Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Appellate Division

Bivins Memorial Nursing Home
Docket No. A-16-127
Decision No. 2771
February 10, 2017

FINAL DECISION ON REVIEW OF ADMINISTRATIVE LAW JUDGE DECISION

Bivins Memorial Nursing Home (Bivins) timely appeals the Administrative Law Judge (ALJ) decision granting summary judgment in favor of the Centers for Medicare & Medicaid Services (CMS) imposing a civil money penalty (CMP) of $350 per day for 21 days of noncompliance (totaling $7,350). *Bivins Memorial Nursing Home*, DAB CR4629 (2016) (ALJ Decision). The ALJ concluded that the undisputed facts established that Bivins was not in substantial compliance with two Medicare requirements from April 26 through May16, 2013 and that the CMP imposed in consequence is reasonable.

For the reasons explained below, we find no error in the ALJ's conclusions that summary judgment was appropriate, that Bivins was not in substantial compliance, and that the CMP is reasonable. We therefore sustain the ALJ Decision and uphold the CMP of $7,350.

Relevant Legal Authority

To participate in the Medicare program, a long-term care facility must maintain "substantial compliance" with the requirements in 42 C.F.R. Part 483.[1] 42 C.F.R. §§ 483.1, 488.400. Under agreements with the Secretary of Health and Human Services, state survey agencies conduct onsite surveys of facilities to verify compliance with the Medicare participation requirements. *Id*. §§ 488.10(a), 488.11; *see also* Social Security Act §§ 1819(g)(1)(A), 1864(a).

[1] In October 2016, the requirements for long term care facilities in subpart B of Part 483 were revised and redesignated effective November 28, 2016. 81 Fed. Reg. 68,688, 68,848 (Oct. 4, 2016). We cite to the prior provisions, which are applicable in this case.

A state survey agency reports any "deficiencies" it finds in a Statement of Deficiencies (SOD), which identifies each deficiency under its regulatory requirement and the corresponding "tag" number. A "deficiency" is any failure to comply with a Medicare participation requirement, and "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 (also defining "noncompliance" as "any deficiency that causes a facility to not be in substantial compliance").

The following two requirements are at issue in this case:

> 42 C.F.R § 483.75(*l*) *Clinical records.* (1) The facility must maintain clinical records on each resident in accordance with accepted professional standards and practices that are—
>
> (i) Complete;
>
> (ii) Accurately documented;
>
> (iii) Readily accessible; and
>
> (iv) Systematically organized. . . .

> 42 C.F.R. § 483.35 **Dietary services**. The facility must provide each resident with a nourishing, palatable, well-balanced diet that meets the daily nutritional and special dietary needs of each resident. . . .
>
> (i) *Sanitary conditions.* The facility must–
>
> (1) Procure food from sources approved or considered satisfactory by Federal, State, or local authorities;
>
> (2) Store, prepare, distribute, and serve food under sanitary conditions; and
>
> (3) Dispose of garbage and refuse properly.

CMS may impose remedies on noncompliant facilities, including per-day CMPs. *Id.* §§ 488.402(b)-(c), 488.406, 488.408(d)(1)(iii)-(iv), 488.408(e)(1)(iii)-(iv), 488.430(a). There are two ranges of per-day CMPs, $50-$3,000 per day for noncompliance at a level less than immediate jeopardy and $3,050-$10,000 per day for noncompliance at the immediate jeopardy level. *Id.* § 488.438. CMS did not allege immediate jeopardy as to either of the deficiencies at issue, so only the first range applies here.

Case Background[2]

A survey of Bivins completed on April 26, 2013 found multiple deficiencies. CMS Ex. 1; CMS Ex. 2, at 7. (We do not identify all the deficiencies because CMS moved for, and the ALJ granted, summary judgment only as to two deficiencies, which related to clinical records and sanitary conditions in dietary services under the regulatory requirements quoted above. ALJ Decision at 2-3.) The clinical records deficiency at issue was based on surveyor findings that the facility's records for the storage and administration of controlled substances for two residents (Residents # 1 and # 7) contained discrepancies and failed to account for the medications adequately. CMS Ex. 1, at 48-50. The dietary deficiency was based on surveyor findings that cold foods were served at improper temperatures for food safety because food handling policies were not followed. *Id*. at 36-39. CMS determined that the facility returned to substantial compliance on May 17, 2013.

As a preliminary matter, we note that, in its request for review, Bivins requested oral argument before the Board. RR at 11. The only reason Bivins offered was that it "believes oral argument will be helpful to the Board members in deciding the issues in this case." *Id*. Board guidelines for this category of appeal explain that –

> Generally, the request for review, the response and the reply are the only record additions on appeal. A party wishing to appear before the Board to present oral argument should request such an opportunity no later than the time for filing its last submission provided for in paragraph (b) or (c) of this section and should state the purpose of the requested appearance.

Guidelines -- Appellate Review of Decisions of Administrative Law Judges Affecting a Provider's Participation in the Medicare and Medicaid Programs (Guidelines), Development of the Record on Appeal at ¶ (f) available online at https://www.hhs.gov/about/agencies/dab/different-appeals-at-dab/appeals-to-board/guidelines/participation/index.html#development .

Bivins failed to submit any reply to CMS's brief in this appeal. Thus, Bivins did not avail itself of the opportunity provided by the Guidelines for it to elucidate its view of the issues. Moreover, Bivins gave only a cursory and vague statement of the purpose of holding any oral argument. We see no reason that oral argument would be helpful on any of the legal issues in this case. Therefore, the request for oral argument is denied.

[2] The following background information is drawn from the ALJ Decision and the record before the ALJ and summarized here for the convenience of the reader, but should not be treated as new findings.

Standard of Review

We review an ALJ's grant of summary judgment de novo, construing the facts in the light most favorable to the petitioner and giving the petitioner the benefit of all reasonable inferences. *See Pearsall Nursing & Rehab. Ctr. – N.*, DAB No. 2692, at 5 (2016), citing *Livingston Care Ctr.*, DAB No. 1871, at 5 (2003), *aff'd, Livingston Care Ctr. v. U.S. Dept. of Health & Human Servs.*, 388 F.3d 168, 172-73 (6th Cir. 2004). Summary judgment is appropriate when there is no genuine dispute about a fact or facts material to the outcome of the case and the moving party is entitled to judgment as a matter of law. *Celotex Corp. v Catrett*, 477 U.S. 317, 322-25 (1986). The party moving for summary judgment (here, CMS) has the initial burden of demonstrating that there is no genuine issue of material fact for trial and that it is entitled to judgment as a matter of law. *Celotex*, 477 U.S. at 323. If the moving party carries that burden, the non-moving party must "come forward with 'specific facts showing that there is a genuine issue for trial.'" *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986) (quoting Rule 56(e) of the Federal Rules of Civil Procedure).

"To defeat an adequately supported summary judgment motion, the non-moving party may not rely on the denials in its pleadings or briefs, but must furnish evidence of a dispute concerning a material fact – a fact that, if proven, would affect the outcome of the case under governing law." *Senior Rehab. & Skilled Nursing Ctr.*, DAB No. 2300, at 3 (2010), *aff'd, Senior Rehab. & Skilled Nursing Ctr. v. Health & Human Servs.*, 405 F. App'x 820 (5th Cir. 2010). A party "must do more than show that there is 'some metaphysical doubt as to the material facts . . . . Where the record taken as a whole could not lead a rational trier of fact to find for the nonmoving party, there is no 'genuine issue for trial.'" *Mission Hosp. Reg'l Med. Ctr.*, DAB No. 2459, at 5 (2012) (quoting *Matsushita*, 475 U.S. at 587), *aff'd, Mission Hosp. Regional Med. Ctr. v. Sebelius*, No. SACV 12-01171 AG (MLGx), 2013 WL 7219511 (C.D. Cal. 2013), *aff'd sub nom. Mission Hosp. Reg'l Med. Ctr. v. Burwell*, 819 F.3d 1112 (9th Cir. 2016). In examining the evidence to determine the appropriateness of summary judgment, an ALJ must draw all reasonable inferences in the light most favorable to the non-moving party. *Brightview Care Ctr.*, DAB No. 2132, at 2, 9 (2007). Drawing factual inferences in the light most favorable to the non-moving party does not require that an ALJ draw unreasonable inferences or accept the non-moving party's legal conclusions. *Brightview* at 10; *Cedar Lake Nursing Home*, DAB No. 2344, at 7 (2010).

Our standard of review on a disputed conclusion of law is whether the ALJ Decision is erroneous. *See Guidelines.*

Analysis

1. Undisputed facts establish that Bivins was not in substantial compliance with clinical record requirements.

This deficiency finding arises entirely from Bivins' documentation of the dispensing and administration of narcotics to two residents, more precisely, discrepancies in that documentation between the number of doses of narcotics dispensed for each of two patients and the number of doses administered to those patients. It is not disputed that staff were required to sign out narcotics when obtained from the storage supply for administration to an individual using a form entitled "Individual Patient Controlled Substance Record" (IPCSR). *See, e.g.*, CMS Ex. 53, at 1. It is also uncontested that all administrations of narcotics to an individual were required to be recorded, for which Bivins used a "Medication Administration Record" (MAR). *See, e.g.*, CMS Ex. 52. Bivins does not deny that the removal of doses shown in the IPCSR should correspond to the administration of doses shown in the MAR for a given resident, nor does Bivins offer additional records of either resident at issue. Bivins contends, however, that the records presented by CMS, properly read, do not show a discrepancy between the doses of narcotics dispensed and the doses of narcotics administered to these residents. RR at 8.

The ALJ set out a chart showing all the dates and times on which Resident #1's narcotics[3] were dispensed from storage. ALJ Decision at 8-9, citing CMS Ex. 53, at 1. The ALJ proceeds to describe the records of administration of those narcotics in two ways – first, using only the record which CMS identified as Resident #1's MAR and next, adding the entries from a page which CMS had submitted but had not identified as part of the MAR. *Id*. at 9-10. Finally, the ALJ compiled all three sets of dosage records in a single chart. *Id*. at 11. The ALJ concluded that "[c]omparing Rl's MAR with her controlled substance record shows significant discrepancies between the number of tablets removed from the locked storage unit and the number administered to her." *Id*. at 9.

Bivins' argument as to Resident #1 is as follows:

> If CMS were to properly move page 2 of Ex. 53 to its rightful place in Ex. 52, then CMS and the ALJ would have seen that the combination of notations on the front and back of the MAR corresponds to the entries on page 1 of CMS Ex. 53, the IPCSR. Further, the IPCSR form would not show the administration of medication on 4/2/13 and 4/6/13 because, as the

[3] The medications are variously referred to by their brand and generic names in the record but the parties do not dispute which entries relate to the narcotics and so we merely use the term "narcotics" to refer to all the controlled substance medications at issue.

> top of the IPCSR form demonstrates, this document was not created until 4/8/13 (CMS Ex. 53 p. 1). The back of the MAR, the front of the MAR, and the IPCSR accurately reflects the Hydrocodone/Lortab administered to Resident #1 during April 2013, and there is no evidence to the contrary.

RR at 9. In short, Bivins claims that, if you view the records as it describes, you find that the withdrawals of medicine from storage will correspond to the record of administration of medicine to the resident.

The records simply do not support Bivins' claim, even under the most generous view. At the outset, we note that the purpose of the IPCSR is to show when medication was dispensed, not when it was administered to the patient, which is the function of the MAR. Accordingly, we find no relevance in Bivens' statement that the IPCSR form "would not show the administration of medication on 4/2/13 and 4/6/13." To the extent Bivens is arguing that we should not find any discrepancy based on the fact that that the MAR shows administration of narcotics (Lortab) to Resident #1 on those dates but the IPCSR does not show dispensing of narcotics for her on those dates, we do not find a discrepancy based on those facts. Our decision with respect to this resident is based only on the information on the IPCSR and the MAR from April 13, 2013 through April 23, 2013, the same dates on which the ALJ relied for this resident. Moreover, we presume for purposes of summary judgment that every administration noted on the "back" of the MAR is in addition to every administration noted on the front.[4] Even so, there are four dates – April 13, 14, 17, and 18 – on which two doses of narcotics were withdrawn for Resident #4 but on which no doses of narcotics were recorded as administered to the

[4] While our presumption is the inference most favorable to Bivins, we note that the accuracy of that presumption is not apparent from the documents themselves. What Bivins calls the "front" of the MAR is prefilled with the prescribed medication and staff indicates by a mark in a column by date whether a dose was administered on a given date. CMS Ex. 52, at 3. The notations for the narcotic do not record the time of administration. What Bivins calls the "back" of the MAR (which it says is typically to be used for PRN [as-needed] medications) calls for staff to write in the medication and date, as well as the time and reason for administration, the staff's initials, and the effectiveness. CMS Ex. 53, at 2. There is no way to determine from the documents whether the staff was to note the administration on the front and provide the further information on the back for a PRN administration or whether the instances recorded on the back were intended to be in addition to those noted on the front. CMS apparently made the first assumption, i.e., that where a dose was recorded on the same date on both MAR sheets, the "back" merely provided more information on the same administration of a single dose. Thus, CMS viewed both sides of the MAR for Resident #1 as showing only a total of 14 doses between April 13, and April 23. CMS Br. at 3, citing CMS Exs. 53, at 1, 2, and 52, at 3. Even if we accept the more favorable inference for Bivins, that all doses recorded on the back should be added to those marked on the front of the MAR, the total still rises to only 21 doses administered in that period. This would still leave two doses of narcotics removed (according to the IPCSR which shows 23 doses) but never administered during the entire period. Moreover, as noted in the text, the doses administered do not correspond accurately to the dates on which doses were taken out of storage and Bivins has not identified any authority that would permit narcotics to be removed from storage and unused for more than a day.

resident. *Compare* CMS Ex. 53, at 1 *with* CMS Ex. 53, at 2 and 52, at 3. These eight unaccounted-for doses of controlled substances would be sufficient in themselves to establish noncompliance with the requirements for maintaining complete and accurate clinical records.

Moreover, the records for the month of April, viewed most favorably to Bivins, show other discrepancies, as the ALJ's chart demonstrates. ALJ Decision at 11. For example, on April 16, 2013, three doses were removed from storage but only (at most) two were delivered to the patient (one shown on the front and one on the back of the MAR). On April 23, 2013, two doses were taken out of storage supply at 9:50 a.m. and 12:40 p.m., but the only dose recorded as administered to the resident that day was before either removal at 9:00 a.m. CMS Ex. 53, at 1-2.

As with Resident #1's records, we accept with respect to Resident #7 Bivins's contention that the "back" of the MAR contains evidence of additional administration of doses of narcotics removed from storage. However, while this reduces the discrepancies relating to Resident #7, it does not eliminate them. We accept for summary judgment purposes that doses removed on April 3 and 15, 2013, were recorded as administered on the front of the MAR. CMS Ex. 57, at 2; CMS Ex. 56, at 4. We also accept Bivins' assertion that the notation next to the first dose dispensed on April 15, 2013 of "wasted" explains the absence of two doses administered on that date. RR at 10; CMS Ex. 57, at 2. We further accept that the doses removed on April 19 and 20 were recorded as administered on the back of the MAR. CMS Ex. 57, at 2; CMS Ex. 56, at 8. However, Resident #7's IPCSR also records the removal of a dose of narcotic on April 10, 2013, and Bivins identifies no record on either side of the MAR showing any narcotic administered to Resident #7 on that date. CMS Ex. 57, at 2. In all, then, viewed in the most favorable light, the clinical records show that six doses were taken out of storage, one was wasted, four were administered to the patient, and one was unaccounted for. Thus, as to this resident as well, the clinical records are not complete or accurate.

We conclude that the undisputed facts, even viewed in the light most favorable to Bivins, establish that the facility was not in substantial compliance with section 483.75(*l*)(1) .

2. Undisputed facts establish that Bivins was not in substantial compliance with requirements for sanitary conditions in dietary services.

The relevant allegations relating to sanitary conditions focus on whether cold foods were maintained at required safe temperatures when being served to residents. The surveyor reported testing the temperature of various cold foods being served to residents and finding a number of them to be above 41 degrees Farenheit. Specifically, Surveyor

Farrell testified to finding cottage cheese at 49.8 degrees F; boiled eggs as high as 51.2 degrees F; Jello pieces in whipped cream as high as 46.5 degrees F; lettuce and tomato salad as high as 56.1 degrees F; and potato salad at 44 degrees F, among other measurements of excessive temperature. CMS Ex. 71, at 5 (Farrell Decl.).

The core of the ALJ's summary judgment analysis on this deficiency is as follows:

> Petitioner does not dispute CMS's claims as to the food temperatures measured by the surveyors. Petitioner claims that the facility did not use temperature control to ensure proper cold storage; it used a combination of temperature and time control, which provides a four hour window from the time the food is removed from a temperature controlled environment. P. Response at 4-5, *citing* P. Ex. A and P. Ex. 66 (Dunnam Decl.).[] In his testimony, however, Chef Dunnam suggests that the facility used temperature as a health control and relied on time as a control[] standard only when "temperature, as a health control, has ... glitched or failed." P. Ex. 66 at 20 (Dunnam Decl.).
>
> But the facility's written policy is explicit: "cold food will be held cold (at or below 41degrees F)," and "[t]emperatures of food will be taken routinely to ensure that proper temperatures are maintained." CMS Ex. 48 at 2. Staff are required to measure the food's internal temperature "after one hour to ensure holding at proper temperature." CMS Ex. 48 at 3. The policy also addresses using time as a temperature control measure. It requires a written log that specifies the foods for which time, rather than temperature, is used to limit bacteria growth. Staff are required to document the temperature of the product, the time the product was removed from temperature control, and the time they discard the product. CMS Ex. 48 at 3-4. Petitioner has not come forward, indeed, has not even claimed, that it maintained such a log or that its staff documented food temperatures. To the contrary, it concedes that staff did not take food temperatures and argues that they were not required to do so.

ALJ Decision at 7 (footnote omitted).

On appeal, Bivins again does not deny the temperatures observed by the surveyors, and again does not assert that it maintained any log (or other documentation) or control of either temperature or serving time. Instead, Bivins insists that all that was required was that the food be served within four hours of removal from a temperature controlled container and that service at the facility occurred within four hours. RR at 5-7. Thus, Bivins asserts that whether it "has temperature logs, checks temperature after the food is removed from cold storage, and whether Bivins otherwise complied with a policy that

may not even apply is absolutely irrelevant because the regulation in question does not mention a facility's own policies, and such regulation requires only compliance with applicable statutes, regulations, and ordinances, *not* internal policies." RR at 7 (italics in original). Bivins seeks to emphasize its "state of the art" "cook-chill method" for food preparation involving an off-site "culinary center," managed under the same foundation as the facility in the present case, and providing prepared and frozen food for delivery to multiple Bivins facilities as well as outside food services. RR at 4; P. Exs. 66-68.

The "facility's written policy" to which the ALJ refers is from the Bivins Culinary Center's Standard Operating Procedures manual. ALJ Decision at 7; CMS Ex. 48, at 1. That policy sets out practices for both holding and serving food, which include the elements cited by the ALJ. ALJ Decision at 7, citing CMS Ex. 48, at 2-4. Bivins contends that this policy might not even apply within its facility and that, in any case, a facility policy cannot be controlling because otherwise "a facility could set the threshold temperature anywhere it so chose, ignoring regulations promulgated by agencies with authority to regulate such topics." RR at 5. Bivins is mistaken that facility policies for compliance with regulatory requirements have no relevance. The Board has regularly found in other contexts that a facility's policy for implementing a regulatory requirement may reflect that facility's own judgment about how best to achieve compliance and hence failure to comply with its own policies can support a finding that the facility did not achieve compliance with the regulatory standard. *See, e.g., Life Care Ctr. of Bardstown*, DAB No. 2233, at 21-22 (2009) (facility's failure to comply with its own policies can constitute a deficiency under section 483.25), and other cases cited therein. We see no reason why the same principle would not apply here. We also note that Bivens cites no support for its speculation that holding a facility responsible for using the methods it selects for compliance would mean that a facility could adopt a policy disowning compliance with otherwise applicable statutory, regulatory or professional standards In any event, our review authority does not exend to evaluation of CMS's policy choices. We also find reasonable the ALJ's reference to Bivens' reliance on the Bivins Culinary Center's Standard Operating Procedures manual as setting Bivens' policy since the Center provided food service to all Bivens facilities. In the final analysis, however, we do not need to rely on the food handling requirements stated in that policy to determine that Bivins did not meet applicable standards for food temperature control. The Bivins policy cites to state rules (Texas Food Establishment Rules, 2009) and federal guidance (Food and Drug Administration (FDA) 2005 Food Code summary changes) which themselves make clear that Bivins was not in compliance with applicable authorities, which, as we explain below, require facilities relying on time as a control to mark all food items to monitor when the time period for ensuring food safety will expire.

As the ALJ mentioned, the executive chef at Bivins' Culinary Center made a number of not-entirely-consistent statements about the role of temperature and time controls in ensuring the safety of cold foods provided by the Culinary Center to Bivins' facility. ALJ Decision at 7, and record citations therein. The surveyors asserted that they interviewed him twice and that he first stated that the facility "used time rather than temperature as a public health control" but did not have any facility policy available to review. Later, according to the surveyors, he provided the Culinary Center manual to show the policies "regarding time as a temperature control measure," and then stated that "if the nursing facility had been using time as a temperature control measure, the written log would have been out [visible] and in use on the day of observation." CMS Ex. 1, at 41, 45 (bracketed material in original).

In his testimony, the chef disputed the accuracy of the surveyor's report of their interactions. P. Ex. 66, at 19. He stated that during the survey, when the surveyor's involvement slowed down food preparation resulting in a higher temperature, he was pointing out that the state and federal regulations also allow time to be used "as a temperature control measure." *Id*. at 19-20. He was not, he testified, making any retractions, but only explaining they "do use temperature as a health control," but that "when temperature, as a health control, has at any point in time glitched or failed, then time is still a controlled standard," and that the entire meal service takes less than four hours. *Id*. In supplemental testimony, he stated that Bivins "was using a combination of the temperature and time control methods." P. Ex. A, at 2. In other words, he said, "prior to the time the food is served, it is maintained in a temperature controlled structure/container," and once it is removed, "the time control method is then used in that FDA guidelines allow a facility to serve temperature control items within a 4 hour window from the time the food is removed from the controlled environment." *Id*. In the context of summary judgment, we read the chef's testimony as to the facility's policies and practices in food handling in the manner most favorable to Bivens and further draw all favorable inferences from it that we reasonably can to reconcile apparent inconsistencies.[5]

[5] As to the specific foods tested by the surveyors, the chef alleges that he had knowledge that the items were tested "within the four hour window" but then says he is aware of this "because all cold items are served within 4 hours of their removal from temperature control." P. Ex. A, at 2. This statement is unclear as to whether he is alleging personal knowledge as to when the particular items were removed from control or only confidence that all items are served promptly or discarded. However, he also stated that he was "at the facility when the surveyors made their observations." *Id*. at 1. We infer for these purposes that he had personal knowledge that the tested items had been removed from control less than four hours earlier, and therefore do not rely further on the elevated temperatures of the tested foods per se to demonstrate that food service did not comply with sanitary requirements.

Doing so, we infer from the chef's testimony that, at a minimum, temperature measurements are required and taken at the Culinary Center when the food is prepared and packaged for delivery to the facility. At the facility, it is undisputed that temperature is not measured after removal, and that times are not marked or logged, but the chef asserts (and we accept for these purposes) that food service would take less than four hours, so that food would be expected to be served to the residents within the safety window.

We conclude, however, that this is not sufficient, even if true, to demonstrate compliance because the applicable authorities specifically require marking or identifying the food with the time upon removal from temperature control and discarding unmarked food. Thus, the Texas regulations in effect during the relevant time provide the following:

> Time as a public health control.
> (A) Except as specified under subparagraph (B) of this paragraph, if time only, rather than time in conjunction with temperature, is used as the public health control for a working supply of potentially hazardous food before cooking, or for ready-to-eat potentially hazardous food that is displayed or held for service for immediate consumption:
> (i) the food shall be marked or otherwise identified to indicate the time that is four hours past the point in time when the food is removed from temperature control;
> (ii) the food shall be cooked and served, served if ready-to-eat, or discarded, within 4 hours from the point in time when the food is removed from temperature control;
> (iii) the food in unmarked containers or packages or marked to exceed a four hour limit shall be discarded; and
> (iv) written procedures shall be maintained in the food establishment and made available to the regulatory authority upon request, that ensure compliance with . . . clauses (i) - (iv) of this subparagraph . . . .

25 Tex. Admin. Code § 229.164(o)(9) (2012) available at http://texreg.sos.state.tx.us/public/tacctx$.startup and appended to CMS's brief.[6]

[6] The text of the Texas code does not appear elsewhere in the record but Bivins did not object to CMS's inclusion of these sources with the relevant links in its brief. CMS Br. at 7-8. Bivins chef specifically testified that the facility "defers to the Texas Food Establishment regulations," while the Culinary Center uses the same regulations along with its manual. P. Ex. 66, at 20. The language of the code is a matter of legal authority rather than evidentiary fact, and we therefore may rely on the text as set out herein.

Bivins argues that the ALJ should not have considered the requirements of state codes because this is a federal administrative proceeding. RR at 5. We disagree. The ALJ is not enforcing state law but rather appropriately looking to the provisions of authorities applicable to the particular facility in order to determine what constitutes compliance with the federal requirement that food be stored and served "under sanitary conditions." 42 C.F.R. § 483.35.

In any case, the FDA authority to which Bivins' chef himself points as permitting a four-hour window for service (P. Ex. A, at 2), similarly requires that the time of removal of each food item be documented:

> (1) Written procedures [that establish methods of compliance] shall be prepared in advance, maintained in the FOOD ESTABLISHMENT and made available to the REGULATORY AUTHORITY upon request; . . . .
>
> (2) The FOOD shall be marked or otherwise identified to indicate the time that is 4 hours past the point in time when the FOOD is removed from temperature control;
>
> (3) The FOOD shall be cooked and served, served at any temperature if READY-TO-EAT, or discarded, within 4 hours from the point in time when the FOOD is removed from temperature control; and
>
> (4) The FOOD in unmarked containers or PACKAGES, or marked to exceed a 4-hour limit shall be discarded.

FDA Food Code § 3-501.19 (2009), available at http://www.fda.gov/downloads/Food/GuidanceRegulation/UCM189448.pdf and quoted in the Statement of Deficiencies at CMS Ex. 1, at 43-44. Bivins does not offer any evidence, or even allege, that the facility marked or identified the times at which foods were removed from temperature control. (Moreover, Bivins does not identify any written procedures for food handling compliance in the facility apart from the Culinary Center manual, the applicability of which Bivins questions, as noted above.)

We thus conclude that, even assuming for purposes of summary judgment Bivins relied on time (i.e. serving food within four hours) alone to ensure the safety of cold foods after removing them from a temperature controlled environment, that is not enough to establish compliance since the undisputed facts establish that Bivens failed to comply with applicable Texas and federal time documentation requirements designed to ensure sanitary conditions.

3. The amount of the CMP is reasonable.

As noted, CMS imposed a per-day CMP of $350, resulting in a total CMS of $7,350 for the 21 days during which Bivins failed to achieve substantial compliance. The per-day amount is near the lowest end of the range of CMPs for noncompliance at a level less than immediate jeopardy, i.e., $50-$3,000 per day. 42 C.F.R. § 488.438. Although Bivins argues on appeal that we should reverse the summary judgment against it and remand the case for a full hearing, Bivins does not offer any argument that the amount of the CMP is excessive based on the relevant factors (set out in 42 C.F.R. §§ 488.408, 488.438) for the two deficiency findings which we have upheld. We therefore do not disturb the ALJ's conclusion that the amount of the CMP is reasonable. ALJ Decision at 12-13.

Conclusion

For the reasons explained above, we uphold the ALJ Decision and sustain the imposition of the CMP as set by CMS.

/s/
Sheila Ann Hegy

/s/
Constance B. Tobias

/s/
Leslie A. Sussan
Presiding Board Member