

**Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Appellate Division**

Elgin Nursing and Rehabilitation Center
Docket No. A-11-101
Decision No. 2425
December 6, 2011

**FINAL DECISION ON REVIEW OF
ADMINISTRATIVE LAW JUDGE DECISION**

Elgin Nursing and Rehabilitation Center (Elgin), a Texas skilled nursing facility (SNF), appeals the May 26, 2011 decision of Administrative Law Judge (ALJ) Richard J. Smith, *Elgin Nursing and Rehabilitation Center*, DAB CR2376 (2011) (ALJ Decision). Finding that Elgin did not take certain precautions to prevent food-borne illness when cooking unpasteurized eggs for its residents, the ALJ sustained a determination by the Centers for Medicare & Medicaid Services (CMS) that Elgin was not in substantial compliance with Medicare participation requirements. The ALJ also concluded that the amount of the civil money penalty (CMP) imposed by CMS for Elgin's noncompliance was reasonable. For the reasons discussed below, we affirm the ALJ Decision.

Legal Background

In order to participate in Medicare, a SNF must comply with the participation requirements in 42 C.F.R. §§ 483.1- 483.75. State agencies under contract with CMS perform on-site surveys to assess compliance with those requirements. *Id.* §§ 488.300, 488.305. Survey findings are reported in a Statement of Deficiencies. For organizational purposes, the Statement of Deficiencies identifies each “deficiency” – or failure to meet a participation requirement – using a “tag” number that CMS has assigned to that requirement. In an appendix to its State Operations Manual (SOM), CMS publishes “interpretive guidelines” that help surveyors understand and apply the regulatory requirements.¹ SOM (CMS Pub. 100-07), § 7203.1 & App. PP (*Guidance to Surveyors for Long Term Care Facilities*), available at <http://www.cms.hhs.gov/Manuals/IOM/list.asp>.²

¹ Section 7203.1 of the SOM states that the interpretive guidelines in Appendix PP are one element of a “survey protocol” whose “purpose . . . is to provide suggestions, interpretations, check lists, and other tools for use both in preparation for the survey and when performing the survey onsite.” Section 7203.1 further states that the protocol “serves to explain and clarify the requirements for long-term care facilities[,] and all surveyors measuring facility compliance with Federal requirements are required to use it.”

² A complete copy of the interpretive guidelines for section 483.35(i) (last revised on June 12, 2009) is contained in Exhibit A to Elgin's July 28, 2010 response to CMS's summary judgment motion (cited herein as “Response to MSJ Ex. A”). Excerpts of those guidelines are contained in Petitioner's Exhibit 3.

CMS may impose enforcement “remedies” on a SNF if it determines, on the basis of survey findings, that the SNF is not in “substantial compliance” with one or more participation requirements. 42 C.F.R. §§ 488.400, 488.402(b), (c). In choosing an appropriate remedy, CMS considers the “seriousness” of the SNF’s noncompliance and may consider other factors specified in the regulations. *Id.* § 488.404(a), (c).

“Seriousness” is a function of “severity” (whether the noncompliance has created a “potential” for “more than minimal” harm, resulted in “actual harm,” or placed residents in “immediate jeopardy”) and “scope” (whether the noncompliance is “isolated,” constitutes a “pattern,” or is “widespread”). *Id.* § 488.404(b); SOM, App. P – *Survey Protocol for Long Term Care Facilities*, sec. IV. “Immediate jeopardy” is the highest level of severity. *See* 42 C.F.R. §§ 488.404 (setting out the levels of scope and severity that CMS considers when selecting remedies) and 488.438(a) (authorizing the highest civil money penalties for immediate jeopardy-level noncompliance); 59 Fed. Reg. 56,116, 56,183 (Nov. 10, 1994) (scope-and-severity grid). The term “immediate jeopardy” is defined to be “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.

At issue here is whether Elgin was in substantial compliance with the participation requirement in 42 C.F.R. § 483.35(i). In relevant part, that regulation requires a SNF to “[s]tore, prepare, distribute and serve food under sanitary conditions.” According to CMS’s interpretive guidelines in the SOM, section 483.35(i) is intended to ensure that a SNF “[f]ollows proper sanitation and food handling practices to prevent the outbreak of foodborne illness” from bacteria and other pathogenic microorganisms. Response to MSJ Ex. A. The interpretive guidelines identify salmonella bacteria as a “primary agent of concern” in raw or unpasteurized eggs. *Id.*

The interpretive guidelines also specify safe food-handling practices to minimize the growth or presence of salmonella and other food-borne pathogens in “potentially hazardous foods” (such as unpasteurized eggs). P. Ex. 3. “Cooking,” the guidelines explain, “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.

Id. (emphasis added). Applying the above-quoted monitoring standard, the interpretive guidelines state that unpasteurized eggs that are “cooked to order in response to” a resident’s request, and are “to be eaten promptly after cooking,” should reach an internal temperature of “145 degrees F for 15 seconds; until the white is completely set and the yolk is congealed; . . . ” *Id.*

Case Background

From February 9 through February 12, 2010, Elgin underwent a compliance survey by the Texas Department of Aging and Disability (state survey agency), which issued a Statement of Deficiencies containing the survey’s findings. CMS Ex. 2, at 1; CMS Ex. 3. Under tag F371, the state survey agency reported that on February 9, 2010, five of Elgin’s residents were served – and those residents consumed – “soft cooked unpasteurized eggs with runny yolks.” CMS Ex. 3, at 27. The Statement of Deficiencies described observations by the surveyors, including the observations that two residents had egg yolk “smeared around the plate,” and reported that, in an interview on February 9, 2010, Elgin’s kitchen manager “confirmed [that] cooking the non-pasteurized eggs with soft yolks was not following the safe handling instructions on the outside of the egg case,” which indicated that the eggs should be cooked “until yolks are firm.” *Id.* at 28-30. Based on these and other findings, and noting that “[t]he practice of using nonpasteurized shell eggs when served ‘soft-cooked’ increased the risk of residents being infected with Salmonella, which could lead to a life-threatening illness[,]” the state survey agency concluded that Elgin was not in substantial compliance with section 483.35(i) on February 9, 2010. *Id.* at 26-27. The state survey agency further determined that the noncompliance with section 483.35(i) was at the “immediate jeopardy” level of seriousness. *Id.* at 27.

Concurring with the survey findings under tag F371, CMS imposed a “per instance” CMP of \$5,000 on Elgin for its alleged noncompliance with section 483.35(i).³ CMS Ex. 1, at 2. Elgin then requested an ALJ hearing to contest the CMP and the underlying finding of noncompliance. During the ensuing pre-hearing exchange of evidence, Elgin submitted affidavits from the following persons: Mary Abshire, a registered dietician who was asked by Elgin to investigate the circumstances leading to the deficiency finding under tag F371 (P. Ex. 17); Gary Jefferson, the facility’s cook, who described the procedure he used to prepare soft-cooked eggs for residents on the morning of February 9, 2010 (P. Ex. 14); and Pamela Sue Brummit, a registered dietician who testified that Elgin’s method of preparing soft-cooked unpasteurized eggs was sufficient to protect

³ The February 2010 survey found other deficiencies that are not at issue in this case. *See* ALJ Decision at 2.

residents from food-borne illness (P. Ex. 12). Elgin also submitted a video of a cooking demonstration by Pamela Sue Brummit that purports to replicate the cooking procedure used by Mr. Jefferson to prepare residents' soft-cooked eggs on February 9, 2010. *See* P. Ex. 10; P. Ex. 12, ¶¶ 8-9.

In addition, both parties submitted a copy of an October 8, 2004 Regional Survey and Certification Letter authored by CMS's Dallas, Texas regional office. P. Ex. 4; CMS Ex. 14. That letter, addressed to long-term care facilities in the region, states that its purpose is to clarify "the acceptability of serving 'soft-cooked, runny, or raw eggs to residents in nursing homes.'" ⁴ P. Ex. 4, at 1. The letter states that "[s]oft-cooked eggs are **considered undercooked if the yolk is runny** and/or the egg white is not congealed" and urges SNFs to ensure that raw or unpasteurized eggs are served in accordance with the requirement to prepare and serve food "under accepted practices of food safety." *Id.* (emphasis added). The letter states that "[i]f a nursing home serves 'soft-cooked' eggs, [it] must use eggs that are pasteurized, or otherwise treated in an acceptable manner to kill or inactivate bacteria and other harmful microorganisms." *Id.* Attached to the letter is a quotation from a U.S. Department of Agriculture (USDA) *Salmonella Enteritidis (SE) Risk Assessment* noting that persons with "increased susceptibility to infectious agents" include "persons with chronic diseases" and "nursing home residents," and that the "disproportionate impact of severe complications and death from Salmonellosis in the elderly is illustrated by epidemiologic evidence." *Id.* at 3.

A brief hearing was held before the ALJ, but no in-person testimony was taken because, at the hearing's outset, the parties submitted a written "Agreed Stipulation of Facts" and assured the ALJ that the stipulated facts had obviated the need for witness testimony. Tr. at 15-17, 21-22. In their stipulation, the parties agreed to the facts set out in the Statement of Deficiencies, the Brummit video, and the affidavits of Brummit, Abshire, and Jefferson. ALJ Ex. A.

The ALJ Decision

The ALJ concluded that CMS made a prima facie showing that Elgin was not in substantial compliance with section 483.35(i) when it prepared and served soft-cooked unpasteurized eggs for its residents on February 9, 2010, and that Elgin did not rebut CMS's prima facie case because it failed to prove that its kitchen staff "follow[ed] sanitary food handling and preparation guidelines to prevent the outbreak of food-borne illnesses[.]" ALJ Decision at 4, 9-10. In support of these conclusions, the ALJ stated:

⁴ Elgin admits that it "has always been cognizant" of the October 8, 2004 letter. RR at 2.

The somber fact is that the eggs [served on February 9, 2010] 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 [specified in the SOM] – that the eggs be cooked at 145 [degrees] 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.*”

Id. at 9-10 (italics in original). The ALJ also found that Elgin had not shown that it was compliant with safe handling instructions printed on the cases from which the eggs were taken. *Id.* at 9. Finally, the ALJ concluded that the amount of the per-instance CMP imposed by CMS for Elgin’s noncompliance with section 483.35(i) was reasonable. *Id.* at 10-11.

Standard of Review

The Board’s standard of review on a disputed finding of fact is whether the decision is supported by substantial evidence on the record as a whole. *Appellate Review of Decisions of Administrative Law Judges Affecting a Provider's Participation in the Medicare and Medicaid Programs*, <http://www.hhs.gov/dab/divisions/appellate/guidelines/index.html>. The Board’s standard of review on a disputed conclusion of law is whether the ALJ’s decision is erroneous. *Id.*

Substantial evidence is “more than a mere scintilla. It means such relevant evidence as a reasonable mind might accept as adequate to support a conclusion.” *Richardson v. Perales*, 402 U.S. 389, 401 (1971), quoting *Consolidated Edison Co. v. NLRB*, 305 U.S. 197, 229 (1938). Under the substantial evidence standard, the reviewer must examine the record as a whole and take into account whatever in the record fairly detracts from the weight of the evidence relied on in the decision below. *Universal Camera Corp. v. NLRB*, 340 U.S. 474, 488 (1951).

Discussion

In asking the Board to overturn the ALJ Decision, Elgin argues that CMS did not make a prima facie showing of noncompliance. RR at 16. Alternatively, Elgin maintains that it successfully rebutted CMS’s prima facie case. RR at 18. In addition, Elgin contends that the CMP amount is “excessive and unreasonable.” RR at 20. We reject all of these contentions, for the reasons explained below.

1. *CMS made a prima facie case of noncompliance.*

In the ALJ proceeding below, CMS had the “burden of coming forward with evidence related to disputed findings that is sufficient (together with any undisputed findings and relevant legal authority) to establish a prima facie case of noncompliance with a regulatory requirement.” *Evergreene Nursing Care Center*, DAB No. 2069, at 7 (2007); *Batavia Nursing and Convalescent Center*, DAB No. 1904 (2004), *aff’d*, *Batavia Nursing & Convalescent Ctr. v. Thompson*, 129 F. App’x 181 (6th Cir. 2005). Here, Elgin did not dispute the facts found by the surveyors in the Statement of Deficiencies, so CMS met its burden to present a prima facie case if those facts support a conclusion that Elgin did not prepare or serve unpasteurized eggs “under sanitary conditions” and that that deficiency posed a risk of more than minimal harm to residents who consumed the eggs. Assuming that CMS presented a prima facie case, then Elgin bore the burden of persuasion – namely, to demonstrate by a preponderance of the evidence that it was in substantial compliance with section 483.35(i) on February 9, 2010. *Evergreene* at 7.⁵

Elgin contends that CMS did not carry its burden of production because the noncompliance determination is, in Elgin’s view, based solely on the fact that residents received soft-cooked eggs with runny yolks even though CMS’s interpretive guidelines and other authorities – including the Texas Food Establishment Rules (TFER) and the FDA Model Food Code – indicate that the critical factors for eliminating bacteria and other pathogens from unpasteurized eggs are cooking time and temperature, not the “consistency of the final [cooked] product.”⁶ RR at 10-12, 16-18. Elgin asserts that CMS presented no evidence – such as a report of a surveyor’s first-hand observation of soft-cooked eggs being prepared in Elgin’s kitchen, or a statement from Elgin’s cook – that directly or affirmatively proves that Elgin’s soft-cooked eggs did not reach the

⁵ A petitioner may challenge the legal sufficiency of CMS’s case in a summary judgment motion or may simply choose not to present any evidence and seek an ALJ decision that CMS’s case is not legally sufficient to show noncompliance. Here, Elgin sought instead to rebut CMS’s case by presenting evidence it said showed it was in substantial compliance. The Board has held that, once a petitioner has presented evidence, the record as a whole is to be considered in determining whether the petitioner met its burden of persuasion to show substantial compliance. *Jennifer Mathew Nursing & Rehabilitation Center*, DAB No. 2192, at 21 n. 12 (2008) (*citing Oxford Manor*, DAB No. 2167 (2008)); *Hillman Rehabilitation Center*, DAB No. 1663, at 9-10 (1998). We thus discuss CMS’s *prima facie* case here solely in response to Elgin’s argument.

⁶ The Texas Food Establishment Rules (TFER) are administrative regulations published in title 29, chapter 229, subchapter K of the Texas Administrative Code. *See also* CMS Ex. 13. Section 229.164(k)(1)(A)(i)(I) of the TFER requires a regulated “food establishment” (which may include a nursing home) to cook “raw shell eggs that are broken and prepared in response to a consumer’s order and for immediate service” at “63 degrees Celsius (145 degrees Fahrenheit) or above for 15 seconds.” *See* P. Ex. 5, at 2. This time-and-temperature threshold is derived from section 3-401.11(A) of the FDA Food Code, which is publicly available at <http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/FoodCode/default.htm>. *See also* P. Ex. 12 ¶ 6. In its introductory section, the FDA Food Code states that it is “is a model code and reference document” for state and local governments that “establishes practical, science-based guidance and enforceable provisions for mitigating risk factors known to cause foodborne illness.”

specified time-and-temperature thresholds on February 9, 2010. RR at 2. Elgin further contends that the SOM unreasonably “interprets” section 483.35(i) as calling for unpasteurized eggs to be cooked until the “white is completely set and the yolk is congealed,” asserting that this practice is not called for or otherwise “supported by the TFER, the Food Code or any other scientific research.” RR at 9, 16-18. In addition, Elgin contends that the merit of its position is confirmed by the SOM’s text, which states that “[c]ooking 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.” RR at 10.

This argument is undercut by the fact that the Statement of Deficiencies, upon which CMS principally relies, identifies sources of relevant and accepted food safety practices other than the SOM.⁷ According to the Statement of Deficiencies, Elgin cooked and served unpasteurized eggs with “runny” yolks to least five residents on the morning of February 9, 2010. CMS Ex. 3, at 27. The Statement of Deficiencies also indicates that Elgin’s unpasteurized eggs came in a case that displayed the following “Safe Handling Instructions”: “**To prevent illness from bacteria keep eggs refrigerated, cook eggs until yolks are firm** and cook foods containing eggs thoroughly.” *Id.* at 27-28 (emphasis added). In addition, the Statement of Deficiencies reported that Elgin’s Kitchen Manager conceded in a survey interview that cooking unpasteurized eggs with “soft” yolks did not comply with the Safe Handling Instructions on the egg case and that the staff dietician commented that Elgin should have been using pasteurized eggs for health reasons in any event. *Id.* at 28.

The Safe Handling Instructions on the egg case constitute more than gratuitous advice from the egg producer; they are, in fact, mandated by federal law. Regulations published by the FDA require that the instructions appear on the label of “shell eggs” that have not been “specifically processed [by pasteurization or another comparable treatment method] to destroy all viable Salmonella.” 21 C.F.R. § 101.17(h); Final Rule: *Food Labeling, Safe Handling Statements, Labeling of Shell Eggs; Refrigeration of Shell Eggs Held for Retail Distribution*, 65 Fed. Reg. 76,092, 76,111 (December 5, 2000). According to the regulations’ preamble, the purpose of the label is “to protect the public health by providing consumers with material information, i.e., instructions on how to safely handle and prepare eggs in order to reduce the risk of illness.” 65 Fed. Reg. at 76,100. In its totality, the preamble also makes clear that the labeling requirement reflects the informed judgment of an agency (the FDA) with science-based expertise about what measures are reasonably necessary to minimize the risk of food-borne illness.

⁷ Elgin concedes that CMS relied on multiple “sources” for what Elgin calls CMS’s “interpretation” of section 483.35(i). RR at 8. One of those sources was the label on the egg case, as discussed in the text above. *Id.* Another was CMS’s October 8, 2004 Regional Survey and Certification Letter. *Id.*

In short, the facts proffered by CMS in the Statement of Deficiencies (which are undisputed) are legally sufficient to establish that Elgin failed to comply with an accepted standard or practice of sanitary food preparation – namely, the instruction on the egg case label to cook an unpasteurized egg until its yolk is “firm” – when it prepared soft-cooked eggs for its residents. There is no dispute that cooking an unpasteurized egg until its yolk is firm minimizes a significant risk of harm to nursing home residents, a population susceptible to infection or complications from food-borne illness. Thus, Elgin’s apparent failure to adhere to that practice – by serving eggs with runny yolks – is legally sufficient, if not rebutted, to show noncompliance with section 483.35(i).

It is possible, of course, that on February 9, 2010, Elgin’s cook allowed the eggs in question to reach the minimum time-and-temperature thresholds specified in the SOM, the TFER, and the Food Code.⁸ CMS’s evidence permits a contrary inference, however. The Statement of Deficiencies indicates that surveyors interviewed Elgin’s kitchen manager and staff dietician. CMS Ex. 3, at 27, 29. Those employees were in a position to know how the eggs in question were prepared. They also had an obvious incentive to communicate that information to surveyors if it was, in fact, favorable to Elgin. However, there is nothing in the Statement of Deficiencies or other material proffered by CMS which indicates that those employees provided, or sought to provide, the state survey agency with information that would indicate the eggs were actually prepared safely. To the contrary, as noted above, the Kitchen Manager conceded that the safe handling instructions on the egg case were not followed, and the dietician indicated the facility should have been using pasteurized eggs. *Id.* A trier of fact could reasonably infer from the undisputed facts described in the Statement of Deficiencies that Elgin’s cook did not prepare the residents’ eggs under sanitary conditions on February 9, 2010.

For all these reasons, we agree with the ALJ that CMS made a prima facie case that Elgin was not in substantial compliance with section 483.35(i) on February 9, 2010.

2. *Substantial evidence in the record as a whole supports the ALJ’s conclusion that Elgin did not carry its burden of persuasion.*

Elgin maintains that it carried its burden to show by a preponderance of the evidence that it was in substantial compliance with section 483.35(i) because its affidavits and video demonstrate that the soft-cooked eggs in question were prepared in a manner that ensured

⁸ While it is possible, as Elgin sought to demonstrate, that an egg yolk may remain somewhat “runny” (or not “congeal” or become firm) at the time-and-temperature thresholds sufficient to kill salmonella and other microorganisms, that does not necessarily render the firm-yolk instruction unnecessary or unreasonable. Cooking an egg until its yolk is firm is an easy, reliable method to determine if the egg is safe for consumption. Furthermore, that practice seems designed to provide egg consumers with an adequate margin of safety given the possibility of errors or laxity in measuring cooking time and temperature or the possibility that the cooked eggs are not served immediately.

that they reached an internal temperature of 145 degrees Fahrenheit for at least 15 seconds. RR at 13-15, 18-19. Elgin asserts that the ALJ “ignored” the affidavits and failed to state whether he viewed the Brummit video. RR at 2.⁹

In his affidavit, Elgin’s cook, Gary Jefferson, who prepared residents’ breakfast on February 9, 2010, stated that, when a resident ordered eggs either “over easy” or “sunny side up,” he filled the order by placing one-half inch of cooking oil in a frying pan, heating the oil until it was “boiling,” cracking the egg into the boiling oil, then allowing the egg “to cook for several minutes until the egg white was firm and the yolk was “slightly soft” in the middle” (flipping the egg “at least once” during the process). P. Ex. 14, at 1. Mr. Jefferson further stated that a few days after February 9, he prepared four eggs for Mary Abshire (Elgin’s dietician) “in the manner I have described,” and that when he “finished cooking” the eggs, Ms. Abshire took their temperature, which was “higher than 145 degrees.” *Id.*

In her affidavit, Ms. Abshire confirmed that on February 12, 2010, Mr. Jefferson demonstrated how he cooked what he called a “soft fried” egg:

I asked Mr. Jefferson to cook several ‘soft fried’ eggs, and after each egg had been cooked I took the temperature of the egg with a calibrated thermometer immediately after the egg was removed from the frying pan. Each egg that I checked had a temperature of at least 145 degrees Fahrenheit.

P. Ex. 17.

Dietician Pamela Sue Brummit stated in her affidavit that she attempted to duplicate the cooking method described by Gary Jefferson. P. Ex. 12, at 3. According to the affidavit, she placed one-half inch of oil in a frying pan, heated the oil to approximately 200 degrees Fahrenheit, and cooked four unpasteurized eggs in the oil for approximately two minutes and 10 seconds (turning them over once about midway through that time). *Id.* Upon removing the eggs from the pan, she determined that their temperatures were 163 degrees, 153 degrees, 166 degrees and 154 degrees Fahrenheit. *Id.* She further indicated that the “whites were cooked and yolks were thick yet runny.” *Id.* Ms. Brummit also stated that she conducted this exercise three times, with the third exercise being videotaped and obtained similar results on each occasion. *Id.*

⁹ The ALJ did not, however, ignore the affidavits because they are discussed in his decision. ALJ Decision at 8; *see also id.* at 6 (“I have reviewed and considered all the evidence, including the documents and affidavits proffered[.]”). Although the ALJ did not state that he viewed the Brummit video, the video does not detract from the weight of the evidence upon which the ALJ relied. The video is merely a visual depiction of the cooking demonstration described in Brummit’s affidavit. Elgin does not claim that the video contributes any meaningful information or nuance that is not reflected in the affidavit.

We note that Gary Jefferson's affidavit does not indicate that he actually monitored the temperature of the soft-cooked unpasteurized eggs served to residents. In lieu of proffering evidence of such monitoring, Elgin asked the ALJ to infer from the results of the after-the-fact cooking demonstrations that the eggs served to residents on February 9, 2010 reached the minimum time-and-temperature thresholds sufficient to kill salmonella and other pathogens. The ALJ declined to draw this inference, however, accurately noting that the demonstrations' participants did not verify that the cooked eggs' internal temperatures stayed at or above 145 degrees Fahrenheit **for at least 15 seconds**. Elgin's affidavits indicate only that the eggs were at least 145 degrees when they were "finished cooking" or were removed from the heat source. *See* P. Ex. 14, ¶ 4; P. Ex. 17, ¶ 4; P. Ex. 12, ¶ 9. The Brummit video (which we reviewed) suffers from the same omission.

Referring to the Brummit demonstration, Elgin asserts:

It is illogical for the ALJ to conclude [that] eggs cooked for over two minutes in one half inch of 200 degree boiling oil with yolks reaching temperatures between 153 and 166 degrees were not at 145 degrees for 15 of the 130 total seconds of cooking time. In order for the ALJ to conclude there is an absence of evidence confirming "145 degrees for 15 seconds," he must also necessarily speculate it took Brummit's eggs 116 seconds (two minutes and ten seconds minus 14 seconds) to reach 145 degrees when cooking in 200 degree oil and then, only 14 seconds to go from 145 degrees to temperatures between 153 and 166 degrees. This is virtually impossible.

RR at 14-15. While one could arguably infer from Brummit's testimony regarding the temperatures she got after 130 seconds of cooking time that at least part of the eggs were at or exceeded 145 degrees Fahrenheit for at least 15 seconds, the inference is not a necessary one. Moreover, any such inference is undercut by the fact that both the SOM provision and the safe handling instructions on the egg case indicate an expectation that, if unpasteurized eggs are properly cooked, the yolks will be firm or congealed, not "thick yet runny," as Ms. Brummit described the yolks from her demonstration. In any event, as CMS notes, the record does not establish that Ms. Brummit used the same type of grill, frying pan, or oil as Mr. Jefferson. Mr. Jefferson does not attest that he turned over the eggs about midway through the cooking time or that he spooned hot oil over the yolks before turning the eggs, as the video shows Ms. Brummit did. Mr. Jefferson also does not assert that Ms. Brummit's demonstration accurately showed how he prepared residents' eggs on February 9, 2010. In addition, Ms. Abshire, who measured the temperature of eggs actually cooked by Mr. Jefferson, attested only that the temperature exceeded 145 degrees, not that they reached the much higher temperatures Ms. Brummit achieved. These flaws in Elgin's case call into doubt whether Ms. Brummit's demonstration accurately recreated what occurred on February 9, 2010.

We also note that, although Ms. Brummit stated that in her affidavit that the cooked eggs had “soft” yolks that were “thick yet runny,” she did not attest that they were sufficiently runny that they could result in residents’ plates being “smeared” with yolk, like the plates the surveyors observed. Furthermore, her written statement that the eggs’ yolks were “thick yet runny” is not confirmed by the video, as the video does not show her testing the softness of the yolks or show how runny they were.

In light of the flaws in Elgin’s evidence, a reasonable trier of fact could conclude, as the ALJ did, that Elgin did not meet its burden of proof. For these reasons, we affirm the ALJ’s conclusion that Elgin failed to prove by a preponderance of the evidence that it was in substantial compliance with section 483.35(i) on February 9, 2010.

3. *The amount of the per-instance CMP is reasonable.*

When CMS elects to impose a per-instance CMP for a SNF’s noncompliance, as it did here, the penalty amount must be in the range of \$1,000 to \$10,000 per instance, regardless of whether the noncompliance constitutes immediate jeopardy. 42 C.F.R. §§ 488.438(a)(2), 488.408(d)(1)(iv). In appealing a finding of noncompliance, a SNF may contend that the amount of the CMP imposed for that noncompliance is unreasonable. *See, e.g., Lutheran Home at Trinity Oaks*, DAB No. 2111, at 21 (2007).

In deciding whether the CMS-imposed penalty is reasonable, an ALJ (or the Board) may consider only those factors specified in section 488.438 of CMS’s regulations. *See* 42 C.F.R. § 488.438(e), (f); *Senior Rehabilitation and Skilled Nursing Center*, DAB No. 2300, at 19-20 (2010). Those factors are: (1) the SNF’s history of noncompliance; (2) the SNF’s financial condition; (3) factors specified in 42 C.F.R. § 488.404 (i.e., the severity and scope of the noncompliance, and “the relationship of the one deficiency to other deficiencies resulting in noncompliance”); and (4) the SNF’s degree of culpability, which includes neglect, indifference, or disregard for resident care, comfort or safety. 42 C.F.R. §§ 488.438(f), 488.404.

An ALJ (or the Board) reviews the reasonableness of the CMP de novo, based on the facts and evidence contained in the appeal record. *Emerald Oaks*, DAB No. 1800, at 13 (2001); *CarePlex of Silver Spring*, DAB No. 1683, at 17-18 (1999). Once it is determined that CMS had a valid legal basis (namely, the existence of noncompliance) to impose a CMP within one of the regulatory penalty ranges, neither an ALJ nor the Board can reduce the CMP to zero or below the regulatory minimum amount. 42 C.F.R. § 488.438(e)(1); *Somerset Nursing & Rehabilitation Facility*, DAB No. 2353, at 26-27 (2010).

In claiming that the \$5,000 per-instance CMP is “excessive and unreasonable,” Elgin contends first that there is “no evidence CMS considered” many of the regulatory factors and “no indication CMS based its penalty on the necessary factors.” RR at 20. Contrary to Elgin’s assertion, there is evidence in the record that CMS considered and based its penalty determination on the regulatory factors. In its March 2, 2010 notice of noncompliance, CMS stated that “[i]n setting the amount of the civil money penalty, CMS considered the seriousness and pervasiveness of the deficiencies, the degree of facility culpability, facility compliance history, and financial condition. CMS Ex. 1, at 2. How CMS actually weighed the factors is immaterial in any event because, in this proceeding, we presume that CMS considered the regulatory factors and that those factors support the amount imposed. *Coquina Center*, DAB No. 1860, at 32 (2002). “Accordingly, the burden is not on CMS to present evidence bearing on each regulatory factor, but on the SNF to demonstrate, through argument and the submission of evidence addressing the regulatory factors, that a reduction is necessary to make the CMP amount reasonable.” *Oaks of Mid City Nursing and Rehabilitation Center*, DAB No. 2375, at 26-27 (2011).

We agree with the ALJ that no reduction in the CMP is warranted. The noncompliance at issue was found to be at the “immediate jeopardy” level, the highest level of severity. In addition, the surveyors determined that the noncompliance was more than “isolated” and, in fact, constituted a “pattern” deficiency, meaning that the deficiency had affected “more than a very limited number of residents.” See CMS Ex. 3, at 26 (showing scope-and-severity designation of “K”); 59 Fed. Reg. 56,116, 56,183 (Nov. 10, 1994) (scope-and-severity grid); SOM, App. P – *Survey Protocol for Long Term Care Facilities*, sec. IV.C. (stating that a deficiency’s scope “is a pattern when more than a very limited number of residents are affected, and/or more than a very limited number of staff are involved, and/or the situation has occurred in several locations, and/or the same resident(s) have been affected by repeated occurrences of the same deficient practice”). These circumstances alone justify a CMP substantially above the regulatory minimum of \$1,000. Cf. *Lakeridge Villa Healthcare Center*, DAB No. 2396, at 15-16 (2011) (holding that immediate jeopardy findings justified per-instance CMPs substantially higher than the regulatory minimum of \$1,000). Elgin claims that none of its residents were actually harmed by eating undercooked unpasteurized eggs. If true, that fact is merely fortuitous and does not detract at all from the severity finding because an immediate jeopardy situation may exist even when the noncompliance has not harmed residents. 42 C.F.R. § 488.301 (defining “immediate jeopardy 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” (emphasis added)); *Agape Rehabilitation of Rock Hill*, DAB No. 2411, at 20 (2011).

In trying to mitigate the penalty, Elgin further asserts that the CMP was imposed for “only one deficiency”; that it had no “established” history of noncompliance or repeated deficiencies; and that there is “no evidence of neglect, indifference, or disregard for resident care, comfort or safety.” RR at 20. These assertions are not helpful to Elgin. The CMP imposed in this case is a “per-instance” remedy, one that is intended for a single deficiency. *See* 64 Fed. Reg. 13,354, 13,356 (March 18, 1999) (“What [CMS] mean[s] by an ‘instance’ in [the regulations authorizing a per-instance CMP] is a single deficiency identified by the tag number used as a reference on the statement of deficiencies.”). In addition, Elgin offered no evidence to back up its claim of a clean compliance history.

Finally, we agree with the ALJ that Elgin was, to some degree, culpable for the noncompliance. In an interview, Elgin’s kitchen manager told surveyors that, at the request of the facility’s administrator, she stopped buying pasteurized eggs about six or seven months prior to the survey (and then, presumably, began to use unpasteurized eggs). CMS Ex. 3, at 29. Switching to unpasteurized eggs increased the risk of food-borne illness to residents and should have led Elgin to instruct its kitchen staff to take the precautions necessary to minimize that risk. However, there is no evidence that after the decision to stop buying pasteurized eggs, Elgin issued or reinforced a policy to adhere strictly to safe handling practices for unpasteurized eggs.¹⁰ Mr. Jefferson did not say in his affidavit that on February 9, 2010, he was aware of and understood those practices. Nor does anything in his affidavit show that he took action before serving the unpasteurized eggs to verify that they would be safe for consumption such as testing whether his cooking method was sufficient to ensure that the eggs’ internal temperature would reach 145 degrees Fahrenheit for 15 seconds. In our view, these circumstances demonstrate careless disregard of the risk to resident health and safety posed by undercooked unpasteurized eggs.

Because Elgin has failed to demonstrate that a reduction of the \$5,000 per-instance CMP is warranted based on the regulatory factors, we affirm the ALJ’s conclusion that the amount of that penalty was reasonable.

¹⁰ According to the Statement of Deficiencies, the state survey agency was informed by the “Vice President of Operations” that Elgin followed the TFER in preparing food for consumption by residents. CMS Ex. 3, at 30. However, Elgin did not produce a copy of a written policy or any other evidence indicating that its kitchen staff had been trained (prior to the survey) to comply with the TFER, the FDA Code, or another source of accepted food safety practices.

