Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Avon Nursing Home, (CCN: 33-5216),

Petitioner,

v.

Centers for Medicare & Medicaid Services.

Docket No. C-14-549

Decision No. CR4670

Date: August 2, 2016

DECISION

The survey completed at Petitioner, Avon Nursing Home, on September 6, 2013, violated section 1819(g)(2)(E)(i) of the Social Security Act (Act) (42 U.S.C. § 1395i-3(g)(2)(E)(i)) and 42 C.F.R. § 488.314(a)(1). Accordingly, the findings and conclusions of the survey team, which was constituted in violation of the Act and regulations, are invalid and cannot be the bases for the imposition of any enforcement remedy. No enforcement remedy is reasonable absent a lawful basis to impose such a remedy.

I. Background

Petitioner is located in New York, New York, and participates in Medicare as a skilled nursing facility (SNF). Revised Joint Stipulation of Facts (Jt. Stip.) ¶ 1. On September 6, 2013, the New York Department of Health, Office of Long Term Care (state agency), completed a survey of Petitioner's facility.

¹ References are to the 2012 revision of the Code of Federal Regulations (C.F.R.), unless otherwise indicated.

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The Centers for Medicare & Medicaid Services (CMS) notified Petitioner by letter dated November 15, 2013, that it was imposing enforcement remedies against Petitioner based on deficiencies cited by the September 6, 2013 survey. The CMS notice cited Petitioner with violations of 42 C.F.R. §§ 483.13(c) (Tag F225),² at a scope and severity of D,³ and 483.25(h) (Tag F323) at a scope and severity of L. The notice advised Petitioner that a revisit survey conducted on October 17, 2013, determined that Petitioner had returned to substantial compliance with Medicare program participation requirements. CMS advised Petitioner that CMS was imposing a per instance civil money penalty (PICMP) of \$9,500.00, based on the noncompliance cited under Tags F225 and F323. The CMS notice also informed Petitioner that Petitioner was prohibited from conducting a nurse aide training and competency evaluation program (NATCEP) from September 6, 2013 through September 5, 2013, based on the amount of the civil money penalty (CMP). CMS Exhibits (Exs.) 1 and 2.

² This is a "Tag" designation as used in CMS Pub.100-07, State Operations Manual (SOM), Appendix PP – Guidance to Surveyors for Long Term Care Facilities (http://www.cms.hhs.gov/Manuals/IOM/list.asp). The "Tag" refers to the specific regulatory provision allegedly violated and CMS policy guidance to surveyors. Although the SOM does not have the force and effect of law, the provisions of the Act and regulations as interpreted in the SOM clearly do have such force and effect. *Ind. Dep't of Pub. Welfare v. Sullivan*, 934 F.2d 853 (7th Cir. 1991); *Northwest Tissue Ctr. v. Shalala*, 1 F.3d 522 (7th Cir. 1993). Thus, while the Secretary of Health and Human Services (Secretary) may not seek to enforce the provisions of the SOM, she may seek to enforce the provisions of the Act or regulations as interpreted by the SOM.

Scope and severity level is designated by an alpha character, A through L, selected by CMS or the state agency from the scope and severity matrix published in the SOM, Chap. 7, § 7400E. A scope and severity level of A, B, or C indicates a deficiency that presents no actual harm but has the potential for minimal harm, which is an insufficient basis for imposing an enforcement remedy. Facilities with deficiencies of a level no greater than C remain in substantial compliance. 42 C.F.R. § 488.301. A scope and severity level of D, E, or F indicates a deficiency that presents no actual harm but has the potential for more than minimal harm that does not amount to immediate jeopardy. A scope and severity level of G, H, or I indicates a deficiency that involves actual harm that does not amount to immediate jeopardy. Scope and severity levels J, K, and L indicate deficiencies that constitute immediate jeopardy to resident health or safety. The matrix, which is based on 42 C.F.R. § 488.408, specifies which remedies are required and optional at each level based upon the frequency of the deficiency.

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CMS notified Petitioner by letter dated December 5, 2014, that it had reduced the scope and severity of the deficiency cited under Tag F323 to K, and, because Petitioner did not have a NATCEP, the prohibition on conducting a NATCEP cited in the November 15, 2013 notice was not applicable to Petitioner. CMS advised Petitioner that there was no change to the \$9,500.00 PICMP. CMS Ex. 64.

Petitioner requested a hearing before an administrative law judge (ALJ) by letter dated January 6, 2014, specifically challenging the noncompliance cited under Tag F323 by the September 6, 2013 survey.⁴ On January 16, 2014, the case was assigned to me for hearing and decision and an Acknowledgement and Prehearing Order (Prehearing Order) was issued.

A hearing was convened by video teleconference on January 6, 7, and 8, 2015. A transcript of the proceedings was prepared. CMS offered CMS Exs. 1 through 35, 35A, and 36 through 68, all of which were admitted as evidence. Tr. Vol. 1 at 31-32. Petitioner offered Petitioner exhibits (P. Exs.) 1 through 31 that were admitted as evidence. Tr. Vol. 1 at 32-34. Petitioner offered P. Exs. 42 and 43 that were admitted over CMS objection. Tr. Vol. 2 at 20, 28, 63-67. CMS called the following witnesses: Surveyor Linda Werth, R.D., C.D.N. and Surveyor Mary Langworthy, R.D., C.D.N. Petitioner called the following witnesses: Robert M. Rubens, former Administrator of Petitioner; Josette Dobiesz, former Director of Nursing (DON) for Petitioner; Wanda Cobb, Petitioner's Food Service Director; Lisa Jansen, a cook at Petitioner's facility; and Wendy Leakey, a Certified Nursing Assistant (CNA) at Petitioner's facility.

⁴ On January 7, 2015, Petitioner amended its request for review to include both the deficiency citations under Tags F225 and F323. The amendment and the CMS objection to the amendment are discussed hereafter.

⁵ A separate volume of the transcript was prepared for each day the hearing was in session. Rather than number all pages consecutively across all three volumes of the transcript – the usual practice – the court reporting firm began the numbering of the pages of each volume of the transcript with the number 1. Therefore, to avoid potential confusion, references to the transcript must be by volume and page. The transcript for January 6 is referred to as "Tr. Vol. 1" followed by the page number. The transcripts for January 7 and 8 are referred to as "Tr. Vol. 2" and "Tr. Vol. 3," respectively.

⁶ Petitioner did not offer P. Exs. 32 through 41. Petitioner Avon Nursing Home's List of Exhibits Offered dated April 2, 2015.

Subsequent to the hearing, on February 25, 2015, CMS filed an amended exhibit list and offered extracts from the SOM app. PP, marked as CMS Exs. 69 through 72. On March 24, 2015, CMS filed an amended exhibit list and offered CMS Ex. 73, which included a memorandum titled "Incident Reporting System," dated October 4, 2011, and addressed to "Nursing Home Administrators" (CMS Ex. 73 at 1) and a copy of the New York State Department of Health Division of Residential Services', "Nursing Home Incident Reporting Manual," rev. June 14, 2012 (CMS Ex. 73 at 2-39). Petitioner did not object to my consideration of CMS Exs. 69 through 73 and the exhibits are admitted.

The parties filed post-hearing briefs (CMS Br. and P. Br.) and related pleadings on April 2, 2015, and reply briefs (CMS Reply and P. Reply) on May 4, 2015.

II. Discussion

A. Issues

Whether there is a basis for the imposition of an enforcement remedy; and, if so,

Whether the remedy imposed is reasonable.

B. Applicable Law

The statutory and regulatory requirements for participation of a SNF in Medicare are found at section 1819 of the Act and at 42 C.F.R. pt. 483. Section 1819(h)(2) of the Act authorizes the Secretary to impose enforcement remedies against a SNF for failure to comply substantially with the federal participation requirements established by sections 1819(b), (c), and (d) of the Act.⁷ The Act requires that the Secretary terminate the Medicare participation of any SNF that does not return to substantial compliance with participation requirements within six months of being found not to be in substantial compliance. Act § 1819(h)(2)(C). The Act also requires that the Secretary deny payment of Medicare benefits for any beneficiary admitted to a SNF, if the SNF fails to return to substantial compliance with program participation requirements within three months of being found not to be in substantial compliance – commonly referred to as the mandatory or statutory denial of payment for new admissions (DPNA). Act § 1819(h)(2)(D). The

⁷ Participation of a nursing facility (NF) in Medicaid is governed by section 1919 of the Act (42 U.S.C. § 1396r). Section 1919(h)(2) of the Act gives enforcement authority to the states to ensure that NFs comply with the participation requirements established by sections 1919(b), (c), and (d) of the Act. The provisions of sections 1819 and 1919 of the Act are substantially similar.

Act grants the Secretary discretionary authority to terminate a noncompliant SNF's participation in Medicare, even if there has been less than 180 days of noncompliance. The Act also grants the Secretary authority to impose other enforcement remedies, including a discretionary DPNA, CMPs, appointment of temporary management, and other remedies such as a directed plan of correction, when a facility is found not to be in substantial compliance with program participation requirements. Act § 1819(h)(2)(B).

The Secretary has delegated to CMS and the states the authority to impose remedies against a long-term care facility that is not complying substantially with federal participation requirements. "Substantial compliance means a level of compliance with the requirements of participation such that any identified deficiencies pose no greater risk to resident health or safety than the potential for causing minimal harm." 42 C.F.R. § 488.301 (emphasis in original). A deficiency is a violation of a participation requirement established by sections 1819(b), (c), and (d) of the Act or the Secretary's regulations at 42 C.F.R. pt. 483, subpt. B. Noncompliance refers to any deficiency that causes a facility not to be in substantial compliance, that is, a deficiency that poses a risk for more than minimal harm. 42 C.F.R. § 488.301. State survey agencies survey facilities that participate in Medicare on behalf of CMS to determine whether the facilities are complying with federal participation requirements. 42 C.F.R. §§ 488.10-.28, .300-.335. The regulations specify the enforcement remedies that CMS may impose if a facility is not in substantial compliance with Medicare requirements. 42 C.F.R. § 488.406.

The Act and regulations make a hearing before an ALJ available to a long-term care facility such as Petitioner against which CMS has determined to impose an enforcement remedy. Act §§ 1128A(c)(2), 1866(h); 42 C.F.R. §§ 488.408(g), 498.3(b)(13). A facility has a right to request ALJ review of a "certification of noncompliance leading to an enforcement remedy." 42 C.F.R. §§ 488.408(g)(1), 488.330(e), 498.3. However, the choice of remedies, or the factors CMS considered when choosing remedies, are not subject to review. 42 C.F.R. § 488.408(g)(2). A facility may only challenge the scope and severity level of noncompliance determined by CMS if a successful challenge would affect the range of the CMP that may be imposed or impact the facility's authority to conduct a NATCEP. 42 C.F.R. § 498.3(b)(14), (d)(10)(i). The CMS determination as to the level of noncompliance, including the finding of immediate jeopardy, "must be upheld unless it is clearly erroneous." 42 C.F.R. § 498.60(c)(2); Woodstock Care Ctr., DAB No. 1726 at 9, 38 (2000), aff'd, 363 F.3d 583 (6th Cir. 2003). The Departmental Appeals Board (the Board) has long held that the net effect of the regulations is that a provider has no right to challenge the scope and severity level assigned to a noncompliance finding, except in the situation where that finding was the basis for an immediate jeopardy determination. See, e.g., Ridge Terrace, DAB No. 1834 (2002); Koester Pavilion, DAB No. 1750 (2000).

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The hearing before an ALJ is a de novo proceeding, i.e., "a fresh look by a neutral decision-maker at the legal and factual basis for the deficiency findings underlying the remedies." Life Care Ctr. of Bardstown, DAB No. 2479 at 32 (2012) (citation omitted); The Residence at Salem Woods, DAB No. 2052 (2006); Cal Turner Extended Care Pavilion, DAB No. 2030 (2006); Beechwood Sanitarium, DAB No. 1906 (2004); Emerald Oaks, DAB No. 1800 at 11 (2001); Anesthesiologists Affiliated, DAB CR65 (1990), aff'd, 941 F.2d 678 (8th Cir. 1991). The Secretary's regulations do not address the allocation of the burden of proof or the standard of proof. However, the Board has addressed the allocation of the burden of proof in many decisions. The standard of proof is a preponderance of the evidence. CMS has the burden of coming forward with the evidence and making a prima facie showing of a basis for imposing an enforcement remedy. "Prima facie" means generally that the evidence is "[s]ufficient to establish a fact or raise a presumption unless disproved or rebutted." Black's Law Dictionary 1228 (8th ed. 2004). To make a prima facie case that its decision to impose an enforcement remedy was legally sufficient, CMS must: (1) identify the statute, regulation or other legal criteria to which it seeks to hold the petitioner; (2) come forward with evidence upon which it relies for its factual conclusions that are disputed by the petitioner; and (3) show how the deficiencies it found amounted to noncompliance that warrants an enforcement remedy, that is, that there was a risk for more than minimal harm due to the regulatory violation. Evergreene Nursing Care Ctr., DAB No. 2069 at 7 (2007). Petitioner bears the burden of persuasion to show by a preponderance of the evidence that it was in substantial compliance with participation requirements or any affirmative defense. Batavia Nursing & Convalescent Inn, DAB No. 1911 (2004); Batavia Nursing & Convalescent Ctr., DAB No. 1904 (2004), aff'd, 129 F. App'x 181 (6th Cir. 2005); Emerald Oaks, DAB No. 1800; Cross Creek Health Care Ctr., DAB No. 1665 (1998); Hillman Rehab. Ctr., DAB No. 1611 (1997), DAB CR500 (1997) (on remand), rev'd, DAB No. 1663 (1998), aff'd, Hillman Rehab. Ctr. v. United States, No. 98-3789 (GEB), 1999 WL 34813783 (D.N.J. May 13, 1999).

C. Findings of Fact, Conclusions of Law, and Analysis

My conclusions of law are set forth in bold text followed by my findings of fact and analysis. I have carefully considered all the evidence and the arguments of both parties, although not all may be specifically discussed in this decision. I discuss the credible evidence given the greatest weight in my decision-making. I also discuss any evidence that I find is not credible or worthy of weight. The fact that evidence is not specifically discussed should not be considered sufficient to rebut the presumption that I considered

⁸ "Credible evidence" is evidence that is worthy of belief. *Black's Law Dictionary* 596 (18th ed. 2004). The "weight of evidence" is the persuasiveness of some evidence compared to other evidence. *Id.* at 1625.

all the evidence and assigned such weight or probative value to the credible evidence that I determined appropriate within my discretion as an ALJ. There is no requirement for me to discuss the weight given every piece of evidence considered in this case, nor would it be consistent with notions of judicial economy to do so. Charles H. Koch, Jr., *Admin. L. & Prac.* § 5:64 (3d ed. 2013).

- 1. Petitioner did not waive its right to review of the factual bases for either of the deficiencies cited by the survey of Petitioner's facility completed on September 6, 2013.
- 2. The filing of an amended request for hearing was unnecessary as the parties stipulated that the factual bases for both deficiencies cited by the survey of Petitioner's facility completed on September 6, 2013, were at issue before me.
- 3. The factual bases for both deficiencies cited in this case are properly before me for review and fact finding based upon Petitioner's timely request for hearing.
- 4. Whether or not the facts proved are a basis for concluding that there was a violation of 42 C.F.R. \S 483.13(c)(3) is a legal question properly before me for decision.

At the outset it is necessary to determine which deficiency citations are properly before me for review.

CMS notified Petitioner on November 15, 2013, that it was imposing enforcement remedies against Petitioner based on deficiencies cited in the September 6, 2013 survey, specifically, for violations of 42 C.F.R. § 483.13(c) (Tag F225), at a scope and severity of D, and 42 C.F.R. § 483.25(h) (Tag F323) at a scope and severity of L. The notice clearly stated that a \$9,500.00 PICMP was proposed based on the findings of deficiencies and listed both deficiencies. CMS Ex. 2 at 1.

Petitioner's January 6, 2014 request for hearing refers specifically to the noncompliance cited under Tag F323 by the September 6, 2013 survey. The noncompliance cited under Tag F225 is not mentioned in the request for hearing. Jt. Stip. ¶ 22. The request for hearing was signed by Petitioner's Administrator, Robert Rubens. In its prehearing brief, Petitioner specifically states that it is not requesting review of the deficiency cited under Tag F225, except that Petitioner stated that it disputes any facts alleged under Tag F225 that CMS relies upon to show noncompliance under Tag F323. Petitioner's Prehearing Brief at 7-8. At the hearing on January 6, 2015, counsel for Petitioner argued that the PICMP proposed by CMS was based only upon Tag F323 and, therefore, Petitioner had not specifically requested review of the deficiency cited under Tag F225. Petitioner also

argues that it never conceded the facts underlying the Tag F225 deficiency citation to the extent that those facts are also cited in support of the deficiency cited under Tag F323. Tr. Vol. 1 at 59, 61-63. CMS stated at the hearing, consistent with the November 15, 2013 CMS notice of initial determination, that the proposed PICMP is based on both Tags F225 and F323. Tr. Vol. 1 at 61. CMS argued at hearing that Petitioner is barred from requesting my review of Tag F225 because Petitioner failed to specifically request a hearing as to that deficiency and because Petitioner had stipulated it did not seek review of that deficiency. Tr. Vol. 1 at 67-68. At hearing CMS directed questions to its surveyor about Tag F225. Vol. 1 at 96-98, 141; Vol. 2 at 68-75, 110-22, 137-38. At the beginning of the second day of hearing, Petitioner announced that it intended to amend its request for hearing to include Tag F225, citing 42 C.F.R. §§ 498.40(c)(2) and 498.56(a)(1) and (3), as well as the fact that CMS had issued a revised initial determination on December 5, 2014. Tr. Vol. 2 at 5-16.

On January 7, 2015, Petitioner filed a written amendment of its request for hearing in which it challenges both the deficiency citations under Tags F225 and F323. CMS filed an objection to the amendment on January 27, 2015.

Petitioner argues in post-hearing briefing that there is good cause for me to review the noncompliance alleged under Tag F225. Petitioner argues that: CMS elected in its prehearing brief to rely on F225 as a basis for imposing the PICMP; there is no prejudice to CMS; CMS cannot claim surprise; and justice requires my review of Tag F225. P. Br. at 12-14; P. Reply at 8-9.

In its January 27, 2015 objection to the amendment of the request for hearing, CMS argues that the filing of the amended hearing request was untimely and no good cause exists to permit the amendment. CMS argues that it was surprised by the amendment and prejudiced in its ability to prepare and present argument and evidence. CMS argues that the amendment cannot be treated as raising a new issue for hearing under 42 C.F.R. § 498.56 because CMS did not have notice ten days prior to hearing. Finally, CMS argues that the CMS notice of December 5, 2014, did not constitute notice of a reopened or revised determination that would have triggered a new 60-day period for requesting a hearing because CMS only changed the scope and severity of the alleged violation of 42 C.F.R. § 483.25(h) (Tag F323). Objection to Petitioner's Amended Hearing Request.

In the Statement of Deficiencies (SOD) for the survey completed on September 6, 2013, it is alleged under Tag F225 that Petitioner violated 42 C.F.R. § 483.13(c)(1)(ii)-(iii) and (c)(2)-(4). CMS Ex. 1 at 1. The allegations under Tag F225 are that Petitioner failed to

⁹ The regulatory citation is in error because there are no factual allegations by the surveyors that would support a conclusion that Petitioner violated 42 C.F.R. (*Footnote continued next page.*)

thoroughly investigate incidents involving Residents 1 and 2 and burns with hot food and, in the case of Resident 2, it is alleged that Petitioner failed to conduct a timely investigation. CMS Ex. 1 at 2. The regulatory provision implicated by the allegations is 42 C.F.R. § 483.13(c)(3), which requires that a "facility must have evidence that all alleged violations are thoroughly investigated " The SOD alleges under Tag F323 that Petitioner violated 42 C.F.R. § 483.25(h), which requires a facility to keep the resident environment as free of accident hazards as possible and to ensure that each resident receives adequate supervision and assistance devices to prevent accidents. The alleged noncompliance under Tag F323 is that Petitioner failed to ensure the resident environment was as free of accident hazards as possible because it failed to ensure hot foods and beverages were served at "safe temperatures to limit the potential for burns." CMS Ex. 1 at 5. The incidents involving Residents 1 and 2 cited as examples under Tag F323 are the same as those cited under Tag F225. CMS Ex. 1 at 2-4, 6-11. The surveyors also included under Tag F323 statements of their own observations during the survey not directly related to the incidents involving Residents 1 and 2. CMS Ex. 1 at 6-11.

Petitioner's request for hearing dated January 6, 2014, was signed by Petitioner's Administrator at the time. Jt. Stip. ¶ 2. There is no reference in the request for hearing to the alleged noncompliance under Tag F225. The request for hearing clearly states that Petitioner was requesting ALJ review only of the alleged noncompliance under Tag F323. Petitioner agreed in the Revised Joint Stipulation of Facts dated December 18, 2014, that in its request for hearing Petitioner requested review of only the deficiency cited under Tag F323. Jt. Stip. ¶ 22. In a combined Joint Statement of Facts and Issues executed by the parties on June 12 and 13, 2014, the parties agreed under the section titled Joint Statement of Issues:

Petitioner is not appealing the deficiency at 42 C.F.R. § 483.13(c)(1)(ii)-(iii), (c)(2)-(4) [F225], which was cited at a scope and severity of "D" in the Statement of Deficiencies for the September 6 Survey. However, to the extent that CMS is relying on findings related to the deficiency at 42 C.F.R.

(Footnote continued.)

§ 483.13(c)(1)(ii)-(iii). There is no allegation that the facility failed to immediately report an allegation of mistreatment, neglect, abuse, or misappropriation of resident property, which would be a violation of 42 C.F.R. § 483.13(c)(2). There is also no allegation that Petitioner failed to timely report the results of an investigation as required by 42 C.F.R. § 483.13(c)(4). The facts alleged in the SOD under Tag F225 are consistent with an alleged violation of 42 C.F.R. § 483.13(c)(3) only. The incorrect citations to the regulations create no prejudice to either party and are considered to be scrivener's errors.

§ 483.13(c)(1)(ii)-(iii), (c)(2)-(4) [F225] to support its determination of noncompliance with respect to 42 C.F.R. § 483.25(h) [F323], Petitioner reserves the right to contest the findings related to the F225 deficiency as part of this appeal.

My reading of the stipulated issue is that Petitioner agreed that it is not requesting review of the deficiency alleged under Tag F225, but it reserved the right to dispute the facts alleged in the SOD under Tag F225 if CMS sought to rely upon those facts as part of its case under Tag F323. CMS agreed to this stipulated issue as indicated by the signature of CMS counsel on June 12, 2014, with no reservation by CMS. The factual bases cited under both Tags F323 and F225 are mostly related to the incidents involving Residents 1 and 2 save for a few observations of the surveyors in the SOD under Tag F323. The stipulated issue clearly shows that CMS was on notice at least as early as June 12, 2014, that while Petitioner was not seeking review of Tag F225, Petitioner reserved the right to dispute the facts under Tag F225 and did so with the agreement of CMS. The stipulation of fact that Petitioner requested review only as to Tag F323 is correct as Tag F225 is not mentioned in the request for hearing. However, that fact is not inconsistent with the parties' agreement that Petitioner reserved the right to challenge any facts that were alleged by CMS in support of Tag F323 that were also cited in the SOD in support of Tag F225. Because the factual bases for both Tags F323 and Tag F225 are identical in substantial part, were I to conclude that Petitioner requested a hearing but waived its challenge to the facts underlying Tag F225, would effectively result in a conclusion that Petitioner had also waived a hearing as to the facts underlying Tag F323, which clearly was not the apparent intent of Petitioner's Administrator when he filed the request for hearing. Petitioner also stated in its prehearing brief filed June 16, 2014, that it reserved the right to contest the facts underlying Tag F225 to the extent that CMS relied upon the same facts to prove the deficiency alleged under Tag F323. Petitioner's Prehearing Brief at 7-8. In its prehearing brief, CMS stated:

In the summary of the proposed testimony of its witnesses, CMS provided notice that, although Petitioner was not appealing the F225 deficiency, it would be relying on the findings associated with the F225 deficiency to support the F323 deficiency. In particular, the facility's failure to investigate root causes of the injuries of Resident #1 and Resident #2 contributed to its failure to ensure that the resident environment remained as free of accident hazards as is possible, and that each resident received supervision and assistance devices to prevent accidents, as required by F323.

CMS Prehearing Brief at 7. In footnote 14 of its prehearing brief, CMS argued that even if I do not find noncompliance under Tag F323, Petitioner has not appealed the noncompliance under Tag F225, and that undisputed deficiency was sufficient alone as a basis for the \$9,500.00 PICMP. CMS Prehearing Brief at 32 n.14.

Given the foregoing facts, CMS cannot credibly argue that it was surprised that Petitioner did not concede the facts common to both Tags F225 and F323. It is clear from the CMS prehearing brief that CMS intended to present at hearing and rely upon the facts common to both Tags F225 and F323, as evidenced by the CMS argument that the deficiencies cited under both Tags F225 and F323 are bases for imposing a \$9,500.00 PICMP. Therefore, CMS cannot credibly argue that it was not prepared or that it was prejudiced by Petitioner's attempt to amend its request for hearing to request review of Tag F225. Furthermore, if I concluded that Petitioner's Administrator waived review of the facts alleged under Tag F225, that waiver would extend to the same facts alleged under Tag F323, because the factual allegations under the two deficiency citations are essentially the same, and there would be no need to proceed further with fact finding. It would only be necessary to determine whether the conceded facts amounted to noncompliance under Tags F225 and F323. There is no evidence that the Administrator was an attorney, and to strictly apply the doctrine of waiver against Petitioner based upon the Administrator's drafting skills and legal knowledge would be unjust, particularly absent any significant prejudice to CMS. Furthermore, CMS points to no regulation or statute that prevents an aggrieved party from amending its request for hearing at any time after filing and before I make a decision.

A request for hearing need only:

- (1) Identify the specific issues, and the findings of fact and conclusions of law with which the affected party disagrees; and
- (2) Specify the basis for contending that the findings and conclusions are incorrect.

42 C.F.R. § 498.40(b). I have no basis to assume that Petitioner's Administrator, who signed the January 6, 2014 hearing request, had the ability to distinguish between a "finding of fact" and "conclusion of law," legal terms of art that challenge many attorneys. However, the Administrator did a fair job of setting out what he disagreed with. He clearly disagreed with the surveyors' conclusion of law that the facts they found amounted to a violation of 42 C.F.R. § 483.25(h) as cited under Tag F323 of the SOD, and he so stated. The Administrator also clearly stated in the request for hearing that Petitioner disagreed with many factual findings made by the surveyors related to the following: the incidents involving Residents 1 and 2; facility actions and policies; and state requirements. The Administrator did not make specific reference to the surveyors'

conclusion of law that Petitioner violated 42 C.F.R. § 483.13(c)(3) as cited in the SOD under Tag F225. However, the request for hearing clearly disputed most, if not all the facts, cited by the surveyors related to the incidents involving Residents 1 and 2. There is no specific statement in the request for hearing that Petitioner conceded a violation of Tag F225. At most, Petitioner's failure to specifically challenge the conclusion of law that Petitioner violated 42 C.F.R. § 483.13(c)(3) as cited under Tag F225 could be construed as a waiver of review of whether or not the facts, if established, constitute a violation of Tag F225. CMS has cited no statutory or regulatory provision that would prevent the withdrawal of such an implicit waiver or require a showing of good cause for such a withdrawal. In promulgating 42 C.F.R. pt. 498, the procedural regulations applicable to this case, CMS did impose a requirement for a party to show good cause in the event the party sought to withdraw a waiver of an oral hearing. The good cause requirement under such circumstances makes sense as the parties' trial preparation would be suspended in a case where the parties thought the case would be decided on written pleadings and documentary evidence. The circumstances are significantly different in this case because the parties were aware from the early stages of trial preparation that Petitioner did not concede or waive hearing as to the facts alleged as the basis for the surveyors' conclusion of law that Petitioner violated 42 C.F.R. § 483.13(c)(3). In this case, the requested amendment of the request for hearing is really very narrow. Petitioner has never not disputed the facts underlying the alleged violation of 42 C.F.R. § 483.13(c)(3). The amendment simply clarifies that Petitioner also does not concede the legal issue of whether or not, if proven, the facts alleged under Tag F225 support a legal conclusion that Petitioner violated 42 C.F.R. § 483.13(c). There is no dispute that Petitioner's request for hearing was timely and that I have jurisdiction to decide all legal issues, including whether or not the facts constitute the regulatory violations that CMS cites as a basis for the imposition of the PICMP. On the facts of this case, I will not conclude that Petitioner's non-attorney Administrator waived the legal issue particularly where he specifically challenged the underlying facts.

Amending the request for hearing is unnecessary in this case. The attempted amendment is really a clarification by Petitioner of the conclusions of law it seeks to challenge. CMS is not prejudiced as there was no change in the factual bases that CMS had to present to meet its very low evidentiary burden to establish a prima facie case. CMS was also on notice well in advance of the proposed amendment, as early as the filing of the original request for hearing in fact, that Petitioner did not concede the findings of fact that the surveyors allege amounted to a violation of 42 C.F.R. § 483.13(c). At most, CMS was obliged as part of post-hearing briefing to address the legal issue of whether or not the facts established amounted to a violation of 42 C.F.R. § 483.13(c) as well as a violation

of 42 C.F.R. § 483.25(h), which I conclude does not amount to unreasonable prejudice. The burden to CMS of challenging the amendment of the request for hearing was a burden of its own choosing that could have been simply waived with no real prejudice to CMS.¹⁰

- 5. The state agency violated section 1819(g)(2)(C) of the Act and 42 C.F.R. § 488.314(a)(1) by permitting a survey team with no registered nurse participating to conduct the survey of Petitioner that was completed on September 6, 2013.
- 6. Because the survey team that completed the survey of Petitioner on September 6, 2013, was constituted in violation of section 1819(g)(2)(C) of the Act and 42 C.F.R. § 488.314(a)(1), the findings and conclusions of the survey team were reached in violation of the Act and regulations, and are therefore, void and may not be the bases for the imposition of enforcement remedies.
- 7. No enforcement remedy is reasonable in the absence of a basis for imposing such a remedy.

Petitioner argues that the survey in this case was unlawfully constituted because the survey team did not include a registered nurse. P. Br. at 5-8; P. Reply at 15-16. Petitioner is correct that the Act and regulations require that survey teams include a registered nurse. It is undisputed by CMS that the team that conducted the survey of Petitioner's facility that was completed on September 6, 2013, did not include a registered nurse. For the following reasons, I conclude that the unlawfully constituted survey team could not lawfully conduct a survey in violation of the Act and regulations. Furthermore, an unlawfully conducted survey may not be the basis for the imposition of any enforcement remedy.

The Act imposes upon the Secretary and CMS certain requirements for the survey and certification of long-term care facilities, SNFs and NFs. Act §§ 1819(g) (SNFs), 1919(g) (NFs) (42 U.S.C. §§ 1395i-3(g), 1396r(g)). The Act requires that state agencies establish a reporting procedure and a procedure for conducting investigations of allegations of neglect and abuse and misappropriation of resident property. Act § 1819(g)(1)(C). The

¹⁰ On January 29, 2015, Petitioner submitted a letter requesting that I sanction CMS for filing its objection by reducing the pages permitted CMS for its post-hearing brief from 30 to 16. CMS responded by letters dated February 3, 2015 and February 11, 2015. Petitioner's request was not considered as it was not submitted as a motion as required by the Prehearing Order ¶ II.D.6.

Act also requires each state to maintain procedures and staff to investigate complaints of violations of Medicare participation requirements and for monitoring SNF compliance. Act § 1819(g)(4). The parties stipulated that a complaint investigation was conducted on September 5, 2013, which triggered a survey on September 6, 2013. Jt. Stip. ¶¶ 9, 10. The procedures and requirements mandated by Congress for surveying long-term care facilities are established in Act §§ 1819(g)(2) and 1919(g)(2). The Act establishes three types of surveys: ¹¹ the standard survey, the extended survey or partial extended survey, and special surveys such as an abbreviated standard survey. ¹² Act § 1819(g)(2)(A), (B). The Act provides that surveys are to be conducted by a survey team that meets the "minimum qualifications" established by the Secretary. Act § 1819(g)(2)(C). However, section 1819(g)(2)(E) of the Act specifically imposes a requirement for survey team composition:

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The Secretary's regulations are consistent with the Act. Definitions of extended survey, partial extended survey, standard survey, and abbreviated survey are found in 42 C.F.R. § 488.301. According to 42 C.F.R. § 488.30, a complaint survey is a survey conducted on the basis of a substantial allegation of noncompliance. "Complaint survey" is only used in 42 C.F.R. pt. 488, the survey, certification and enforcement regulations, in the context of establishing revisit user fees. The procedures for survey and certification of SNFs and NFs are in 42 C.F.R. pt. 488. State agencies conduct standard or abbreviated standard surveys to investigate complaints of noncompliance against SNFs and NFs, if preliminary review results in a conclusion that a deficiency may have occurred, and only a survey can determine whether or not a deficiency exists. 42 C.F.R. §§ 488.308(e)(2), 488.335. Extended and partial extended surveys are triggered by a finding of substandard quality of care, specifically for the purpose of examining the facility policies and procedures that may have caused the substandard quality of care. 42 C.F.R. §§ 488.301, 488.310.

The Act also provides in sections 1819(g)(3) and 1919(g)(3) for "validation surveys." Validation surveys, under the Act, are surveys conducted by the Secretary or CMS of a representative sample of facilities surveyed by the state to determine the adequacy of state agency compliance with survey requirements in surveying nursing facilities. In conducting a validation survey, the Secretary or CMS must apply the same protocols required of the state survey agency when conducting a survey under section 1919(g)(3) of the Act, which includes the requirement for a registered nurse to be a member of the survey team. Validation surveys of state performance are referenced in 42 C.F.R. §§ 488.301, 488.330(a), (g). Validation surveys and accreditation surveys are also used by CMS to assess the performance of accreditation organizations. 42 C.F.R. §§ 488.5(c)-.7.

- (E) Survey teams.—
- (i) In general.—Surveys under this subsection **shall** be conducted by a multidisciplinary team of professionals (**including a registered professional nurse**).

(Emphasis added.) Therefore, irrespective of the professional qualifications of other survey team members, Congress has required that every survey team include a registered professional nurse. The requirement applies to all types of surveys established by section 1819(g)(2) of the Act, including the standard survey, the extended survey or partial extended survey, and special surveys such as an abbreviated standard survey. Act § 1819(g)(2)(A), (B). There are no surveys authorized by the Act under section 1819(g) of the Act that are exempt from the requirement of section 1819(g)(2)(E) of the Act to include a registered nurse.

The Secretary has by regulation required that all survey teams include a registered nurse. Specifically, 42 C.F.R. § 488.314(a)(1) requires that surveys "be conducted by an interdisciplinary team of professionals, which must include a registered nurse." 59 Fed. Reg. 56,116, 56,119 (Nov. 10, 1994). In proposed rulemaking in 1992, the proponent of the regulations establishing the SNF and NF survey process, which implemented the Omnibus Budget Reconciliation Act of 1987, stated that sections 1819(g)(2)(E) (pertaining to SNFs) and 1919(g)(2)(E) (pertaining to NFs) required that a survey team include a registered nurse, and the drafters included that requirement in the draft regulation. 57 Fed. Reg. 39,278 at 39,286, 39,307 (Aug. 28, 1992). When the final rule was issued in 1994, the drafters of 42 C.F.R. § 488.314 explained that the registered nurse is necessary because SNFs and NFs that are being surveyed are "primarily engaged in providing skilled nursing care and/or related services." 59 Fed. Reg. at 56,142. The drafters failed to mention that a registered nurse is also required to participate by Congress. Act §§ 1819(g)(2)(E), 1919(a)(2)(E).

In *Omni Manor Nursing Home*, DAB No. 1920 at 5 (2004), an appellate panel of the Board stated:

Surveys of long term care facilities "must be conducted by a multidisciplinary team of professionals, which must include a registered nurse." 42 C.F.R. § 488.314(a)(1). Professionals who may be on such a survey team include physicians, nurse practitioners, dieticians, engineers, or social workers. 42 C.F.R. § 488.314(a)(2). The state (with CMS approval) determines what constitutes a survey team professional. 42 C.F.R. § 488.314(a)(3). "Surveyors are professionals who use their judgment, in concert with Federal forms and procedures, to determine compliance." 42 C.F.R.

§ 488.26(c)(3). The state survey agency must use "methods, procedures, and forms that are prescribed by [CMS]." 42 C.F.R. § 488.26(d). The use of federal procedures "ensure[s] uniform and consistent application and interpretation of Federal requirements." 42 C.F.R. § 488.26(c)(4). The use of federal forms "ensure[s] proper recording of findings and [documentation of] the basis for the findings." 42 C.F.R. § 488.26(c)(5).

There is no dispute that a complaint investigation was conducted at Petitioner's facility on September 5, 2013, by Linda Werth, R.D., C.D.N, followed by a partial extended survey or an abbreviated standard survey¹³ on September 6, 2013, that was conducted by Ms. Werth and Mary Langworthy, R.D., C.D.N. Jt. Stip. ¶¶ 9-10; CMS Exs. 2-4. Ms. Werth is not a registered nurse. Tr. Vol. 1 at 100-01. Ms. Langworthy is also not a registered nurse. CMS has not disputed that no registered nurse participated in the complaint investigation or the partial extended or abbreviated standard survey on September 6, 2013. Tr. Vol. 2 at 85-87.

I conclude, based on the undisputed facts, that the state agency violated section 1819(g)(2)(C) of the Act and 42 C.F.R. § 488.314(a)(1) by permitting a survey team with no registered nurse participating to conduct the survey of Petitioner completed on September 6, 2013. I further conclude that the findings and conclusions of the survey team, which was constituted in violation of the Act and regulations, are invalid and cannot be the bases for the imposition of any enforcement remedy. The Secretary is authorized by Congress to impose enforcement remedies against a SNF or NF when it is found "on the basis of a standard, extended, or partial extended survey [under section 1819(g)(2) or 1919(g)(2) of the Act] or otherwise," that a SNF or NF no longer meets conditions for participation in Medicare or Medicaid. Act §§ 1819(h), 1919(h). The Secretary delegated the authority to impose enforcement remedies to CMS. The

The inconsistent and incorrect use of terms by state survey agencies and CMS is a recurring annoyance. The October 4, 2013 letter from the state agency to Petitioner's Administrator plainly states in the first line of the body of the letter that "[o]n September 6, 2013, a partial extended survey was completed at [Petitioner]." CMS Ex. 4. In the SOD, the surveyors referred to the survey completed on September 6, 2013, as an "abbreviated survey." CMS Ex. 1 at 2, 5. In the revised SOD issued by CMS on December 5, 2014, the survey completed on September 6, 2013, is also referred to as an "abbreviated survey." CMS Ex. 64 at 4, 7. Whether or not the September 6, 2013 survey was an abbreviated standard or a partial extended survey need not be resolved in this case because the requirement to have a registered nurse on the survey team applies equally to both.

Secretary provided that "[w]hen CMS or the State chooses to apply one or more remedies specified in [42 C.F.R. § 488.406], the remedies are applied on the basis of noncompliance found during surveys conducted by CMS or by the survey agency." 42 C.F.R. § 488.402(b). In this case, the surveyors' findings and conclusions were invalid because the survey team was constituted in violation of the Act and regulations and thus, may not be the bases for imposing an enforcement remedy. There should be no question that:

An agency has no power to act in conflict with the authority granted to it by the legislature or outside of its own regulations. In addition, an agency may not exceed its statutory authority or constitutional limitations, and administrative actions exceeding authority delegated by law are void.

2 Am. Jur. 2d *Administrative Law* § 51 (2016) (footnotes omitted). "The power of an administrative agency must be exercised in accordance with and in the mode prescribed by the statute or other law bestowing such power." *Id.* § 52.

CMS argues that: there is no requirement to send a registered nurse on a complaint survey;¹⁴ whether or not a registered nurse participated in a survey is not an initial determination subject to my review; and inadequate survey performance does not relieve a facility of noncompliance with participation requirements. CMS Br. at 29. The CMS arguments are without merit.

In its post-hearing briefing, CMS misquotes section 1819(g)(2)(E)(i) of the Act in a way to suggest that Congress left to the Secretary, CMS, or the state agency the discretion to determine whether or not a registered nurse was required to participate as a member of a survey team. ¹⁵ CMS Br. at 30; CMS Reply at 3-5. However, the language of section

The reference to a "complaint survey" is an inaccurate use of the term. The Act provides for complaint investigations (Act § 1819(g)(1)(C) and (g)(4)) and various types of surveys (Act § 1819(g)(2)), including the standard survey, the extended survey or partial extended survey, and special surveys such as an abbreviated standard survey. See footnotes 11 and 12. A complaint may trigger one of the types of surveys established by the Act, as it did in this case. CMS subsequently acknowledges in its post-hearing brief that the survey completed on September 6, 2013, was an abbreviated standard survey, though the state agency also characterized as a partial extended survey. CMS Br. at 30.

¹⁵ CMS states in its brief: "The Act states that '[i]n general...' surveys shall be conducted by a survey team that includes a registered nurse, thus providing the Secretary (Footnote continued next page.)

1819(g)(2)(E)(i) clearly mandates that surveys conducted under the authority of subsection 1819(g)(2) "shall be conducted by a multidisciplinary team of professionals (including a registered professional nurse)." Congress left no room for the exercise of discretion by the Secretary, CMS, or the state agency, and the failure to include a registered nurse on a survey team conducting a partial extended or an abbreviated standard survey clearly violates section 1819(g)(2)(E)(i) of the Act. Contrary to what CMS suggests, the words "In general" at the beginning of section 1819(g)(2)(E)(i) did not open the door for the Secretary to find exceptions to the requirement that a survey team be a multidisciplinary team of professionals that includes a registered nurse. "In general" is the title or topic of the subsection used to show that the subsection applies to all surveys "in general" and not just a particular type of survey. "In general" is separated from the substantive law set forth in section 1819(g)(2)(E)(i) by both a period and a dash and clearly does not modify the requirement established by Congress in that section. The other sections and subsections of section 1819(g) all have similar titles or topics and the use of those titles or topics is consistent with and supports my interpretation.

(Footnote continued.)

with leeway as to the survey team composition. Act §1819(g)(2)(E)(i)." Section 1819(g)(2)(E)(i) as published at www.ssa.gov/OP_Home/ssact/title18/1819.htm actually states:

(E) SURVEY TEAMS.—

(i) IN GENERAL.—Surveys under this subsection shall be conducted by a multidisciplinary team of professionals (including a registered professional nurse).

The codification of section 1819 (g)(2)(E)(i) at 42 U.S.C. § 1395i-3(g)(2)(E)(i), available at www.gpo.gov/fdsys/pkg/USCODE-2010-title42-chap7-subchapXVIII-partA.htm, states:

(E) Survey teams

(i) In general

Surveys under this subsection shall be conducted by a multidisciplinary team of professionals (including a registered professional nurse).

(Emphasis in original.)

CMS also asserts that the SOM "permissibly interprets the statute and regulation as not requiring that a registered nurse be sent on a complaint survey that is an abbreviated standard survey." CMS Br. at 30; CMS Reply at 6-7. The Board has been very clear that the SOM is not a substantive rule that may be applied contrary to the Act or regulations:

The SOM, in general, is a compilation of interpretive guidelines, standards of practice, and internal policies directed to the state survey agencies that conduct long-term care facility surveys and that certify facility compliance. *See, e.g., Columbus Nursing & Rehabilitation Center*, DAB No. 2247, at 23 (2009); *Claiborne-Hughes Health Center*, DAB No. 2223, at 8 (2008); *Aase Haugen Homes, Inc.*, DAB No. 2013, at 15 (2006). While the SOM may reflect CMS's interpretations of the applicable statutes and regulations, the SOM provisions are not substantive rules themselves. *Beverly Health & Rehabilitation Services v. Thompson*, 223 F.Supp.2d 73, at 99-106 (D.D.C.), *aff'g Beverly Health & Rehabilitation-Spring Hill*, DAB No. 1696 (1999).

* * *

[W]e have previously upheld an ALJ's conclusion that "unpublished internal guidance to surveyors in the SOM . . . was not a reliable basis to alter the plain meaning of [a] published regulation." *Beverly Health and Rehabilitation Center - Williamsburg*, DAB No. 1748, at 8 (2000).

Foxwood Springs Living Ctr., DAB No. 2294 at 8-9 (2009) (concluding that the SOM provision was not binding on either the ALJ or the Board).

The interpretation of the SOM urged by CMS in this case is simply in error. CMS policy related to survey team composition is consistent with the Act and the Secretary's regulations in requiring that all survey teams include a registered nurse. SOM, chap. 7, § 7201.2 (rev. 63, eff: Sep. 10, 2010) provides:

The State (or, for Federal teams, the regional office) decides what the composition of the survey team will be, as long as certain statutory and regulatory requirements are met. Sections 1819(g)(2)(E) and 1919(g)(2)(E) of the Act and 42 CFR 488.314 require that:

• Skilled nursing facility and nursing facility standard surveys be conducted by a multidisciplinary team of

professionals, at least one of whom must be a registered nurse:

- Surveyors be free of conflicts of interest (see §7202); and
- Surveyors successfully complete a training and testing program in survey and certification techniques that has been approved by the Secretary. In other words, surveyors must successfully complete the CMS-approved training and pass the Surveyor Minimum Qualifications Test. (See §4009.1 of this manual for additional information concerning Surveyor Minimum Qualifications Test requirements.)

Within these parameters, the States (or, for Federal teams, the regional offices) are free to choose the composition of each team, and it is the State that determines what constitutes a professional.

CMS Ex. 69 at 2 (emphasis added).

CMS argues, citing 42 C.F.R. § 488.318(b), that inadequate survey performance does not relieve a facility of its obligation to remain in substantial compliance with Medicare participation requirements or invalidate adequately documented deficiencies. CMS Br. at 30; CMS Reply at 8-9. I agree with CMS on this point. However, the regulation cited does not authorize CMS to impose an enforcement remedy based on an unlawful survey, which is a different issue than whether or not Petitioner must remain in substantial compliance.

CMS objects in a footnote that I raised this issue sua sponte during the hearing. CMS complains that Petitioner did not raise the issue and asserts prejudice. CMS Br. at 30 n.13. CMS does not articulate what prejudice it suffered and I find none. I am bound to follow the Act and regulations. "An ALJ is bound by applicable laws and regulations and may not invalidate either a law or regulation on any ground, even a constitutional one. But an ALJ may, consistent with the applicable regulations and statutes, take steps to ensure procedural fairness." *1866ICPayday.com*, *L.L.C.*, DAB No. 2289 at 14 (2009). The fact that Petitioner did not identify the issue initially, and the fact that CMS apparently failed to identify the statutory and regulatory violation by the state agency and/or chose not to reveal the violation of the Act, does not relieve me of my responsibility to ensure that the law and regulations are properly executed. Indeed, I have an affirmative responsibility to ensure that the law and regulations are applied correctly. I have a duty to raise issues sua sponte for the parties to address, particularly where, as here, there is a clear statutory and regulatory violation. The administrative hearing process is not a game that CMS wins simply because Petitioner failed to raise an issue. I

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also find no prejudice to CMS in the way the issue was raised or the opportunity provided to CMS to address the issue. The issue was raised early in the proceedings, there is no dispute as to the facts that could have been addressed by additional evidence, and CMS had a significantly long briefing schedule and two pleadings totaling 60 pages in which to address the fatal defect in the survey process.

CMS asserts that I have no jurisdiction to address whether or not the survey was properly constituted because the issue is not an initial determination. CMS Br. at 30. The CMS initial determination to impose a \$9,500.00 PICMP is clearly an initial determination within the meaning of 42 C.F.R. § 498.3(b)(13). The certification of noncompliance on which CMS based the enforcement remedy triggered Petitioner's right to a hearing. 42 C.F.R. § 488.408(g). Therefore, whether or not the certification of noncompliance was correct and provides a basis or bases for the imposition of an enforcement remedy is the general issue that must be resolved. An unlawfully constituted survey team may be found, as I have in this case, to render the findings and conclusions of the survey team invalid, thereby eliminating the basis for the imposition of the enforcement remedy. I agree with CMS that the legal issue is not an "initial determination," but the review of the lawfulness of the "initial determination," which is properly before me, turns on the legal issue.

16 Cf. Foxwood, DAB No. 2294 at 13-14.

¹⁶ CMS cites Perry Cnty. Nursing Ctr. v. U.S. Dep't of Health & Human Servs., 603 Fed.Appx. 265 at 272 (5th Cir. 2015). CMS Br. at 29. The unpublished decision of the U.S. Court of Appeals for the Fifth Circuit is not inconsistent with my understanding of Petitioner's right to request review, the general issue I must address, or the scope of my jurisdiction. If the purpose of the citation is to subtly suggest that I should defer to CMS's interpretation of the scope of my jurisdiction and CMS's interpretation and applications of its regulations and the Act, *Perry* is entitled to no weight as it is not on point. The court in *Perry* discusses in the cited pages the concept of the judiciary deferring to an executive branch administrative agency. Nothing in Perry suggests that the Secretary must defer to CMS, which acts with authority delegated by the Secretary. Nor does *Perry* suggest that an ALJ or the Board, who act with delegated authority for the Secretary, are required to defer to CMS and its interpretations and application of the Act and the Secretary's regulations, and such a requirement would render meaningless the right to ALJ and Board review granted to the regulated entities by Congress. Nor does *Perry* suggest that the Secretary may avoid responsibility for execution of the Act by the simple expedient of delegating her authority to a component agency and then deferring to the acts of the agent to which she delegated that authority.

III. Conclusion

For the foregoing reasons, I conclude that there is no basis for the imposition of an enforcement remedy and no enforcement remedy is reasonable in this case.

/s/ Keith W. Sickendick Administrative Law Judge