norris entered the resident's name and other information into the facility's computer system but did not indicate that labs were to be drawn. As a result, according to the document, labs were not drawn as ordered. The document is signed by RN Norris and by RN Patricia Cowgar, who is identified as RN Norris's supervisor. CMS Ex. 9 at 3, 4.

An accompanying written warning, signed by the facility's Director of Nursing (DON), instructs RN Norris "to follow established procedures [and] enter all lab orders into [the] lab computer when received." CMS Ex. 9 at 4.

A second employee documentation form describes a May 21, 2010 "incident" involving RN Tami Novak. According to the form, R99 "had lab ordered to be drawn on 5/21/10 – a weekly PT/INR," but the lab order was not entered into the facility's computer system, and RN Novak did not "thoroughly read" the resident's treatment administration record (TAR), which "would have brought the situation to her attention [and] resulted in the lab being drawn appropriately." The document is signed by RN Novak and by her supervisor, RN Cowgar. CMS Ex. 9 at 1, 2.

In an accompanying written warning, signed by the facility's DON, RN Novak is directed "to check TAR nightly for lab draws due," to "follow up with lab tech," and to "make sure" the ordered draws are "added to draw list if not on there." She is also directed to initial the TAR when the lab draw has been done. She is warned that "any further episodes of failing to do satisfactory work will/may result in further disciplinary action . . . ." CMS Ex. 9 at 2.

Petitioner tenders no evidence showing a dispute over any of the facts set forth in these documents. The undisputed evidence thus establishes that Dr. Oliverio ordered PT/INR testing weekly on Fridays. Facility staff did not clarify any purported ambiguity as to the start date of the test, because they understood that they were supposed to begin the weekly testing on Friday, May 21. Although the facility seems to have had systems in place to insure that tests would be performed as ordered, staff failed to follow those systems, and R99's blood was not tested.

The May 28, 2010 PT/INR test that did not happen. The parties also agree that R99 developed a respiratory infection, for which, on May 25, 2010, Dr. Oliverio prescribed the antibiotic Levaquin. CMS Ex. 8 at 3, 22, 46; CMS Br. at 3; P. Br. at 8. On May 26, the pharmacy filling that prescription alerted the facility that Levaquin interacts with

Coumadin. The pharmacy recommended a PT/INR test within 48 hours, or no later than May 28. *See* CMS Ex. 8 at 6; *see also* CMS Ex. 13 at 6 (Patterson Decl. ¶ 29); CMS Ex. 14 at 2 (listing antibiotics among the drugs that interact with Coumadin). RN Cowgar brought the pharmacy warning to Dr. Oliverio's attention, and, according to her note, he told her to continue the Levaquin at the ordered dose and to obtain an "INR in 4 days." CMS Ex. 8 at 6. A written order, dated May 26 and signed by the physician, says "INR 4 days." CMS Ex. 8 at 24.

Petitioner suggests that this May 26 order meant that Dr. Oliverio discontinued his order for a PT/INR test on Friday, May 28. I find it highly questionable whether such an inference is reasonable. First, no order, written or oral, instructs staff to discontinue the order for weekly testing, and the two existing orders are compatible, particularly considering that Dr. Oliverio had been advised to test within 48 hours. Second, Petitioner does not provide a statement from Dr. Oliverio, or anyone else, claiming that he intended to delay the test. Third, the employee disciplinary document described above says that the labs should have been drawn on May 28, but were not performed because of staff errors. CMS Ex. 9 at 3. Finally, accepting Petitioner's inference would mean that, upon learning how important it was to monitor very closely R99's blood levels, Dr. Oliverio decided to monitor them *less* frequently than he had planned before learning of her increased risks. Inasmuch as the regulation imposes on the facility an independent obligation to ensure that drugs are adequately monitored, if staff thought that Dr. Oliverio intended to cancel the Friday test (and Petitioner points to no evidence indicating that anyone thought this), they should have brought to the physician's attention that this would mean a lengthy gap between tests, putting the resident at significantly increased risk. Dr. Oliverio should then have documented some justification for the ongoing delays in testing.

The May 30, 2010 PT/INR test that did not happen. The parties agree that Dr. Oliverio wrote an order on May 26 calling for a PT/INR test four days later, which would have been on May 30. They also agree that no test was provided on May 30. CMS Br. at 4; P. Br. at 9, 12. CMS sees this as more inadequate drug monitoring. Petitioner, however, justifies the delays by claiming again that Dr. Oliverio changed his order.

In a signed statement dated June 24, 2010, RN Cowgar writes that, on May 26, after Dr. Oliverio wrote his order for PT/INR testing in 4 days, the nurse pointed out that May 30 was a Sunday and asked if they could delay the test until Monday. "He told her ok." Then the nurse noted that Monday was a holiday and asked if they could delay the test for yet another day. "He said, 'Yeah, whatever.'" CMS Ex. 9 at 9. In another written statement, dated June 23, 2010, Licensed Practical Nurse (LPN) B. Aul corroborates RN Cowgar. LPN Aul says that she asked Dr. Oliverio if they could delay the test until Tuesday, and he "ok'd the lab for Tuesday, June 1." She adds that the lab normally does not draw routine labs on weekends or holidays. CMS Ex. 9 at 10.

The first problem is that Dr. Oliverio did not modify his order in writing; the only written evidence indicates that he ordered that R99's PT/INR be tested on May 30. Second, the facility itself determined that the testing should have been performed on May 30, but was not because RN Cowgar "failed to follow [through] and write an order, and to put [the order] on TAR for 5/30 when it would have been due." CMS Ex. 9 at 5.

Nevertheless, I accept, for summary judgment purposes, that the nurses asked Dr. Oliverio to delay the test, and he orally agreed. The facility is deficient because they cancelled the May 28 test and did not bring to the physician's attention the increasing delay in providing the critically important test.

What happened on May 31, 2010. So, as of May 31, R99's PT/INR levels had not been measured for almost two weeks, and the pharmacy recommendation for additional testing had not been followed. In fact, the opposite happened. Instead of testing within 48 hours, as the pharmacy recommended, staff would have allowed six days (May 26-June 1) to pass without monitoring the resident's PT/INR.

On the morning of May 31, R99's nose began to bleed. A nurse's note, written at 10:25 a.m., says "small constant nose bleed," and a note written at 3:00 p.m. says that the bleeding had been "persistent throughout the day." CMS Ex. 8 at 69. When the resident's sons initially expressed concern about the bleeding, the responsible nurse, Marybeth Wintrow, RN, would not contact a physician. According to an employee documentation form, she told them that the staff "don't like to bother the doctor on the weekends." CMS Ex. 9 at 6. By three o'clock that afternoon, when R99's nose was still bleeding, her sons became more insistent, and RN Wintrow finally contacted the physician on call, Dr. Coleman, who ordered an immediate PT/INR test. CMS Ex. 8 at 26, 69. Again, Petitioner presents no evidence suggesting a dispute over these facts.

In a written statement, RN Wintrow concedes that, when R99's son asked her about the nose bleed that morning, she told him that the resident needed to relax and rest. Later in the afternoon, when family told her that R99's last nosebleed was caused by high Coumadin levels, RN Wintrow called the physician, but "[a]t no time did [she] feel that the nose bleed was severe enough to be overly concerned," and she "was keeping [a] close eye on [the] resident." CMS Ex. 9 at 7. RN Wintrow does not say whether she knew all along that the resident was on Coumadin. Certainly, she should have known. Moreover, R99's care plan says "report to the physician any [signs or symptoms of] abnormal bleeding or hemorrhage." CMS Ex. 8 at 28. The nurse's long delay in contacting the physician suggests that RN Wintrow was either unaware or chose to

disregard the care plan instructions.[5]

At 5:19 p.m. R99's blood was drawn. CMS Ex. 8 at 4. At 6:10 p.m., the lab reported a PT of over 150 and an INR value of more than 15.7. CMS Ex. 8 at 4, 70. Without question, these values are very dangerously high. The facility notified Dr. Coleman, who ordered R99 sent to the emergency room. CMS Ex. 8 at 27, 70. She apparently survived but did not return to the facility, the family complaining about the facility's response to her bleeding. CMS Ex. 9 at 11.

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.

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 Care Ctr.*, DAB No. 1848 at 21 (2002); *Cmty. Nursing Home*, DAB No. 1807 at 22 *et seq*. (2002); *Emerald Oaks*, DAB No. 1800 at 12 (2001); *CarePlex of Silver Spring*, DAB No. 1683 at 8 (1999).

CMS imposed a penalty of $6,000 per instance, which is in the middle of the penalty range for a per-instance CMP ($1,000-$10,000) and is modest considering what CMS might have imposed. 42 C.F.R. §§ 488.408(d), 488.438(a)(2); *see Plum City Care Ctr.*,

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[5] The regulations also require that facility staff "immediately" consult a resident's physician of any "significant change in the resident's physical, mental, or psychosocial status (*i.e.*, a deterioration in health, mental, or psychosocial status in either life-threatening conditions or clinical complications)," or need to alter treatment significantly. 42 C.F.R. § 483.10(b)(11). "Immediately" means "as soon as the change . . . is detected, without any intervening interval of time." *Magnolia Estates Skilled Care*, DAB No. 2228 at 8 (2009); *The Laurels at Forest Glenn*, DAB No. 2182 at 13 (2008). However, CMS did not cite a deficiency under this regulation.

DAB No. 2272, at 18-19 (2009) (observing that even a $10,000 per instance CMP can be "a modest penalty when compared to what CMS might have imposed").

The facility has a history of substantial noncompliance. Based on its prior annual survey, completed in May 2009, the facility was not in substantial compliance with regulations governing medically related social services and medication error rates, at scope and severity level D (isolated instance that caused no actual harm with the potential for more than minimal harm). The prior year, based on an annual survey completed in June 2008, it was not in substantial compliance with the regulation governing medication error rates at scope and severity level E (a pattern of noncompliance that causes no actual harm with the potential for more than minimal harm). During both surveys, the facility had life safety code violations. CMS Ex. 11 at 1.[6]

Petitioner does not claim that its financial condition affects its ability to pay this relatively small CMP.

With respect to the remaining factors, the undisputed evidence establishes multiple staff errors, any one of which could have justified the penalty imposed. R99's PT/INR levels were supposed to be monitored at least weekly from the time of her admission to the facility. Thereafter, she began taking antibiotics, which made careful – and probably more frequent – monitoring all the more important. But, far from monitoring more carefully, the facility did not even provide the tests weekly. No evidence suggests that staff were even aware that R99's blood levels had not been monitored at all from the time of her admission until the day her nose started bleeding. Then, when the resident displayed symptoms consistent with high INR levels – *i.e.*, actual bleeding – facility staff ignored the instructions contained in her care plan, minimized the significance of the bleeding, and, for hours, refused to consult a physician. By the time her blood levels were measured, R99's health was seriously compromised. The failure of multiple staff members to monitor the resident's drug levels and then to respond to her significant symptoms shows indifference or disregard for the resident's safety, for which the facility must be considered culpable.

I reject as wholly unsupported RN Trexler's conclusory assertion that R99 "did not suffer a negative outcome or undergo actual harm." P. Ex. 3 at 3 (Trexler Decl. ¶ 18). The undisputed evidence establishes that this 91-year-old woman's INR was almost four times greater than the level Coumadin's manufacturer identifies as unsafe (exposing the patient to higher risks of bleeding without any benefit). She suffered a bloody nose, an

[6] Petitioner incorrectly claims that "CMS presents no evidence concerning the facility's history of noncompliance . . . to support the CMP imposed." P. Br. at 13. In fact, CMS proffered the facility's CASPER (Certification and Survey Provider Enhanced Reports) report, which includes a synopsis of survey findings for the years 2007 through 2010. CMS Ex. 11.

emergency room visit, and hospitalization. Any reasonable person would consider what she suffered "serious harm."

For these reasons, I conclude that a $6,000 per instance CMP is reasonable.

IV. Conclusion

I grant CMS's motion for summary judgment, because the undisputed facts establish that the facility was not in substantial compliance with 42 C.F.R. § 483.25(l), and the penalty imposed ($6,000 per instance) is reasonable.

/s/
Carolyn Cozad Hughes
Administrative Law Judge