

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Elgin Nursing and Rehabilitation Center,
(CCN: 67-6180),

Petitioner

v.

Centers for Medicare and Medicaid Services.

Docket No. C-10-679

Decision No. CR2376

Date: May 26, 2011

DECISION

Petitioner Elgin Nursing and Rehabilitation Center contests a determination by the Centers for Medicare and Medicaid Services (CMS) that it was not in substantial compliance with certain requirements for participation in the Medicare and Medicaid programs. Below, I sustain CMS's determination that Petitioner was not in substantial compliance with the regulatory requirement outlined at 42 C.F.R. § 483.35(i) and identified during the February 12, 2010 survey as deficiency tag F-371. I also sustain the per-instance civil monetary penalty (PICMP) of \$5000 imposed by CMS.

I. Background

Petitioner is a long-term care facility located in Elgin, Texas, that participates in the Medicare and Medicaid programs. The Texas Department of Aging and Disability Services completed a survey of Petitioner's facility on February 12, 2010. The survey cited a deficiency under 42 C.F.R. § 483.35(i) (tag F-371, at a scope and severity level of "K").¹ CMS Ex. 3, at 26-33. By letter dated March 2, 2010, CMS notified Petitioner that

¹ A scope and severity level of "K" denotes a pattern of deficiencies that constitute immediate jeopardy to resident health and safety. 42 C.F.R. § 488.408; State Operations Manual (SOM), Ch. 7 § 7400E (scope and severity matrix).

it was imposing the following remedies: a PICMP of \$5000; termination of Petitioner's provider agreement; a denial of payment for new admissions (DPNA) beginning March 17, 2010; and withdrawal of approval for Petitioner to conduct a nurse aide training and competency evaluation program (NATCEP) for a period of two years. By letter dated May 13, 2010, CMS rescinded the termination and DPNA remedies. CMS Ex. 1, at 1-4. Petitioner requested a hearing by letter dated May 3, 2010.

CMS filed a motion for summary judgment on June 10, 2010, asserting that there were no genuine issues of material fact. Petitioner filed a response resisting CMS's motion on July 28, 2010. Having determined that Petitioner offered evidence in direct contradiction of CMS's arguments, I denied CMS's motion for summary judgment. *See* Ruling issued August 13, 2010.

Although Petitioner was cited for other deficiencies during the survey, Petitioner appeals only the alleged deficiency cited as tag F-371. Request for hearing; Prehearing Order issued October 15, 2010, at 3-4. Because the PICMP proposed by CMS is within the single range available, Petitioner may not challenge the assessment of its alleged noncompliance at the "K" level of scope and severity. 42 C.F.R. §§ 498.3(b)(14), (d)(10)(i). Consequently, the only citation for my review and the only citation which is the sole basis for the imposed remedies is that based on 42 C.F.R. § 493.35(i), tag F-371.

A brief hearing was held on Thursday, November 4, 2010, in Dallas, Texas. At hearing the parties informed me for the first time that they had agreed to all of the material facts in the case and presented me with a written Agreed Stipulation of Facts. They then represented to me that because they had reached this agreement to eliminate all factual disputes in this case, they believed that they had thereby eliminated the need for evidentiary testimony. Tr. at 15-16. Consequently, no evidence was taken by oral testimony and in the absence of objection CMS Exs. 1-14 and P. Exs. 1-18² were admitted. Tr. at 26-27. The Agreed Stipulation of Facts has been marked as ALJ Ex. A and admitted into the record. The parties' post-hearing submissions were received and this matter is now before me for decision.

² I note that on page 3 of the hearing transcript there is an incorrect notation that CMS Ex. 15 was proffered and admitted. It is clear from the hearing transcript at page 21 that CMS proffered only 14 exhibits and that all were admitted at hearing. *Compare* Tr. at 3 with Tr. at 21, 26. At hearing, P. Exs. 11-18 were conditionally admitted with the proviso that Petitioner provide to my office an accurate exhibit list of all of its exhibits. Tr. at 21-22. Petitioner satisfied this requirement subsequent to the hearing. I note also that although P. Exs. 11-18 are properly paginated, the cover sheet for each of these exhibits incorrectly lists the docket number as C-10-670 instead of C-10-679. In order not to delay the proceedings in this case, Petitioner was not asked to re-file the exhibits and they were admitted as noted above. Where the parties have submitted duplicate copies of exhibits or pages contained in exhibits, I generally refer to CMS's exhibit.

II. Issues, Applicable Law, Findings of Fact and Conclusion of Law

A. Issues

The issues in this case are:

1. Whether Petitioner failed to comply with the Medicare participation requirement at 42 C.F.R. § 483.35(i) (tag F-371); and
2. Whether the remedies imposed are reasonable.

B. Applicable Law and Regulations

Petitioner's participation in Medicare and Medicaid is governed by sections 1819 and 1919 of the Social Security Act (Act) and the regulations at 42 C.F.R. Part 483. Sections 1819 and 1919 of the Act vest the Secretary of Health and Human Services (Secretary) with authority to impose civil money penalties (CMPs) and other remedies against a long-term care facility for failure to comply substantially with participation requirements. Pursuant to the Act, the Secretary has delegated to CMS the authority to impose various remedies against a long-term care facility that is not complying substantially with federal participation requirements.

The applicable regulations at 42 C.F.R. Part 488 provide that facilities participating in Medicare and Medicaid may be surveyed on behalf of CMS by state survey agencies in order to ascertain whether the facilities are complying with participation requirements. 42 C.F.R. §§ 488.10-488.28; 488.300.335. A state or CMS may impose a CMP against a long-term care facility if a state survey agency ascertains that the facility is not complying substantially with participation requirements. 42 C.F.R §§ 488.406; 488.408; and 488.430. The CMP may begin to accrue as early as the date the facility was first substantially out of compliance, and may continue to accrue until the date the facility achieves substantial compliance or until CMS terminates the facility's provider agreement. 42 C.F.R. § 488.440.

The regulations define the term "substantial compliance" to mean "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." Noncompliance that is immediate jeopardy is defined as "a situation in which 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.

Sections 1819(f)(2)(B) and 1919(f)(2)(B) of the Act prohibit approval of a NATCEP if within the last two years the facility has been subject to, among other things, an extended

or partial extended survey; imposition of a CMP of not less than \$5,000; or imposition of a DPNA.

A facility may challenge the scope and severity that CMS cites only if a successful challenge would affect the range of CMP amounts that CMS imposed or would affect the facility's NATCEP. 42 C.F.R. § 498.3(b)(14), (d)(10)(i). CMS's determination as to the scope and severity of noncompliance "must be upheld unless it is clearly erroneous." 42 C.F.R. § 498.60(c)(2). This includes CMS's finding of immediate jeopardy. *Woodstock Care Center*, DAB No. 1726, at 9 (2000), *aff'd*, *Woodstock Care Center v. U.S. Department of Health and Human Services*, 363 F.3d 583 (6th Cir. 2003).

When a penalty is imposed and appealed, CMS has the burden of coming forward with evidence related to disputed findings that are sufficient, together with undisputed findings and relevant legal authority, to establish a *prima facie* case of noncompliance with a regulatory requirement. If CMS makes this *prima facie* showing, a petitioner must then carry its ultimate burden of persuasion by showing by a preponderance of the evidence on the record as a whole that it was in substantial compliance during the relevant period. CMS makes its *prima facie* showing if the evidence it relies on is sufficient to support a decision in its favor absent an effective rebuttal. An effective rebuttal of CMS's *prima facie* case would mean that the petitioner has shown that a preponderance of the evidence supports the facts on which its case depends. *Evergreene Nursing Care Center*, DAB No. 2069, at 7 (2007). For the reasons enumerated below, I conclude that CMS did make its *prima facie* showing here, which Petitioner has failed to rebut successfully.

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

I make findings of fact and conclusions of law (Findings) to support this decision. I set them forth below as separate headings in bold and italic type, and discuss each in detail.

1. Petitioner failed to comply substantially with the participation requirement at 42 C.F.R. § 483.35(i), cited as tag F-371.

The violation that CMS alleges in this case involves Petitioner's improper cooking and serving of eggs to five facility residents. The alleged lapse was discovered during a survey of Petitioner's facility in February 2010. The regulation at issue establishes guidelines for the procurement, storage, preparation, and service of food provided to facility residents, and provides, in pertinent part, that:

(i) *Sanitary conditions.* The facility must—

(1) procure food from sources approved or considered satisfactory by Federal, State, or local authorities; [and]

(2) store, prepare, distribute, and serve food under sanitary conditions

42 C.F.R. § 483.35(i).

As guidance for safe food preparation, the State Operations Manual (SOM), Appendix PP – Guidance to Surveyors for Long Term Care Facilities advises, in pertinent part, that:

• **Final Cooking Temperatures** – Cooking is a critical control point in preventing foodborne illness. Cooking to heat all parts of food to the temperature and for the time specified below will either kill dangerous organisms or inactivate them sufficiently so that there is little risk to the resident if the food is eaten promptly after cooking. Monitoring the food’s internal temperature for 15 seconds determines when microorganisms can no longer survive and food is safe for consumption. Foods should reach the following internal temperatures:

Unpasteurized eggs when cooked to order in response to resident request and to be eaten promptly after cooking; - 145 degrees F for 15 seconds; until the white is completely set and the yolk is congealed; . . .

SOM, App. PP, Tag F-371.

As guidance in the proper manner of preparing “soft-cooked eggs”, David Wright, Chief of the Long Term Care Branch, Division of Survey and Certification for CMS, issued Regional Survey and Certification Letter 04-08, dated October 8, 2004, and titled “Serving Undercooked or Raw Eggs to Nursing Home Residents.” The intent of the letter was to provide clarification as to “the acceptability of serving ‘soft-cooked, runny, or raw’ eggs to residents in nursing homes.” The letter stated that “[s]oft-cooked eggs are considered undercooked if the yolk is runny and/or the egg white is not congealed.” The letter further clarified that “[i]f a facility serves ‘soft-cooked’ eggs, they must use eggs that are pasteurized, or otherwise treated in an acceptable manner to kill or inactive bacteria and other harmful microorganisms.” The letter warned that if “undercooked eggs are not pasteurized or otherwise treated, it is likely that the nursing home is placing residents who consume these eggs in immediate jeopardy.” The letter contained an attachment from the Food and Drug Administration (FDA) observing that the U.S. Department of Agriculture, Food Safety and Inspection Service, through its Salmonella Enteritidis Risk Assessment noted that persons with chronic diseases and nursing home residents are particularly susceptible to salmonella infections. The attachment also notes that a weekly report from the Center for Disease Control, dated January 3, 2003, included a recommendation on how to prevent the risk of contracting salmonella infection associated with the ingestion of eggs, which stated: “In hospitals, nursing homes, adult or childcare facilities, and senior centers, pasteurized egg products or pasteurized in-shell eggs should be used in place of pooled eggs or raw or undercooked eggs.” P. Ex. 4.

Although the parties have stipulated to the facts in this case³ they differ as to the legal consequences resulting from the application of the facts to law. I have reviewed and considered all the evidence, including the documents and affidavits proffered, and the arguments of both parties, although not all may be specifically discussed in this decision. Based on that review, I find that the following undisputed material facts require a finding that Petitioner was out of compliance with 42 C.F.R. § 483.35(i).

Petitioner purchased unpasteurized shelled eggs between August 2009 and February 2010 and served those eggs “soft-cooked” to residents in its facility. During a survey in February 2010, surveyors found two-and-a-half cases (40 dozen, or 480 eggs) of unpasteurized eggs in the facility’s refrigerator. Each egg case contained the following instructions: “Safe handling instructions. To prevent illness from bacteria keep eggs refrigerated, cook eggs until yolks are firm and cook foods containing eggs thoroughly.” CMS Ex. 3, at 27; CMS Ex. 6, at 74; P. Br. at 4. On the morning of February 9, 2010, five facility residents (Residents 6, 20, 21, 22, and 23) were served — and the residents consumed by eating — “soft-cooked” unpasteurized shelled eggs. That morning the facility cook prepared the eggs in the manner requested by the residents which included either “over easy” or “soft-cooked” – also referenced as a “soft fried” egg. P. Ex. 14; CMS Ex. 3, at 27. That same morning the surveyors observed smeared egg-yolks on the plates of the residents. CMS Ex. 3, at 27. The surveyors did not observe the eggs being cooked that morning. The internal temperature of each egg served to the five residents after the eggs were cooked that morning was not taken by either the surveyor or Petitioner’s cook. P. Ex. 1, at 1; P. Ex. 14, at 1, paragraphs 2, 3; CMS Ex. 3, at 26-33; P. Ex. 18. Nevertheless, the parties stipulate and all the evidence agrees: the eggs were not prepared according to the safety handling instructions on the egg cases. Tr. at 35; CMS Ex. 3, at 28.

The surveyors allege in the SOD for the September 12, 2010 survey that Petitioner violated 42 C.F.R. § 483.35(i) when Petitioner served “soft-cooked” unpasteurized eggs with “runny” yolks from its facility kitchen to five residents (Residents 6, 20, 21, 22, and 23). CMS Ex. 3, at 27. CMS relies on the regulatory language of section 483.35(i) and the SOM’s interpretive guidance to support its view that Petitioner failed properly to distribute and serve food under sanitary conditions by serving “soft-cooked” eggs that were neither pasteurized nor otherwise treated in an acceptable manner to kill or inactive bacteria and other harmful microorganisms in order to prevent food-borne illness resulting from bacteria contamination such as salmonella. CMS Br. at 3, 4. According

³ The parties stipulated to the facts established in the Statement of Deficiencies (SOD) Form 2567 (CMS Ex. 3, at 26-33) for the February 12, 200 survey, tag F-371, including surveyor observations, interviews and record reviews; and to the facts stated in the affidavits of Pamela Sue Brummit, Gary Jefferson, Mary Abshire, and the video of Pamela Sue Brummit. ALJ Ex. A; P. Exs. 10, 12, 14, and 17.

to CMS, the smeared yolk noted by the surveyors on the residents' plates was an indication that the yolks were not cooked until firm as required by the safe-handling instructions listed on the egg cases. CMS Br. at 5.

Petitioner adopts a different view of the implications of these undisputed facts and advances several arguments. First, as for CMS's reliance on the SOM, Petitioner argues that although the SOM provides guidance in the interpretation of the regulations, the manual's provisions as policy guidance do not have the effect of enforceable, substantive regulation. P. Br. at 4-5. Petitioner argues that CMS has failed to provide evidence via scientific research that the SOM's requirement that unpasteurized eggs "not be served runny and/or with uncongealed egg white" supports the regulatory requirement. P. Br. at 5.

In addressing Petitioner's first argument, I note that the regulatory language of section 483.35(i)(2) does not outline how unpasteurized eggs are to be cooked in order to assure they are sanitary and thus safe for consumption. However, the SOM clearly outlines that facilities are to cook unpasteurized eggs until the eggs reach 145 degrees for 15 seconds until the white is completely set and the yolk is congealed. As Petitioner has correctly noted, a federal agency's interpretation of a regulation is entitled to deference with the caveat of as long as the interpretation is reasonable. Here, I find CMS's interpretation to be reasonable for the following reasons. Although the SOM is not enforceable as a regulation or statute it is a policy statement from CMS and provides guidance to surveyors. Moreover, although the SOM does not have the force and effect of law, the provisions of the Act and regulations interpreted clearly do have such force and effect. *See Vencor Nursing Centers, L.P. v. Shalala*, 63 F. Supp. 2d 1, 11-12 (D.D.C. 1999); *Beverly Health & Rehabilitation Services, Inc., et al v. Thompson*, 223 F. Supp. 2d 73, 98-103 (D.D.C. 2002); *Cal Turner Extended Care Pavilion*, DAB No. 2030 (2006); *see also Northwest Tissue Center v. Shalala*, 1 F.3d 522 (7th Cir. 1993); *State of Indiana by Indiana Department of Public Welfare v. Sullivan*, 934 F.2d 853 (7th Cir. 1991). Thus, while the 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. In this case, the interpretation of the SOM which CMS urges is consistent with both the Secretary's regulations and the Act. The SOM provision is a reasonable interpretation of the regulation and I afford it substantial deference. *Missouri Department of Social Services*, DAB No. 2185 (2008).

Second, Petitioner seeks to establish its compliance through reliance on Texas state law which provides that unpasteurized eggs must be cooked to heat all parts of the egg to 145 degrees or above for 15 seconds but does not address, as the SOM does, the requirement that the "egg white is completely set and the yolk is congealed." 25 TEX. ADMIN. CODE § 229.164(c)(4)(A); P. Ex. 5, at 1-2. Petitioner maintains that the condition of the egg-whites outlined in the SOM is an additional requirement that is not supported by the regulatory language. Petitioner asserts that Texas state law does not mention any degree

of “runniness” or congealment of the egg as a factor in the safe preparation of the eggs, and that to impose such a restriction is not supported by state law or even the FDA Food Code § 3-401.11 (raw animal food is to be cooked at 145 degrees F or above for 15 seconds). P. Br. at 7, 12; Tr. at 30. Petitioner alleges that it follows state law and FDA Food Code guidelines for the preparation of foods in its facility. Petitioner claims that CMS focuses on the mere presence of “runny” eggs rather than on the temperature or cooking time of the eggs, and that the evidence presented by CMS does not establish a *prima facie* case of its noncompliance. P. Br. at 11. I first point out that it is federal statutory and regulatory standards, not state law, that apply in ascertaining substantial compliance or noncompliance with Medicare participation requirements and impose uniform participation requirements across state lines. *Woodstock Care Center*, DAB No. 1726, at 19-20 (2000), *aff’d*, *Woodstock Care Center v. Thompson*, No. 01-3889 (6th Cir. 2003). While useful reference may sometimes be made to state law, it is federal law that ultimately governs here.

According to Petitioner the unpasteurized eggs served to the residents were cooked to the temperature and for the time specified in order to “either kill dangerous organisms or inactive them” to ensure little risk to residents. P. Br. at 12. In support of this assertion, Petitioner provides the affidavit of Mary Abshire, RD, a dietary consultant for Petitioner’s facility. Ms. Abshire contends that a cooking demonstration by the facility’s cook, performed on February 12, 2010, after the survey, resulted in eggs that reached a temperature of at least 145 degrees. P. Ex. 17, at 1, paragraphs 3, 4; *see also* P. Ex. 18. Petitioner provides also the affidavit of Pamela Sue Brummit, a registered dietician, who claims also to have recreated the cooking method used by the facility’s cook, Gary Jefferson, on the morning of February 9, 2010; Ms. Brummit asserts that she was able to produce eggs that reached temperatures of at least 145. P. Ex. 12. The affidavit of the facility cook, Gary Jefferson, who cooked the eggs for breakfast on the morning of February 9, 2010, provides details as to the steps he took in cooking the eggs, but his statements do little to provide support to Petitioner’s assertion that the eggs were cooked at 145 degrees for 15 seconds as required. P. Ex. 14, at 2, paragraph 2; P. Ex. 15. Additionally, neither Ms. Abshire nor Ms. Brummit address in their affidavits whether the internal temperature of the eggs were at 145 degrees or above for at least 15 seconds as required. P. Ex. 5, at 1-2. Consequently, I find Petitioner has not provided sufficient evidence that the eggs served to the five residents that are at issue here, were cooked to a temperature of at least 145 degrees in all parts of the egg for at least 15 seconds. The SOM guidance requires a measurement of both time and temperature as an assurance that the unpasteurized eggs were properly cooked — as does the Texas state law and FDA Food Code with which Petitioner purports to have been in compliance.

Last, Petitioner maintains that the eggs were cooked the way the residents wanted them, implying that it was adhering to their right to make such choices. A resident has the right to make choices about significant aspects of his or her life in the facility. 42 C.F.R. §§ 483.10(b)(4); 483.15(b)(1); and 483.15(b)(3). However, the facility is entrusted with balancing necessary care and services with resident rights. 54 Fed. Reg. 5316, 5332

(Feb. 2, 1989); *Koester Pavillion*, DAB No. 1750, at 28 (2000). Here, Petitioner had a countervailing duty to protect the individuals under its care against choices that could place their health and safety in danger. This is rarely an easy balance to strike, and it frequently obliges a facility to elevate safety concerns above residents' preferences. *Ussery Roan Texas State Veterans Home*, DAB CR2251 (2010). Beyond that, however, I also note that as much as Petitioner may suggest that it was honoring its residents' right to choose how their eggs were to be cooked, that argument is undercut by the affidavit of James P. Chudleigh, M.D., its Medical Director and the attending physician for four of the five residents at issue (Residents 6, 20, 22 and 23) at the time of the survey. Any attempt by Petitioner to suggest that the residents' preferences were to be honored strictly must be based on the assumption that the residents understood the health risks implicit in what they preferred and were able to communicate those preferences clearly, and Dr. Chudleigh's affidavit is of very little help to Petitioner on that point. Dr. Chudleigh states that each of these residents had "limitations of cognitive functioning and ability to communicate owing to their disease condition" P. Ex. 13, at 1-2, paragraphs 7, 10, 13, 16.

Petitioner has failed to provide evidence that it complied with the SOM guidance, the safe handling instructions on the egg cases, or even the Texas state law it claims to have been following when it cooked the "soft-cooked" eggs for the five residents on February 9, 2010. Petitioner's witness statements fail to provide evidence that can rebut CMS's *prima facie* showing of noncompliance. This record shows that Petitioner failed to follow sanitary food handling and preparation guidelines to prevent the outbreak of food-borne illnesses in its facility, placing the five residents at risk of food-borne illnesses such as salmonella.

Petitioner asserts that none of its residents were harmed and that none were at risk of being harmed. P. Br. at 13. A finding of immediate jeopardy does not require a finding of actual harm but encompasses as well a situation likely to cause harm. 42 C.F.R. § 488.301. The record files for the five residents who consumed "soft-cooked" unpasteurized eggs on February 9, 2010, show that they ranged in age at the time of the survey from 57 to 90, and had suspect immune systems and chronic illnesses that placed them at risk of serious illness or even death from exposure to salmonella. *See* CMS Ex. 3, at 26-33; CMS Ex. 7, at 9-10; CMS Ex. 8, at 5-8; CMS Ex. 9, at 5-7; CMS Ex. 10, at 5-6; CMS Ex. 11, at 5-7. The somber fact is that the eggs at issue were undercooked, and no argument can get around the fact that they were. Petitioner does not deny that the eggs were "runny;" that they were not prepared in accordance with the controlling safe food-handling instructions; or that the temperature of each egg was not taken the morning of February 9, 2010. Petitioner has not proven it adhered to both the time and temperature requirements — that the eggs be cooked at 145 Fahrenheit *for 15 seconds* to kill pathogenic microorganisms — on the morning of February 9, 2010. The SOM specifically states that "[s]anitary preparations of unpasteurized eggs require a final cooking temperature of 145 degrees F *for 15 seconds until the egg white is*

completely set and the yolk is congealed.” (emphasis added). The language in the SOM is not ambiguous. I find that the SOM is sufficiently-clear guidance on the subject to control this situation. Petitioner simply was not in compliance with the regulation when it prepared, distributed, and served undercooked, unpasteurized eggs to the five residents.

Accordingly, I conclude that there was a *prima facie* showing of a violation of 42 C.F.R. § 483.35(i), cited as tag F-371. I conclude also that Petitioner has failed to rebut the CMS *prima facie* showing of the violation.

2. The \$5000 PICMP imposed is reasonable.

I have concluded that Petitioner was not in substantial compliance with all program participation requirements due to a violation of 42 C.F.R. § 483.35(i), tag F-371, and that the violation posed immediate jeopardy. Therefore, there is a basis for CMS to impose an enforcement remedy in this case. If a facility is not in substantial compliance with program requirements, CMS has the authority to impose one or more of the enforcement remedies listed in 42 C.F.R. § 488.406, including a PICMP for each instance that a facility is not in substantial compliance. 42 C.F.R. § 499.430(a). When a PICMP is imposed against a facility based on an instance of noncompliance, the PICMP will be in the range of \$1000 to \$10,000 per instance. 42 C.F.R. § 488.438(a)(2).

Here, Petitioner disagrees with the amount of the PICMP stating that it is excessive in light of the factors outlined at 42 C.F.R. § 488.438(f). Request for Hearing; P. Br. at 12. My review of the reasonableness of the PICMP imposed is *de novo* and is based upon the evidence in the record before me. In determining the reasonableness I apply the factors listed at 42 C.F.R. § 488.438(f) which include: (1) the facility’s history of noncompliance; (2) the facility’s financial condition; (3) 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.

CMS does not urge me to consider any history of noncompliance in determining whether the proposed PICMP is reasonable. Petitioner has not presented evidence that it cannot pay the PICMP. However, as I have explained above, a number of this facility’s residents were placed in immediate jeopardy. Because it did so, Petitioner’s noncompliance was serious, and I therefore find that Petitioner was culpable within the meaning of the regulations.

CMS proposes a \$5000 PICMP which is in the middle range of PICMPs when immediate jeopardy is found. Given Petitioner’s failure, the amount of the CMP imposed is

reasonable. The prohibition of Petitioner's offering any NATCEP follows as a matter of law. Act §§ 1819(f)(2)(B)(iii); 1919(f)(2)(B)(iii).

III. Conclusion

For the foregoing reasons, I conclude that Petitioner was not in substantial compliance with program requirements at 42 C.F.R. § 483.35(i), cited as tag F371, and the \$5000 PICMP for one instance of noncompliance is reasonable.

/s/

Richard J. Smith
Administrative Law Judge