Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:	)	
	)	
Hazel Hawkins Memorial Hospital, D/P SNF (CCN: 05-5462),	)	Date: March 18, 2008
	)	
Petitioner,	)	
	)	
- v. -	)	Docket No. C-06-124
	)	Decision No. CR1753
Centers for Medicare & Medicaid Services.	)	
	)	

DECISION

Petitioner, Hazel Hawkins Memorial Hospital, D/P SNF (distinct part, skilled nursing facility), violated 42 C.F.R. § 483.25(m)(2)[1] (Tag F333[2]) between July 19 and 26, 2005. A per-instance civil money penalty (PICMP) of $3000 is a reasonable enforcement remedy.

[1] All references to the Code of Federal Regulations (C.F.R.) are to the version in effect at the time of the surveys in issue unless otherwise specified.

[2] This is a "Tag" designation as used in the State Operations Manual (SOM), Appendix PP – Guidance to Surveyors for Long Term Care Facilities. The "Tag" refers to the regulatory provision allegedly violated and CMS's guidance to surveyors. Although the SOM does not have the force and effect of law, the provisions of the Social Security Act (Act) and the regulations that interpret the Act clearly do have such force and effect. *State of Indiana by the Indiana Department of Public Welfare v. Sullivan*, 934 F.2d 853 (7th Cir. 1991); *Northwest Tissue Center v. Shalala*, 1 F.3d 522 (7th Cir. 1993). Thus, while the Secretary of Health and Human Services (Secretary) may not seek to enforce the provisions of the SOM as law, he may seek to enforce the provisions of the Act or regulations as interpreted by the SOM.

I. Background

Petitioner, a long-term care facility participating in Medicare as a skilled nursing facility (SNF) and in the California MediCal program as a nursing facility (NF), was subject to surveys by the California Department of Health Services (state agency) on July 14, 2005, July 19, 2005, and September 23, 2005. The state agency alleged that Petitioner did not comply with program participation requirements during each survey. Request for Hearing. By letter dated October 5, 2005, the Centers for Medicare & Medicaid Services (CMS) notified Petitioner that it was imposing the following enforcement remedies: termination of Petitioner's provider agreement effective March 23, 2006; a PICMP of $3000 for an alleged violation of 42 C.F.R. § 483.25(m)(2) (Tag F333) as identified during the September 23, 2005 survey; and denial of payment for new admissions (DPNA) effective October 20, 2005. CMS exhibit (CMS Ex.) 6. CMS notified Petitioner by letter dated October 25, 2005 that, (1) based on an October 20, 2005 survey, Petitioner returned to substantial compliance effective October 20, 2005, and (2) CMS rescinded the termination and DPNA remedies. CMS Ex. 7.

Petitioner requested a hearing before an administrative law judge (ALJ) by letter dated December 2, 2005. In its hearing request, Petitioner challenged the findings of noncompliance resulting from the surveys conducted on July 14, 2005, July 19, 2005, and on September 23, 2005, and the remedies CMS proposed to impose. The case was assigned to me on December 23, 2005 for hearing and decision. A Notice of Case Assignment and Prehearing Case Development Order was issued at my direction on December 23, 2005.

On February 13, 2006, CMS filed a motion for partial dismissal of Petitioner's request for hearing on the following grounds: (1) with respect to Petitioner's challenge of all deficiencies identified by the surveys of July 14 and July 19, 2005, no remedies were imposed for any deficiencies cited; and (b) with respect to the September 23, 2005 survey, Tag F333 was the only deficiency for which a remedy was imposed and only Tag F333 is subject to appeal and review. On March 6, 2006, Petitioner opposed CMS's motion. On March 29, 2006, I granted the CMS motion and limited the issues for hearing to (1) whether or not Petitioner violated 42 C.F.R. § 483.25(m)(2) (Tag F333); and (2) whether or not the remedy proposed by CMS is reasonable.

On June 27, 2006, I convened a hearing in San Francisco, California. CMS offered, and I admitted, exhibits (CMS Exs.) 1 through 12. Transcript (Tr.) 23-34, 149-52. Petitioner offered exhibits (P. Exs.) 1 through 32. Petitioner's exhibits 18 through 29, 30 (pages 9 and 10), 31, and 32 were admitted. Tr. 36-41, 286-90, 294-304. CMS called Brenda B. Ryan, R.N.C., the state surveyor, to testify in its case-in-chief and in rebuttal. CMS also called Magda F. Gabali, Pharm.D., a pharmaceutical consultant, and Captain John S.

Motter, R.N., M.P.H., a CMS Team Leader and Survey and Certification Review Specialist, as expert witnesses. Petitioner called as it witnesses Anna M. Valentine, Petitioner's Director of Nursing (DON); Rosemary Gonzales-Bustillos, a nurse at Petitioner's facility; and Robert S. Hill, Petitioner's Administrator of Long-Term Care Facilities. Post-hearing, the parties filed briefs and reply briefs.

On July 18, 2006, Petitioner moved for relief from an order entered at hearing to produce an incident report purportedly prepared by DON Valentine related to the alleged medication error. Petitioner argued that the records are quality-assurance records protected from disclosure by 42 C.F.R. § 483.75(o)(3). Tr. 319-26, 360-69, 377-78, 450-56. Petitioner submitted with its motion P. Ex. 33 and 34. P. Ex. 33 is composed of copies of four photographs of an empty medication cassette or pill case allegedly of the same type Petitioner used to administer medication to Resident B and the declaration of Petitioner's counsel. Petitioner also submitted P. Ex. 34, the declaration of Brenda Gatcomb, Petitioner's Director of Quality Assurance and Risk Management. Ms. Gatcomb indicated in her declaration that (1) it was her responsibility to receive incident reports concerning medication errors committed by Petitioner's staff; (2) she did not have a record of receiving an incident report from DON Anna Valentine regarding the alleged medication error in this case; (3) if she had received such a report, she did not consider the incident serious enough to refer it to the Medications Continuous Quality Improvement Committee for review; and (4) if an incident report was received from DON Valentine, it had been destroyed. P. Ex. 34.

On August 3, 2006, CMS filed a response opposing Petitioner's motion for relief, objecting to P. Exs. 33 and 34, and requesting that I sanction Petitioner for failure to produce the records as ordered. On October 30, 2006, I issued an Order establishing the post-hearing briefing schedule and instructed Petitioner to respond to CMS's request for sanctions in its post-hearing brief. I also advised the parties that I would address Petitioner's motion for relief and the CMS motion for sanctions in the decision on the merits. P. Exs. 33 and 34 are admitted. Admission of P. Exs. 33 and 34 results in no prejudice to CMS as CMS prevails. I need not address Petitioner's assertion of "privilege" and to do so would be nothing but dicta. CMS's motion for sanctions is denied as discussed in some detail below.

II. Discussion

A. Findings of Fact

The following findings of fact are based upon the exhibits admitted. Citations to exhibit numbers related to each finding of fact may be found in the analysis section of this decision if not indicated here.

1. During the time period relevant to this case, Resident B was an 87 year-old woman diagnosed with polymyalgia rheumatica, lupus, and a history of chronic pain, for which she was under palliative care. Joint Stipulation; CMS Ex. 4, at 5, 7; P. Exs. 18, 19, 20, at 1, and 27.

2. Resident B was to be given prednisone daily to manage the symptoms of polymyalgia rheumatica. CMS Ex. 4, at 12, 22, 30, 32.

3. On eight consecutive days beginning July 19, 2005, through July 26, 2005, Resident B was not administered prednisone. CMS Exs. 4, at 32; P. Ex. 32.

4. Resident B suffered actual harm due to not receiving doses of prednisone July 19 through 26, 2005, including not feeling well; she suffered increased pain on movement; and she was emotionally distressed and anxious because she did not trust Petitioner's staff to give her medication she needed. CMS Exs. 12, at 13-19.

5. Failure to administer prednisone for eight consecutive days from July 19, 2005 to July 26, 2005, was abrupt withdrawal of prednisone contrary to manufacturer's prescribing instructions and Resident B's prescribing physician's orders; exposed Resident B to adverse consequences such as exacerbated polymyalgia rheumatica; and it was a significant medication error considering Resident B's medical condition, drug category, and the frequency of the error. CMS Ex. 12, at 8-20.

B. Conclusions of Law

1. Petitioner timely requested a hearing and I have jurisdiction over this case.

2. Petitioner violated 42 C.F.R. § 483.25(m)(2).

3. There is a basis for the imposition of an enforcement remedy.

4. A PICMP of $3000 is a reasonable enforcement remedy.

C. Issues

The issues in this case are:

> Whether there is a basis for the imposition of an enforcement remedy; and
>
> Whether the remedy imposed is reasonable.

D. Applicable Law

Petitioner is a long-term care facility participating in the federal Medicare program as a SNF and in the state Medicaid program as a NF. The statutory and regulatory requirements for participation by a long-term care facility are found at sections 1819 and 1919 of the Act and at 42 C.F.R. Part 483 of the regulations. Sections 1819 and 1919 of the Act vest the Secretary with authority to impose a civil money penalty (CMP) against a long-term care facility for failure to comply substantially with federal participation requirements.

Facilities that participate in Medicare are subject to surveys by state agencies on behalf of CMS to determine whether the facilities are complying with federal participation requirements. 42 C.F.R. §§ 488.10-488.28, 488.300-488.335. Pursuant to 42 C.F.R. Part 488, CMS may impose various sanctions for failure to substantially comply with Medicare program requirements, including a PICMP or per-day CMP against a long-term care facility. 42 C.F.R. §§ 488.406; 488.408; 488.430.

Per-day CMPs fall into one of two broad ranges of penalties. 42 C.F.R. §§ 488.408, 488.438. The upper range of CMP, from $3050 per day to $10,000 per day, is reserved for deficiencies that constitute immediate jeopardy to a facility's residents and, in some circumstances, for repeated deficiencies. 42 C.F.R. §§ 488.438(a)(1)(i), (d)(2). The lower range of CMP, from $50 per day to $3000 per day, is reserved for deficiencies that do not constitute immediate jeopardy, but either cause actual harm to residents, or cause no actual harm, but have the potential for causing more than minimal harm. 42 C.F.R. § 488.438(a)(1)(ii). As for PICMPs, the regulations provide for a single range from $1000 to $10,000, which could be imposed whether or not immediate jeopardy is found. 42 C.F.R. §§ 488.408(d)(1)(iv); 488.438(a)(2).

A long-term care facility against which CMS has determined to impose an enforcement remedy is entitled to a hearing by an ALJ. Act, § 1128A(c)(2); 42 C.F.R. §§ 488.408(g); 498.3(b)(13). A hearing before an ALJ is a *de novo* proceeding. *Anesthesiologists Affiliated, et al.*, DAB CR65 (1990), *aff'd*, *Anesthesiologists Affiliated, et al. v. Sullivan*, 941 F.2d 678 (8th Cir. 1991); *Emerald Oaks*, DAB No. 1800, at 11 (2001); *Beechwood Sanitarium*, DAB No. 1906 (2004); *Cal Turner Extended Care Pavilion*, DAB No. 2030 (2006)*; The Residence at Salem Woods*, DAB No. 2052 (2006). A facility has a right to appeal a "certification of noncompliance leading to an enforcement remedy." 42 C.F.R. § 488.408(g)(1); *see also* 42 C.F.R. §§ 488.330(e) and 498.3. However, the choice of remedies by CMS or the factors CMS considered when choosing remedies are not subject to review. 42 C.F.R. § 488.408(g)(2). A facility may only challenge the scope and severity level of noncompliance found by CMS if a successful challenge would affect the amount of the CMP that could be collected by CMS or impact upon the facility's Nurse

Aide Training and Competency Evaluation Program. 42 C.F.R. §§ 498.3(b)(14) and (d)(10)(i). CMS's determination as to the level of noncompliance "must be upheld unless it is clearly erroneous." 42 C.F.R. § 498.60(c)(2). This includes CMS's finding of immediate jeopardy. *Woodstock Care Center*, DAB No. 1726, at 9, 38 (2000), *aff'd, Woodstock Care Center v. Thompson*, 363 F.3d 583 (6th Cir. 2003). The Departmental Appeals Board has long held that the net effect of the regulations is that a provider has no right to challenge the scope and severity level assigned to a noncompliance finding, except in a situation where that finding was the basis for an immediate jeopardy determination. *See, e.g.*, *Ridge Terrace*, DAB No. 1834 (2002); *Koester Pavilion*, DAB No. 1750 (2000). Review of a CMP by an ALJ is governed by 42 C.F.R. § 488.438(e).

When a penalty is proposed and appealed, CMS must make a *prima facie* case that the facility has failed to comply substantially with federal participation requirements. "*Prima facie*" means that the evidence is "[s]ufficient to establish a fact or raise a presumption unless disproved or rebutted." *Black's Law Dictionary* 1228 (8th ed. 2004); *see also*, *Hillman Rehabilitation Center*, DAB No. 1611, at 8 (1997), *aff'd, Hillman Rehabilitation Center v. U.S. Dept. of Health and Human Services*, No. 98-3789 (D.N.J. May 13, 1999). To prevail, a long-term care facility must overcome CMS's showing by a preponderance of the evidence. *Batavia Nursing and Convalescent Center*, DAB No. 1904 (2004); *Batavia Nursing and Convalescent Inn*, DAB No. 1911 (2004); *Emerald Oaks*, DAB No. 1800 (2001); *Cross Creek Health Care Center*, DAB No. 1665 (1998); *Evergreene Nursing Care Center*, DAB No. 2069, at 7-8 (2007).

E. Analysis

1. Petitioner violated 42 C.F.R. § 483.25(m)(2).

A long-term care facility participating in Medicare is obligated and agrees to ensure that its residents are "free of any significant medication errors." 42 C.F.R. § 483.25(m)(2). CMS has instructed its surveyors that a medication error exists when the preparation or administration of drugs or biologicals is not in accordance with (1) a physician's orders; (2) manufacturer's specifications, as opposed to recommendations, regarding the preparation and administration of the drug or biological; or (3) accepted professional standards and principles that apply to professionals providing services. SOM, Interpretive Guidelines, Tag F333. A "significant medication error" is one that causes a resident discomfort or jeopardizes his or her health and safety. *Id.* Determining the significance of medication error is a matter of professional judgment that involves three general factors: resident condition; drug category; and frequency of error. *Id.* Petitioner has not disputed that the CMS construction is consistent with applicable industry standards of practice.

CMS alleges that Petitioner committed a significant medication error because it failed to administer prednisone to Resident B on eight consecutive days, which caused her harm that included increased pain and mental distress. CMS Ex. 3, at 3. To demonstrate a *prima facie* case of this deficiency, CMS must show that there was a medication error and that it was significant. I conclude that CMS made a *prima facie* showing of a violation and that Petitioner has failed to show by a preponderance of the evidence that it was in substantial compliance or that it had an affirmative defense.

CMS offers the Medication Administration Record (MAR) for Resident B from July 2005, as a key piece of evidence, but not the only evidence as Petitioner would have me believe, that a significant medication error occurred. Resident B had a physician's order to receive prednisone daily, but the MAR, a document that Petitioner uses to record that medication was administered by its staff, does not show that Petitioner's staff administered the prednisone for eight consecutive days from July 19 through 26, 2005. CMS concluded that the absence of initials of the person or persons who administered the drug shows the medication was not administered. CMS Ex. 4, at 32; P. Ex. 32. CMS argues that Petitioner failed to comply with the five "rights" of administration of medication: "right" dose of the "right" medication, administered by the "right" route, to the "right" patient, at the "right" time, citing *Franklin Care Center*, DAB No. 1900, at 11 (2003). CMS's Post-Hearing Brief (CMS Br.) at 27; CMS Ex. 3, at 4.

Petitioner does not dispute that there are no initials on the MAR for eight consecutive days from July 19 through July 26, 2005. Petitioner's Post-Hearing Brief (P. Br.) at 8. Petitioner argues that this case does not involve a medication error, significant or not, i.e., Petitioner gave Resident B prednisone as ordered, but rather, the error involves failure to document the administration of prednisone. Petitioner asserts that a "documentation error" does not trigger a presumption that the medication was not administered. P. Br. at 8-9. On this point, Petitioner relies upon the SOM, Interpretive Guidelines, Tag F333, submitted as Appendix C to its Pre-Hearing Brief, which, in pertinent part, instructs surveyors:

> Do not rely solely on a paper review to determine medication errors. Detection of blank spaces on a medication administration record does not constitute the detection of actual medication errors. Paper review only identifies possible errors in most cases. In some cases paper review can help identify actual errors but research has shown that the procedure is time consuming for the number of actual errors detected.

Petitioner's position is that Surveyor Ryan failed to conduct even a *de minimis* investigation before concluding that a significant medication error occurred, by improperly relying upon "unexplained" blank spaces in the MAR contrary to SOM guidelines; and that such reliance resulted from a combination of factors, including, significantly, Ms. Ryan's lack of objectivity. Petitioner also asserts that CMS relied upon uncorroborated hearsay statements made to Surveyor Ryan by DON Valentine and Rosemary Gonzales-Bustillos, a staff nurse. P. Br. at 1-2.

I conclude that Petitioner violated 42 C.F.R. § 483.25(m)(2). I find Surveyor Ryan credible. I find no inconsistencies in the records associated with her survey and investigation of the incident, or in her hearing testimony. Ms. Ryan pursued her duties aggressively and diligently, which I find commendable, and I conclude that it does not reflect poorly upon her credibility.

My conclusion that a medication error occurred is consistent with the credible evidence. The blank spaces on the MAR for eight consecutive days from July 19 through 26, 2005, certainly give rise to an inference that the medication was not administered. CMS Ex. 4, at 32; P. Ex. 32; Tr. 321. Petitioner's DON agreed that it *is* standard nursing practice and consistent with Petitioner's policy or practice to interpret the absence of an entry on a MAR as evidence that the medication was not administered. Tr. 312. Petitioner's Administrator, Robert S. Hill, also testified that the absence of entries on the MAR created the appearance that the medication was not given and that corrective action was required. Tr. 385, 402-403. CMS's expert witness, Captain Motter, also opined that it is consistent with standards of practice to construe the absence of initials on the MAR for eight consecutive days from July 19 through July 26, 2005, to reflect failure to administer prednisone on those days. Tr. 251.

I am not convinced by arguments that Surveyor Ryan's survey was incomplete or insufficient, or otherwise inconsistent with SOM guidelines for determining whether a medication error occurred. CMS offered evidence in addition to the MAR that I find credible and that supports the conclusion that a medication error occurred. Surveyor Ryan recounts in testimony and in her records that on September 22, 2005, DON Valentine reported that a medication error occurred during an eight-day period in July 2005 consistent with the absence of the initials in the MAR, and that three nurses were involved in the medication error. CMS Exs. 3, at 3-4; 4, at 1; 33; Tr. 73-77, 87-90, 111, 426-30. I find this hearsay statement credible, particularly because the statement is not denied by DON Valentine and because it is consistent with other evidence of record. Nurses' notes for Resident B from Petitioner's clinical records created near the time of the alleged medication error indicate that Resident B's family was informed that some doses of prednisone were missed. These records show that Petitioner acknowledged to the family that a medication error occurred. CMS Ex. 4, at 10, 11. The evidence shows

that Resident B's daughter and son were told about the medication error within days after July 26, 2005, the last day of the eight-day period of the medication error. CMS Ex. 1, at 1-2, 7-9; and P. Exs. 21; 29, at 2. A "social services notes" dated July 28, 2005 also reflects that Resident B's family members were advised by Petitioner's staff that there were missed doses of prednisone. CMS Ex. 4, at 48; P. Ex. 20, at 2. Surveyor Ryan testified that it is standard of practice to notify a resident's family when a facility determines that a medication error occurred, but not where the facility is uncertain that such an error occurred. Tr. 434-35.

DON Valentine's testimony is that she initially thought that a medication error occurred. However, her subsequent investigation led her to conclude that there was no error, but that Resident B was given prednisone as ordered and staff merely failed to document the doses given. Tr. 283, 291. Multiple inconsistencies between her testimony and other evidence in the record cause me to conclude that DON Valentine's testimony is not credible. Petitioner's argument that Surveyor Ryan misconstrued DON Valentine's statements to her, or that she deliberately construed them against Petitioner based upon a predisposition for finding a deficiency, are not supported by the record or DON Valentine's own testimony. DON Valentine testified that it is standard practice to initiate an investigation upon learning that a MAR has blank entries. Tr. 268. She also testified that she herself wrote the words "8 days missing med" and drew circles (for July 19 through 26, 2005) on the MAR, as she began her investigation. Tr. 292-293; CMS Ex. 4, at 32. She conceded that the event was deemed significant enough to trigger the preparation of an incident report, but that the "facility" ultimately determined, following a root-cause analysis, that the error concerned only documentation. Tr. 316-17. At the hearing, DON Valentine did not deny Surveyor Ryan's version of their conversation. Rather, she said that she could not recall what she told Ms. Ryan when they met on September 22, 2005. Tr. 284, 316-19. DON Valentine also did not recall informing Ms. Ryan about the conclusion or finding reached in the incident report that she prepared. Tr. 318. She could not recall whether she wrote the first names of the three nurses who might have been involved in the incident on the document marked CMS Ex. 4, at 33, when she began her investigation or when she was interviewed by Surveyor Ryan. Tr. 326-327. She did recall that she told the social worker that Resident B did not receive her prednisone for eight days. Tr. 327. Surveyor Ryan testified that at no time during her survey and investigation did DON Valentine ever state that the error merely involved documentation. CMS Ex. 2, at 1-2; 3, at 3-4; and Tr. 426-28. I find it incredible that a facility that conducted an investigation, including a root-cause analysis, and concluded that no medication error occurred, failed to inform a surveyor about potentially exculpatory findings, even if, for no other reason than that the investigation is evidence of good remedial action by Petitioner. One nurse involved in the medication error wrote a note to DON Valentine with the date July 29, 2005. In that note she states that she recalled administering prednisone for the last two of the eight days in question, but

inadvertently failed to note the administration on the MAR. P. Ex. 31; Tr. 284-86; P. Ex. 32. The "PRN Medication Record and Profile" has "stars" - but not a person's initials - marked in the boxes for July 25 and July 26, perhaps indicating that prednisone was given those two days. Even if I find this hearsay entirely credible, the evidence does not account for the first six days of missed doses. However, the credibility of the note and DON Valentine's testimony is negatively impacted as DON Valentine's explanation for her failure to inform the surveyor about this potentially exculpatory evidence is not credible. Tr. 289. Surveyor Ryan's testimony that she was never given a copy of the note at P. Ex. 31, is unrebutted. Tr. 430-433.

Although I draw no adverse inference against Petitioner for failure to produce the incident report as that would be a sanction, I do not have that report before me to help bolster DON Valentine's credibility. Brenda Gatcomb, Petitioner's Director of Quality Assurance and Risk Management, indicates in her declaration that: (1) it was her responsibility to receive incident reports concerning medication errors committed by Petitioner's staff; (2) she did not have a record of receiving an incident report from DON Anna Valentine regarding the alleged medication error in this case; (3) if she had received such a report, she did not consider the incident serious enough to refer to the Medications Continuous Quality Improvement Committee for review; and (4) if an incident report was received from DON Valentine, it had been destroyed. P. Ex. 34. Ms. Gatcomb neither confirms nor denies that an incident report was ever prepared and she gives no insight regarding its contents.

I find credible Surveyor Ryan's testimony that Rosemary Gonzales-Bustillos admitted to her during the survey that she was one of the nurses involved in the medication error. Tr. 87-89. According to Surveyor Ryan, Nurse Gonzales-Bustillos told her that she was responsible for one of the missed doses of prednisone. Nurse Gonzales-Bustillos told Surveyor Ryan that she was doing orientation with Nurse Estella Queszada; that the entry for prednisone on the MAR was highlighted, which caused her to believe it had been discontinued; that Nurse Queszada agreed with that interpretation; and the prednisone was not given. Tr. 88-89. In her testimony, Nurse Gonzales-Bustillos stated that she did not recognize Surveyor Ryan in the courtroom. She did, however, recall certain details about her meeting with Surveyor Ryan in September 2005, including that she spoke to the surveyor for approximately five minutes and that she told Surveyor Ryan to see Nurse Queszada, as Nurse Queszada was actually giving the medication while she merely observed. Tr. 348-49. Nurse Gonzales-Bustillos denied the statements Surveyor Ryan attributed to her regarding the prednisone being discontinued. Tr. 347. Nurse Gonzales-Bustillos testified that she did remember that Nurse Queszada did give Resident B medication, but she never specifically said that the medication given included the prednisone. Tr. 344-50.

Because I have found that there was a medication error, the question is whether the error was significant, i.e., whether it harmed Resident B. Petitioner argues that even if I find that it failed to administer prednisone, the evidence does not support a conclusion that Resident B suffered any harm. Petitioner argues that the clinical records show Resident B actually was feeling and doing better during that time. P. Brief at 13-17; P. Reply Brief (P. Reply), at para. II.B.1. My review of the evidence leads me to a different conclusion.

Resident B told Surveyor Ryan on September 22, 2005, that she could not walk from her chair to her bed due to an increase of severe pain during the period of the missed doses of prednisone. Resident B also expressed that she no longer trusted facility staff to give her medication. CMS Exs. 2, at 2; 3, at 5; Tr. 90-91, 99. I am not convinced by Petitioner's argument that Resident B was not a reliable historian of her own condition during the period at issue. P. Br. at 12-13. In particular, records associated with Ms. Ryan's investigation and clinical records dated shortly before the event in question indicate that Resident B was oriented, alert, cooperative, and trustworthy, and that her cognitive ability was intact. CMS Exs. 2, at 2; 3, at 5; 4, at 44-46; Tr. 91, 93. Petitioner's clinical records for Resident B do not reflect the level of cognitive impairment or limitation that Petitioner suggests. Her palliative care initial assessment dated June 22, 2005, shows that she was not depressed or anxious. P. Ex. 18, at 1. Resident B was assessed only on July 23, 2005, as making poor decisions and requiring cues and supervision, but her memory was noted to be "Okay," she had no indicators of delirium, such as easy distractability, lethargy, variation in mental function, altered perception, disorganized speech, or restlessness. She was also assessed on July 23, 2005, as being able to hear adequately and to speak clearly; she was able to be understood; there were no negative indications related to mood or behavior. She was noted to interact with others. She was doing planned and self-initiated activities. A note indicated that she had "a few days of not feeling good" and she refused stool softeners. P. Ex. 22. Petitioner's records also show that from July 18 through 31, 2007, Resident B was consistently alert, with no confusion and no depression. P. Ex. 23. Petitioner provided me with one page of Resident B's Minimum Data Set (MDS), signed by DON Valentine on June 28, 2005, which shows that during the preceding 90 days Resident B had a diagnosis of anxiety syndrome, but the page provided does not include the section of the MDS that shows the assessment of Resident B's cognitive ability. P. Ex. 24, at 1. A Nurse's Note dated June 26, 2005, records that a nurse assistant reported Resident B was confused and hallucinating two nights, but that is an isolated incident in the records Petitioner provided and did not occur around the time of the events in issue. P. Ex. 29, at 1. I find the evidence does not support Petitioner's characterization of Resident B's mental status and I find no reason to consider Resident B's reports other than fully credible.

Resident B suffered polymyalgia rheumatica for which she received palliative care to manage chronic pain. She was to be administered prednisone daily to manage her polymyalgia rheumatica. CMS Ex. 4, at 12, 22, 30, 32. Dr. Gabali noted in her declaration that Resident B had been on long-term prednisone therapy. CMS Ex. 12, at 6, 10, 11.[3] She stated that the lowest possible doses of a corticosteroid like prednisone are administered to control a condition but, even at a low dose reduction in dosage should be gradual and tapered, not abrupt, consistent with manufacturer's prescribing information. CMS Ex. 12, at 8, 10, 12, 15. Dr. Gabali further stated that rapid dose reduction could result in recurrence or exacerbation of the symptoms of the underlying disorder for which the prednisone was ordered or other physiologic effects, including anorexia, nausea or vomiting, weight loss, lethargy, headache, fever, joint or muscle pain, and postural hypotension. CMS Ex. 12, at 11, 12. I note that beginning July 6, 2005, Resident B's prednisone dose was to be increased to 20 mg for a day and then gradually decreased to 15 mg a day. CMS Ex. 4, at 32. Dr. Gabali observed that the adjustment in dosage did make Resident B more comfortable and improved the quality of her life. CMS Ex. 12, at 9-10. She also opined that, in light of Resident B's medication condition, omission of eight doses of prednisone caused Resident B "significant harm" in the form of "deleterious effects" on her condition manifested by "increased discomfort and pain" and "decreased mobility and activity." CMS Ex. 12, at 11-19. Resident B's clinical signs were consistent with abrupt withdrawal of prednisone during the time period in question. These clinical signs included gastrointestinal discomfort, lethargy, disrupted sleep, and increased generalized discomfort and pain as apparent based on an increased frequency of dosage of Tylenol 650 mg during the time period when prednisone was not administered. CMS Ex. 12, at 11-19. Captain John Motter concurred with Dr. Gabali's opinion. Tr. 214-217, 235-241. The failure to administer prednisone for eight consecutive days was a significant medication error considering Resident B's medical condition, the drug category, and frequency of error. CMS Ex. 12, at 19-20; Tr. 95-99, 212-215, 223-224.

Based on the foregoing, I conclude that a significant medication error occurred based on the failure to give Resident B prednisone for eight consecutive days from July 19, 2005 through July 26, 2005. Furthermore, the error resulted in actual harm to B as described above. Thus, there is a basis for the imposition of an enforcement remedy.

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[3] Dr. Gabali was subject to cross-examination by Petitioner and further examination by CMS at hearing. Her testimony at hearing is consistent with her declaration.

The CMS request that I sanction Petitioner for failure to produce the incident report by striking DON Valentine's testimony or by dismissing Petitioner's hearing request is denied. Given the result in this case, the imposition of the sanctions requested by CMS would have little impact. Furthermore, the evidence does not support the imposition of sanctions.

2. A PICMP of $3000 is reasonable.

Because Petitioner violated 42 C.F.R. § 483.25(m)(2), there is a basis for the imposition of an enforcement remedy. The remaining issue is whether a PICMP of $3000 is reasonable.

If a facility is not in substantial compliance with program requirements, CMS has the authority to impose one or more of the enforcement remedies listed in 42 C.F.R. § 488.406, including a CMP. CMS may impose a CMP for the number of days that the facility is not in compliance or for each instance that a facility is not in substantial compliance. 42 C.F.R. § 488.430(a). In this case, CMS imposed a PICMP of $3000. To determine whether the CMP is reasonable, the following factors in 42 C.F.R. § 488.438(f) must be considered: (1) the facility's history of non-compliance, including repeated deficiencies; (2) the facility's financial condition; (3) the seriousness of the deficiencies as set forth in 42 C.F.R. § 488.404; and (4) the degree of culpability.

I have no evidence of a history of non-compliance by Petitioner and CMS does not argue that there is a history of non-compliance for me to consider. CMS Brief at 24-28; CMS Post Hearing Response Brief at 20-24.[4] Petitioner has not alleged that it is unable to pay the PICMP. There is credible evidence of actual harm to Resident B. Petitioner is culpable for the failure to ensure that prednisone was administered as ordered and there is evidence of the potential for serious adverse consequences of sudden withdrawal of prednisone. Based on these considerations, and particularly, the degree of seriousness of the noncompliance in light of circumstances specific to Resident B, I conclude that the PICMP of $3000 is a reasonable remedy.

[4] Petitioner reveals in its request for hearing that deficiencies were cited by surveys completed on July 14 and 19, 2005. However, CMS did not impose any enforcement remedies based upon those surveys and none of the specific findings from those surveys are disclosed. Thus, I do not consider the surveys completed on July 14 and 19 as indicative of a history of noncompliance.

III. Conclusion

For the foregoing reasons, I conclude that (1) Petitioner violated 42 C.F.R. § 483.25(m)(2); and (2) a PICMP of $3000 is a reasonable enforcement remedy.

/s/
Keith W. Sickendick
Administrative Law Judge