Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Envoy of Stratford Hills
(CCN: 49-5223),

Petitioner,

v.

Centers for Medicare & Medicaid Services.

Docket No. C-15-3317

Decision No. CR4735

Date: November 10, 2016

AMENDED DECISION

Envoy of Stratford Hills (Envoy or Petitioner) challenges the Centers for Medicare & Medicaid Services' (CMS) determination that it was not in substantial compliance with multiple Medicare program participation requirements on July 9, 2015, and for six months prior to that date. Based on Envoy's failure to be in substantial compliance, CMS imposed a per-day civil money penalty (CMP) from June 11, 2015, through July 7, 2015, and terminated Petitioner's Medicare provider agreement on July 8, 2015. Envoy challenges the CMS remedies. For the reasons discussed below, I affirm CMS's determination.

I. Background

The Social Security Act (Act) sets forth requirements for a skilled nursing facility's (SNF's) participation in the Medicare program and authorizes the Secretary of Health and Human Services (the Secretary) to promulgate regulations implementing those statutory provisions. Act § 1819; 42 U.S.C. § 1395i-3. The Secretary's regulations are found at 42 C.F.R. Parts 483 and 488. To participate in the Medicare program, an SNF must maintain substantial compliance with program participation requirements. To be in

substantial compliance, an SNF's deficiencies may "pose no greater risk to resident health or safety than the potential for causing minimal harm." 42 C.F.R. § 488.301. "Noncompliance" means "any deficiency that causes a facility to not be in substantial compliance." *Id.*

The Secretary contracts with state agencies to conduct periodic surveys to determine whether SNFs are in substantial compliance. Act § 1864(a), 42 U.S.C. § 1395aa(a); 42 C.F.R. § 488.10. The Act also authorizes the Secretary to impose enforcement remedies against SNFs that are not in substantial compliance with the program participation requirements. Act § 1819(h), 42 U.S.C. § 1395i-3(h). An SNF found not to be in substantial compliance is subject to one or more enforcement remedies, including termination. *Id.*; 42 C.F.R. §§ 488.402, 488.406, 488.408.

A per-day CMP may range from either $50 to $3,000 per-day for less serious noncompliance, or $3,050 to $10,000 per-day for more serious noncompliance that poses immediate jeopardy to the health and safety of residents. 42 C.F.R. § 488.438(a). "Immediate jeopardy" exists when "the provider's noncompliance with one or more requirements of participation has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident." 42 C.F.R. § 488.301. The authorized range for a per-instance CMP is $1,000 to $10,000. 42 C.F.R. § 488.438(a)(2).

The statute authorizes the Secretary to terminate a provider agreement if she finds substantial noncompliance with program requirements whether or not CMS has determined that the noncompliance poses immediate jeopardy. Act § 1819(h)(2), 42 U.S.C. § 1395i-3(h)(2); Act § 1866(b)(2)(A), 42 U.S.C. § 1395cc(b)(2)(A); 42 C.F.R. § 488.412; *see also Shalala v. Ill. Council on Long Term Care, Inc.*, 529 U.S. 1, 21 (2000). CMS must terminate the provider agreement of an SNF that has been out of substantial compliance for more than six months, even if the noncompliance only involves one Medicare participation requirement. *See* 42 C.F.R. § 488.412; *see also* Act § 1819(h)(2)(C), 42 U.S.C. § 1395i-3(h)(2)(C).

If CMS imposes a remedy, including termination, based on a noncompliance determination, then the facility may request a hearing before an administrative law judge (ALJ) to challenge the noncompliance finding and enforcement remedy. Act § 1128A(c)(2), 42 U.S.C. § 1320a-7a(c)(2); Act § 1819(h)(2)(B)(ii), 42 U.S.C. § 1395i(h)(2)(B)(ii)); Act § 1866(h)(1), 42 U.S.C. § 1395cc(h)(1); 42 C.F.R. §§ 488.408(g), 488.434(a)(2)(viii), 498.3(b)(13), 498.5(b). The hearing before an ALJ is a *de novo* proceeding. *CarePlex of Silver Spring*, DAB No 1683 (1999) (holding that ALJs hold de novo hearings based on issues permitted under the regulations and ALJ review is not a quasi-appellate review); *see also Claiborne-Hughes Health Ctr. v. Sebelius*, 609 F.3d 839, 843 (6th Cir. 2010) (The DAB "reviewed the finding under the *de novo* standard that the ALJ would have applied."). A facility has a right to appeal a "certification of noncompliance leading to an enforcement remedy." *See* 42 C.F.R.

§ 488.408(g)(1); *see also* 42 C.F.R. §§ 488.330(e), 498.3. However, CMS's choice of remedies and the factors CMS considered when choosing remedies are not subject to review. 42 C.F.R. § 488.408(g)(2).

In regard to the burden of proof, CMS must make a *prima facie* case that the SNF failed to comply substantially with federal participation requirements and, if this occurs, an SNF must, in order to prevail, prove substantial compliance by a preponderance of the evidence. *Hillman Rehab. Ctr.*, DAB No. 1611, at 8 (1997); *see Batavia Nursing & Convalescent Inn*, DAB No. 1911 (2004); *Batavia Nursing & Convalescent Ctr.*, DAB No. 1904 (2004); *Emerald Oaks*, DAB No. 1800 (2001); *Cross Creek Health Care Ctr.*, DAB No. 1665 (1998).

Envoy was an SNF located in Richmond, Virginia, that participated in the Medicare program. The Virginia Department of Health, Office of Licensure and Certification (state agency) performed an annual standard survey of Envoy on January 8, 2015. Based on the survey findings, CMS found Petitioner not in substantial compliance with Medicare program requirements as of January 8, 2015. CMS Exhibits (Exs.) 1-9. The state agency conducted a subsequent revisit survey on March 2, 2015; however, the state agency found that Petitioner was still not in substantial compliance. CMS Ex. 10.

In a March 17, 2015 letter, CMS imposed on Petitioner a denial of payment for new admissions (DPNA) beginning April 8, 2015, based on the January and March surveys. CMS Ex. 29 at 2. In an April 6, 2015 letter, CMS imposed a CMP based on the January and March surveys of $5,150 per-day beginning February 6, 2015, through February 24, 2015, and $750 per-day thereafter. Petitioner (P.) Ex. 2 at 3. The state agency conducted another revisit survey on April 30, 2015, which resulted in findings of a continued failure to substantially comply with Medicare program requirements. CMS Ex. 13.

The state agency later conducted two more subsequent revisit surveys on June 11, and July 9, 2015, both of which found a failure to be in substantial compliance with Medicare participation requirements. CMS Exs. 17, 21. The deficiencies found during the June 11, 2015 survey were:

- 42 C.F.R. § 483.15(e)(1), (F246 – quality of life: accommodation of needs) at the scope and severity (s/s) level D (isolated instance of noncompliance that causes no actual harm with the potential for more than minimal harm);

- 42 C.F.R. § 483.25, (F309 – quality of care) at the s/s level D;

- 42 C.F.R. § 483.25(e)(2), (F318 – quality of care: range of motion) at the s/s level D;

- 42 C.F.R. § 483.25(g)(2), (F322 – quality of care: naso-gastric tubes) at the s/s level D;

- 42 C.F.R. § 483.25(k), (F328 – quality of care: special needs) at the s/s level D;

- 42 C.F.R. § 483.25(m)(2), (F333 – quality of care: medication errors) at the s/s level D; and

- 42 C.F.R. § 483.65, (F441 – infection control) at the s/s level D.

CMS Ex. 17.

The deficiencies found during the July 9, 2015 survey were:

- 42 C.F.R. § 483.10(b)(11), (F157 – resident rights: notice of rights and services, notification of changes) at the s/s level D;

- 42 C.F.R. § 483.20(k)(3)(i), (F281 – resident assessment: comprehensive care plans) at the s/s level E (pattern of noncompliance that causes no actual harm with the potential for more than minimal harm);

- 42 C.F.R. § 483.25, (F309 – quality of care) at the s/s level D;

- 42 C.F.R. § 483.25(k), (F328– quality of care: special needs) at the s/s level D;

- 42 C.F.R. § 483.25(*1*), (F329– quality of care: unnecessary drugs) at the s/s level D;

- 42 C.F.R. § 483.40(b)(4), (F386– physician services: physician visits) at the s/s level D;

- 42 C.F.R. § 483.65, (F441– infection control) at the s/s level D;

- 42 C.F.R. § 483.75(g), (F499– administration: staff qualifications) at the s/s level D; and

- 42 C.F.R. § 483.75(*1*)(1), (F514– administration: clinical records) at the s/s level D.

CMS Ex. 21.

Based on these surveys, CMS continued the $750 per-day CMP through July 7, 2015. P. Ex. 5 at 1. CMS also terminated Petitioner's participation in the Medicare program effective July 8, 2015. P. Ex. 4 at 1-3.

Petitioner timely requested a hearing before an ALJ to dispute CMS's findings. Following receipt of Petitioner's hearing request, I issued an Acknowledgment and Initial Prehearing Order. In that order, I directed the parties to file written direct testimony for all witnesses they wanted to present.

CMS filed a prehearing brief (CMS Br.) and 44 proposed exhibits (CMS Exs. 1-44),[1] including the written direct testimony for 11 witnesses.[2] Petitioner filed a prehearing brief (P. Br.) and 41 proposed exhibits (P. Exs. 1-40),[3] including the written direct testimony for eight witnesses. Both parties asked to cross-examine all of the opposing party's witnesses. I admitted CMS Exhibits 1 through 44 and Petitioner's Exhibits 1 through 40.

Petitioner stipulated that CMS's determinations related to the January 8, 2015 and March 2, 2015 surveys are final, and Petitioner withdrew its appeal related to the April 30, 2015 survey. Petitioner's Proposed Stipulations of Fact and Statements of Issues Presented for Hearing ¶¶ 10, 20. Petitioner does not dispute the January, March, or April surveys, or the remedies associated with this noncompliance, namely - $5,150 per-day beginning February 6, 2015, through February 24, 2015, and $750 per-day from February 25, 2015, through June 11, 2015. Accordingly, the determinations and associated remedies related

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[1] By Order dated November 4, 2015, I admitted CMS Exhibits 1 through 41 and 43, and Petitioner's Exhibits 1 through 40. Although CMS listed CMS Exhibit 42 ("Excerpt for State Operations Manual, Appendix PP, Interpretive Guidelines Regarding F-333") on its final exhibit list, it did not submit the exhibit. However, on November 5, CMS submitted CMS Ex. 42 and added a new exhibit, CMS Ex. 44. Furthermore, on November 6, CMS filed a clean copy of CMS Ex. 22 part E. During the hearing on November 9, 2015, I admitted CMS Exs. 42 and 44 and the clean copy of CMS Ex. 22 part E. Tr. 11/9 at 14.

[2] CMS submitted CMS Ex. 43 on October 5, 2015. This exhibit is the written direct testimony of Marilyn Dayton, RN. On October 28, 2015, CMS submitted a revised version of CMS Ex. 43. In my November 4, 2015 Order, I admitted CMS Ex. 43 as revised. However, during the hearing, Petitioner's counsel questioned Ms. Dayton concerning the October 5 version of CMS Ex. 43, which I then admitted in addition to the revised version of that exhibit. Tr. 11/10 at 14. I note that the hearing transcript incorrectly identified the October 5 version of CMS Ex. 43 as Petitioner Exhibit 43. All references in the rest of this decision to CMS Ex. 43 are to the revised version of that exhibit submitted on October 28 and admitted on November 4.

[3] Petitioner submitted exhibits marked 17 and 17A.

to the January 8, March 2, and April 30, 2015 surveys are administratively final and not before me.

Petitioner asserts that it returned to substantial compliance by June 2, 2015, and disputes all of the deficiencies found in the June 11, 2015 and July 9, 2015 surveys, the associated CMP of $750 per-day from June 11, 2015, through July 7, 2015, the imposition of a DPNA on April 8, 2015, and its termination effective July 8, 2015.

On November 9, 10, and 18, 2015, I held a video hearing.[4] I heard testimony on cross-examination on behalf of CMS from: CMS nurse consultant, Linda Brown, R.N. (CMS Ex. 41 at 15-18); CMS surveyor and nurse consultant, Gerald Hahn, R.N. (CMS Ex. 41 at 19-22); state agency surveyor, Celinda Lovett, R.N., M.P.A. (CMS Ex. 41 at 39-41); state agency surveyor, Shyrn Nyarko, Ph.D., LCSW (CMS Ex. 41 at 30-34); state agency surveyor supervisor, Elaine Cacciatore, R.N. (CMS Ex. 41 at 51-57); state agency surveyor, Raymond R. Polakoski, R.N. (CMS Ex. 41 at 58-70); state agency surveyor, Meghan Garret, R.D., M.S. (CMS Ex. 41 at 35-38); state agency surveyor, Marilyn Dayton, R.N. (CMS Ex. 43); state agency surveyor, Joyce Wilburn, R.N. (CMS Ex. 41 at 42-50); state agency surveyor, Rose M. Trevilian, R.N. (by telephone) (CMS Ex. 41 at 23-29); and CMS medical expert, Jefferson Lesesne, M.D. (CMS Ex. 41 at 1-14). I heard testimony on cross-examination on behalf of Petitioner from: Petitioner's maintenance Director, Johnny Wimmer (P. Ex. 35); Petitioner's charge nurse, Tammy Springer, L.P.N., (Ex. 37); Petitioner's Medical Director, James Thompson, M.D. (P. Ex. 38); Petitioner's regional director of nutrition services, Diana Bruen, R.D., M.S., C.S.G. (P. Ex. 36); Petitioner's administrator, Stacie Shive, NHA, (P. Ex. 34); a nurse employed by Petitioner, Kimberly Christian, L.P.N. (P. Ex. 40); Petitioner's regional nurse consultant, Melinda Hirn, R.N. (P. Ex. 33); and Petitioner's corporate compliance nurse, Marilyn Nalley, R.N., (P. Ex. 39).

After the hearing, CMS and Petitioner filed post hearing briefs (CMS Post-Hrg. Br. and P. Post-Hrg. Br.) and post hearing reply briefs (CMS Reply and P. Reply). With its post hearing brief, Petitioner submitted an unmarked exhibit it initialed referred to as "Attachment 1," and later as P. Ex. 42, which is a November 18, 2015 letter to Petitioner from the state agency stating that after the Informal Dispute Resolution (IDR) review,[5] CMS determined that all deficiencies would remain as originally written. Later, Petitioner also filed a motion to supplement the record with a document marked as P. Ex.

[4] A transcript was prepared for each day of the hearing. The transcripts for November 10 and 18 were not marked with continuous pagination from the prior date's hearing. Accordingly, I will refer to the transcripts by the date of the hearing in which they correspond: Tr. 11/09, Tr. 11/10, or Tr. 11/18.

[5] SNFs have the right to request informal dispute resolution regarding survey findings. 42 C.F.R. § 488.331.

41, an internal October 20, 2015 IDR recommendation from the state ALJ who held the IDR conference. Petitioner asserted that I should enter into the record proposed P. Ex. 41 and P. Ex. 42. Petitioner argued the following for inclusion in the record: these documents were not available prior to the hearing; the findings of the IDR undercut the testimony of CMS's witnesses; the IDR recommendations to delete deficiencies, which CMS has not expressly rejected, may be considered dispositive as to those deficiencies; and these documents are necessary for a complete and clear administrative record. P. Motion to Supplement at 3. CMS objects to both P. Exs. 41 and 42 as untimely and irrelevant, pointing out that P. Ex. 42 shows that CMS rejected the IDR recommendations and that the state ALJ did not consider all of the evidence that is in the record in this proceeding; CMS requested that I either exclude the proposed exhibits or give them no weight. CMS Objection to P. Motion to Supplement. I agree with Petitioner that I should admit P. Exs. 41 and 42 into the record to ensure a complete administrative record; however, I view these documents as procedural and not substantive exhibits. I interpret P. Ex. 42 as CMS's rejection of all of the IDR recommendations (P. Ex. 42); therefore, P. Ex. 41 does not affect my adjudication of this case, which is *de novo*. *Britthaven of Chapel Hill*, DAB No. 2284 at 5-9 (2009).

II. Issues

1. Whether CMS had a basis to terminate Envoy's Medicare provider agreement for failing to be in substantial compliance with Medicare program participation requirements on July 9, 2015, and for six months before that date;

2. Whether CMS had a basis to impose a per-day CMP on Envoy from June 11, 2015, through July 7, 2015, due to Envoy's failure to be in substantial compliance with Medicare program participation requirements; and

3. If CMS had a basis for imposing a per-day CMP on Envoy from June 11, 2015 through July 7, 2015, whether the amount of CMP imposed is reasonable.

III. Findings of Fact

June 11, 2015 survey:

1. Resident 312[6] (R312) is male and was born on September 14, 1964. P. Ex. 18 at 1.

2. Petitioner admitted R312 to its facility on June 3, 2014, with an admitting diagnosis that included diabetes. P. Ex. 18 at 1-2.

[6] To ensure their privacy, I do not refer to the residents by their names. Instead, I refer to the residents by the resident identifier number that they are assigned for each survey.

3. By November 2014, R312 had an extensive regimen to treat his diabetes, including: a rapid-acting insulin, Novolog, at 6:30 AM and 4:30 PM (units were based on a sliding scale dependent on his blood glucose levels); 30 units of a long-acting insulin, Levemir, at 9 AM; 30 units of an intermediate-acting insulin, Novolin, at 9 AM and 20 units at 9 PM. P. Ex. 18 at 5.

4. Before June 2, 2015, R312 experienced complications due to his diabetes, including coronary artery disease, peripheral vascular disease, and left foot osteomyelitis. CMS Ex. 18 Part D at 33-34; CMS Ex. 41 at 6; P. Ex. 18 at 1-3.

5. On June 2, 2015, Dr. Thompson, Petitioner's medical director, determined that R312's type 2 Diabetes Mellitus was "poorly controlled" and changed R312's insulin regimen; he discontinued the Novolin, and increased the amount of Levemir from 30 units once a day, to 40 units twice a day and his Novolog sliding scale remained the same. CMS Ex. 18 Part D at 30, 31, 32, 33, 34, 39.

6. On June 2, 2015, staff discontinued the 30 units of Novolin at 9 AM, the 20 units of Novolin at 9 PM, and the 30 units of Levemir. However, Petitioner failed to initiate the 40 units of Levemir twice a day at 9 AM and 9 PM. CMS Ex. 17 at 5-8, 21-23; CMS Ex. 18 Part D at 30; CMS Ex. 41 at 37; *see also* P. Ex. 38 at 4.

7. Petitioner's staff only administered Novolog at 6:30 AM and 4:30 PM, until June 7, 2015. CMS Ex. 18 Part D at 30; *see also* P. Ex. 38 at 4.

8. On June 3, 2015, staff documented R312's blood sugar as 389. Doctor's orders required administration of five units of insulin with that blood sugar level; however, staff administered seven units of insulin. CMS Ex. 17 at 5-8, 21-23; CMS Ex. 18 Part D at 30; CMS Ex. 41 at 37; Tr. 11/9 at 359.

9. Resident 307 (R307) is male and was born on July 24, 1947. CMS Ex. 18 Part I at 36; P. Ex. 20 at 1.

10. Petitioner admitted R307 to its facility on November 20, 2012, with an admitting diagnosis that included multiple joint contractures. P. Ex. 20 at 1.

11. Commencing September 17, 2014, Petitioner's staff applied splints to R307's left hand and left elbow. CMS Ex. 18 Part J at 5; CMS Ex. 41 at 48.

12. On April 17, 2015, R307's physician ordered that he wear two splints, one on his left hand and another for his left elbow, from 10:00 AM until 4:00 PM as tolerated, as needed, due to the contractures. CMS Ex. 18 Part J at 7.

13. On June 9, 2015, at 2:10 PM, Surveyor Garrett observed that R307 was not wearing a hand splint. Additionally, although R307 was wearing an elbow splint, it was not secure and, when R307 lifted his arm, the elbow splint hung below R307's arm. CMS Ex. 41 at 37-38 (Garrett Decl.); CMS Ex. 17 at 8-11; CMS Ex. 18 Part I at 33, 60; Tr. 11/9 at 367-369, 371-372, 376.

14. On June 10, 2015, at noon, Surveyor Wilburn observed R307 wearing the hand splint, but noted that the elbow splint was located on R307's arm midway between his shoulder and elbow. CMS Ex. 41 at 48-49; CMS Ex. 18 Part I at 33 (drawing of elbow splint placement); CMS Ex. 41 at 37-38; CMS Ex. 17 at 10-11; Tr. 11/10 227-28.

15. At 2:30 PM on June 10, Surveyors Garrett and Wilburn observed R307 with the splints essentially unchanged from the noon observation. CMS Ex. 41 at 37-38, 48-49; CMS Ex. 17 at 10; Tr. 11/9 at 371-72, 374-76.

16. On June 11, 2015, at 10:00 AM, Surveyor Wilburn observed R307 wearing his hand splint, but his elbow splint was loose and again placed mid-arm rather than over the elbow joint. CMS Ex. 17 at 10-11; CMS Ex. 41 at 48-49.

17. Licensed Practical Nurse (LPN) A admitted to Surveyor Wilburn that on June 10, 2015, the Certified Nursing Assistant (CNA) failed to correctly apply R307's splints. CMS Ex. 17 at 11; CMS Ex. 41 at 49; *see* CMS Ex. 20 Part B at 13.

18. CNA A, who applied the splints, explained to Surveyor Wilburn that the hand/wrist splint was too long to fit properly at the same time as the elbow splint. CMS Ex. 17 at 11; CMS Ex. 20 Part B at 13; CMS Ex. 41 at 49; Tr. 11/10 at 218.

19. Petitioner's staff did not care plan for R307's splints. The only care plan that referenced R307's splints was his wound care plan showing left hand and elbow splints were implemented on September 17, 2014. However, that care plan did not contain application times, instructions on how to apply the splints, instructions to clean, alternatives to the splints, or adjunct services such as restorative nursing, massage, or how to prevent skin issues from wear. CMS Ex. 17 at 11; CMS Ex. 18 Part J at 5; CMS Ex. 41 at 49.

20. On June 11, 2015, Petitioner referred R307 for an occupational therapy evaluation. An Occupational Therapist (OT) stated that R307's splints were an "incorrect fit" and discontinued them. P. Ex. 20 at 5, 11. The OT prescribed two alternative models instead. P. Ex. 20 at 5, 8, 17.

21. On June 17, 2015, R307's clinician established a new timeline for R307 to wear the newly ordered splints as follows: splints on at midnight, off at 6 AM; splints on at 8 AM, off at 2 PM; splints on at 4 PM, off at 10 PM. P. Ex. 20 at 8.

22. On June 19, 2015, and again on June 22, 2015, the OT provided in-service training on the splints - specifically, how to apply the splints, techniques to facilitate proper resident positioning prior to application of the splint, skin integrity checks, laundering and schedules. P. Ex. 20 at 17-18.

July 9, 2015 survey:

23. Resident 416 (R416) is a female born on January 24, 1965. P. Ex. 29 at 1.

24. Petitioner admitted R416 to the facility on November 10, 2014, principally due to chronic airway obstruction; however, she also had numerous other diagnosed maladies. P. Ex. 29 at 1-2.

25. On June 12, 2015, R416's doctor prescribed for her Percocet (i.e., Oxycodone with acetaminophen 5 mg/ 325 mg tablet) by mouth every 4 hours as needed. CMS Ex. 22 Part A at 40; P. Ex. 29 at 17; *see also* CMS Ex. 21 at 14.

26. At approximately 2:15 PM on July 8, 2015, Surveyor Polakoski observed R416 request pain medication from LPN Pollard. LPN Pollard opened his medication cart and gave R416 a Percocet tablet. R416 swallowed the Percocet and immediately left the vicinity. Surveyor Polakoski observed LPN Pollard remain at the nurses' station until 3:00 PM and R416 did not return during this period. CMS Ex. 21 at 14; CMS Ex. 41 at 63; Tr. 11/9 at 301-02, 328-29.

27. Petitioner's policy and procedure for pain assessment requires nursing staff to assess the resident and complete the pain flow record/sheet when a resident identifies that he has pain. Petitioner's policy and procedure requires nursing staff to document the following information in the pain flow record/sheet: date and time, site/location, type of pain, intensity, precipitating/ aggravating, interventions – non-med/ medication, intensity of pain after intervention, side effects, and the nurse's initials. P. Ex. 29 at 30.

28. Petitioner's policy and procedure for oral medication administration requires the nurse to "Chart on nurse's notes: Pertinent observations immediately after administration." CMS Ex. 22 Part A at 9.

29. Surveyor Polakoski reviewed and photocopied the "Pain Flow Sheet" for R416 at 3:00 PM on July 8, 2015. CMS Ex. 41 at 63.

30. The pain flow sheet Surveyor Polakoski photocopied on July 8, 2015, contained only seven entries for medication provided between July 2 and July 6, 2015 and nothing thereafter. CMS Ex. 22 Part A at 33.

31. On July 9, the facility's Director of Nursing and its Regional Director of Clinical Services provided Surveyor Polakoski with a pain flow sheet for R416, but now it contained new entries for July 8, 2015: at 10:30 AM, 2:30 PM, and 6:30 PM. CMS Ex. 22 Part A at 43; CMS Ex. 21 at 14-15; CMS Ex. 41 at 63.

32. The narcotics inventory sheets used to document and track narcotics administration of Percocet to R416 indicated that staff administered Percocet ten times between July 6, 2015 at 10:00 AM and July 8, 2015 at 2:30 PM. CMS Ex. 22 Part A at 44, 45.

33. The narcotics inventory sheets are the most accurate record of Petitioner's Percocet administration to R416. *Cf.* P. Ex. 33 at 10.

34. Between July 1, 2015, at 6:00 AM and July 8, 2015, at 3:00 PM, the narcotics inventory sheets showed that Petitioner administered Percocet 32 times to R416. CMS Ex. 22 Part A at 44-45. However, Petitioner's modified pain flow sheet only reflected that Petitioner administered Percocet to R416 ten times during that period. CMS Ex. 22 Part A at 43. Petitioner did not assess R416 for pain, attempt interventions, assess for effectiveness, and document all on the pain flow sheet as required by its policy 23 out of 32 times during an 8-day period.

35. "[S]pecial risk patients" for Percocet are individuals with severe respiratory impairment, severe renal impairment, or hypothyroidism. CMS Ex. 39 Part A at 44-45. R416 had chronic obstructive pulmonary disease, chronic kidney disease, and hypothyroidism. P. Ex. 29 at 1-2.

36. Resident 405 (R405) is a male born on May 22, 1957. P. Ex. 25 at 1.

37. Petitioner admitted R405 to the facility on April 15, 2014, and then readmitted him after a hospitalization on February 19, 2015. His diagnoses included Down's syndrome, quadriplegia, acute respiratory failure, arthropathy, anxiety, hypertension, hypotension, convulsions, sleep apnea, dementia, and senile dementia with depressive features. He had a tracheotomy and a percutaneous endoscopic gastrostomy (PEG) tube. P. Ex. 25 at 1-2, 70-71.

38. R405's most recent MDS with an assessment reference date of June 12, 2015, indicated that he was not capable of making himself understood or of understanding others. He was not able to speak. Although he could make eye contact, he was not able to follow commands. He expressed anxiety and pain

through facial expressions, restlessness, and involuntary movements. He received all of his nutrition and medication through a PEG tube and received nothing by mouth. P. Ex. 25 at 70-71, 78-79; Tr. 11/18 at 175, 177-178.

39. As early as February 19, 2015, R405's physician ordered that he receive nothing by mouth - including medication. CMS Ex. 22 Part F at 6, 9; P. 25 at 71.

40. On April 9, 2015, R405's doctor drafted a clarification order to administer one tablet "Prednisone 40 mg PO [(by mouth)] daily" for five days. P. Ex. 25 at 10. However, later that day the order was clarified to "via Peg." P. Ex. 25 at 11.

41. On April 15, 205, R405's nurse practitioner ordered Glycopyrrolate three times a day "PO." P. Ex. 25 at 14.

42. R405's May and July physician's order sheets reiterate the error that R405 is to receive Glycopyrrolate "by mouth." CMS Ex. 22 Part F at 6, 9.

43. On June 17, 2015, R405's doctor ordered 0.5 mg Clonazepam to be administered "by mouth" at bedtime for seizures. CMS Ex. 22 Part F at 6, 9.

44. R405's July physician's order sheet reiterates the error that R405 is to receive Clonazepam "by mouth." CMS Ex. 22 Part F at 6, 9.

45. In May, June and July, 2015, Petitioner's nursing staff initialed that they provided R405 with Glycopyrrolate "by mouth," and in July, Clonazepam "by mouth." P. Ex. 25 at 44, 50, 58. Petitioner's staff did not actually follow the doctor's orders and provided the medication to R405's via his PEG tube.

46. Petitioner did not obtain a modified physician order for the medications to be administered by PEG tube until after the surveyors brought the error to Petitioner's staff's attention. Tr. 11/10 at 139-40; P. Ex. 25 at 92.

47. Had Petitioner's staff followed the doctor's order to administer the medication by mouth, R405 could have aspirated, resulting in harm. CMS Ex. 43 at 23.

IV. Conclusions of Law and Analysis[7]

My conclusions of law are in italics and bold.

[7] I have not discussed every deficiency appearing in the June and July Statements of Deficiencies because the deficiencies I uphold below are more than sufficient to justify the remedies CMS imposed. *See Claiborne-Hughes Health Ctr.*, 609 F.3d 839, 847 (6th Cir. 2010); *Carrington Place of Muscatine*, DAB No. 2321 at 20-21 (2010).

1. The deficiencies cited at Petitioner's facility in the surveys that concluded on January 8, 2015, March 2, 2015, and April 30, 2015, are administratively final because Petitioner did not contest them.

As previously noted, Petitioner does not contest the deficiencies cited in the surveys concluding January 8, 2015, March 2, 2015, and April 30, 2015, and, therefore, the deficiencies and related remedies are administratively final. Accordingly, it is not at issue in this case that Petitioner was not in substantial compliance beginning on January 8, 2015, through the April 30, 2015 survey.

2. Petitioner failed to demonstrate that it returned to substantial compliance by June 2, 2015.

Petitioner argues that, while it does not challenge the deficiencies identified in the April 30, 2015 survey, it corrected all of the deficiencies identified in that survey by June 2, 2015, several days before the revisit survey that concluded on June 11, 2015.

In asserting its return to substantial compliance by June 2, 2015, Petitioner relies on the following: the state agency approved Petitioner's plan of correction (P. Ex. 7) in which Petitioner asserted it would correct all deficiencies by June 2, 2015; the state agency concluded at the end of the June 11, 2015 revisit survey that Petitioner corrected a number of the deficiencies identified in the April 30, 2015 survey by June 2, 2015 (P. Ex. 8); CMS did not specifically find that all of the deficiencies from the April 30, 2015 survey were not corrected; and Petitioner submitted evidence in this proceeding of its return to compliance by June 2, 2015. P. Post Hrg. Br. at 6-8.

I conclude that Petitioner's arguments are not availing. "Under the regulations, the mere submission of a [plan of correction] d[oes] not establish that any cited deficiencies had been corrected." *Hermina Traeye Memorial Nursing Home*, DAB No. 1810 (2002). Although CMS had the option of accepting that Petitioner corrected all deficiencies under a plan of correction without conducting an additional survey, CMS did not do this here. 42 C.F.R. §§ 488.454(a)(1), 488.401.

The April 30, 2015 survey identified the following deficiencies at the D level of scope and severity or higher: 42 C.F.R. § 483.10(n) (F176); 42 C.F.R. § 483.15(h)(1) (F252); 42 C.F.R. §§ 483.20(d)(3), 483.10(k)(2) (F280); 42 C.F.R. § 483.20(k)(3)(i) (F281); 42 C.F.R. § 483.25 (F309); 42 C.F.R. § 483.25(a)(3) (F312); 42 C.F.R. § 483.25(c) (F314); 42 C.F.R. § 483.25(g)(2) (F322); 42 C.F.R. § 483.25(h) (F323); 42 C.F.R. § 483.25(k) (F328); 42 C.F.R. § 483.25(m)(2) (F333); and 42 C.F.R. § 483.65 (F441). CMS Ex. 13 Parts A, B. During the June 11, 2015 revisit survey, the state agency determined that Petitioner corrected the following deficiencies as of June 2, 2015: 42 C.F.R. § 483.10(n) (F176); 42 C.F.R. § 483.15(h)(1) (F252); 42 C.F.R. §§ 483.20(d)(3), 483.10(k)(2) (F280); 42 C.F.R. § 483.20(k)(3)(i) (F281); 42 C.F.R.

§ 483.25(a)(3) (F312); 42 C.F.R. § 483.25(c) (F314); and 42 C.F.R. § 483.25(h) (F323). CMS Ex. 33 at 3. However, the state agency determined that five deficiencies from the April 30, 2015 survey remained uncorrected: 42 C.F.R. § 483.25 (F309); 42 C.F.R. § 483.25(g)(2) (F322); 42 C.F.R. § 483.25(k) (F328); 42 C.F.R. § 483.25(m)(2) (F333); and 42 C.F.R. § 483.65 (F441). CMS Ex. 17 at 1, 5-8, 12-27. Further, CMS expressly adopted the state agency's findings that Petitioner did not correct those five deficiencies. P. Ex. 4 at 2. Therefore, it is clear that CMS concluded that Petitioner had not corrected all of the deficiencies from the April 30, 2015 survey by June 2, 2015.

Petitioner also asserts that it submitted evidence (P. Exs. 9-16), including written testimony (P. Ex. 33 at 2; P. Ex. 34 at 1-6), of the action that it took to correct the deficiencies from the April 30 survey by June 2, 2015. P. Post Hrg. Br. at 7-8. However, a review of Petitioner's evidence reveals that it fails to demonstrate that Petitioner returned to substantial compliance by June 2, 2015. Almost all of the evidence, including the witness testimony, is directed at the efforts made to correct the deficiencies for which the state agency found that Petitioner had returned to substantial compliance by June 2, 2015 (i.e., the corrected deficiencies listed in CMS Ex. 33 at 3). "[O]nce a facility has been found to be out of substantial compliance, it remains so until it affirmatively demonstrates that it has achieved substantial compliance once again." *Premier Living & Rehab Ctr.*, DAB No. 2146, at 23 (2008). This, Petitioner plainly failed to do. Therefore, I conclude Petitioner did not return to substantial compliance by June 2, 2015.

3. Petitioner was not in substantial compliance with Medicare program participation requirements based on the survey concluding on June 11, 2015.

a. Petitioner was not in substantial compliance with 42 C.F.R. § 483.25 (F309) and subsection (m)(2) (F333) because Envoy did not provide R312 the necessary care and services to manage his diabetes when its staff failed to administer the proper long-acting diabetes medication for more than four days and, at the same time, failed to administer the correct dose of the short-acting diabetes medication, constituting a significant medication error.[8]

Petitioner admitted R312, a 50-year-old man, on June 3, 2014 for treatment of uncontrolled diabetes, cerebrovascular disease with hemiplegia of his left side, an aortic valve replacement, peripheral vascular disease, hypertension, depression, and pressure ulcers, among other issues. He had osteomyelitis with gangrene of his left foot, which required amputation at some point after admission. P. Ex. 18 at 1-3; P. Post-Hrg. Br. at 12; CMS Ex. 18 Part D at 33-34.

[8] Both F309 and F333 were repeated violations from the April 30, 2015 survey. CMS Ex. 13 Part A at 40-49; CMS Ex. 13 Part B at 19-30. The F333 deficiency from that survey also involved a failure to administer diabetic medication. CMS Ex. 20 Part A at 1.

By November 2014, R312 had an extensive regimen to treat his diabetes. He was receiving rapid-acting insulin (Novolog), intermediate-acting insulin (Novolin N), and long-acting insulin (Levemir). Specifically, his physician ordered:

- Novolog at 6:30 AM (rapid-acting) every morning, based on a sliding scale,
- 30 units of Levemir (long-acting) at 9 AM every morning,
- 30 units of Novolin (intermediate-acting) at 9 AM every morning,
- Novolog at 4:30 PM every evening based on a sliding scale, and
- 20 units of Novolin at 9 PM every evening.

CMS Ex. 18 Part D at 30-31, 41-42; P. Ex. 18 at 5. On June 2, 2015, Dr. Thompson determined that Petitioner's diabetes was "poorly controlled" and changed R312's regimen; he discontinued the Novolin, and increased the amount of Levemir from 30 units once a day, to 40 units twice a day and his Novolog sliding scale remained the same. CMS Ex. 18 Part D at 30, 31, 32, 33, 34, 39. During the revisit survey that ended on June 11, 2015, the surveyors found the following, as described in the Statement of Deficiencies under violations of both 42 C.F.R. § 483.25 (F309) ("Provide Care/Services for Highest Well Being") and 42 C.F.R. § 483.25(m)(2) (F333) ("Resident Free of Significant Med Errors"):

> Resident #312's clinical record was reviewed. Included was a physician progress note dated 6/2/15. The "Assessment and Plans" section read "1) DM2 (diabetes mellitus)-ongoing-poorly controlled." "Levemir 40 u (units) q12h (every 12 hours". A telephone order dated 6/2/15 read "D/C (discontinue) current Levemir" "start Levemir 40 u (units) q12h (every 12 hours").
>
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>
> The June 2015 Medication Administration Record (MAR) was reviewed. The current order for Levemir (30 units) was discontinued on 6/2/15. The new order for Levemir (40 units) was not started until 6/7/15. Resident #312 did not receive Levemir for 4 days.
>
> Resident #312 had a physician order dated 7/4/14 for Novolog sliding scale insulin. The sliding scale read, "Sliding scale blood sugar at 6:30 a.m. & 4:30 p.m. 200-299 give 3 units subq (subcutaneous): 300-399 give 5 units subq: 400 units or above give 7 units subq: And call MD".

> On 6/3/15, 4:30 p.m., Resident #312's blood sugar was documented as 389 on the June 2015 MAR. It was documented that 7 units of insulin was administered at this time. According to the sliding scale order, Resident #312 should have received 5 units of insulin. Resident #312 received 2 extra units of insulin.
>
> On 6/10/15 at 2:30 p.m., the issue with the wrong amount of sliding scale insulin was reviewed with 3rd Floor Assistant Director of Clinical Services (RN A). She agreed that the wrong amount was administered stating "I see what you mean."

CMS Ex. 17 at 6-7, 22-23.

In response to this, Petitioner stated that "CMS' factual allegations basically are true" and that "it is true that a nurse confused her transcription of [Dr. Thompson's June 2, 2015] order in a way that the Resident was not administered any Levemir for all four days (at which point a Center audit found and corrected the error)." P. Post-Hrg. Br. at 12-13. Petitioner does challenge the conclusion that its actions are substantial noncompliance.

Petitioner argues that its failure to give eight consecutive doses of long acting insulin (Levemir) and its administration of the incorrect dose of short acting insulin (Novolog) did not result in the potential for more than minimal harm. P. Post-Hrg. Br. at 12. Petitioner asserts that its staff continued to make routine blood sugar checks on R312 and that during the time Petitioner did not administer the Levemir, R312's blood sugar levels remained in the same general range of the preceding weeks. P. Post-Hrg Br. at 13. For this argument, Petitioner relies primarily on the testimony of Dr. Thompson, Petitioner's medical director and the physician who ordered the June 2, 2015 changes. P. Ex. 38 at 4. Dr. Thompson testified that the facility's errors did not result in the potential for more than minimal harm to R312 because facility staff was closely monitoring his blood sugar, staff was still administering short-term insulin, and his blood sugar never rose to the point that necessitated informing the doctor. P. Ex. 18 at 28-29; P. Ex. 38 at 4; Tr. 11/10 at 314, 318, 320. Dr. Thompson also thought it insignificant that Petitioner administered too much Novolog to R312. P. Ex. 38 at 5.

The quality of care regulation requires that the facility provide the necessary care or services to attain or maintain "the highest practicable physical, mental, and psychosocial well-being, in accordance with the comprehensive assessment and plan of care." 42 C.F.R. § 483.25; *see also* Act § 1819(b)(2), 42 U.S.C. § 1395i-3. The "quality-of-care" regulation also requires that the facility "ensure" that its "r[e]sidents are free of any significant medication errors." 42 C.F.R. § 483.25(m)(2).

A "medication error may be significant if it 'jeopardizes' - that is, has the potential to harm - the resident's health." *Life Care Ctr. of Tullahoma*, DAB No. 2304, at 44 (2010) (emphasis in the original). No showing of actual harm to a resident is necessary to conclude that an error is significant. *Id*.; *Northern Montana Care Ctr*., DAB No. 1930 (2004); *Rosewood Care Ctr. of Peoria*, DAB No. 1912 (2004).

CMS's State Operations Manual (SOM) provides the following framework for considering potential violations of 483.25(m)(2):

> Resident Condition - The resident's condition is an important factor to take into consideration. For example, a fluid pill erroneously administered to a dehydrated patient may have serious consequences, but if administered to a resident with a normal fluid balance may not. If the resident's condition requires rigid control, a single missed or wrong dose can be highly significant.
>
> Drug Category - If the medication is from a category that usually requires the patient to be titrated to a specific blood level, a single medication error could alter that level and precipitate a reoccurrence of symptoms or toxicity. This is especially important with a medication that has a Narrow Therapeutic Index (NTI) (i.e., a medication in which the therapeutic dose is very close to the toxic dose) . . . .
>
> Frequency of Error - If an error is occurring with any frequency, there is more reason to classify the error as significant. For example, if a resident's medication was omitted several times . . ., classifying that error as significant would be in order. This conclusion should be considered in concert with the resident's condition and the drug category.

SOM, App. PP (tag 333).

Based on applying the law to the facts in this case, I conclude that Petitioner was not in substantial compliance with 42 C.F.R. §§ 483.25 (F309) and 483.25(m)(2) (F333). As indicated above, on June 2, 2015, Petitioner's staff discontinued the administration of 30 units of Levemir, 30 units of Novolin at 9 AM and 20 units of Novolin at 9 PM to R312, and failed to implement the order for 40 units of Levemir at 9 AM and 40 units of Levemir at 9 PM until June 7, 2015. As such, Petitioner did not provide R312 with either a morning or an evening dose of the increased dosage and frequency of the long-acting

insulin. Therefore, R312 was only receiving the short acting insulin twice a day:

- Novolog at 6:30 AM every morning based on a sliding scale, and
- Novolog at 4:30 PM every evening based on a sliding scale.

CMS Ex. 18 Part D at 30. Further, the evidence shows that during the period when facility staff failed to treat R312's diabetes properly, they also failed to administer the correct dose of Novolog. *See* Tr. 11/9 at 359. On June 3, 2015, staff documented R312's blood sugar as 389. According to the doctor's order, staff was to administer five units of insulin. However, facility staff administered seven units of insulin. CMS Ex. 17 at 5-8, 21-23; CMS Ex. 18 Part D at 30; CMS Ex. 41 at 37.

CMS's expert witness, Dr. Lesesne, provided specific testimony as to each of the SOM's three factors quoted above. Dr. Lesesne stated that R312's condition involved poorly controlled type 2 diabetes, which had already led to "serious complications due to the diagnosis (coronary artery disease, peripheral vascular disease, left foot osteomyelitis) which reflected the severity of his diabetes . . . . As a result, it was extremely important that Envoy nursing staff implement physician orders correctly regarding the management of Resident 312's diabetes." CMS Ex. 41 at 6. As to the drug category involved, Dr. Lesesne testified that both Levemir and Novolog are indicated for glycemic control and that "the failure to administer these medications or the administration of the incorrect dosage may result in the failure to control the individual's blood glucose levels." CMS Ex. 41 at 6. Finally, Dr. Lesesne testified that the frequency of the error of four straight days involving two medications (Levemir and Novolog), which were meant to act in concert with each other, "increased the resident's risk of out of control blood sugar levels because it was not an isolated error." CMS Ex. 41 at 6.

In regard to R312's blood sugar level, Dr. Lesesne explained that monitoring a resident does not alleviate the risk of harm that can result from the failure to administer a long-acting medication because it *does nothing to prevent, manage, or control* "wide swings" in blood sugar levels. Tr. 11/18 at 364-365. Dr. Lesesne explained that monitoring a resident would only alert the staff of these "wide swings" after they have already occurred. *Id*. at 365. Indeed, providing some treatment to R312 is better than providing no treatment. However, as Dr. Lesesne explained: "[I]t's like having a car going down the road. There are guardrails to keep you out of a critical care situation, but it's not anywhere close to control." *Id*. at 366. Non-critical, but out of control blood sugar can lead to severe consequences. Dr. Thompson conceded that an "extremely elevated blood sugar level can cause in a patient lethargy and nausea, especially if the patient is not accustomed to elevated blood sugar levels." Tr. 11/10 at 322. However, in the context of R312's condition, Petitioner's failure to administer the proper medication could have led to hyperglycemia or hypoglycemia. Hyperglycemia, or elevated blood glucose levels, can cause dehydration, low blood pressure, altered mental status and could exacerbate R312's complications from diabetes, including coronary artery disease and peripheral

vascular disease. CMS Ex. 41 at 6. Hypoglycemia, or low blood glucose levels, could cause confusion, weakness, flushing/sweating, coma, and even death. CMS Ex. 41 at 6. I accept Dr. Lesesne's opinion and conclude that Petitioner's medication errors regarding R312 posed a potential for more than minimal harm to R312. Dr. Thompson's conclusion that Petitioner's failure to administer both the long and short acting medications did not cause the potential for minimal harm is not persuasive, especially since Dr. Thompson thought R312's condition required his intervention on June 2, 2015, to change the administration of the Levemir and Novolog. Dr. Lesesne explained that Dr. Thompson ordered both the short acting and the long acting medications to act in concert to improve R312's glycemic control. He notes that errors implementing both medications reduced the medication's effectiveness in controlling R312's diabetes. CMS Ex. 41 at 6. In the context of R312's condition, Dr. Thompson himself termed R312's diabetes as "poorly controlled." CMS Ex. 18 Part D at 34. I do not believe that Dr. Thompson would note R312's "poorly controlled" diabetes and change R312's insulin medication by increasing the long-acting medication substantially if it were not necessary. I find it unlikely that a failure to provide 40 units of Levemir twice daily would be negligible to a diabetic, let alone to R312. Therefore, I conclude that Petitioner was not in substantial compliance with 42 C.F.R. §§ 483.25, 483.25(m).

b. Petitioner was not in substantial compliance with 42 C.F.R. § 483.25(e)(2) (F318) when it failed to provide properly fitting splints to R307 to increase his range of motion or prevent further decrease in range of motion, but instead left him with ill-fitting splints, and painful and exacerbated contractures.

R307 was born on July 24, 1947, and was admitted to Petitioner's facility on November 20, 2012. P. Ex. 20 at 1. R307 was at Petitioner's facility for treatment of his medical conditions including Parkinson's disease, cerebrovascular accident, joint contractures, paralysis agitans, seizure disorder, depression, and dementia. P. Ex. 20 at 1-2, 11; CMS Ex. 18 Part I at 43.

A joint contracture is a serious condition. With a joint contracture, there "is a decrease in angle in the joint. As the joint becomes contracted, the extremity or the body part will move toward the midline and become frozen." Tr. 11/10 at 211. Apparently in an effort to combat this problem, on September 17, 2014, Petitioner's staff commenced providing R307 with braces for his left arm and left elbow. CMS Ex. 18 Part J at 5. However, there was no other documentation about the splints from 2014. Tr. 11/10 at 211-12. Further, when the surveyors reviewed R307's care plan, it only mentioned splints with regard to his wound care plan and the wound care plan only referenced that there were "splints to left hand and left elbow," but added no further information such as application times when they were to apply them or even how to assure proper fitting to prevent contractures and any related skin issues. CMS Ex. 18 Part J at 5; CMS Ex. 17 at 11. Although there was an evaluation on April 14, 2015, the documentation of this evaluation

contained nothing about the elbow splint and only barely referenced R307's hand splint. However, on April 17, 2015, a physician ordered that splints for R307's left hand and left elbow be worn from 10:00 AM until 4:00 PM as tolerated and as needed. CMS Ex. 18 Part J at 5, 7; P. Ex. 20 at 3.

Upon request of Surveyor Wilburn, Petitioner's administrator and DON provided the manufacturer's instructions for the wrist splint, but did not provide instructions for the elbow splint. CMS Ex. 41 at 48. The hand splint manufacturer's instructions stated the splint was to treat contractures in the fingers, hand, and wrist, through progressive static positioning. The device featured supportive positioning to prevent contractures of flaccid hands and wrists. CMS Ex. 18 Part I at 35. The hand splint was physically extensive; it encased R307's entire forearm, extending from under his fingers to his antecubital space. CMS Ex. 17 at 9; Tr. 11/9 at 375-376.

Both Surveyors Garrett and Wilburn testified that throughout the survey, they observed R307 either not wearing both splints or wearing improperly applied splints. CMS Ex. 41 at 37-38 (Garrett Decl.), 47-50 (Wilburn Decl.); CMS Ex. 17 at 8-11; Tr. 11/9 at 367-369, 371-372, 374-76; Tr. 11/10 227-28. On June 9 at 2:10 PM, Surveyor Garrett, a Registered Dietitian, observed R307 without a hand splint. *Id.*; CMS Ex. 18 Part I at 60. R307 was wearing an elbow splint but Surveyor Garrett described it as so loose that it could essentially spin around his arm; she could fit the width of a hand between the splint and the resident's arm and there would still be room for the splint to rotate around his arm freely. *Id.*; CMS Ex. 18 Part I at 33.

On June 10, 2015, both Surveyors Garrett and Wilburn observed R307 wearing the hand splint appropriately, but the elbow splint loose and unsupportive. At noon, Surveyor Wilburn observed R307 wearing the hand splint, but described the elbow splint similarly loose as Surveyor Garrett described the previous day. Namely, Surveyor Wilburn testified that staff applied the Velcro straps "so loose that it could easily be moved in a full circle around the resident's arm and there was a space between the resident's arm and the splint that was so large the width of a hand could fit in the space." CMS Ex. 41 at 49. She explained that staff applied the splint so loose that it did not even stabilize R307's elbow. In addition, staff applied the elbow splint not to R307's elbow, but midway between R307's shoulder and elbow joints, rendering the splint useless. *Id.*; CMS Ex. 18 Part I at 33 (surveyor's drawing of elbow splint placement); CMS Ex. 41 at 37-38; CMS Ex. 17 at 10-11. Later that day at 2:30 PM, both surveyors Garrett and Wilburn observed R307 with the splints essentially unchanged from Surveyor Wilburn's observation at noon. CMS Ex. 41 at 37-38, 48-49; CMS Ex. 17 at 10; Tr. 11/9 at 371-372.

On June 10, Surveyor Wilburn interviewed facility staff about the observed problems with the splints. When she asked LPN A about the issue, LPN A responded: "They are not on right, the CNA's put them on." Surveyor Wilburn next interviewed CNA A, who applied the splints. CNA A explained, "the wrist splint is so long that the elbow splint

doesn't fit right over it." CMS Ex. 17 at 11; CMS Ex. 20 Part B at 13; CMS Ex. 41 at 49; Tr. 11/10 at 218. Both the LPN and CNA conceded that they had not notified the therapy department to address the problem. *Id*. Significantly, Petitioner did not submit written testimony from either LPN A or CNA A to dispute the surveyors documented statements of these two individuals.

On June 11, Surveyor Wilburn observed a fourth incidence where Envoy's staff failed to apply R307's splints properly. She testified that the splint was in the same position as the prior to observations. CMS Ex. 17 at 10-11; CMS Ex. 41 at 48-49. These observations form the factual basis for a deficiency under 42 C.F.R. § 483.25(e)(2) (F318) of the quality of care regulation that requires that an SNF ensure that a "resident with a limited range of motion receives appropriate treatment and services to increase range of motion and/or to prevent further decrease in range of motion." 42 C.F.R. § 483.25(e)(2).

Petitioner primarily argues in opposition to this deficiency that the observation of Surveyor Garrett is unreliable because she is not a nurse. P. Post-Hrg Br. at 16-17. However, Surveyor Garrett was the sole witness to only one of the four occurrences of problems noted with R309's splints. In any event, although she may not be an expert in splint fitting, she can observe whether a resident is wearing a splint on his hand, which he was not. Further, she can observe if an elbow splint is so loose that it is obviously incorrect, even to an untrained eye. Importantly, Surveyor Wilburn, a registered nurse with extensive experience, several times observed similar problems with R307's splints and, thus, validated Surveyor Garrett's concerns.

Petitioner also asserts that its staff correctly applied the splints, but that R307 was responsible for removing his splints, whether intentionally or just by moving his arm, and that there was not a violation because the physician's order was for R307 to wear the splints "as tolerated" or "as needed." P. Post-Hrg. Br. at 16-17; P. Reply at 8-9. Petitioner's witnesses, Ms. Springer and Ms. Hirn testified that R307 asked for the splints to be removed because they were uncomfortable or removed them himself. P. Ex 37 at 1; Tr. 11/18 at 240.

Although Ms. Springer and Ms. Hirn testified that Petitioner's lack of compliance with a physician's order to wear the splints would be documented (Tr. 11/10 at 264; Tr. 11/18 at 239-40), Petitioner provides no such documentation to support its contention that Petitioner regularly asked to have the splints removed or that he removed them himself. Further, it is questionable that R307 had the fine motor control to remove the splints himself. Tr. 11/10 at 241.

Petitioner's staff admitted and the surveyors' observations showed that not only did the staff apply the elbow splint improperly, but that it was not even possible to apply it properly because both splints could not be applied at the same time. CMS Ex. 17 at 11; CMS Ex. 20 Part B at 13; CMS Ex. 41 at 49; Tr. 11/10 at 218. This is consistent with the

June 11, 2015 OT evaluation of R307. The OT determined that R307 presented with "progression of flexor tone abnormality [related to the] disease processes of Parkinson['s Disease] and Cerebral Vascular Disease causing inability to tolerate and **incorrect fit** of [left upper extremity] orthotics." P. Ex. 20 at 11 (emphasis added). The OT evaluated R307's range of motion. P. Ex. 20 at 17. The OT discontinued the prior elbow and wrist splints and prescribed two alternative models. P. Ex. 20 at 5, 8. The OT ordered staff to apply the new splints three times a day. Therefore, even if Petitioner sought to remove his splints, he did so because they did not fit him. If the movement of his arms caused the splints to loosen, then Petitioner's staff should have addressed this immediately.

When the splints were not fitting together correctly, the staff should have sought the expertise of a therapist who could properly assess R307. Instead, they simply applied the elbow splint so loose that it fit more like a "bracelet." Tr. 11/10 at 218. By not addressing R307's contractures, the facility caused the potential for more than minimal harm. Surveyor Wilburn stated that in her expert option, the facility's failure to apply R307's splints correctly deprived R307 of the "therapeutic benefit of treatment/intervention for [R307's] contractures which could result in a decrease in range of motion and the further development and progress of the contractures. Additionally, the facility's failure to properly address [R307's] hand and elbow contractures may result in an increased risk of pressure ulcers due to chafing of skin on the fingers from hand contractures and the chafing of skin on the elbow/arm to body." CMS Ex. 41 at 50. In fact, after reading the therapy evaluation, Surveyor Wilburn went a step further stating that she would have increased the scope and severity of the citation. Tr. 11/10 at 216.

Unfortunately, Petitioner waited until the surveyors brought it to their attention to address the issue. The chart reflects that R307's condition had declined. Once the OT conducted a thorough assessment, the therapist changed to different wrist and elbow splints, different application cycles, and noted decreased range of motion. The therapist noted that his impairments were exacerbated, the splints did not fit correctly, and R307 experienced pain in his extremity which also needed to be addressed with not only new splints but training in pain management techniques. P. Ex. 20 at 11. The appropriate treatment was an altogether different set of splints, and to treat his now deteriorated condition through a significant increase in the length of time R307 was to wear them – from six to *eighteen hours* a day. P. Ex. 20 at 8. Petitioner did not provide the needed care and services to treat R307's contractures and to prevent them from worsening. It is clear that Petitioner was not providing appropriate treatment and services to increase R307's range of motion and/or to prevent further decrease in his range of motion.

As stated above, section 483.25(e)(2) (F318) of the quality of care regulation requires that an SNF ensure that a "resident with a limited range of motion receives appropriate treatment and services to increase range of motion and/or to prevent further decrease in range of motion." 42 C.F.R. § 483.25(e)(2). Based on the evidence before me, I conclude that Petitioner was not in substantial compliance with that regulation.

4. Petitioner was not in substantial compliance with Medicare program participation requirements based on the survey concluding on July 9, 2015.

a. Petitioner was not in substantial compliance with 42 C.F.R. § 483.25 (F309) when staff administered pain medication to R416 without first assessing for pain and attempting non-pharmacological interventions in accordance with Petitioner's policy, and when Petitioner failed to monitor the effectiveness of pain medication administered to R416 and to maintain adequate records of the amount of pain medication administered to R416.

As previously explained, the quality-of-care regulation requires the facility to provide the necessary care and services to residents to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the resident's comprehensive plan of care. Act § 1819(b)(2), 42 U.S.C. § 1395i-3; 42 C.F.R. § 483.25. The intent is for the facility to ensure that each resident obtains optimal improvement or does not deteriorate within the limits of a resident's right to refuse treatment, and within the limits of recognized pathology and the normal aging process.

The quality of care legislative and regulatory requirements are "based on the premise that the facility has (or can contract for) the expertise to first assess what each resident's needs are (in order to attain or maintain the resident's highest practicable functional level) and then to plan for and provide care and services to meet the goal." *Spring Meadows Health Care Ctr.*, DAB No. 1966, at 16 (2005). The regulation thus "imposes on facilities an affirmative duty designed to achieve favorable outcomes to the highest practicable degree." *Windsor Health Care Ctr.*, DAB No. 1902, at 16-17 (2003), *aff'd, Windsor Health Ctr. v. Leavitt*, 127 F. App'x 843 (6th Cir. 2005). The facility must take "reasonable steps" and "practicable measures to achieve that regulatory end." *Clermont Nursing & Convalescent Ctr.*, DAB No. 1923, at 21 (2004), *aff'd, Clermont Nursing & Convalescent Ctr. v. Leavitt*, 142 F. App'x 900 (6th Cir. 2005).

A failure to follow a resident's plan of care that is based on the comprehensive resident assessment is a clear case of failing to meet the requirements of 42 C.F.R. § 483.25. *Cedar Lake Nursing Home*, DAB No. 2288, at 6-7, 10 (2009), *aff'd, Cedar Lake Nursing Home v. U.S. Dep't of Health & Human Servs.*, 619 F.3d 453 (5th Cir. 2010); *Spring Meadows Health Care Ctr.*, DAB No. 1966, at 17 (2005). Further, the language of 42 C.F.R. § 483.25 not only requires skilled nursing facilities to furnish the care and services set forth in a resident's care plan, but also to implement doctors' orders, monitor and document the resident's condition, and follow its own policies. *See, e.g., Alexandria Place*, DAB No. 2245 (2009) (upholding this deficiency when a petitioner did not provide care in accordance with a doctor's order); *Oxford Manor*, DAB No. 2167, at 5-6 (2008) (affirming an ALJ's reliance on a facility's policy as evidence of the standard of care the facility expected its staff to provide, noting "if facility staff exercise professional

judgment in deciding not to follow facility policy with respect to a particular resident, they document that judgment and give a reason why not. In the absence of such contemporaneous documentation, it is certainly reasonable to infer, when staff do not follow the policy, either they are not aware of it or that they are simply disregarding it."); *Spring Meadows Health Care Ctr*., DAB No. 1966, at 17 ("[T]he clearest case of failure to meet [section 483.25] is failure to provide one of the specific services outlined in the subsections or failure otherwise to follow the plan of care based on the comprehensive resident assessment. . .").

Petitioner admitted R416, a 50-year-old female, to the facility on November 10, 2014. P. Ex. 29 at 1-2. Her diagnoses included past stroke, chronic obstructive pulmonary disease, history of falls, chronic pain, coronary artery disease, psychosis, chronic kidney disease, depression, diabetes, anemia, and hypothyroidism. P. Ex. 29 at 1-2. She had no cognitive impairment, but was completely dependent on facility staff for activities of daily living. CMS Ex. 22 Part A at 5-50. R416's doctor prescribed her: "Oxycodone/APAP [acetaminophen] 5 mg/ 325 mg Tablet . . . Percocet 1 [tablet] by mouth[,] every 4 hours as needed . . . ." CMS Ex. 21 at 14; *see* CMS Ex. 22 Part A at 40; P. Ex. 29 at 17, 18.

Surveyor Polakoski testified that at 2:15 PM on July 8, 2015, he observed R416, who was in her wheelchair, approach LPN Pollard and request "pain medication." LPN Pollard responded by opening his medication cart and giving R416 a Percocet tablet. R416 swallowed the Percocet and immediately left the vicinity by taking the elevator to a different floor of the facility. Surveyor Polakoski observed LPN Pollard remain at the nurses' station until 3:00 PM. Surveyor Polakoski did not observe further interaction between R416 and LPN Pollard and R416 did not return to the area during this period. CMS Ex. 21 at 13-20; CMS Ex. 41 at 63; Tr. 11/9 at 301-02, 328-29.

Petitioner's policy and procedure for pain assessment is contained in the record. That policy instructs the nursing staff to complete the pain flow record when a resident has identified they have pain. Petitioner instructs its staff to include the following information in the pain flow record (P. Ex. 29 at 30):

- date and time,
- site/location,
- type of pain,
- intensity,
- precipitating/ aggravating,
- interventions – non-med/ medication,
- intensity of pain after intervention,
- side effects, and
- the nurse's initials.

However, Petitioner did not follow its policy and procedure when treating R416.

Surveyor Polakoski further testified that at 3:00 PM, he reviewed and copied the "Pain Flow Sheet" for R416. CMS Ex. 41 at 63. The facility's policy and procedure explains that the purpose of the pain flow record is to document nursing's assessment of a resident's pain, non-pharmaceutical interventions attempted, and the effectiveness of both pharmaceutical and non-pharmaceutical interventions. P. Ex. 29 at 30. In addition, it is to assure non-pharmaceutical interventions are utilized and as a reference for past successful or unsuccessful interventions. *Id*. However, R416's pain flow sheet did not contain any entries regarding pain assessment, non-pharmaceutical interventions, their effectiveness, or the administration of the Percocet at 2:15 PM or its effectiveness. In fact, the last entry was from July 6, 2015 at 10:00 AM. CMS Ex. 22 Part A at 33.

On July 9, 2015 at 9:30AM Surveyor Polakoski interviewed Petitioner's Director of Nursing, Sherri Stith, and the Regional Director of Clinical Services, Melinda Hirn. They provided the surveyor with the pain flow sheet for R416; however, the document now contained three entries on July 8, 2015, which documented pain levels and interventions. CMS Ex. 22 Part A at 43. Surveyor Polakoski showed them the original pain flow sheet he copied the previous day, which did not contain any entries on July 8, 2015. *Compare* CMS Ex. 22 Part A at 33 (as of July 8) *with* 43(as of July 9). The staff had no comment. CMS Ex. 21 at 14-15; CMS Ex. 41 at 63.

Surveyor Polakoski conducted a review of the narcotics inventory sheets used to document and track narcotics administration of Percocet for R416. CMS Ex. 22 Part A at 44, 45. These forms indicated that staff administered R416 Percocet nine times between July 6, 2015 at 10:00 AM and July 8, 2015 at 2:30 PM. *Id*. Yet, the pain flow sheet did not reflect that the facility conducted pain assessments during that period. CMS Ex. 22 Part A at 33 (pain flow sheet obtained on July 8, 2015).

LPN Pollard, who administered the medication in front of the surveyor, completed a witness statement on July 9, 2015. P. Ex. 29 at 25. LPN Pollard states that R416 came to him at approximately 12:45 PM "complaining of pain in her neck and various other places" and requested pain medication. *Id*. "But due to the medication being administered at 10:30 AM it was too soon for her to receive it." *Id*. LPN Pollard explains, "The order for medication is [every four hours]. [R416] left and came back to the cart at [2:30 PM] and requested . . . the medication once again. And the medication was administered at [that] time." *Id*. Except to the extent that the alleged administration of pain medication at 10:30 AM was not documented, I find this contemporaneous witness statement believable. LPN Pollard asserts that R416 requested medication, but the LPN could not provide it to R416 until four hours had passed between doses. LPN Pollard says nothing about assessing R416 or attempting alternative interventions either at 12:45 PM or at 2:30 PM. I assume that had LPN Pollard conducted an assessment or

attempted alternative interventions, he would have included that information in his witness statement.

Several days later, on July 13, 2015, LPN Pollard completed a formal statement that he signed under penalty of perjury. P. Ex. 29 at 26-27. In this new statement, LPN Pollard asserted that when R416 complained of pain at 12:45 PM, he physically assessed R416 in her room where he "observed a boil under her arm." P. Ex. 29 at 26. Also in this statement, LPN Pollard asserts that he repositioned R416 as a non-pharmacological intervention to manager her pain at that time. However, Petitioner does not provide any contemporaneous nursing notes documenting his assessment, interventions, and effectiveness, and there is nothing indicating that R416 even had a boil. Importantly, Petitioner did not offer LPN Pollard as a witness and CMS did not have the opportunity to cross-examine him on his purported statement. I find LPN Pollard's July 13, 2015 statement to be unsupported by the record. Both statements do indicate that LPN Pollard only attempted alternative interventions prior to 2:30 PM because, essentially, the physician order did not allow him to administer another does until 2:30 PM.

R416's clinical record likewise did not reveal documentation indicating that staff regularly conducted pain assessments and or followed-up to see if interventions were effective, even though Petitioner had a care plan to address R416's chronic pain. P. Ex. 29 at 3-7, 9-10. The care plan identified a number of non-pharmaceutical interventions including: "Identify previous pain history and management of that pain and impact on function. Identify previous response to analgesia including pain relief, side effects and impact on function."; "Monitor & report to Nurse, resident complaints of pain or requests for pain treatment."; and "Observe and report changes in usual routine, sleep patterns, decrease in functional abilities, decrease [range of motion], withdrawal or resistance to care to (specify physician and/or hospice nurse)." CMS Ex. 22 Part A at 12-13.

Additionally, R416's care plans identified non-pharmacological interventions including sitting in the porch in warm sun; participation in activities; and repositioning her. CMS Ex. 22 Part A at 14, 19. Staff even documented other interventions that were successful in the past. Specifically, participating in activities and sitting outside on the porch in the warm sun was effective in relieving her pain or taking her mind off the pain. *Id*.

Although the facility had developed an extensive care plan for R416's pain, there is no evidence that they used it. Without completed pain management forms, nursing notes, or other medical records, there is no evidence that Petitioner attempted any alternatives or documented effectiveness of either pharmacological or non-pharmacological interventions.

Petitioner provided a copy of its administration of oral medication policy and procedure. P. Ex. 29 at 31-32. In the policy and procedure, it instructs the nurse to chart "on MAR according to policy." It further instructs to "Chart on nurse's notes: Pertinent

observations immediately after administration." *Id*. Nevertheless, nurses document the time and their initials on the front of the MAR when they administer a medication to a resident. CMS Ex. 22 Part A at 32, 40; P. Ex. 29 at 17, 18. Nurses use the rear of the MAR, titled "PRN, STAT AND MEDICATIONS NOT ADMINISTERED" to document medication anomalies, including as needed or PRN medications. This form provides columns to document the date and hour the nurse provided the medication, the name of the medication, the reason, result, and the initials of the nurse administering. *See* CMS Ex. 22 Part A at 32, 40; P. Ex. 29 at 17, 18.

However, facility staff failed to correctly document the pain medication it provided to R416. For example, the MAR indicated that nursing staff administered R416 Percocet *ten times* on July 4, 2015. CMS Ex. 22 Part A at 40. (Fortunately, Petitioner's staff did not actually administer R416 ten doses of Percocet on that date.) The PRN, STAT and Medications Not Administered form reflects another picture of how nursing staff managed R416's pain. It indicates that facility staff administered Percocet to R416 only five times on July 4,. CMS Ex. 22 Part A at 31, 41.

Petitioner provided the pharmacy Controlled Medication Utilization Record for R416's Percocet. CMS Ex. 22 Part A at 44, 45; P. Ex. 29 at 20, 21. The pharmacy Controlled Medication Utilization Record for R416's Percocet administration is most likely to accurately reflect the pain medication that Petitioner's staff provided to R416 because licensed nurses are required to count and sign out every controlled substance and requires additional protections to obtain the medication and is frequently reconciled. Tr. 11/9 at 342-345.[9] R416's medical record presents an inconsistent picture of how the facility treated R416's chronic pain. The chart below shows the number of Percocet tablets Petitioner's staff documented it administered to R416 between July 1 at 6:00 AM and July 8 at 3:00 PM.

[9] As Surveyor Polakoski testified, the Controlled Medication Utilization Record involves significant protocols. However, Petitioner also failed to comply with standard protocol. Usually, at least two nurses are involved in reconciling the medication, often every time a nurse administers a pill, or at least every shift. The Controlled Medication Utilization Record contains a column titled "checked by" for a second nurse to sign indicating that the remaining amount of the controlled substance is correct. Tr. 11/9 at 343-344. However, Petitioner ignored the second nurse "checked by" column for reconciliation. Petitioner's management of its Controlled Medication Utilization Record is yet another example of Petitioner's lackluster adherence to nursing standards.

DATE	Controlled Medication Utilization Record[10]	MAR[11]	PRN, STAT and Medications Not Administered form (rear of MAR)[12]	Pain Flow Sheet obtained July 8 at 3:00 PM[13]	Pain Flow Sheet obtained July 9 at 9:30 AM[14]
July 1	4	0	0	0	0
July 2	4	3*	4	2	2
July 3	4	1*	3	2	2
July 4	5	10*	5	2	2
July 5	4	3*	2	0	0
July 6	4	3*	4	1	1
July 7	4	3*	1	0	0
July 8	3	4*	4	0	2
Total:	33	n/a	23	7	10

*Because the MARs are illegible, the entries are approximate.

It is clear that Petitioner did not follow its policy requiring nursing staff to document the administration of controlled pain medication to R416 when she experienced pain. However, the facility is required to do much more than document administration. As discussed, it must assess, attempt non-pharmaceutical interventions before pharmaceutical interventions, monitor the effectiveness of the non-pharmaceutical interventions, and if staff eventually administers medication, the facility is required to monitor the resident for the effectiveness of the medication. *See* P. Ex. 29 at 30. The Controlled Medication Utilization Record does not provide that information, nor does the MAR, even if legible. The PRN, STAT and Medications Not Administered form provides slightly more information; however, Petitioner's policy requires the use of the pain flow sheet, which does provide a place to record necessary information. However, as the chart above demonstrates, Petitioner's staff utilized this document only a percentage of the time. Petitioner has not provided corresponding nursing notes that

[10] CMS Ex. 22 Part A at 44-45; P. Ex. 29 at 20-21.

[11] CMS Ex. 22 Part A at 32, 40; *see* P. Ex. 29 at 17, 18 (the MARs at P. Ex. 29 at 17 and 18 are labeled "re-written" but provide little, if any, clarity on the issue).

[12] CMS Ex. 22 Part A at 31, 41; P. Ex. 29 at 19.

[13] CMS Ex. 22 Part A at 33.

[14] CMS Ex. 22 Part A at 43.

document the assessments, interventions, and outcomes to treat R416's pain. Moreover, her physician would certainly have a difficult time determining whether her pain medication was effective.

As stated in *Oxford Manor*, "if facility staff exercise professional judgment in deciding not to follow facility policy with respect to a particular resident, they document that judgment and give a reason why not. In the absence of such contemporaneous documentation, it is certainly reasonable to infer, when staff do not follow the policy, either they are not aware of it or that they are simply disregarding it." DAB No. 2167, at 5-6. Here, Petitioner has failed to point to contemporaneous documentation that shows why the staff chose to not follow facility policy.

From July 1 through July 8, Petitioner administered R416 controlled pain medication 33 times. Even if I accept the altered pain flow sheet Petitioner provided on July 9 as accurate, Petitioner still falls short. Taking the July 8 additions into account, Petitioner still only assesses R416's pain, attempts non-pharmaceutical interventions, evaluates their effectiveness, and if necessary medication intervention, and evaluates their effectiveness on managing R416's pain – what is required – less than one third of the time. I do not find Petitioner's later entries in the pain flow sheet convincing. If the surveyor truly took the pain flow sheet away from the LPN before he could document his work (which in itself is in contravention with Petitioner's policy), I could understand a late entry for the 2:15PM July 8, 2015 medication. However, when reviewed in light of the number of times the facility failed to document in the pain flow sheet according to its policy, I find that Petitioner did not properly follow its policy and procedure when addressing R416's pain, on July 8, or beginning July 1 through July 8.

Petitioner also did not follow professional standards of nursing practice in this case. Surveyor Polakoski explained professional standards of nursing practice related to PRN (as needed) order for pain medicine. CMS Ex. 41 at 64-65. Professional standards of nursing require the nurse to perform a pain assessment before administering medication to ensure that the nurse is not administering unnecessary medication. Professional standards of nursing also require the nurse attempt non-pharmacological interventions prior to administering as needed pain medication. Professional standards of nursing also require the nurse monitor the effectiveness of the medication after the nurse administers the medicine because it is important to know whether the pain medication was actually effective to relieve the indicated pain, because the staff may need to address the resident's pain in another way. It is also important to monitor the effectiveness of the medication. The staff also needs to monitor (and of course document) the effectiveness of an as needed pain medication because staff may need to consult the resident's physician who may need to prescribe a different dosage, a different pain medication, or address the resident's pain in another way. CMS Ex. 41 at 64-65.

Here, R416 was asking for pain medication not long after she was administered medication. According to LPN Pollard, R416 was administered Percocet at 10:30 AM and R416 began experiencing pain again by 12:45 PM. So in this case, it was particularly important to assess R416's different kinds of pain (e.g., general body pain, neck pain, back pain, foot pain, leg pain), and monitor the effectiveness of all interventions, as well as to document episodes of breakthrough pain. P. Ex. 29 at 25; CMS Ex. 22 Part A at 43. Dr. Lesesne explained that without information about the relative effectiveness of the Percocet in relieving R416's pain, her physician would not be in a position to determine whether Percocet continued to be appropriate at that particular dosage or whether Percocet continued to be appropriate at all. CMS Ex. 41 at 11.

Both Dr. Lesesne and Surveyor Polakoski testified that the facility's non-compliance resulted in the potential for more than minimal harm to R416 and I agree. CMS Ex. 41 at 11, 66-67. Percocet is an opioid analgesic that physicians prescribe to relieve moderate to moderately severe pain. CMS Ex. 39 Part A at 42. Dr. Lesesne explained that unnecessary narcotic pain medication to R416 was additionally important in this case because R416 had diagnoses of depression and psychosis, both of which narcotic pain medication could exacerbate. CMS Ex. 41 at 11. It was important to determine if R416 was experiencing moderate pain or if they could manage her pain with a less aggressive medication.

The prescribing information for Percocet cautions physicians when prescribing to the elderly because of danger of cardiac or respiratory depression. However, "special risk patients" include individuals with severe respiratory impairment, severe renal impairment, or hypothyroidism. CMS Ex. 39 Part A at 44-45. R416 had chronic obstructive pulmonary disease, chronic kidney disease, and hypothyroidism. Because R416 was a special risk patient, it was particularly important to ensure that the medication was necessary and to monitor effectiveness.

Additionally, Petitioner's witness, Ms. Hirn, testified, ". . . if one document happens to be confusing, a nurse can reconcile it with other narcotics records." P. Ex. 33 at 10. Surveyor Polakoski, a RN, explained that if a resident is experiencing issues, it is standard nursing practice to consult the MAR, and not to compare various documents to determine (or guesstimate) what medications facility staff administered. Surveyor Polakoski explained that had R416 experienced any respiratory issues around July 4, as a nurse, he would have checked the MAR and seen that the facility provided R416 ten doses of Percocet – an overdose. Even if he were unsure if staff administered R416 ten doses of Percocet, he would still need to treat R416 with the overdose protocol. Tr. 11/9 at 293-294, 297, 299-300.

Accordingly, I conclude that Petitioner has failed to meet its burden of proving by a preponderance of the evidence that it provided the necessary care and services to R416.

Petitioner did not demonstrate that it was in substantial compliance with Medicare and Medicaid participation requirements, in this instance, 42 C.F.R. § 483.25.

b. *Petitioner was not in substantial compliance with 42 C.F.R. § 483.75(l)(1) (F514) because Petitioner failed to ensure clinical records were correct for R405 when the resident's clinical record contained two orders for medication to be administered by mouth to a resident who could not ingest anything by mouth and should have received medication only through his PEG-Tube.*

R405 was a 58-year-old male who Petitioner admitted to the facility on April 15, 2014, and then readmitted after a hospitalization on February 19, 2015. His diagnoses included Down's syndrome, quadriplegia, acute respiratory failure, arthropathy, anxiety, hypertension, hypotension, convulsions, sleep apnea, dementia, and senile dementia with depressive features. He had a tracheotomy and a PEG tube. P. Ex. 25 at 1-2, 70-71.

R405's most recent MDS with an assessment reference date of June 12, 2015, indicated that he was not capable of being understood or of understanding others. He was not able to speak. Although he could make eye contact, he was not able to follow commands. Staff administered pain medication if it concluded he was agitated, which they interpreted as R405 not feeling well. Tr. 11/18 at 175, 177-178. He received all of his nutrition and medication through a PEG tube and was not to receive anything by mouth. P. Ex. 25 at 70-71, 78-79.

As early as February 19, 2015, the date of R405's return from the hospital, R405's physician ordered that he receive nothing by mouth - including medication. CMS Ex. 22 Part F at 6, 9; P. 25 at 71. Indeed, Petitioner's staff manually modified R405's physician's order sheet to indicate that R405 was to receive the drug Aricept "via peg" rather than by mouth. P. Ex. 25 at 31. However, on April 15, 2015, R405's nurse practitioner ordered 2 mg tablet of Glycopyrrolate to be administered "PO" (by mouth) three times a day – at 6 AM, 2 PM, and 9 PM. P. Ex. 25 at 14.

Although this order was inconsistent with the physician's order that R405 not receive anything by mouth, the staff did not obtain a clarification order for the correct route of administration. Instead, the staff promulgated the error in R405's medical record, including in his physician's order sheet and his MAR as well. The record contains R405's May and July physician's order sheets, both of which specify that on April 16, 2016 the doctor ordered 2 mg tablet of Glycopyrrolate to be administered "*by mouth*" at 6 am, 2 pm, and 9 pm. CMS Ex. 22 Part F at 6, 9 (emphasis added). The same order sheet also indicated that on June 17, 2015, R405's doctor ordered 0.5 mg Clonazepam to be administered "*by mouth*" at bedtime for seizures, even though in March, the order sheet correctly limited Clonazepam to administration through the PEG tube. CMS Ex. 22 Part F at 6, 9. Rather than catching the error on the order, or the physician order sheets,

numerous staff continued to complicate matters by indicating with their initials on R405's MAR that they had provided the Glycopyrrolate as ordered (by mouth) from May through July 2015, and the Clonazepam as ordered (by mouth) in July 2015. P. Ex. 25 at 44, 50, 58. It was not until July 7, 2015, when the surveyors brought the error to the staff's attention that Petitioner obtained a clarification order for administration by PEG tube rather than by mouth. P. Ex. 25 at 92.

Petitioner was responsible for administering the facility in a manner that enables it to use its resources effectively and efficiently to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident. 42 C.F.R. § 483.75. This administrative obligation includes the requirement that the facility maintain clinical records on each resident in accordance with accepted professional standards and practices that are complete, accurately documented, readily accessible, and systematically organized. 42 C.F.R. § 483.75*(l)*(1). In this case, Petitioner failed to maintain a complete and accurate clinical record for R405. Specifically, Petitioner failed to ensure that the medication orders for Clonazepam and Glycopyrrolate were accurate for R405. CMS Ex. 21 at 41-44.

Petitioner argued that this deficiency was frivolous because it could not pose a plausible potential for harm because R405 is unresponsive, has orders to receive nothing by mouth, and is incapable of swallowing. P. Post-Hrg. Br. at 44. Petitioner further asserts that R405's brother, who visited daily, would not have allowed a nurse to provide any medication by mouth. P. Post-Hrg. Br. at 44. Petitioner also argued that Petitioner made certain that they only assigned experienced nurses and nursing assistants who were familiar with R405 to his care, and Petitioner assured that they did not assign registry staff to care for him. P. Post-Hrg. Br. at 32, 44-45; P. Ex. 33 at 7; Tr. 11/10 at 265; Tr. 11/18 at 175-179, 186, 214. Nurse Hirn testified that the nursing staff was "very familiar with [R405's] condition" so it was "extremely unlikely" that any nurse would have administered the medication by mouth. P. Ex. 33 at 7.

CMS argued that Petitioner did not deny that its documentation showed that R405 was to receive the Glycopyrrolate and Clonazepam by mouth, simply that oral administration of those medications was not likely to happen because Petitioner's staff knew of R405's condition. CMS asserts that Petitioner could not guarantee that R405 would always be cared for by nurses who were familiar with his condition, given employee turnover, illnesses, and vacations. Further, CMS posits that the order to administer the medication by mouth was in place long enough to have potentially resulted in oral administration of the medication. CMS Post-Hrg. Br. at 40-41.

I agree with CMS that although Petitioner believes that it was not likely that its staff would administer medication orally, had it done so, there is no doubt more than minimal harm would have resulted. Therefore, Petitioner's failure to maintain accurate clinical records for R405 had the potential to cause him more than minimal harm.

Surveyor Dayton testified that because the incorrect physician orders persisted for such an extensive period (at least since April 16, 2015) that this increased the potential that R405 was subject to harm. Tr. 11/10 at 139-140; *see* CMS Ex. 22 Part F at 6. Surveyor Dayton testified that there is an increased risk of harm every time a nurse administers the medication, and because nurses are required to implement physician orders as written, that risk of harm is intensified. Tr. 11/10 at 60-61, 63. This, of course, placed Petitioner's staff in the position of having to disobey an order to ensure R405's safety.

In addition, Petitioner's assertion that R405's family members would intercede and stop Petitioner's staff from orally administering medication is not sufficient to overcome the potential of more than minimal harm here. Although R405's family visited daily (CMS Ex. 22 Part E at 44), Petitioner cannot rely on a resident's family to ensure safe administration of medication.

Further, Petitioner's staff development coordinator explained that the physician's order sheets and MAR come from the pharmacy at the end of every month. Once Petitioner receives these records, a facility staff member reviews the records for accuracy and then an additional staff member double-checks them for accuracy. The staff development coordinator said she was unaware of how the inaccurate "Physician's order sheet" and MAR were missed during the checking process. CMS Ex. 21 at 44; CMS Ex. 43 at 22. This further indicates a more systemic problem; that the systems in place were not sufficient to detect such glairing errors, by not one, but two of Petitioner's staff members – in addition to each nurse who documented providing the medication. Therefore, Petitioner did not demonstrate that it was in substantial compliance with Medicare and Medicaid participation requirements at 42 C.F.R. § 483.75(*l*)(1).

5. CMS was required to terminate Petitioner's provider agreement for failing to be in substantial compliance with Medicare program participation requirements on July 9, 2015, and for six months preceding that date.

The Act only permits the Secretary to continue to provide Medicare program reimbursements to an SNF for a maximum of six months when the SNF is not in compliance with the Act's requirements for SNFs. Act §1819(h)(2)(C), 42 U.S.C. § 1395i-3(h)(2)(C). Consistent with this, the regulations require CMS to terminate an SNF's participation in the Medicare program if they are not in substantial compliance for a six-month period, even if the SNF's deficiencies do not place residents in immediate jeopardy. 42 C.F.R. § 488.412. Once CMS demonstrates that a facility is out of substantial compliance, the burden shifts to the facility to demonstrate its return to substantial compliance. *Premier Living & Rehab. Ctr.*, DAB No. 2146 at 23 (2008). Therefore, if CMS has shown, and Petitioner has failed to rebut, that Petitioner was not in substantial compliance with even one program participation requirement with the potential for more than minimal harm, (at the scope and severity of level "D" or above) during a six month period, Petitioner must be found to have not been in substantial

compliance with the applicable requirement and CMS's determination to terminate Petitioner must be upheld. *See Beverly Health & Rehab. Servs., Inc. v. Thompson*, 223 F. Supp. 2d 73, 111 (D. D.C. 2002).

As indicated above, Petitioner did not demonstrate that it returned to compliance at some point prior to July 8, 2015. As concluded above, Petitioner had not fully returned to substantial compliance following the April 30, 2015 survey by June 2, 2015, and remained out of substantial compliance with at least one program requirement in both the June 11, 2015 (42 C.F.R. §§ 483.25 and 483.25(e)(2)) and the July 9, 2015 (42 C.F.R. §§ 483.25 and 483.75(*1*)(1)) surveys. Accordingly, CMS was required to terminate Petitioner's provider agreement effective July 8, 2015, and I must uphold that termination.

6. CMS was required to impose a denial of payment for new admissions (DPNA) not later than April 8, 2015, because Petitioner failed to return to substantial compliance over the preceding three months.

CMS imposed a DPNA beginning April 8, 2015, based on the January and March surveys. CMS Ex. 29 at 2. Although Petitioner now challenges the DPNA, that remedy is administratively final. CMS *may* impose a DPNA any time there is a breach of substantial compliance, 42 C.F.R. § 488.417(a), and *must* impose a DPNA if the facility has not returned to substantial compliance within three months. Act § 1819(h)(2)(A)(ii), (B), 42 U.S.C. § 1395i-3(h)(2)(A)(ii) (circumstances permitting DPNA), implemented at 42 C.F.R. § 488.417(a); Act § 1819(h)(2)(D), (E) 42 U.S.C. § 1395i-3(h)(2)(D), (E) (circumstances requiring DPNA), implemented at 42 C.F.R. § 488.417(b).

Here, Petitioner did not challenge the January 8, 2015 survey findings of substantial noncompliance; therefore, Petitioner was not in substantial compliance on January 8, 2015. The statute requires CMS to impose a DPNA if Petitioner cannot demonstrate that it returned to substantial compliance within three months, specifically by April 8, 2015. But Petitioner also did not challenge the findings of substantial noncompliance from the March 2, 2015 survey, which found continued compliance from the January survey; nor did it challenge the April 30, 2015 survey, which again found continued noncompliance. CMS Ex. 33. In fact, Petitioner did not substantially comply with the participation requirements for a single day of this survey cycle, and remained out of compliance with the quality of care requirement at 42 C.F.R. § 483.25 throughout the survey cycle and its eventual termination. CMS Exs. 1, 10, 13. Accordingly, Petitioner did not demonstrate that it returned to substantial compliance at any point between January 8 and April 8. CMS Ex. 33; P. Ex. 8. Therefore, CMS lawfully was required to impose a DPNA effective April 8, 2015.

7. The CMP CMS imposed for the period between June 11, 2015, and July 7, 2015, is reasonable.

In determining whether the CMP amounts imposed against Petitioner are reasonable, I apply the factors listed in 42 C.F.R. § 488.438(f). 42 C.F.R. § 488.438(e)(3). These factors include: (1) the facility's history of compliance; (2) the facility's financial condition; (3) the factors specified at 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 at 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. Unless a facility contends that a particular regulatory factor does not support the CMP amount, the ALJ must sustain it. *Coquina Ctr.*, DAB No. 1860, at 32 (2002).

In the present case, CMS imposed a CMP based on the March 2 survey at $5,150 per-day beginning February 6, 2015, through February 24, 2015, and $750 per-day thereafter. CMS continued the CMP through July 7, 2015, based on its determinations that Petitioner remained out of compliance with the Medicare participation requirements. Petitioner does not dispute the January, March, or April surveys, or the remedies associated with this noncompliance. Accordingly, the $5150 per-day CMP from February 6, 2015, through February 24, 2015, and $750 per-day CMP from February 25, 2015, through June 11, 2015 are administratively final. Although Petitioner generally contests the CMP associated with the June and July surveys of $750 per-day from June 11, 2015, through July 7, 2015, Petitioner provides no specific argument related to the amount of the CMP.

Petitioner has an extensive history of noncompliance. Petitioner has had many repeated deficiencies. Nor does Petitioner appear to learn from prior deficits. In the January survey, surveyors cited Petitioner for F441. Rather than correcting that deficiency, on revisit, Petitioner again violated F441, this time at the immediate jeopardy level. Also, during the January survey, surveyors cited Petitioner for F224 and F312 noncompliance that did not amount to immediate jeopardy. Rather than resolve these issues, on the revisit, surveyors found that Petitioner violated the same provisions; however, this time they were at the level of actual harm. Petitioner's compliance history includes a total of four actual harm deficiencies, which were in addition to two immediate jeopardy citations. In addition to many repeat deficiencies, Petitioner had two repeat deficiencies cited in each of the four surveys in this survey cycle. CMS Exs. 1, 10, 13.

In regard to consideration of Petitioner's financial condition, I cannot conclude that this is a reason to reduce the penalty amount in this case. The record neither contains any information about Petitioner's financial condition nor has Petitioner even argued that I should consider its financial condition as a basis to reduce the CMP.

I consider Petitioner to have a medium degree of culpability in this case. Although the deficiencies in the June and July surveys were not at the immediate jeopardy level, Petitioner's violations were still significant. Petitioner's facility did not provide the necessary care and services to its residents, which is central to a facility's participation in the Medicare program. Medicare pays for placement in a SNF specifically so that residents can receive the care they need. Petitioner repeatedly failed to provide that needed care.

Since Petitioner provides no specific argument concerning the amount of the CMP, and after considering the factors in the regulations, I conclude that the CMP amounts imposed in this case are reasonable. A per-day CMP may range from $50 to $3,000 per-day for noncompliance that does not amount to immediate jeopardy to the health and safety of residents. 42 C.F.R. § 488.438(a). Here, CMS imposed a $750 per-day CMP, which is in the lower end of available penalty. This penalty amount is reasonable.

V. Conclusion

I conclude that Petitioner was not in substantial compliance with program requirements at 42 C.F.R. §§ 483.25, 483.25(m)(2), 483.25(e)(2), and 483.75(*l*)(1), based on the surveys concluding on June 11, 2015 and July 9, 2015, and I further conclude that Petitioner was not in substantial compliance with Medicare program requirements for a six month period. Accordingly, CMS was required to terminate Petitioner's provider agreement as a skilled nursing facility in the Medicare program and impose a DPNA. Finally, I conclude that a $750 per-day CMP from June 11, 2015, through July 7, 2015, is reasonable.

/s/
Scott Anderson
Administrative Law Judge