Department of Health and Human Services DEPARTMENTAL APPEALS BOARD Appellate Division

Omni Manor Nursing Home Docket No. A-11-119 Decision No. 2431 December 22, 2011

FINAL DECISION ON REVIEW OF ADMINISTRATIVE LAW JUDGE DECISION

Omni Manor Nursing Home (Omni Manor) appeals the June 27, 2011 decision of Administrative Law Judge (ALJ) Steven T. Kessel. *Omni Manor Nursing Home*, DAB CR2391 (2011) (ALJ Decision). The ALJ upheld the determination by the Centers for Medicare & Medicaid Services (CMS) to impose a \$550 per-day civil money penalty (CMP) on Omni Manor for the period April 24, 2008, through May 21, 2008, based on surveys of the facility that ended on April 24, 2008, and May 22, 2008. The only issue presented was the duration of Omni Manor's noncompliance with Medicare and Medicaid participation requirements. The ALJ held that Omni Manor failed to prove that it returned to substantial compliance prior to May 22, 2008, the date determined by CMS.

Omni Manor argues that the ALJ erred in determining that it did not return to substantial compliance on April 29, 2008. For the reasons discussed below, we conclude that the ALJ's findings and conclusions are legally correct and supported by substantial evidence. We therefore uphold the ALJ Decision.

Applicable Law

The Social Security Act (Act) and federal regulations provide for state agencies to conduct surveys of long-term care facilities that participate in Medicare or Medicaid to evaluate their compliance with the participation requirements of the programs. Act §§ 1819, 1919; 42 C.F.R. Parts 483, 488, and 498.¹ A facility's failure to meet one or more participation requirements constitutes a "deficiency." 42 C.F.R. § 488.301. "Substantial compliance" means a level of compliance "such that any identified deficiencies pose no greater risk to resident health or safety than the potential for causing minimal harm." *Id.* "Noncompliance" is defined as "any deficiency that causes a facility to not be in substantial compliance." *Id.*

 $^{^{1}\,}$ The current version of the Social Security Act can be found at http://www.ssa.gov/OP_Home/ssact/ssacttoc.htm.

The seriousness of a facility's noncompliance is a function of its "severity" (whether the noncompliance has created a "potential for minimal harm" or 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"). 42 C.F.R. §§ 488.301, 488.404(b).

A facility determined to be not in substantial compliance is subject to enforcement remedies, including CMPs. 42 C.F.R. §§ 488.402(b)-(c), 488.406, 488.408. A per-day CMP may accrue from the date the facility was first out of compliance until the date it achieved substantial compliance. 42 C.F.R. § 488.440(a)(1), (b). For noncompliance determined to pose less than immediate jeopardy to facility residents, CMS may impose a per-day CMP ranging from \$50-\$3,000 per day. 42 C.F.R. § 488.408(d)(1)(iii).

Section 488.440(h)(1) provides that if a revisit survey is necessary to confirm a facility's return to substantial compliance, and the facility can supply documentation acceptable to CMS or the State agency that it achieved substantial compliance on a date preceding the revisit, the CMP accrues only until the "date of correction for which there is written credible evidence." Similarly, section 488.454(e) provides:

If the facility can supply documentation acceptable to CMS or the State survey agency that it was in substantial compliance and was capable of remaining in substantial compliance, if necessary, on a date preceding that of the revisit, the remedies terminate on the date that CMS or the State can verify as the date that substantial compliance was achieved and the facility demonstrated that it could maintain substantial compliance, if necessary.

Case background

The Ohio Department of Health (State agency) conducted a standard survey of Omni Manor that ended on April 24, 2008. The survey found that Omni Manor was not in substantial compliance with twelve Medicaid and Medicare program requirements. CMS Ex. 5. The most serious of the deficiencies was identified at scope and severity level G, (isolated, actual harm that is not immediate jeopardy). *Id.* Three of the deficiencies were identified at scope and severity level E (pattern, no actual harm with potential for more than minimal harm that is not immediate jeopardy). *Id.* The remaining deficiencies were identified at scope and severity level D (isolated, no actual harm with potential for more than minimal harm that is not immediate jeopardy). *Id.*

By letter dated May 6, 2008, CMS notified Omni Manor that based on the survey findings, CMS was imposing, among other things, a CMP of \$550 per day beginning April 24, 2008, and continuing "until substantial compliance is achieved or your provider agreement is terminated." CMS Ex. 3. On May 22, 2008, the State agency conducted a revisit survey of Omni Manor and found that the corrections for the deficiencies

identified during the April 24, 2008 standard survey were completed May 22, 2008. CMS Ex. 6. By letter dated July 29, 2008, CMS notified Omni Manor of the "Disposition of Remedies" based on the revisit survey findings. CMS Ex. 1. CMS stated that it was imposing the \$550 per-day CMP for a period of 28 days beginning April 24, 2008, and continuing through May 21, 2008, for a total of \$15,400.² CMS also notified Omni Manor that the facility was prohibited from conducting a nurse aide training and competency evaluation program for a two-year period. Omni Manor timely requested an ALJ hearing to contest CMS's determination.

Pending the appeal, the parties stipulated that there was a "factual and legal basis" for CMS to impose a \$550 per-day CMP for Omni Manor's noncompliance. November 24, 2009 Agreed Scheduling Order and Joint Stipulation Governing Further Proceedings. Specifically, the parties stipulated that at the time of the April 24, 2008 survey, Omni Manor was not in substantial compliance with the participation requirements at 42 C.F.R. §§ 483.25 (Quality of Care), 483.25(d) (Urinary Incontinence), 483.25(g)(2) (Naso-Gastric Tubes), 483.25(h) (Accidents and Supervision), 483.25(m)(l) (Medication Errors), and 483.65(a) (Infection Control). The parties further stipulated that the only factual issue in dispute was the duration of Omni Manor's noncompliance with those requirements.

CMS thereafter moved for summary judgment. The ALJ initially assigned to the appeal denied CMS's motion. Subsequently, the appeal was reassigned to ALJ Kessel, who vacated the prior ALJ ruling and on August 12, 2010, granted summary judgment to CMS. *Omni Manor Nursing Home*, DAB CR2213 (2010). The ALJ concluded that given the nature of Omni Manor's noncompliance, as a matter of law Omni Manor could not establish that it achieved substantial compliance prior to the date of the revisit survey. Omni Manor appealed that conclusion to the Board. The Board found the ALJ's legal conclusion erroneous and reversed and remanded the matter for a hearing on the issue of whether Omni Manor, as a matter of fact, returned to substantial compliance on a date earlier than the date determined by CMS. *Omni Manor Nursing Home*, DAB No. 2374 (2011). We made clear in our remand order that while it is legally possible for a facility bears the burden to show as a matter of fact that it returned to substantial compliance on a date earlier than that determined by CMS. *Id.* at 8 (citations omitted).

On remand, Omni Manor waived its right to an in-person ALJ hearing. The ALJ granted the parties a final round of briefing with the opportunity to submit additional written evidence. In addition to the exhibits previously entered into the record, Omni Manor

² CMS also imposed a per-day CMP of \$100 for May 22, 2008, because CMS determined that Omni Manor had not corrected all of the deficiencies identified in a separate, April 22, 2008, life safety code survey. The life safety code deficiencies and related CMP are not at issue here. *See* CMS Br. at 3.

submitted a declaration of Paulette Trexler, Omni Manor's Quality Assurance Director, dated May 2, 2011 (Trexler Declaration).³

The ALJ Decision

The ALJ determined that Omni Manor failed to prove that it returned to substantial compliance prior to May 22, 2008. To support this conclusion, the ALJ addressed the noncompliance findings cited under sections 483.25 and 483.25(d) and the evidence that Omni Manor submitted to show that it had corrected those deficiencies as of April 29, 2008.⁴ First, the ALJ discussed the most serious deficiency identified in the survey, which involved the quality of care requirements at section 483.25. Section 483.25 provides that each "resident must receive and the facility must provide the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the comprehensive assessment and plan of care." This provision imposes on a nursing facility the duty to meet professional standards of quality. Sheridan Health Care Center, DAB No. 2178, at 15 (2008); accord Greenbrier Nursing and Rehabilitation Center, DAB No. 2335, at 7-8 (2010). The survey found that Omni Manor's staff failed to properly assess, treat and monitor a resident in respiratory distress, failed to document the resident's condition, and failed to timely implement a physician order to transfer the resident to a hospital "when his rapidly deteriorating medical condition failed to improve." CMS Ex. 5, at 5-8. Omni Manor's noncompliance, the survey found, resulted in actual harm to the resident. Id. In response to this finding, Omni Manor provided evidence that it immediately took disciplinary action against the employees responsible for the deficiency, conducted retraining for some nursing staff on April 25, 28, and 29, 2008, and implemented the use of chart audit forms to monitor staff performance "to assure that changes in residents' conditions were properly detected and observed." ALJ Decision at 4.

The ALJ found that these "measures may have been necessary elements of assuring compliance," but failed to show that "in actual cases . . . staff was actively monitored, and their performance measured against applicable standards of care." *Id.* The ALJ stated that evidence of staff training "is not proof that the staff actually provided care in compliance with the training that they received." *Id.* at 3. This is particularly true, the

³ In response to CMS's motion for summary judgment in the initial appeal, Omni Manor submitted a declaration by Ms. Trexler executed on January 15, 2010. The May 2, 2011 declaration in part repeated, deleted, or added to statements in the January 15, 2010 declaration.

⁴ "The Board has held that an ALJ has discretion, as an exercise of judicial economy, not to address findings that are immaterial to the outcome of an appeal." *Alexandria Place*, DAB No. 2245, at 27 n.9 (2009) (citing decisions); *see also Community Skilled Nursing Centre*, DAB No. 1987, at 5 (2005) (holding that "ALJs are not required to make findings of fact and conclusions of law on deficiencies that are not necessary to support the CMP imposed"). Omni Manor does not argue that it was improper for the ALJ to rule on the duration of the noncompliance period based on fewer than all of the deficiencies cited in the parties' stipulation as providing a "factual and legal basis" for the imposition of the CMP here. Joint Stipulation, ¶ 1.

ALJ noted, where the noncompliance involves failure to comply with a specific physician order and failure to follow facility protocols and policies already in effect. *Id.* The ALJ found, "What is singularly lacking from Petitioner's evidence is proof that the staff actually implemented, at any date prior to May 21, the training that was provided to them." *Id.* In addition, the ALJ noted, Omni Manor's Plan of Correction (POC) called for audits of staff performance to be conducted for a one-month period after the completion of staff retraining on April 29, indicating that Omni Manor's "own Management was not confident that retraining alone would produce instantaneous compliance" *Id.* at 4.

The ALJ next addressed the evidence that Omni Manor submitted to show correction of its noncompliance under section 483.25(d), which provides that the facility must ensure that –

(1) A resident who enters the facility without an indwelling catheter is not catheterized unless the resident's clinical condition demonstrates that catheterization was necessary; and

(2) A resident who is incontinent of bladder receives appropriate treatment and services to prevent urinary tract infections and to restore as much normal bladder function as possible.

The surveyors determined that Omni Manor failed to promptly discontinue a Foley catheter for one resident and failed to provide appropriate incontinence care to another resident. CMS Ex. 5, at 10-15. Omni Manor asserted that its corrections included reviewing the records of all residents with catheters to ensure that they continued to require them; providing in-service training to all nurses on April 25, 28, and 29, 2008; monitoring the residents to ensure that the catheters were removed when no longer medically necessary; providing immediate in-service training to two nursing assistants on infection control during incontinence care; and providing in-service training to all nurse aide staff as of April 29, 2008 on appropriate incontinence care.

The ALJ found, however, that Omni Manor's records showed that "numerous individuals failed to sign" the training attendance form. *Id.* at 5, citing P. Ex. 48, at 18-22. "That failure of proof," the ALJ stated, "in and of itself, is sufficient for me to conclude that [Omni Manor] did not attain compliance with all participation requirements prior to May 22, 2008." *Id.* In addition, the ALJ determined, "the fact that nurse aides were retrained in providing incontinence care is not by itself proof that they implemented the training that was given to them." *Id.* The ALJ found that Omni Manor did not provide proof that they applied their training correctly." *Id.* Consequently, the ALJ concluded that Omni Manor "was substantially noncompliant with Medicare participation requirements from April 24 through May 21, 2008." *Id.* at 2.

Standard of Review

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

Discussion

As we stated in DAB No. 2374, Omni Manor had the burden to prove that it returned to substantial compliance prior to May 22, 2008, the date determined by CMS. DAB No. 2374, at 8 (citations omitted). To meet this burden, the ALJ correctly held, Omni Manor could not rely solely on the date it identified on its approved POC as the "completion date" for its corrections, April 29, 2008. Rather, the regulations and prior Board decisions make clear that a facility's "noncompliance is deemed to be corrected or removed only when the incidents of noncompliance have ceased and the facility has implemented appropriate measures to ensure that similar incidents will not recur." Oceanside Nursing and Rehabilitation Center, DAB No. 2382, at 20 (2011), quoting Life Care Center of Elizabethton, DAB No. 2367, at 16 (2011). Even after a POC has been accepted, a facility is not considered to be in substantial compliance until a determination has been made, through a revisit survey or based on "credible written evidence" that "CMS or the State can verify without an on-site visit," that the facility returned to substantial compliance. DAB No. 2382, at 20, citing 42 C.F.R. § 488.454(a)(1); Barn Hill Care Center, DAB No. 1848, at 10 (2002); Cross Creek Health Care Center, DAB No. 1665, at 3 (1998). "Completion of an approved plan of correction," moreover, "does not per se imply correction of prior deficiencies." Warren N. Barr Pavilion of Illinois Masonic Medical Center, DAB No. 1705, at 5 (1999). Rather, whether a facility has returned to substantial compliance "depends on a factual assessment that the preexisting deficiency has been eliminated, not merely on determining that the POC has been complied with and no new deficiencies discovered." Id. at 6, n.3.⁵

⁵ The legal background section of Omni Manor's brief includes a lengthy discussion of the Board's decision in *Foxwood Springs Living Center*, DAB No. 2294 (2009), calling the decision "instructive to this case" but not claiming the ALJ Decision here is inconsistent with that precedent. P. Br. at 7-12. Indeed, there is no inconsistency. *Foxwood* involved CMS's reading of a State Operations Manual (SOM) provision not involved in this case. The Board agreed with the ALJ in *Foxwood* that the SOM provision was inconsistent with the regulations that bind the ALJ and Board and allow a facility to try to establish an earlier compliance date, although giving the facility the burden of proof on that issue. That is entirely consistent with the ALJ Decision here. The difference is that the ALJ here did not find Omni Manor's evidence sufficient to meet its burden to establish an earlier date. We note, in particular, that in *Foxwood*, it was undisputed that the facility had fully implemented its POC. By contrast, as discussed above, Omni Manor's own evidence unequivocally shows that it did not fully implement its POC.

7

The evidence on which Omni Manor relied to show that it returned to substantial compliance on April 29, 2008, included its approved POC, the Trexler Declaration, records documenting that staff directly involved in the deficiencies were disciplined and reeducated, attendance/sign-in sheets and agendas for in-service training conducted on April 25, 28, and 29, 2008, "Change in Condition Audits" forms, incontinence care evaluation forms, medication administration competency audit forms, and meal audit forms. P. Br. at 12-21, citing CMS Ex. 5; Trexler Decl.; P. Exs. 22, 41, 43, 44, 48-49. For the reasons detailed below, we agree with the ALJ that this evidence was insufficient to show that as of April 29, 2008, Omni Manor had eliminated the deficiencies and taken all steps necessary to ensure that similar incidents would not recur.

Omni Manor failed to prove that prior to May 22, 2008, all staff received the training required under its POC.

Central to the corrective actions that Omni Manor listed on its POC, and to which Ms. Trexler attested, was "in-servicing" or training all staff responsible for providing the same types of care and services that had been found deficient during the April 2008 standard survey. CMS Ex. 5, at 5, 8-9, 13-15, 17, 20-21, 24-25; Trexler Decl. ¶¶ 8, 9, 11, 15. For example, the POC and Ms. Trexler stated that to correct for the deficiencies cited under the quality of care requirements at section 483.25, "All nursing staff was reinserviced" on April 25, 28, and 29, 2008, "on assessments for change in condition, physician notification and frequent monitoring to assess if there is an improvement in condition or if resident requires additional medical attention/evaluation in the acute care setting." CMS Ex. 5, at 5 (emphasis added); Trexler Decl. ¶ 8, citing P. Ex. 49, at 6-8. Similarly, Ms. Trexler declared that to correct for the incontinence care deficiencies cited under section 483.25(d), the "entire nurse aide staff was in-serviced and re-educated on incontinence care" on April 25, 28 and 29, 2008. Trexler Decl. ¶ 9 (emphasis added), citing P. Ex 49, at 17-23. To correct for the deficiencies cited under the accidents and supervision requirements at section 483.25(h), the POC stated, among other things, that the "housekeeping supervisor inserviced all housekeepers and porters on safe chemical storage on 4/28, 4/29." CMS Ex. 5, at 17 (emphasis added). "In summary," Ms. Trexler declared, "facility staff directly involved were appropriately and timely disciplined and re-educated . . . and all similarly-positioned staff were timely in-serviced to ensure ongoing and/or recapture substantial compliance" Trexler Decl. ¶ 15 (emphasis added).

The primary source documentation that Omni Manor proffered, and Ms. Trexler cited, as evidence of the training consists of summary agendas and attendance sheets listing the names of Omni Manor's employees (by their position), with corresponding signatures by the individuals' names to indicate their attendance. Contrary to the POC and Ms. Trexler's representations, however, this evidence shows, as the ALJ found (ALJ Decision at 5), that many staff members required to undergo in-service training did **not** attend the training sessions. Specifically, since the signatures of two nurses, 16 nurse aides, and one

housekeeping employee were missing from the attendance sheets for the in-services Ms. Trexler indicated they were required to attend, it is reasonable to conclude that they did not attend the training sessions. P. Ex. 48, at 1, 7-8, 11-22; P. Ex. 49, at 6-7, 18-23, 70-71. In light of the clear requirement in Omni Manor's approved POC that correction of the deficiencies involved training **all** employees in these positions to abate the noncompliance, we conclude that the training documentation constitutes substantial evidence to support the ALJ's conclusion that Omni Manor failed to return to substantial compliance on April 29, 2008, as it alleged.

Before the Board, Omni Manor does not deny that numerous employees failed to attend the training sessions described in its POC. Instead, Omni Manor now asserts that "the argument" that all staff did not attend the training "is a red herring." P. Reply at 3. "The critical issue of whether Omni Manor returned to substantial compliance on the completion date set forth on its POC, April 29, 2008," Omni Manor contends, "is whether the documentation submitted . . . evidenced the implementation of appropriate measures to ensure that similar incidents will not recur." *Id.* Omni Manor asserts that the documentation, including the evidence of the training sessions, is the same documentation that it provided to the survey team during the May 22, 2008 revisit. Because the surveyors at the revisit reviewed the same documentation "and STILL found Omni Manor to be in substantial compliance," Omni Manor argues, "the only rational conclusion is that the documentation . . . verified a return to substantial compliance prior to the revisit." *Id.* (emphasis in original).

We agree that the critical issue here is whether the record evidence demonstrates that, prior to May 22, 2008, Omni Manor had taken appropriate measures to eliminate the deficiencies and ensure that similar incidents would not recur in order to demonstrate a return to substantial compliance. The question whether all staff attended the training described in the POC, however, is not immaterial to that issue, as Omni Manor argues. That Omni Manor's approved POC required in-servicing to correct numerous deficiencies and represented that all staff responsible for delivering the types of care at issue attended the in-servicing, demonstrates that Omni Manor itself recognized that training was not merely "appropriate," but an essential step to ensure that incidents similar to those cited in the survey would not recur. In light of the survey findings of multiple staff failures to provide care consistent with professional standards and program participation requirements, re-training all staff responsible for the same types of care logically would be the most comprehensive and effective corrective step to prevent the recurrence of the deficiencies. Indeed, CMS states that "proper retraining of employees is the sine qua non of virtually every successful implementation of a POC," and we find no reason to disagree. CMS Br. at 5. Moreover, Ms. Trexler herself emphasized the necessity of full attendance at the training, stating that "all similarly-positioned staff were timely in-serviced to ensure ongoing and/or recapture substantial compliance" Trexler Decl. ¶ 15 (emphasis added).

Furthermore, we reject Omni Manor's argument that we should, in effect, ignore the evidence that numerous employees did not attend the required training because, Omni Manor alleges, the revisit surveyors determined that Omni Manor returned to substantial compliance based on the very same documentation. Omni Manor repeatedly argues that "there is no evidence in this case that the state surveyors made any observations of the provision of care or conducted any interviews to verify the implementation of [the] corrective actions during their May 22, 2008, revisit to the facility." P. Reply at 4; P. Br at 21-24. "The uncontroverted evidence in this case," Omni Manor contends, "is that the State surveyors did nothing to verify or confirm substantial compliance during the revisit survey other than review . . . the same documentation used by Omni Manor to prove the implementation of its plan of correction by April 29, 2008." P. Br. at 22. Therefore, Omni Manor argues, "it is only logical to conclude that the evidence produced by Omni Manor in this case (i.e. the documentation) was sufficient for [the State agency] to *verify* on revisit that Omni Manor had returned to substantial compliance." P. Br. at 23 (emphasis in original).

As we address in greater detail in the next section of this decision, the documentation that the surveyors reviewed included not only evidence of the training that was completed as of April 29, 2008, but also documentation of activities that took place **after** the training, as required by the POC itself. In particular, the documentation, as shown by Omni Manor's own exhibits in this case, included chart audits and staff monitoring records related to the POC requirement that regular monitoring take place for a one-month period after the training to correct multiple deficiencies. *See, e.g.,* CMS Ex. 5, at 5, 13-14; P. Ex. 49, at 10-12, 44-50. Because CMS reasonably could consider the audits and monitoring to be necessary elements of Omni Manor's return to substantial compliance, we disagree with Omni Manor that the only logical conclusion that can be drawn from the revisit surveyors' review is that Omni Manor achieved substantial compliance as of the day the training portion of its POC was completed, April 29, 2008.

Furthermore, Omni Manor's argument reflects a fundamental misunderstanding of the issue before the ALJ, and the Board on appeal, and the burden of proof on that issue. As stated earlier, the Board has made it clear, in such cases as *Lake Mary Health Care*, that when a facility disputes the compliance date determined by CMS, the facility has the burden of proving it achieved compliance at an earlier date. DAB No. 2081, at 29-30 (2007). The Board has "consistently rejected the contention . . . that CMS must affirmatively prove that noncompliance exists on each day that a remedy is in effect after the first day of noncompliance." *Chicago Ridge Nursing Center*, DAB No. 2151 at 27 (2008), citing *Cal Turner Extended Care Pavilion*, DAB No. 2030 (2006). Thus, the issue is not whether the evidence of record supports CMS's determination that Omni Manor achieved substantial compliance on May 22, 2008, but, rather, whether the evidence of record supports Omni Manor's assertion that it was in substantial compliance on April 29, 2008 rests, in important part, on evidence related to the in-

service training sessions described in Omni Manor's POC and Ms. Trexler's declaration that all staff required to attend particular types of the in-service training did attend. That evidence, as we explained, plainly shows that all staff did not attend the training sessions they were required to attend. Indeed, Omni Manor's "red herring" argument implicitly admits this. Accordingly, we agree with the ALJ that Omni Manor's "failure of proof" relating to the training of facility staff, "in and of itself, [was] sufficient for [the ALJ] to conclude that [Omni Manor] did not attain compliance with all participation requirements prior to May 22, 2008."⁶ ALJ Decision at 5.

Substantial evidence supports the ALJ's finding that Omni Manor failed to prove that staff implemented the training that was provided to them.

As noted above, the ALJ further found that the evidence failed to show that Omni Manor's staff was actively monitored and provided care implementing the training that was provided. Omni Manor argues that the ALJ's "analysis of the evidence" relating to staff implementation of the training "was cursory and prejudicial." P. Br. at 19. Contrary to the ALJ's statements, Omni Manor argues, it "produced evidence that the training was being 'implemented,'....'' Id. For example, Omni Manor states with respect to the deficiency cited under section 483.25 that it "presented evidence of completed Change of Condition Audit Forms" showing that "nursing staff was identifying and noting residents' condition changes and that supervisors were monitoring same." Id. citing Trexler Decl. ¶ 6-8; P. Ex. 49, at 10-13. "Similarly," Omni Manor asserts, it proffered "evidence of the implementation of daily observations and assessments of its nurse aid[e] staff in the delivery of urinary incontinence care and infection control," as well as observations and assessments of "at least six nurses properly administering urinary incontinence care and infection control processes to residents." Id. at 19-20, citing Trexler Decl. ¶ 9; P. Ex. 49, at 24-29. Omni Manor also argues that it "presented uncontroverted evidence of its implementation of medication administration and naso-gastric tube audits during which" staff was "observed performing proper g-tube medication administration." Id. at 20, citing Trexler Decl. ¶ 11; P. Ex. 49, at 38-50. Further, Omni Manor argues that it implemented both meal audit forms and chemical storage audit forms, in addition to completing training for its staff. Id. at 20, citing Trexler Decl. ¶ 15; P. Ex. 49, at 61-75.

⁶ In any event, Omni Manor's assertions about what procedures the State surveyors employed (or did not employ) or what evidence they reviewed or relied on are ultimately irrelevant because, as we discuss later, CMS, not the State, determines the date the facility achieved substantial compliance, and the ALJ had the authority to make an independent determination as to whether the facility returned to substantial compliance prior to May 22, 2008 based on a de novo review of the evidence on that issue. *See Meadowbrook Manor—Naperville*, DAB No. 2173, at 15 (2008) (where facility alleged it had come into substantial compliance between surveys, the Board stated that "the ALJ had the authority to make an independent, de novo determination about whether [the facility] was in substantial compliance" at any time within that period), *aff'd sub nom.*, *Butterfield Health Care II, Inc. v. Charles E. Johnson*, Case No. 08-CV-3604 (N.D. Ill. June 16, 2009).

On review of the record, we agree with the ALJ that the evidence is insufficient to prove that prior to May 22, 2008, Omni Manor's nursing staff implemented the training provided by following all of the protocols necessary to meet the professional standards of care at issue. For example, Omni Manor's admitted noncompliance with the quality of care requirements at section 483.25 involved the facility's delay in treating a resident for acute respiratory problems "when his rapidly deteriorating medical condition failed to improve," which resulted in actual harm to the resident. CMS Ex. 5, at 5-8; P. Br. at 12. As the ALJ explained, and Omni Manor does not deny, between approximately 4:00 and 5:00 a.m. on April 9, 2008, "the nursing staff failed to recognize obvious signs that the resident was in respiratory distress ... and failed to keep close watch on the resident and record their observations," even though a 4:00 a.m. physician's order directed staff to transfer the resident to a hospital if he showed continued signs of respiratory distress. ALJ Decision at 3, citing CMS Ex. 5, at 5-8. Contravening accepted standards of professional care, Omni Manor's nursing staff thus failed to "comply with an explicit order by a physician; recognize the clinical signs and symptoms of respiratory distress; document those signs and symptoms; and take immediate action necessary to protect the resident's welfare." ALJ Decision at 3; CMS Ex. 5, at 5-8.

The corrective actions that Omni Manor listed in its POC for this deficiency included disciplining and reeducating the staff directly responsible for the noncompliance and, as discussed above, providing training to all nursing staff. According to the agenda of the "Change in Condition" training, the trainers instructed nursing staff to conduct complete assessments of the residents exhibiting changes, including checking "vital signs, fingerstick blood sugars, pulse oximeter readings, lung sounds, circulation assessment, bowel sounds, skin turgor and any mental status changes." P. Ex. 49, at 8. The trainers also directed nursing staff to call and update the doctor on the resident's full condition, follow the doctor's orders, and ask questions "to clarify any order that is unclear." *Id.* Furthermore, the training agenda stated that nurses were to document all of their findings and their actions "to take care of this resident." *Id.* The trainers also instructed the nurses to "call the doctor again" if they did not believe that a resident was improving and "to document the times of their assessments, calls to the physician, and interventions." *Id.*

To ensure that nursing staff implemented the change-in-condition training directives, the corrective actions listed in Omni Manor's POC included the following steps:

- Monitoring nursing staff on the implementation of the training "through chart audits on residents exhibiting a change in condition by Assistant DON, Clinical Director, QA Nurse 5 x week x 2 weeks then 3 x week x 2 weeks then randomly thereafter;"
- "[R]eviewing discharge records to monitor for prompt assessment/monitoring and intervention/treatment for residents exhibiting a

change in condition. These records will be reviewed by the DON, QA nurse, Assistant DON or clinical director for 1 month;" and

• "The DON will be responsible for monitoring that facility residents receive prompt treatment for changes in condition on an ongoing basis."

CMS Ex. 5, at 5-6. While Omni Manor designated April 29, 2008 (the last day of the training) on its POC as the "completion date" of its corrections for the quality of care deficiency, the monitoring required under the POC could not be completed until weeks after the last day of the training. We conclude that the ALJ reasonably inferred from these additional POC requirements that Omni Manor's "own management was not confident that retraining alone would produce instantaneous compliance by staff but that there would be a necessary period of observation and, if necessary, correction to assure that all staff were in compliance with necessary participation requirements." ALJ Decision at 4. As the Board stated with respect to the corrective actions at issue in Oceanside, the nature and prospective operation of the monitoring activity here "necessarily means that in-service training of facility staff . . . could not alone establish that the facility had successfully implemented the practices and procedures required in the POC and training materials." DAB No. 2382, at 20. Furthermore, in light of Omni Manor's own recognition of the need to monitor staff on a regular basis for a one-month period after the training, "CMS could reasonably require evidence that" the protocols addressed in the training "were actually put into effect in order to verify that the facility had attained substantial compliance with the requirements for nursing facilities to participate in Medicare." Id.

Omni Manor disagrees, arguing that all "POCs are inherently prospective in nature because they set forth the corrective actions a facility *will implement* to correct cited deficiencies." P. Reply at 2 (emphasis in original). Moreover, Omni Manor contends that "[m]erely because POCs operate prospectively . . . does not mean that Omni Manor cannot establish, as a matter of fact, a return to substantial compliance with program requirements prior to the date of a revisit survey." *Id.* Here, Omni Manor contends, the change-in-condition audit documentation showing that chart audits were done from April 25, 2008, through May 20, 2008, (as well as the documentation of observations of corrected delivery of care, random g-tube audits, and dining and medication pass audits, relating to the other deficiencies), verified that staff was in fact implementing the training and providing care and services in compliance with professional standards and the program requirements. Thus, in Omni Manor's view, the completion of the monitoring called for under its POC was merely for the facility to verify its return to substantial compliance as of the last day of staff training.

Even if we were to accept Omni Manor's argument, the evidence that it proffered fails to establish that staff had in fact implemented the corrective training prior to May 22, 2008. To prove that the nursing staff was putting into practice the training directives, Omni

Manor needed to show that nursing personnel were, as the ALJ stated, "actively monitored, and their performance measured against applicable standards of care." ALJ Decision at 4. With respect to Omni Manor's abatement of the quality of care deficiency under section 483.25, those standards included following the resident assessment, physician notification, documentation, and intervention protocols required under the program participation regulations and addressed at the in-servicing.

The documentation Omni Manor submitted, however, does not show that supervisors were actively monitoring all nursing personnel to confirm that staff was following the requisite protocols. Omni Manor offered Ms. Trexler's declaration, in which she summarily stated that "in response to the survey, Facility management staff – [its Director of Nursing (DON), Clinical Director, Quality Assurance Nurse, and Assistant DON] immediately began an enhanced period of observations of delivery of care . . . to focus on the alleged deficiencies' corrective actions to assure staff had conformed practice to in-service instruction." Trexler Decl. ¶ 13. Yet, Omni Manor provided no testimony or evidence of what direct care those managers actually observed, nor did it provide documentation to show that **all** nursing personnel were monitored to ensure full staff compliance with the applicable standards of care.

Instead, Omni Manor provided copies of the "Change in Condition Audits" form that it "instituted" as "part of the facility's ongoing Q/A-Q/C (Quality Assurance/Quality Control) program." Trexler Decl. ¶ 8; P. Ex. 49, at 9-13. The single-page form consists of a table to record information for up to 32 change-of-condition incidents. P. Ex. 49, at 9. For each incident, there are spaces to enter information under the following categories: "Resident Name," "Date of Change," "Nurse on Shift," "Change Noted," "NN Checks," "Date of Audit," and "Nurse Completing Audit." Id. Ms. Trexler identified the copies of the partially-filled-in forms provided as "examples of the performance of the Q/A-Q/C protocols." Trexler Decl. ¶ 8. The entries on the forms appear to reflect chart audits conducted by management of 25 change-of-condition incidents that occurred between April 24, 2008, and May 20, 2008. P. Ex. 49, at 10-12. Under "Change Noted," the forms were filled in with cursory descriptions, such as "pain," "IV Therapy, "Direct Admit," and "audible wheeze." Id. Under "NN Checks," the majority of entries were filled in either with check marks or the word, "yes." Id. For only one of the 25 documented incidents is there an indication that staff provided the physician with notice of the resident's change in condition. P. Ex. 49, at 12. None of the entries show whether, consistent with the in-servicing agenda, the assessments were complete based on resident signs and symptoms; whether, in all but one case, staff had notified the doctor of the change and updated the doctor on the residents' full condition; or whether any of the doctors had provided specific instructions for the care of the residents and, if so, whether those instructions had been followed. In light of the fact that the POC required Omni Manor to monitor regularly for one month the nursing staff's implementation of the change-in-condition training directives, and the fact that the documentation that Omni Manor offered as proof of its monitoring was less than compelling, we agree with the

ALJ that CMS could reasonably conclude that Omni Manor did not show that at any date prior to May 22, 2008 all personnel had put into practice the protocols necessary to eliminate the quality of care deficiency.

We also find that Omni Manor's evidence fails to show that all of the in-service training it conducted was sufficient to ensure that, as of April 29, 2008, the deficiencies identified in the survey would not recur. For example, Omni Manor's admitted noncompliance with the urinary incontinence care standards at section 483.25(d) involved, among other things, two nursing assistants' failure to follow appropriate infection control procedures during incontinence care. CMS Ex. 5, at 13-15; P. Ex. 49, at 14-15. Specifically, the nursing assistants did not remove their gloves and wash their hands when required, nor did they clean the resident's skin sufficiently or properly dry it. *Id*.

To address Omni Manor's noncompliance with the incontinence care requirements, Ms. Trexler declared that in addition to re-educating the staff directly responsible for the deficiency, "The entire nurse aide staff was in-serviced and re-educated on incontinence care" on April 25, 28, and 29, 2008. Trexler Decl. ¶ 9; *see also* CMS Ex. 5, at 14. To support this statement, Ms. Trexler cited Omni Manor Exhibit 49, at pages 17-23, "documents demonstrating the education provided and attendance of staff." Trexler Decl. ¶ 9. Yet, the cited documentation of the incontinence care education merely states: "see attached procedure. If you are wearing gloves to provide any resident care, be sure to remove the gloves and wash your hands before touching anything else in the room." P. Ex. 49, at 17. No incontinence care procedure is attached to this document, and there is no evidence that the in-service training addressed how to sufficiently clean the resident's skin and properly dry it. For all of the reasons stated, we find the evidence fails to show that the in-service training provided was sufficient to ensure that by April 29, 2008, the incontinence care deficiency would not recur.

Omni Manor's allegation that the surveyors told the facility's administrators that Omni Manor achieved substantial compliance on April 29, 2008 does not warrant reversal of the ALJ Decision.

Finally, Omni Manor contends that we should conclude that it returned to substantial compliance as of April 29, 2008, because the State agency surveyors allegedly told Omni Manor's administrators during the revisit that they found the facility "had achieved substantial compliance effective April 29, 2008." P. Br. at 17-18; Trexler Decl. ¶ 16. Omni Manor's allegation, based on hearsay, is directly contradicted by the surveyor-signed, post-certification revisit report, in which the surveyor certified that Omni Manor's corrections were completed by May 22, not April 29, 2008. CMS Ex. 6; P. Ex. 45. Furthermore, under the governing statutes and regulations, a state agency makes recommended findings regarding noncompliance and recommends actions to remedy the noncompliance, but CMS makes the actual findings of noncompliance and decides what remedial actions to take. Act §§ 1819(h)(1), (2); 1919(g)(3)(A); 1919(h)(3)(B); 42

C.F.R. §§ 488.11, 488.12, 488.24, 488.452(a)(2); *see Britthaven of Chapel Hill*, DAB No. 2284, at 6-7 (2009) (State agency merely recommends findings of compliance (or noncompliance) and CMS ultimately determines whether the facility is in substantial compliance); *Lake Mary*, DAB No. 2081, at 5-7 (ultimate responsibility for the interpretation and enforcement of federal participation requirements lies with CMS, not with the state surveyors). Accordingly, we reject Omni Manor's argument that we should reverse the ALJ's determination based on alleged oral statements by the State agency surveyors that the facility returned to substantial compliance on April 29, 2008.

Conclusion

For the reasons discussed above, we uphold the ALJ's decision to sustain CMS's imposition of a \$550 per-day CMP on Omni Manor for a period of 28 days beginning April 24, 2008, and continuing through May 21, 2008.

<u>/s/</u> Stephen M. Godek

/s/

Leslie A. Sussan

/s/

Sheila Ann Hegy Presiding Board Member